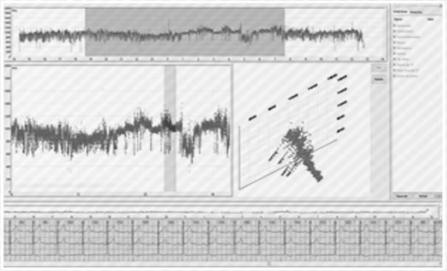
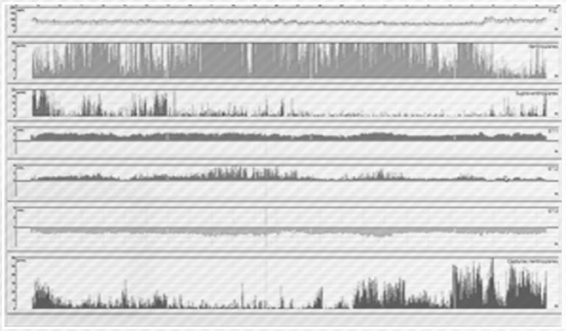
CardioSmart

(Part of CardioLight+ Holter System)

CS550 EN





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CARDIOS

User's Manual

CE 1434

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CONTENTS

1. Introduction 10
1.1. Copyright Notice and Manufacturer Information 10
1.2. Symbols used in this manual and packaging 10
1.3. General Warnings 11
1.4. General Aspects 13
1.5. Technical Compatibility with other devices 13
1.6. ST Methods and Analysis 14
1.7. Manufacturer Settings 15
1.8. Holter Report 27
1.9. About this Manual 47
1.9.1. Content 47
1.9.2. Conventions 47
2. Initializing the System 47
2.1. User License Activation 50
2.2. Exam Code Generator 50
3. Main menu 52
3.1. Exam 52
3.2. Edit 53
3.3. Database 54
3.3.1. Editing data 55
3.4. Settings 56
3.4.1. System 56
3.4.1.1. Global settings 56
3.4.1.2. General 57

3.4.1.3. Report 58
3.4.1.4. Exporting Report Data 59
3.4.1.5. CardioNet 60
3.4.1.5.1. Internet Connection 60
3.4.1.5.2. Exam Folder 63
3.4.1.5.3. Network Directories 63
3.4.1.5.4. Internet Log 64
3.4.1.5.5. Analyst Record 65
3.4.1.5.6. Diary of Patient 66
3.4.1.5.7. Header Edit 67
3.4.1.5.8. General Settings 67
3.4.1.6. CardioSmart CS550 - Arrhythmias Parameters 68
3.4.1.6.1. ABPM Consensus 69
3.4.1.6.2. Pacemaker 70
3.4.1.6.3. Heart Rate Variability - HRV 71
3.4.1.6.4. Apnea 72
3.4.1.6.4.1. Tachogram settings 72
3.4.1.6.4.2. Analysis Settings 72
3.4.1.6.4.3. General Settings 73
3.4.1.6.5. Atrial Fibrillation 74
3.4.1.6.5.1. Configuring the system globally 74
General Field Setting 75
Configuration Steps 75
3.4.1.6.6. HRT - Heart Rate Turbulence 77
3.4.1.6.7. Advanced Settings 77
3.4.1.7. Devices 79
3.4.2. Printer Settings 80
3.5. View 81

3.6. Help 81
4. Preparing the Exam 82
4.1. Preparing the Device 82
4.2. Patient's Diary 95
4.3. Exam Transfer After Holter Recording 96
5. Tools with open Exam 100
5.1. Exam 100
5.2. Edit 103
5.3. Analysis 103
5.3.1. Selective analysis 103
5.3.2. Atrial Fibrillations 105
5.3.3. Automatic context editing 105
5.3.4. Reanalysis 105
5.3.4.1. ABPM Clinical Limits 106
5.3.4.2. Pacemaker 107
5.3.4.3. HRV 107
5.3.4.4. Apnea 109
5.3.4.5. Atrial Fibrillation 110
5.3.4.6. Filters 111
5.3.4.7. Heart Rate Turbulence 112
5.3.5. Synchronize analysis 113
5.3.6. Generating automatic examples 113
5.4. Record 113
5.5. Tables 114
5.6. Settings 114
5.6.1. Report 114
5.6.2. System 115
5.6.3. Printer 116

5.7. View 116
5.8. Window 117
5.9. Help 118
5.10. Toolbar - Shortcut Keys 118
5.11. Filter-up 123
6. Menu (Window Bar) 126
6.1. General 126
6.2. Morphologies 129
6.3. Arrhythmias 134
6.3.1. Ventricular 135
6.3.2. Supraventricular 137
6.3.3. Pauses 139
6.3.4. Tachycardias / Bradycardias 140
6.3.5. ST C1 / ST C2 / ST C3 141
6.4. Histograms 143
6.5. 24-hour Charts 146
6.6. Compressed ECG 146
6.7. Tables 148
6.7.1. Pacemaker Table 150
6.7.2. ST Table 151
6.8. Heart Rate Variability 153
6.9. Tachogram 153
6.10. Apnea 154
6.10.1. HR variations tachogram 154
6.11. Atrial Fibrillation 158
6.12. Heart Rate Turbulence 158
6.13. Example 159
7. HR Variability RR Variability Module 160

7.1. Roll Over 162
8. Tachogram 163
8.1. Compressed Tachogram 164
8.1.1. Compressed Tachogram Vertical Scale 164
8.1.2. Pop-up on Compressed Tachogram 164
8.2. Expanded Tachogram 165
8.2.1. Expanded Tachogram Zoom Feature 165
8.2.2. Expanded Tachogram Vertical Scale 167
8.2.3. Pop-up on Expanded Tachogram 167
8.2.4. Heartbeats Reclassification 167
8.2.5. Cursor Navigation in Expanded Tachogram 168
8.2.6. Linking the Compressed Tachogram, Expanded Tachogram, and ECG Bar 168
9. Pacemaker Analysis 170
9.1. Preparing, Acquiring, and Analyzing Pacemaker Patients Exams 170
9.2. Some important concepts 170
9.2.1. Interval limits (in ms) 170
9.2.2. HR 170
9.2.3. VC form similarity 171
9.3. Settings 171
9.3.1. Pacemaker Data 171
9.3.2. Limits for the intervals (in ms) 172
9.3.3. VC form similarity 172
9.4. Pacemakers and Specifications 172
9.4.1. Dual Chamber Pacemaker 172
9.4.2. Atrial Pacemaker 173
9.4.3. Ventricular Pacemaker 174
9.5. Pacer Software Features 174
9.5.1. QRSs Morphologies Screen 174

9.5.2. Edit 174
9.5.3. Pacemaker Filter And Spikes Indicator 175
9.6. Pacemaker table 176
9.6.1. Some important concepts 176
9.6.1.1. Stimulation Failure 176
9.6.1.2. Capture Failure 176
9.6.1.3. Sensitivity Failure 176
9.6.2. Pacemaker Tabular Summary Review Module 176
9.6.3. Tabular Summary Resources 177
9.6.3.1. Column Data Editing 177
9.6.3.2. Time Events View on the ECG Bar 178
9.7. Pacemaker Tachogram 178
9.8. ECG bar 179
9.9. Compressed Pacemaker Tachogram 179
9.10. Compressed Pacemaker Tachogram Features 180
9.10.1. Compressed Pacemaker Tachogram Vertical Scale 180
9.10.2. Pop-up 180
9.11. Expanded Pacemaker Tachogram 180
9.12. Expanded Pacemaker Tachogram Features 182
9.12.1. Zoom - Precisely selecting a specific point in the chart 182
9.12.2. Expanded Pacemaker Tachogram Scale 182
9.12.3. Heartbeats Reclassification 182
9.12.4. Cursor Navigation in Expanded Pacemaker Tachogram 182
10. Atrial fibrillation 184
10.1. Atrial Fibrillation Component Setting - Individual Mode 184
10.2. Atrial Fibrillation Module Overview 186
10.2.1. Analysis Summary 186
10.2.2. Table of Atrial Fibrillation episodes detected by software 187

10.2.2.1. Table Editing 191
10.2.2.2. Delete episodes 192
10.2.2.3. Table and Tools 194
10.2.3. Episode Complements Bar 196
10.2.4. RR Tachogram 198
10.2.5. RR histogram 199
10.3. Tachogram evaluation 201
10.4. Printing setup 202
10.4.1. 1st Print Option - General Setup 202
10.4.2. 2nd Printing Option - Single 202
11. Sleep Apnea Analysis Component 210
11.1. Overview 211
11.2. Reanalysis Settings 212
11.3. Analysis Tools 214
11.3.1. Episodes Table 214
11.3.2. Heart Rate Tachogram 214
11.3.3. ECG bar 215
11.3.4. Episodes Analysis 216
11.3.4.1. Episodes Detection 216
11.3.4.2. Episodes view 216
11.3.4.3. Editing data 220
11.3.4.4. Episodes Inclusion 220
11.3.4.5. Episodes Exclusion 224
11.3.4.6. Episodes Merging 225
11.3.5. Reanalysis 226
11.3.6. Selection of examples for the report 228
11.3.7. Report of episodes suggestive of Apnea/Hypopnea 229
12. CardioNet 235

12.1. Screen description 236
12.1.1. Main Menu 236
12.1.2. Toolbar 236
12.1.3. Side Menu Bar 236
12.1.4. Workspace 238
12.1.5. Statistics - Main Window 238
12.2. Preparing Exam 239
12.3. Reading the digital recorder 241
12.3.1. Patient Diary 244
12.4. Sending Exams 246
12.4.1. Sending Exams via Internet 247
12.4.2. Sending Exams via Local Network 250
12.4.3. Sending Exams via E-Mail 252
12.5. Retrieving Exams 253
12.5.1. Retrieving Exams via Internet 254
12.5.2. Retrieving Exams via Local Network 257
12.5.3. Color coding in lists 258
12.6. Sending Reports 258
12.6.1. Sending Reports via Internet 259
12.6.2. Sending Reports via Local Network 262
12.7. Retrieving Reports 263
12.7.1. Retrieving Reports via Internet 263
12.7.2. Retrieving Reports via Local Network 265
12.8. Deleting Files 266
13. Installing CardioSmart CS550 on your computer 267
14. Troubleshooting 269
15. Software License Agreement 286
16. Revision History 298

1. INTRODUCTION

1.1. COPYRIGHT NOTICE AND MANUFACTURER INFORMATION

COPYRIGHT
The computer program object of this license to use belongs to CARDIO SISTEMAS COML. INDL. LTDA. and is protected by national and international laws of computer programs and by international copyright laws and treaties. The manuals and other printed publications accompanying this license to use should not be copied and/or reproduced in any way. This license does not cover the transfer of any right, property, title, or interest in the program object of this license, including any patent, patent application, trade or industrial secret, trademark or copyright.

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CardioSmart CS550 - Analyzer software part of CardioLight+ Holter System

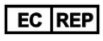
COMMENTS
As part of our ongoing effort to improve our products and documentation, Cardios invites you to share your comments with us. If you have any suggestions, criticism or if you wish to notify us of any inaccuracy or impropriety, please send us your comments. We appreciate your cooperation.

1.2. SYMBOLS USED IN THIS MANUAL AND PACKAGING

Find below the description of the symbols used in this manual and packaging:

Symbols

	**General warning sign**
	**Recyclable Material**
	**Fragile** The contents of the transport packaging are fragile so it should be handled with care.

	**This Side Up** Indicates the correct position for the transport packaging.
	**Keep Dry** The transport packaging should be kept away from water.
	**Temperature Limit** Indicates the temperature limit at which the transport packaging can be stored or handled.
	**Maximum Limit** Indicates the maximum limit at which the transport packaging can be stored or handled.
	**Follow instructions for use** Warns the reader to follow the operating instructions when using the product.
	https://ifu.cardios.com.br Consult electronic instructions for use
	**Medical Device**
	**Unique Device Identifier**
	**Authorized representative in the European Community**
	**CE Marking**
	**Serial number**
	**Batch code**
	**Date of manufacture**
	**Manufacturer**
	**Do Not Use if Package is Damaged**
	**Maximum weight supported by the case**

1.3. GENERAL WARNINGS

Like any diagnostic auxiliary system, CardioSmart CS550 requires professional training and medical knowledge in order to correctly interpret ECG data and issue reports.
The software provides automation and tools to support the diagnosis, but at no time, it is intended to replace the physician judgment.
Cardio Sistemas is not responsible for errors caused by system operator's misuse or lack of knowledge, as well as any consequences this may cause to third parties. It is the license owner's responsibility to ensure that users are trained and capable to use the program.

Like any other software, CardioSmart CS550 may be modified for either correction of problems, adaptation to new computational resources or improvements. The license owner is responsible for keeping the system updated on all computers on which it is installed. Cardio Sistemas releases periodic software updates and provides technical support for its installation. The license owner is advised to keep periodic contact with Cardio Sistemas in order to check for any available updates, if they are not contacted.

The license owner should use the software and its updates made available only by Cardio Sistemas. Any other form of acquisition and its consequences are the license owner's responsibility.

Cardio Sistemas strongly recommends that the software be executed on a computer with active and up-to-date anti-virus and antispyware software to minimize the risk of infection by viruses, spyware, and other unwanted programs that may affect system performance in an unpredictable way.

Cardio Sistemas does not guarantee the error-free operation of the software, nor the corruption of data that may interfere with the final results, in case of using the software in a virtualized operating system, such as Oracle VM VirtualBox©, Parallels©, VMWare©, among others.

System screen format and messages may vary depending on the operating system version used, as well as the environment settings defined by the user.

The Software features may vary according to the configuration requested by the LICENSEE and/or according to the region or country in which the LICENSEE is located. The LICENSEE may not require Software features that are not compatible with the configuration requested by the LICENSEE or that violate applicable law or the right of any third party.

The LICENSOR is not responsible for incompatibilities caused by changes of the appropriate settings made by the LICENSEE. In case of doubt, please contact Cardio Sistemas Customer Service.

The user should make sure that the operating instructions (user manual) being used refer to the corresponding software version. This information can be found on the user manual cover and in software information screens. In case of doubt, please contact Cardio Sistemas Customer Service.

When start editing an exam, remember that the Atrial Fibrillation component (if available) may be already activated for arrhythmia automatic identification.
If the Atrial Fibrillation component is activated and unidentified atrial ectopies are observed, the automatic arrhythmia identification tool should be disabled in this exam and an exam reanalysis should be performed according to the procedure described below:
[Analysis] [Reanalyze...] [select Atrial Fibrillation settings] [uncheck the option enable Atrial Fibrillation component] [Analysis] [Reanalyze...][OK]

To disable the Atrial Fibrillation component for all new exams, use the procedure described below:
[Settings] [System] [select Atrial Fibrillation settings] [uncheck the option enable Atrial Fibrillation component]

In order to avoid possible problems with the database used by the software, such as the loss of exams, we suggest the software installation on a computer equipped with an Uninterrupted Power Supply (UPS) or with its own battery, which avoids unexpected shutdown.

For the patient and software operator safety, it is recommended the operator does not make simultaneous physical contact with the patient and the computer on which the software is running, and furthermore, the computer is connected to power mains compatible with the current regulations.

Software life cycle:
Cardios is responsible for keeping the software compatible with the following Microsoft Windows© operating system versions, until the dates stated below, corresponding to the end of the support of those operating systems by the developer entity:

Operating systems (with latest updates available)	Final date
Windows 8 / Windows 8.1	January 10, 2023
Windows 10	October 14, 2025

The license owner is responsible for using the software on an operating system that is no longer supported by its developer entity, as well as using it on any other client or server version that is not listed in the table above. It is also the customer's responsibility to keep the operating system updated. Cardio Sistemas cannot be held liable in the law or in any other aspects, in the case of loss of exams or any other problem with them, if the license owner decides to continue using the operating system that is no longer supported by its developer entity.
The customer should contact Cardios Customer Service for information on how to proceed after the dates mentioned.

1.4. GENERAL ASPECTS

The CardioSmart CS550 analysis software represents the state of the art in processing algorithms, associated with a flexible set of intelligent editing tools, in a cost-effective modular solution for non-invasive electrocardiographic studies.

CardioSmart CS550 is an intelligent software developed and tested in partnership with industry professionals, resulting in an analytical system that combines high performance, reliability, and versatility with a wide variety of features and applications.

This allows users to interact with the software while optimizing their work time and analysis results. The data processing and reporting are quick and accurate, enabling fast operation and reliability in results.

The system supports the acquisition of data recorded in digital mode, providing a comprehensive analysis of arrhythmias and heart rate variability.
Optional features can be added to the basic systems, in the form of “PLUGINS” (components), and modules, improving performance and flexibility according to user needs. The advanced CardioSmart CS550 module provides the database management of exams, patients, referring and analyst physicians, medications and diagnostics, as well as the digital interfaces control. The system programming and data acquisition are managed by the CardioManager module.
All possible system modules and components are accessible via the CardioManager module selector.

1.5. TECHNICAL COMPATIBILITY WITH OTHER DEVICES

The CardioSmart CS550 is technically compatible with the following devices:

CardioLight+ (Digital Holter Recorder)

The CardioSmart CS550 is technically compatible with the digital files provided by the following software:

CardioNet® Server Software
CardioNet® Client Software
CardioNet® DICOM Software
CardioNet® Client DICOM Software

1.6. ST METHODS AND ANALYSIS

Method for calculating the Heart Rate
The Heart Rate (HR) calculation uses the moving window method and HR is determined by considering the previous 4 RRs, the current RR, and the 3 subsequent RRs. The window is then moved forward, and everything restarts until the recording is finished. All HR values are the result of the moving window of 8 RRs. TV and TSV classifiers compute ectopic HR directly at the time of episode detection.

The analyzer does not calculate the HR for Artifacts. A series of Ventricular Heartbeats and Interrogated Ventricular Heartbeats is “skipped” and treated as a single RR interval. In this case, the RR interval value is the first Heartbeat of the series.

Method to determine a Pause
The Pauses are determined considering:

- Heartbeats for which RR interval is indicated.

The software suppresses this information when it precedes two or more consecutive Artifact Heartbeats or a Deleted Heartbeat mark.

- Heartbeat RR interval is greater than the criteria set in the analysis configuration (Factory default value is: 2.0 seconds);
- Heartbeat RR interval is longer than 30 seconds.

ST analysis
The ST analysis evaluates all selected channels and/or recording Derivations independently, using any available calibration signal.

The user can disconnect a channel from the analysis through the Reanalysis or Selective Analysis configuration.

ST Analysis selectable criteria

The software allows the configuration of the following criteria for ST Analysis:

- Interval minimum length;
- Maximum proximity of two ST episodes that will allow combined them in a single episode;
- ST elevation limit; and
- ST depression limit.

Method used to determine an ST episode
The software uses a detection method which considers that an ST interval will initiate only if it is preceded by a series of 3 N heartbeats and the previous 8 heartbeats should be valid, normal or not. In addition, in this series there can be no variation greater than 2 mm from the ST level. The heartbeats will be evaluated as long as the ST displacement lasts. The interval will be extended if displacements sufficiently close are detected, and thus extending until no more displacements occur according to the programmed interval. Then it is registered, and a new search starts until the recording is completed.

ST Analysis Report

The ST episodes are presented to the analyst containing:
- Time (HH: MM: SS);
- Duration in minutes;
- Depression or elevation maximum value (mm);
- Inclination (Ascending, Horizontal or Descending);
- Detected channel (channels are independent);
- Basal HR (is the value at the episode's beginning); and
- Maximum HR.

There is a highlight to the consolidated value per channel, separated by elevation and depression, containing:
- Episodes total number;
- Total duration (in minutes); and
- Value and time of the maximum displacement.

All the above data is presented in the printed report, in tabular format.

In addition, the printed report presents two tables on the cover sheet (depressions and elevations) with the consolidated figures, containing:
- Number of episodes; and
- Maximum value and time.

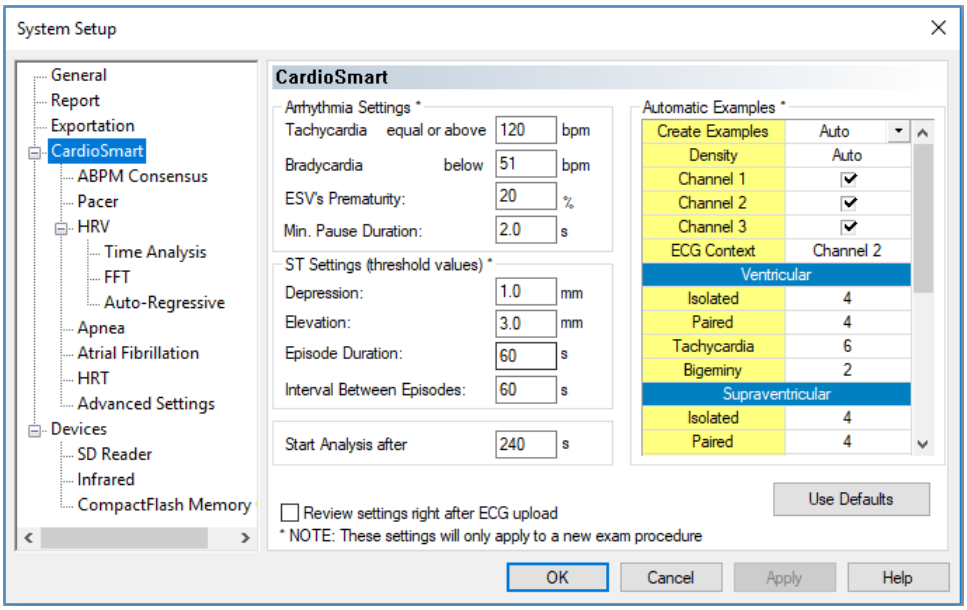
1.7. MANUFACTURER SETTINGS

System Configuration
The Manufacturer System Configuration for the operator-selectable analysis criteria are presented in the following sub-items.

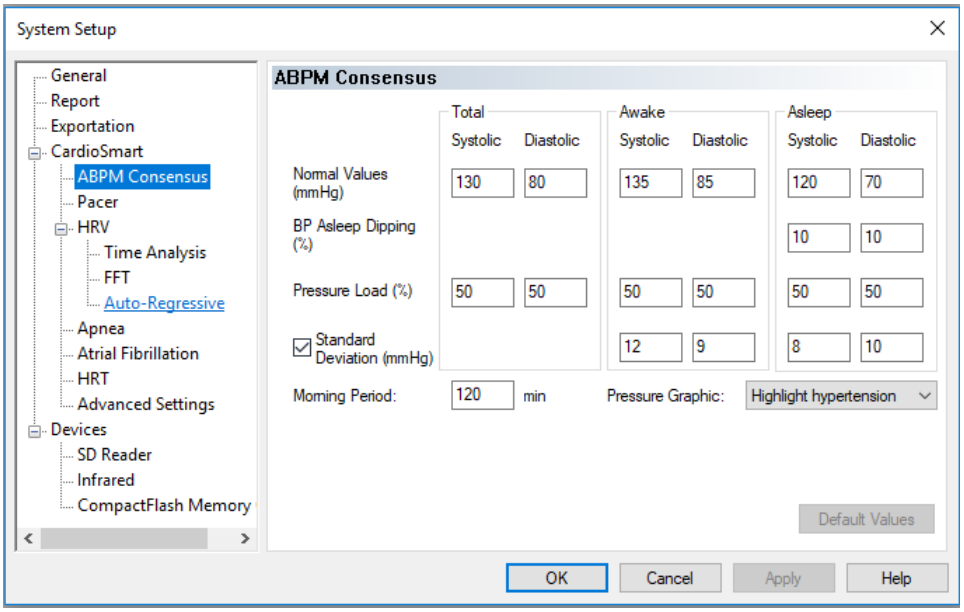
The System Configuration can be selected by the Operator through the Settings -> System menu.

The Analyst Physician is responsible for checking the selected Analysis Criteria in the System Configuration.

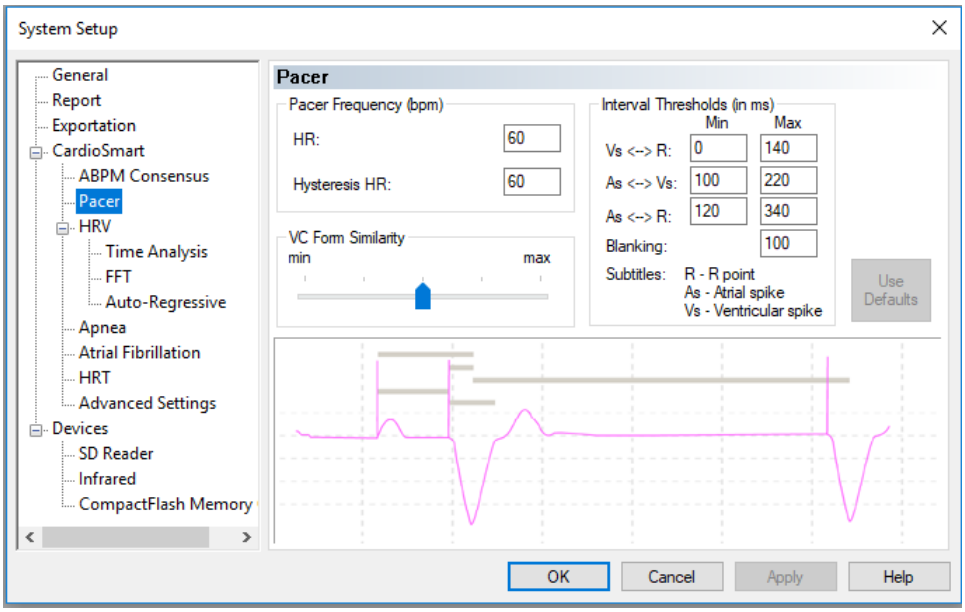
CardioSmart CS550 Software Configuration



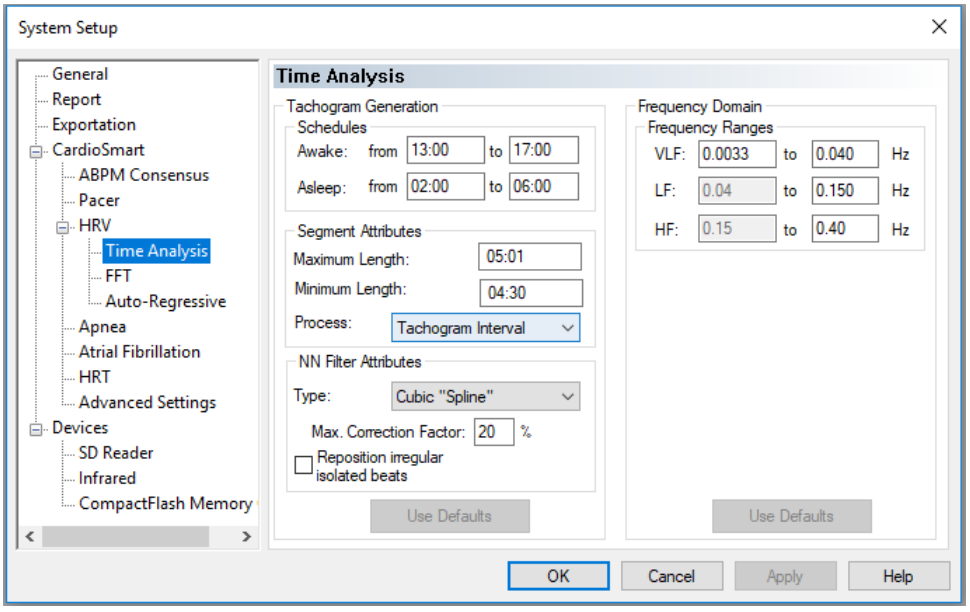
CardioSmart CS550 Software Configuration for ABPM Consensus



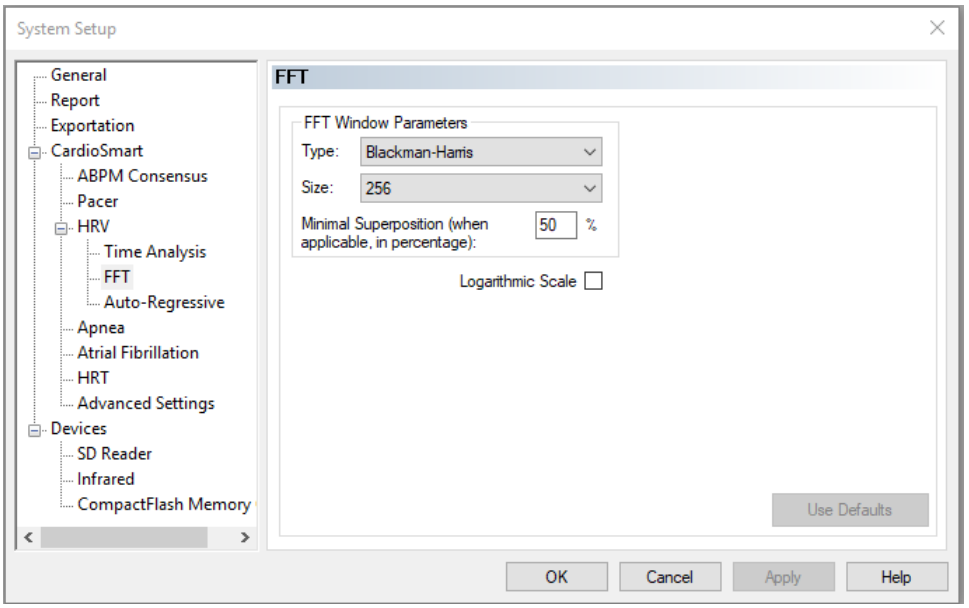
CardioSmart CS550 Software Configuration for Pacemaker



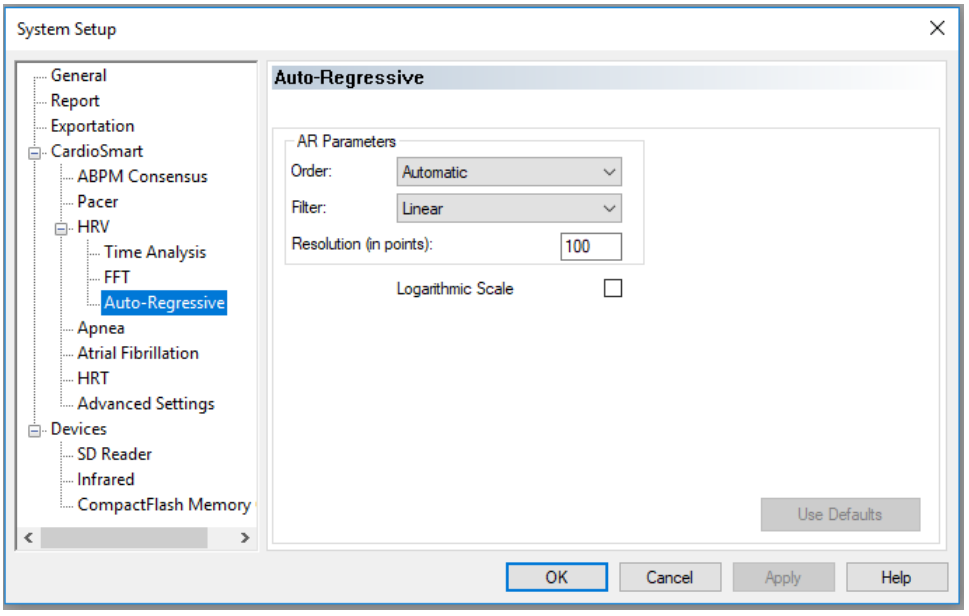
CardioSmart CS550 Software Configuration for Basic Parameters HRV



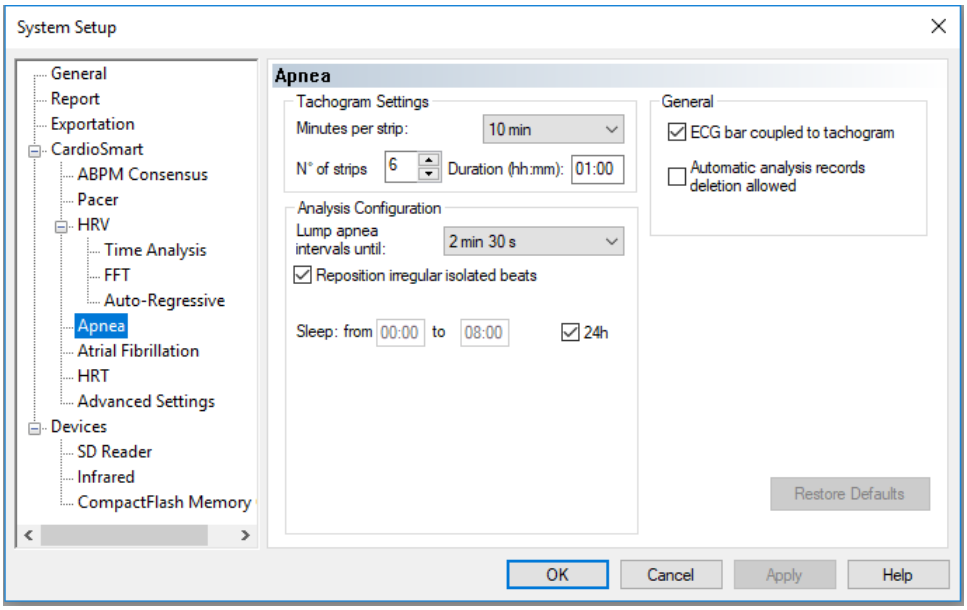
CardioSmart CS550 Software Configuration for FFT Analysis of HRV



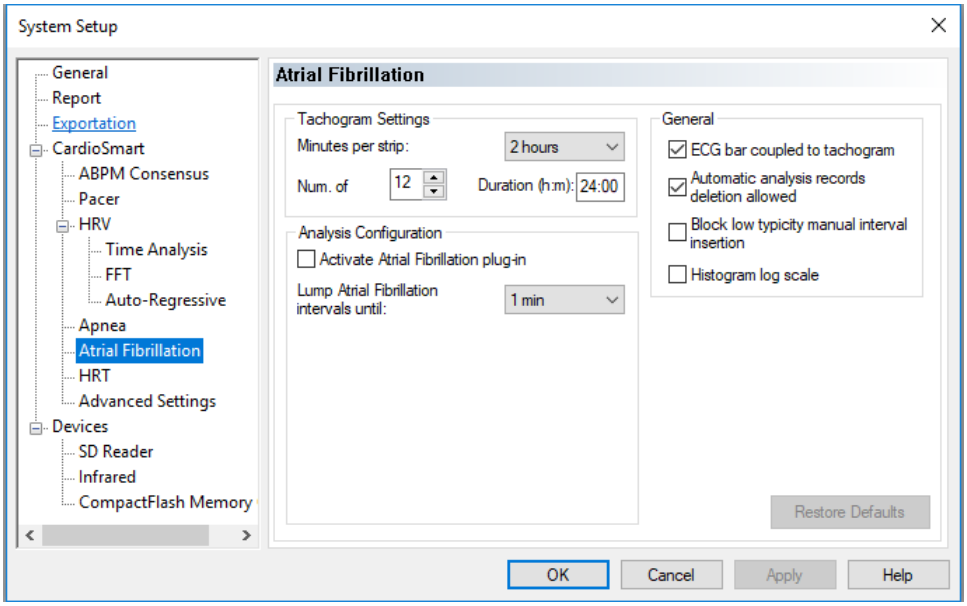
CardioSmart CS550 Software Configuration for HRV Autoregressive Analysis



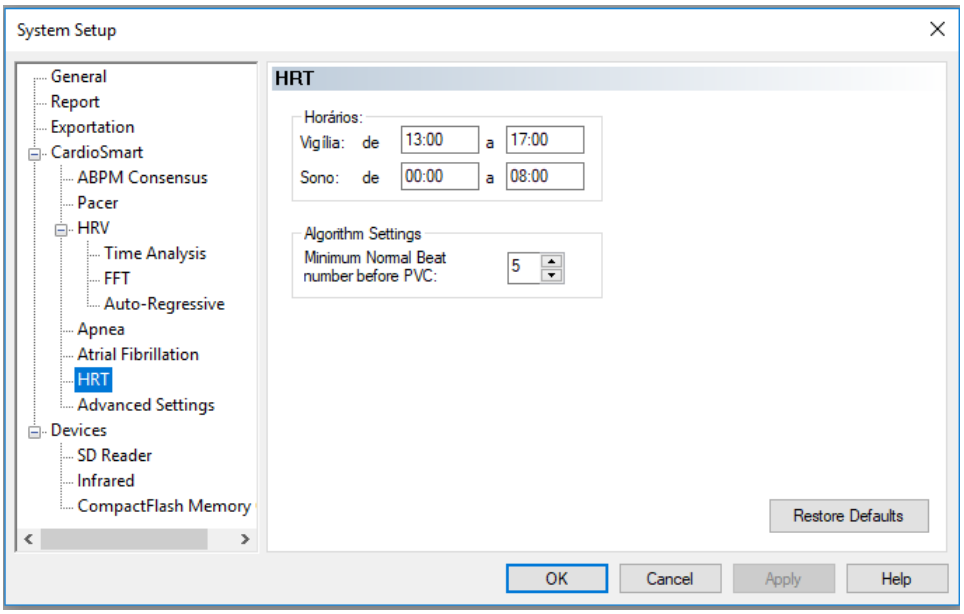
CardioSmart CS550 Software Configuration for Apnea



CardioSmart CS550 Software Configuration for Atrial Fibrillation



CardioSmart CS550 Software Configuration for HR Turbulence



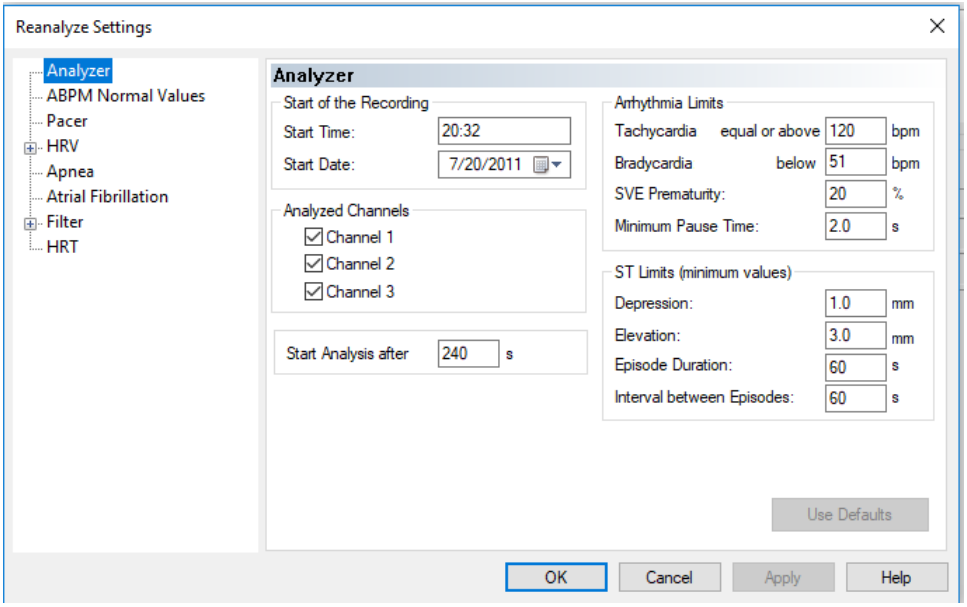
Reanalysis Configuration

The Manufacturer Reanalysis Configuration for the operator-selectable analysis criteria are presented in the following sub-items.

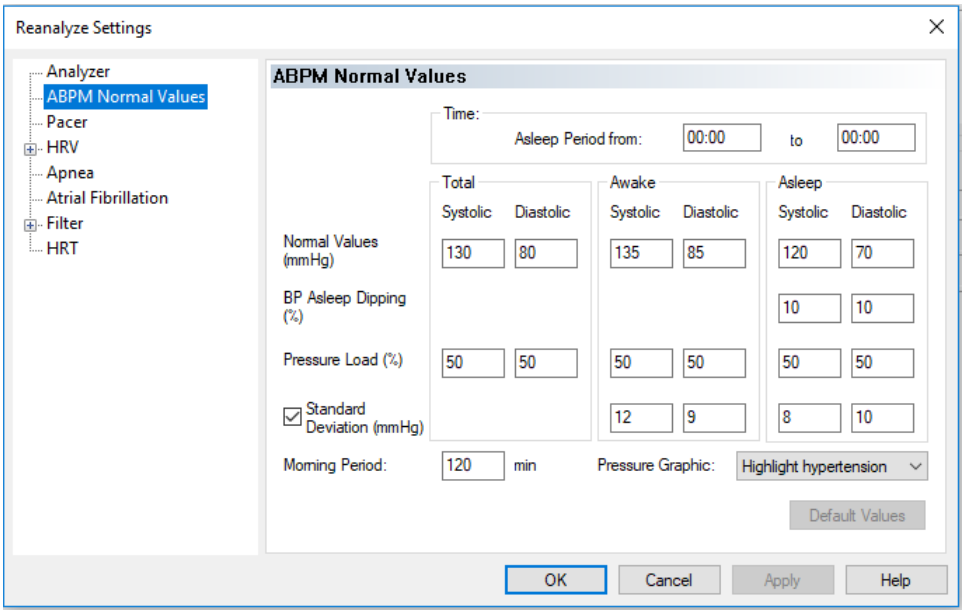
The Reanalysis Configuration can be selected by the Operator through the Analysis -> Reanalyze menu.

The Analyst Physician is responsible for checking the selected Analysis Criteria in the Reanalysis Configuration.

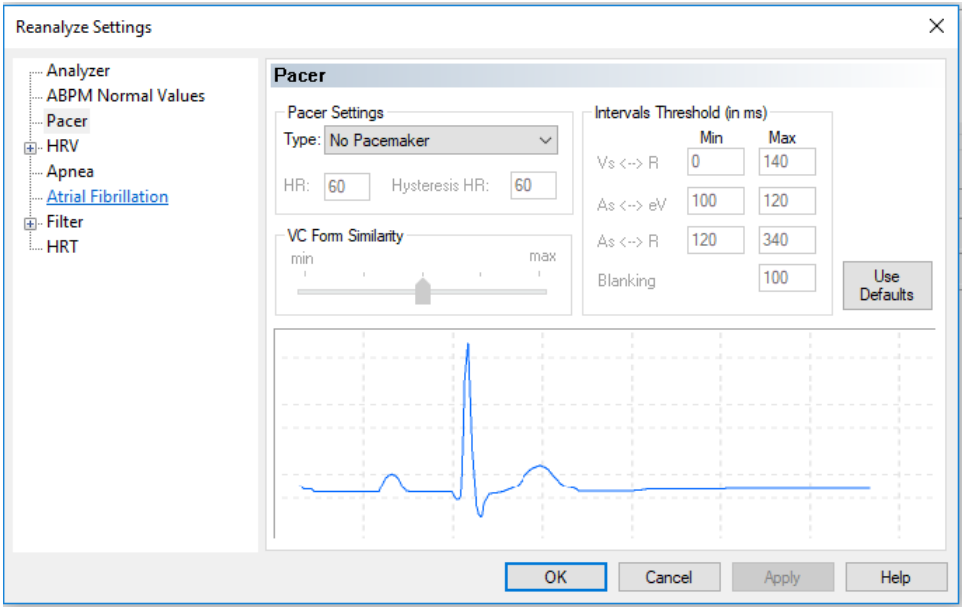
Reanalysis Configuration for Analysis



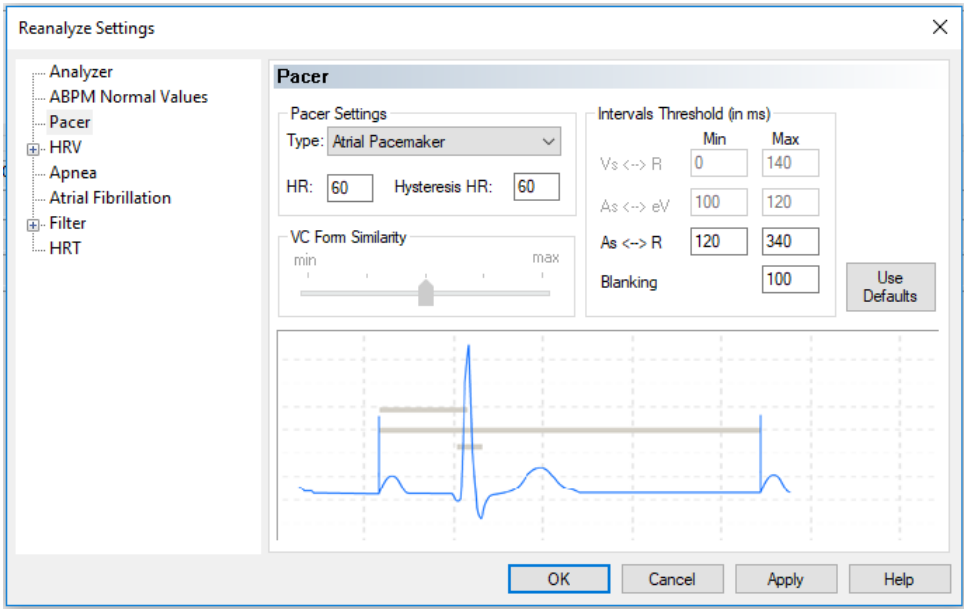
Reanalysis Configuration for ABPM Clinical Limits



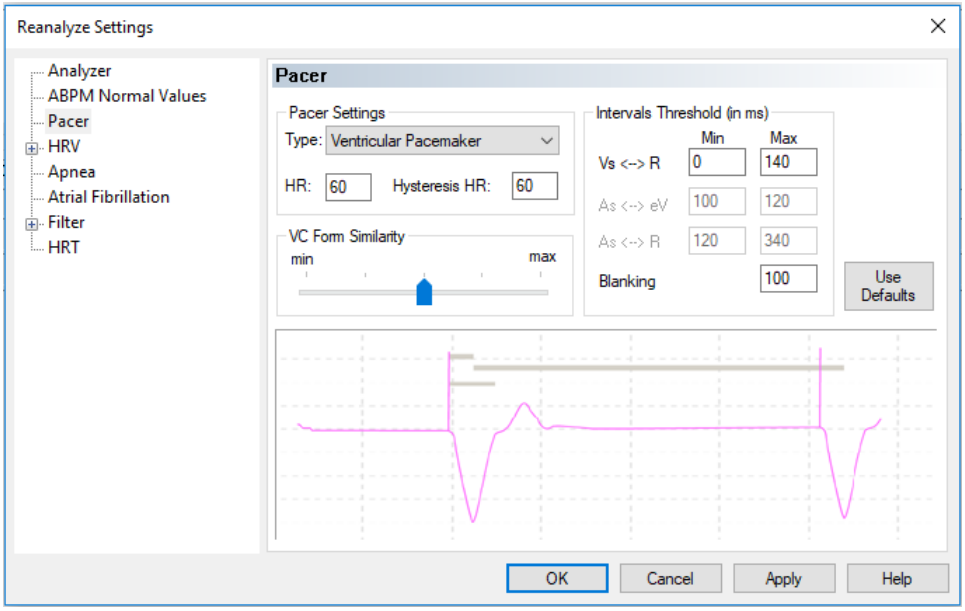
Reanalysis Configuration for Pacemaker



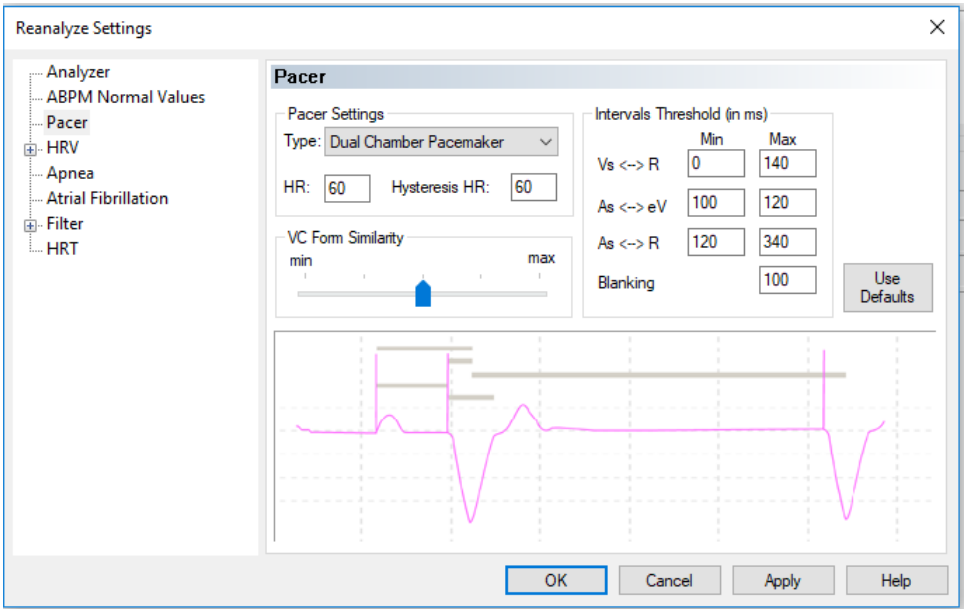
Reanalysis Configuration for Atrial-Type Pacemaker



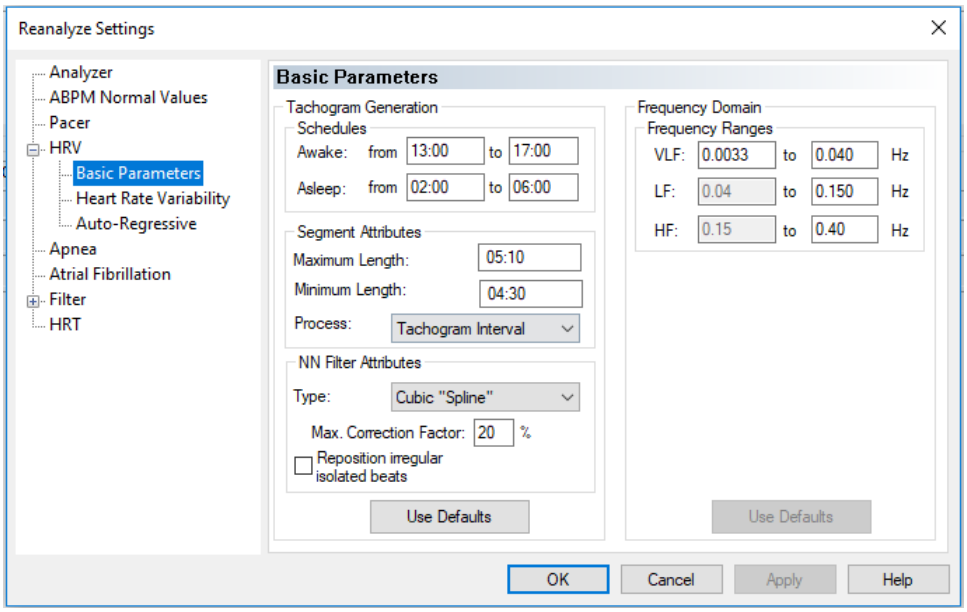
Reanalysis Configuration for Ventricular-Type Pacemaker



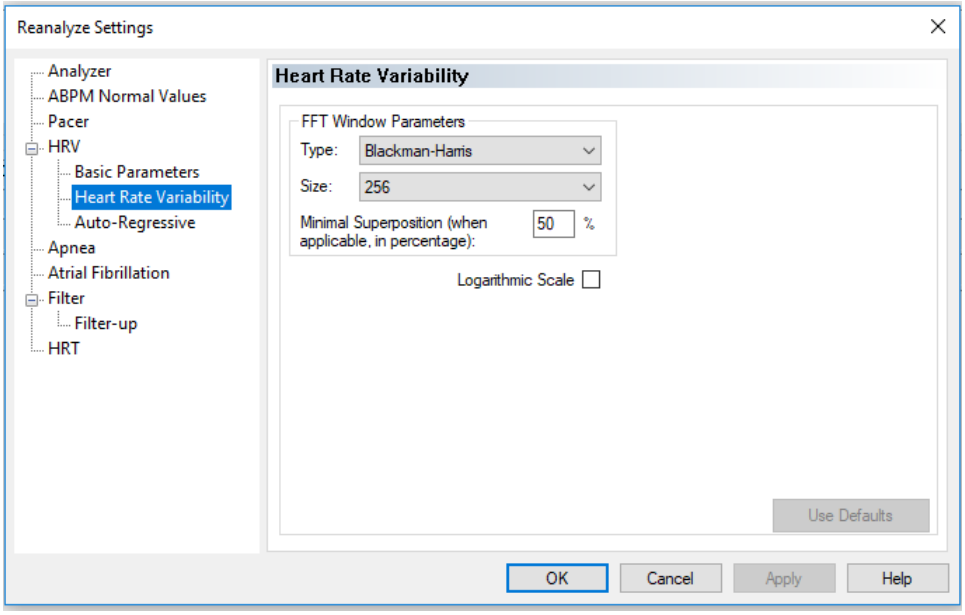
Reanalysis Configuration for Dual-Chamber-Type Pacemaker



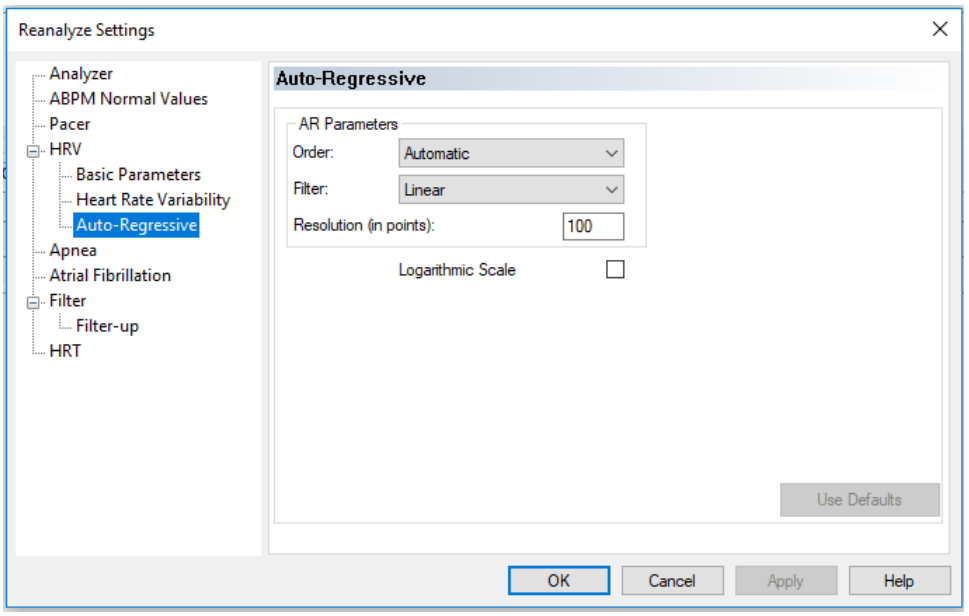
Reanalysis Configuration for Basic Parameters HRV



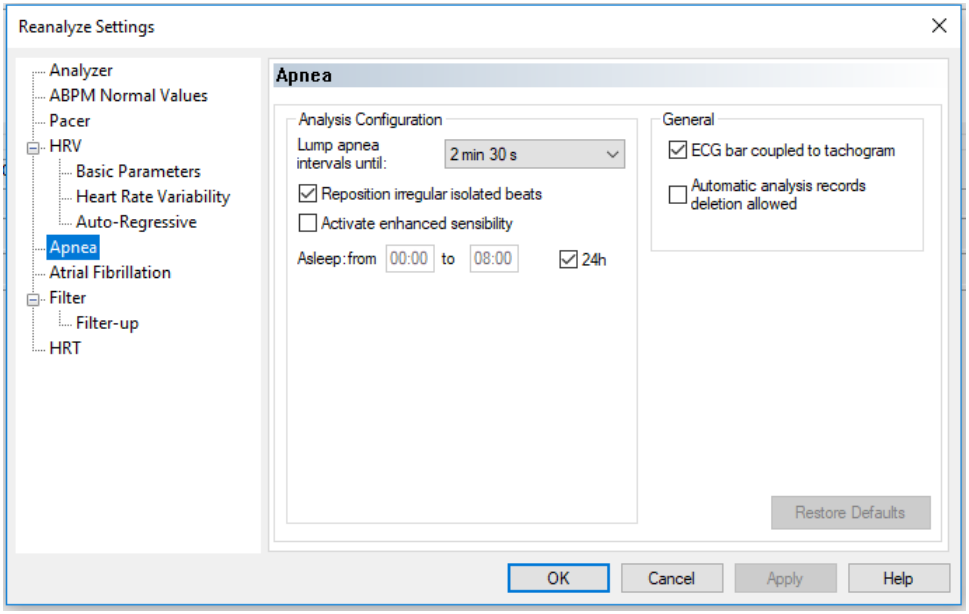
Reanalysis Configuration for FFT Analysis of HRV



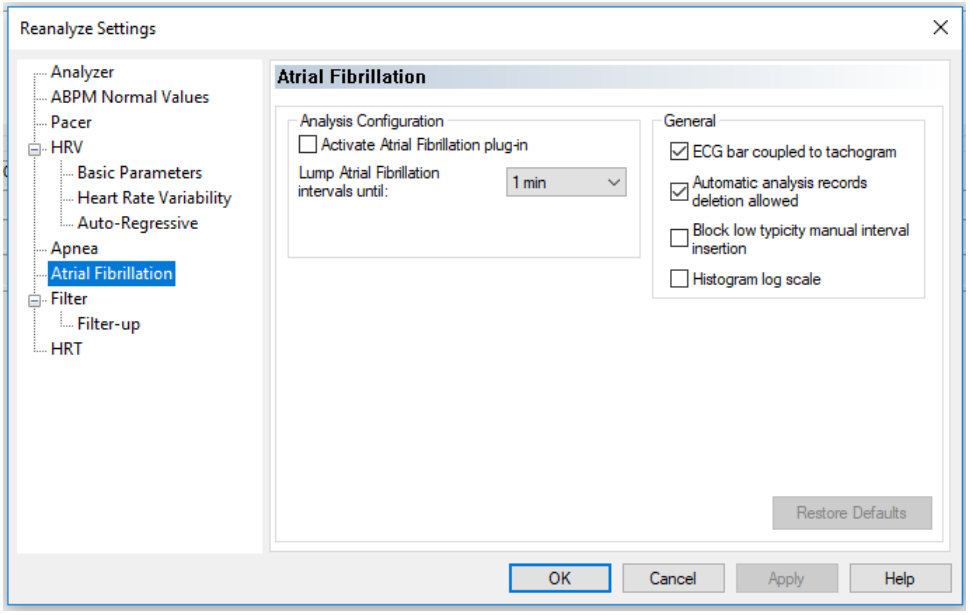
Reanalysis Configuration for Autoregression Analysis of HRV



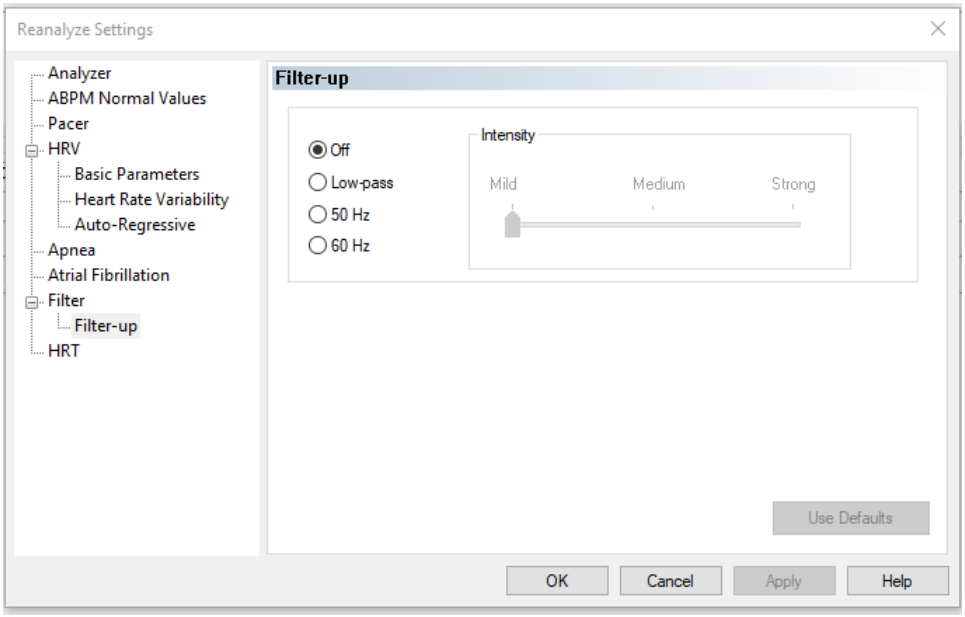
Reanalysis Configuration for Apnea



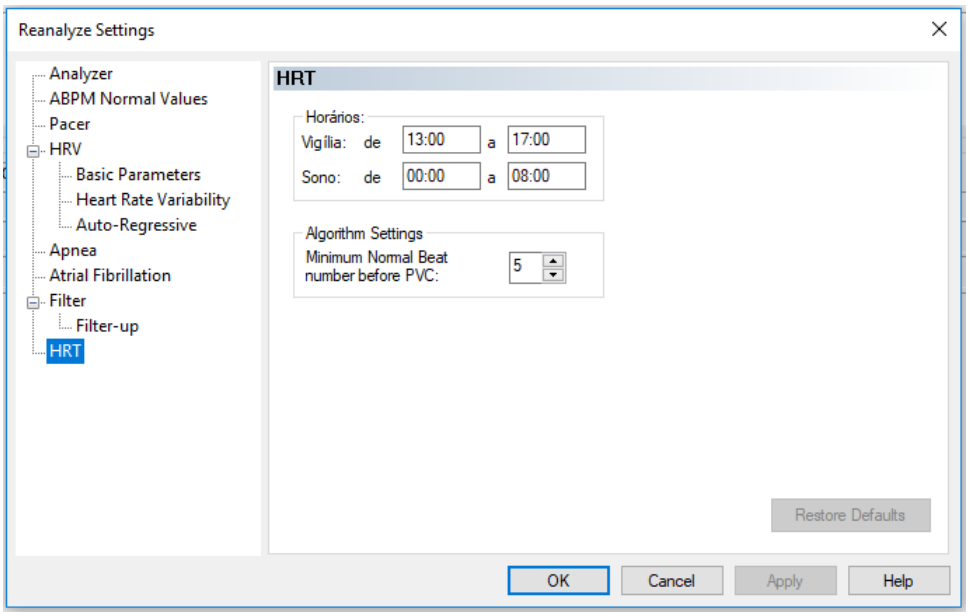
Reanalysis Configuration for Atrial Fibrillation



Reanalysis Configuration for Filters



Reanalysis Configuration for HR Turbulence

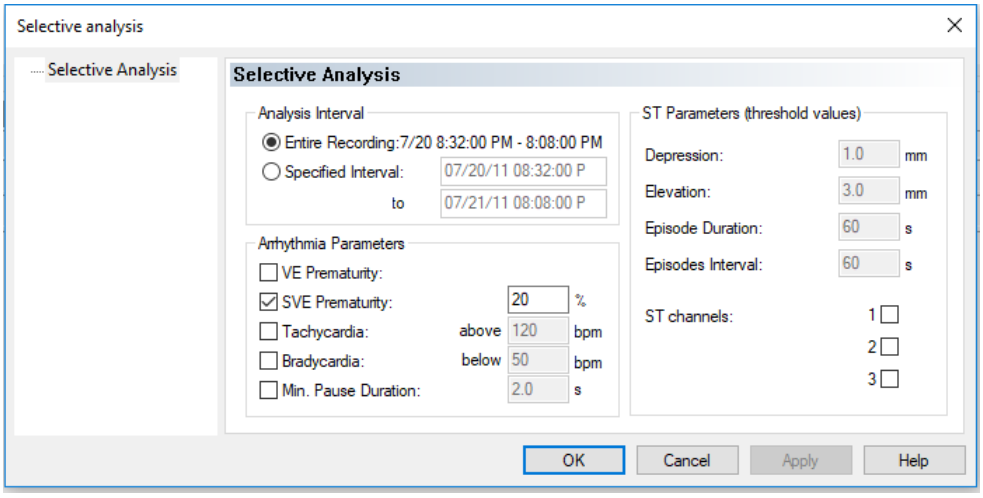


Selective Analysis Configuration

The Manufacturer Selective Analysis Configuration for the operator-selectable analysis criteria are presented in the following sub-items.

The Analysis Configuration can be selected by the Operator through the Analysis -> Selective Analysis menu.

The Analyst Physician is responsible for checking the selected Analysis Criteria in the Selective Analysis Configuration.



1.8. HOLTER REPORT

Holter Report Configuration

The Holter Report setting defines the items that will be displayed in the report and some parameters for printing.

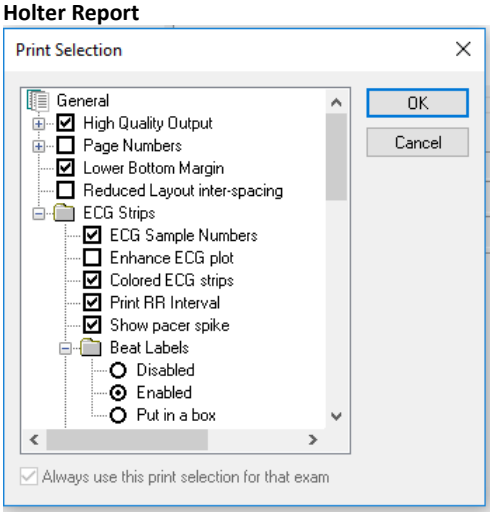
Exam Holter Report Configuration

The Software Configuration for the Holter Report can be selected by the Operator through the Settings -> System -> Report menu.

The Holter Report Configuration for a given Exam can be selected by the Operator through the Settings -> Report menu.

The Analyst Physician is responsible for checking the Holter Report Configuration according to the selected Analysis Criteria.

Holter Report



The Holter Report can be printed by the Operator through the Exam -> Print menu.

The following are Holter Report examples.

Holter Report Cover Sheet Example

Holter Report

1 - Exam data

Exam Number	Exam date: 6/15/2011 7:00	Code:
M	Protocol: Holter - 3 channels	14L-00121

2 - Patient Data

Name: B
Sex: F **Height:** 1,68 **Weight:** 70 **Age:** 25 **Smoker:** Yes

Medication: AAS.

3 - Doctor

Name: Doctor Luiz **Phone:**
Office: Cardio Dinâmica **Fax:**

4 - Statistical Report

Totals:

Duration (h):	**23:58**	
Total QRS's:	**105,268**	
Ventricular Ectopics:	**1**	(<1%)
Supraventricular Ectopics:	**6**	(<1%)
Artifacts (%):	**<1**	

Heart Rate:

Min: **45** bpm at **1:17:33 AM**
Average: **74** bpm
Max: **113** bpm at **8:48:02 AM**

HR >= 120 bpm not found
HR <= 50 bpm during **12:55:47 AM**h

Ventricular Arrhythmias:

1 Isolated, of which
0 in 0 Bigeminy episodes
0 Couplets
0 Tachychardias

Pauses:

0 Pauses (>= 2.0 s.)

ST Depression

C1: **0** episodes
C2: **0** episodes
C3: **0** episodes

Supraventricular Arrhythmias:

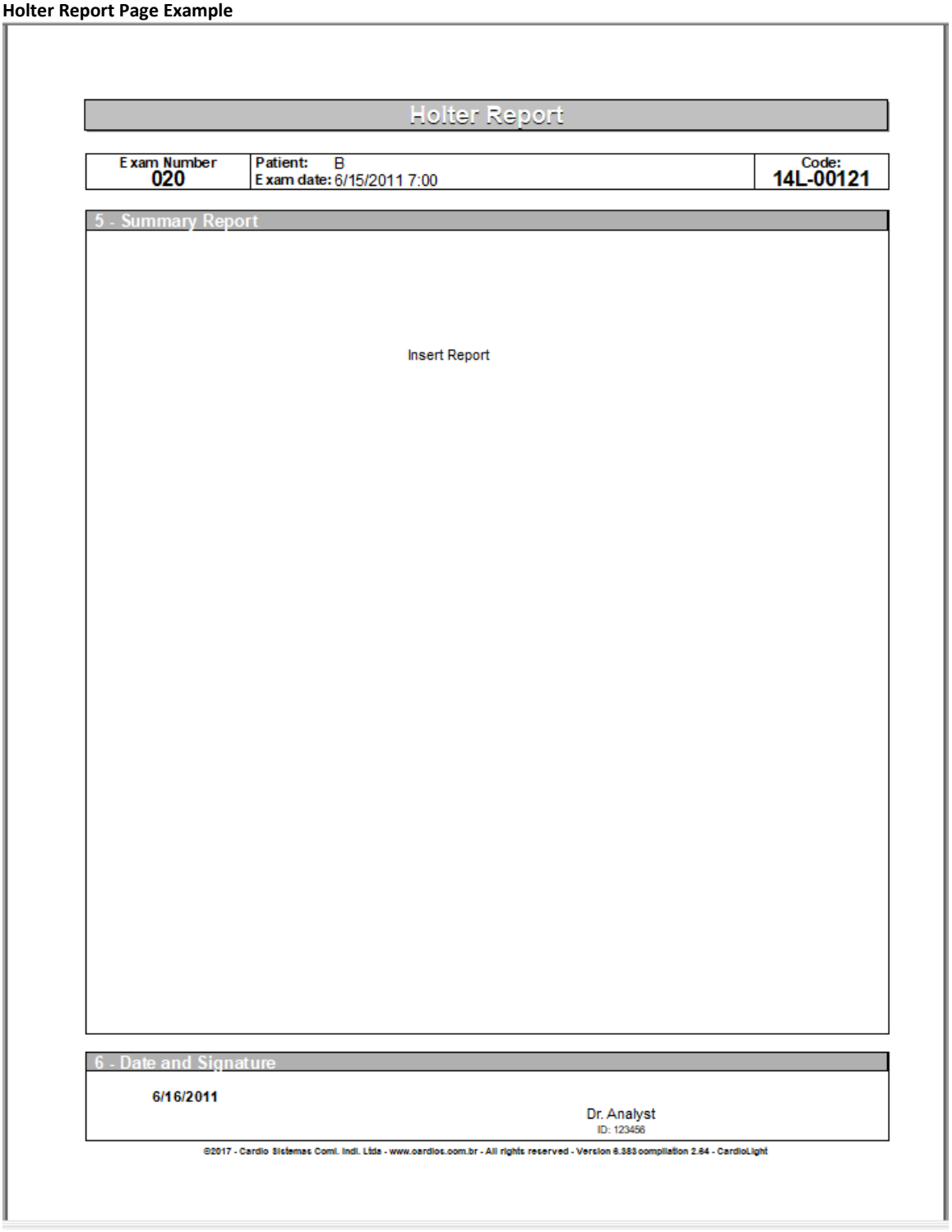
6 Isolated
0 Couplets
0 Tachychardias

ST Elevation

C1: **0** episodes
C2: **0** episodes
C3: **0** episodes

Criteria: *Channels analyzed: 1,2,3; Start analysis after 240.0 s; Total analyzed time: 23:55:00; Parameters of arrhythmias: Tachycardias equal to or greater than 120 bpm, Bradycardia below 50 bpm, Prematurity of SVs 20 %, Minimum pause time 2.0 s; Parameters of ST (minimum values): Depression 6.0 mm, Elevation 3.0 mm, Duration of the episode 60 s, Interval between episodes 60 s.*

Holter Report Page Example



Holter Report

Exam Number	Patient: B	Code:
020	Exam date: 6/15/2011 7:00	14L-00121

5 - Summary Report

Insert Report

6 - Date and Signature

6/16/2011

Dr. Analyst
ID: 123456

Holter Report Tabular Summary Example

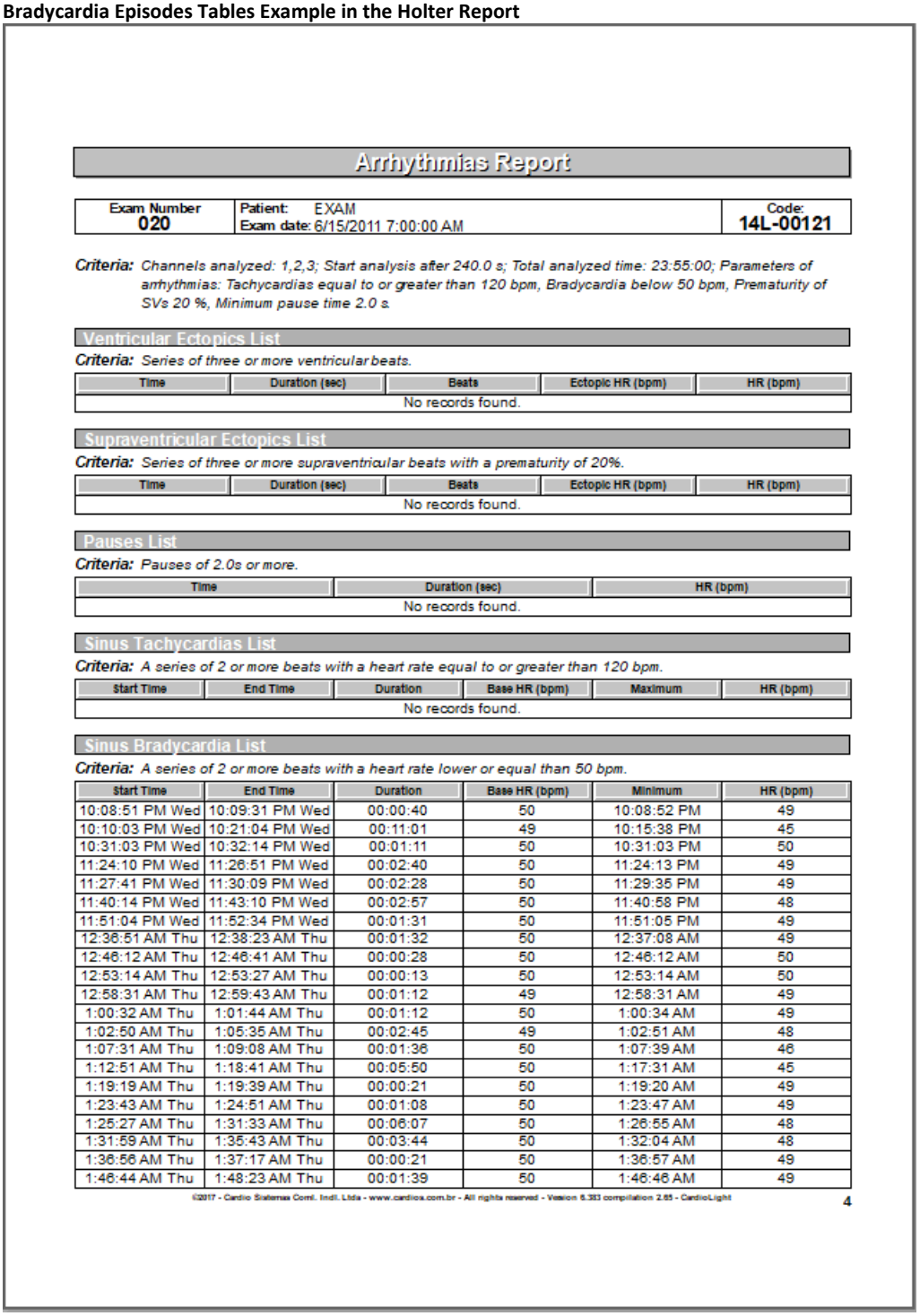
Tabular Report

Exam Number	Patient: EXAM	Code:
020	Exam date: 6/15/2011 7:00:00 AM	14L-00121

Time	HR(min)	HR(avg)	HR(max)	QRS's	V Iso	V pair	V Tach	Tot V	SV Iso	SV pair	SV Tach	Tot SV	Pauses
7:00	58	75	96	4,153				0					
8:00	61	80	113	4,752				0					
9:00	61	81	101	4,786				0	1			1	
10:00	70	82	104	4,898				0					
11:00	66	82	110	4,920				0	1			1	
12:00	67	85	106	5,070				0					
1:00	63	78	103	4,669				0					
2:00	63	79	105	4,702				0					
3:00	61	80	103	4,752				0	1			1	
4:00	60	73	94	4,351				0	1			1	
5:00	55	66	85	3,937				0	1			1	
6:00	55	65	85	3,859				0					
7:00	56	70	93	4,173				0					
8:00	52	61	81	3,646				0					
9:00	51	58	81	3,472				0					
10:00	45	57	80	3,406				0	1			1	
11:00	48	58	79	3,432				0					
12:00	49	56	89	3,369	1			1					
1:00	45	56	86	3,292				0					
2:00	56	82	106	4,808				0					
3:00	72	96	111	5,716				0					
4:00	66	85	108	5,066				0					
5:00	63	83	106	4,939				0					
6:00	65	87	110	5,100				0					
Totals:	45	74	113	105,268	1			1	6			6	

Criteria: *Channels analyzed: 1,2,3; Start analysis after 240.0 s; Total analyzed time: 23:55:00; Parameters of arrhythmias: Tachycardias equal to or greater than 120 bpm, Bradycardia below 50 bpm, Prematurity of SVs 20 %, Minimum pause time 2.0 s; Parameters of ST (minimum values): Depression 6.0 mm, Elevation 3.0 mm, Duration of the episode 60 s, Interval between episodes 60 s.*

Bradycardia Episodes Tables Example in the Holter Report



Arrhythmias Report

Exam Number	Patient: EXAM	Code:
020	Exam date: 6/15/2011 7:00:00 AM	14L-00121

Criteria: *Channels analyzed: 1,2,3; Start analysis after 240.0 s; Total analyzed time: 23:55:00; Parameters of arrhythmias: Tachycardias equal to or greater than 120 bpm, Bradycardia below 50 bpm, Prematurity of SVs 20 %, Minimum pause time 2.0 s.*

Ventricular Ectopics List

Criteria: *Series of three or more ventricular beats.*

Time	Duration (sec)	Beats	Ectopic HR (bpm)	HR (bpm)
No records found.				

Supraventricular Ectopics List

Criteria: *Series of three or more supraventricular beats with a prematurity of 20%.*

Time	Duration (sec)	Beats	Ectopic HR (bpm)	HR (bpm)
No records found.				

Pauses List

Criteria: *Pauses of 2.0s or more.*

Time	Duration (sec)	HR (bpm)
No records found.		

Sinus Tachycardias List

Criteria: *A series of 2 or more beats with a heart rate equal to or greater than 120 bpm.*

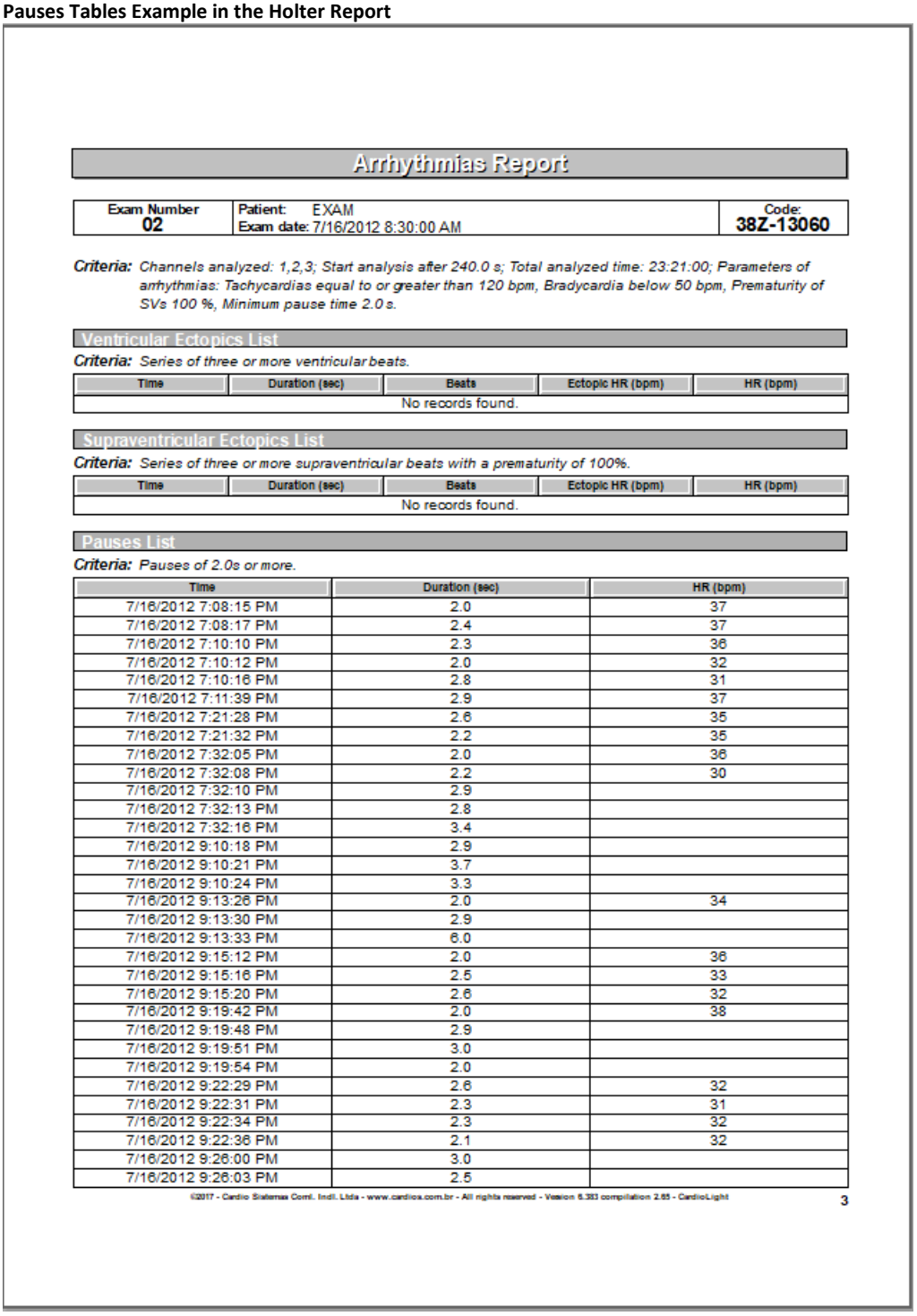
Start Time	End Time	Duration	Base HR (bpm)	Maximum	HR (bpm)
No records found.					

Sinus Bradycardia List

Criteria: *A series of 2 or more beats with a heart rate lower or equal than 50 bpm.*

Start Time	End Time	Duration	Base HR (bpm)	Minimum	HR (bpm)
10:08:51 PM Wed	10:09:31 PM Wed	00:00:40	50	10:08:52 PM	49
10:10:03 PM Wed	10:21:04 PM Wed	00:11:01	49	10:15:38 PM	45
10:31:03 PM Wed	10:32:14 PM Wed	00:01:11	50	10:31:03 PM	50
11:24:10 PM Wed	11:26:51 PM Wed	00:02:40	50	11:24:13 PM	49
11:27:41 PM Wed	11:30:09 PM Wed	00:02:28	50	11:29:35 PM	49
11:40:14 PM Wed	11:43:10 PM Wed	00:02:57	50	11:40:58 PM	48
11:51:04 PM Wed	11:52:34 PM Wed	00:01:31	50	11:51:05 PM	49
12:36:51 AM Thu	12:38:23 AM Thu	00:01:32	50	12:37:08 AM	49
12:46:12 AM Thu	12:46:41 AM Thu	00:00:28	50	12:46:12 AM	50
12:53:14 AM Thu	12:53:27 AM Thu	00:00:13	50	12:53:14 AM	50
12:58:31 AM Thu	12:59:43 AM Thu	00:01:12	49	12:58:31 AM	49
1:00:32 AM Thu	1:01:44 AM Thu	00:01:12	50	1:00:34 AM	49
1:02:50 AM Thu	1:05:35 AM Thu	00:02:45	49	1:02:51 AM	48
1:07:31 AM Thu	1:09:08 AM Thu	00:01:36	50	1:07:39 AM	46
1:12:51 AM Thu	1:18:41 AM Thu	00:05:50	50	1:17:31 AM	45
1:19:19 AM Thu	1:19:39 AM Thu	00:00:21	50	1:19:20 AM	49
1:23:43 AM Thu	1:24:51 AM Thu	00:01:08	50	1:23:47 AM	49
1:25:27 AM Thu	1:31:33 AM Thu	00:06:07	50	1:26:55 AM	48
1:31:59 AM Thu	1:35:43 AM Thu	00:03:44	50	1:32:04 AM	48
1:36:56 AM Thu	1:37:17 AM Thu	00:00:21	50	1:36:57 AM	49
1:46:44 AM Thu	1:48:23 AM Thu	00:01:39	50	1:46:46 AM	49

Pauses Tables Example in the Holter Report



Arrhythmias Report

Exam Number	Patient: EXAM	Code:
02	Exam date: 7/16/2012 8:30:00 AM	38Z-13060

Criteria: *Channels analyzed: 1,2,3; Start analysis after 240.0 s; Total analyzed time: 23:21:00; Parameters of arrhythmias: Tachycardias equal to or greater than 120 bpm, Bradycardia below 50 bpm, Prematurity of SVs 100 %, Minimum pause time 2.0 s.*

Ventricular Ectopics List

Criteria: *Series of three or more ventricular beats.*

Time	Duration (sec)	Beats	Ectopic HR (bpm)	HR (bpm)
No records found.				

Supraventricular Ectopics List

Criteria: *Series of three or more supraventricular beats with a prematurity of 100%.*

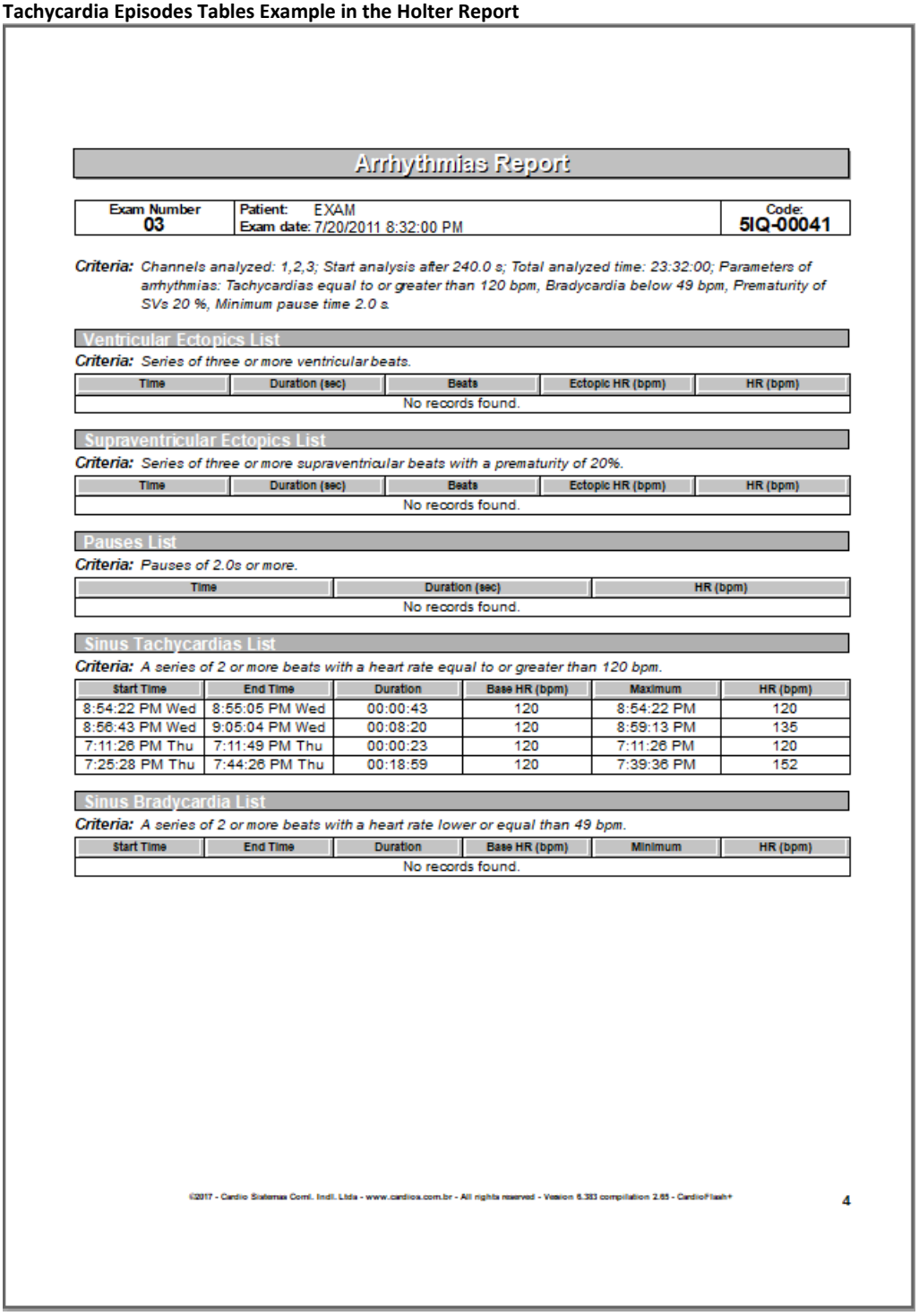
Time	Duration (sec)	Beats	Ectopic HR (bpm)	HR (bpm)
No records found.				

Pauses List

Criteria: *Pauses of 2.0s or more.*

Time	Duration (sec)	HR (bpm)
7/16/2012 7:08:15 PM	2.0	37
7/16/2012 7:08:17 PM	2.4	37
7/16/2012 7:10:10 PM	2.3	36
7/16/2012 7:10:12 PM	2.0	32
7/16/2012 7:10:16 PM	2.8	31
7/16/2012 7:11:39 PM	2.9	37
7/16/2012 7:21:28 PM	2.6	35
7/16/2012 7:21:32 PM	2.2	35
7/16/2012 7:32:05 PM	2.0	36
7/16/2012 7:32:08 PM	2.2	30
7/16/2012 7:32:10 PM	2.9	
7/16/2012 7:32:13 PM	2.8	
7/16/2012 7:32:16 PM	3.4	
7/16/2012 9:10:18 PM	2.9	
7/16/2012 9:10:21 PM	3.7	
7/16/2012 9:10:24 PM	3.3	
7/16/2012 9:13:26 PM	2.0	34
7/16/2012 9:13:30 PM	2.9	
7/16/2012 9:13:33 PM	6.0	
7/16/2012 9:15:12 PM	2.0	36
7/16/2012 9:15:16 PM	2.5	33
7/16/2012 9:15:20 PM	2.6	32
7/16/2012 9:19:42 PM	2.0	38
7/16/2012 9:19:48 PM	2.9	
7/16/2012 9:19:51 PM	3.0	
7/16/2012 9:19:54 PM	2.0	
7/16/2012 9:22:29 PM	2.6	32
7/16/2012 9:22:31 PM	2.3	31
7/16/2012 9:22:34 PM	2.3	32
7/16/2012 9:22:36 PM	2.1	32
7/16/2012 9:26:00 PM	3.0	
7/16/2012 9:26:03 PM	2.5	

Tachycardia Episodes Tables Example in the Holter Report



Arrhythmias Report

Exam Number	Patient: EXAM	Code:
03	Exam date: 7/20/2011 8:32:00 PM	5IQ-00041

Criteria: *Channels analyzed: 1,2,3; Start analysis after 240.0 s; Total analyzed time: 23:32:00; Parameters of arrhythmias: Tachycardias equal to or greater than 120 bpm, Bradycardia below 49 bpm, Prematurity of SVs 20 %, Minimum pause time 2.0 s.*

Ventricular Ectopics List

Criteria: *Series of three or more ventricular beats.*

Time	Duration (sec)	Beats	Ectopic HR (bpm)	HR (bpm)
No records found.				

Supraventricular Ectopics List

Criteria: *Series of three or more supraventricular beats with a prematurity of 20%.*

Time	Duration (sec)	Beats	Ectopic HR (bpm)	HR (bpm)
No records found.				

Pauses List

Criteria: *Pauses of 2.0s or more.*

Time	Duration (sec)	HR (bpm)
No records found.		

Sinus Tachycardias List

Criteria: *A series of 2 or more beats with a heart rate equal to or greater than 120 bpm.*

Start Time	End Time	Duration	Base HR (bpm)	Maximum	HR (bpm)
8:54:22 PM Wed	8:55:05 PM Wed	00:00:43	120	8:54:22 PM	120
8:56:43 PM Wed	9:05:04 PM Wed	00:08:20	120	8:59:13 PM	135
7:11:26 PM Thu	7:11:49 PM Thu	00:00:23	120	7:11:26 PM	120
7:25:28 PM Thu	7:44:26 PM Thu	00:18:59	120	7:39:36 PM	152

Sinus Bradycardia List

Criteria: *A series of 2 or more beats with a heart rate lower or equal than 49 bpm.*

Start Time	End Time	Duration	Base HR (bpm)	Minimum	HR (bpm)
No records found.					

ST Segment Depression and Elevation Examples in the Holter Report

Print ST Report

Exam Number	Patient: EXAM	Code:
04	Exam date: 7/24/2012 10:49:00 AM	12B-10094

ST Depression	Total Episodes	Total Duration (minutes)	Maximum ST Depression (slope/time)
C1	0		
C2	1	37.2	-4.4 Wednesday 7:18:36 AM
C3	1	127.3	-6.5 Wednesday 5:57:40 AM

ST Elevation	Total Episodes	Total Duration (minutes)	Maximum ST Elevation (slope/time)
C1	0		
C2	0		
C3	0		

Time	Max Depr	Max Elev	Slope A/D/H	Duration	Channel	Initial HR	HR
5:57:40 AM Wed	-6.5		H	2:07:19 AM	3	76	146
7:18:36 AM Wed	-4.4		H	12:37:14 AM	2	108	132

Criteria: *Channels analyzed: 1,2,3; Start analysis after 240.0 s; Total analyzed time: 21:12:00; Parameters of arrhythmias: Tachycardias equal to or greater than 120 bpm, Bradycardia below 50 bpm, Prematurity of SVs 20 %, Minimum pause time 2.0 s; Parameters of ST (minimum values): Depression 1.1 mm, Elevation 3.0 mm, Duration of the episode 60 s, Interval between episodes 60 s.*

Print ST Report

Exam Number	Patient: EXAM	Code:
05	Exam date: 3/11/2011 4:39:00 PM	237-00284

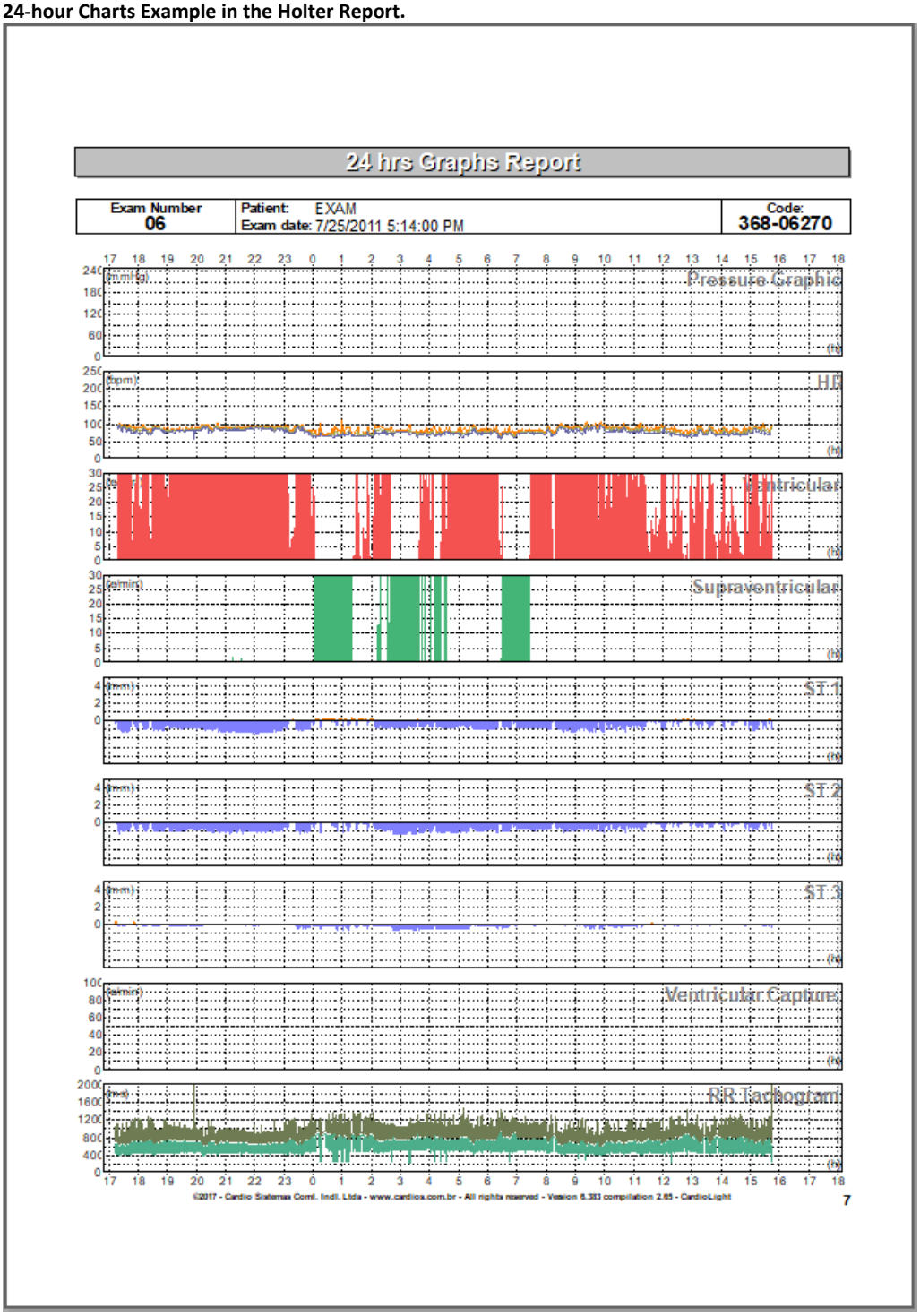
ST Depression	Total Episodes	Total Duration (minutes)	Maximum ST Depression (slope/time)
C1	0		
C2	0		
C3	1	10.9	-2.7 Friday 10:19:29 PM

ST Elevation	Total Episodes	Total Duration (minutes)	Maximum ST Elevation (slope/time)
C1	21	175.6	4.9 Saturday 7:49:07 AM
C2	8	47.4	3.3 Saturday 5:25:01 AM
C3	0		

Time	Max Depr	Max Elev	Slope A/D/H	Duration	Channel	Initial HR	HR
6:03:13 PM Fri		4.9	A	12:01:13 AM	1	71	73
10:01:43 PM Fri		5.2	A	12:03:45 AM	1	66	66
10:19:29 PM Fri	-2.7		H	12:10:54 AM	3	64	64
10:51:33 PM Fri		4.9	A	12:05:57 AM	1	71	70
11:03:50 PM Fri		5.1	A	12:19:10 AM	1	70	76
11:40:13 PM Fri		4.9	A	12:18:04 AM	1	71	72
1:19:09 AM Sat		5.1	A	12:06:57 AM	1	72	74
1:28:07 AM Sat		4.6	H	12:01:43 AM	2	74	76
1:50:53 AM Sat		5.0	A	12:13:15 AM	1	67	67
2:07:50 AM Sat		9.2	H	12:01:51 AM	2	72	81
2:15:11 AM Sat		4.4	H	12:01:41 AM	2	66	69
2:18:25 AM Sat		3.6	H	12:03:29 AM	2	73	71
2:50:32 AM Sat		5.2	A	12:01:53 AM	1	72	69
3:02:20 AM Sat		5.4	A	12:02:47 AM	1	67	66
3:06:33 AM Sat		8.6	H	12:04:17 AM	2	69	56
3:12:04 AM Sat		5.3	A	12:06:15 AM	1	60	59
3:39:24 AM Sat		5.0	A	12:03:50 AM	1	78	79
3:50:01 AM Sat		5.1	A	12:03:22 AM	1	77	83
4:14:49 AM Sat		4.9	H	12:01:03 AM	2	74	86
4:16:27 AM Sat		4.9	A	12:03:18 AM	1	71	70
4:38:53 AM Sat		5.3	A	12:14:29 AM	1	67	77
5:00:40 AM Sat		5.1	A	12:09:03 AM	1	63	76
5:21:10 AM Sat		5.0	A	12:03:10 AM	1	72	72
5:25:01 AM Sat		3.3	A	12:02:12 AM	2	72	80
6:02:29 AM Sat		4.2	A	12:31:07 AM	2	62	88
6:41:27 AM Sat		4.9	A	12:05:57 AM	1	69	71
6:51:02 AM Sat		5.6	A	12:27:20 AM	1	72	88
7:26:36 AM Sat		5.0	A	12:08:11 AM	1	62	62
7:49:07 AM Sat		4.9	A	12:02:28 AM	1	65	68
8:55:18 AM Sat		5.3	A	12:15:12 AM	1	70	71

Criteria: *Channels analyzed: 1,2,3; Start analysis after 240.0 s; Total analyzed time: 23:56:00; Parameters of arrhythmias: Tachycardias equal to or greater than 120 bpm, Bradycardia below 50 bpm, Prematurity of SVs 100 %, Minimum pause time 2.0 s; Parameters of ST (minimum values): Depression 2.0 mm, Elevation*

24-hour Charts Example in the Holter Report.

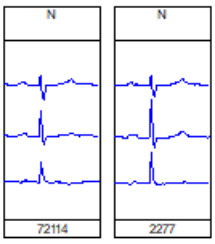


Forms Example in the Holter Report

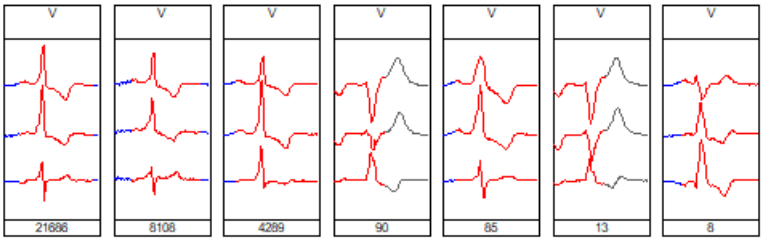
Forms Report

Exam Number	Patient: EXAM	Code:
06	Exam date: 7/25/2017 5:14:00 PM	368-06270

Normals: 2 Morphs with 74391 beats



Ventricular: 7 Morphs with 34279 beats



* - Revised morph

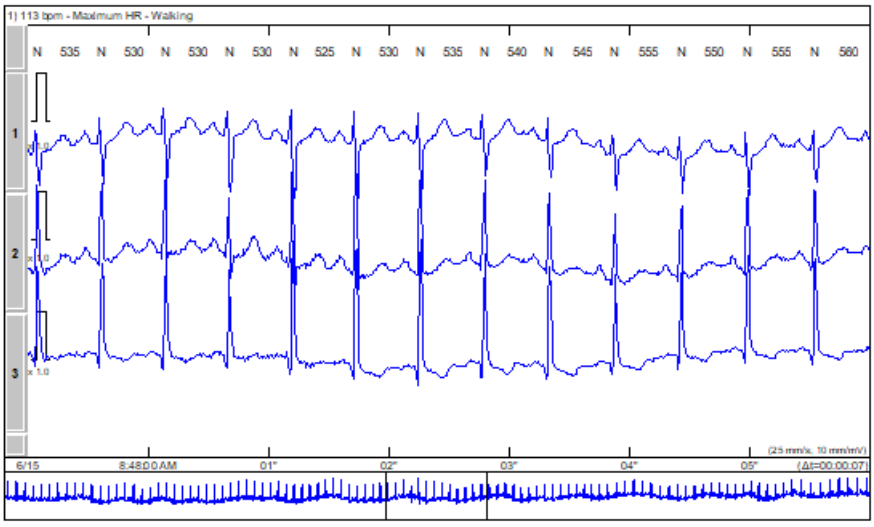
Criteria: *Channels analyzed: 1,2,3; Start analysis after 240.0 s; Total analyzed time: 22:28:00; Parameters of arrhythmias: Tachycardias equal to or greater than 120 bpm, Bradycardia below 50 bpm, Prematurity of SVs 20 %, Minimum pause time 2.0 s; Parameters of ST (minimum values): Depression 1.0 mm, Elevation 3.0 mm, Duration of the episode 60 s, Interval between episodes 60 s.*

ECG Example in the Holter Report

Electrocardiographic Examples

Exam Number	Patient: EXAM	Code:
020	Exam date: 6/15/2011 7:00:00 AM	14L-00121

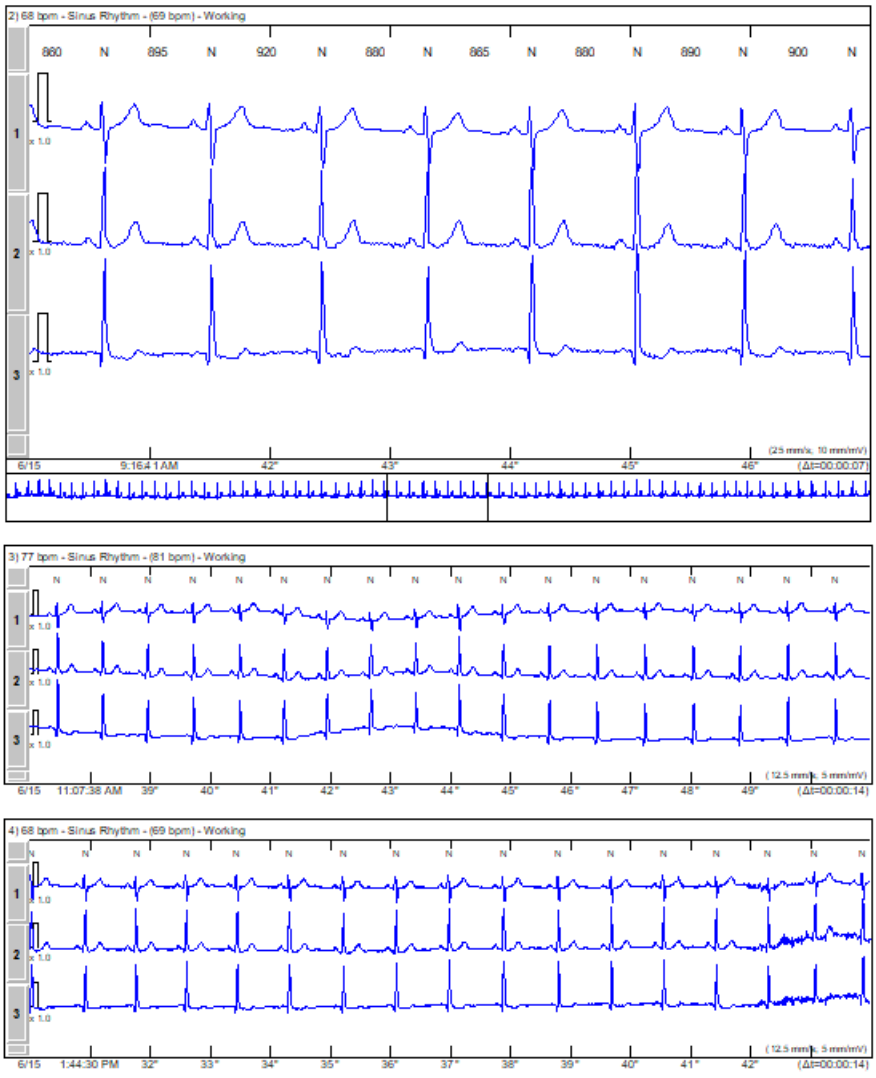
Time	Dur.	Activity	Symptoms	Diagnosis	Base HR	HR
8:47:59 AM	7	Walking		Maximum HR	113	113
9:16:40 AM	7	Working		Sinus Rhythm	68	69
11:07:44 AM	7	Working		Sinus Rhythm	77	81
1:44:33 PM	7	Working		Sinus Rhythm	68	69
3:36:49 PM	7	Working		Isolated SVE	73	73
4:45:47 PM	7	Working		Isolated SVE	76	76
10:25:08 PM	7	Watching TV		Isolated SVE	55	55
11:24:10 PM	7	Watching TV		Bradycardia	50	49
12:05:51 AM	7	Sleeping		Isolated VE	59	59
12:08:25 AM	7	Sleeping		Sinus Rhythm	58	57
1:17:30 AM	7	Sleeping		Minimum HR	45	45
1:26:52 AM	7	Sleeping		Bradycardia	50	48
1:46:43 AM	7	Sleeping		Bradycardia	50	49
4:09:25 AM	7	Sleeping		Sinus Rhythm	90	90
6:50:45 AM	7	Breakfast		Sinus Rhythm	97	98



Criteria: *Channels analyzed: 1,2,3; Start analysis after 240.0 s; Total analyzed time: 23:55:00; Parameters of arrhythmias: Tachycardias equal to or greater than 120 bpm, Bradycardia below 50 bpm, Prematurity of SVs 20 %, Minimum pause time 2.0 s; Parameters of ST (minimum values): Depression 6.0 mm, Elevation 3.0 mm, Duration of the episode 60 s, Interval between episodes 60 s.*

8

Exam Number	Patient: EXAM	Code:
020	Exam date: 6/15/2011 7:00:00 AM	14L-00121



Time Domain HRV Analysis Example in the Holter Report

HRV Report - Time Domain

Exam Number	Patient: EXAM	Code:
05	Exam date: 3/11/2017 4:39:00 PM	237-00284

Start	End	NNs	Mean NN (ms)	SDNN (ms)	SDANN (ms)	SDNNIDX (ms)	NNNs	RMSSD (ms)	TINN (ms)	pNN>50 (%)
11/03 16:39	12/03 16:39	108283	795	86	72	45	108,243	21	426.5	1.63
12/03 13:00	12/03 16:39	17559	746	73	61	41	17,542	13	343.8	0.29
12/03 02:00	12/03 06:00	16615	864	94	63	65	16,600	38	396.3	5.68

4:39	5:00	1437	709	32	8	30	1,436	9	154.0	0.00
5:00	6:00	4823	746	53	38	37	4,821	11	281.8	0.04
6:00	7:00	4593	783	65	53	38	4,591	12	342.2	0.00
7:00	8:00	4935	729	53	38	39	4,933	12	275.3	0.04
8:00	9:00	4920	732	46	28	33	4,919	12	207.0	0.00
9:00	10:00	4198	857	75	61	39	4,196	21	269.0	1.36
10:00	11:00	4193	858	78	54	56	4,192	23	339.0	3.58
11:00	12:00	4298	837	45	25	31	4,297	19	199.5	0.65
12:00	1:00	4385	821	36	17	30	4,383	18	157.0	0.41
1:00	2:00	4352	827	63	36	48	4,351	18	272.4	0.90
2:00	3:00	3945	901	106	74	75	3,931	48	340.4	5.49
3:00	4:00	4421	814	85	32	74	4,420	44	369.4	4.77
4:00	5:00	4190	859	72	40	56	4,189	23	306.5	3.08
5:00	6:00	4056	887	86	61	56	4,054	32	348.1	9.55
6:00	7:00	4079	878	77	48	60	4,075	28	313.7	7.07
7:00	8:00	4281	840	89	49	69	4,279	24	375.9	3.88
8:00	9:00	4471	805	67	37	53	4,470	14	339.5	0.09
9:00	10:00	4742	759	55	36	42	4,741	13	291.8	0.08
10:00	11:00	4888	736	45	23	38	4,887	13	228.1	0.06
11:00	12:00	4854	741	44	24	37	4,853	13	228.5	0.04
12:00	1:00	4642	775	50	33	37	4,641	13	239.0	0.15
1:00	2:00	4592	784	91	75	44	4,591	13	338.0	0.20
2:00	3:00	4802	750	73	60	42	4,801	15	366.2	0.77
3:00	4:00	4914	730	52	31	39	4,911	12	260.1	0.02
4:00	4:39	3248	714	42	15	39	3,233	12	169.0	0.09

Criteria: *Awake Period: from 13:00 to 17:00; Sleep Period: from 2:00 to 6:00; Minimum segment length: 270 s; Maximum segment length: 310 s; Processing: tachogram interval; NN Filter: cubic "spline"; Maximum correction factor: 20%; Repositioning irregular isolated beats: no.*

Frequency Domain (FFT) HRV Analysis Example in the Holter Report

HRV Report - Frequency Domain (FFT)

Exam Number	Patient: EXAM	Code:
05	Exam date: 3/11/2017 4:39:00 PM	237-00284

Time	Duration (min)	NN avg (ms)	HR (bpm)	Total Power (ms²)	VLF Power (ms²)	LF Power (ms²)	HF Power (ms²)	LF Power (nu)	HF Power (nu)	LF/HF
4:39	5	700	86	1,056	675	353	28	92.7	7.3	12.68
5:00	5	749	80	565	421	121	23	84.2	15.8	5.34
6:00	5	778	77	594	248	323	22	93.6	6.4	14.68
7:00	5	717	84	1,057	747	269	41	86.9	13.1	6.61
8:00	5	689	87	450	308	133	10	93.2	6.8	13.63
9:00	5	744	81	865	582	224	59	79.0	21.0	3.77
10:00	5	922	65	1,171	171	365	635	36.5	63.5	0.57
11:00	5	855	70	1,100	685	212	203	51.1	48.9	1.04
12:00	5	774	78	1,147	960	129	57	69.4	30.6	2.26
1:00	5	815	74	2,032	1,444	429	159	72.9	27.1	2.69
2:00	5	928	65	5,564	2,649	2,553	361	87.6	12.4	7.06
3:00	5	862	70	22,224	15,315	5,618	1,291	81.3	18.7	4.35
4:00	5	838	72	884	543	255	86	74.8	25.2	2.97
5:00	5	944	64	1,067	264	482	321	60.0	40.0	1.50
6:00	5	939	64	3,070	674	1,535	861	64.1	35.9	1.78
7:00	5	888	68	1,169	391	309	468	39.8	60.2	0.66
8:00	5	827	73	6,356	5,721	518	117	81.5	18.5	4.41
9:00	5	819	73	477	269	149	59	71.7	28.3	2.54
10:00	5	781	77	1,653	1,051	502	100	83.4	16.6	5.04
11:00	5	714	84	1,158	806	302	50	85.8	14.2	6.03
12:00	5	767	78	863	623	201	40	83.5	16.5	5.06
1:00	5	825	73	2,249	1,621	573	55	91.2	8.8	10.34
2:00	5	847	71	871	242	219	409	34.9	65.1	0.54
3:00	5	748	80	1,357	861	396	100	79.8	20.2	3.95
4:00	5	671	89	884	484	356	44	89.1	10.9	8.18

Criteria: *Awake Period: from 13:00 to 17:00; Sleep Period: from 2:00 to 6:00; Minimum segment length: 270 s; Maximum segment length: 310 s; Processing: tachogram interval; NN Filter: cubic "spline"; Maximum correction factor: 20%; Repositioning irregular isolated beats: no; VLF: 0.0033 to 0.040; LF: 0.040 to 0.150; HF: 0.150 to 0.400; FFT Window: Blackman-Harris; FFT Size: 256; Minimum FFT window override: 50%.*

Domain of Frequency (AR) HRV Analysis Example in the Holter Report

HRV Report - Frequency Domain (AR)

Exam Number	Patient: EXAM	Code:
05	Exam date: 3/11/2017 4:39:00 PM	237-00284

Time	Duration (min)	NN avg (ms)	HR (bpm)	Total Power (ms^2)	VLF Power (ms^2)	LF Power (ms^2)	HF Power (ms^2)	LF Power (nu)	HF Power (nu)	LF/HF
4:39	5	700	86	234		211	23	90.0	10.0	9.04
5:00	5	749	80	114		95	20	82.8	17.2	4.83
6:00	5	778	77	225		209	16	93.0	7.0	13.36
7:00	5	717	84	154		125	29	81.2	18.8	4.33
8:00	5	689	87	84		79	6	93.1	6.9	13.48
9:00	5	744	81	160		94	66	58.8	41.2	1.43
10:00	5	922	65	1,569	963	82	525	13.5	86.5	0.16
11:00	5	855	70	1,590	1,305	83	202	29.2	70.8	0.41
12:00	5	774	78	90		24	66	26.8	73.2	0.37
1:00	5	815	74	2,099	1,896	41	162	20.1	79.9	0.25
2:00	5	928	65	4,562		4,347	216	95.3	4.7	20.14
3:00	E42	862	70							
4:00	5	838	72	290		211	79	72.7	27.3	2.67
5:00	5	944	64	1,557	970		587		100.0	
6:00	5	939	64	3,462	1,960	639	862	42.6	57.4	0.74
7:00	5	888	68	1,482		1,008	474	68.0	32.0	2.13
8:00	5	827	73	81			81		100.0	
9:00	5	819	73	402		360	42	89.6	10.4	8.62
10:00	5	781	77	397		321	77	80.7	19.3	4.19
11:00	5	714	84	220		190	29	86.6	13.4	6.49
12:00	5	767	78	979	833	110	35	75.7	24.3	3.12
1:00	5	825	73	299		248	50	83.2	16.8	4.94
2:00	5	847	71	1,681	1,252	84	345	19.6	80.4	0.24
3:00	5	748	80	48			48		100.0	
4:00	5	671	89	336		303	33	90.2	9.8	9.19

Criteria: *Awake Period: from 13:00 to 17:00; Sleep Period: from 2:00 to 6:00; Minimum segment length: 270 s; Maximum segment length: 310 s; Processing: tachogram interval; NN Filter: cubic "spline"; Maximum correction factor: 20%; Repositioning irregular isolated beats: no; AR order: automatic; AR filter: linear; Resolution (points): 100.*

Tabular Summary Example and ECG Example for Pacemaker in the Holter Report

Tabular Report

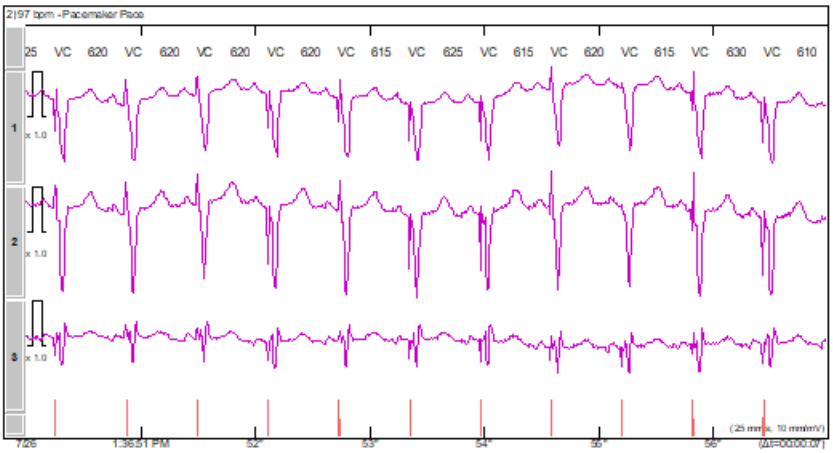
Exam Number	Patient: EXAM	Code:
10	Exam date: 7/26/2011 12:42:00 PM	13W-00791

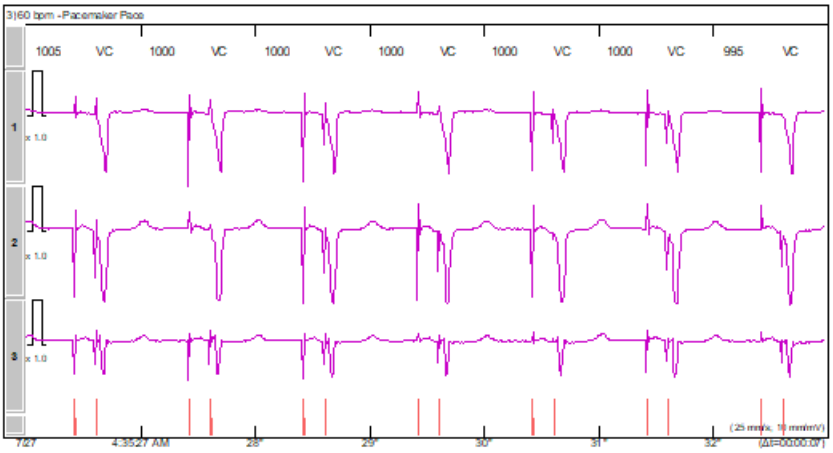
Time	HR(min)	HR(avg)	HR(max)	QRS's	V Iso	V pair	V Tach	Tot V	SV Iso	SV pair	SV Tach	Tot SV	Pauses
12:42	83	94	115	1,318	2			2	3			3	
1:00	87	98	173	5,872	23	1		25	18			18	
2:00	66	87	140	5,169	12			12	12			12	
3:00	60	76	141	4,454	9			9	9			9	
4:00	60	71	133	4,229	6	1		7	7			7	
5:00	68	75	120	4,466	3			3	4			4	
6:00	60	72	111	4,242	2			2	1			1	
7:00	60	73	105	4,324	1			1	6			6	
8:00	65	80	119	4,800	5			5	10			10	
9:00	62	75	110	4,406	1			1					
10:00	60	67	96	4,016	3			3	2			2	
11:00	59	62	82	3,717	1			1	2			2	
12:00	60	66	76	3,919				0					
1:00	60	64	76	3,833				0					
2:00	60	61	85	3,669				0	1			1	
3:00	60	61	84	3,640				0	1			1	
4:00	57	61	87	3,667				0	1			1	
5:00	59	60	76	3,604				0	1			1	
6:00	59	60	80	3,611	1			1	5			5	
7:00	59	71	116	4,135	8			8	10			10	
8:00	60	60	71	3,602				0					
9:00	59	62	102	3,707	3			3	1			1	
10:00	60	82	125	4,797	5			5	4			4	
11:00	80	109	146	6,488	7			7	7			7	
12:00	78	91	185	3,784	7			7	9			9	
Totals:	57	74	186	103,469	98	2		102	114			114	

Time	QRS's	NpAs	Vs
12:42	1,318		1,313
1:00	5,872	1	5,812
2:00	5,169	1	5,142
3:00	4,454		4,436
4:00	4,229	3	4,212
5:00	4,466		4,459
6:00	4,242		4,237
7:00	4,324		4,322
8:00	4,800		4,790
9:00	4,406		4,398
10:00	4,016		4,011
11:00	3,717		3,715
12:00	3,919		3,919
1:00	3,833		3,832
2:00	3,669		3,669
3:00	3,640		3,638
4:00	3,667		3,667
5:00	3,604		3,604
6:00	3,611	1	3,608
7:00	4,135	1	4,120
8:00	3,602		3,601
9:00	3,707		3,701
10:00	4,797		4,779
11:00	6,488		6,456
12:00	3,784		3,767
Totals:	103,469	7	103,208

Criteria: *Channels analyzed: 1,2,3; Start analysis after 240.0 s; Total analyzed time: 23:56:00; Parameters of arrhythmias: Tachycardias equal to or greater than 120 bpm, Bradycardia below 50 bpm, Prematurity of SVs 20 %, Minimum pause time 2.0 s; Parameters of ST (minimum values): Depression 1.0 mm, Elevation 3.0 mm, Duration of the episode 60 s, Interval between episodes 60 s. Pacemaker data: type Dual Chamber; HR 60; Hysteresis HR 60; VC form similarity 2; Intervals threshold (ms): Vs <-> R (0 min. 140 max.), As <-> eV (100 min. 220 max.), As <-> R (120 min. 340 max.); blanking 100.*

Exam Number	Patient: EXAM	Code:
10	Exam date: 7/26/2011 12:42:00 PM	13W-00791





The Analyst Physician is responsible for checking the Holter Report according to the selected Analysis Criteria.

Manufacturer Software Configuration for Holter Report

The Software Configuration for the Holter Report can be selected by the Operator through the Settings -> System -> Report menu.

Holter Report Configuration Example for Report Printing with all the analysis components:

General Configuration Options for Print Quality

[High Quality Printing]
[High Quality Printing] -> [Titles with high contrast]
[Number the Pages]
[Number the Pages] -> [Include the total of pages]

ECG tracings -> [Number the ECG examples]
ECG tracings -> [Enable tracing reinforcement]
ECG tracings -> [Colored Tracings]
ECG tracings -> [Print RR interval]
ECG tracings -> [Display pacemaker spikes]
ECG tracings -> Heartbeat Labels -> [Print]
ECG tracings -> [Context in the upper table]
ECG tracings -> ECG Context Time -> [60s]
ECG tracings -> [Thicken Grid in high resolution (above 450 dpi)]
ECG tracings -> ECG graphical composition -> [GL with stamped grid (recommended)]

Holter Report Configuration Options

Filters -> [Enable filters in printing]
Cover Page -> [1 copy]
[Tabular Report]
[Heart Rates Report]
ST Report -> [Always print]

HRV Report -> [Time Domain]
HRV Report -> [Time Domain] -> [Summary Chart]
HRV Report -> [Time Domain] -> NN Charts -> [12 charts per page]

HRV Report -> [Frequency Domain (FFT)]
HRV Report -> [Frequency Domain (FFT)] -> [Summary Chart]
HRV Report -> [Frequency Domain (FFT)] -> PSD Charts -> [12 charts per page]

HRV Report -> [Frequency Domain (AR)]
HRV Report -> [Frequency Domain (AR)] -> [Summary Chart]
HRV Report -> [Frequency Domain (AR)] -> PSD Charts -> [12 charts per page]

[ABPM Report]
[ABPM Report] -> [Measurements list]
[ABPM Report] -> [Blood Pressure Statistical Summary]
[ABPM Report] -> [Pressure chart]
[ABPM Report] -> [Trend chart]
[ABPM Report] -> [Correlation chart]
[ABPM Report] -> [Histogram]

[Apnea Report]

[Atrial Fibrillation Report]

[HR Turbulence Report]

[Forms Report]
[Forms Report] -> [Include indeterminate forms]
[Forms Report] -> [Include deleted forms]

[ECG Examples]
[Compressed ECG]

[24h Charts]
[24h Charts] -> [Pressure Chart]
[24h Charts] -> [Ventricular]
[24h Charts] -> [Supraventricular]
[24h Charts] -> [ST 1]
[24h Charts] -> [ST 2]
[24h Charts] -> [ST 3]
[24h Charts] -> [Ventricular Captures]
[24h Charts] -> [RR Tachogram]

1.9. ABOUT THIS MANUAL

1.9.1. CONTENT

This manual covers the CardioSmart CS550 characteristics in its state of evolution at the date of manual revision. Some features described here can be changed without prior notice to users. If your software does not have any of the features described in this manual, contact Cardios for information about optional software or system upgrades.

The chapters describe the operations by category, gradually accompanying exams creation, data acquisition, and report analysis, preparation, and printing, following the natural daily work sequence.

1.9.2. CONVENTIONS

This manual aims to bring the necessary information in simple and direct language. Therefore, some conventions were adopted.

The chapters describe the operations by category, gradually accompanying exams creation, data acquisition, and report analysis, preparation, and printing, following the natural daily work sequence.

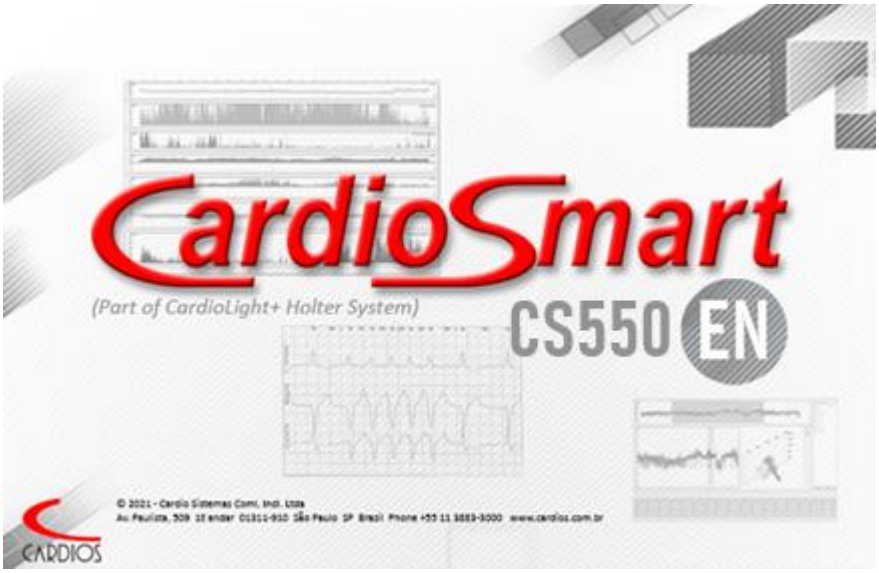
Most commands are accessible through both the mouse and keyboard, and the manual covers both methods. Commands or menu items appear in bold brackets, for example: “...press [Enter]...” or “...select the [Data] option in the menu and click on [Import]...”.

2. INITIALIZING THE SYSTEM

The CardioSmart CS550 module aims to provide an integrated platform for operation with various program modules. CardioSmart CS550 supports multiple modules and devices (Holter, ABPM, etc.). The goal is to easily integrate several technologies and devices generations with ECG analysis modules.

To start, double-click on the icon of your CardioManager program, previously installed on your computer.

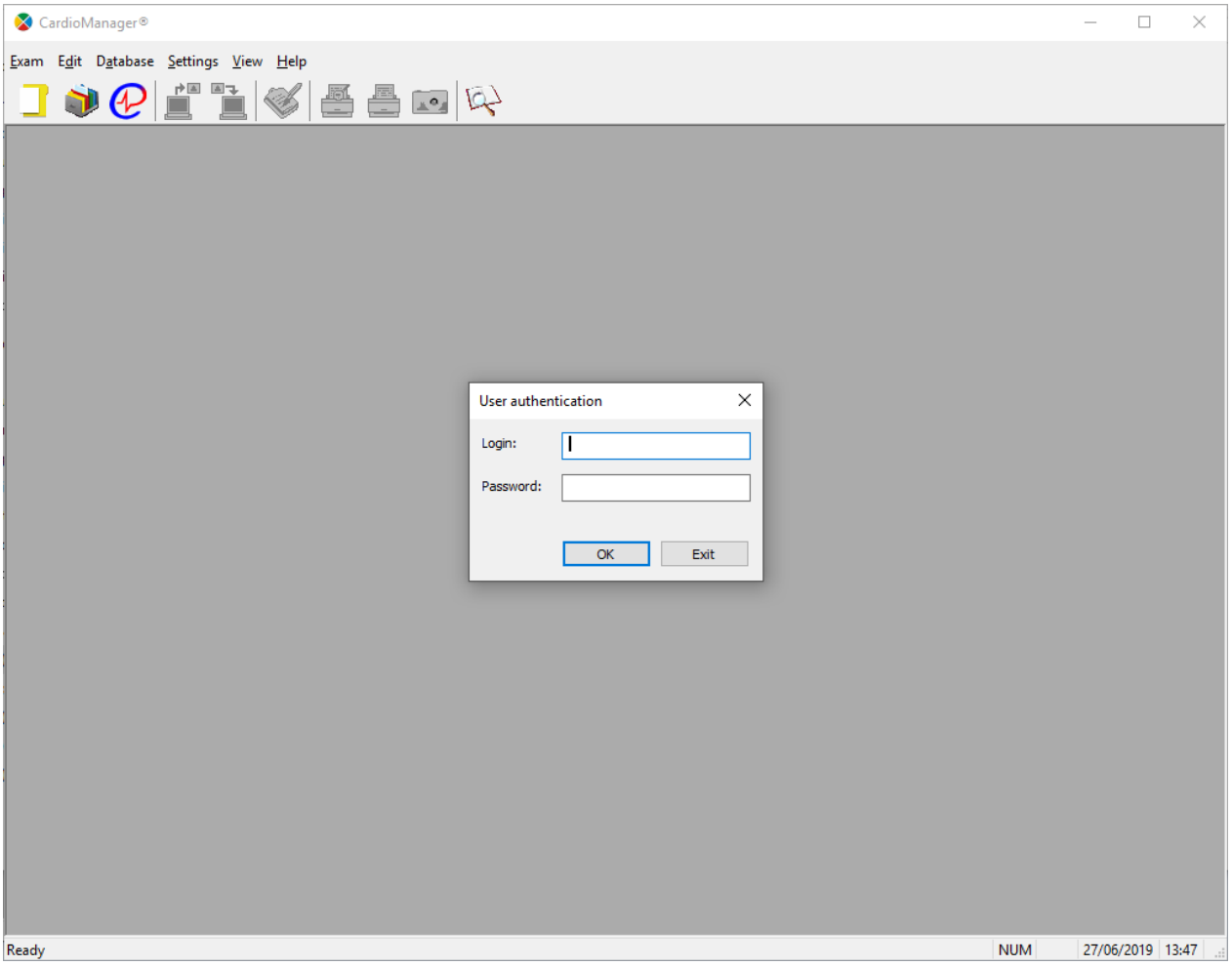
The software splash screen is then displayed.
During loading, all system modules and devices will be registered. On the first system run, the main database is also created.



User authentication
After initialization, the user and password are required to access the CardioSmart CS550.

The default values for the first access are:
User: cardios
Password: cardios

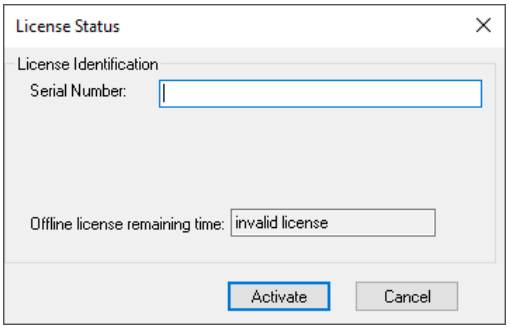
After logging in to the software, access the User Registration to create a user and change the default user password as a security measure.


CardioManager®
Exam Edit Database Settings View Help
User authentication
Login:
Password:
OK
Exit
Ready
NUM
27/06/2019
13:47

2.1. USER LICENSE ACTIVATION

In the first use of the software or after the license expiration, you will be required to activate the user software license. The license will be made available to you upon purchase through an authorized dealer.

Enter the license number you received and click Activate.

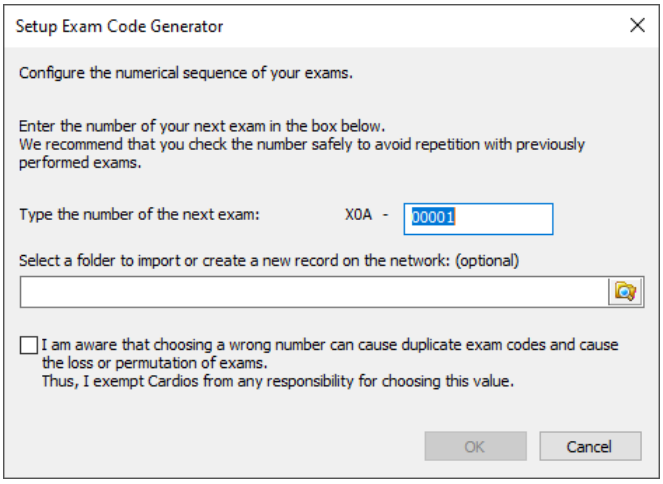


Upon successful activation, CardioSmart CS550 will check if any exam code generator is already configured. If it exists, it will be used by the software, otherwise the Exam Code Generator setup screen will be displayed.

2.2. EXAM CODE GENERATOR

The CardioSmart CS550 software uses the Exam ID to identify the exams registers. The Exam ID consists of 3 letters prefix, dash "-", followed by 5 digits.

The exam code prefix will be automatically set by the software license, but you will be able to configure the exam code numbering.

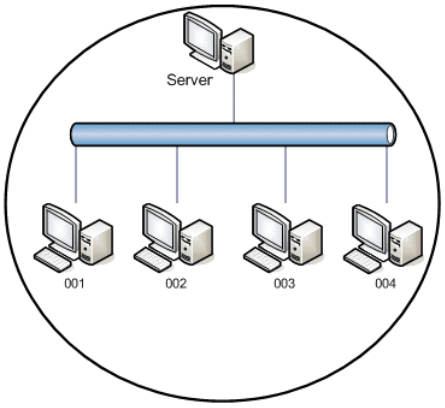


Set the sequential number of the next exam in the format: ANNNN, where [A] may be used with alphanumeric characters (A..Z and 0..9), and [N] in numeric format 0..9 which will be auto-incremented as used.

Check the option "I am aware that choosing a wrong number can cause duplicate exam codes and cause the loss or permutation of exams. Thus, I exempt Cardios from any responsibility for choosing this value." an click OK to proceed.

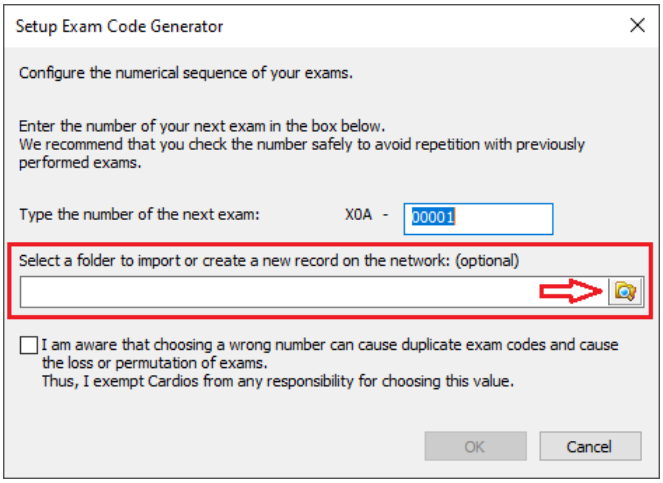
Network Exam Code Configuration

It is possible to share the Exam Code Generator with others computers in a network, keeping the sequential numbering among them.

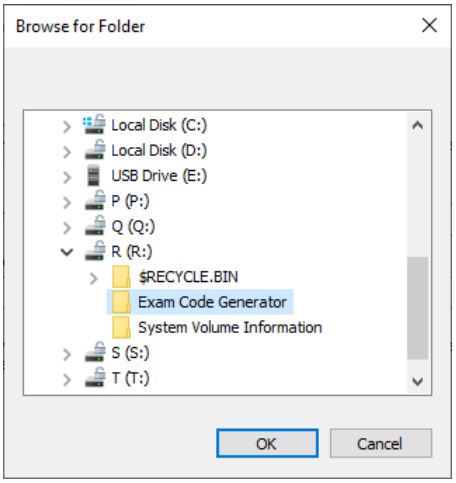


This mode should only be selected if your internal network has the following characteristics:
- Dedicated server;
- Network shared folder;
- Workstations configured.

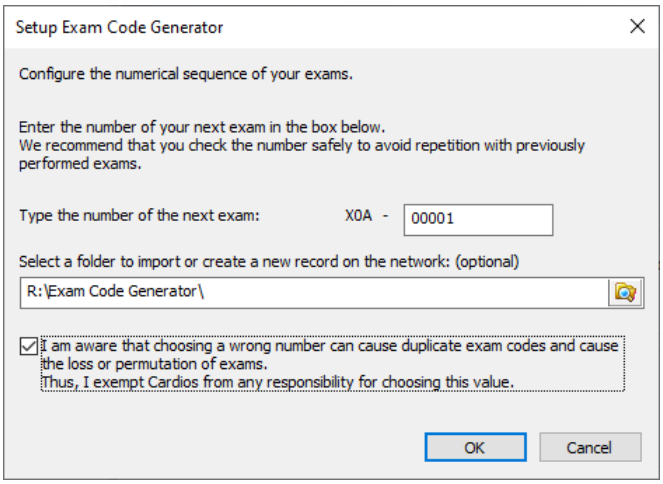
Click in the search button on "Select a folder to import ...":



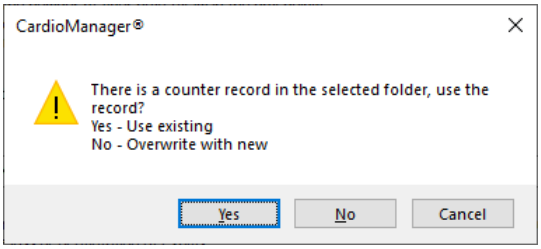
Browse to the network folder where you want to create or there is already a register to be used.



Check the option "I am aware that choosing a wrong number can cause duplicate exam codes and cause the loss or permutation of exams. Thus, I exempt Cardios from any responsibility for choosing this value." an click OK to proceed.



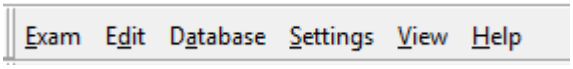
If there is a "Record.guc" file previously created in the selected folder, you can choose to use it by clicking "Yes", or to create and overwriting it with a new one pressing "No", click "Cancel" to return to previous screen.



If this exam prefix was previously used, or if this register is used on a network share, check the exam number carefully to avoid repeating with previous exams.
Cardio Sistemas is not responsible for the incorrect use of the Exam Code Generator configuration.

3. MAIN MENU

The main screen consists of a menu bar, the desktop, a toolbar, and the status bar.



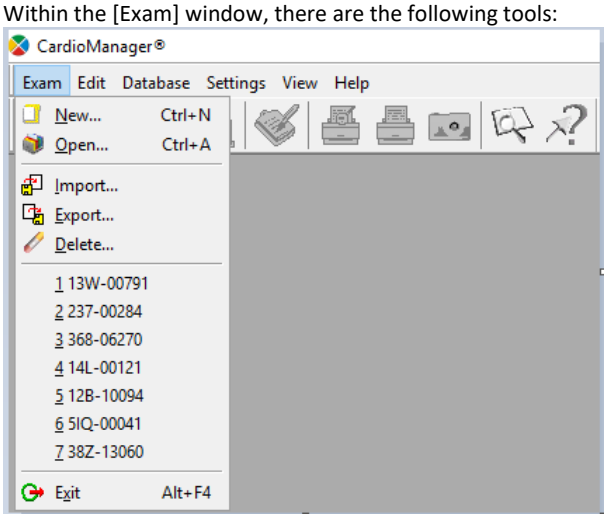
The menu bar displays commands for general software operations with files and data. When there are no open exams, the available options are [Exam], [Edit], [Registrations], [Settings], [Display], and Help.

Immediately below the menu bar, there is the toolbar. The toolbar has a collection of commonly used commands. For example, the first button in the figure is equivalent to click on the [Exams] and [New] menu, making the use of mouse much faster.

At the bottom, there is the status bar, which displays information on the operation being performed, and informs the date and time.

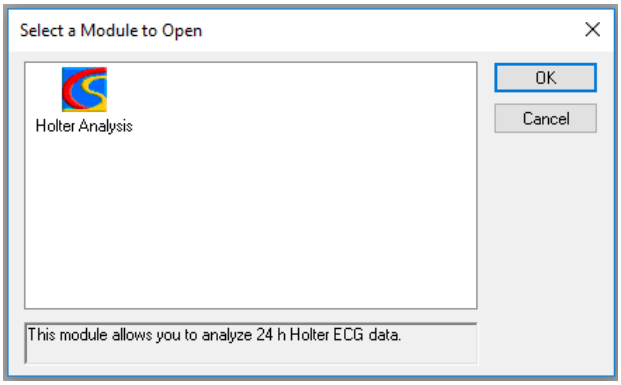
3.1. EXAM

Within the [Exam] window, there are the following tools:



[New]
It will open a window with a module to be selected.

It is possible to program the device with the exam requested by the physician for installation in the patient, by selecting one of the modules below:



- Holter analyzer module: Holter exams (24, 48 and 72 hours).

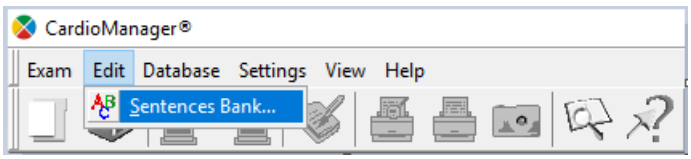
[Open]
Displays the list of patients' names whose exams can be analyzed, or whose devices have been prepared in the system and will subsequently be transferred to CardioSmart CS550 after the recording. (See Chapter on Exam preparation).

[Import exams]
Used to import exams received in the Cardionet (module for exam reception and transmission via internet), from flash drives, CDs, DVDs, or other media types (.xcm files).

[Export exams]
It allows transferring exams (.xcm file) to flash drives, DVDs, HDs, or other compatible media.

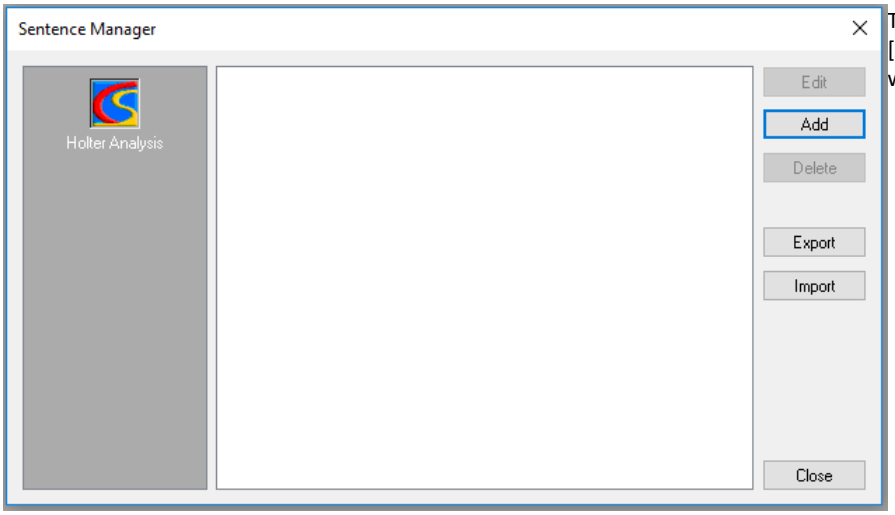
[Delete exams]
The software has an exam storage limit (999), which is independent of the computer's capacity. After the backup is performed, the exams should be erased from the software.

3.2. EDIT

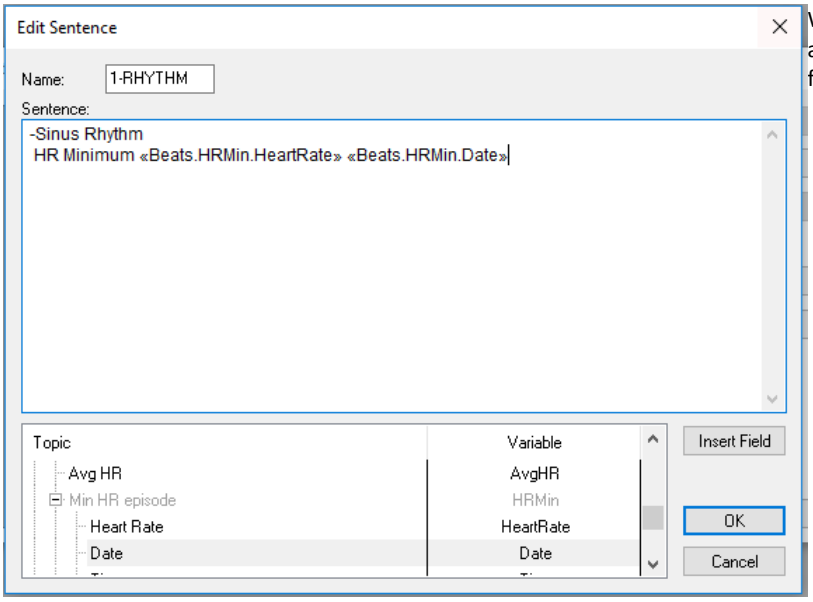


Sentences Bank

The software provides a bank of sentences to be used on the reports. It is possible, however, to interact with this bank of sentences by aggregating information, adding new sentences, deleting existing sentences, or even creating a custom bank of sentences.



To add new sentences just click on [Add] and enter the information you want.

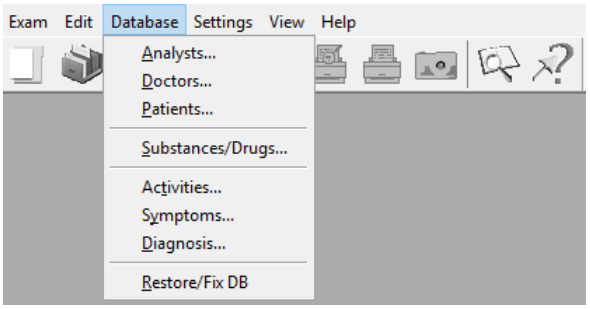


When creating sentences, it is also possible to automatically insert some numeric values from the exam.

To use this tool, just open the desired field, select the sentence, and double click on the corresponding item.

NOTE: The “name” field should be prepared by the user. It is advisable to be easy to remember.

3.3. DATABASE



Analysts
This table lists all the Analyst Physicians data, such as name, CRM (Medical registration), clinic name, and address. This information is especially useful when there are several physicians performing exams reports. Data such as the analyst physician's name and ID are also printed on the report page. There is the possibility of linking the scanned signature to the analyst physician's name.

Doctors
This table lists all Physicians data, such as name, clinic, and address. This information is especially useful when providing services to others.

Patients
This table lists all patient data, such as name, address, age, weight, height, etc.

Substances/Drugs
The software provides a database of substances that can be related to patients, facilitating the medications administration control*.

Activities
This register stores the activities reported by patients in the patient's diary. Some optional modules can make use of these * records.

Symptoms
In this register are stored references to the symptoms described by the patients in the patient's diary. Some optional modules can make use of these * records.

Diagnosis
As in the registers of symptoms and activities, here are stored references to the diagnoses assigned by the analyst physician. Some optional modules can make use of these * records.

Users
List of software users.

* These data can be previously registered or stored automatically during the editing of an exam (activities, symptoms, and diagnostics).

3.3.1. EDITING DATA

In general, you can include, change, and delete software records. The records that can be edited are as follows: Patients, Referring Physicians, Analyst Physicians, Medications, Activities, Symptoms, Diagnoses, and Users.

There is, however, a limitation on the possibility of excluding data from the registers. In order to maintain the database records integrity, the exclusion of a patient, for example, who has tests related to it, will result in the exclusion of ALL exams related to that record. This is done so that an exam is not allowed without the corresponding patient registration, which would cause a records integrity loss (it would be something like an account in a bank without any related accountant).

Therefore, caution is required when deleting data from the software so that other records related to that data are not also excluded. In any delete operation where related records exist, the software will inform you that those records will be deleted, and you will be prompted to confirm the operation before completing it. Once confirmed, the operation is irreversible.

3.4. SETTINGS

In this tool, we have the system settings, according to which the exams that are inserted in CardioSmart CS550 will be analyzed. This setting is general, that is, it will be valid for all exams.

The user acquires the analysis software with a previous configuration. However, if there is a desire or need to change this setting, according to the standards used in the institution where you work, or according to parameters the user considers ideal to work, this is possible for most of them.

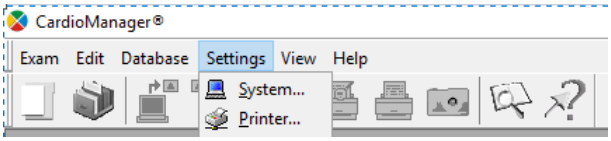
It is worth remembering that any changed general configuration will only be valid for the exams that are inserted in the program from that moment. The existing exams will retain the configuration used at the time they were transferred to the software.

3.4.1. SYSTEM

There are two levels of the CardioSmart CS550 analysis components configuration:
1. "Global or General" type ([System Setup]): which determines the default values to be used in new exams
2. “Local” ([Configure Reanalysis]) type: which only applies to the open exam. This setting will work directly on items such as Apnea and Atrial Fibrillation, for example.

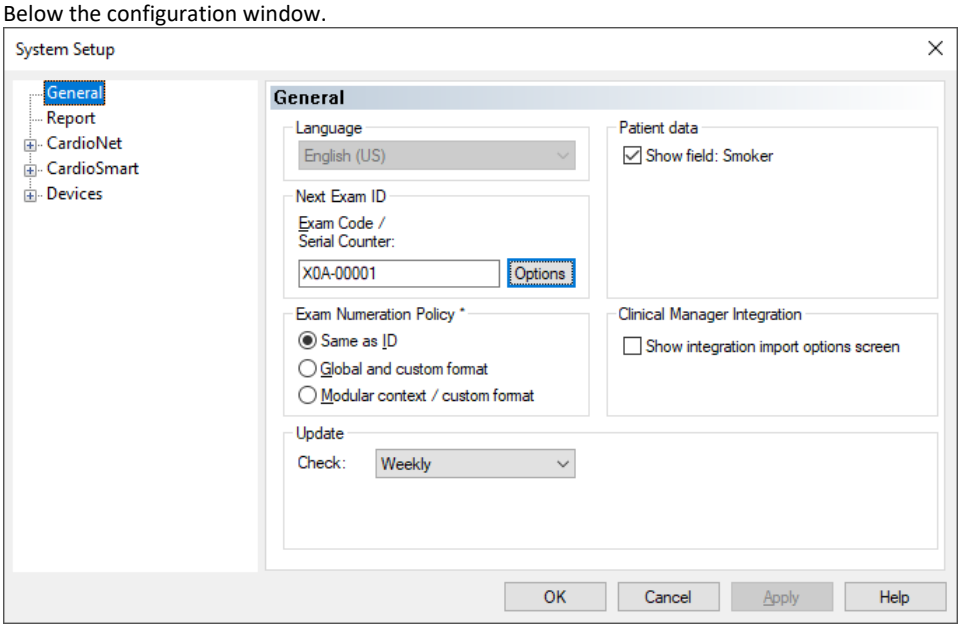
3.4.1.1. GLOBAL SETTINGS

On the System Configuration page, the values and settings chosen are applied to all new exams that are created on the system.



The global settings are accessible through the main menu by clicking on the [Settings] option and selecting [System], when no exam is open.

Below the configuration window.



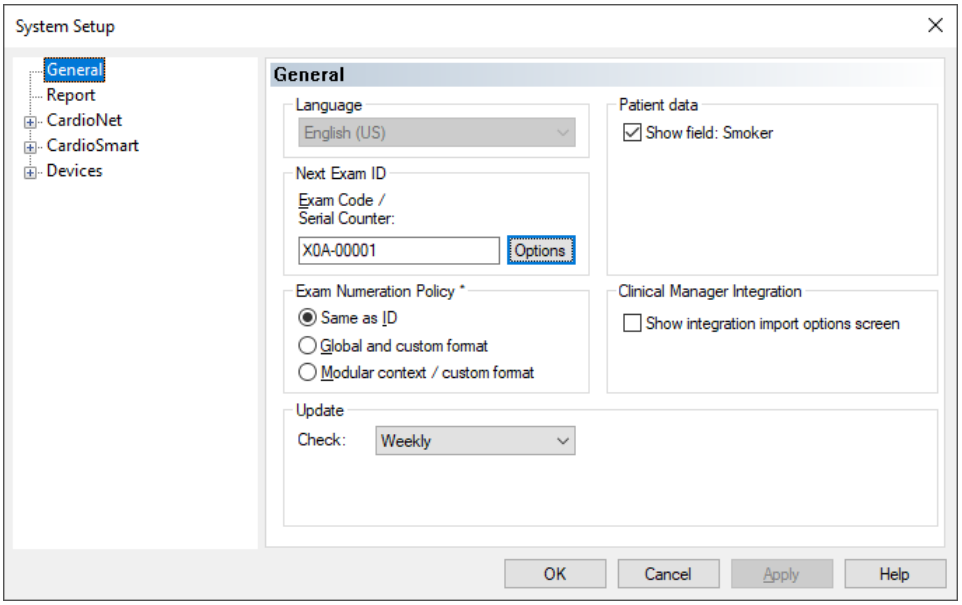
Global settings act on items such as:

1. Report
2. CardioSmart
3. HRV
4. Apnea
5. Atrial Fibrillation
6. HR Turbulence, as we will see next

NOTE: Global settings are only available when there is no open exam in the system. These settings affect only the new exams that will be created after the changes.

3.4.1.2. GENERAL

The general software configuration.



Language
Display the current software language.

Next Exam ID
This field informs the next Exam ID that will be created.
To change the sequence or to create/choose a record in a network folder, click on the options button and follow the same instructions as the topic "Exam Code Generator" in the "Initializing the Software" chapter.

Exam Numeration Policy
The exam number is a sequence that can be customized by the user.
Same as ID - generates the exam number same as Exam ID;
Global and custom format - You can customize it and it will be auto incremented for all kinds of exam.
Modular context / custom format - You can customize it and it will be auto incremented for each kind of exam, for instance Holter and Event exams can have different numbering.

Update
Configure the software update checking period: Always, Weekly, Monthly, Never.

Patient data
Enable/disable the patient smoker input display.

Clinical Manager Integration
It is possible to enable some custom data integration with external sources. Contact our sales representative for more information.

3.4.1.3. REPORT

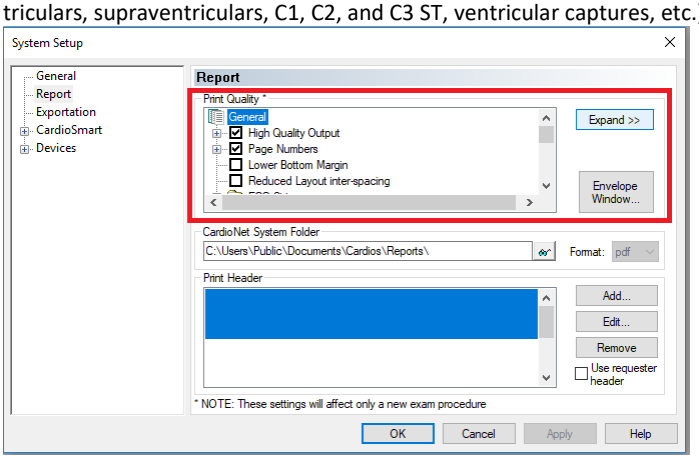
Divided in:

Printing Options

In this item should be marked what you want to print.

The printing configuration will be valid for all exams; however, as we will see in another chapter, this configuration can be changed individually according to the need of the exam analyzed.

In addition to the configuration of what the user wants to print (see some items below), this window has items such as HR variability in time and frequency domain, forms report, and 24-hour chart (with option to select for printing items such as HR, ventriculars, supraventriculars, C1, C2, and C3 ST, ventricular captures, etc.).

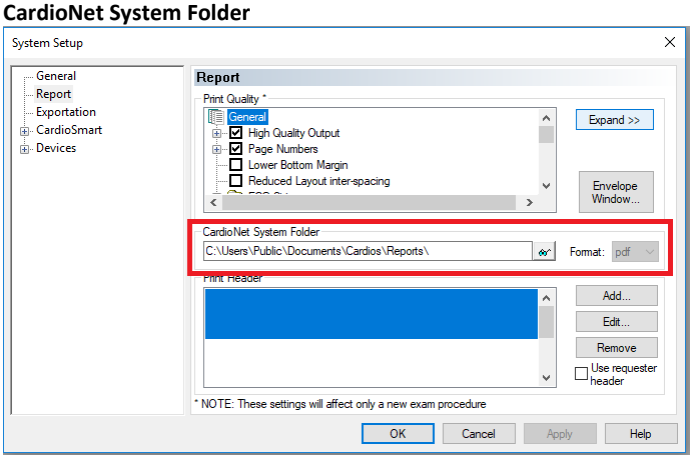


On the Expand screen, to the right, you can see more items within the print options.

The "Number Pages" and "Include total pages" options should be checked to allow the report pages to be numbered sequentially, starting counting from the Cover Sheet, and including the total Pages in the footer.

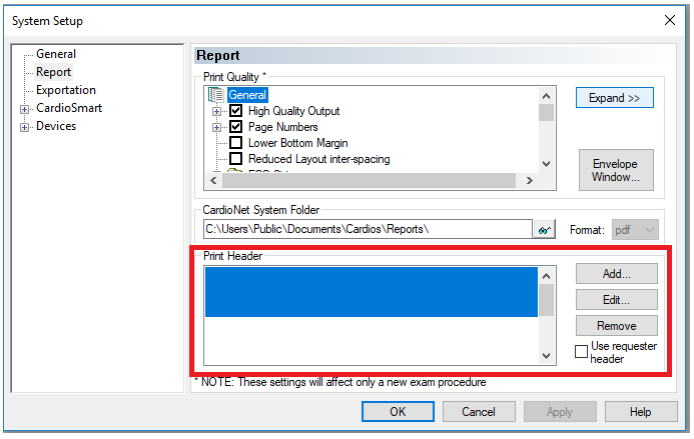
Envelope Window...
You can enter some text on the exam cover preceding the cover sheet.

CardioNet System Folder



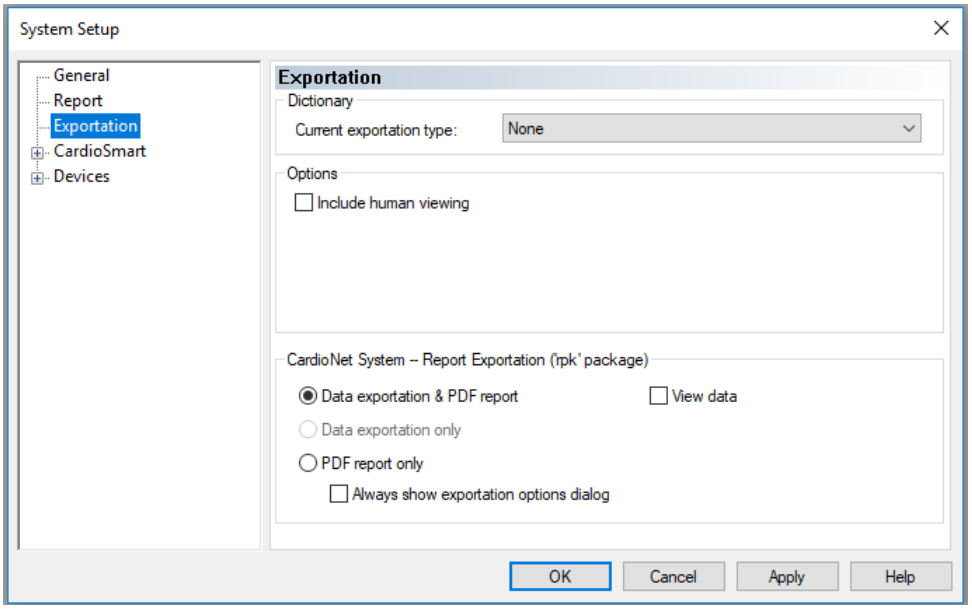
A folder is displayed in which the reports sent in PDF format will be stored if the CardioNet Server System is used.

Print Header



It is possible to create a bank of headers for the clinics that send exams for appraisal and want to receive their reports with their own headers, as well as logos.

3.4.1.4. EXPORTING REPORT DATA



Tool available for exporting files in XML format. Contact Cardios for details on using this option.

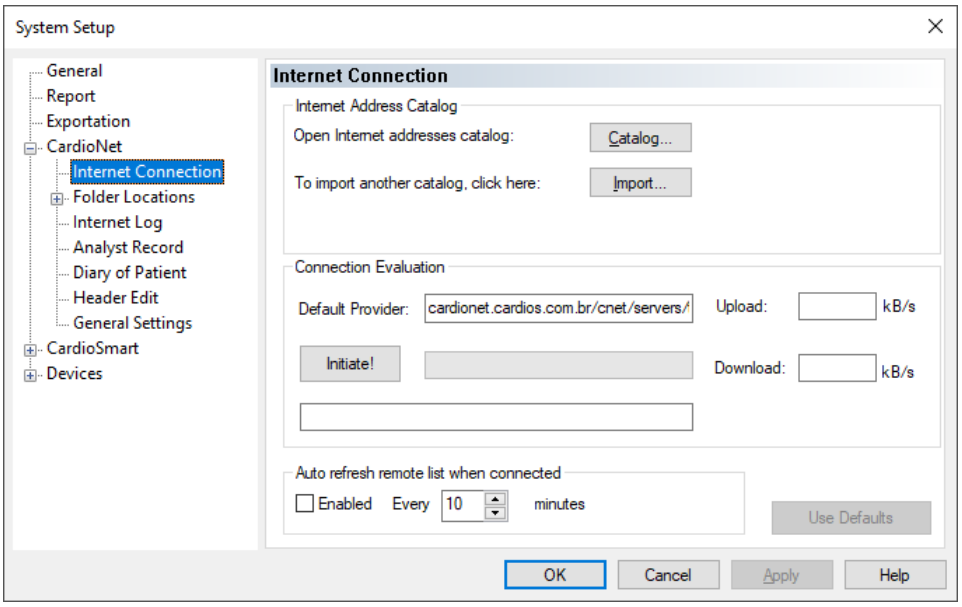
3.4.1.5. CARDIONET

This section describes the configurations screens for the CardioNet module.

3.4.1.5.1. INTERNET CONNECTION

It is one of the most important CardioNet configuration, where the data is designated by the analysis service provider.

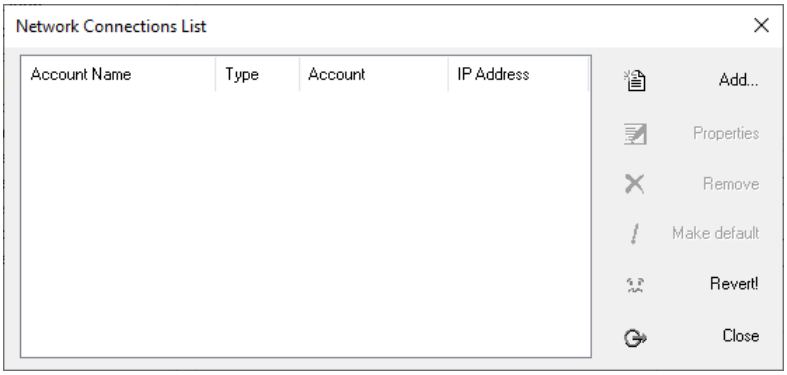
This area allows the configuration of a "portfolio" of Internet addresses, from servers where the exams and reports will be stored (or "hosted") until the analysis service will download them into the system.



Open Internet addresses catalog:	Catalog...	An Internet address must be configured so that the system can receive and send files.

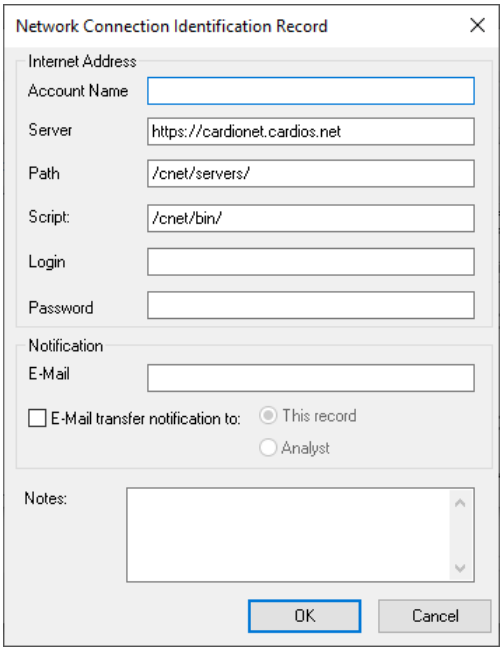
To set up an Internet address, click on the [Catalog ...] button, which will open the Internet address manager.

Initially, the system will display an empty window.



To start registering Internet addresses, click the [Add ...] button.

The system will display a window where we will enter information about the account being configured.



Account Name: The first field of the form corresponds to the Name by which the connection will be identified. It must be a name through which the connection can easily be identified.

Server: The DNS name of the server to be used to send the files.

Path: The path where the files will be stored on the server. The default value is "/cnet/server/", in this path the folder designated by the service provider must be added.

Script: The path where the remote functions are located. The default value is "/cnet/bin/"

Account: The analysis service will assign you a "login" name, which must be configured in this area.

Password: The analysis service should assign you a password, which will be configured here.

E-mail: Associates an e-mail account with the configured Internet address. This address can be used by the system for automatic message sending.

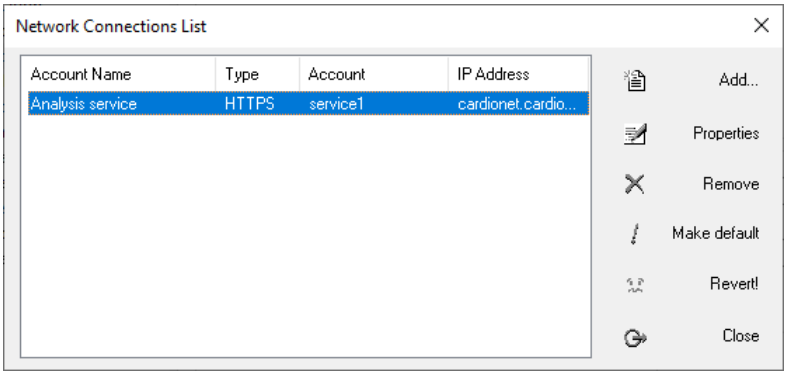
Notification: When enabled, the system automatically sends an email notifying you the file transfered to the Internet area. The email address to which the notification will be sent, may be the same as the configured in the previous item, or the address configured on the Analyst Tab.

Note: Description or remarks regarding the account you are configuring.

To complete the account setup, click on the **[OK]** button.

All fields must be correctly filled for the proper functioning of the new account.

The configured account becomes part of a register.



We can manage this registry using the controls that are on the right side of the window, as described below:

Properties: Displays the account details, allowing you to change the connection data.

Remove: This control deletes the selected account. A confirmation window appears, prompting you to explicitly confirm the record deletion.

Make Default: When you have multiple accounts configured on the system, one of them must be selected by default. Which will initially be available in the connection control. To make a default account, select the desired record and click on the make default control.

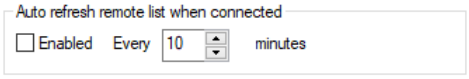
Revert: This is a very handy control, which allows you to undo the last change made to the Internet connection register.
NOTE: The command only undoes the last change made. If more than one change has been made, the previous changes will be lost.

Close: Close the address manager, returning to the settings window.

Connection Evaluation
After creating the internet connection, and selected one as default, you can perform a Download and Upload rate evaluation using the "Connection Evaluation" feature.

Click the [Start] button to check the status of the default account.

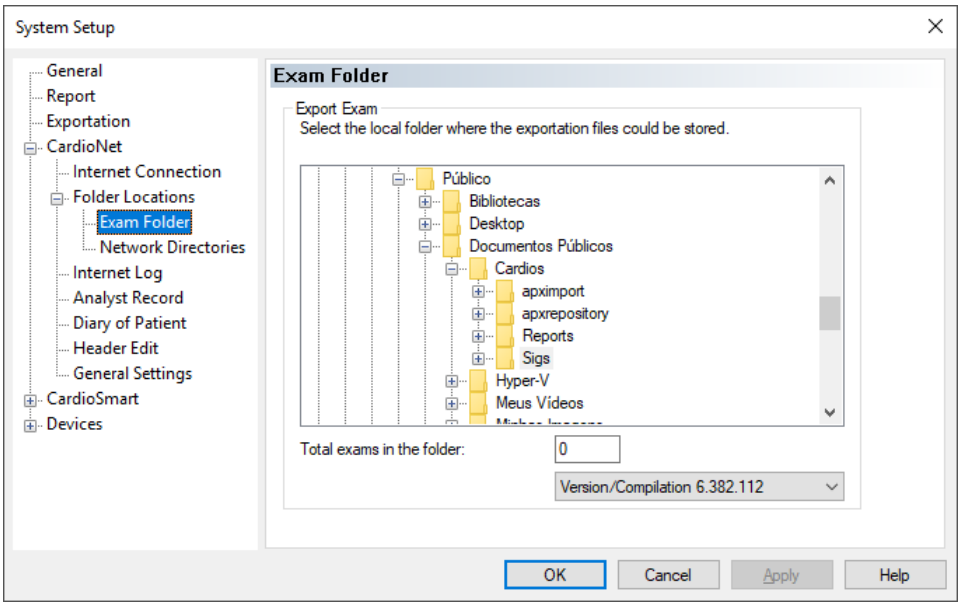
Refresh List Option
To enable the automatic remote list updating of exams and reports after connecting to the desired account, check the "enable" option in the "Automatically update remote list when connected" box. The refresh interval can be set every 10, 20 or 30 minutes.



3.4.1.5.2. EXAM FOLDER

You may change the default folder of the exam files that will be used by the software.

Locate the folder in which you want to store the exam files in the directory tree. Once located, click on it, selecting it as shown in the figure. The [Apply] button will be enabled after selecting the folder, click on it to make this default folder.



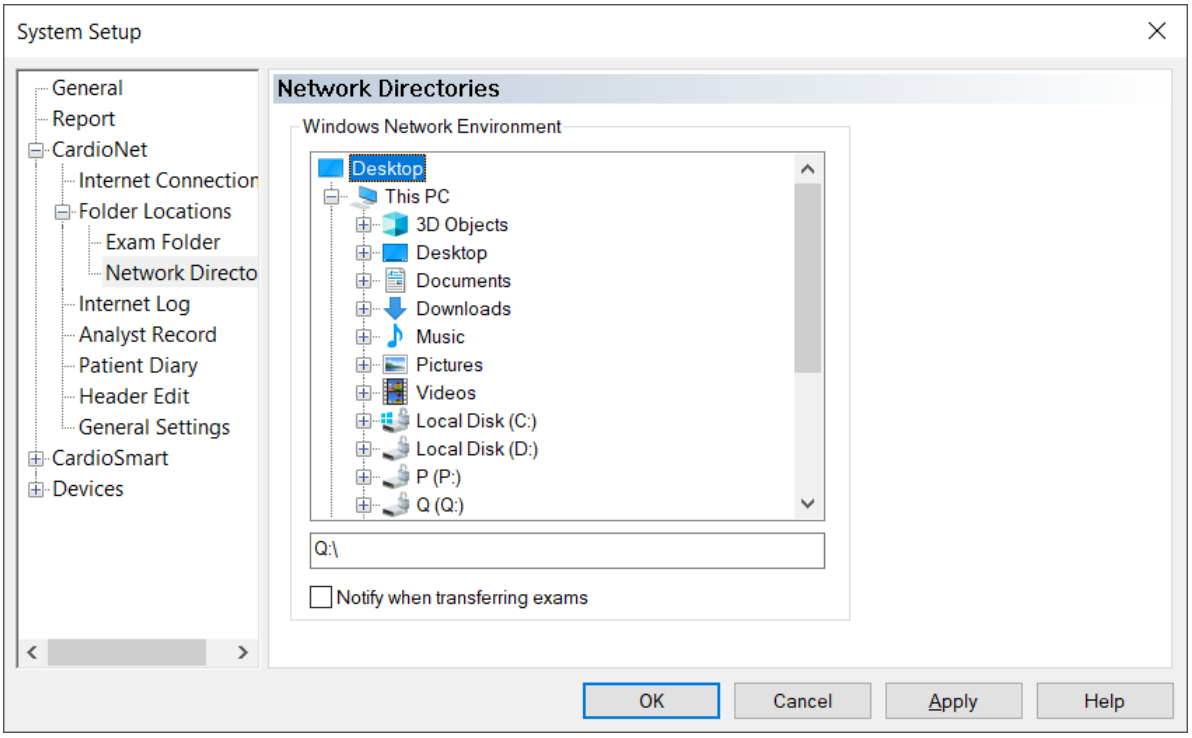
The exams can also be exported to a shared network folder by simply selecting the folder on the local network.

There is also an exams counter at the bottom of the window that identifies the total number of files in the selected folder.

3.4.1.5.3. NETWORK DIRECTORIES

In this area we can configure a folder on the local network where we can transfer the exams that are downloaded to the system. The CardioNet® module enables a local exam preparation and, afterward, transfers the recording files through a local network to a shared folder. This folder can be located on the machine where the analysis system is located or where these files can be collected over the network.

To select the shared folder on a network, click the Folder Configuration option and then Network Directory.



Before selecting the folder on the network, it must be shared. Consult the network administrator and identify the folder where the exams will be posted.

In the directory tree, select the shared folder.

Notify when transferring exams
There is also, at the foot of this configuration option, a control where, when an exam is sent to the designated folder, the system sends an e-mail to the address configured in the Analyst Tab option.

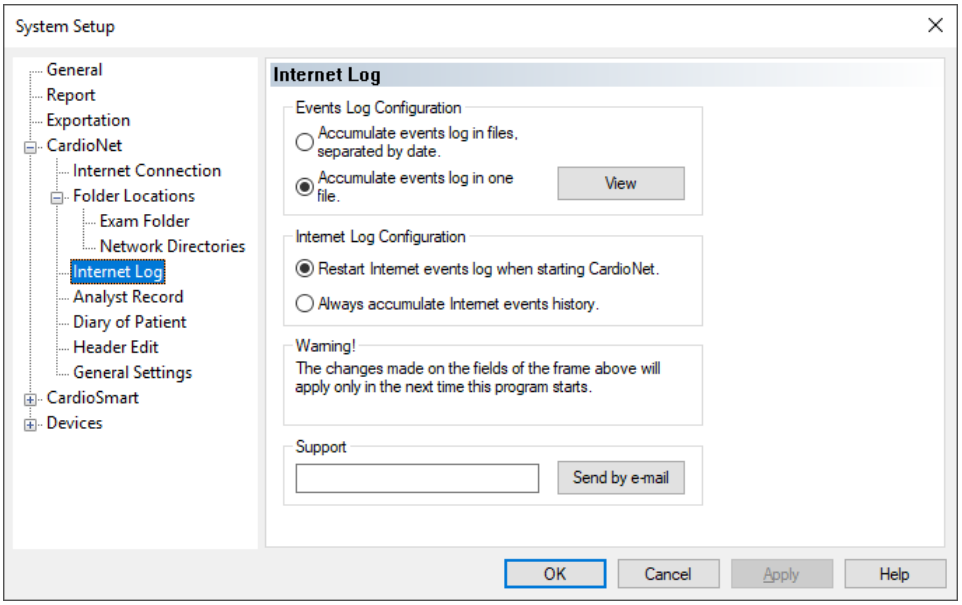
If this option is checked, an email will be sent to the address configured on the Analyst Tab when sending a file to the designated network folder.

3.4.1.5.4. INTERNET LOG

This section allows the activity log files to be configured, useful for technical support in diagnosing problems with internet connection.

You can configure two types of history:

- Events log;
- Internet log.



The Event Log configuration is cumulative, but with different ways of writing the log file. We can record the log information in files separated by date or perform the recording in the same file.

In the Internet Log Configuration, the history log file can be accumulated or overwritten. Preferably, we should keep the setting in "Always accumulate internet events history", which allows, in case of problems, to have a list of all performed operations.

Although this configuration implies having a growing log file, we can easily diagnose operational problems through this archived history.

Keep in mind that the settings applied above only take effect if the application is reinitialized.

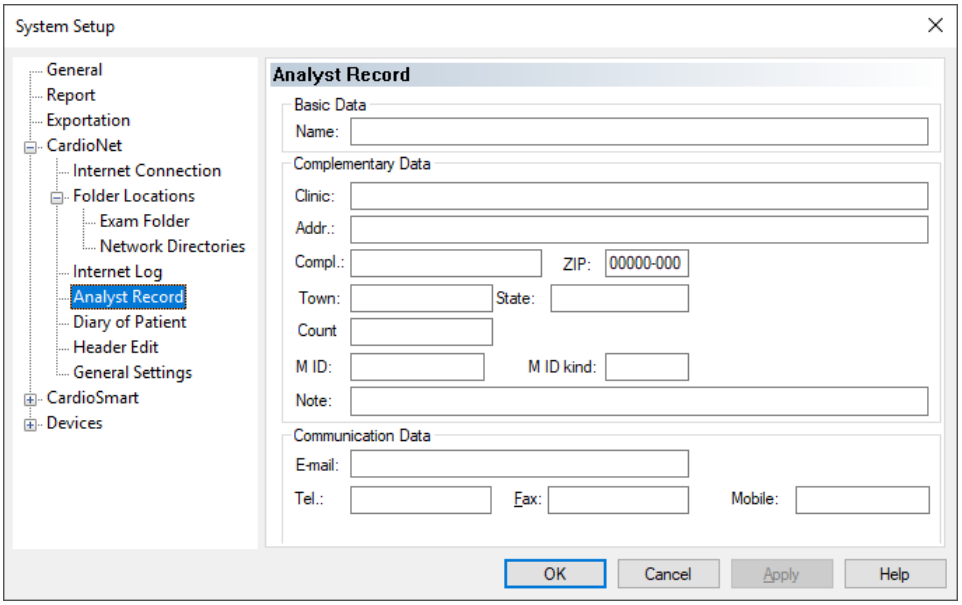
In this window, we have an email address for technical support, to fill out this field it is necessary to contact the administrator of the analysis service, then the [Send by email] button can be pressed.

The ability to send the history by email should only be used upon request from Customer Support Service.

Upon pressing the button, the internet history file will be attached to a message and sent to the configured address.

3.4.1.5.5. ANALYST RECORD

When configuring the CardioNet®, the analysis service that will receive the exams must already have been defined. To configure the analysis service data, select the Analyst Tab option.



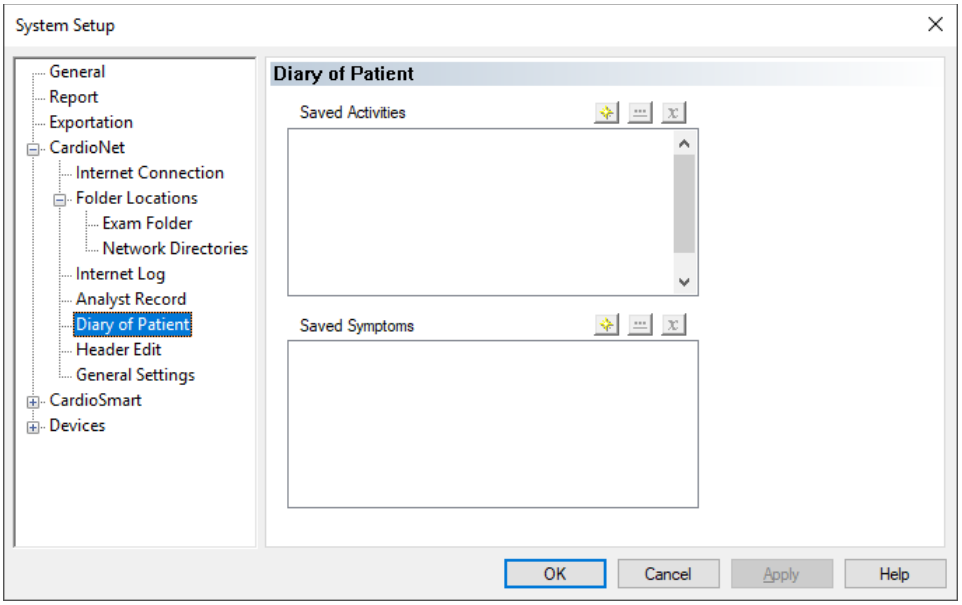
The data to fill in all the fields of the Analyst Sheet are provided by the analysis service administrator, so before configuring the fields, contact them and ask for all possible information.

The configuration of this data defines the service to which the exams will be routed. Fill in the form as completely as possible, but only the name and clinic are mandatory.

3.4.1.5.6. DIARY OF PATIENT

The Patient Diary allows you to enter, in a specific area, the activities and symptoms reported by the patient during your exam.

In the Patient Diary setup option, we have the resources to manage an activity and symptom record, with controls for entering, deleting, or modifying any of the records in the lists.



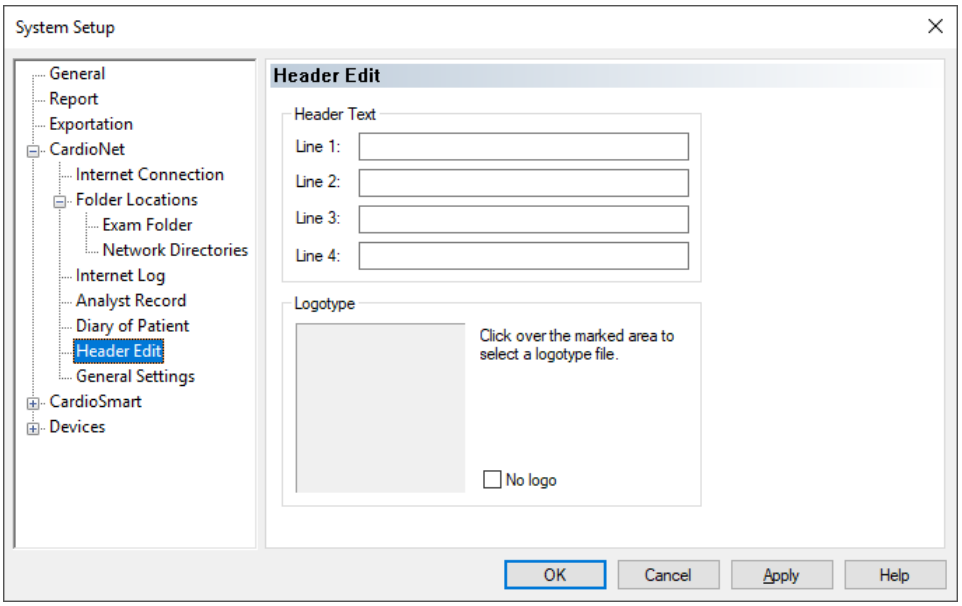
Inserting, Editing, and Deleting Records:
To insert, edit, or delete an activity in the registry, click on the corresponding buttons at the top of the window.

Add Edit Delete

3.4.1.5.7. HEADER EDIT

The Header Editor allows you to define the data and logo that will be printed in the patient diary header.

Select Edit Header to enter header text and logo as shown in the following figure.



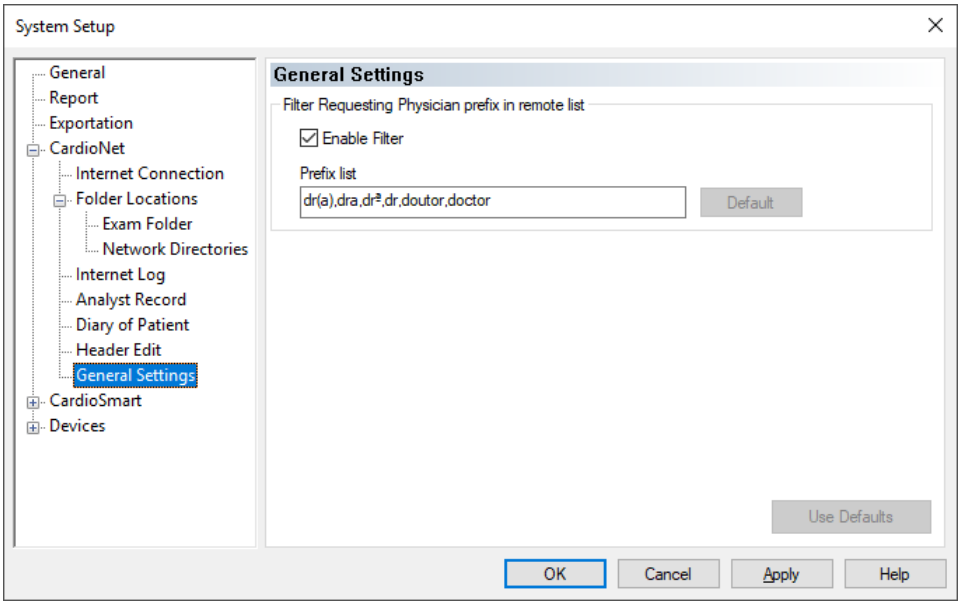
The header editor comes with a predefined data as default to exemplify how to insert header text.

To change it, simply select the lines and insert the new text.

To change the logo, click with the mouse on the logotype area and select the new image that will be part of the header.

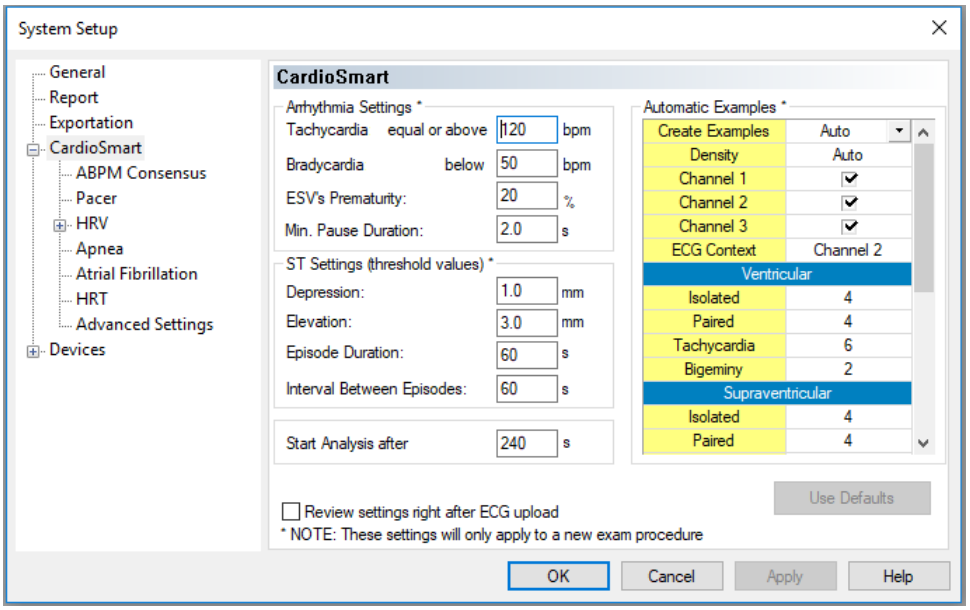
The image to be used in the logo should be in the following format: BMP, PNG or JPG. The [No logo] option disable the logo printing.

3.4.1.5.8. GENERAL SETTINGS



It is possible to filter some name prefix of the physician requester on the remote files listing by defining them in the "Prefix list" input. It improves the sort mechanism to display the names in a better order.

3.4.1.6. CARDIOSMART CS550 - ARRHYTHMIAS PARAMETERS



Values / parameters should be entered in which you want the system to analyze the exam.

For example:
Tachycardia: Above 120 bpm. The system will quantify the time the HR was around or above the set reference value for tachycardia for 24 hours.

Bradycardia: Below 50 bpm. The system will quantify the time the HR was around or below the reference value set for bradycardia for 24 hours.

ESVs prematurity: 20% is the sensitivity set for the system to quantify supraventricular arrhythmias based on the prematurity of QRS complexes. (NN interval)

Minimum Pause Duration: 2.0 seconds. The system will quantify, if any, all pauses that have been around or above 2.0 seconds.

ST Parameters (minimum values): The minimum values are inserted in which the software will interpret the ST segment behavior so that it is quantified / valued.

Depression: 1 mm - the system will use preset parameters to quantify (if any) ST segment depression episodes.

Elevation: 3 mm - the system will use preset parameters to quantify (if any) ST segment elevation episodes.

Episode duration: 60s - the time each episode considered as ischemic should have, in order to be quantified as ST depression or elevation.

Interval between episodes: 60s - the minimum interval between depression or elevation episodes that the exam should have, in order to be considered as a depression or elevation episode.

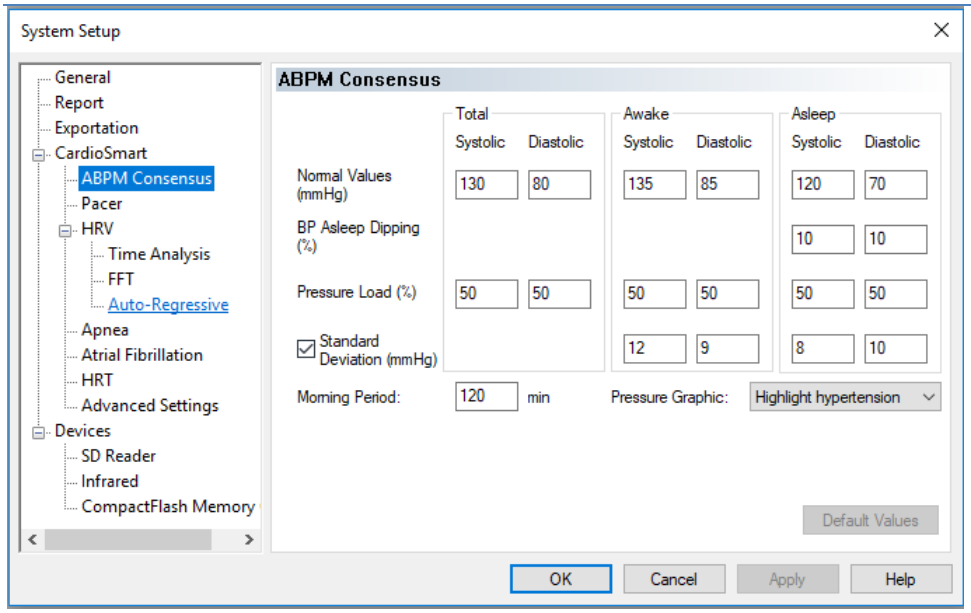
Start analysis after: In the first 240s (4 min), the system will show the electrocardiograph signal, but will not identify the QRS. These first 4 minutes were setup so the patient can adapt to the electrodes installation and the recording does not start with interference.

Automatic examples: It is possible to configure the system to automatically select a predetermined number by the user, of examples of ventricular / supraventricular arrhythmias / bradycardia / tachycardia / ST depression / ST elevation / patient and random events. These tracings will be selected by the software automatically and demonstrated in the “Examples” item.

It is important to note that even when the system selects the number of examples pre programmed automatically, it is possible to insert other examples, or to delete as many tracings as are required or desired by the user.

NOTE: These settings are general, that is, all the exams entered into the system will be analyzed by the software according to the desired parameters. Any changes you make to this setting will only be applied to the new exams. It is further emphasized that, if necessary, it is possible to change this configuration individually according to the case being analyzed.

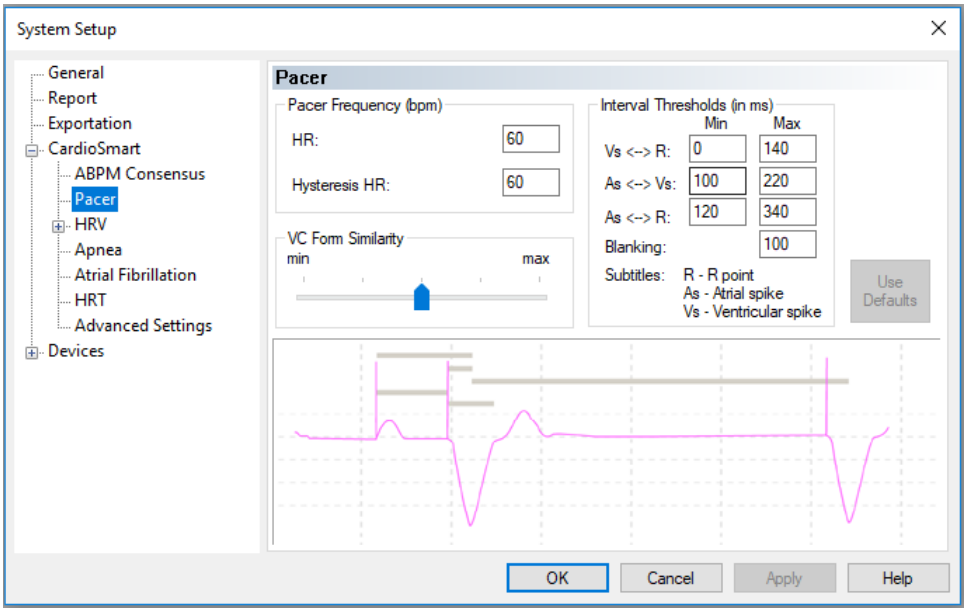
3.4.1.6.1. ABPM CONSENSUS



The software is configured according to the 7th BRAZILIAN DIRECTOR OF BLOOD HYPERTENSION of SBC (Brazilian Society of Cardiology). However, the values used can be changed, and the analyst physician will be in charge of the configuration as desired. It is worth noting that both "pressure loading" and "standard deviation" are not determined by consensus but can be quantified in this item.

3.4.1.6.2. PACEMAKER

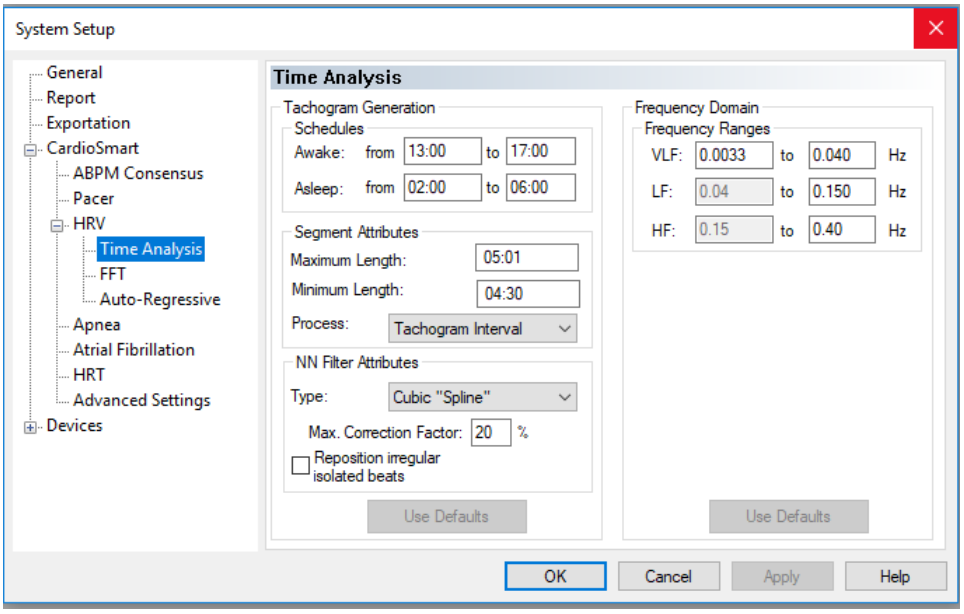
The Pacer module was developed to analyze recordings of patients with pacemaker who underwent Holter exams, allowing greater precision and agility in the diagnoses of these exams.



There are pre programmed values for analysis and refer to baseline HR, HR in hysteresis, similarity in VC form, ventricular capture (that is, it is possible that the system identifies more pacemaker-like heartbeats by changing sensitivity in the similarity). There are also limits for the intervals (in ms).

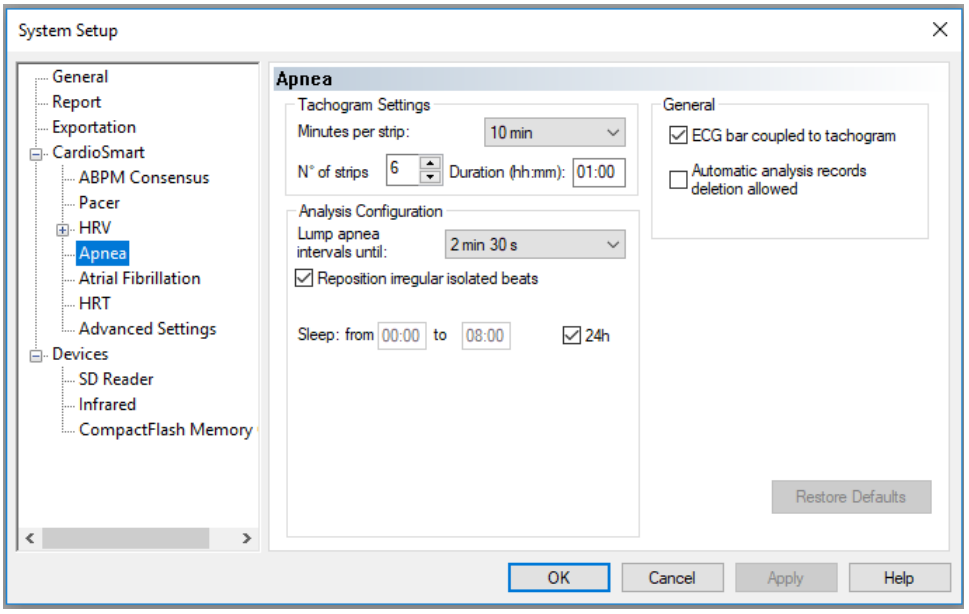
3.4.1.6.3. HEART RATE VARIABILITY - HRV

The HR variability tool already has preprogrammed values in its configuration. The HR variability analysis module allows a complete RR variability analysis, with configurable time domain and frequency parameters.

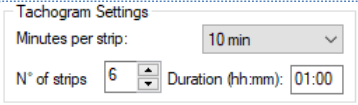


3.4.1.6.4. APNEA

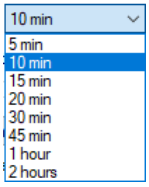
This CardioSmart CS550 analysis component is intended for the processing, evaluation and visualization of heart rate variation (HRV) that occurs during episodes suggestive of obstructive sleep apnea and/or hypopnea (OSA or OSAH).
It can be set to "Global" or "Local".



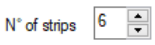
3.4.1.6.4.1. TACHOGRAM SETTINGS



In the tachogram settings, we can establish the duration, in minutes, of each range displayed, in addition to the number of ranges we want to see.



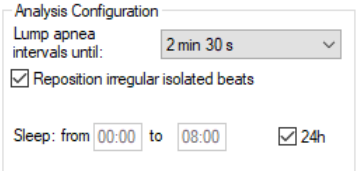
The duration of each tachogram range can be set from 5 minutes to 2 hours, with the default value being 10 minutes per range.



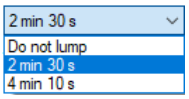
The number of ranges to be displayed can be set between 1 and 12, through the corresponding control.

By determining the duration of each range and the number of ranges to be displayed, we set the tachogram temporal range.
The configuration window displays, in the lower right portion, the displayed period “duration”.

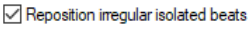
3.4.1.6.4.2. ANALYSIS SETTINGS



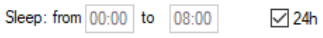
The analysis settings act on the algorithm behavior of apnea assessment.



"Agglutination of Intervals" determines how the algorithm will segment or not the apnea episodes detected. By default, episodes less than 2 minutes and 30 seconds apart will be considered as a single episode. This setting allows you to use a longer interval for agglutination (up to 4 minutes and 10 seconds) or even to determine the non-agglutination of "temporally close" ("do not join") episodes.



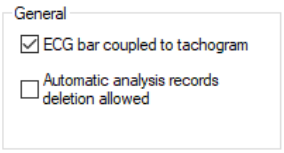
The "Repositioning isolated irregular heartbeats" control allows the system, under certain conditions, to move arrhythmic heartbeats over time, which tend to subdivide or impair the detection of apnea episodes. Keeping this control active, the system redistributes these heartbeats and "rebuilds" the ECG interval with synthetic heart-beats replacing the irregular ones, generating a tachogram with less disturbances. In this way, a more adequate heart rate behavior evaluation is allowed from the point of view of the apnea analysis. By default, this control is kept alive.



The system also has a configurator to determine the sleep period, in which episodes suggestive of apnea/hypopnea will be considered.
This period, by default, is set between 00:00 and 08:00 hours, and may be changed according to the needs of the exam.
The system can also be setup to analyze and consider any episodes that fit the patterns suggestive of apnea / hypopnea over the entire exam duration. To do this, select the “24h” option.

3.4.1.6.4.3. GENERAL SETTINGS

In this configurator section, we have two controls. The first one related to navigation in the exam context and the second related to the table of episodes.



The [Toggle ECG Control to Tachogram] control enables navigation through the Tachogram and ECG context to be integrated. That is, by clicking on any specific point in the ECG context, the tachogram will display the corresponding time. Similarly, when you click on an episode in the table or move the tachogram (via the vertical scroll bar), the ECG context is shifted to the corresponding time.

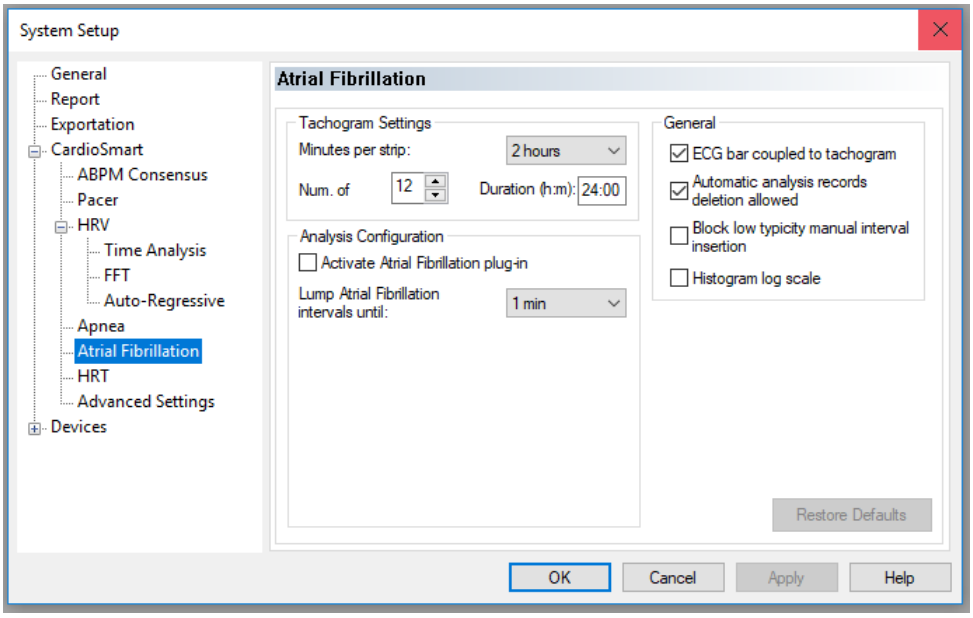
NOTE: Regardless of the "Toggle ECG control to the tachogram" control state when the operator toggles the selection between table entries, the ECG bar is always positioned for one minute before the apnea episode onset.

The [Automatic analysis records deletion allowed] control allows the user to delete any episodes automatically detected by the system directly in the table. By default, this setting is disabled. This is extremely useful to eliminate false positives that may have been inserted into the table.

To reset all the controls according to the original settings, just click on the corresponding button.

3.4.1.6.5. ATRIAL FIBRILLATION

It is possible for the user to preset the atrial fibrillation software with a standard that he or she considers ideal for working. In this configuration, all exams transferred and/or imported into the software will be analyzed with the atrial fibrillation component activated.



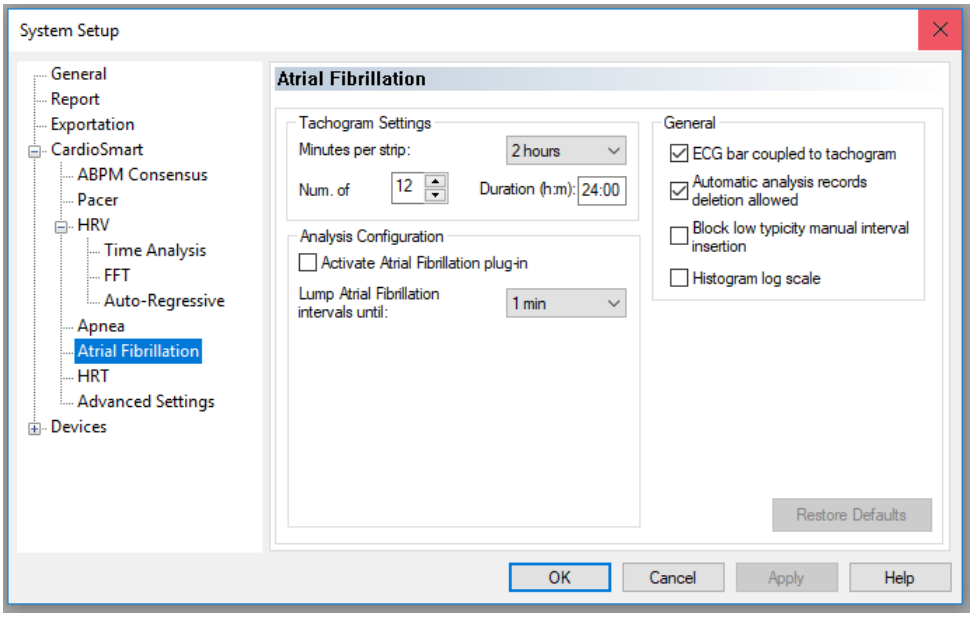
NOTE: This configuration will be validated from the moment of the configuration made by the user and will only affect new exams.

It is also possible for the user to do this configuration individually whenever he/she wishes, but this can be done only with the open exam (recommended).

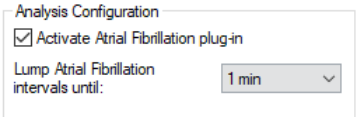
3.4.1.6.5.1. CONFIGURING THE SYSTEM GLOBALLY

Select [Atrial Fibrillation]

This screen will be opened, which configuration to be performed by the user, as already mentioned, will affect all the exams imported and/or transferred from the moment of configuration onwards.

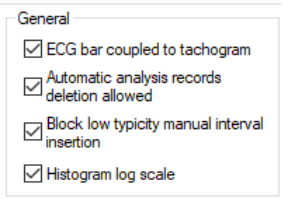


GENERAL FIELD SETTING



In order to set this software automatically it is necessary to select the item [Analysis Settings], [Activate Atrial Fibrillation component]

Agglutinating intervals between fibrillations
It means that the user can determine at which distance (time) between one episode and another it will be possible to join atrial fibrillation events.



Attach ECG bar to the Tachogram
It means, as previously mentioned, that all points detected by the software represented in the tachogram when selected by the user will be demonstrated electrocardiographically at the bottom in the corresponding period.

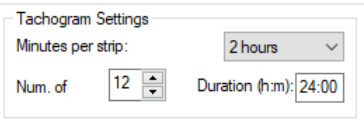
Allow removal of automatic review records
It will allow the user to remove episodes that he/she considers not to be atrial fibrillation even in episodes that have been automatically detected by the system.

Block Manual insertion of low typicality intervals
The user can leave this item enabled whose function is to not allow the insertion of events the software considers (through the NN intervals distribution) as of low typicality.

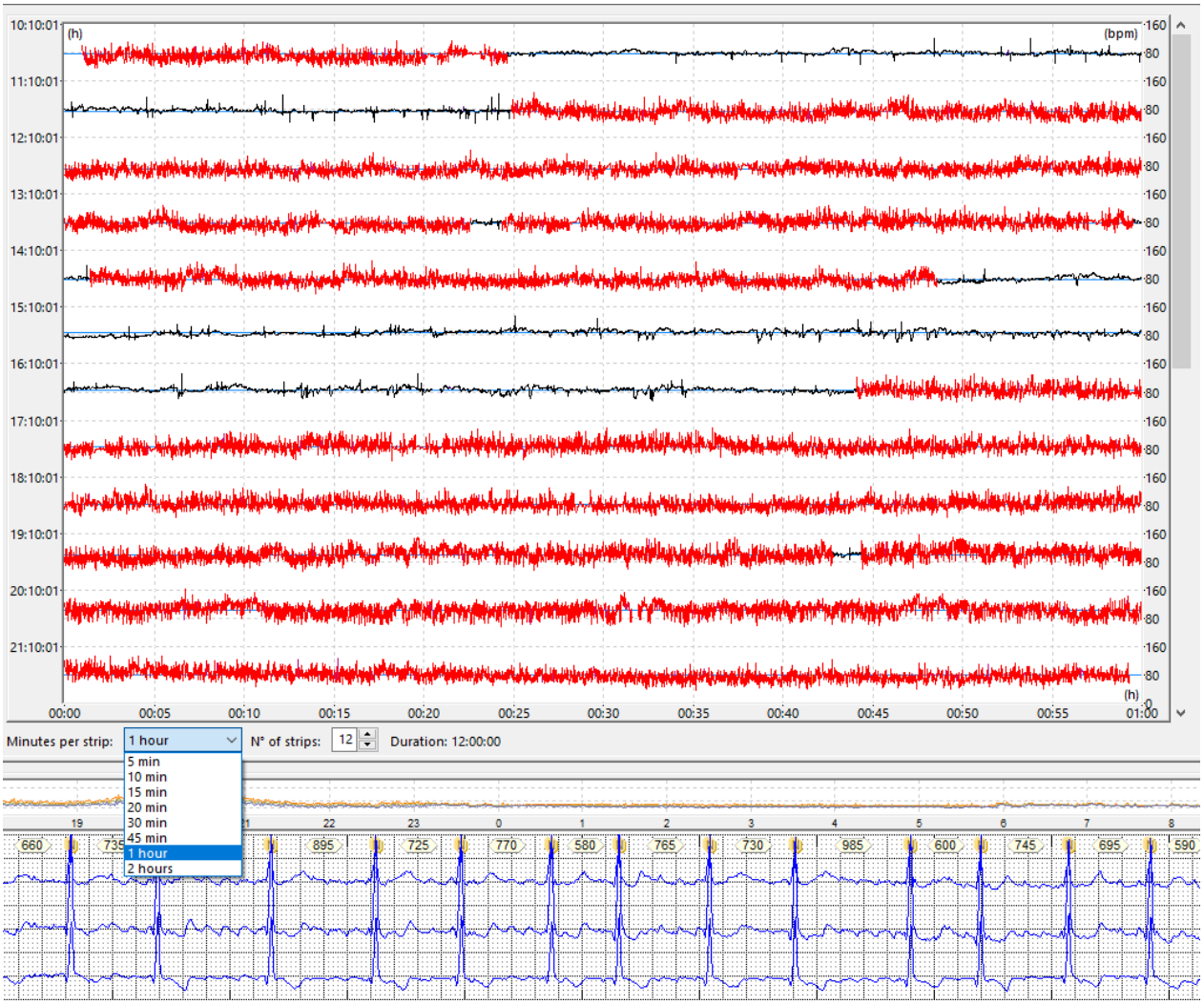
Logarithmic scale
It is related to the display scale in the table / histogram item.

CONFIGURATION STEPS

The atrial fibrillation program main characteristic is the possibility of visualization and analysis of the RR intervals, automatically selecting suggestive periods of the atrial fibrillation behavior.



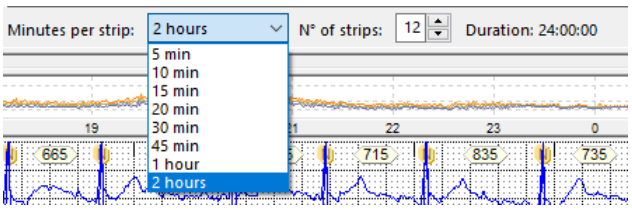
These intervals are observed in a tachogram, which provides graphical observation in time relation.



All items are configurable.

They are identified in the program as Minutes per range.

This configuration can be done globally, that is, default on the system or individual with the open exam.
The standard configuration prepared indicates 12 rows of 2 hours each, allowing the tachogram direct observation of the 24 hours exam.

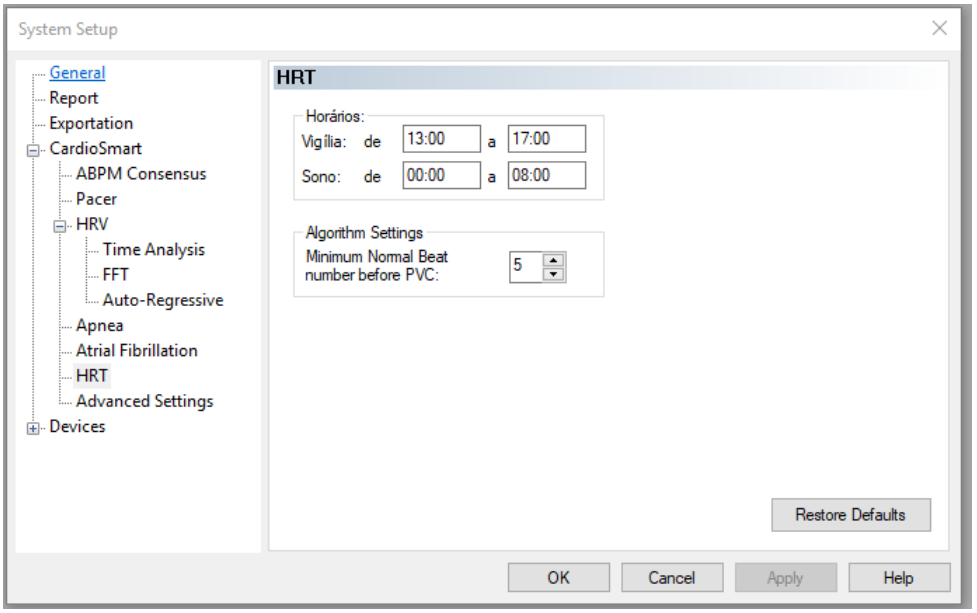


Restore Defaults

To restore all the controls according to the original configuration, just click on the corresponding button.

3.4.1.6.6. HRT - HEART RATE TURBULENCE

The System Setup dialog box has a screen for component specific configuration, which includes the following control tools:
• Edit boxes to set the beginning and end of the Wake Period
• Edit boxes to define the beginning and end of the Sleep Period
• The minimum number of normal heartbeats that should exist before PVC.
The Configure Reanalysis dialog box contains the same features

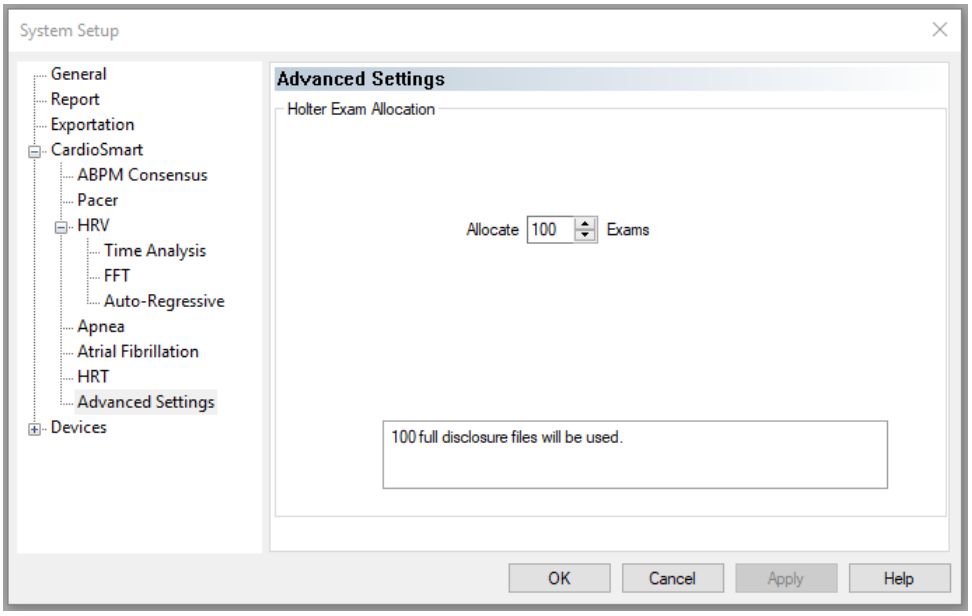


Restore Defaults

To restore all the controls according to the original configuration, just click on the corresponding button.

3.4.1.6.7. ADVANCED SETTINGS

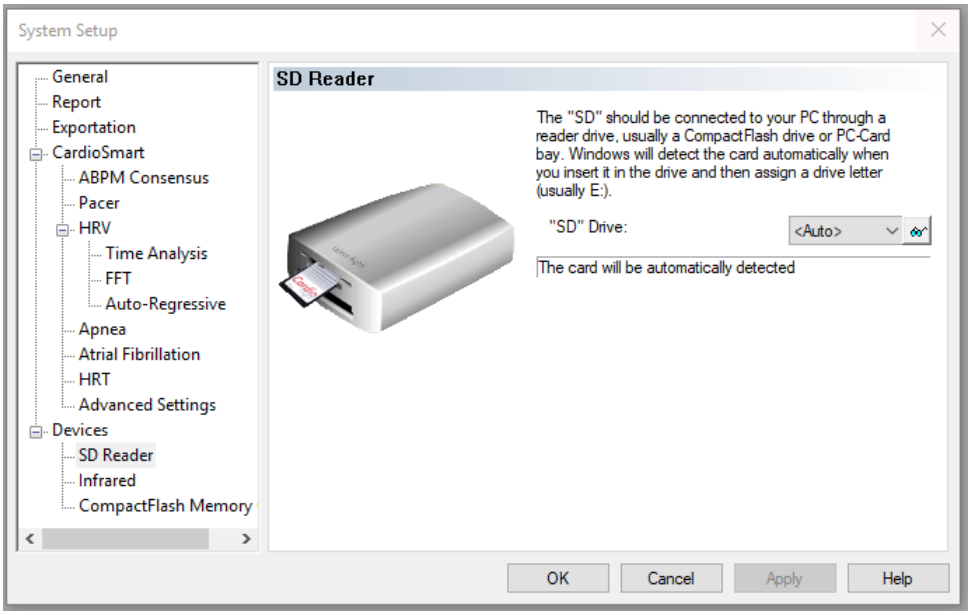
Location of ECG Files
Common Area (with network support)
Allocate “n” exams



In this field, you should enter the number of exams the program will store. The Cardios analysis system can hold up to 999 exams, regardless of the computer's capacity. It should be noted that working at full capacity is not recommended. The recommendation is that 300 exams should be allocated as a safety margin.

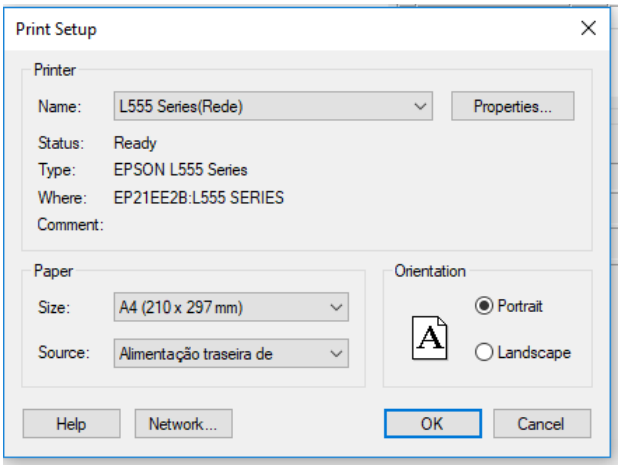
3.4.1.7. DEVICES

Device automatic detection that was inserted in the reader. To do this, just leave the reader card drive in automatic mode.



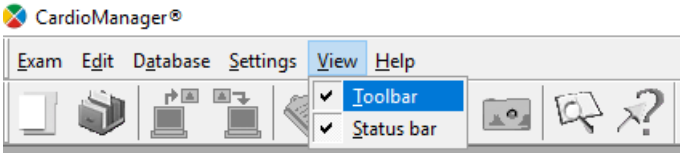
3.4.2. PRINTER SETTINGS

Window in which the printers installed on the computer appear.



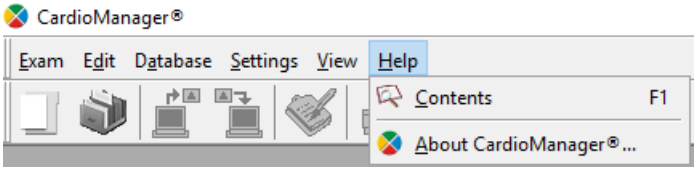
3.5. VIEW

View control for Toolbars and Status Bars



3.6. HELP

Help topics: displays Help Online.



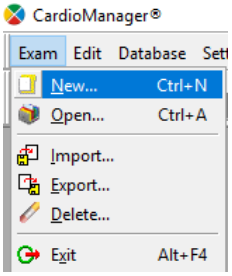
4. PREPARING THE EXAM

4.1. PREPARING THE DEVICE

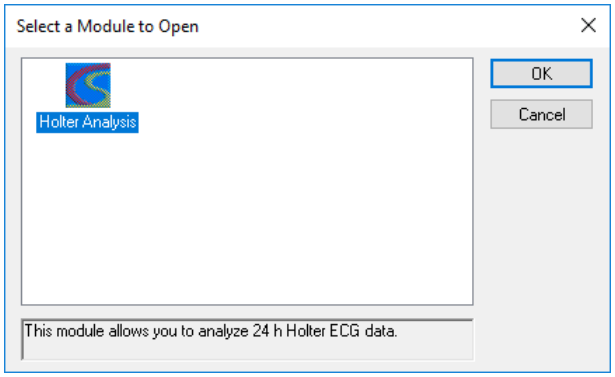
Open the CardioSmart CS550 program.

Connect the device through the USB cable with the computer.

Select [Exam], [New].

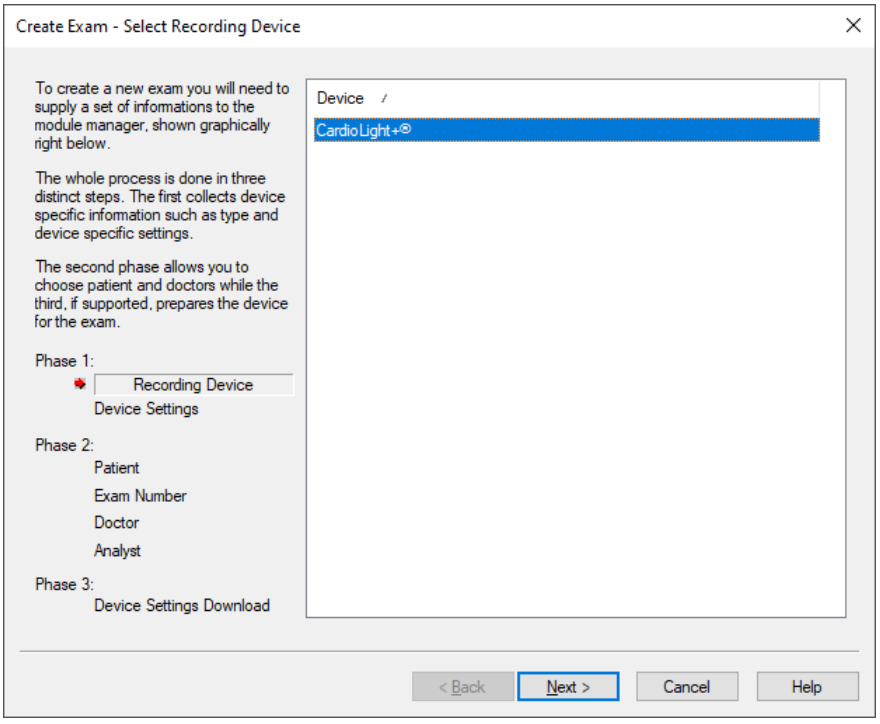


A window with three icons will be opened. Select Holter analyzer and [OK]

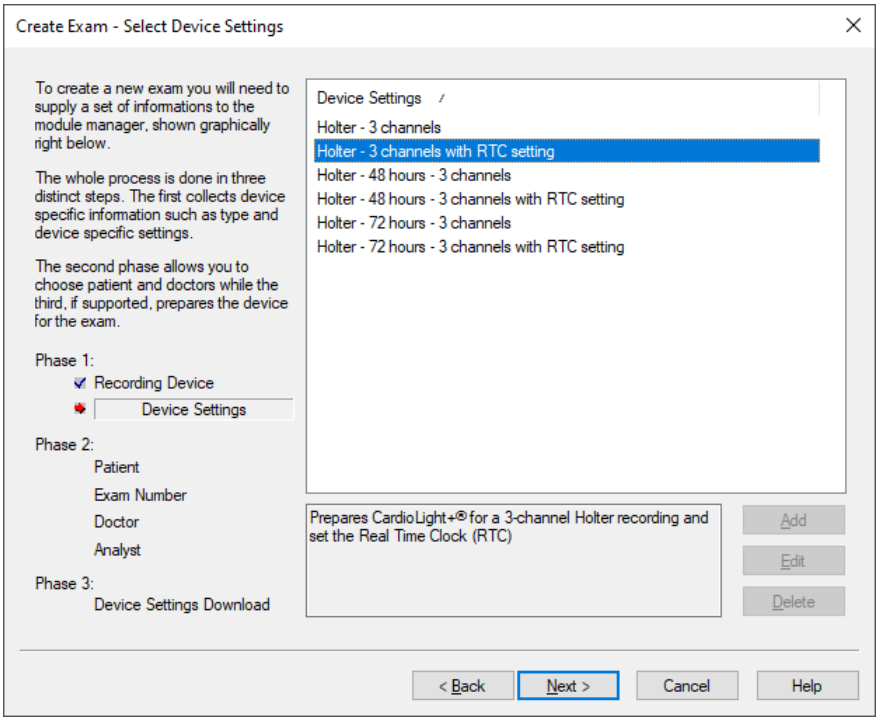


A window will be opened to choose the recorder that will be used to perform the patient recording.

Select the CardioLight+ and click on [Next]

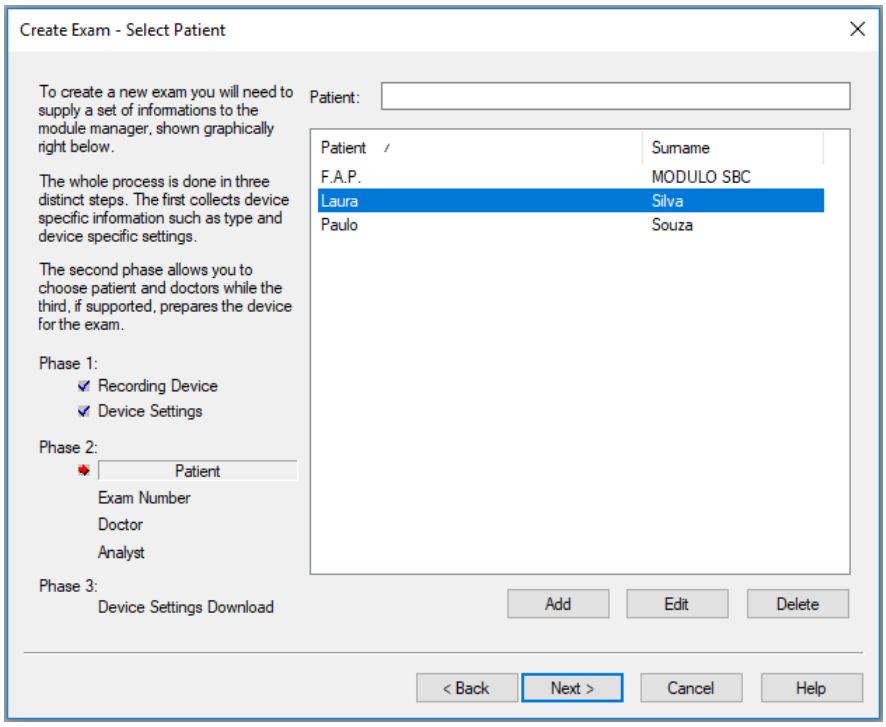


The next step is to setup the recorder as requested in the medical order, that is, 24, 48 or 72 hours.



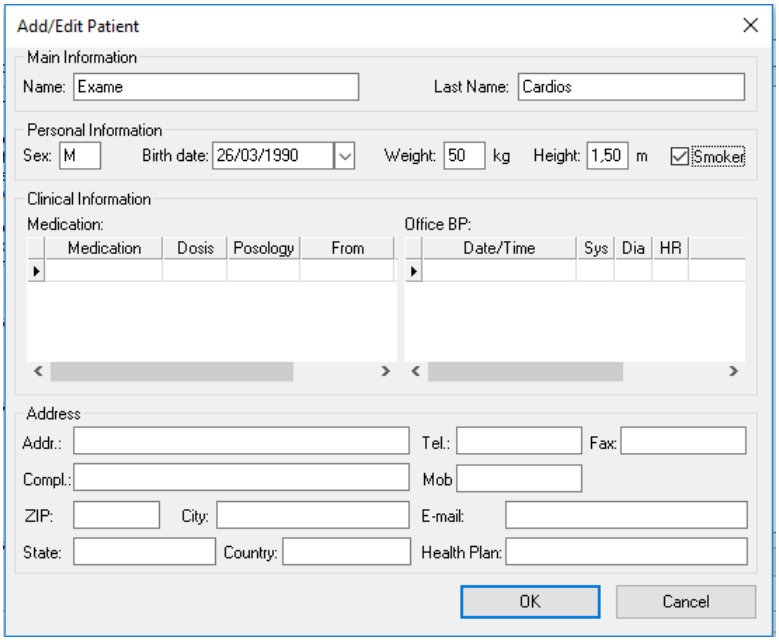
The clock setting should be selected if the recorder internal clock needs to be set.

Click on [Next].



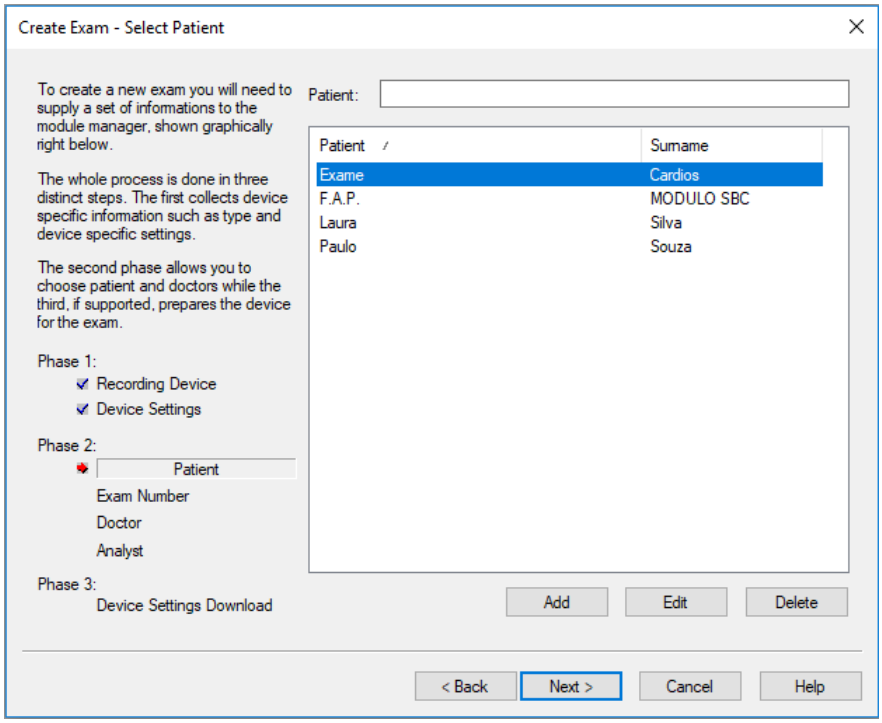
Window for choosing the patient previously registered, or for the patient's data insertion.

If it is chosen to create a new patient, a screen will be opened in which the patient personal data as well as the medication in use, if any, should be entered.



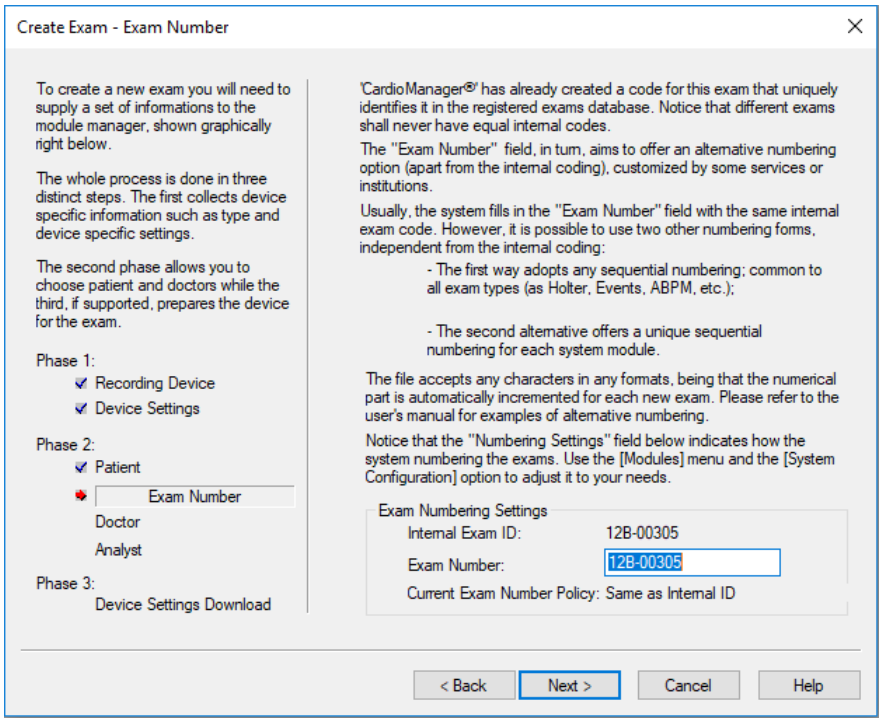
After the patient inclusion, the system will return to the previous window with the name that has just been inserted highlighted.

Click on [Next].



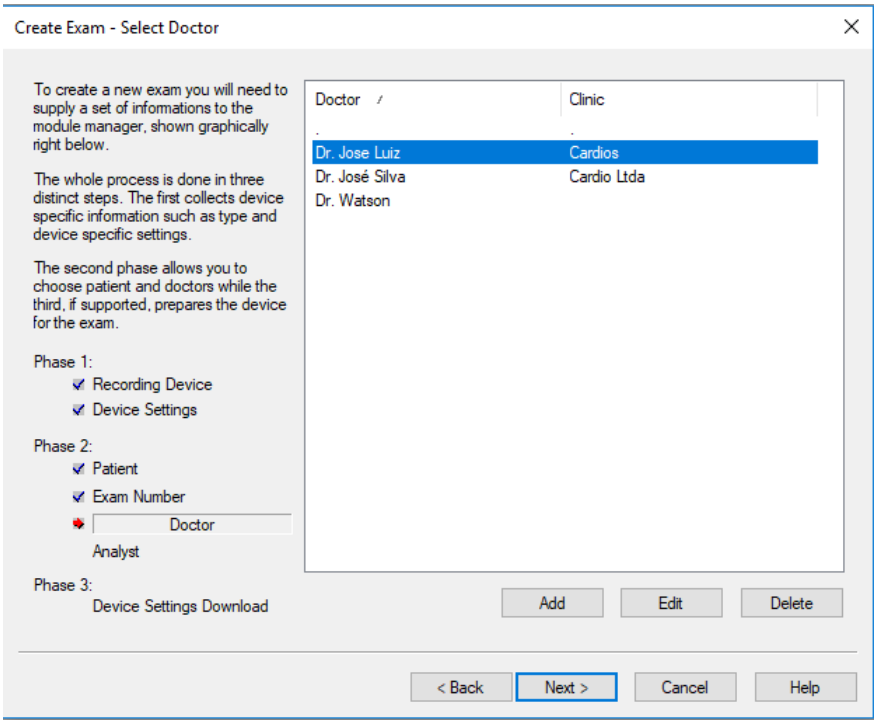
In this area, the exam number can be inserted referring to the patient whose device is being prepared. You can enter the number the customer wants, be it an internal control referring to Holter number, protocol number, etc. The system can automatically generate numbering.

Click on [Next].



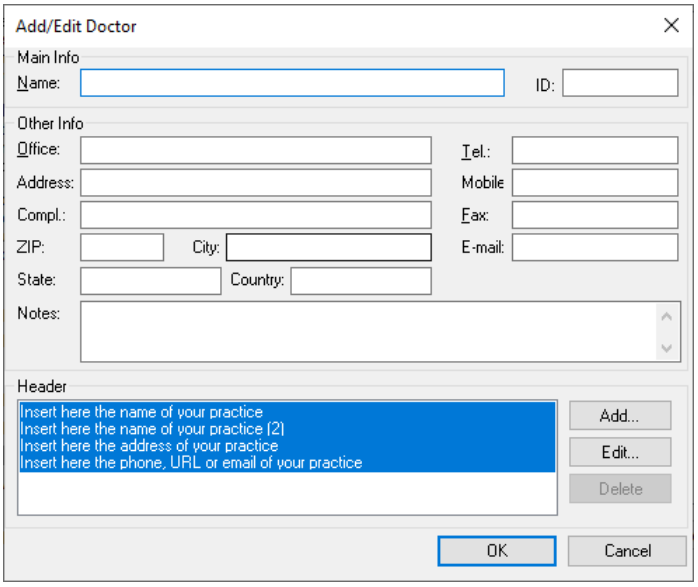
In this field, the referring physician name should be entered. If he/she is already registered, just select his/her name and [Next].

If the name is not already registered click on [New].

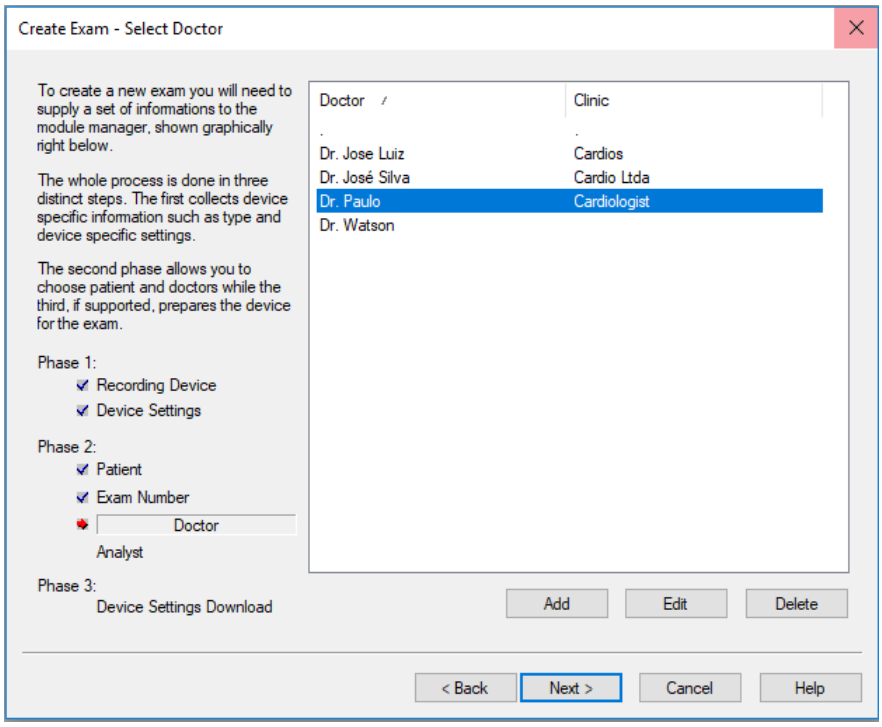


In this field, the referring physician data should be entered.

Click on [OK].



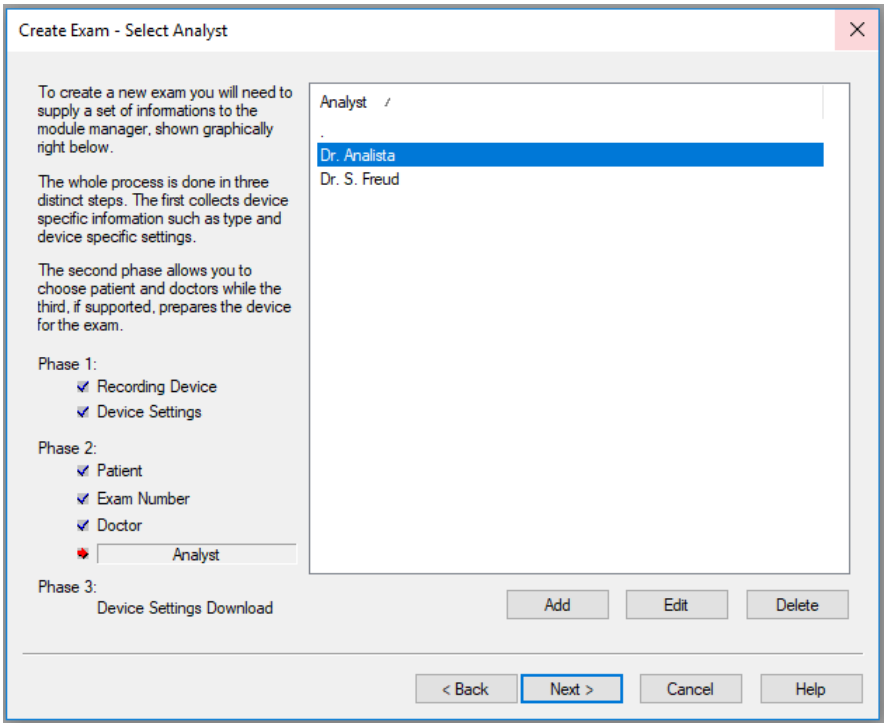
The system will return to the previous screen with the referring physician name already inserted in the registry, highlighted.



Click on [Next].

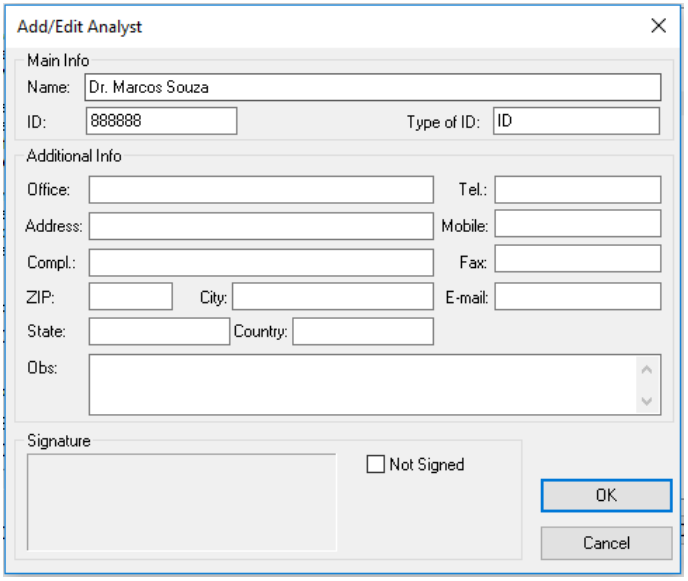
In this field, the Analyst Physician name should be selected or registered.

If the name is already registered click on it, otherwise click on [New].



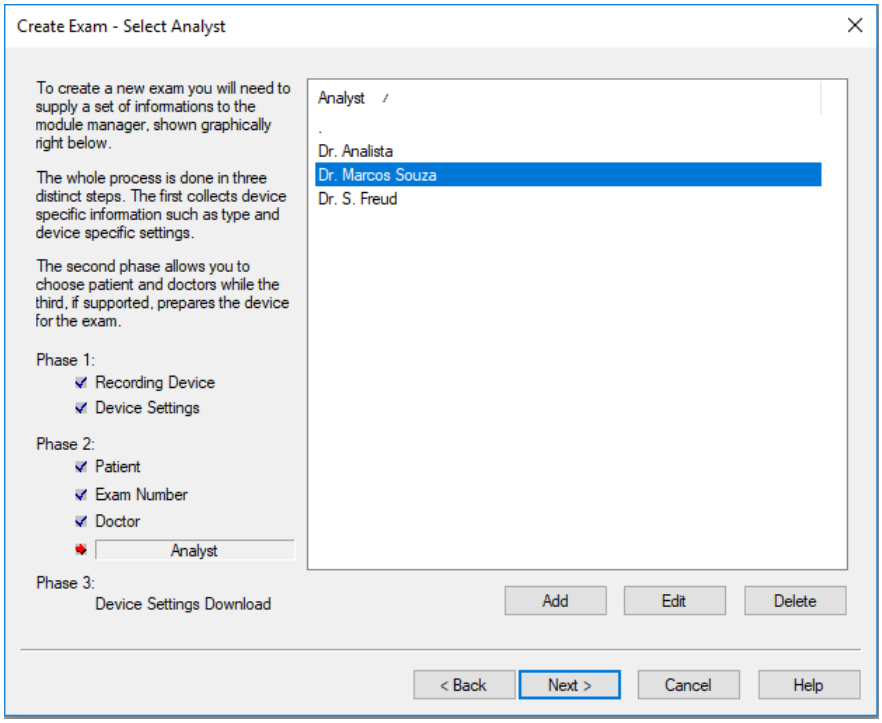
The analyst physician data and CRM should be inserted.

In the signature field, the scanned signature can be inserted. This signature should have been previously saved in jpg, png or bmp format. To associate it with the name, just click on the "Signature" box and select it in the folder where it was saved.

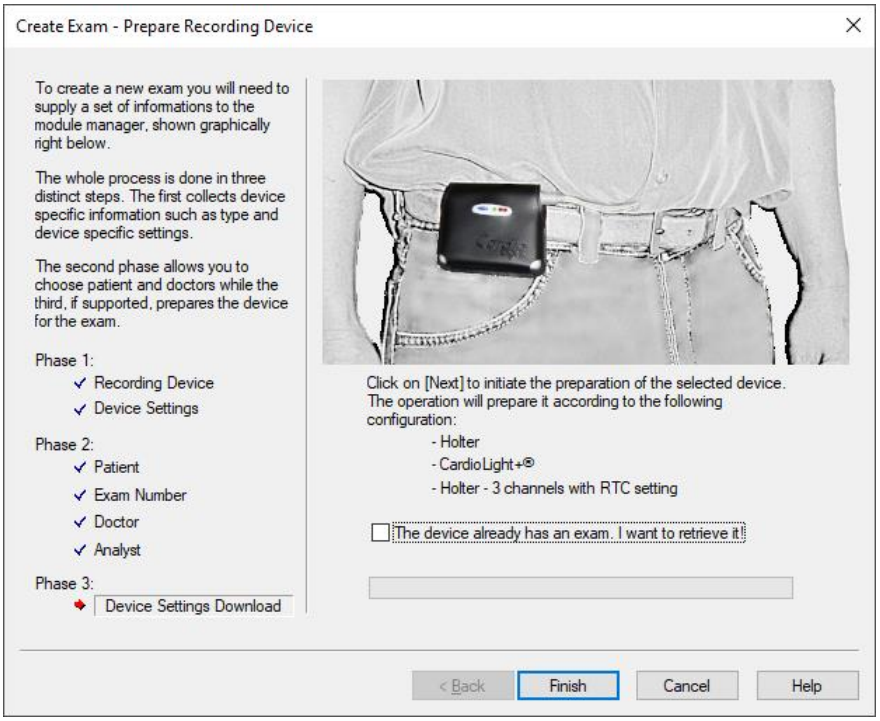


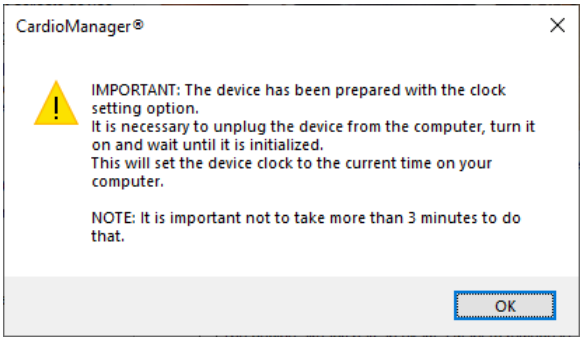
The system will return to the previous screen with the analyst physician name inserted in the registry, in highlight.

Click on [Next].



The final stage of the exam preparation for recording will be demonstrated.
On the right, it is possible to see the exam and recorder types, and whether the time has been set or not.
Click on [Finish].



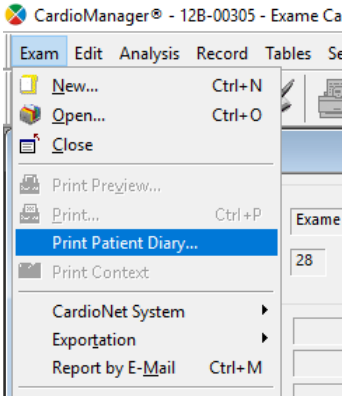


If the clock setting (RTC) has been selected, the system will send a message stating that it is important not to take more than 3 minutes to initialize the device. This notice is issued only so that there is not much discrepancy in the time recorded on the device and the effective start of the exam.

Click on [OK].

4.2. PATIENT'S DIARY

The screen with the patient's newly created data will be opened.
If you want, you can print the Patient's Diary using the system.
Just click on [Exam] [Print Patient's Diary].



Diary model provided by the system for filling by the patient during the exam.

Diary of Patient

Exam Number	Patient: Exam	Exam ID
12B-00305	Exam Start Date: Thursday, August 16, 2018	12B-00305

	Start	End	Activity	Time	Symptom
1	14:43		Start of Recording		
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
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24					
25					
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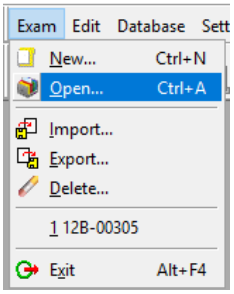
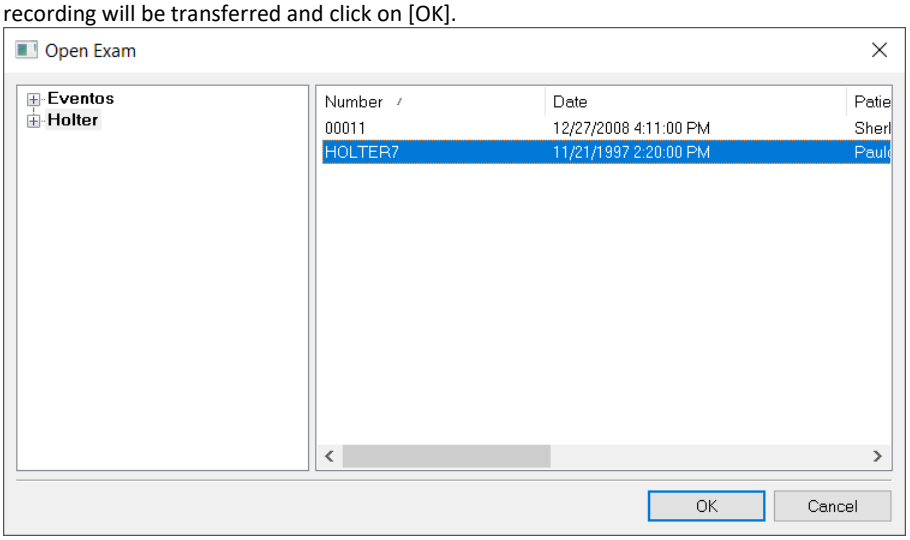
27					
28					

4.3. EXAM TRANSFER AFTER HOLTER RECORDING

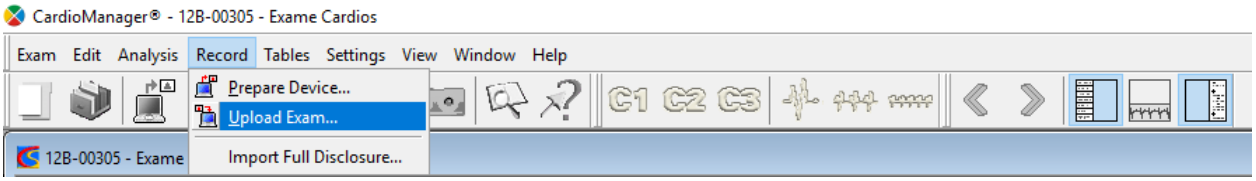


Click on [Exam] [Open]

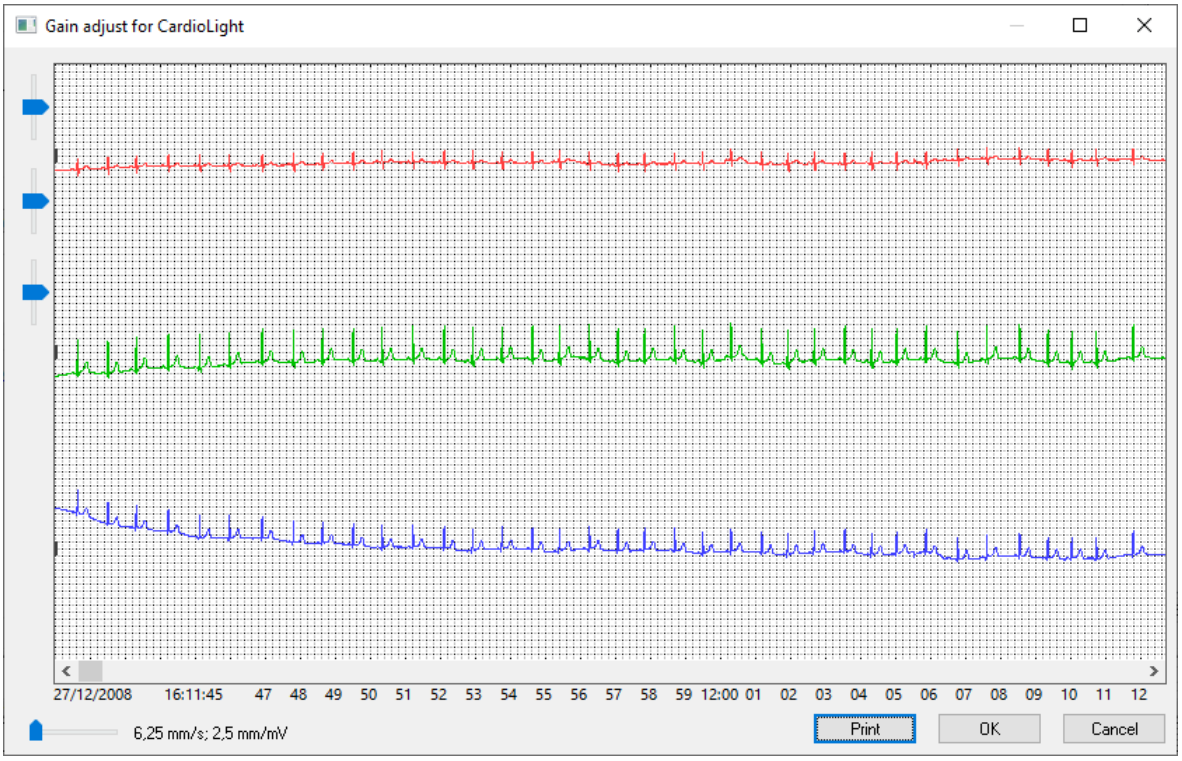
A list of patients' names that are registered with CardioSmart CS550 will be displayed. Select the patient's name to whom the recording will be transferred and click on [OK].



A screen with the patient's name will be opened.
Make sure the device containing the opened exam is already connected through the USB cable.
Click on [Record] [Transfer recording]



Immediately the initial minutes of the exam will be demonstrated. At this point, the user can set the electrocardiograph signal gains if he/she considers it necessary.
In the upper left corner, you can see three sliders that selected and dragged up or down, allow the signal gain to be changed, to a greater or lesser extent.

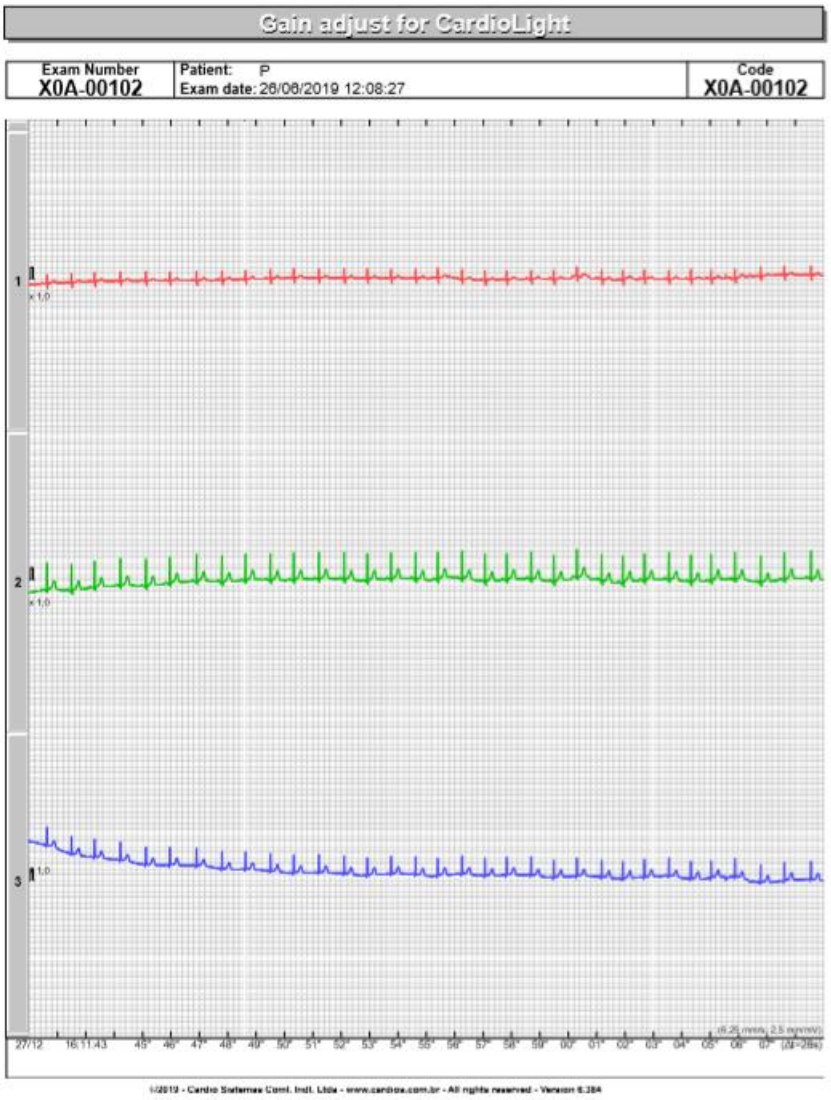


After verification click on [OK].

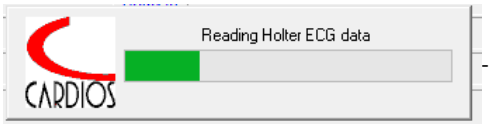
The exam data will be transferred to the analysis system.

On the Gain Settings screen, a report can be printed after clicking [Print].

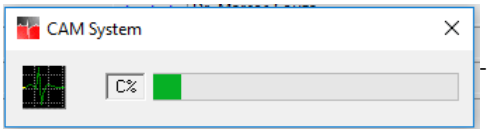
The report is generated with the Recording Device ID, Exam Number, Exam Code, Patient's Name, and Exam Date and Time.



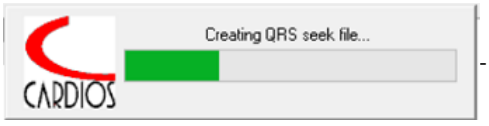
During the transfer, three stages will occur through a progress bar:



- Holter Data Transfer

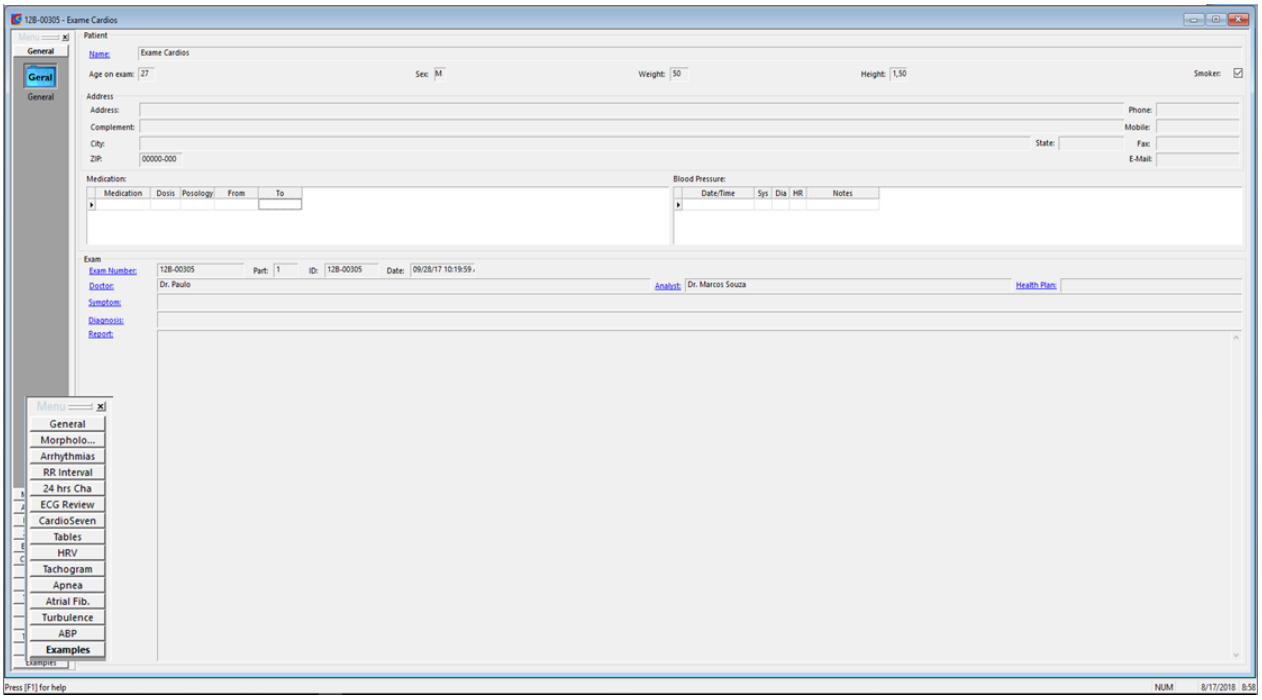


- CAM Analysis System



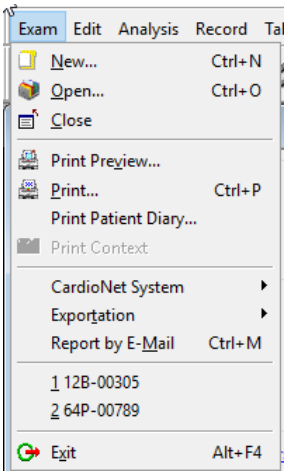
- Creating search file and QRS.

After the transfer of the ECG signal is completed, the system will display a menu (also called the Window Bar), located to the left of the screen, to assist navigation between the review tools.



5. TOOLS WITH OPEN EXAM

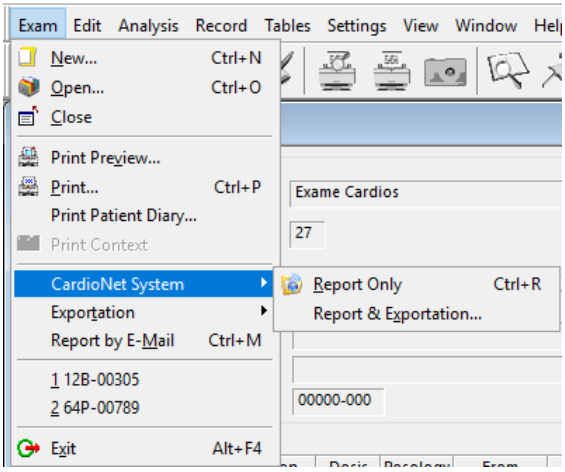
5.1. EXAM



Print Preview
It is possible to visualize how the exam will be at the time of printing and check the inserted tracings with the reports. This item can be accessed directly on the screen through the icon

Print out
Print the exam at the analysis site.

Print Patient's Diary
Select when the exam was prepared with this option (according to the exam preparation chapter)

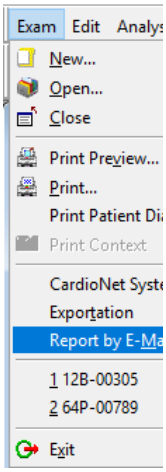


CardioNet System
Report Only - Generate report file in pdf format to the CardioNet folder.

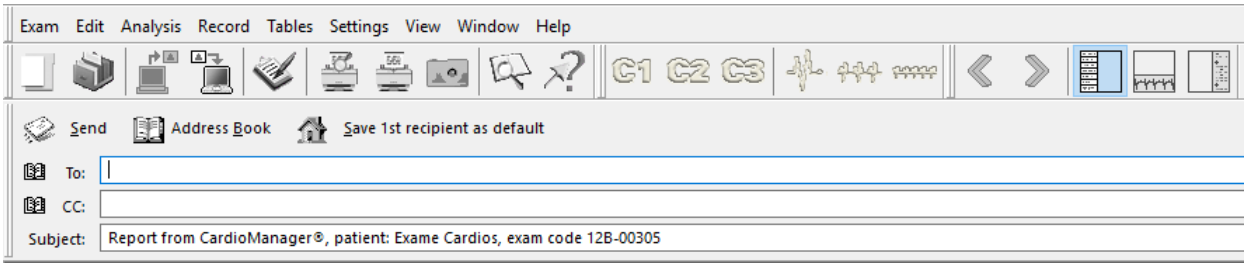
Report & Exportation
Generates the report file in pdf combined with XML. (If the institution does not have integration with XML this option is not necessary)

Export:

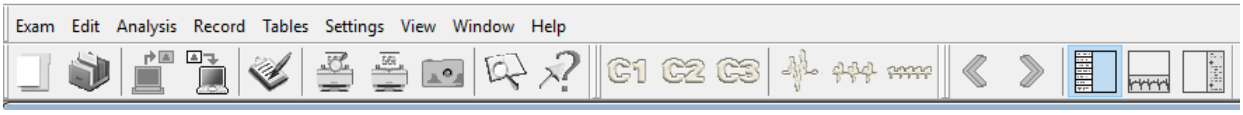
XML Export
Exam export standard for integration with hospital systems, which requires customer system preparation. Contact Cardios for more details.

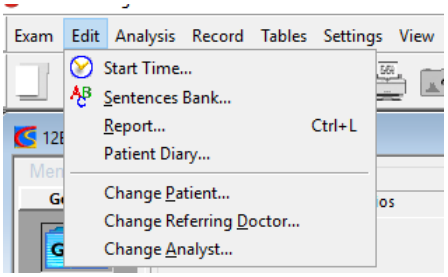


E-mail Report
Return / sending of exams in pdf format via e-mail. Selecting the report option by e-mail opens a window with the e-mail address field to fill in.



5.2. EDIT





Start Time
Correct the starting time and exam date if necessary.

Bank of sentences
Ability to store sentences at any time by the user (as described in previous chapter).

Report
Item accessed to select the sentences that will appear in the report.

Patient's Diary
In the case of the exams received via the Internet (CardioNet) whose diary was filled in the clinic of origin, select this tool to print the diary sent by the client. To print, just select Patient's Diary. A screen with four options will open. Select Print.

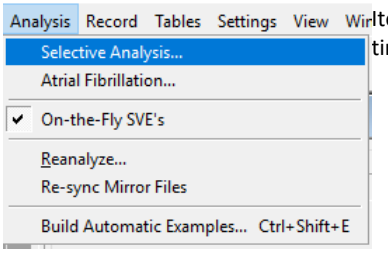
Change patient
Tool used when you want to correct or add some information regarding the patient data whose exam is being edited (possibility of direct access on the screen).

Change Referring Physician
If it is necessary to insert a referring physician or modify some information (possibility of access right on the screen).

Change Analyst Physician
Enter the physician's name who will do the exam analysis (possibility of direct access on the screen).

5.3. ANALYSIS

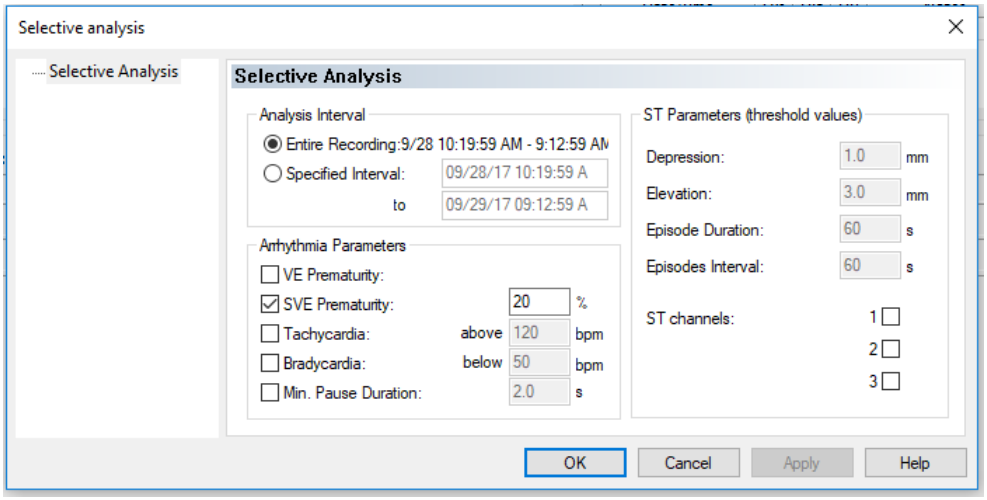
5.3.1. SELECTIVE ANALYSIS



Item selected when there is a need to individually change any preset settings in the settings item quoted in the previous chapter.

The Analysis Configuration can be selected by the Operator through the Analysis -> Selective Analysis menu.

The Analyst Physician is responsible for checking the selected Analysis Criteria in the Selective Analysis Configuration.



Prematurity of SVESs

The configuration of supraventricular extrasystoles prematurity refers to the system sensitivity to quantify early heartbeats based on NN cycles. This pre-established percentage of prematurity can be changed to interfere in both sensitivity and specificity. For example: in cases of atrial fibrillation / atrial flutter observed during the 24-hour recording in which system quantifies supraventricular extrasystoles (based on the irregularity of the RR intervals) it is possible to change the parameters from prematurity to 100% so that the system does not quantify heartbeats precocious.

Also regarding the supraventricular extrasystoles prematurity, the sensitivity can be increased or decreased, that is, if the analyst physician concludes that the supraventricular arrhythmias are a little underestimated, it is possible to numerically decrease the prematurity percentage to increase the software sensitivity in quantifying supraventricular arrhythmias that have not been so precocious.

Tachycardias and Bradycardias

In this same window, it is possible to change parameters related to tachycardias or bradycardias in cases where greater specificity in the patient's HR behavior is required.

Minimum pause time

In situations where the analyst does not want to quantify pauses around 2.0 seconds, it is possible to increase the parameter value so that this quantification is not made. There is also the possibility of decreasing the pause parameter value to try to track some event, such as, for example, AV block Grade II block episodes or non-conducted ESV that did not cause pauses exceeding 2.0 seconds.

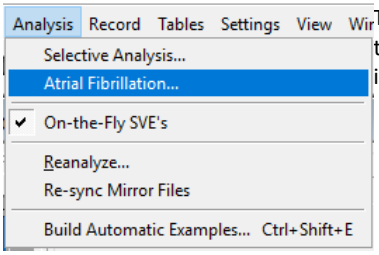
ST Parameters

It is possible to change the preset numerical values in the general setting to more or less, in order to change the software sensitivity in the episode quantification of depression or ST segment elevation, depending on the case. Sometimes the system quantifies episodes of depression or elevation of the ST segment by secondary factors and cannot be valued as ischemic events. For example, in exams in which T waves are negative, or when the ST segment remains continuously or temporarily unbalanced by some pathology (ventricular overload for example), changes in early ventricular re-polarization or even electrode positioning in which the system has made this quantification.

NOTE: When any parameter is changed within the selective analysis item, there is no need for reanalysis of the exam. Just click on OK and the software automatically takes over the changes made. The changes are not final. If the analyst physician makes any changes and then wants to return the previous parameter value, it is possible to do so at any time.

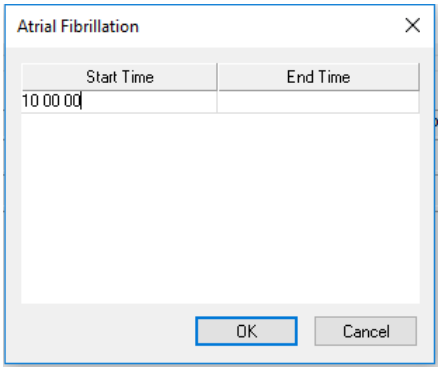
IMPORTANT: Any parameter changes that are made at that time will only affect the exam being analyzed (open). The preset general settings for the other exams are retained.

5.3.2. ATRIAL FIBRILLATIONS



This tool is used for exams that have atrial fibrillation / paroxysmal atrial flutter. Based on the irregularity of the NN intervals the software will quantify supraventricular arrhythmia in the periods of atrial fibrillation / flutter (as already mentioned).

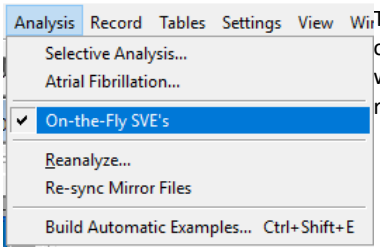
To eliminate supraventricular arrhythmia during periods of atrial fibrillation / flutter and maintain them (if they occur) during sinus rhythm, it will be necessary to inform the software at which time the supraventricular arrhythmia should not be quantified.



In the table presented, after the episodes are detected, the start time and the final atrial fibrillation / flutter time are entered so that the system does not quantify supraventricular arrhythmia at this time.

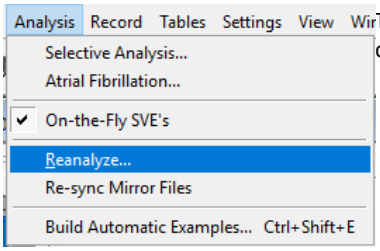
NOTE: This table will be used in systems that do not have the atrial fibrillation module (see corresponding chapter).

5.3.3. AUTOMATIC CONTEXT EDITING



Tool that helps the edition of the exam, mainly by the speed of analysis. You can leave this option selected or not. When selected, the previous and subsequent editing heartbeats will also be automatically re-evaluated (interpreted) according to this new parameter, correcting possible errors and increasing the speed of editing.

5.3.4. REANALYSIS

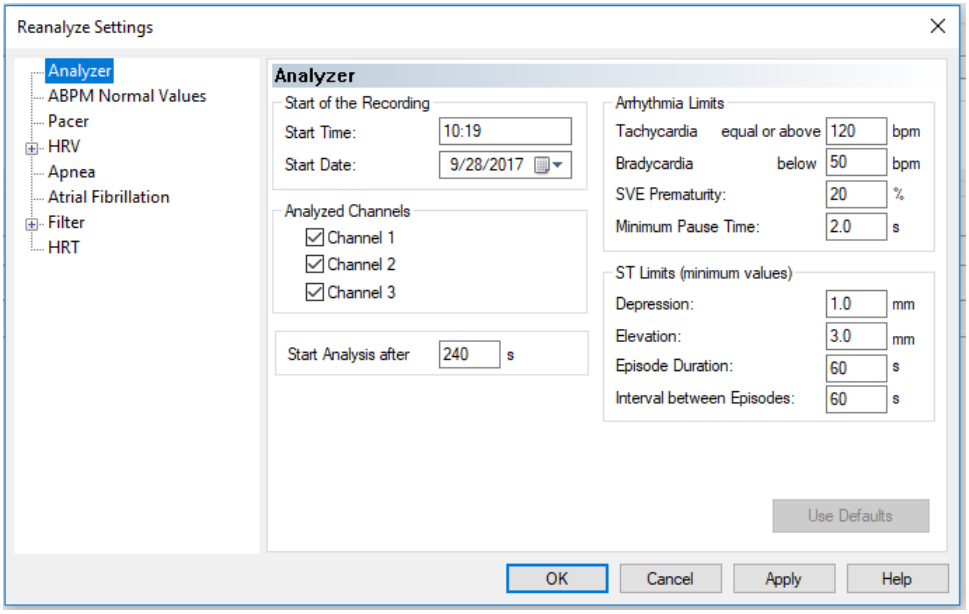


Tool that can be used in various situations according to the need of the exam in the process of analysis.

Attention: in some situations, during the Reanalysis process, what has already been done in the edition of the exam is lost. Therefore, if there is a need to reanalyze the exam, it is best to do it before any editing.

The Reanalysis Configuration can be selected by the Operator through the Analysis -> Reanalyze menu.

The Analyst Physician is responsible for checking the selected Analysis Criteria in the Reanalysis Configuration.

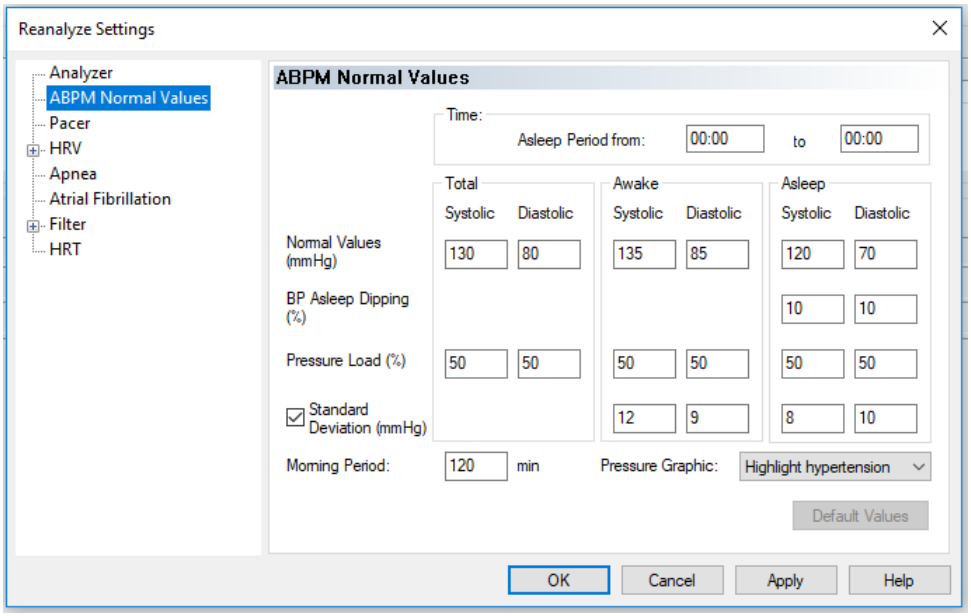


Situations where the reanalysis tool is used:
In some exams, according to the need, in which one perceives that one of the analyzed channels has a lot of interference, it is possible to reanalyze the exam, disregarding that channel. The channel omitted in the analysis will continue to appear in the exam, but the system will not count the QRS of that channel.

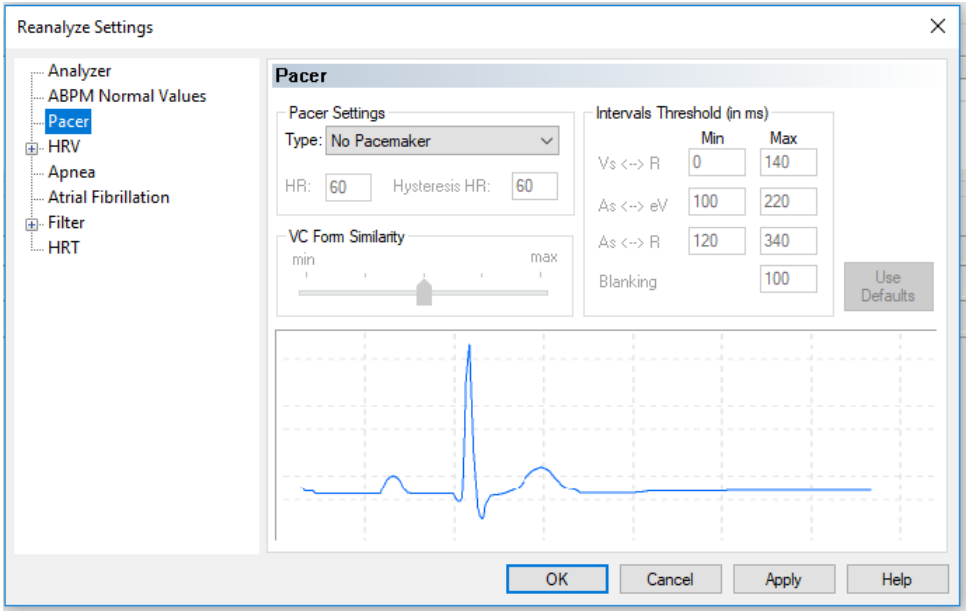
NOTE: It is not possible to perform the reanalysis of the exam considering only the C3 channel. The system does not analyze only that channel.

5.3.4.1. ABPM CLINICAL LIMITS

It is possible to modify some item of the clinical limits of ABPM according to the necessity.

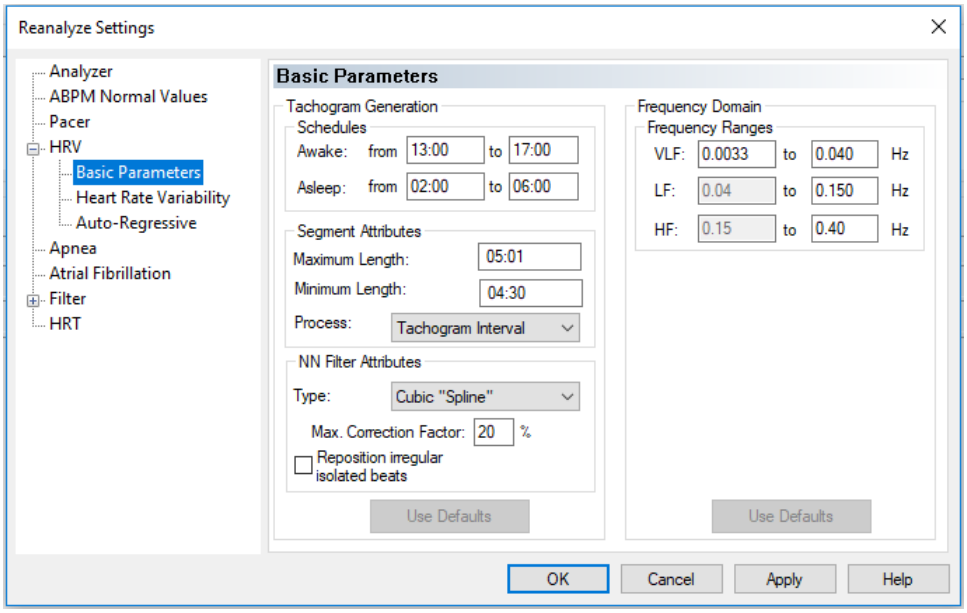


5.3.4.2. PACEMAKER



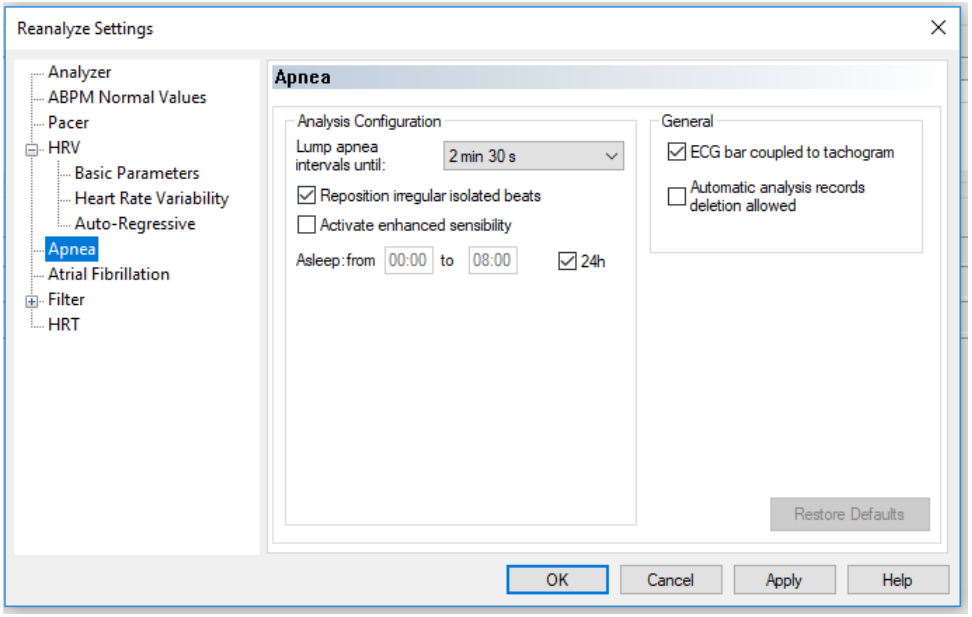
In exams in which the patient has an artificial electrical pacemaker.
After identifying the predominant mode of stimulation in the 24 hours of the Holter, it is necessary to use the reanalysis tool informing which pacemaker type the patient is a carrier.
(See Pacemaker Module for details.)

5.3.4.3. HRV



If the analyst physician wants to change any preset parameters.

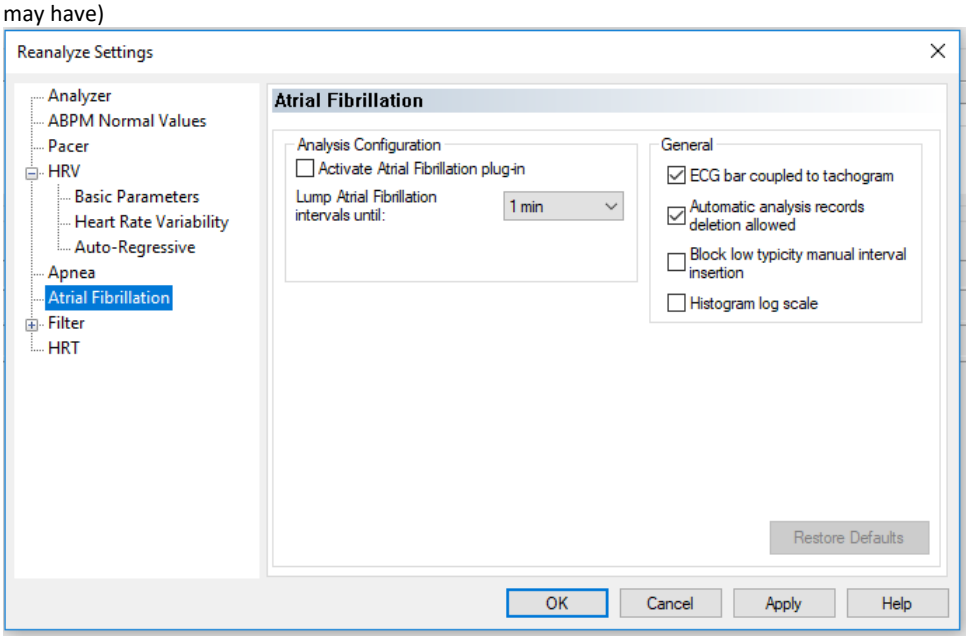
5.3.4.4. APNEA



Possibility to reanalyze the exam by configuring periods, repositioning or not isolated irregular heartbeats (extrasystoles), increasing sensitivity, altering sleep period.
It is also possible to connect ECG control to the tachogram, that is, when a period classified as apnea is selected in the tachogram, it is possible to see the ECG of the corresponding moment in the ECG bar.
There is also the possibility of removing periods the analyst physician disagrees with the quantified event (Chapter 11).

5.3.4.5. ATRIAL FIBRILLATION

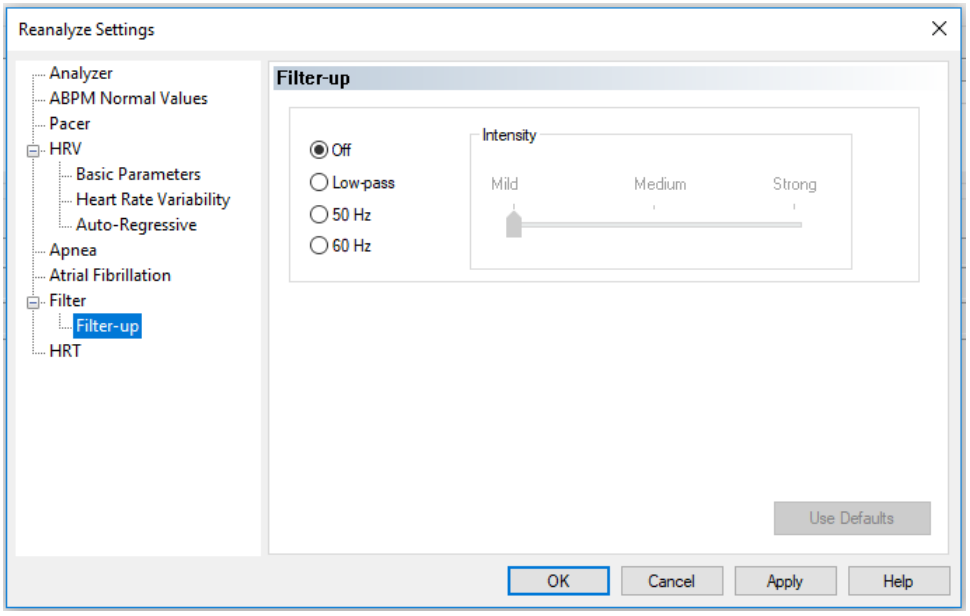
Can be set individually or default. It allows the software to identify and classify the episodes of atrial fibrillation (which the exam may have)



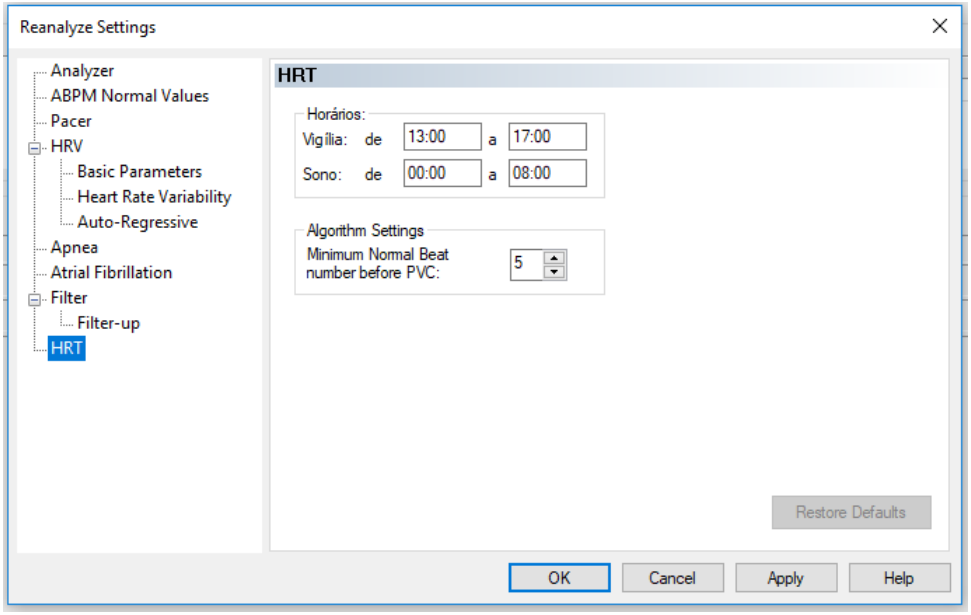
5.3.4.6. FILTERS

Possibility to reanalyze the exam using the filter to eliminate or minimize noise.

ATTENTION: the more intense the filter selection the wider the QRS complexes will be. In this process, the software reanalyzes the exam by debugging the signal, thus improving the interpretation of the morphologies.

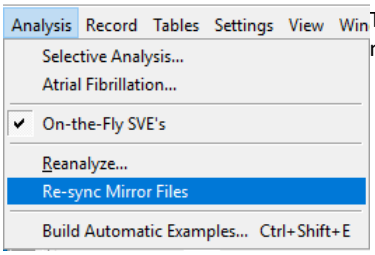


5.3.4.7. HEART RATE TURBULENCE



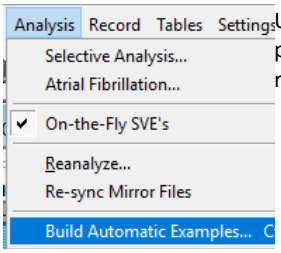
If the analyst physician wants to change any preset parameters.

5.3.5. SYNCHRONIZE ANALYSIS



Tool used to ensure that the system assimilates all edits made. The use of this tool is not mandatory and will not result in the loss of any previous edition.

5.3.6. GENERATING AUTOMATIC EXAMPLES



Used in one of the final stages in the assembly of the examples (tracings that will be selected for printing), and of extreme importance. During the analysis process some corrections are made, corrected artifacts, etc.

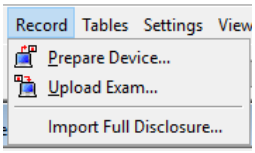
When selecting the [Examples] item it is necessary to update the tracings, that is, an edition recompilation. The software will remove the examples that may be wrong from the examples and look for the right examples.

Basal HR, Maximum HR, diagnostic annotations and symptoms are available in the title, the strip duration time on the right side of the scale, and channel identification, calibration pulse and gain are available in the chart.

The Analysis Configuration can be selected by the Operator through the Analysis -> Reanalyze menu.

The Analyst Physician is responsible for checking the Reanalysis Configuration for the selected Analysis Criteria.

5.4. RECORD



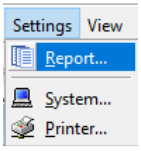
Tool used to transfer recording after 24 hours of exam (see chapter on Preparing Exam and Exam transfer).

5.5. TABLES

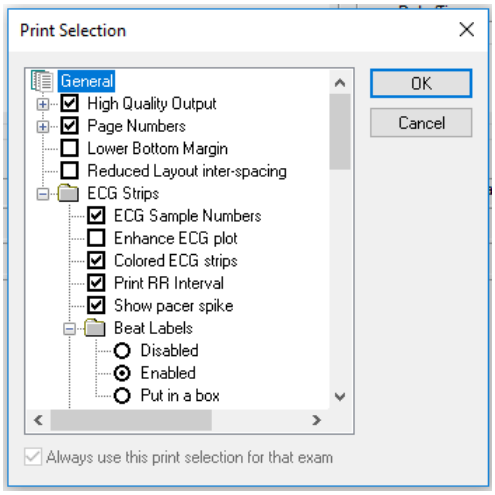
Displays the list of previously registered analyst physicians, referring physicians, patients, substances, medications, activities, symptoms, and diagnoses (as discussed in previous chapter).

5.6. SETTINGS

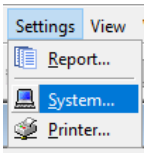
5.6.1. REPORT



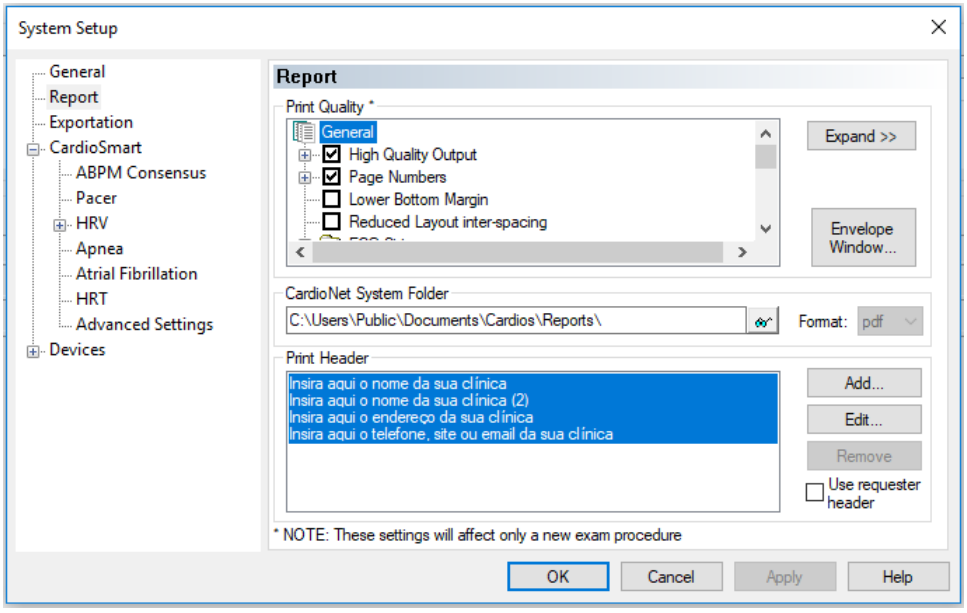
In this item, it is possible to add or delete some item in the impression of the exam that is being analyzed individually, without affecting the configuration for the other exams.



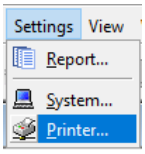
5.6.2. SYSTEM



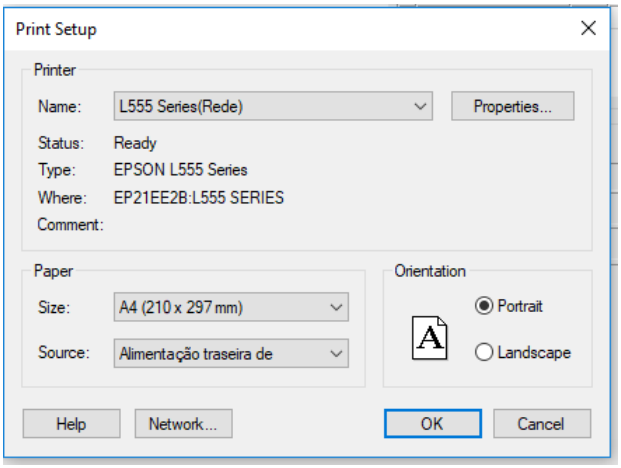
Refers to the system general configuration already described above. Tool also used when there is a need to select a header (previously registered) at the time of printing.



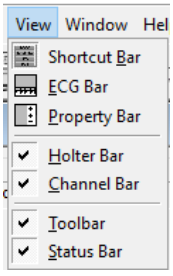
5.6.3. PRINTER



Tool that lists the printers configured on the system to be used.

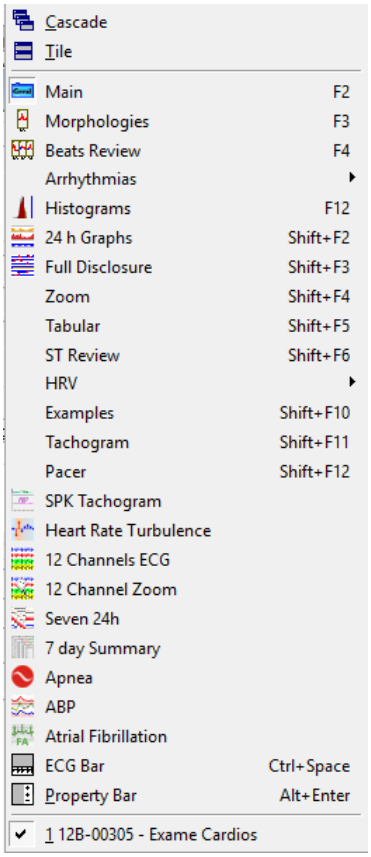


5.7. VIEW



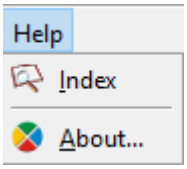
Possibility to select items that you want to hide or display.

5.8. WINDOW



Tool that provides the display format of the screens and shortcut keys with their respective commands.

5.9. HELP



They bring some tips on using the software.

About CardioSmart CS550
Displays the program level that the client has, and the version being used.

5.10. TOOLBAR - SHORTCUT KEYS

Refers to the new exam creation, as already discussed.

Shows the list of exams available in the system.

Allows the device to be “cleared” for recording an exam. Initialize recording

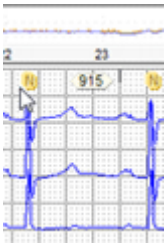
Transfer of the ECG signal after recording.

Prints the current text

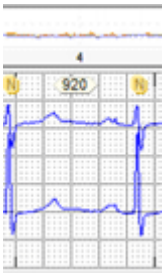
Help Topic.

Just click directly on the toolbar on one of the channels, to delete it or to add it from the view.

3 channel



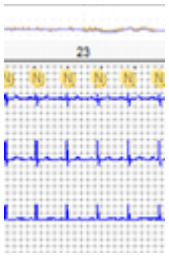
2 channel

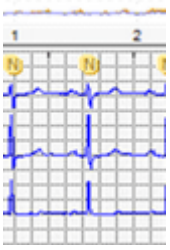


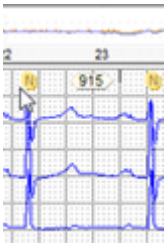
1 channel

Selects the density in the signal view.

Low **Normal** **High**



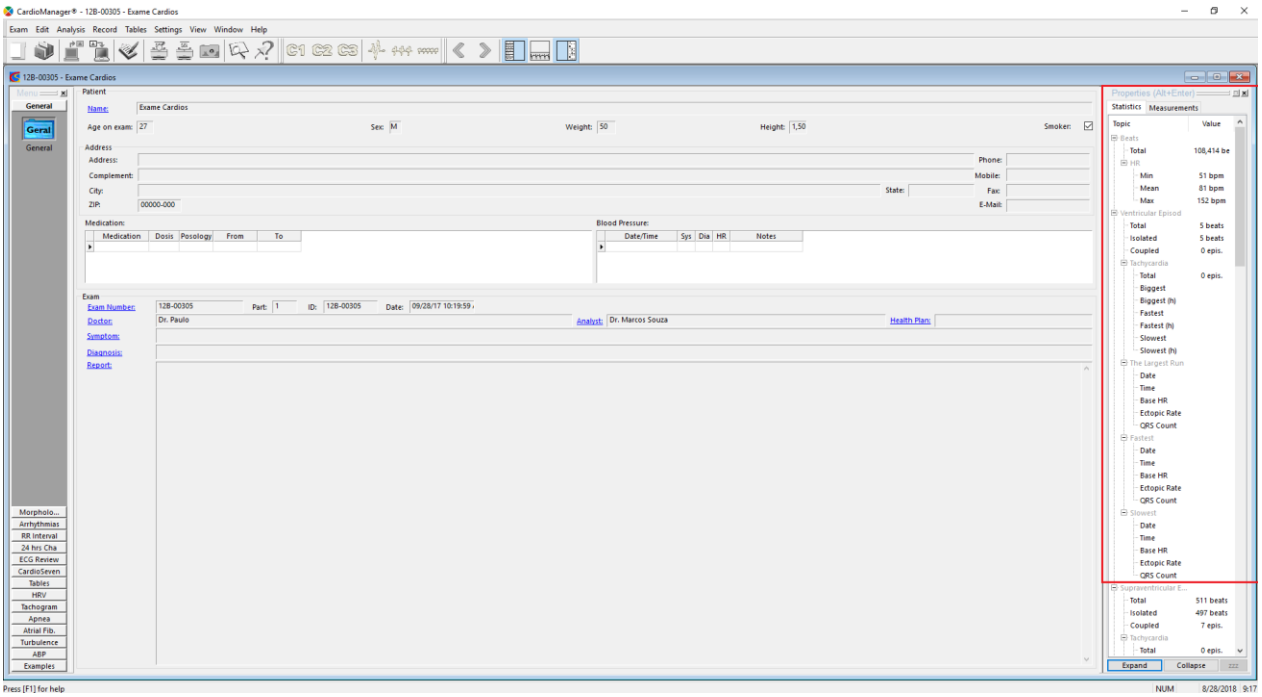


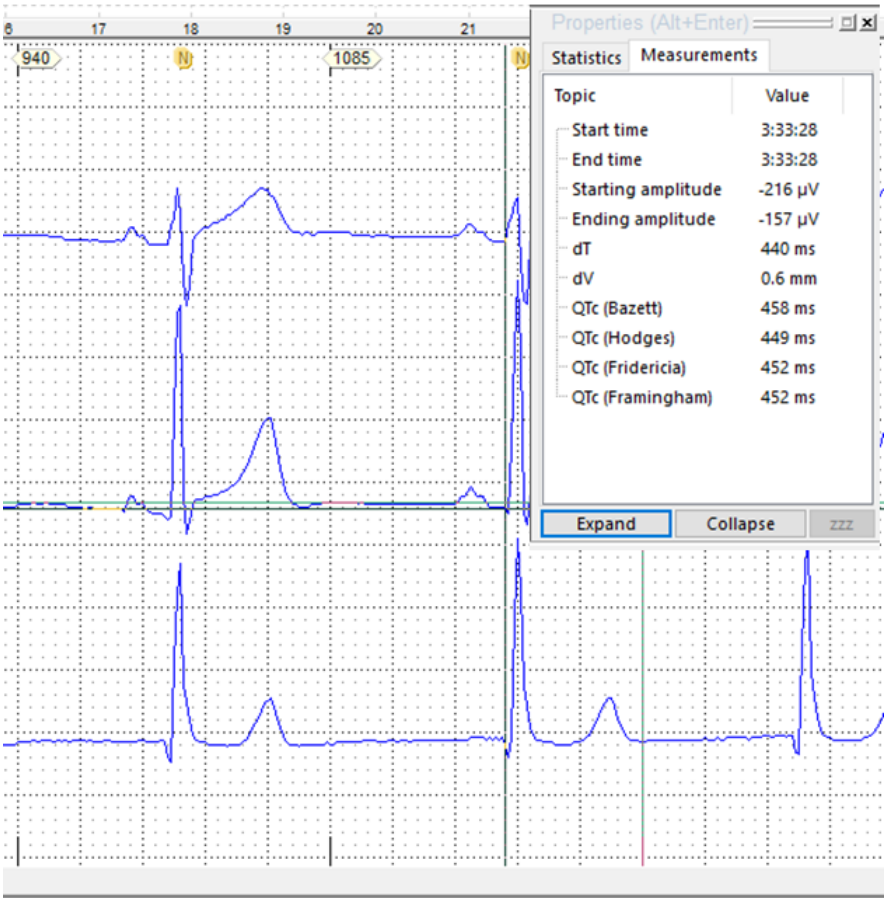


Clicking on the corresponding arrows allows you to return to the previous or later screen of the one being viewed / analyzed.

Windows whose functions will be explained soon after.

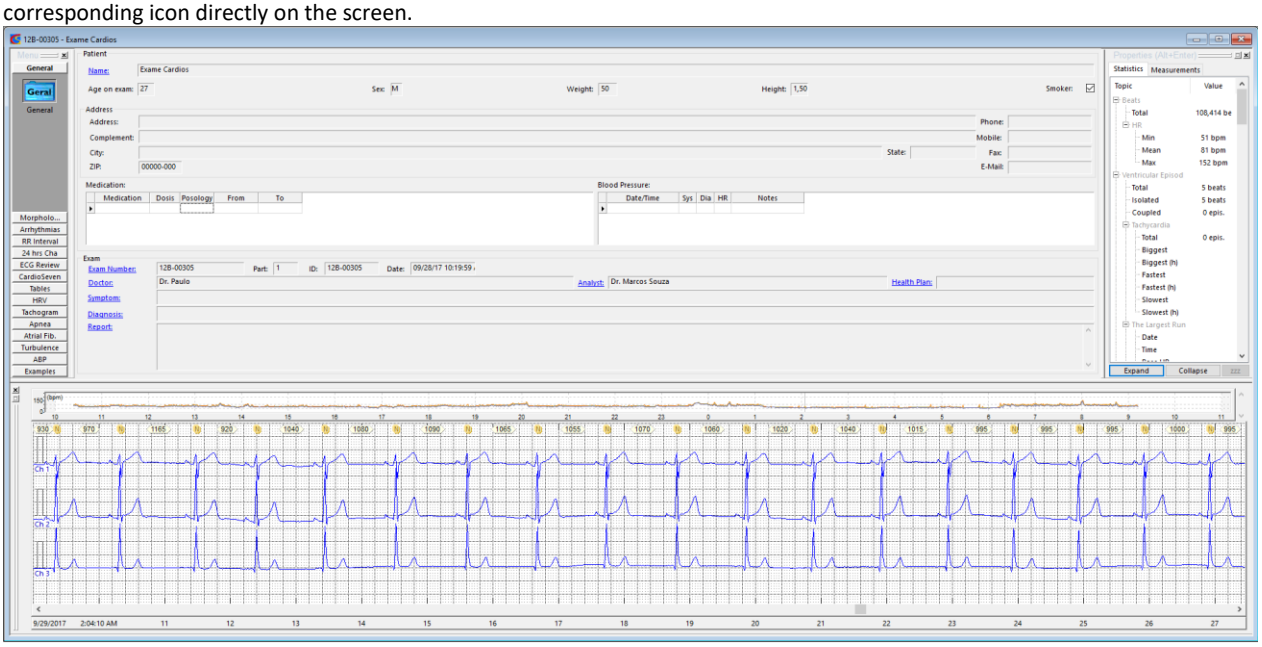
Direct access to exam information. Statistical summary of 24-hour recording with information such as: total heartbeats, ventricular extrasystoles, supraventricular, pauses, ST depression, exam duration, quality, time in tachycardia and bradycardia.
To get this information just click on the corresponding item called Properties.



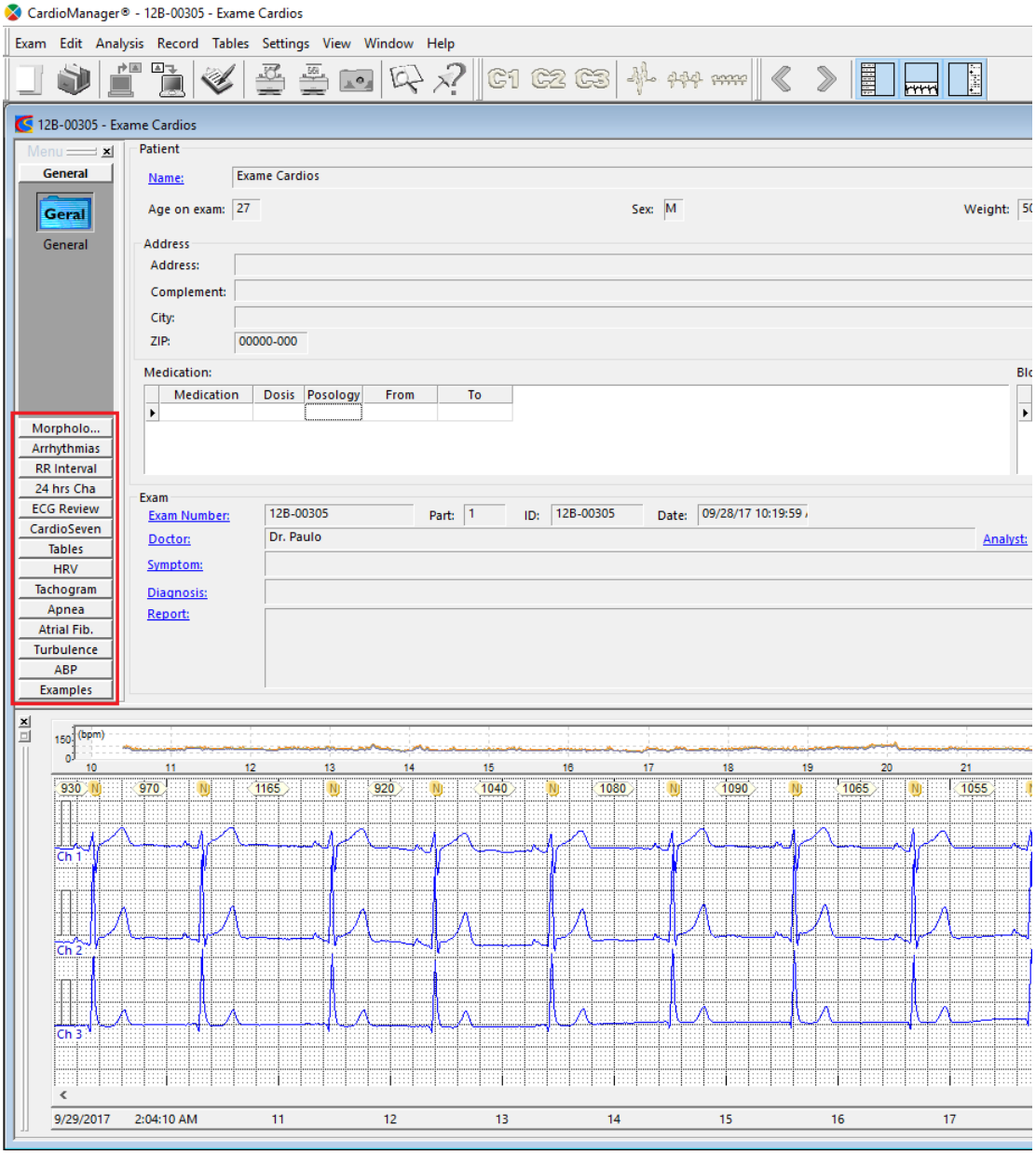


In the Property window, there is a measurement tab, which contains details of the measured QRS (in the use of the ZOOM tool that will be discussed later), P-wave, or amplitude.

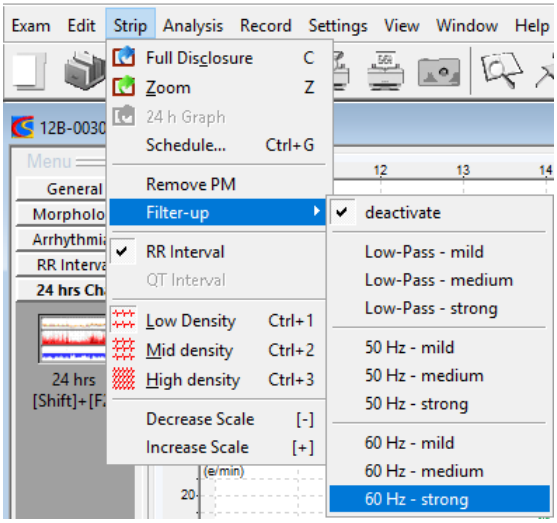
The ECG bar allows the ECG to be viewed at any point in the exam, in the desired period (selected) or randomly. Just access the corresponding icon directly on the screen.



The Window Bar displays to the left of the screen several options to select during the editing process. Each one of them will have a purpose that we will explain next.

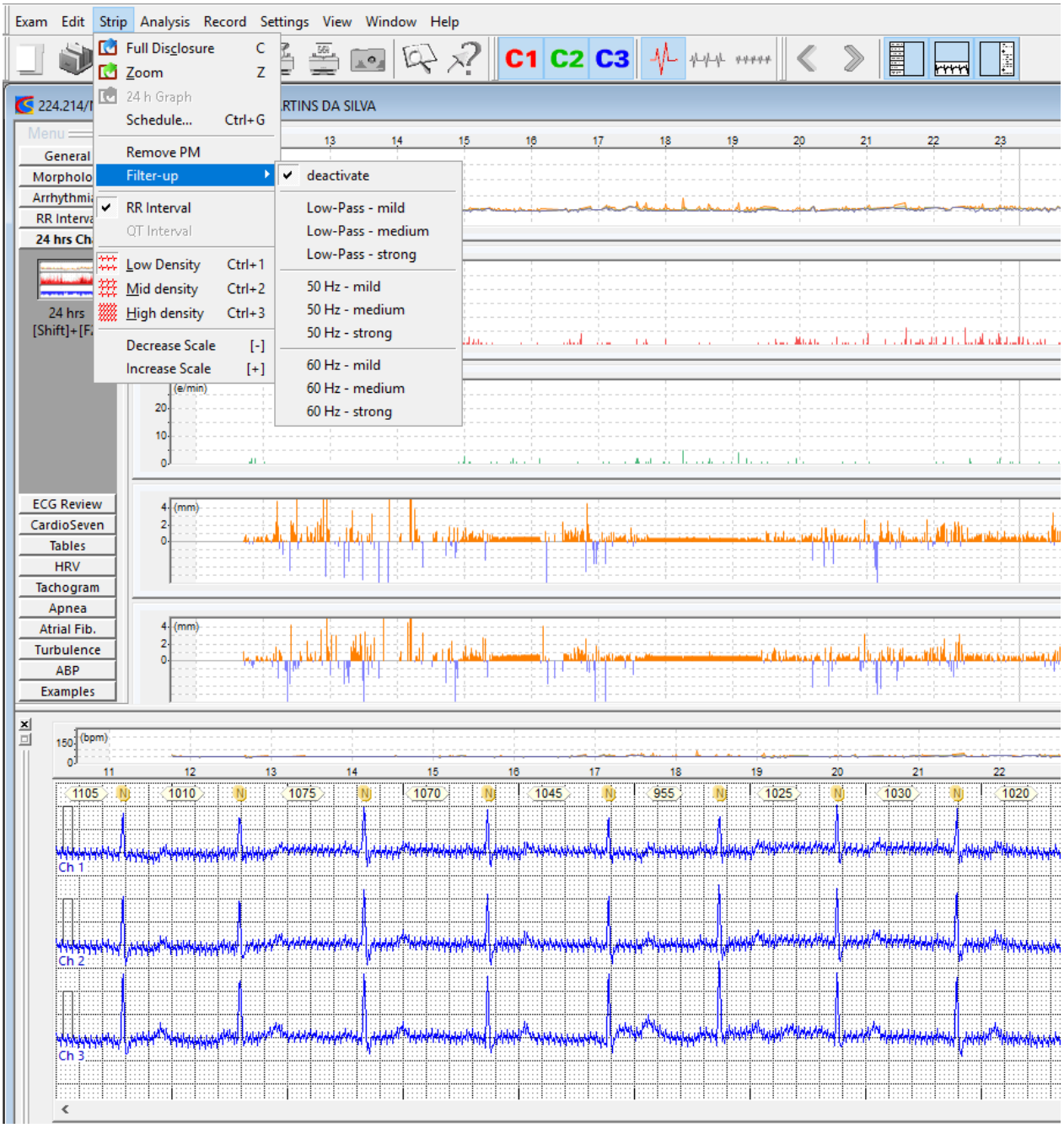


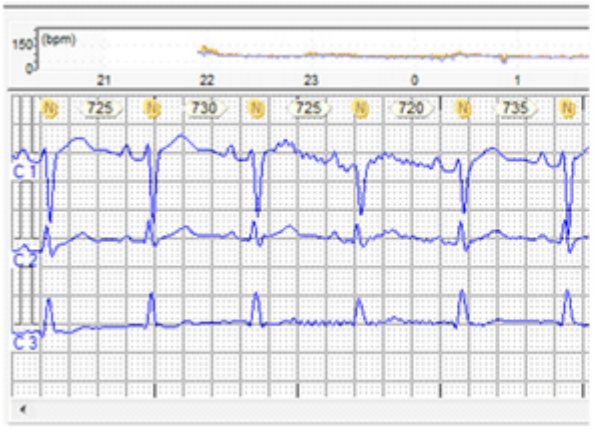
5.11. FILTER-UP

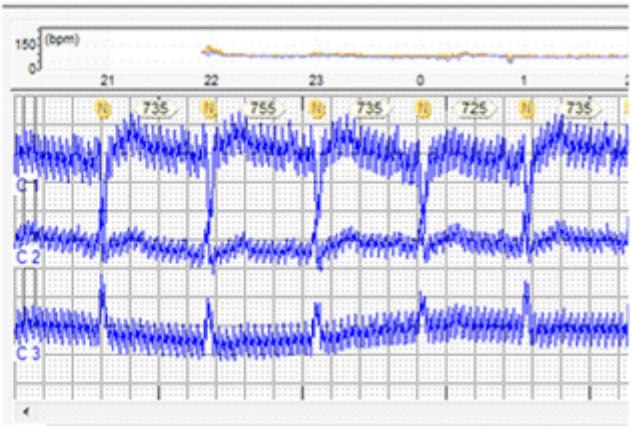


Available on the toolbar with direct screen access (not available on the general page).

It is possible to use a filter in order to improve the tracing visualization.
Just click on a QRS, select the [Tracings] item in the menu bar, go to the [Filter-up] item and select the desired filter strength.


Exam
Edit
Strip
Analysis
Record
Settings
View
Window
Help
Full Disclosure C
Zoom Z
24 h Graph
Schedule... Ctrl+G
Remove PM
Filter-up
RR Interval
QT Interval
Low Density Ctrl+1
Mid density Ctrl+2
High density Ctrl+3
Decrease Scale [-]
Increase Scale [+]
deactivate
Low-Pass - mild
Low-Pass - medium
Low-Pass - strong
50 Hz - mild
50 Hz - medium
50 Hz - strong
60 Hz - mild
60 Hz - medium
60 Hz - strong
C1 C2 C3
General
Morpholo
Arrhythmia
RR Interva
24 hrs Ch
24 hrs
[Shift]+[F
ECG Review
CardioSeven
Tables
HRV
Tachogram
Apnea
Atrial Fib.
Turbulence
ABP
Examples
(e/min)
(mm)
(mm)
(bpm)
Ch 1
Ch 2
Ch 3

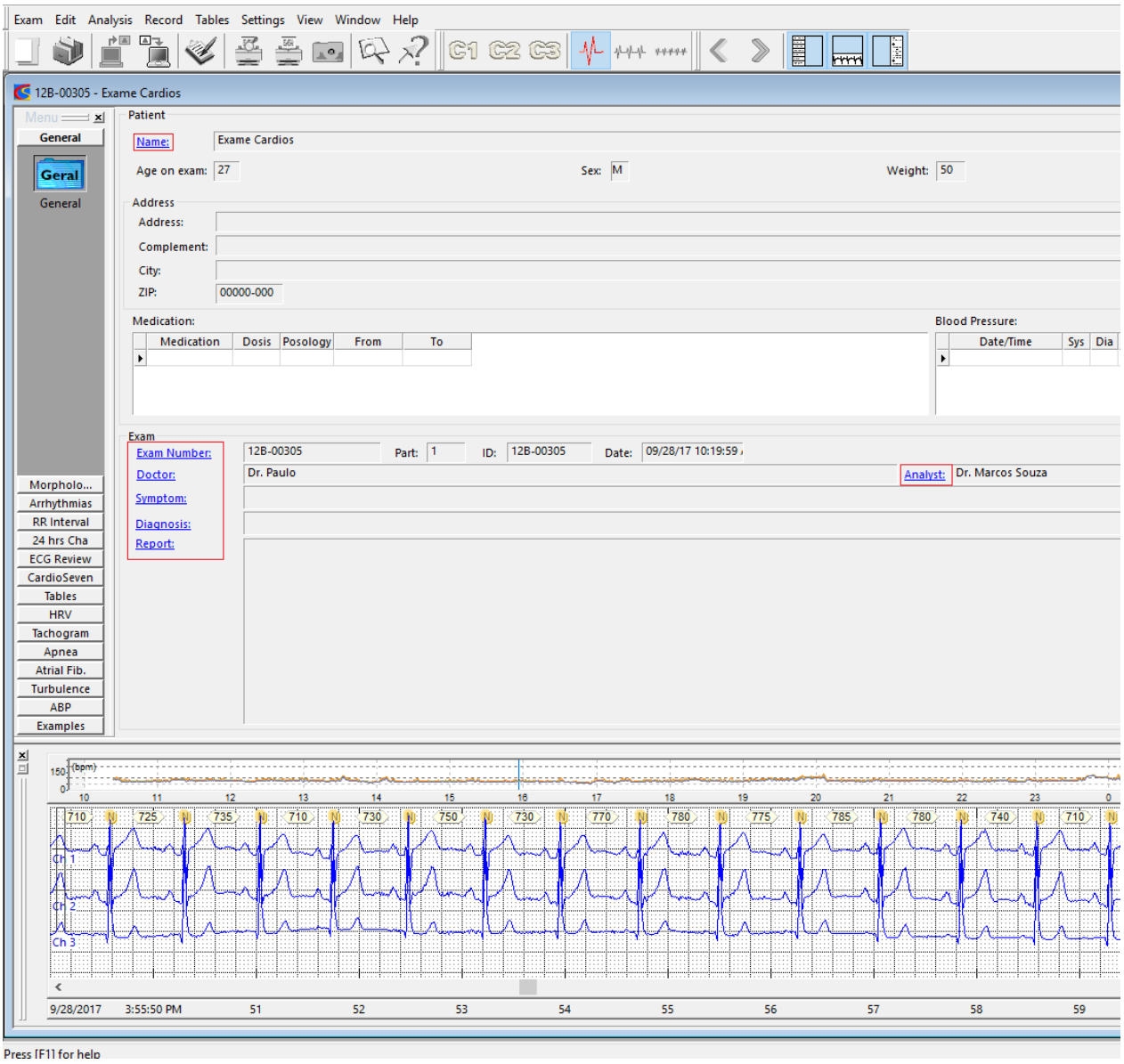




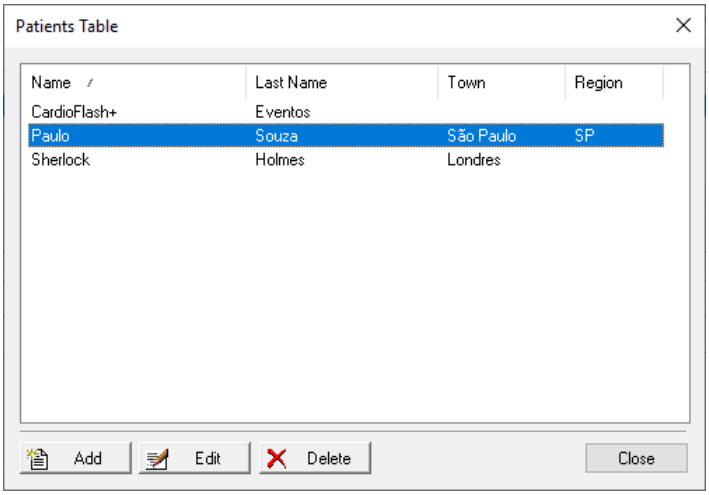
6. MENU (WINDOW BAR)

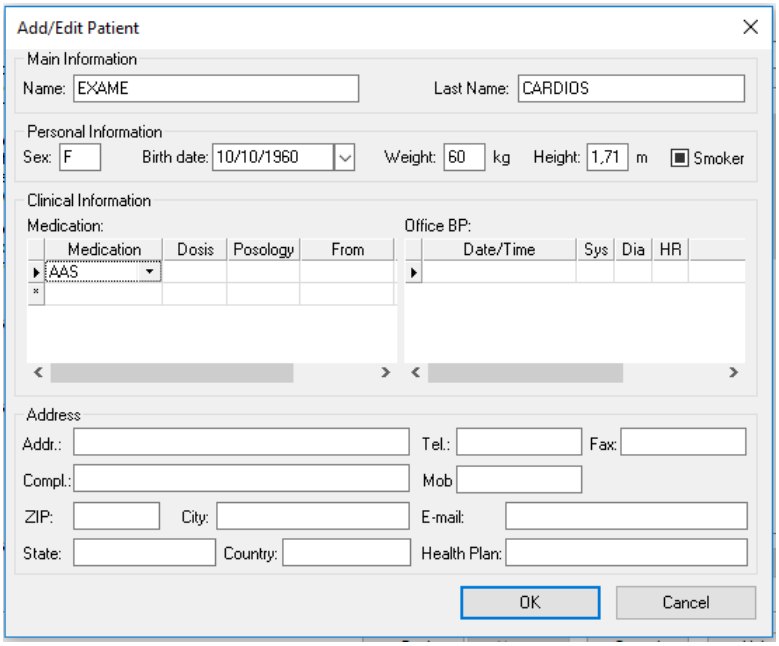
6.1. GENERAL

Display the patient data.
If you need to correct or add some information, you can interact with the data by clicking directly on the corresponding items highlighted in blue.



Whenever correction or addition of any patient data is required, click on [Patient], then select [Edit] and make the desired change.





Medication
Edit and insert drugs.

Exam Number
If the clinic wants to customize the exam number according to its own control, it is possible to enter it in this field. You can modify or maintain the numbers generated by the system itself.

Referring physician
If you need to make any corrections to this item.

Reason for exam
Reason why Holter is being performed.

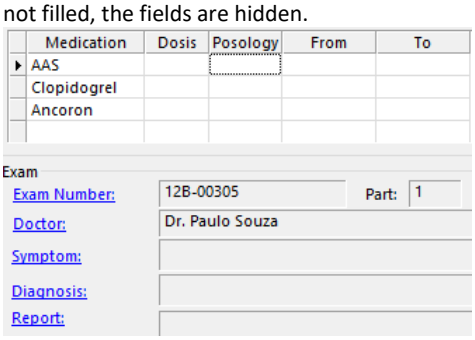
Clinical diagnosis
When the patient already has a diagnosis.

Analyst Physician
The name of the examining physician should be entered.

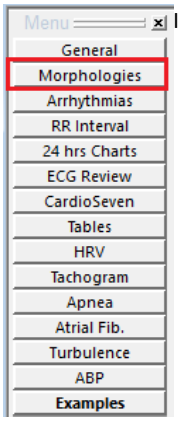
Health Plan
If necessary, it is possible to enter the Health Plan name that was used by the patient during the exam.

Report
At the end of the edition, you can click on the item Report and insert the sentences related to what was found in the exam.

* The Medication, Reason for Exam and Clinical Diagnostic fields will only appear on the first page if they are filled in. If they are not filled, the fields are hidden.

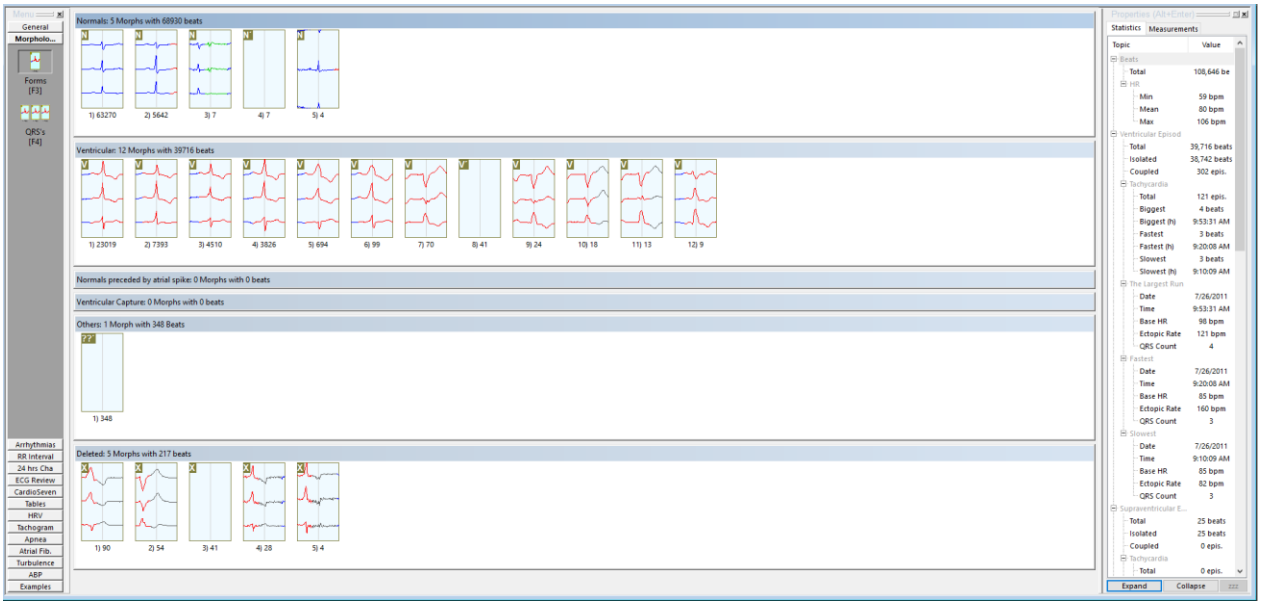


6.2. MORPHOLOGIES



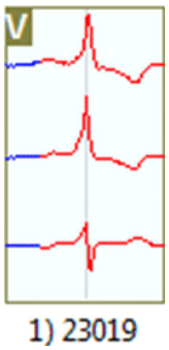
In this area, you can review all the heartbeats identified by the system during recording.

The system divides the morphologies into groups of normal, ventricular, pacemaker heartbeats (after reclassifying the heartbeats), others (questionable), and deleted (artifacts).
Once the form is opened, it will be up to the analyst physician to check whether the heartbeats are classified correctly or not.
You can also view the properties window if you wish.



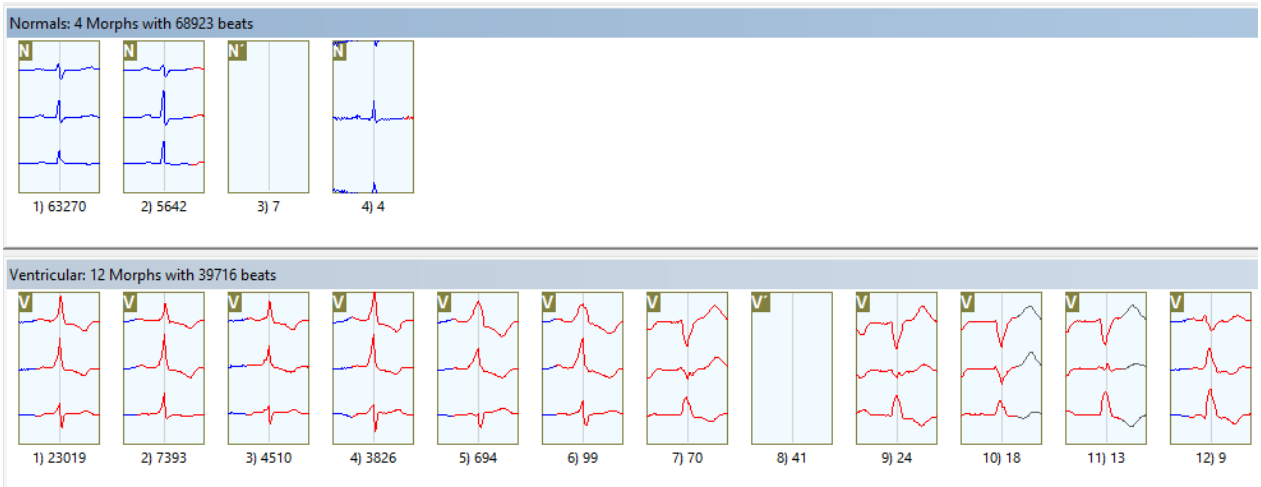
In the process of heartbeats monitoring, some aspects should be considered:

- In the middle of each form there will be a line, and the QRS should be centralized. This presentation will be valid for normal heartbeats, ventricular extrasystoles, pacemakers (in case of patients with pacemaker), and deleted.



- The system will group the heartbeats within the forms according to the QRS morphological aspect, that is, it will group similar heartbeats.

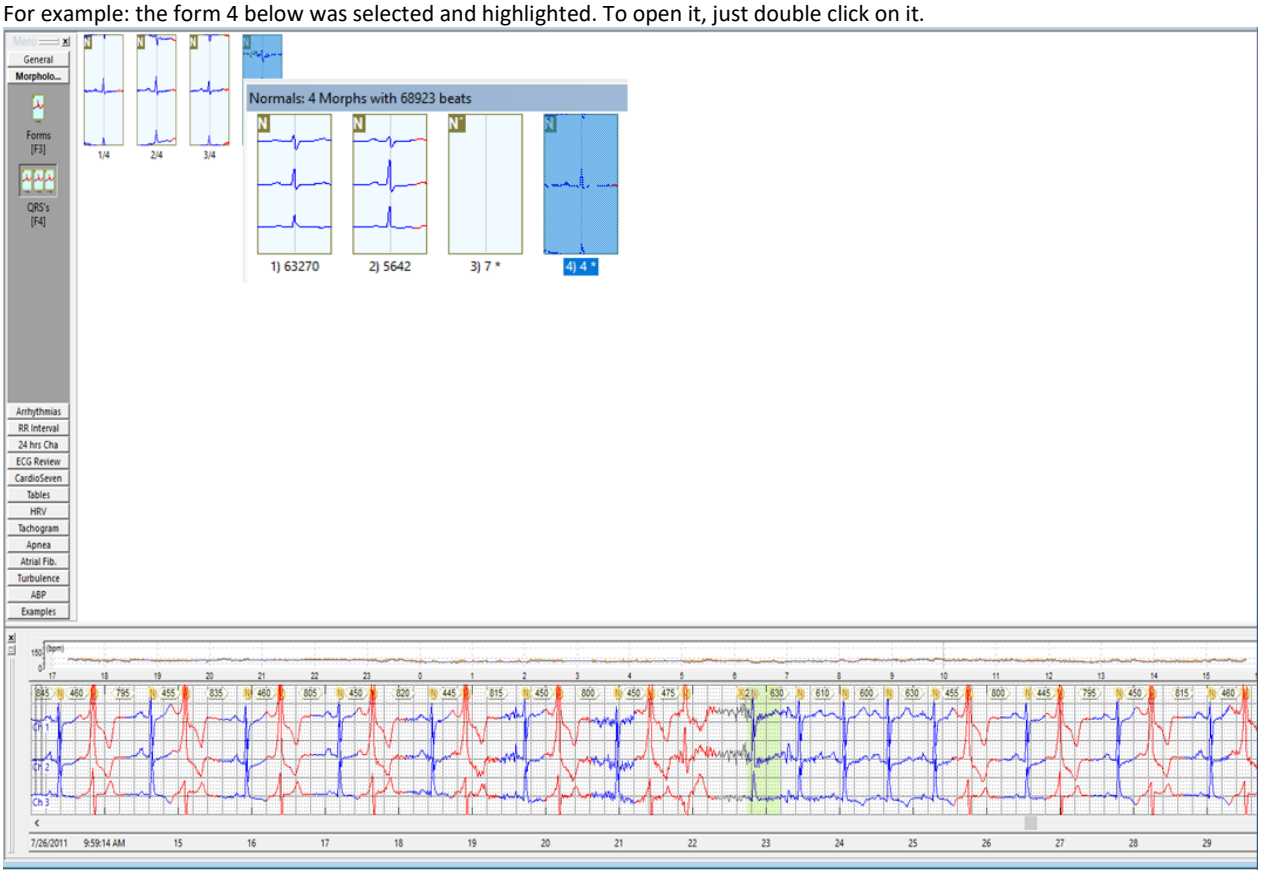
For example, the morphologies that presents N' or V' labels are those which heartbeats do not fit in any other form, that is, they are different from all other heartbeats.



It is recommended the analyst physician to check the heartbeats grouped by forms in order to find any artifacts or heart-beats classified incorrectly.

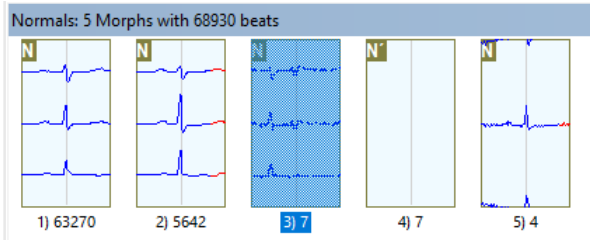
When an incorrectly grouped heartbeat is identified, just right-click on it and select the desired option to regroup it.

For example: the form 4 below was selected and highlighted. To open it, just double click on it.



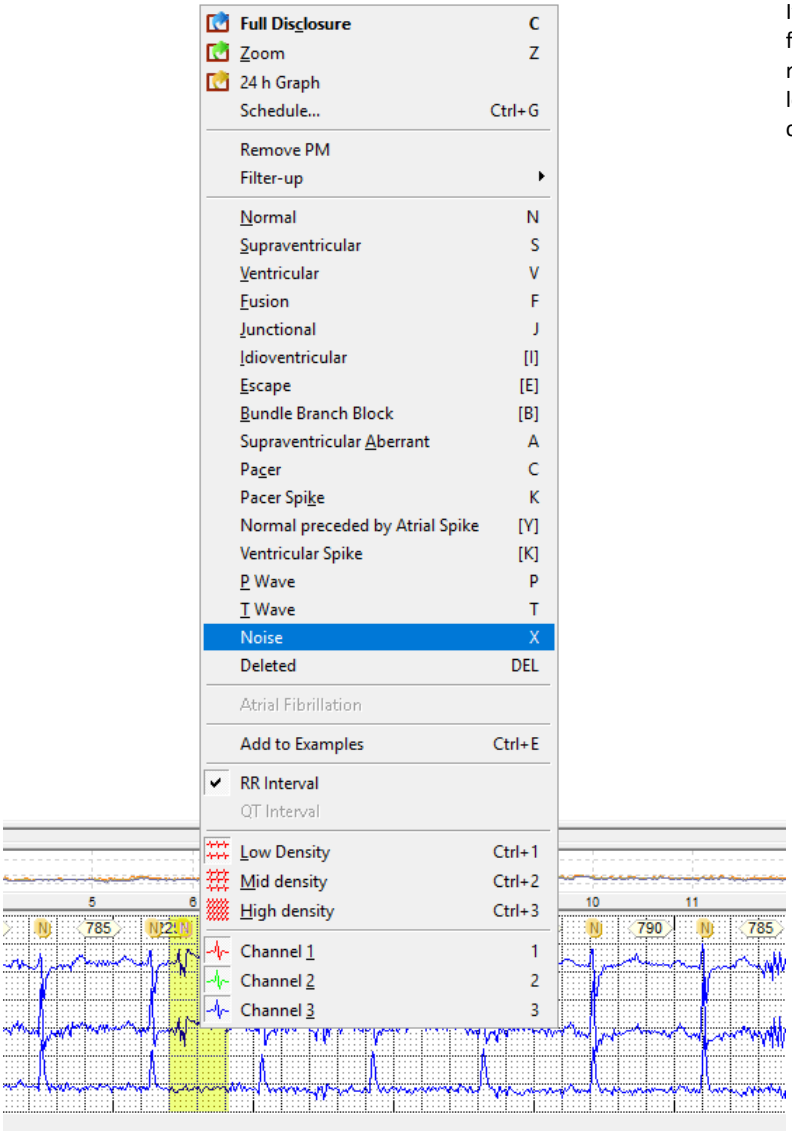
It is possible to check its heartbeats and verify if they are centered. In case of any doubt, click on the heartbeat and check it on the ECG bar in the bottom. The selected heartbeat will be highlighted.

The heartbeats should only be reclassified if they are incorrect, otherwise the analyst physician will not need to interact.



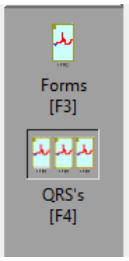
In this example, the form number 3 with 7 heartbeats does not present centered QRS complexes. The analyst physician will check which heartbeats are correct and which ones need correction.

We can see the open form below. The analyst physician will see the highlighted heartbeat on the ECG bar at the screen bottom.



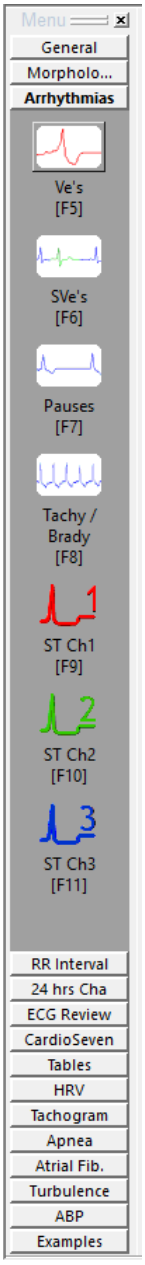
If the analyst physician disagrees with the classification, he/she can select the heartbeat and right-click on it to open a context menu. Just select the desired option. This heartbeat will be corrected immediately.

To return to the previous screen, or in this case, to close the form, just click on the toolbar arrow that indicates [Previous page].



Or press [F3], or in the window bar:

6.3. ARRHYTHMIAS



This item opens several sub-items.
Observe below each item the shortcut key it refers to:

(F5) Ventricular arrhythmias
All isolated, paired extrasystoles and ventricular tachycardias will be displayed.

(F6) Supraventricular arrhythmias
All isolated, paired extrasystoles and supraventricular tachycardias will be displayed.

(F7) All pauses will be displayed, according to the configured parameter.

(F8) Tachycardias and bradycardias
They will be displayed according to the settings.

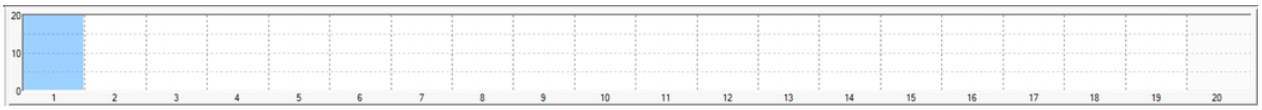
(F9) All episodes of ST segment depression or elevation the system has classified on channel C1.

(F10) All episodes of ST segment depression or elevation the system has classified on channel C2.

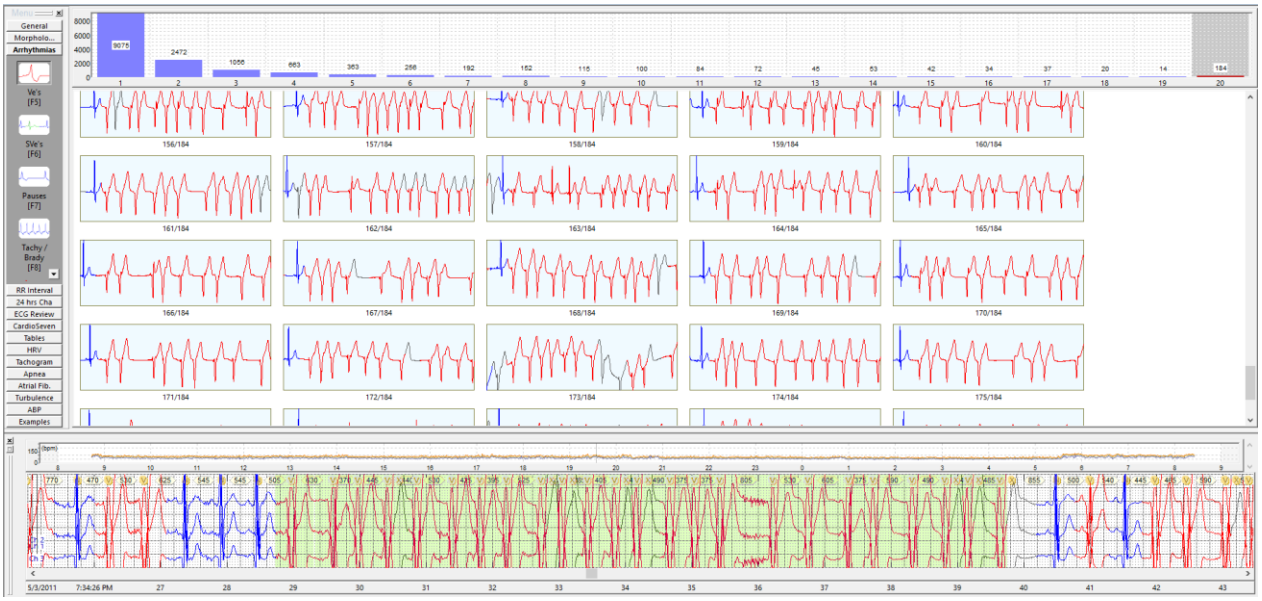
(F11) All episodes of ST segment depression or elevation the system has classified on channel C3.

6.3.1. VENTRICULAR

The ventricular extrasystoles will be distributed in a “ruler” (see the figure below) according to their complexity. The heart-beats will be displayed in the horizontal part in an ascending manner: isolated heartbeats (1), paired (group of 2), and thus progressively, until reaching the number 20 in the ruler, in which will be the ventricular tachycardias with 20 or more successive heartbeats.

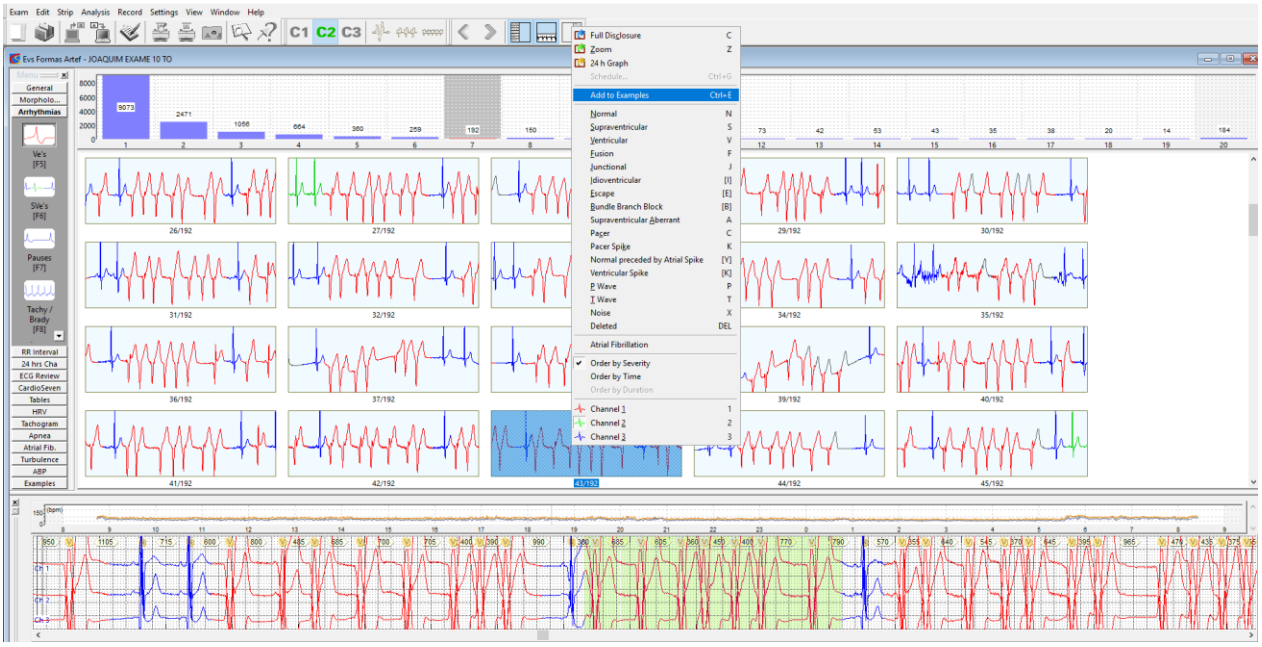


Just click on one of the squares to check these events and eventually insert tracings for later printing. The ruler's vertical part shows how many times the arrhythmia occurred in each event.



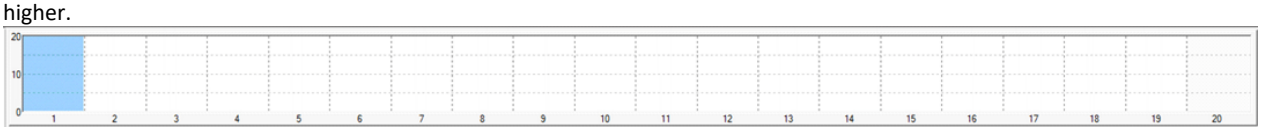
By clicking on an arrhythmia in the group, it will be highlighted in the ECG bar, as shown below.
If the analyst physician wants to insert it into the Examples, just right-click and select [Add to Examples] from the menu that appears. This process can be performed by clicking on episodes of ventricular tachycardias, ventricular, paired, and isolated ventricular.

In this view, one more check is performed in the arrhythmias' classification. On the screen right side of the screen, a scroll bar can be used when the events number is larger than the display capacity. The system will show all classifications within each group. Note, in the example below, that the ventricular tachycardias group with 11 heartbeats was selected.
At this moment, the analyst physician can begin to select the most important tracings, speeding up the exam edition.

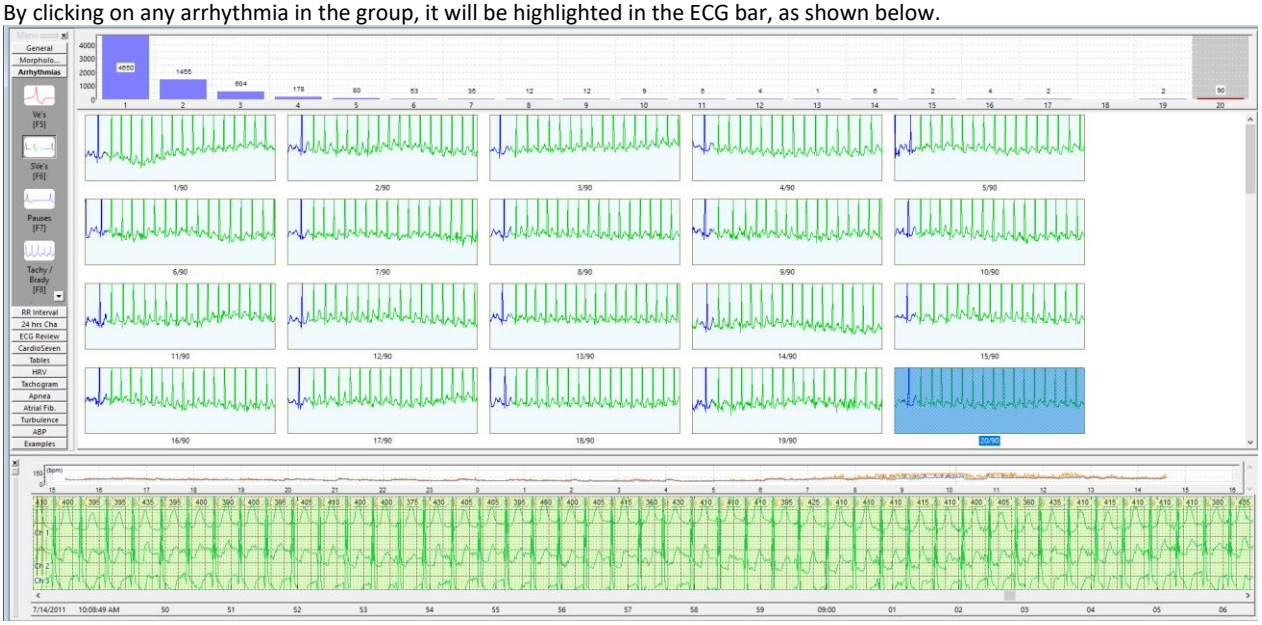


6.3.2. SUPRAVENTRICULAR

The supraventriculars are displayed in the same way as the ventriculars.
In the ruler, the supraventricular arrhythmias will be separated by groups of isolated, paired, and supraventricular tachycardias by the number of successive heartbeats until reaching the 20 heartbeats group, which will include PSVTs with this number or higher.



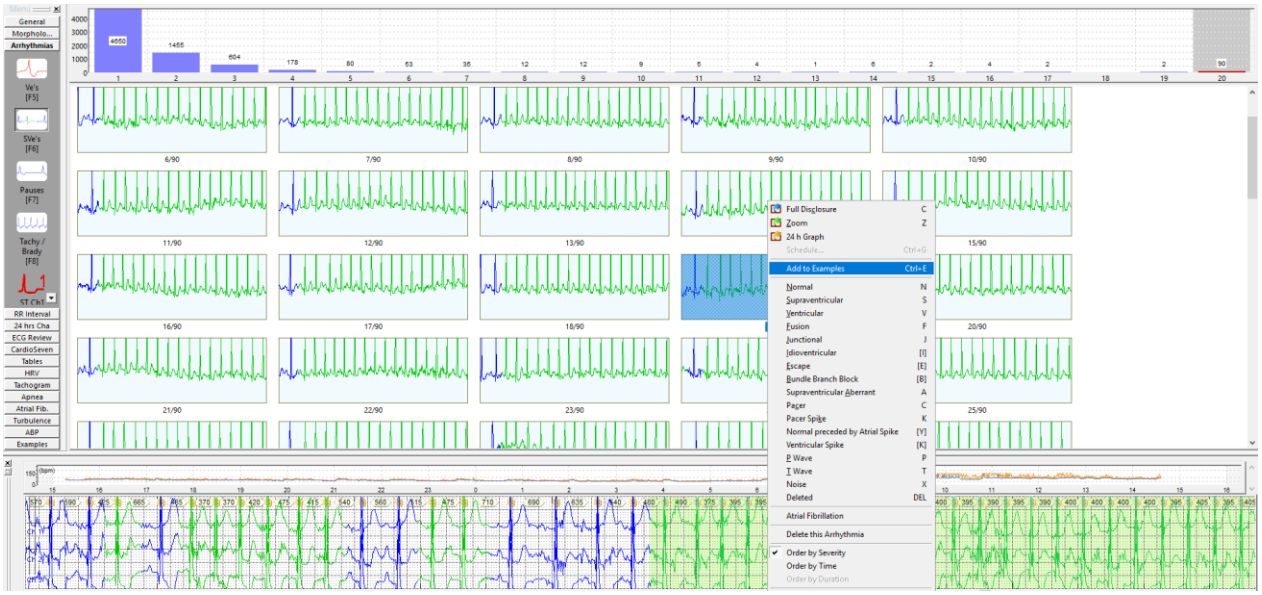
By clicking on any arrhythmia in the group, it will be highlighted in the ECG bar, as shown below.



If the analyst physician wants to insert it into the Examples, just right-click and select [Add to Examples].
This process can be performed by clicking on episodes of supraventricular tachycardias, supraventricular, paired, and isolated supraventricular. Note, in the following example, that the supraventricular tachycardias group with episodes of 20 or more heartbeats was selected.

In this view, one more check is performed in the arrhythmias' classification. On the right side of the screen, a scroll bar can be used when the events number is larger than the display capacity. The system will show all classifications within each group.

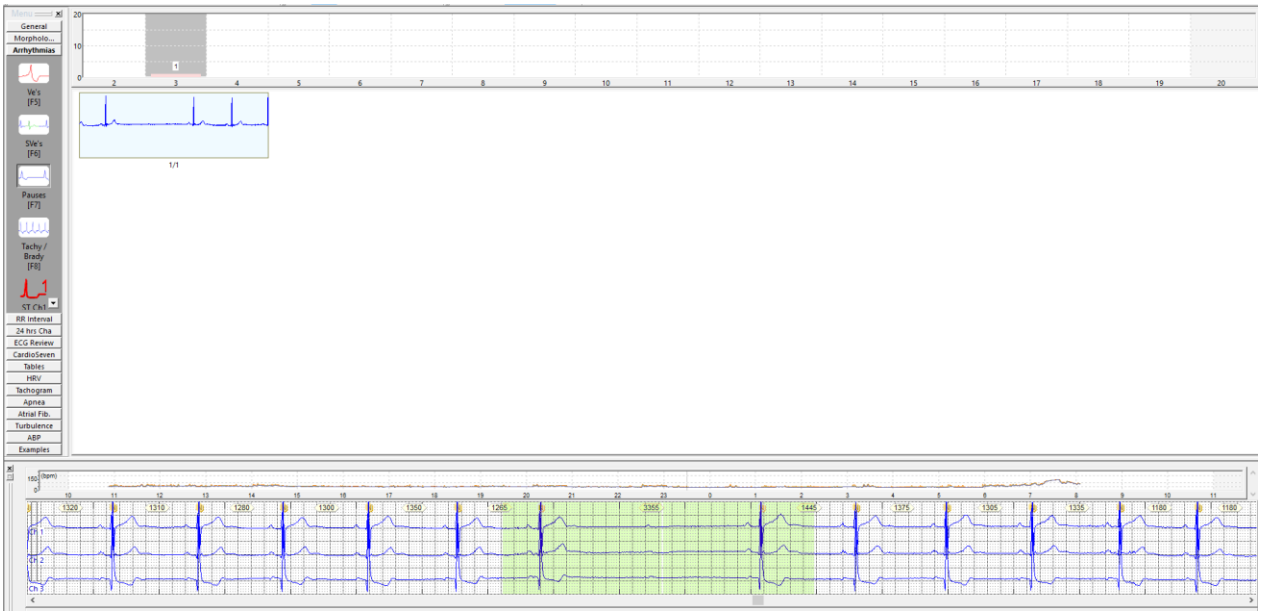
At this moment, the analyst physician can begin to select the most important tracings, speeding up the exam edition.


General
Morpholo...
Arrhythmias
Ve's [F5]
SVe's [F6]
Pauses [F7]
Tachy / Brady [F8]
ST Ch1
RR Interval
24 hrs Cha
ECG Review
CardioSeven
Tables
HRV
Tachogram
Apnea
Atrial Fib.
Turbulence
ABP
Examples
Full Disclosure C
Zoom Z
24 h Graph
Schedule... Ctrl+G
Add to Examples Ctrl+E
Normal N
Supraventricular S
Ventricular V
Fusion F
Junctional J
Idioventricular [I]
Escape [E]
Bundle Branch Block [B]
Supraventricular Aberrant A
Pacer C
Pacer Spike K
Normal preceded by Atrial Spike [Y]
Ventricular Spike [K]
P Wave P
T Wave T
Noise X
Deleted DEL
Atrial Fibrillation
Delete this Arrhythmia
Order by Severity
Order by Time
Order by Duration

6.3.3. PAUSES

The pauses will be displayed according to the general configuration (as seen in previous chapter) used for this item. If these parameters are individually changed for this exam, the pauses will be displayed in the same way.

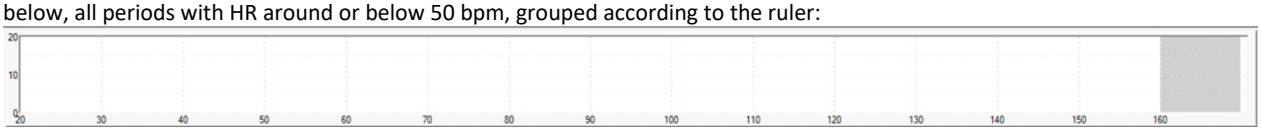
In the example below, pauses with duration equal to or greater than 2.0 seconds are displayed.



6.3.4. TACHYCARDIAS / BRADYCARDIAS

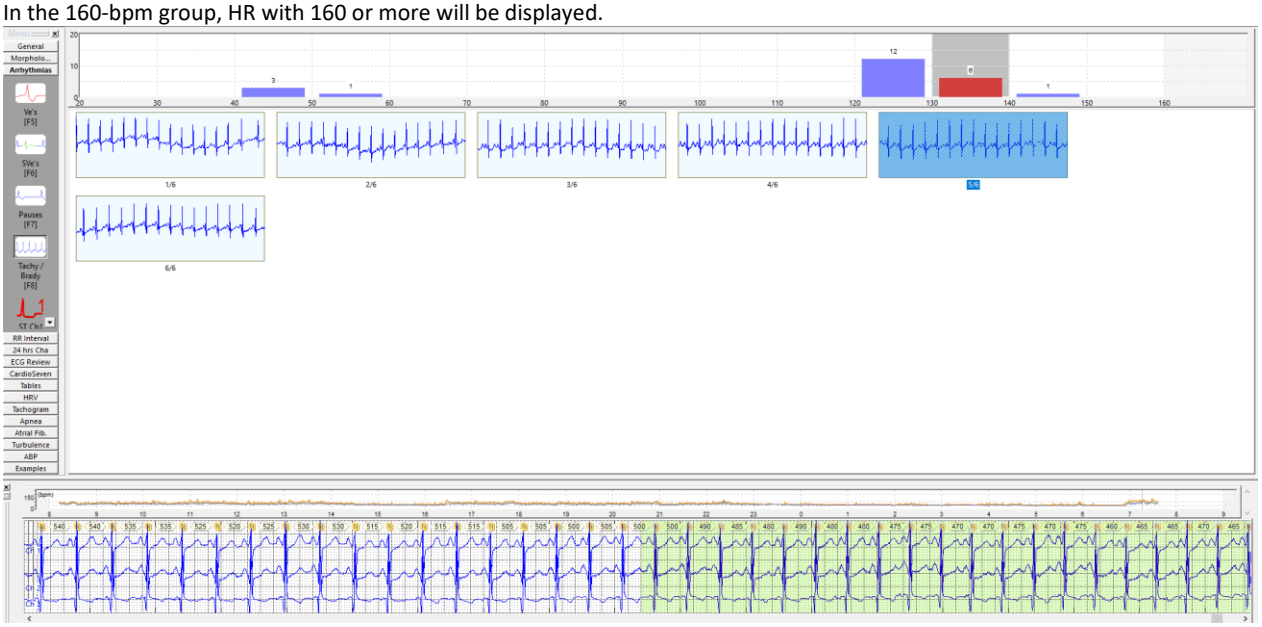
They will be displayed according to the pre-established settings.

For example, if the pre-programmed frequency for bradycardia is 50 bpm, the system will quantify and display in the windows below, all periods with HR around or below 50 bpm, grouped according to the ruler:



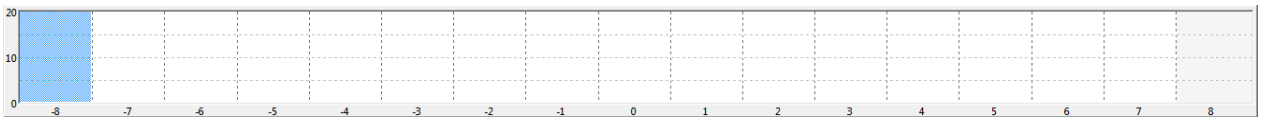
Frequencies around 50 bpm, between 40 and 50 bpm, between 30 and 40 bpm, and between 20 and 30 bpm.

In the tachycardia group, for example, if 120 bpm is set, the system will display HR between 120 and 130, between 130 and 140 bpm, and between 140 and 150 bpm.
In the 160-bpm group, HR with 160 or more will be displayed.



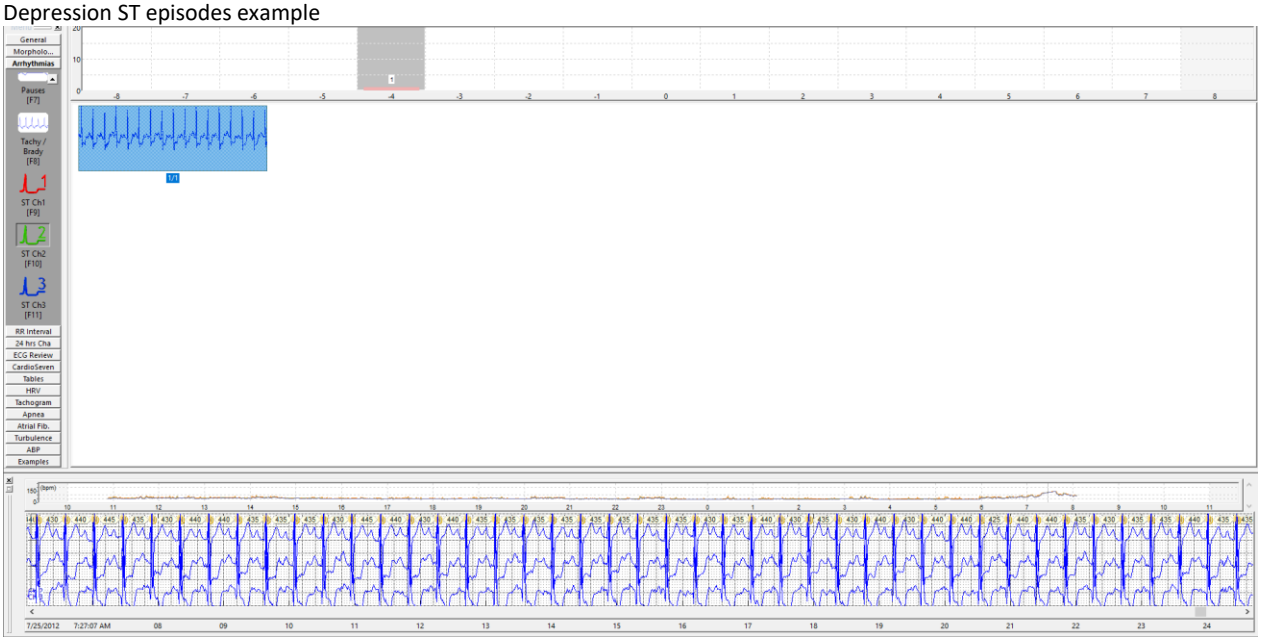
6.3.5. ST C1 / ST C2 / ST C3

The ruler is divided into ST depressions and elevations with zero mark. Below zero, to the ruler's left, depression ST episodes will appear, and to the right of zero, elevation ST episodes will be displayed.

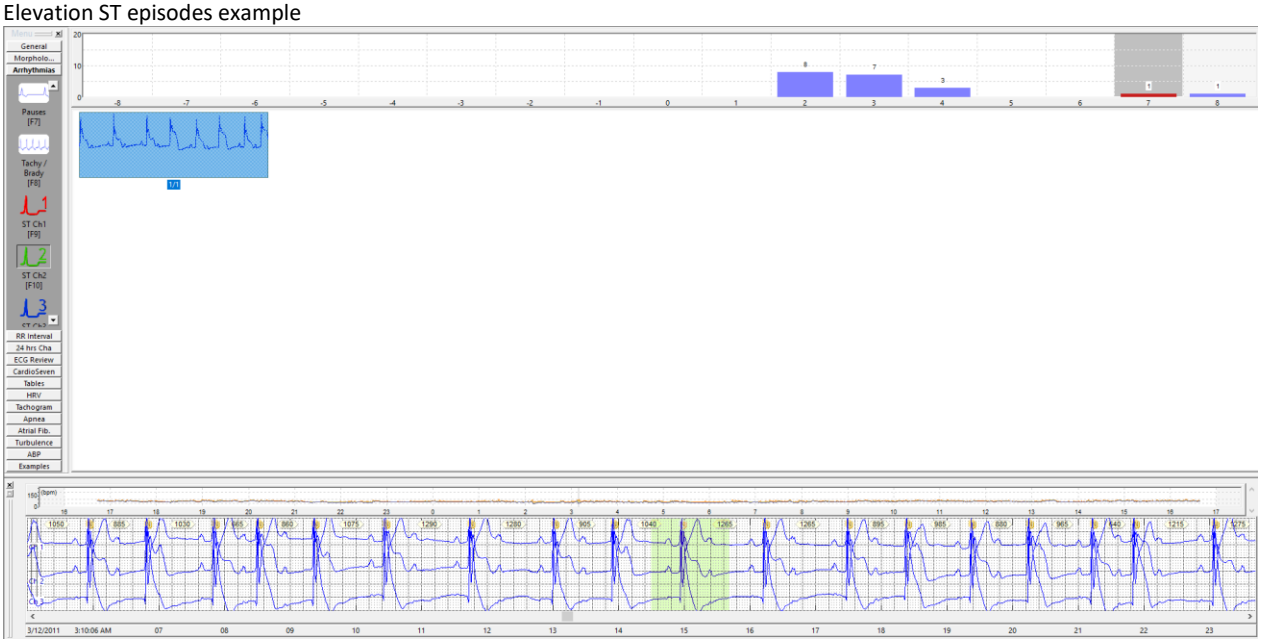


The ways in which the elevation and depression ST episode will be displayed are the same for channels C1, C2, and C3.

Depression ST episodes example

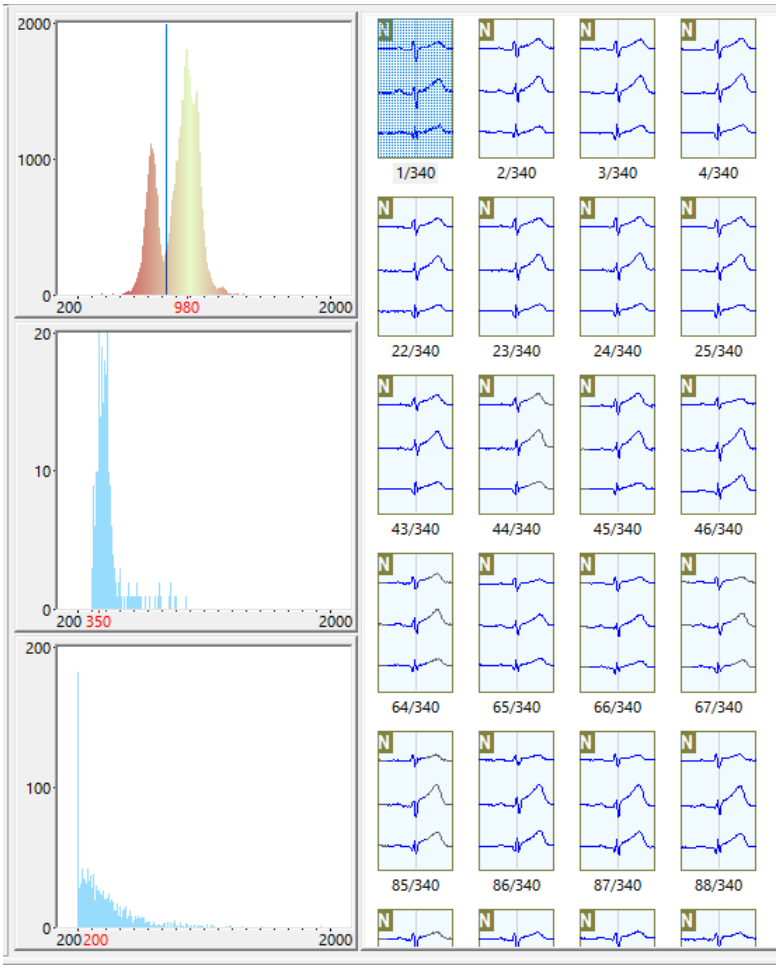


Elevation ST episodes example

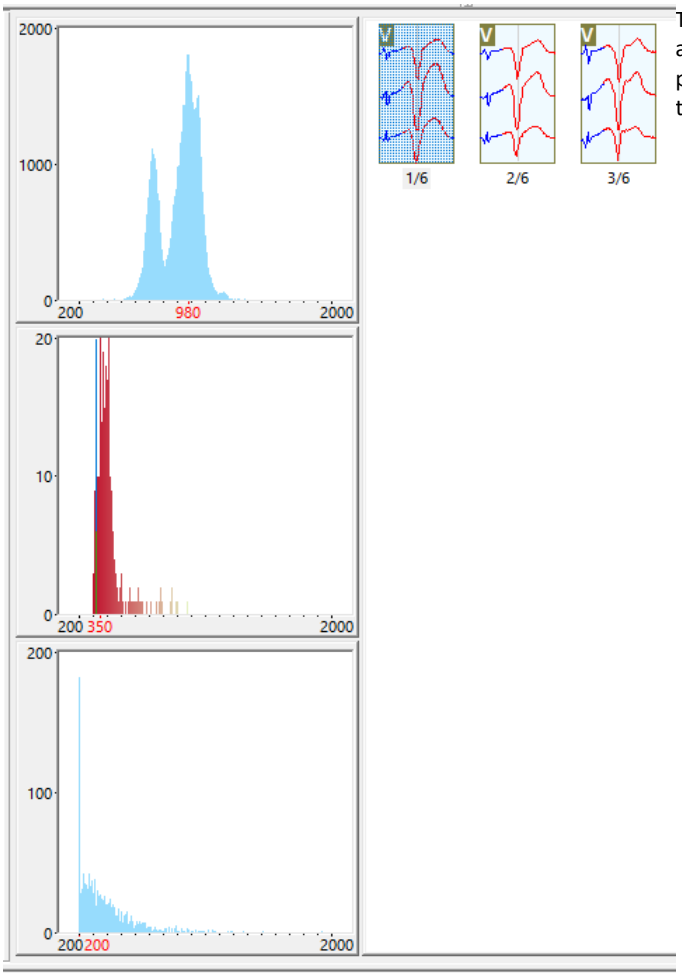


6.4. HISTOGRAMS

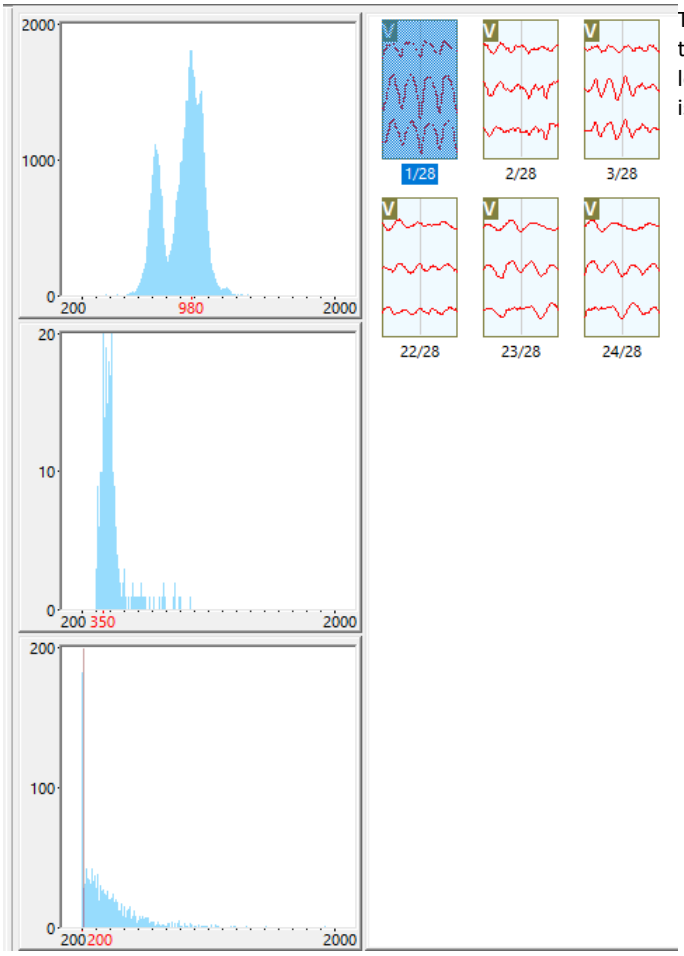
The histogram presents three contexts through which you can navigate and review each of the heartbeats individually.



In the first, the distances between the NN intervals will be displayed.
The shorter intervals are to the left and the longer to the right. It means the higher frequencies will be on the left and the lower on the right.
By clicking on a certain point in this chart, it will be displayed on the right side of the screen, all the heartbeats with the corresponding frequency.



The second chart will show the distances between normal and ventricular heartbeats. On the left, the smallest coupling interval between the N heartbeat and ventricular extrasystole is displayed.



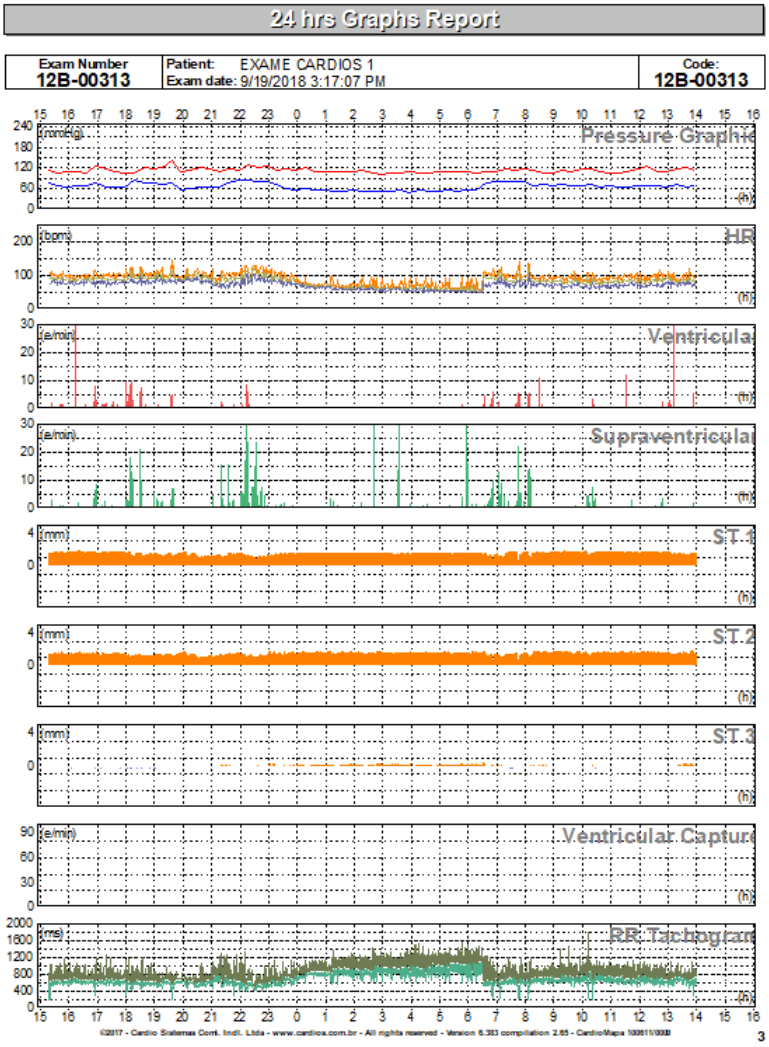
The third chart shows the distances (in ms) between ventricular heartbeats. The further to the left on the chart, the lower the coupling interval. The farther to the right, slower is the cycle.

NOTE: You can also edit the complexes on these screens. Right-clicking on a heartbeat opens the navigation/edit menu, through which you can reclassify the heartbeat, view the Zoom, the Compressed ECG, the 24-hour Chart, or turn on/off the display of some channel.

6.5. 24-HOUR CHARTS

This item graphically displays:

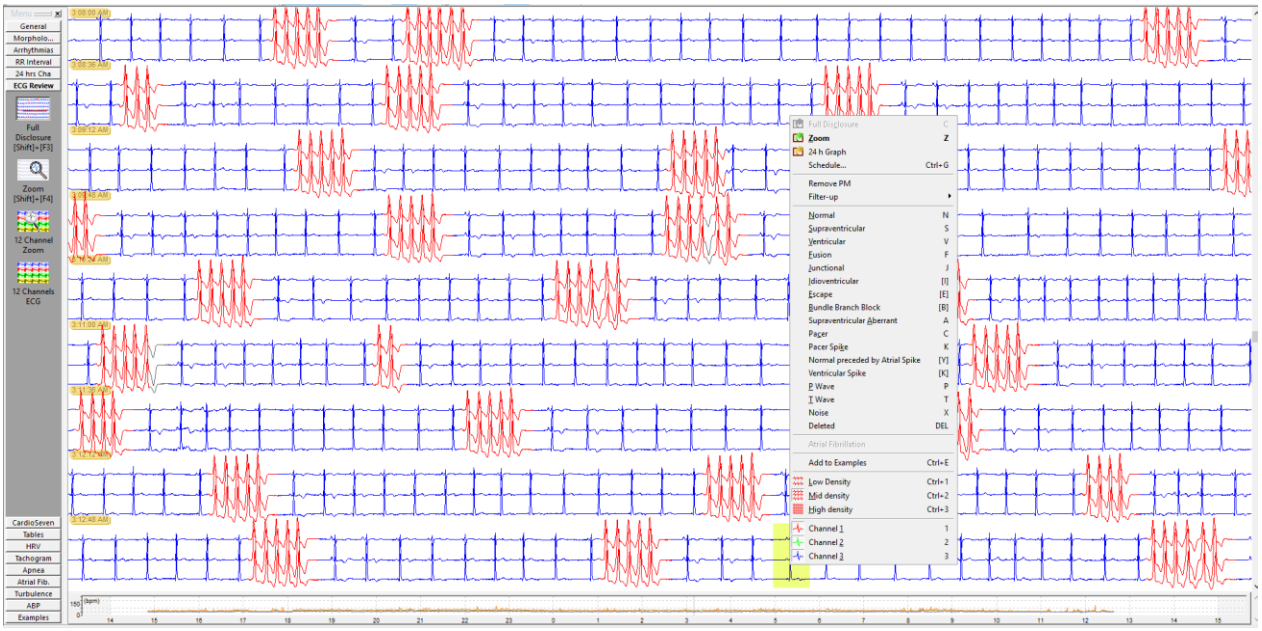
- At the top, the exam start and end times;
- HR with the maximum, mean and minimum frequency lines;



- Ventricular arrhythmias, which hourly density will be demonstrated in red color;
- Supraventricular arrhythmias, which density is shown in green color;
- ST on Channel C1, C2, and C3. Above the orange line indicates a positive repolarization.
- ST on channels C1, C2, and C3. Below the line, in blue, it indicates negative repolarization, negative T wave, ventricular overload, etc.
- For patients with pacemaker, whose heartbeats have already been edited and classified as a pacemaker, it will be demonstrated, in purple, the graphical representation regarding the pacemaker participation during recording.
- RR intervals tachogram.

6.6. COMPRESSED ECG

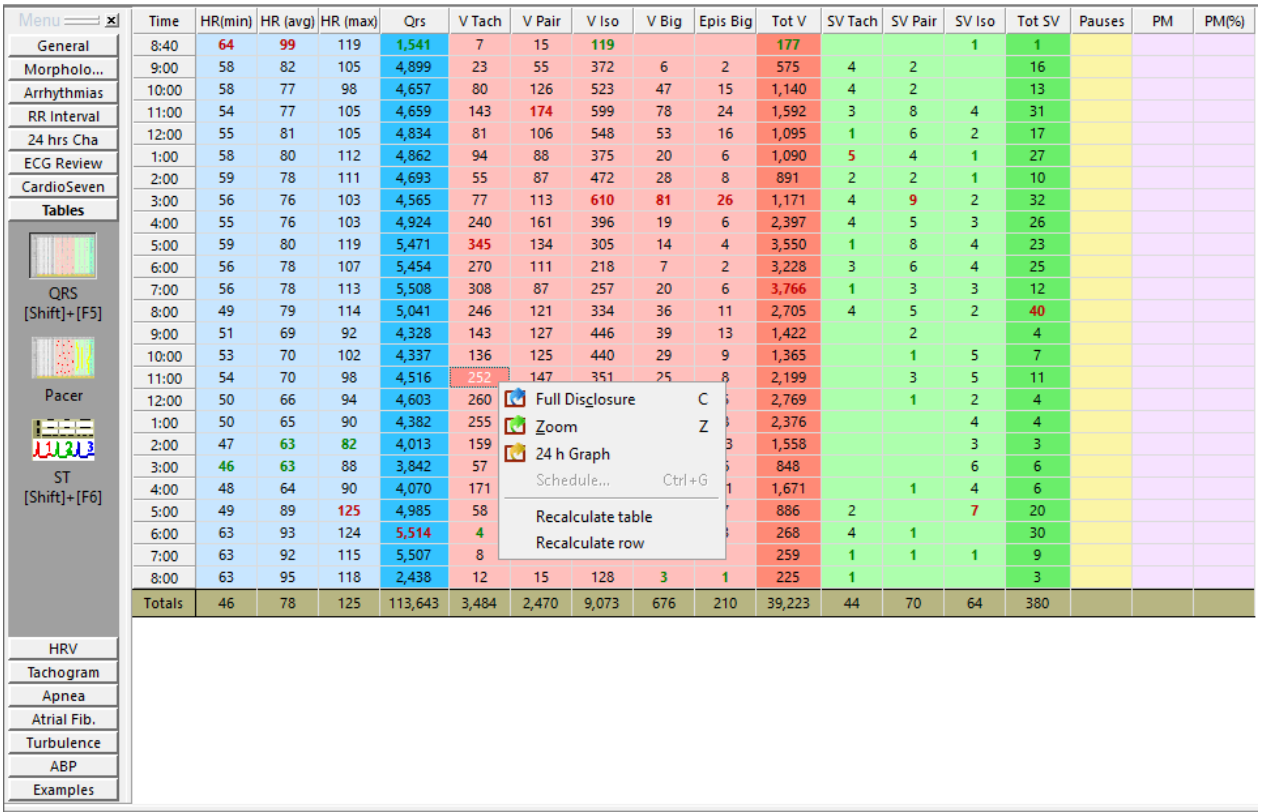
It allows the electrocardiographic visualization of the complete recorded period.
To advance in time, just click on the scroll bar to the right of the window.
While viewing the ECG, it is possible to increase or decrease the signal, that is, change the density. You can also add tracings to the examples and interact with the tracing, by correcting or renaming the heartbeat. To do this, just right-click on the heartbeat and select the desired option. You can also turn on/off the display of some channel.



6.7. TABLES

In this module will be presented a table divided into three items:
1. Heartbeats (QRS),
2. ST table, and
3. Pacemaker table.

QRS
It shows, hour by hour, the QRS number, the minimum, mean and maximum heart rates, ventricular arrhythmias, supra-ventricular, and pauses. For patients with pacemaker, it also shows the number of stimulated heartbeats and its participation percentage in the exam.
The average total found on the 24 hours of exam is displayed at the end.
The table view also allows the analyst physician to correlate the extrasystoles incidence with the hours listed to the left of the table.
Within this item, there are links to all events.
In order to obtain these links, just click, for example, on the “n” number of ventricular extrasystoles (as in the following example, where the ventricular tachycardias column was selected). The system will specify, in the lower left corner, all moments when the event occurred within the selected hour.
This tool is known as smart tabular summary.
To visualize it, just click on the time and the selected event will be displayed in the ECG bar, if it is active.



Time	HR(min)	HR (avg)	HR (max)	Qrs	V Tach	V Pair	V Iso	V Big	Epis Big	Tot V	SV Tach	SV Pair	SV Iso	Tot SV	Pauses	PM	PM(%)
8:40	64	99	119	1,541	7	15	119			177			1	1			
9:00	58	82	105	4,899	23	55	372	6	2	575	4	2		16			
10:00	58	77	98	4,657	80	126	523	47	15	1,140	4	2		13			
11:00	54	77	105	4,659	143	174	599	78	24	1,592	3	8	4	31			
12:00	55	81	105	4,834	81	106	548	53	16	1,095	1	6	2	17			
1:00	58	80	112	4,862	94	88	375	20	6	1,090	5	4	1	27			
2:00	59	78	111	4,693	55	87	472	28	8	891	2	2	1	10			
3:00	56	76	103	4,565	77	113	610	81	26	1,171	4	9	2	32			
4:00	55	76	103	4,924	240	161	396	19	6	2,397	4	5	3	26			
5:00	59	80	119	5,471	345	134	305	14	4	3,550	1	8	4	23			
6:00	56	78	107	5,454	270	111	218	7	2	3,228	3	6	4	25			
7:00	56	78	113	5,508	308	87	257	20	6	3,766	1	3	3	12			
8:00	49	79	114	5,041	246	121	334	36	11	2,705	4	5	2	40			
9:00	51	69	92	4,328	143	127	446	39	13	1,422		2		4			
10:00	53	70	102	4,337	136	125	440	29	9	1,365		1	5	7			
11:00	54	70	98	4,516	252	147	351	25	8	2,199		3	5	11			
12:00	50	66	94	4,603	260					2,769		1	2	4			
1:00	50	65	90	4,382	255					2,376			4	4			
2:00	47	63	82	4,013	159					1,558			3	3			
3:00	46	63	88	3,842	57					848			6	6			
4:00	48	64	90	4,070	171					1,671		1	4	6			
5:00	49	89	125	4,985	58					886	2		7	20			
6:00	63	93	124	5,514	4					268	4	1		30			
7:00	63	92	115	5,507	8					259	1	1	1	9			
8:00	63	95	118	2,438	12	15	128	3	1	225	1			3			
Totals	46	78	125	113,643	3,484	2,470	9,073	676	210	39,223	44	70	64	380			

You can also access the compressed ECG, ZOOM, and 24-hour chart by just selecting the option with the right mouse button. Note that if you need to do some values correction in the table, just click on the field to be corrected and enter the desired value. The table total value will be corrected automatically.

6.7.1. PACEMAKER TABLE

It will be displayed/analyzed only when the acquired exam is retested using the Pacemaker module.
The table displays the number of stimulated heartbeats hour by hour (60-minute interval)

eA
Total number of atrial spikes

eV
Total number of ventricular spikes

eV/eT
Ventricular spikes percentage of the total

NpeA
Total number of normal heartbeats preceded by atrial spike

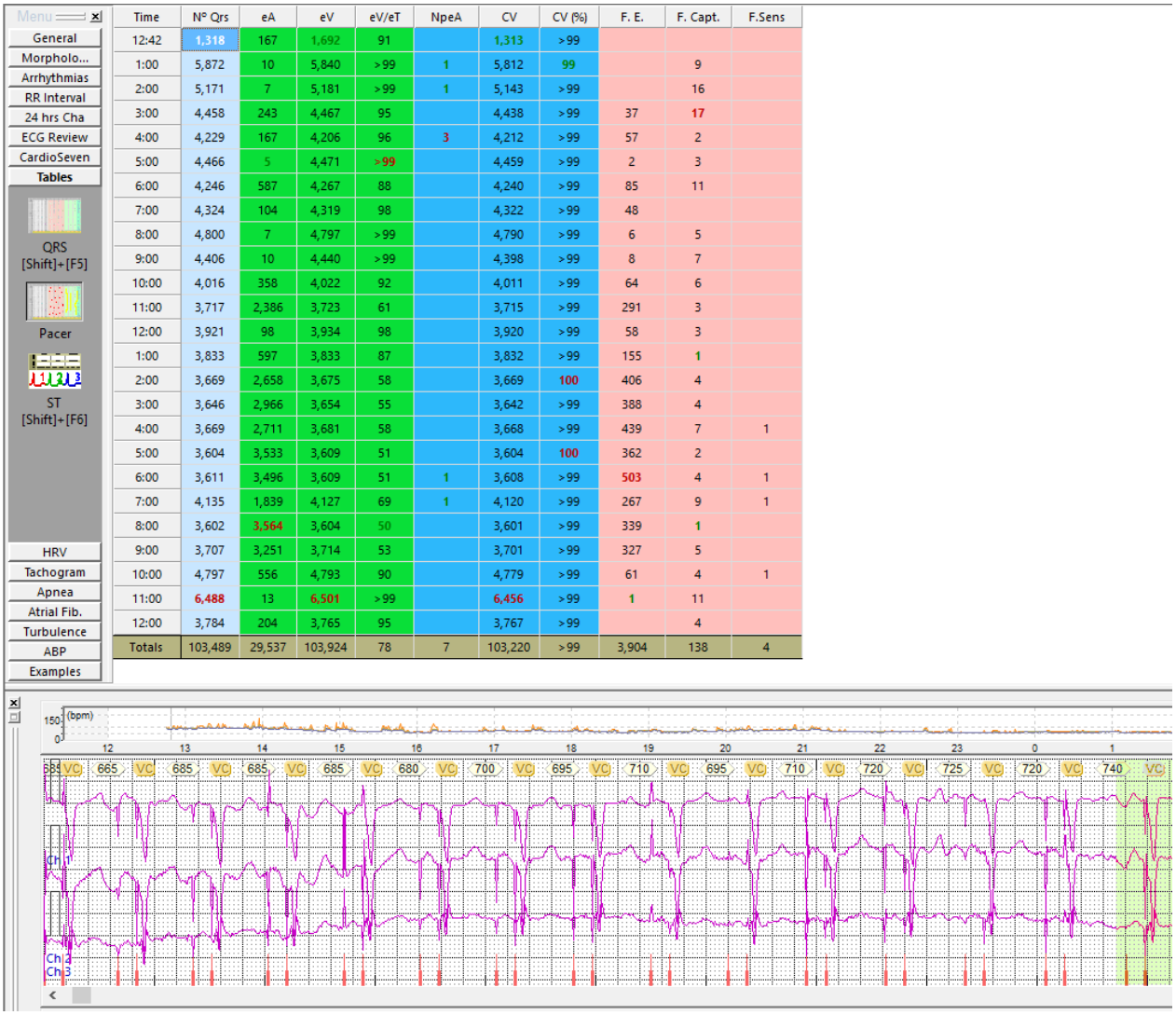
VC
Total number of ventricular captures

VC (%)
Percentage of ventricular captures in relation to the total heartbeats

S. F.
Total number of stimulus failures

Capture F.
Total number of capture failures

Sensitivity F.
Total number of sensitivity failures.



Time	N° Qrs	eA	eV	eV/eT	NpeA	CV	CV (%)	F. E.	F. Capt.	F.Sens
12:42	1,318	167	1,692	91		1,313	>99			
1:00	5,872	10	5,840	>99	1	5,812	99		9	
2:00	5,171	7	5,181	>99	1	5,143	>99		16	
3:00	4,458	243	4,467	95		4,438	>99	37	17	
4:00	4,229	167	4,206	96	3	4,212	>99	57	2	
5:00	4,466	5	4,471	>99		4,459	>99	2	3	
6:00	4,246	587	4,267	88		4,240	>99	85	11	
7:00	4,324	104	4,319	98		4,322	>99	48		
8:00	4,800	7	4,797	>99		4,790	>99	6	5	
9:00	4,406	10	4,440	>99		4,398	>99	8	7	
10:00	4,016	358	4,022	92		4,011	>99	64	6	
11:00	3,717	2,386	3,723	61		3,715	>99	291	3	
12:00	3,921	98	3,934	98		3,920	>99	58	3	
1:00	3,833	597	3,833	87		3,832	>99	155	1	
2:00	3,669	2,658	3,675	58		3,669	100	406	4	
3:00	3,646	2,966	3,654	55		3,642	>99	388	4	
4:00	3,669	2,711	3,681	58		3,668	>99	439	7	1
5:00	3,604	3,533	3,609	51		3,604	100	362	2	
6:00	3,611	3,496	3,609	51	1	3,608	>99	503	4	1
7:00	4,135	1,839	4,127	69	1	4,120	>99	267	9	1
8:00	3,602	3,564	3,604	50		3,601	>99	339	1	
9:00	3,707	3,251	3,714	53		3,701	>99	327	5	
10:00	4,797	556	4,793	90		4,779	>99	61	4	1
11:00	6,488	13	6,501	>99		6,456	>99	1	11	
12:00	3,784	204	3,765	95		3,767	>99		4	
Totals	103,489	29,537	103,924	78	7	103,220	>99	3,904	138	4

6.7.2. ST TABLE

The ST Table shows all the channels elevations and depressions found in the exam.

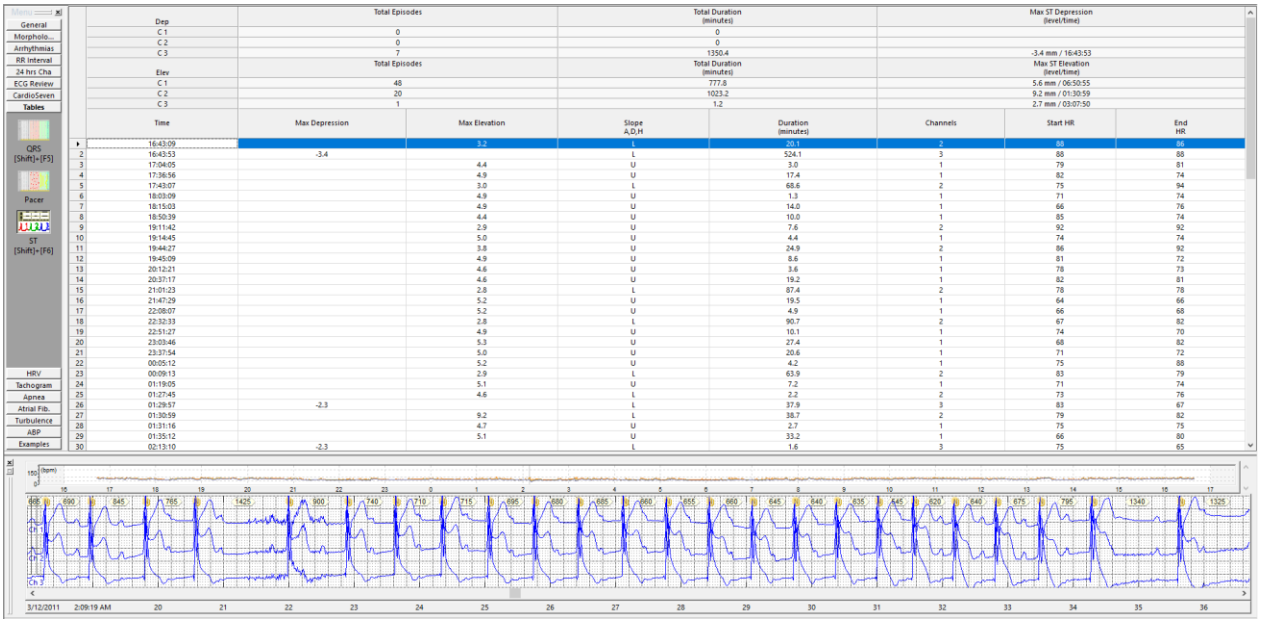
The ST episodes are presented in two ways in this table:
1. Separated by channel and type (upper part of the ST table), and
2. By time (bottom of ST table).

In the first column of the upper part, the events are separated in Depression (Dep), and Elevation (Elev), and are classified by the channel in which they occurred (channel 1, 2, and 3).

The next three columns show, respectively, the Total number of episodes in the channel, the Total events duration and the ST interval maximum depression/elevation of a given channel.

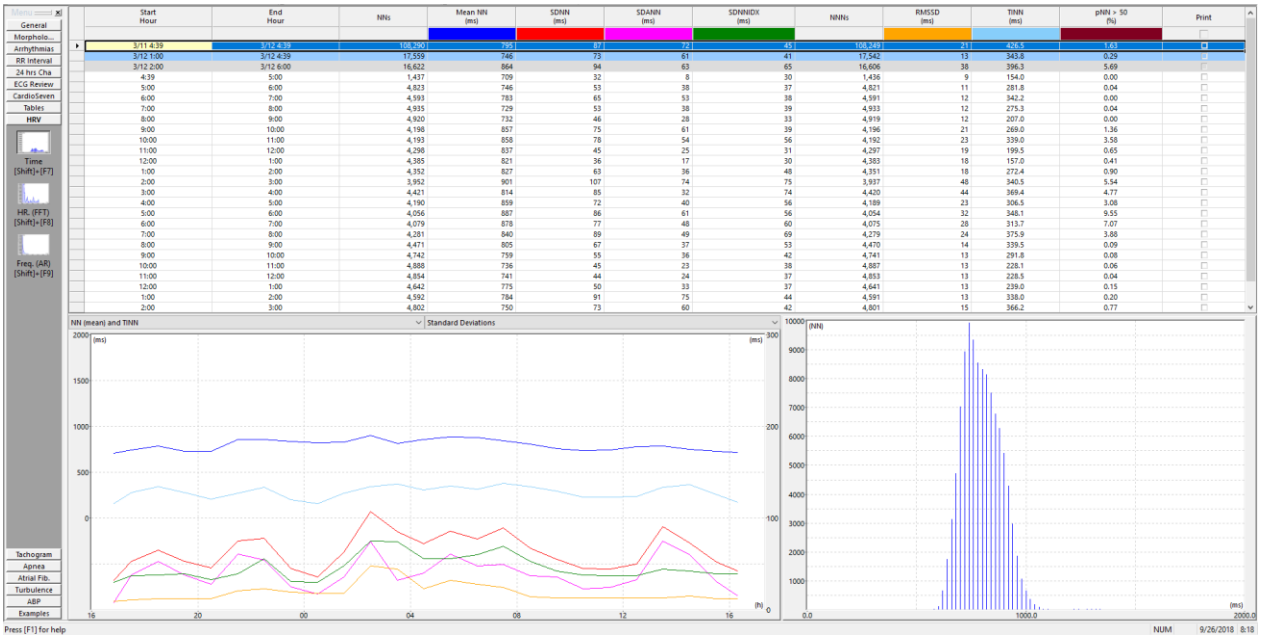
At the bottom of the table are presented the events separated by time. This part of the table displays the event Maximum Depression/Elevation, its inclination, duration, basal and maximum heart rate, and the channel in which it occurred.

If the “ECG bar” is open, clicking on any hour at the bottom of the table will automatically displays the event.


General
Morpholo...
Arrhythmias
RR Interval
24 hrs Cha
ECG Review
CardioSeven
Tables
QRS [Shift]+[F5]
Pacer
ST [Shift]+[F6]
HRV
Tachogram
Apnea
Atrial Fib.
Turbulence
ABP
Examples
Dep
Total Episodes
Total Duration (minutes)
Max ST Depression (level/time)
C 1 0 0
C 2 0 0
C 3 7 1350.4 -3.4 mm / 16:43:53
Elev
Total Episodes
Total Duration (minutes)
Max ST Elevation (level/time)
C 1 48 777.8 5.6 mm / 06:50:55
C 2 20 1023.2 9.2 mm / 01:30:59
C 3 1 1.2 2.7 mm / 03:07:50
Time | Max Depression | Max Elevation | Slope A,D,H | Duration (minutes) | Channels | Start HR | End HR
1 16:43:09 3.2 L 20.1 2 88 86
2 16:43:53 -3.4 L 524.1 3 88 88
3 17:04:05 4.4 U 3.0 1 79 81
4 17:36:56 4.9 U 17.4 1 82 74
5 17:43:07 3.0 L 68.6 2 75 94
6 18:03:09 4.9 U 1.3 1 71 74
7 18:15:03 4.9 U 14.0 1 66 76
8 18:50:39 4.4 U 10.0 1 85 74
9 19:11:42 2.9 U 7.6 2 92 92
10 19:14:45 5.0 U 4.4 1 74 74
11 19:44:27 3.8 U 24.9 2 86 92
12 19:45:09 4.9 U 8.6 1 81 72
13 20:12:21 4.6 U 3.6 1 78 73
14 20:37:17 4.6 U 19.2 1 82 81
15 21:01:23 2.8 L 87.4 2 78 78
16 21:47:29 5.2 U 19.5 1 64 66
17 22:08:07 5.2 U 4.9 1 66 68
18 22:32:33 2.8 L 90.7 2 67 82
19 22:51:27 4.9 U 10.1 1 74 70
20 23:03:46 5.3 U 27.4 1 68 82
21 23:37:54 5.0 U 20.6 1 71 72
22 00:05:12 5.2 U 4.2 1 75 88
23 00:09:13 2.9 L 63.9 2 83 79
24 01:19:05 5.1 U 7.2 1 71 74
25 01:27:45 4.6 L 2.2 2 73 76
26 01:29:57 -2.3 L 37.9 3 83 67
27 01:30:59 9.2 L 38.7 2 79 82
28 01:31:16 4.7 U 2.7 1 75 75
29 01:35:12 5.1 U 33.2 1 66 80
30 02:13:10 -2.3 L 1.6 3 75 65
3/12/2011 2:09:19 AM

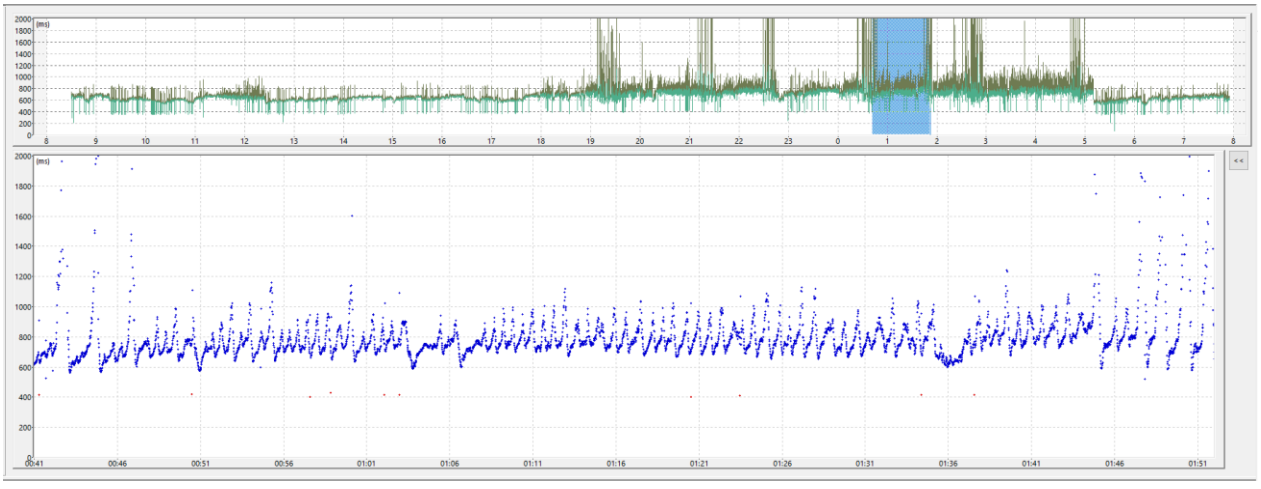
6.8. HEART RATE VARIABILITY

Due to the large amount of information and charts of this module, its functions are detailed in a separate chapter (07).



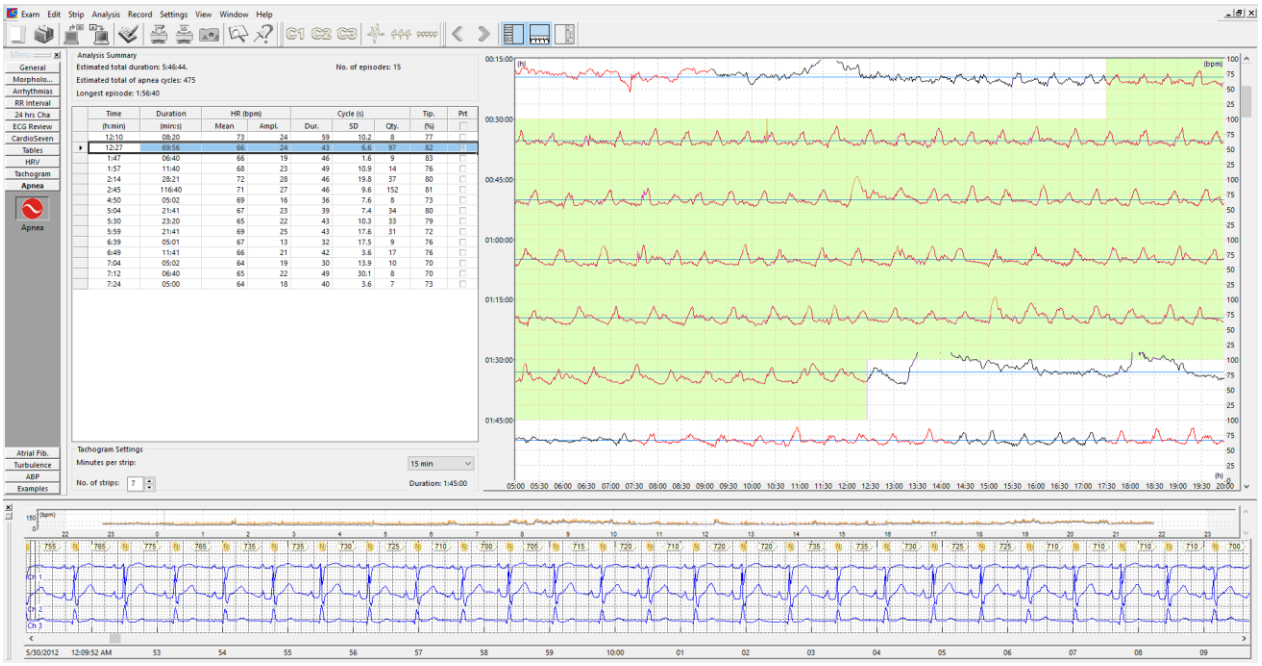
6.9. TACHOGRAM

Tool used to identify and verify several cardiac arrhythmias patterns.
Due to its complexity and number of charts, a specific chapter was created detailing its manipulation (08).



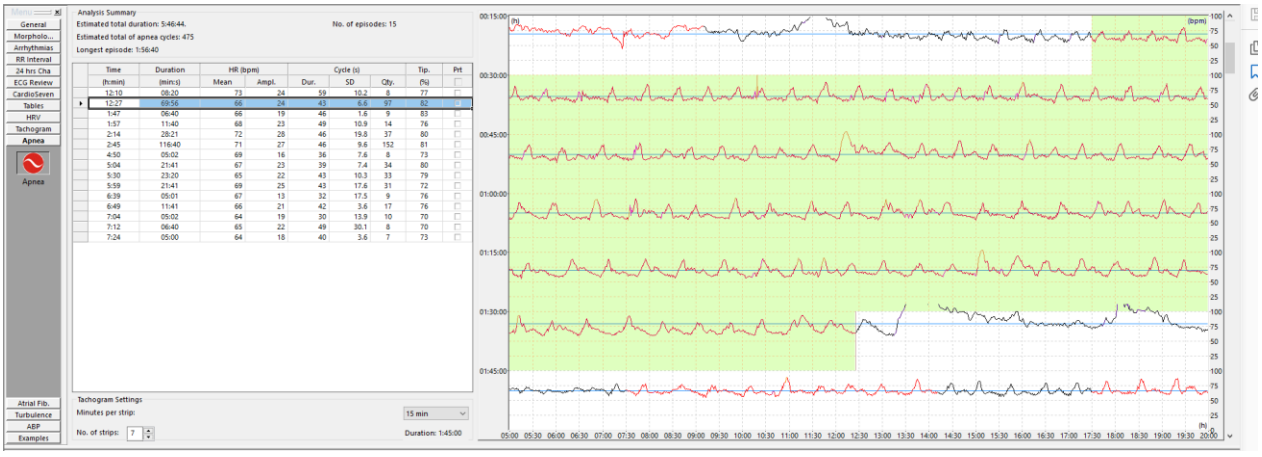
6.10. APNEA

The Apnea module makes a frequency spectral analysis of the sleep period electrocardiographic records. Through a mathematical algorithm, the software suggests the presence or absence of apnea/hypopnea episodes. (See Chapter 11, which details Apnea).



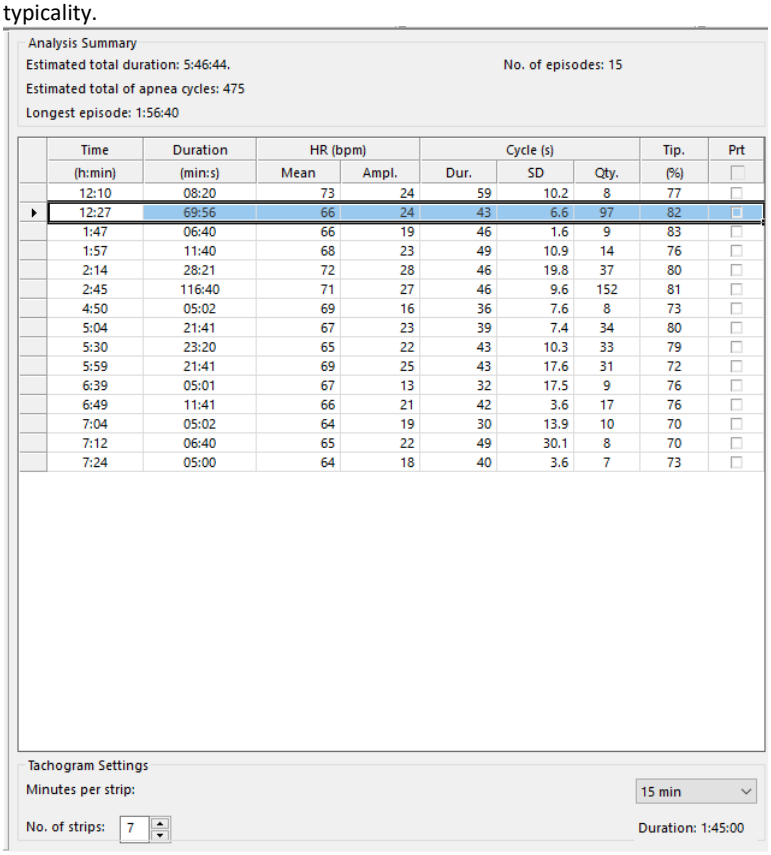
6.10.1. HR VARIATIONS TACHOGRAM

The periods with episodes suggestive of apnea/hypopnea are in red.
These charts are configurable from 5 minutes to 2 hours per line, in order to view specific details or the entire sleep period.
You can also select the number of ranges to display during each event.



If the analyst physician, when viewing the tachogram, finds that there is some period the system has not quantified, can just drag the mouse over the period until it changes color, right-click and select [Save the Period]. This period is automatically inserted into the table.

On the left side, are listed all the times in which the suggested apnea episodes were detected, as well as their duration, HR, and typicality.



Time	Duration	HR (bpm)		Cycle (s)			Tip.	Prt
(h:min)	(min:s)	Mean	Ampl.	Dur.	SD	Qty.	(%)	
12:10	08:20	73	24	59	10.2	8	77	
12:27	69:56	66	24	43	6.6	97	82	
1:47	06:40	66	19	46	1.6	9	83	
1:57	11:40	68	23	49	10.9	14	76	
2:14	28:21	72	28	46	19.8	37	80	
2:45	116:40	71	27	46	9.6	152	81	
4:50	05:02	69	16	36	7.6	8	73	
5:04	21:41	67	23	39	7.4	34	80	
5:30	23:20	65	22	43	10.3	33	79	
5:59	21:41	69	25	43	17.6	31	72	
6:39	05:01	67	13	32	17.5	9	76	
6:49	11:41	66	21	42	3.6	17	76	
7:04	05:02	64	19	30	13.9	10	70	
7:12	06:40	65	22	49	30.1	8	70	
7:24	05:00	64	18	40	3.6	7	73	

Reports of Apnea/Hypopnea episodes with estimated quantification of cycles, partial, and total time

To the right of the table you can select a single tachogram with the total result, some periods or even select all events for printing

Below is the table view that can be enabled for printing.

CARDIOS

Apnea/Hypopnea Suggestive Episodes

Exam Number	Patient: WN	Code:
S. C.	Exam date: 5/29/2012 10:45:21 PM	12B-10051

Hour	Duration (min)	HR (bpm)	HR Amplit. (bpm)	Cycle Duration (s)	Cycle Std. Dev. (s)	Cycles Qty.	Tipicality (%)
12:10	08:20	73	24	59	10.2	8	77
12:27	69:56	66	24	43	6.6	97	82
1:47	06:40	66	19	46	1.6	9	83
1:57	11:40	68	23	49	10.9	14	76
2:14	28:21	72	28	46	19.8	37	80
2:45	116:40	71	27	46	9.6	152	81
4:50	05:02	69	16	36	7.6	8	73
5:04	21:41	67	23	39	7.4	34	80
5:30	23:20	65	22	43	10.3	33	79
5:59	21:41	69	25	43	17.6	31	72
6:39	05:01	67	13	32	17.5	9	76
6:49	11:41	66	21	42	3.6	17	76
7:04	05:02	64	19	30	13.9	10	70
7:12	06:40	65	22	49	30.1	8	70
7:24	05:00	64	18	40	3.6	7	73

Totals

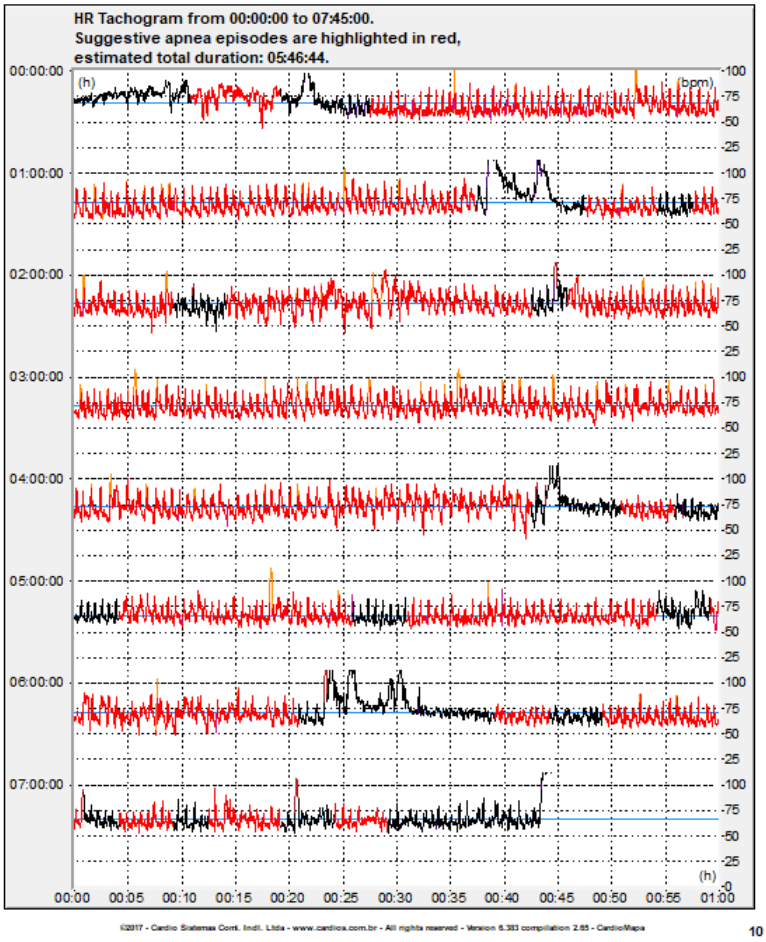
Estimated apnoea total time:	**5:46:44 AM**
Number of episodes:	**15**
Estimated quantity of cycles:	**475**
Longest episode:	**1:56:40 AM**

Criteria: *Period of analysis: only sleep, Sleep Period: from 0:00 to 7:45; Agglutinate intervals between apneas up to: 2min 30s; Repositioning irregular isolated beats: yes; Enhanced sensitivity activation: no.*

CARDIOS

Apnea/Hypopnea Suggestive Episodes

Exam Number	Patient: WN	Code:
S. C.	Exam date: 5/29/2012 10:45:21 PM	12B-10051



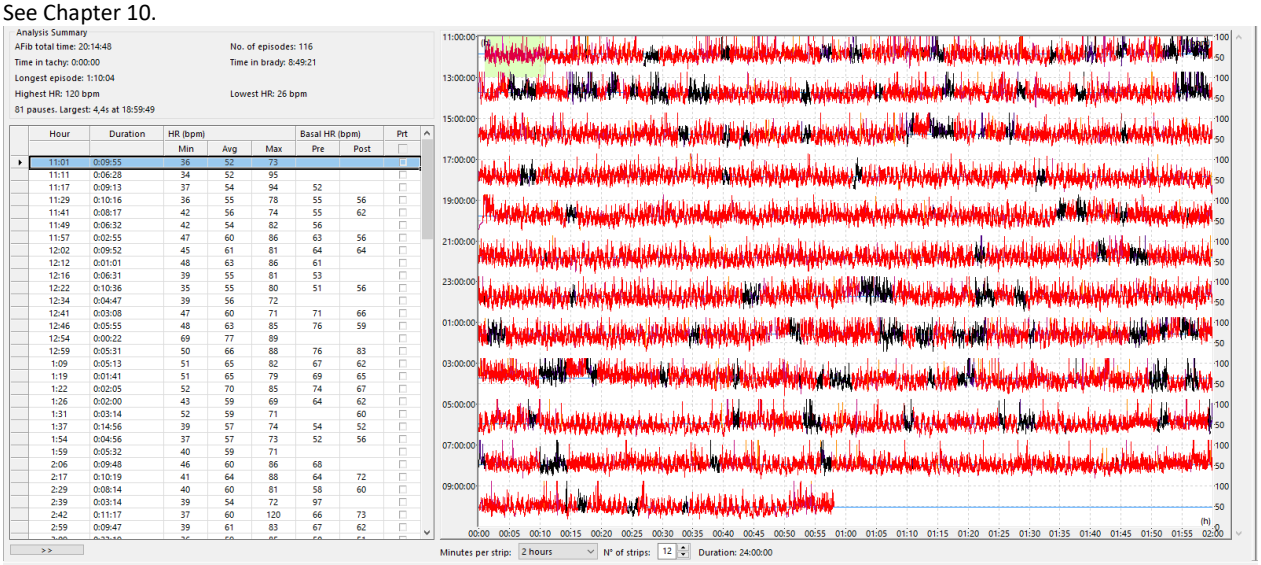
10

Condensed tachogram of all apnea/hypopnea periods.

6.11. ATRIAL FIBRILLATION

It can be activated in a “global” or individual mode, for automatically detecting paroxysmal or permanent Atrial Fibrillation episodes.

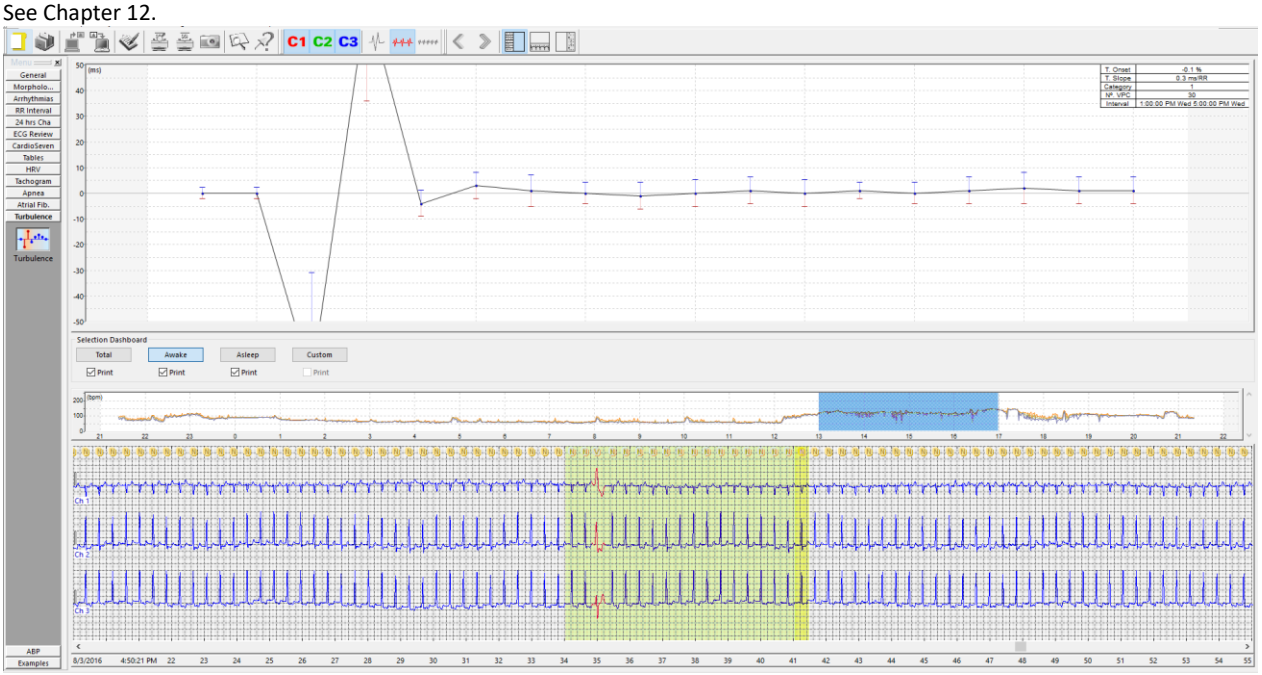
See Chapter 10.



6.12. HEART RATE TURBULENCE

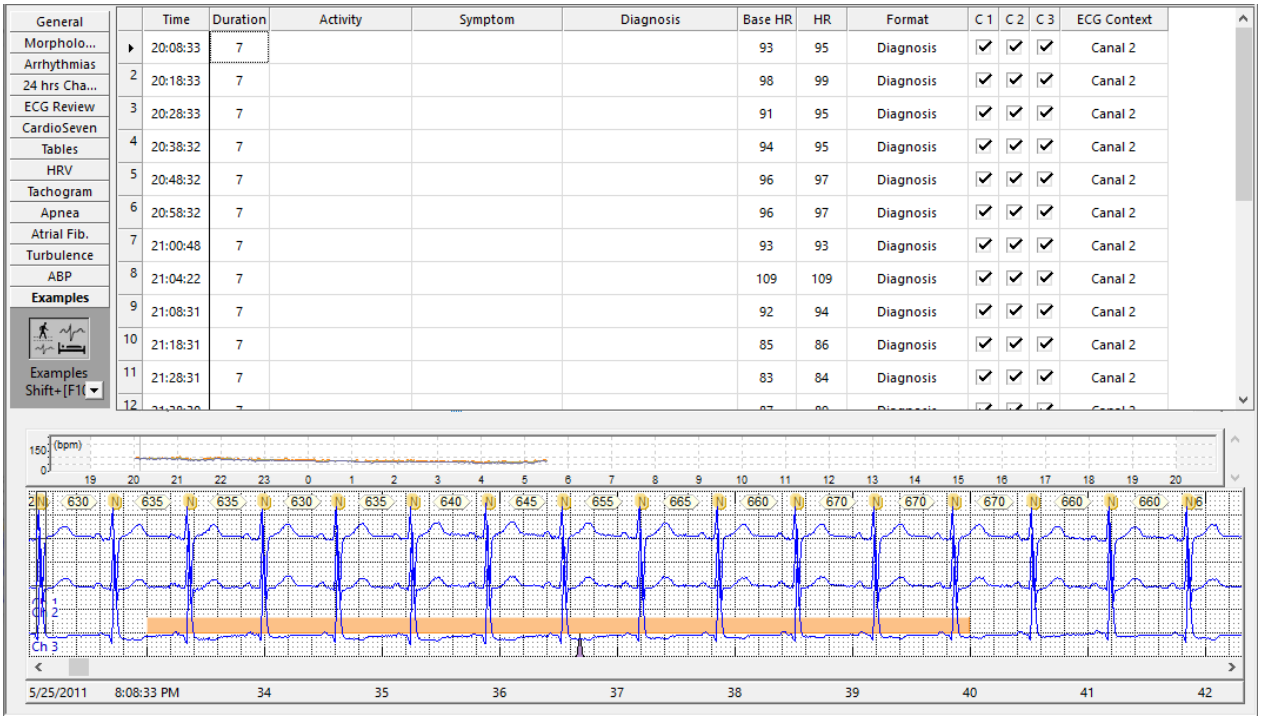
The Heart Rate Turbulence (HRT) quantifies the sinus rhythm transient disturbance that happens after ventricular extrasystoles (VE).

See Chapter 12.



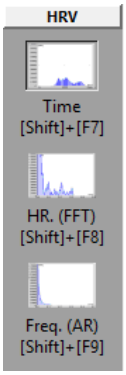
6.13. EXAMPLE

Tracings selected by the analyst physician for printing.
In this item, there are the tracings that illustrate what was visualized in the exam.
The physician can program the system to select the tracings automatically (with a preset number of each event) or add and choose the tracings when editing the exam.



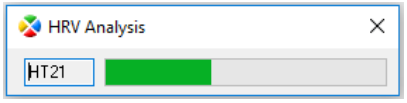
7. HR VARIABILITY RR VARIABILITY MODULE

The Heart Rate Variability analysis module has several settings, depending on the software installed. Remember that a lower level system may not have all the easiness described here.
The Heart Rate Variability module allows a complete RR variability analysis, with configurable time and frequency domain parameters.
The configuration parameters are accessible in the main configuration screen and are described in detail in the system configuration section.

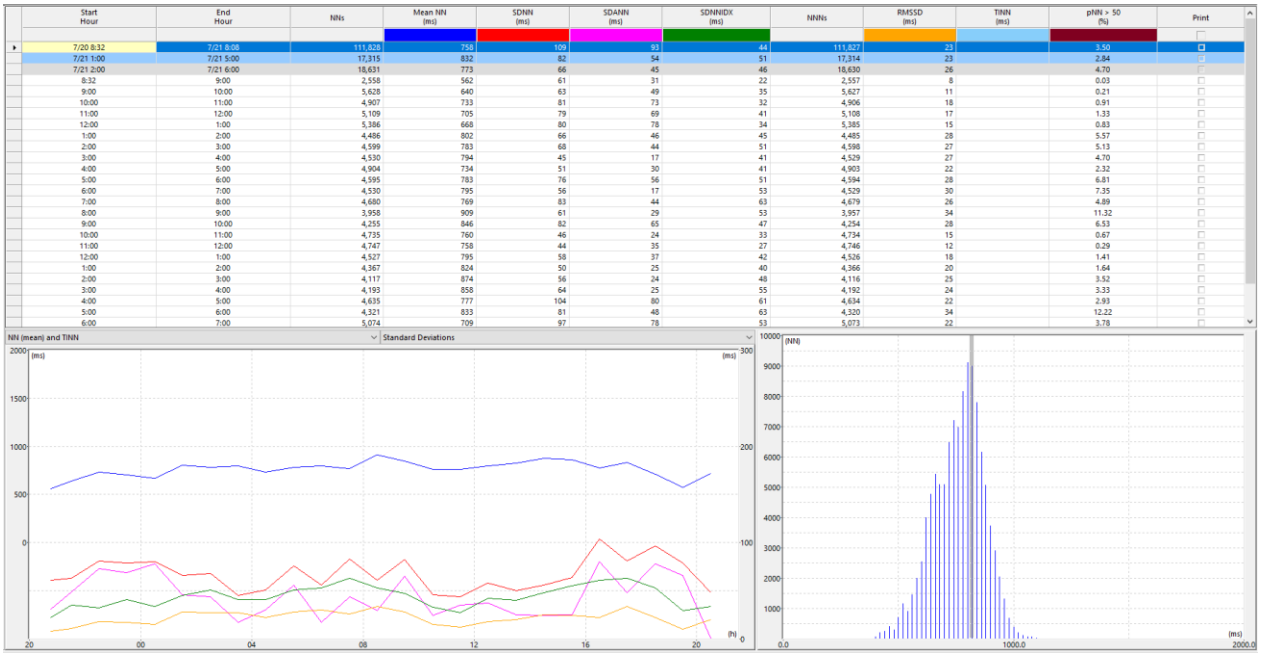


When you access the HRV module, the main menu shows three possible options for HRV analysis.
The default mode is time domain analysis, but you can analyze the data in the frequency domain.
When using the frequency domain, data can be analyzed through the FFT algorithm or by Autoregression.

When the HRV menu is accessed for the first time, it displays a dialog window, indicating that the HRV is being analyzed.

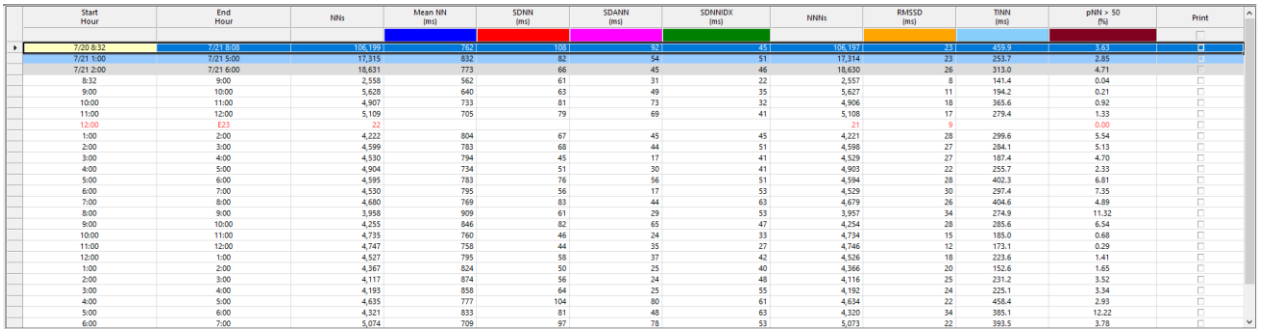


After being analyzed, the main HRV window shows a table of segments and two charts.

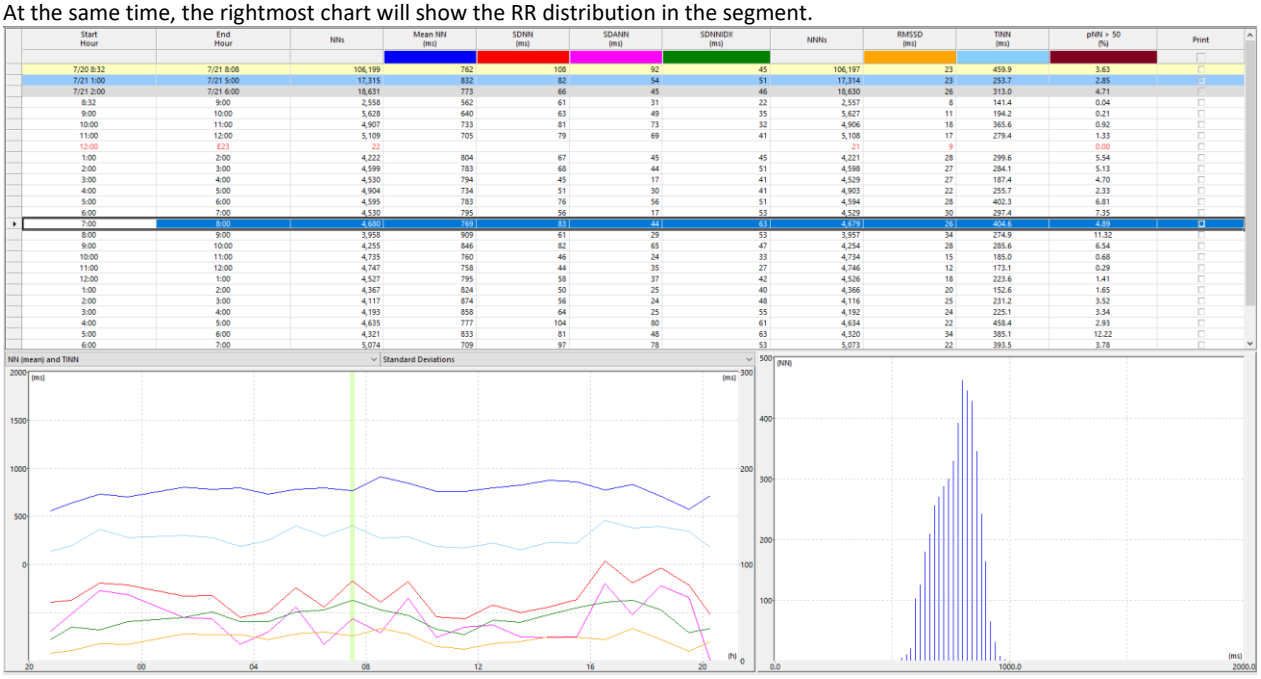


The table shows all possible segments to be analyzed. In Time domain, the first line (yellow) corresponds to the 24-hour segment. The second and third lines (blue and gray) represent the day and night segments. The next 24 segments have 1 hour each.

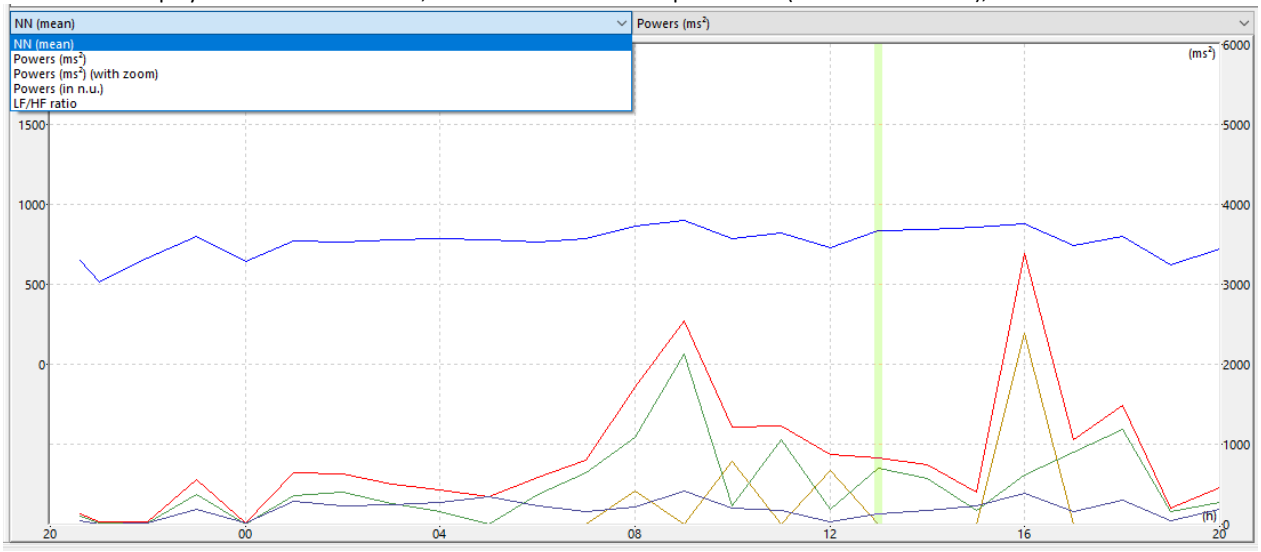
If a segment fails during analysis, an error will be displayed.

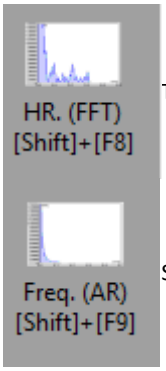


The chart will show the analysis result and clicking the mouse on some point of the curves will access the corresponding segment in the table.
At the same time, the rightmost chart will show the RR distribution in the segment.



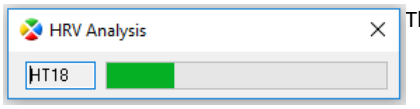
The chart on the left is configurable. You can select what to display by using the radio boxes at the top of the chart. You can combine the display of combo boxes of NN, standard deviations and pNN > 50% (in two zoom levels), on both sides of the chart.





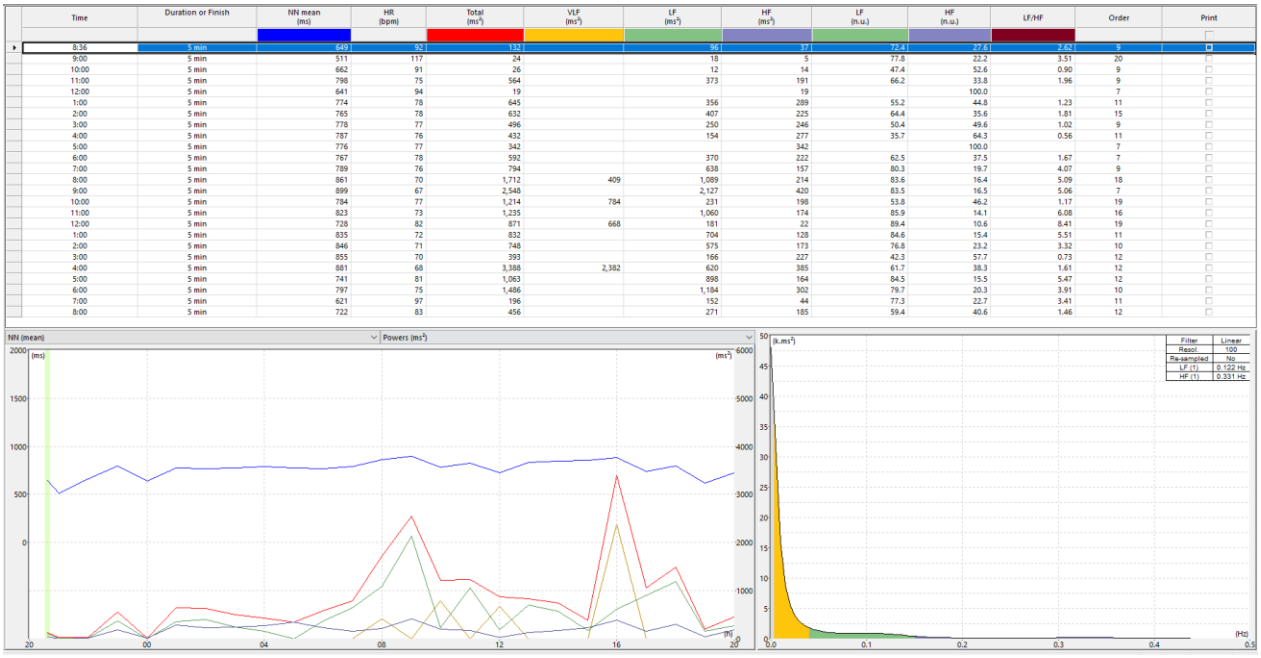
The frequency domain analysis is also available. It can be analyzed using FFT or Autoregression.

Select an option to enter the frequency domain analysis module.



The analysis progress bar will be displayed.

When the system completes data processing, the table and charts will be displayed as an analysis result.



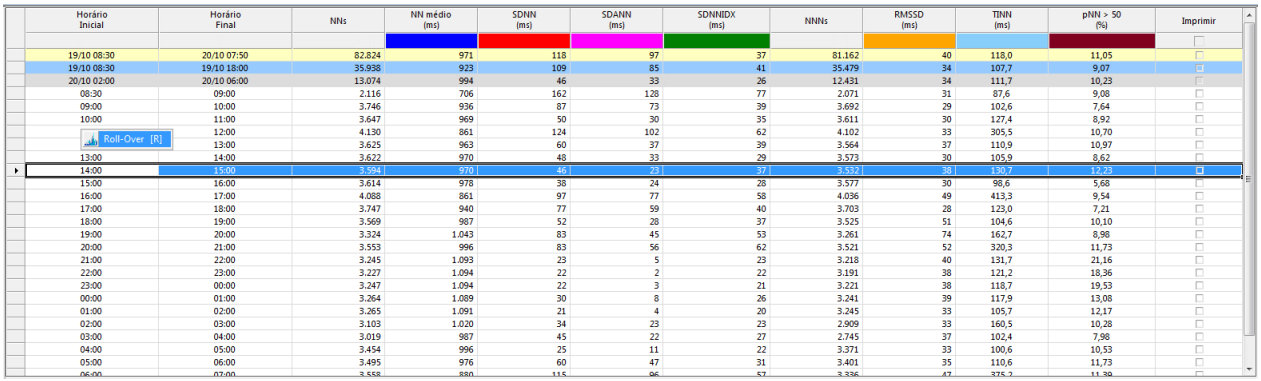
Time	Duration or Finish	NN mean (ms)	HR (bpm)	Total (ms²)	VLF (ms²)	LF (ms²)	HF (ms²)	LF (n.u.)	HF (n.u.)	LF/HF	Order	Print
8:36	5 min	649	93	134		96	31	72.4	27.6	2.62	9	
9:00	5 min	511	117	24		18	5	77.8	22.2	3.51	20	
10:00	5 min	662	91	26		12	14	47.4	52.6	0.90	9	
11:00	5 min	798	75	564		373	191	66.2	33.8	1.96	9	
12:00	5 min	641	94	19			19		100.0		7	
1:00	5 min	774	78	645		356	289	55.2	44.8	1.23	11	
2:00	5 min	765	78	632		407	225	64.4	35.6	1.81	15	
3:00	5 min	778	77	496		250	246	50.4	49.6	1.02	9	
4:00	5 min	787	76	432		154	277	35.7	64.3	0.56	11	
5:00	5 min	776	77	342			342		100.0		7	
6:00	5 min	767	78	592		370	222	62.5	37.5	1.67	7	
7:00	5 min	789	76	794		638	157	80.3	19.7	4.07	9	
8:00	5 min	861	70	1,712	409	1,089	214	83.6	16.4	5.09	18	
9:00	5 min	899	67	2,548		2,127	420	83.5	16.5	5.06	7	
10:00	5 min	784	77	1,214	784	231	198	53.8	46.2	1.17	19	
11:00	5 min	823	73	1,235		1,060	174	85.9	14.1	6.08	16	
12:00	5 min	728	82	871	668	181	22	89.4	10.6	8.41	19	
1:00	5 min	835	72	832		704	128	84.6	15.4	5.51	11	
2:00	5 min	846	71	748		575	173	76.8	23.2	3.32	10	
3:00	5 min	855	70	393		166	227	42.3	57.7	0.73	12	
4:00	5 min	881	68	3,388	2,382	620	385	61.7	38.3	1.61	12	
5:00	5 min	741	81	1,063		898	164	84.5	15.5	5.47	12	
6:00	5 min	797	75	1,486		1,184	302	79.7	20.3	3.91	10	
7:00	5 min	621	97	196		152	44	77.3	22.7	3.41	11	
8:00	5 min	722	83	456		271	185	59.4	40.6	1.46	12	

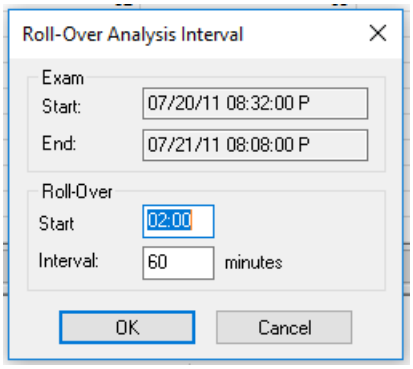
The leftmost chart shows the RR behavior during the exam, while the right one shows the spectral analysis of each segment.
The same procedure is valid for spectral data analysis extraction using the Autoregression algorithm.

7.1. ROLL OVER

It is a tool to evaluate the HRV in short periods in the time and frequency domain.
A period of 5 minutes was covenanted for the frequency domain. In the time domain, the SDANN and SDNN indexes are referenced to this period.

The Roll Over allows you to divide a certain time interval into five-minute overlapping intervals, with a one-minute lag between them.
To access this feature, just right-click on a given HRV table time, whether in the time or frequency domain, as in the example below.

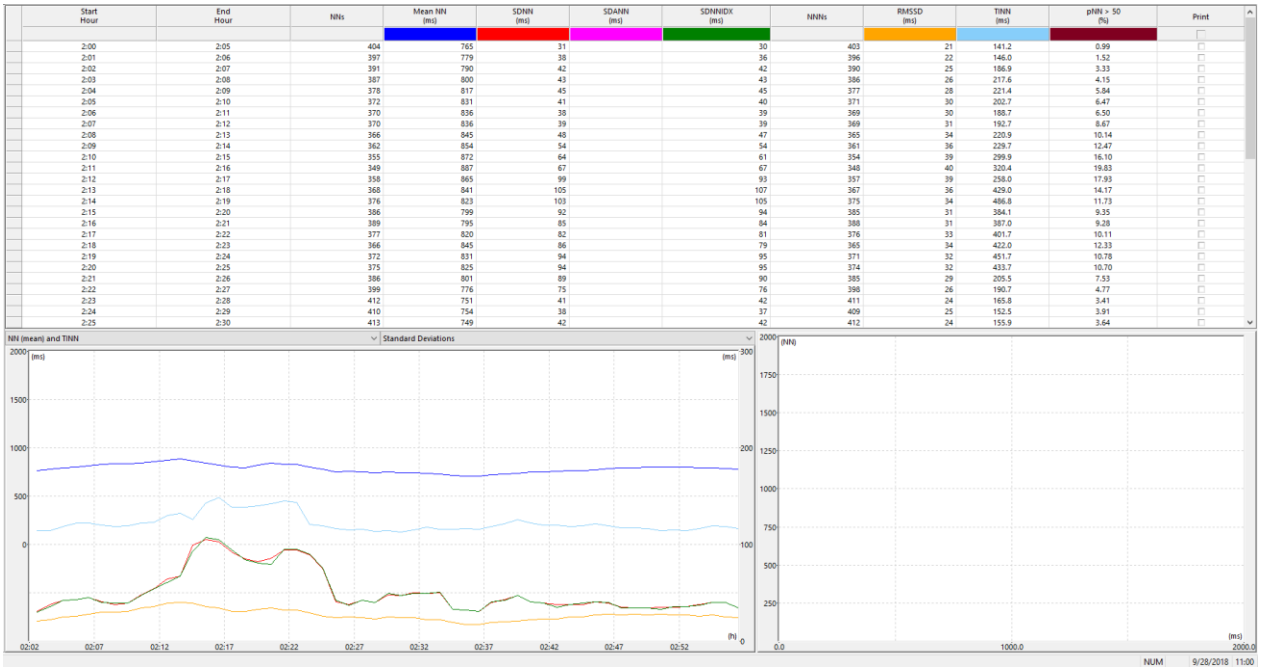




The menu for the “Roll Over” option will be displayed. Click to open the Roll-Over Analysis Interval dialog window.

Note that the starting time is the same as the one selected in the table. If you need to insert a new time, just enter it.

The default value for the scope field is sixty minutes, but it can be changed as per user convenience.

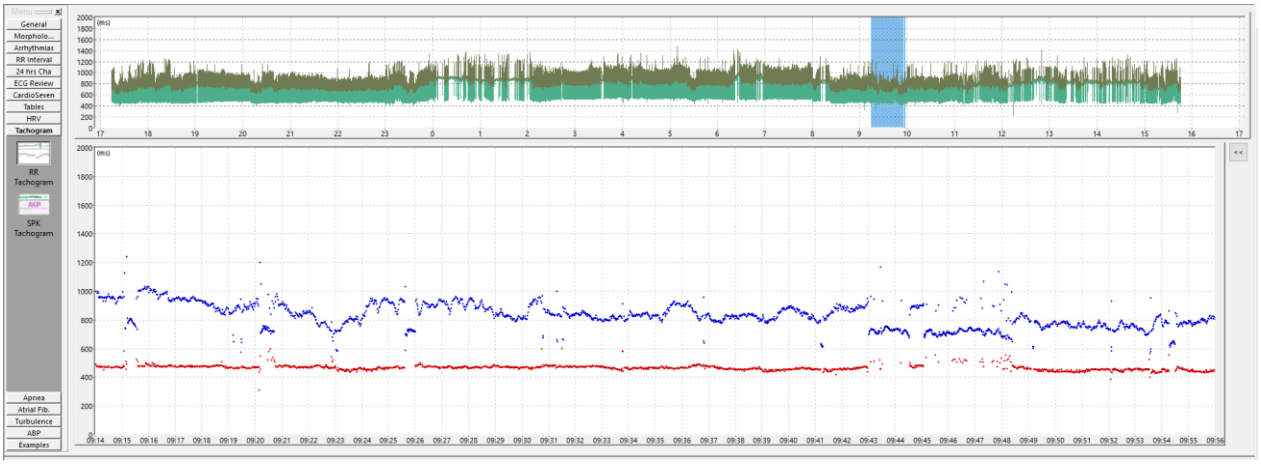


The previous example shows a table and its charts in the time domain, analyzed with the 15-minute Roll Over.

8. TACHOGRAM

A tool used to identify and verify several cardiac arrhythmias patterns. It is possible to visualize all RRs or Pacemaker intervals, in adjustable periods from a few seconds to several hours, along with the corresponding electrocardiographic tracings.

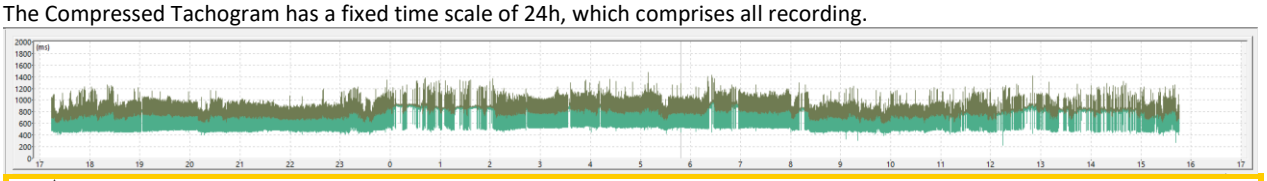
As the points keep the analyzed QRS (Vs, Svs, etc.) colors, this allows to identify from isolated complexes to behavioral patterns of several cardiac arrhythmias in a faster and more precise way, facilitating the diagnosis and increasing the information provided.
The RR Tachogram represents the RR intervals measured in ms (vertical scale) related to the recording time (horizontal scale). It consists of two charts: Compressed Tachogram and Expanded Tachogram.



8.1. COMPRESSED TACHOGRAM

This chart is represented by maximum RR values (dark green color), minimum RR values (light green color), and mean RR values (represented by the splitting line between the two shades).

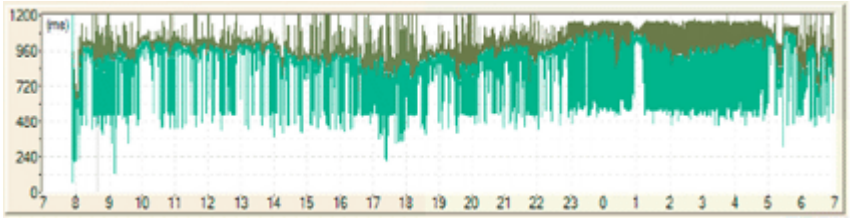
The Compressed Tachogram has a fixed time scale of 24h, which comprises all recording.



NOTE: The mouse arrow in the figure shows the RR intervals mean values.

8.1.1. COMPRESSED TACHOGRAM VERTICAL SCALE

The chart vertical values scale of RR intervals (in ms) is configurable, which zoom can be increased or decreased by the shortcut keys [+] and [-], when the focus is on the chart.

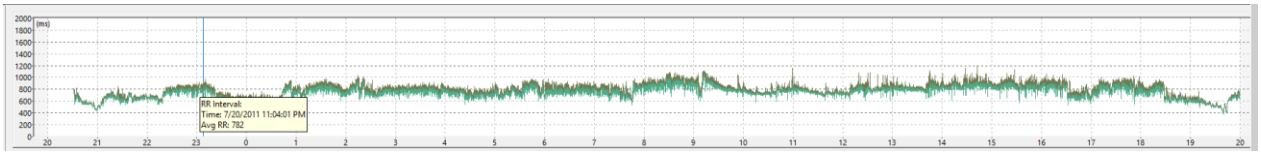


The figure above represents the Compressed Tachogram with the scale changed through the shortcut keys.

NOTE: To change the Compressed Tachogram scale you should first click on any point of it to activate the focus.

8.1.2. POP-UP ON COMPRESSED TACHOGRAM

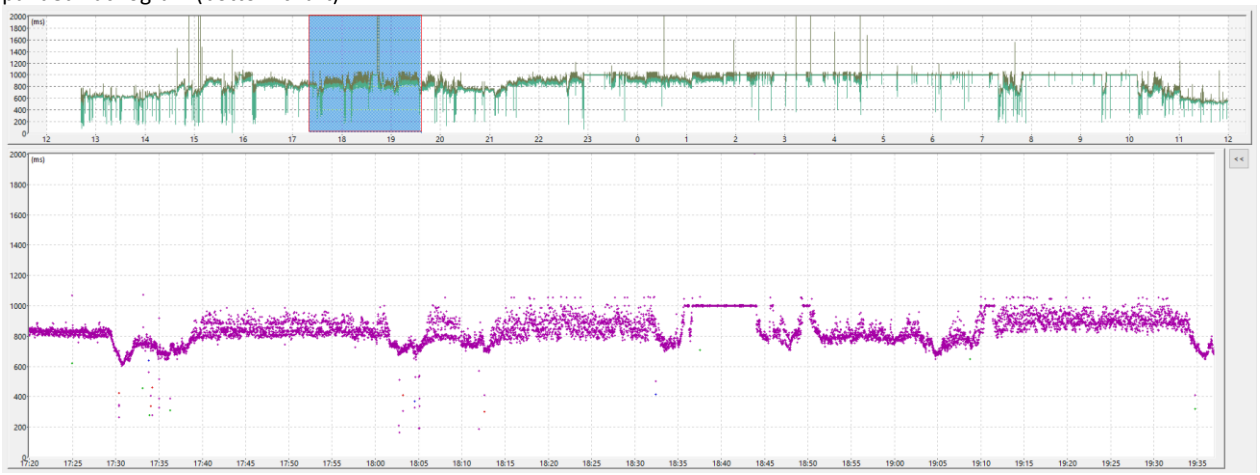
This feature allows the visualization of RR interval time and average value with the mouse. To do this, select a chart location which you want information about, and hover the mouse over it. Then, the pop-up containing the RR interval data will appear on the screen.



This figure shows the pop-up feature (yellow rectangle) activated after selecting a specific chart location (blue vertical line).

8.2. EXPANDED TACHOGRAM

The selected period in the Compressed Tachogram (top chart) can be seen in detail, by expanding the time scale, in the Expanded Tachogram (bottom chart).

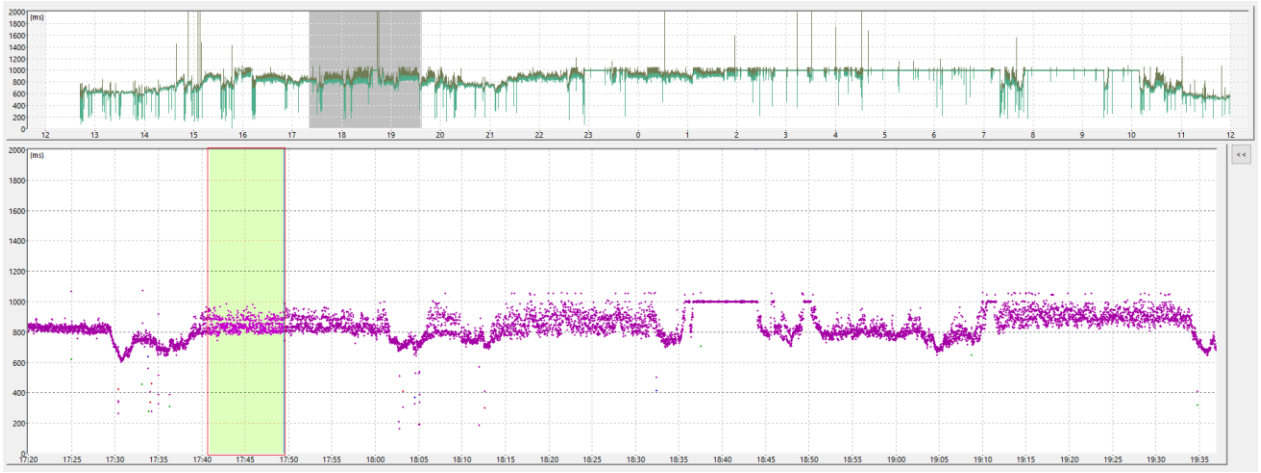


The Expanded Tachogram shows the points representing the intervals between heartbeats. These points follow the typical heartbeat colors as in other screens, for example, the normal heartbeat color is blue, the ventricular heartbeat is red, and so on. It has variable time scale, from a minimum of 30s, to the maximum time of the whole recording, 24h.

8.2.1. EXPANDED TACHOGRAM ZOOM FEATURE

This feature allows you to precisely select a specific point in the Expanded Tachogram chart.

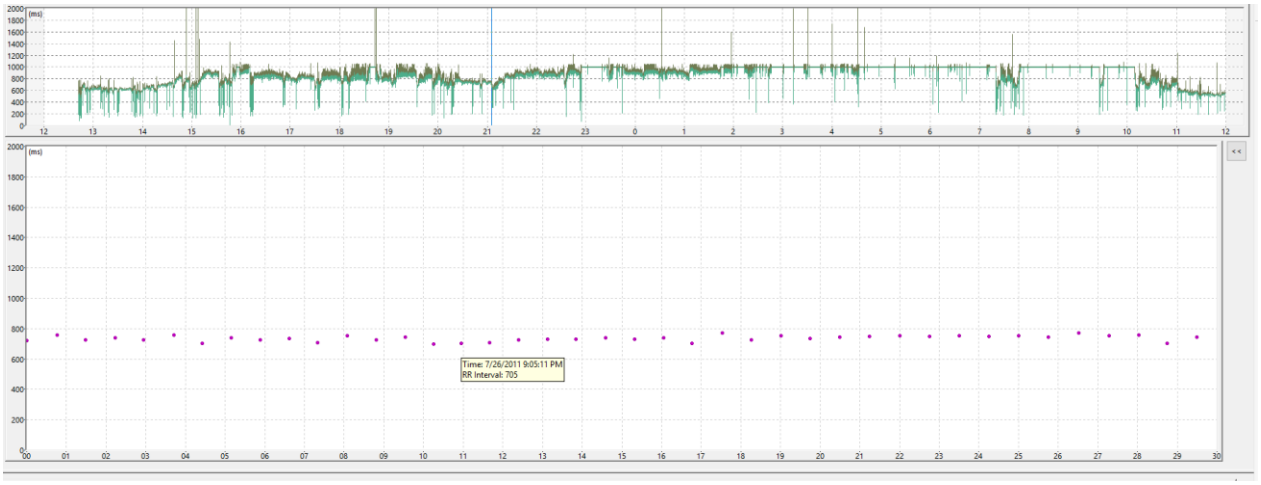
Since the precise selection of a given point in the Compressed Tachogram is difficult, another procedure can be adopted: with the mouse, select an excerpt in the Compressed Tachogram (upper chart) that appears in the time and in the RR interval of interest.



This interval will be expanded automatically by varying the Expanded Tachogram (bottom chart). In this tachogram, an interest interval can be selected with the mouse.

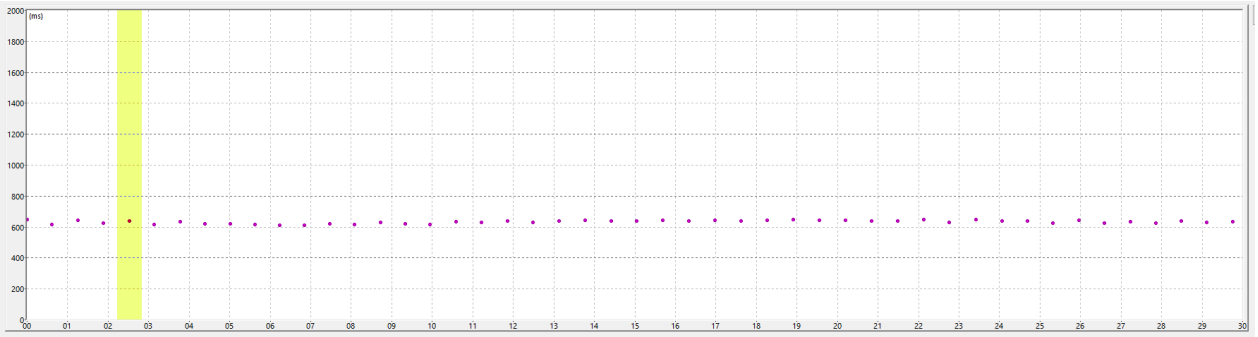
By pressing [Enter], the period will expand until it occupies the entire screen (this operation will be limited to the chart horizontal axis resolution of 30 seconds).

NOTE: The interval selection on the Expanded Tachogram chart may be performed multiple times, followed by pressing the [Enter] key until you find the point with the highest resolution.



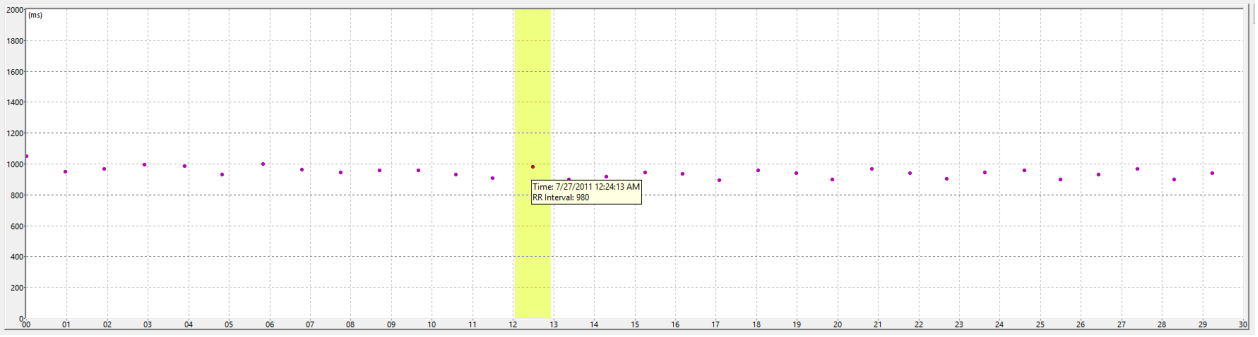
8.2.2. EXPANDED TACHOGRAM VERTICAL SCALE

The scale setting in this chart follows the same sequences as the Compressed Tachogram chart.
Just select the Expanded Tachogram chart and use the [+] and [-] keys to change the scale.



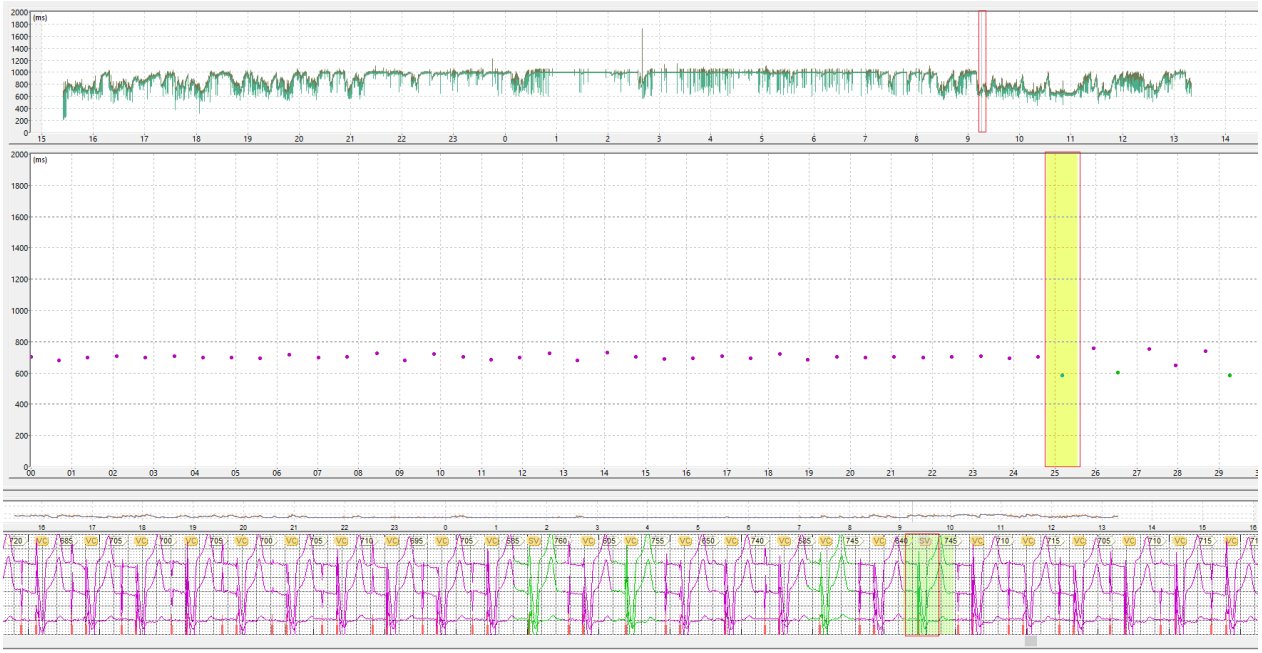
8.2.3. POP-UP ON EXPANDED TACHOGRAM

This feature is the same as shown in the Compressed Tachogram. It is only necessary to select the point and leave the mouse pointer over the selection marker until the pop-up is automatically displayed.



8.2.4. HEARTBEATS RECLASSIFICATION

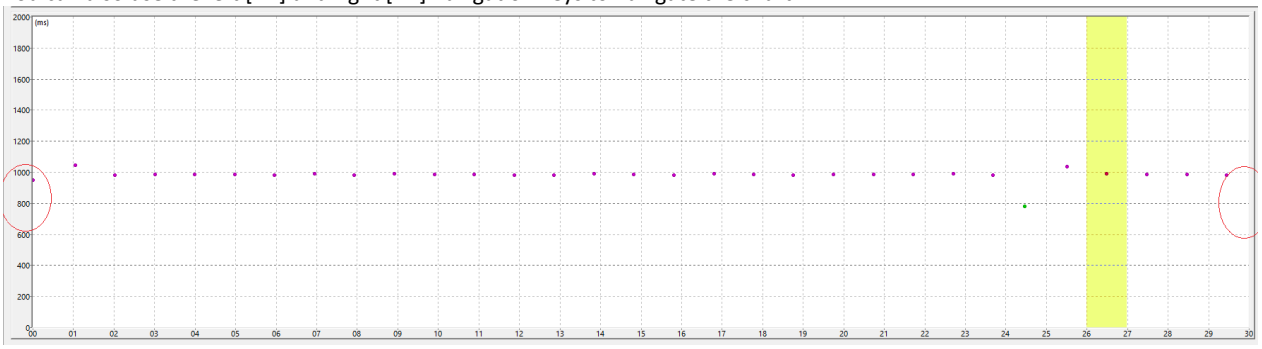
Once the resolution limit has been reached with Zoom, the heartbeat reclassification is done by selecting the heartbeats with the mouse and then changing them with the shortcut keys (example: [N] key for Normal, etc.).



In the heartbeats reclassification it is appropriate that the ECG bar is active, in order to see more clearly the heartbeats types displayed in the expanded tachogram.
The previous figure shows how to use the RR Tachogram with the help of ECG bar.

8.2.5. CURSOR NAVIGATION IN EXPANDED TACHOGRAM

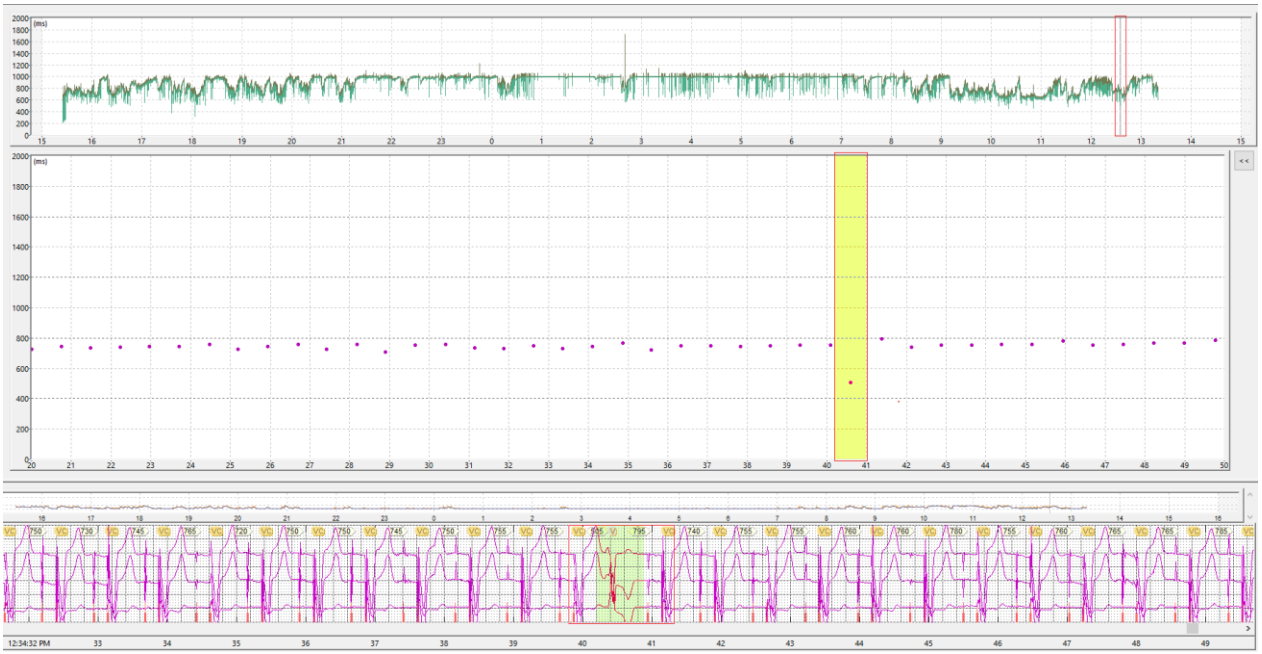
In order to optimize the user's observation through the several hours represented in the system, the Expanded Tachogram shows the “Navigation” feature between the screens, just click on the chart left or right edges to position the cursor on the next screen. You can also use the left [<--] and right [-->] navigation keys to navigate the chart.



Thus, to visualize the RR intervals values in a posterior or previous interval, just use the mouse or the keys to navigate through the chart. If the ECG Context bar is present, the tracings times will follow the RR Tachogram ones.

8.2.6. LINKING THE COMPRESSED TACHOGRAM, EXPANDED TACHOGRAM, AND ECG BAR

In order to facilitate the user visualization of certain RR interval, the system allows the combination of these tools.



The Expanded Tachogram represents the relationship between the RR intervals values (in ms), and the selected time in the Compressed Tachogram.
Thus, for a more detailed view (specific time and interval), the desired interval is selected in the Compressed Tachogram, which will automatically appear in the Expanded Tachogram.
The RR interval selected with the mouse in the Expanded Tachogram (yellow selection) appears in green in the ECG bar, allowing a more detailed view of the selected RR interval.

9. PACEMAKER ANALYSIS

The PACER software was developed to analyze recordings of patient with pacemaker who underwent Holter exams, allowing greater precision and agility in the diagnoses of these exams.

The PACER Software is composed of three parts:
1. Pacemaker spike detection by CardioLight+ digital recorder through specific circuit.
2. Creation of a unique database of pacemaker ventricular and atrial spikes.
3. Consolidation of this database with the QRSs database of conventional Holter recording.

For a correct pacemaker activity evaluation, the software is based on three pillars that should work in an integrated way:
I. Proper spikes detection by the digital recorder;
II. Data software analysis provided by the recorder; and,
III. Viewing features and information editing.

9.1. PREPARING, ACQUIRING, AND ANALYZING PACEMAKER PATIENTS EXAMS

The procedures for acquiring and preparing exams of patients with pacemaker are the same as for patients without a pacemaker.

However, you should program the Software to reanalyze them as exams with pacemaker activity, be it Atrial, Ventricular, or Dual-chamber.

Thus, for exams of patients with pacemaker, the system makes it possible to analyze them in a different way from the exams of patients who do not have pacemaker.

9.2. SOME IMPORTANT CONCEPTS

For a correct understanding of software settings, such as Interval Limits, Pacemaker Intrinsic HR, HR in Hysteresis, and VC Form Similarity, some concepts should first be explained.

9.2.1. INTERVAL LIMITS (IN MS)

eA – eV (atrial spike - ventricular spike)
It is used to define the interval between the atrial and ventricular spikes in the Dual Chamber Pacemakers;

eA – R (atrial spike – R)
It differentiates the normal QRS following the patient intrinsic atrial activity from that caused by the pacemaker's atrial stimulation;

eV – R (ventricular spike – R)
The ventricular spikes not followed by QRSs after the determined values are considered “Command failures”; and,

Refractory period
Pacemaker blindness interval after intrinsic ventricular depolarization. The early pacemaker activity after this interval is considered “undersensing”.

9.2.2. HR

Intrinsic pacemaker HR
The value 60,000 divided by the pacemaker's HR gives the maximum interval (in ms) for the appearance of ventricular depolarization (when the pacemaker has no hysteresis programming). Intervals greater than this value without patient intrinsic activity and without pacemaker activity are considered as stimulation failure, or oversensing;

HR in hysteresis
When the pacemaker is programmed to trigger with hysteresis, this HR should enter the calculations to define the maximum allowable interval without pacemaker activity in the absence of intrinsic QRS.

9.2.3. VC FORM SIMILARITY

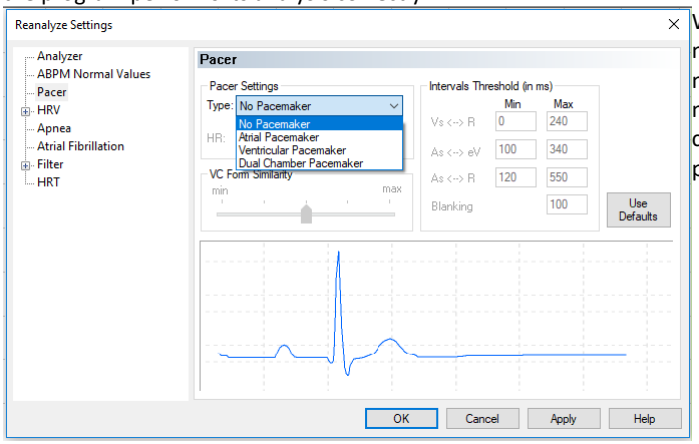
This feature allows a greater or lesser weight in the analysis to assess the QRS form similarity triggered by the pacemaker, even in the absence of spike detection by the recorder.

9.3. SETTINGS

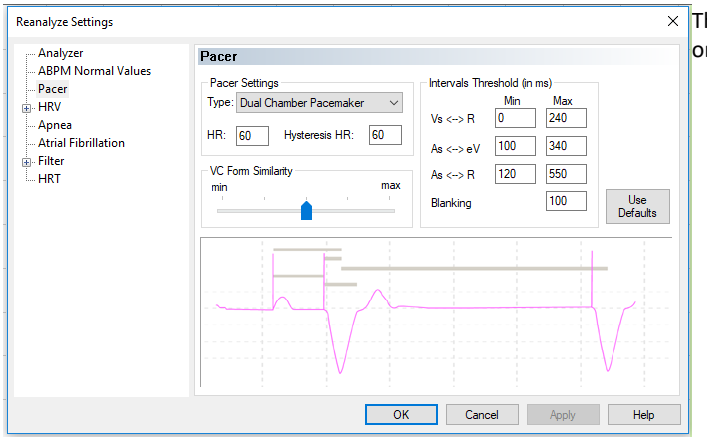
It is suggested that the first change in Settings should be made in Pacemaker Data.

9.3.1. PACEMAKER DATA

According to patient or referring physician information, the pacemaker type active during the exam should be indicated, so that the program performs its analysis correctly.



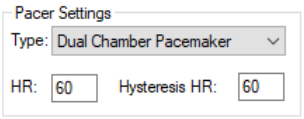
When presenting the window, the pacemaker type automatically activated by the program will be "No Pacemaker", and the analyst should select the actual pacemaker type used in the exam. Thus, the analyst should click on the desired pacemaker type, as indicated in the previous figure.



The figure shows the type selection by the user, then click on [OK].

After the pacemaker is selected, the heartbeat type representation displayed in the window will be changed so that the user can see the limits on it. Notice in the figure above, the heartbeat representation (Ventricular Capture) that appears when the Dual

Chamber Pacemaker is triggered. The same happens when the user selects the other Pacemaker types, and for each type, there will be a heartbeat type, according to the needing of view the limits for the intervals on it.

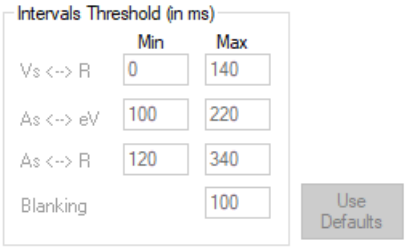


Another changeable item present in “Pacemaker Data” is the Heart Rate, which are two:

- HR
- HR in hysteresis

Both allow you to choose the values you want.

9.3.2. LIMITS FOR THE INTERVALS (IN MS)

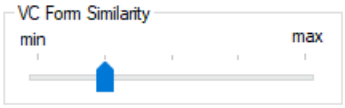


This tool allows the edition of minimum and maximum intervals (in ms), between:
- Atrial Spike and R (eA <-> R);
- Ventricular Spike and R (eV <-> R);
- Atrial Spike and Ventricular Spike (eA <-> eV);
- Refractory period.

Enabling the “Limits for the Intervals (in ms)” fields will be according to the Pacemaker type selected.

9.3.3. VC FORM SIMILARITY

As this feature allows a greater or lesser weight in the analysis to evaluate the similarity of the pacemaker-triggered QRS form, it allows the user to configure the Ventricular Captures similarity in five degrees, ranging from minimum to maximum.

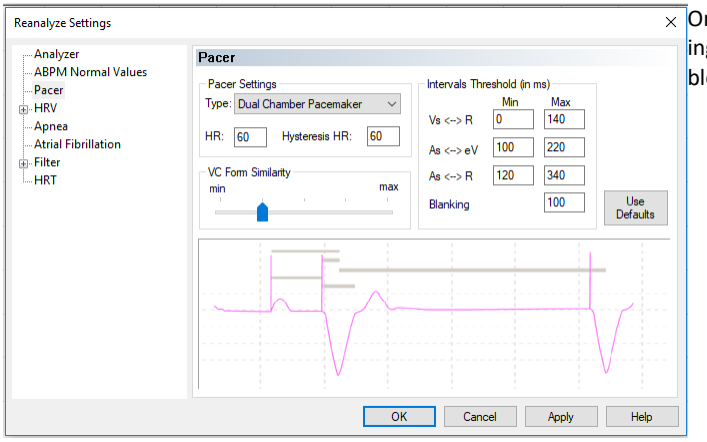


This feature allows the system to analyze some QRSs as Ventricular Captures, when the recorder did not detect pacemaker spike, which can occur in some bipolar pacemakers. It may be required a greater or lesser similarity of the analyzed QRS in relation to the VCs with pacemaker spikes present.

This feature should only be used in the reanalysis to reduce eventual presence of false negative and false positive.

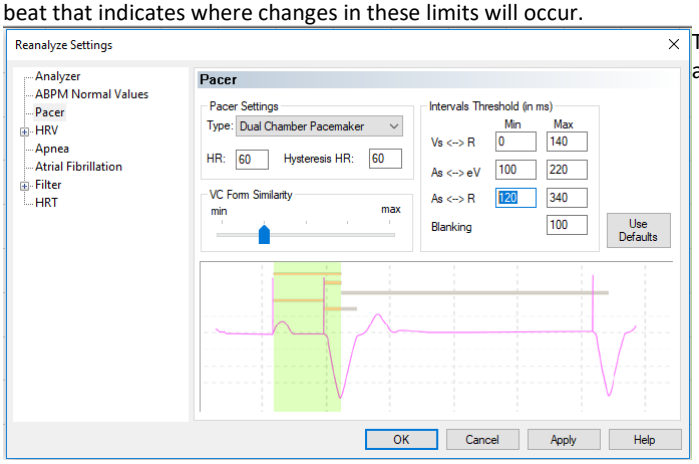
9.4. PACEMAKERS AND SPECIFICATIONS

9.4.1. DUAL CHAMBER PACEMAKER



On exams with Dual Chamber Pacemaker activity, all editing options in “Limits for the Intervals (in ms)” will be enabled.

The Dual Chamber Pacemaker type selection enables all available options in “limits for the intervals (in ms)” and shows a heartbeat that indicates where changes in these limits will occur.



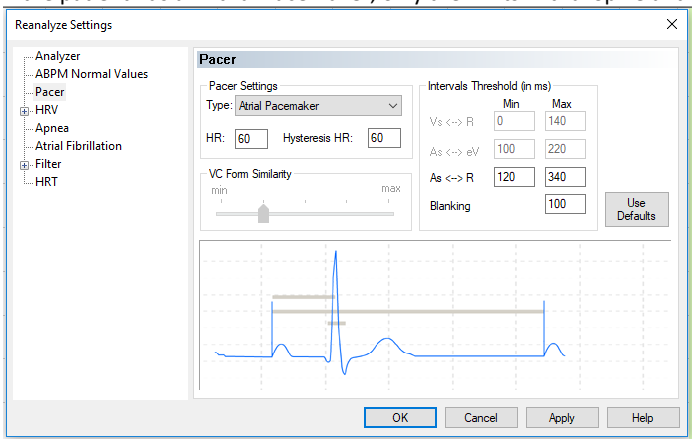
To do this, select the interval to be changed and it will be automatically highlighted in the heartbeat.

For example: minimum threshold between atrial and ventricular spikes (eA <-> eV):
The heartbeat illustrated in the figure indicates where the user's change will be performed in the exam's heartbeats.

NOTE: The software will analyze the exam according to the limit values edited by the user.

9.4.2. ATRIAL PACEMAKER

If the patient has an Atrial Pacemaker, only the limits “Atrial Spike and R (eA <-> R)” and “Refractory Period” will be enabled.

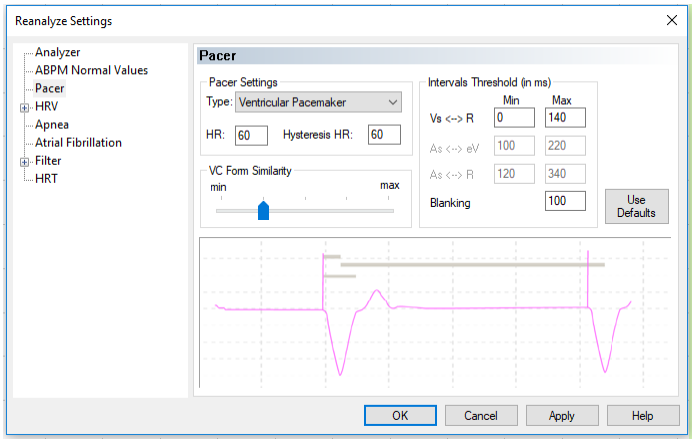


Note that in the figure, the Atrial Pacemaker activation enables the “Limits for the Intervals (in ms)”, which can be useful for the exam analysis containing this pacemaker type.

Also note a Normal heartbeat representation preceded by Atrial Spike (NpeA), generated by this pacemaker type, to demonstrate where will be the changes made by the user in the limits.

9.4.3. VENTRICULAR PACEMAKER

In exams of patients with Ventricular Pacemaker, the options available for editing in Limits for the Intervals are: “Ventricular Spike and R (eV <-> R)” and “Refractory Period”.



Note that in the figure above, the Ventricular Pacemaker activation enables the “Limits for the Intervals (in ms)”, which can be useful for the exam analysis containing this pacemaker type. Also note a Ventricular Capture heartbeat representation (VC), generated by this pacemaker type, to demonstrate where will be the changes made by the user in the limits.

9.5. PACER SOFTWARE FEATURES

The pacemaker activity can be evaluated, in addition to CardioSmart CS550's own resources, through three specific screens created for this purpose:

QRSs Morphologies Screen

Pacemaker table with all events related to the pacemaker

Pacemaker Tachogram

9.5.1. QRSS MORPHOLOGIES SCREEN

This screen automatically presents two new QRSs families that the software identifies as:

VC (Ventricular captures)
QRSs originated by stimuli of the pacemaker electrode located in the ventricle; and,

NpeA (Normal preceded by atrial spike)
QRSs originated by atrial stimulation with preserved AV conduction.
In this case, the patient's intrinsic ventricular QRS atrial spike - P-wave - will be observed.

9.5.2. EDIT

The individually (or grouped) viewing and editing of the complexes is the same as the other heartbeats already in the program (see the Morphologies item in the User Manual - CardioSmart CS550).

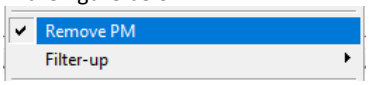
9.5.3. PACEMAKER FILTER AND SPIKES INDICATOR

To facilitate the visualization and acceptance (or not) of the diagnosis made by the heartbeat software, go to “ECG bar”, located at the bottom of the screen, where two new features are presented: “Pacemaker spikes indicator” and “Pacemaker filter”.

The Pacemaker spikes indicator appears as a red mark at the bottom of the ECG screen, at the heartbeat location where the digital recorder has detected the spike (the spike mark is highlighted with a circle in the figure).

However, if the “Pacemaker Filter” command is activated, this mark will be replaced by the spike in the tracing itself.

The “Pacemaker Filter” is activated by right-clicking on the “ECG bar” and then selecting the “Pacemaker Filter” option as shown in the figure below.



We can notice the changes that occurred in the ECG tracing, through the circles highlighted in the figure.

Observe through the ECG tracing figures that, by holding the mouse over the selected heartbeat spike, the Pop-up is triggered, indicating its data.

NOTE: These two features are also present in the tracing ZOOM.

9.6. PACEMAKER TABLE

9.6.1. SOME IMPORTANT CONCEPTS

For the correct understanding of the information provided in the Pacemaker Table columns ("S. F.", "Capt. F.", and "Sens. F."), some concepts should first be explained.

9.6.1.1. STIMULATION FAILURE

Lack of pacemaker spike.

9.6.1.2. CAPTURE FAILURE

Spike not followed by QRS.

9.6.1.3. SENSITIVITY FAILURE

There are two types:

Undersensing
Spike triggered before the expected moment because the pacemaker did not detect the previous QRS;

Oversensing
Spike triggered after the expected moment because the pacemaker has detected an electrical activity that it should not have.

9.6.2. PACEMAKER TABULAR SUMMARY REVIEW MODULE

The pacemaker tabular summary review module (Pacemaker Table) describes all events related to the pacemaker, being possible to check all the pacemaker spikes and failures of capture, sensitivity, and stimulation, hour by hour.

The Pacemaker Table is like the QRS Table, that is, it is also a Smart Table, as it allows data editing through the same commands described in the QRS Table (except some non-editable columns).

The columns in this table indicate the total amount of the respective event in the hourly (60-minute) recording.
They are:

QRS No.
Total number of QRS;

eA
Total number of atrial spikes

eV
Total number of ventricular spikes

eV/eT
Ventricular spikes percentage of the total;

NpeA
Total number of normal heartbeats preceded by atrial spike

VC
Total number of ventricular captures

VC (%)
Percentage of ventricular captures in relation to the total heartbeats

S. F.
Total Number of Pacemaker Stimulus Failures and Oversensing Failures;

Capt. F.
Total number of pacemaker Capture Failures; and,

Sens. F.
Total Number of Pacemaker Sensitivity Failures due to Undersensing.

Time	N° Qrs	eA	eV	eV/eT	NpeA	CV	CV (%)	F. E.	F. Capt.	F.Sens
3:25	2,548	2,853	2,899	50		2,548	100		1	
4:00	4,574	4,474	4,572	51		4,573	>99	15		
5:00	4,228	4,152	4,227	50		4,225	>99	7	1	
6:00	4,297	3,904	4,295	52		4,295	>99	66		
7:00	4,406	4,249	4,403	51		4,404	>99	25		
8:00	4,030	3,778	4,030	52		4,030	100	189		
9:00	3,818	3,577	3,817	52		3,817	>99	479		
10:00	3,791	3,552	3,791	52		3,791	100	170		
11:00	3,666	3,441	3,666	52		3,666	100	347		
12:00	3,853	3,545	3,852	52		3,852	>99	261		
1:00	3,603	3,590	3,603	50		3,603	100	469		
2:00	3,744	3,501	3,745	52		3,744	100	219	1	
3:00	3,614	3,565	3,613	50		3,612	>99	422		
4:00	3,608	3,541	3,608	50		3,608	100	651		
5:00	3,667	3,607	3,667	50		3,667	100	215		
6:00	3,626	3,576	3,626	50		3,626	100	265		
7:00	3,795	3,495	3,795	52		3,795	100	190		
8:00	4,152	3,777	4,152	52		4,152	100	97		
9:00	4,698	4,227	4,698	53		4,696	>99	125		
10:00	5,262	5,053	5,262	51		5,262	100	1		
11:00	4,794	4,523	4,794	51		4,794	100	1		
12:00	4,350	3,469	4,349	56		4,349	>99	18		
1:00	1,307	1,199	1,307	52		1,307	100	49		
Totals	89,431	84,648	89,771	51		89,416	>99	4,281	3	

The Pacemaker Table in the previous figure has ten columns. Each column's row quantity is equal to the number of hours in the record, plus the Totals row (sum of values for the entire column).
The maximum and minimum hourly values for each column are respectively in red and green.

9.6.3. TABULAR SUMMARY RESOURCES

9.6.3.1. COLUMN DATA EDITING

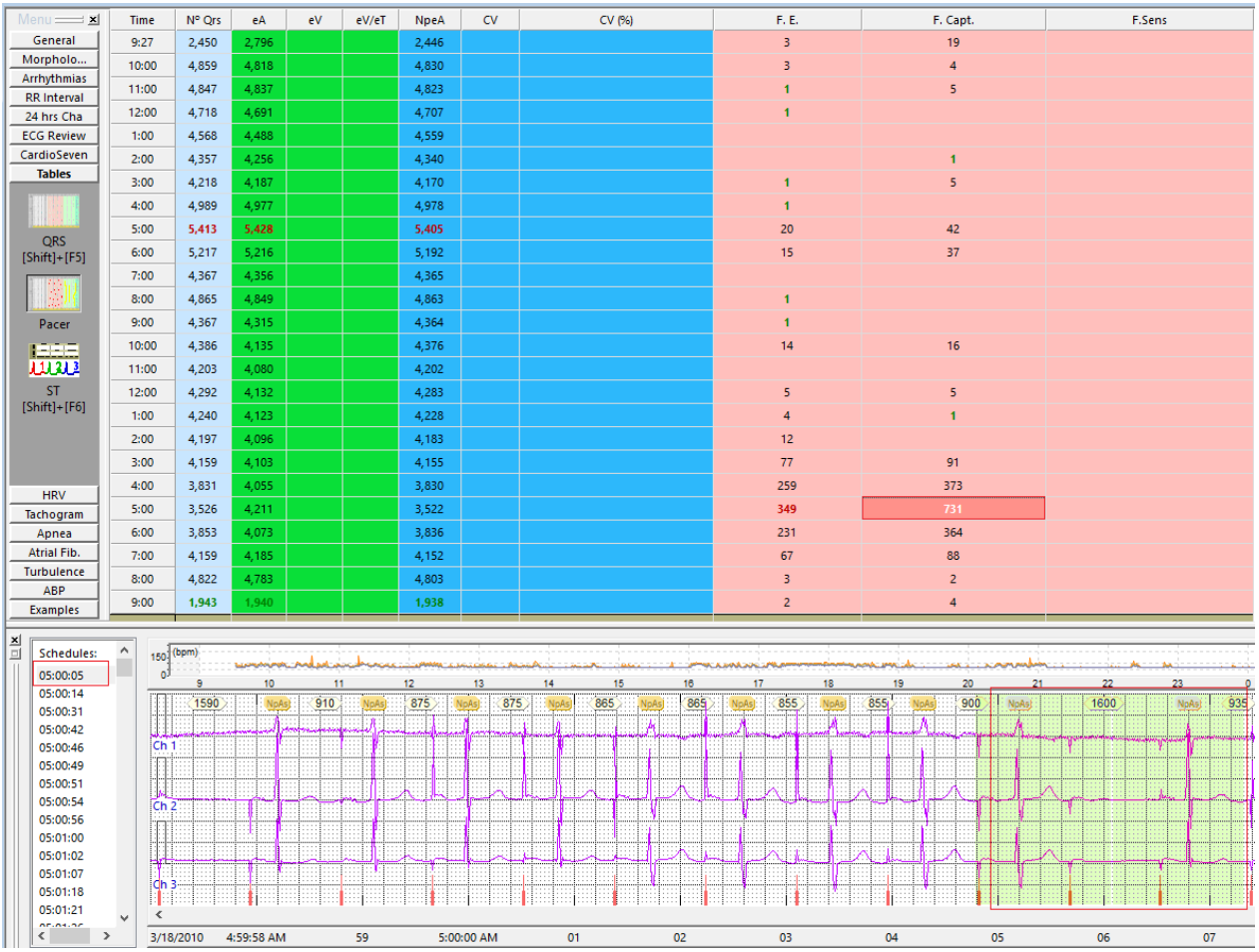
Except for the first, second, fifth, and seventh columns, all others can be changed.
To do this, double-click on the column and hour to be changed.

3:25	2,548	2,853	2,899	50		2,548	100		1	
4:00	4,574	4,474	4,572	51		4,573	>99	15		
5:00	4,228	4,152	4,227	50		4,225	>99	7	1	
6:00	4,297	3,904	4,295	52		4,295	>99	66		
7:00	4,406	4,249	4,403	51		4,404	>99	25		
8:00	4,030	3,778	4,030	52		4,030	100	189		
9:00	3,818	3,577	3,817	52		3,817	>99	479		
10:00	3,791	3,552	3,791	52		3,791	100	170		

The field selected by double-clicking the mouse is highlighted in the table shown in the previous figure. To change this field's values, just insert the desired value or delete the existing one to clear the field.

9.6.3.2. TIME EVENTS VIEW ON THE ECG BAR

This feature allows you to list all the times in which Pacemaker-related events have occurred.



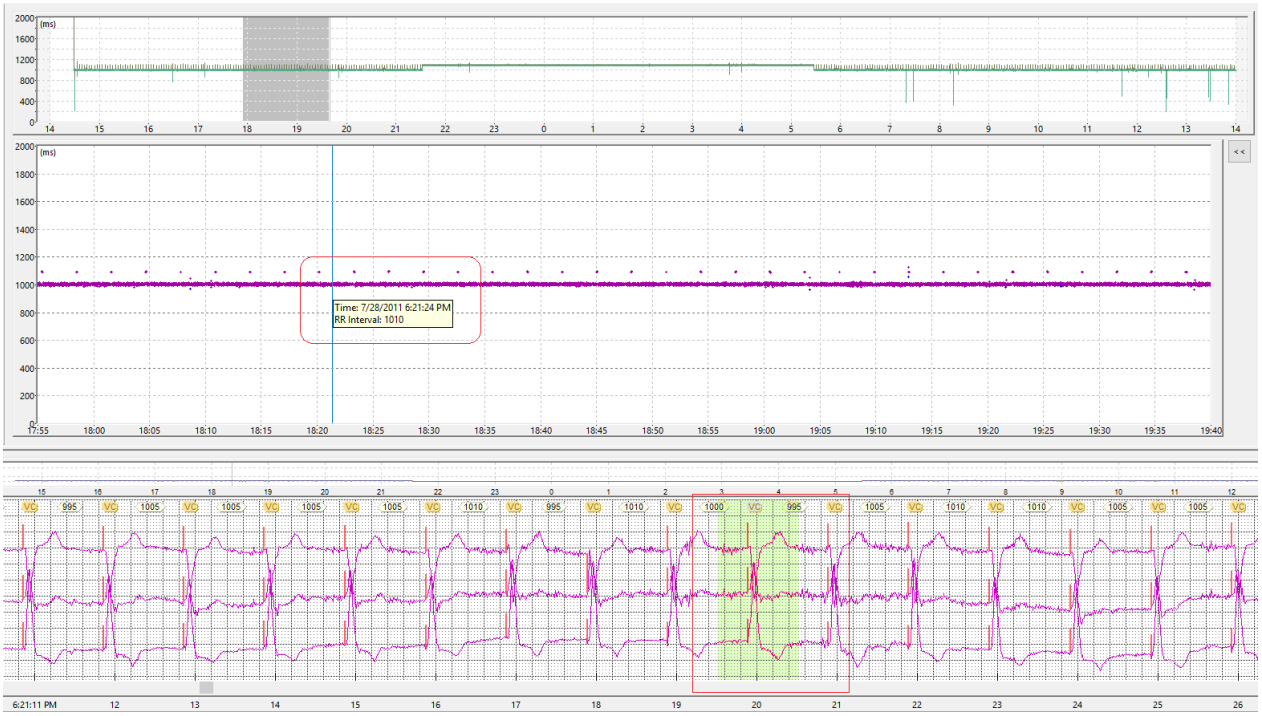
By clicking on any field in the columns “NpeA”, “VC”, “S. F.”, “Capt. F.”, or “Sens. F.”, the event times will appear in the lower left corner of the screen (if the ECG bar is active).

In the Times List, are all events in the table's selected field in chronological order. Selecting any time in this list will show the event in the ECG Bar, highlighted in green.

9.7. PACEMAKER TACHOGRAM

The Pacemaker Tachogram represents the intervals values of the pacemaker spikes and allows the pacemaker activity analysis in the patient.
It consists of two charts:

Compressed Pacemaker Tachogram or 24h Pacemaker Tachogram, at the top of the screen; and,
Extended Pacemaker Tachogram or Pacemaker Tachogram of the Selected Period, in the lower area.



The pacemaker spike interval values are measured in ms (vertical scale) and are related to the recording time (horizontal scale). The Compressed Tachogram has a fixed time scale: 24h, which comprises the entire recording. The Expanded Tachogram has a variable time scale, from a minimum of 30 seconds, to a maximum of the entire recording, 24h.

9.8. ECG BAR

To facilitate the visualization of a given pacemaker spike interval value by the user, the software allows the use of the Tachograms in conjunction with the ECG Bar.

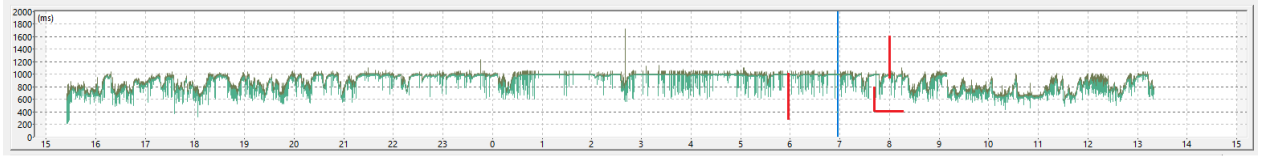
The pacemaker interval selected with the mouse on the Extended Pacemaker Tachogram (yellow or blue line) appears below the ECG Bar in Green, allowing a more detailed view of the selected interval value.

The previous figure represents the Pacemaker Tachogram tool of the CardioSmart CS550 software, with the two charts available for analysis of the pacemaker's functioning during the 24-hour exam.

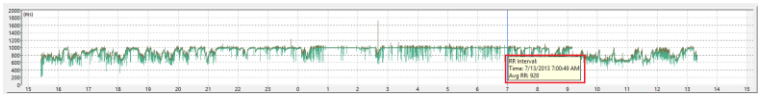
NOTE: The Pacemaker Tachogram will only present values for exam with pacemaker activity, be it Dual Chamber, Atrial or Ventricular.

9.9. COMPRESSED PACEMAKER TACHOGRAM

This chart is represented by maximum, minimum, and mean values of intervals between the pacemaker spikes (represented respectively by red, pink, and the dividing line between the two shades), as shown in the figure below.



NOTE: The mouse pointer shows where the mean values of intervals between the pacemaker spikes occur.

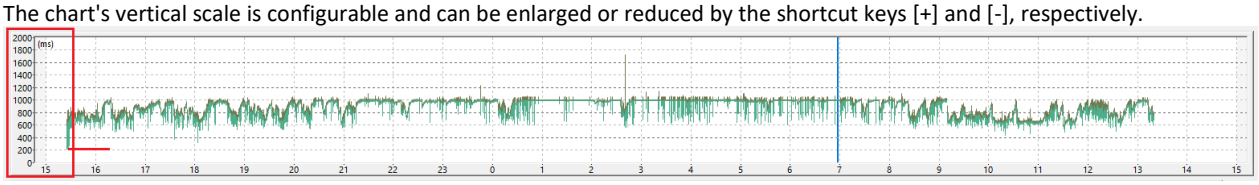


This figure shows the pop-up feature (yellow rectangle) requested after selecting a specific chart location (blue line).

9.10. COMPRESSED PACEMAKER TACHOGRAM FEATURES

9.10.1. COMPRESSED PACEMAKER TACHOGRAM VERTICAL SCALE

The chart's vertical scale is configurable and can be enlarged or reduced by the shortcut keys [+] and [-], respectively.



The figure above represents the Compressed Pacemaker Tachogram with the scale changed through the shortcut keys.

NOTE: To change the Pacemaker Tachogram scale you should first click on any point of it to activate the focus.

9.10.2. POP-UP

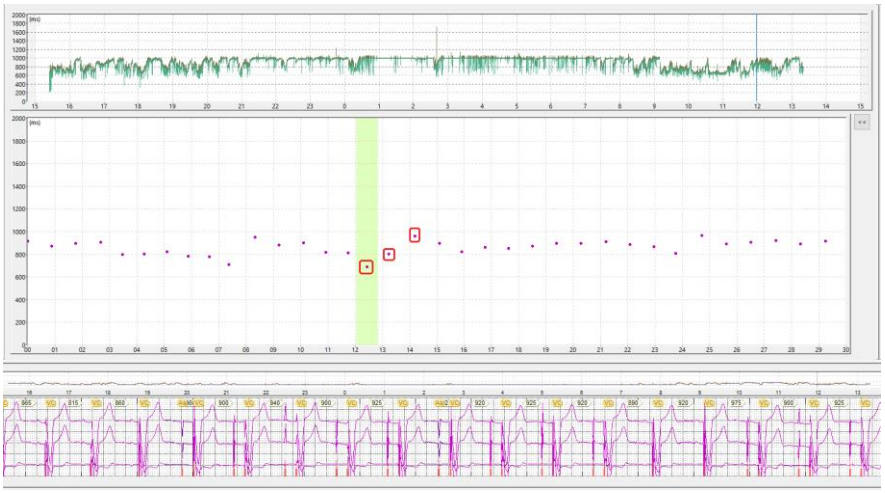
This feature allows the visualization of pacemaker interval between spikes time and average value with the mouse.
To do this, select a chart location which you want information about, and hover the mouse over it.
The screen will then pop-up with the data from the interval between the pacemaker spikes.

9.11. EXPANDED PACEMAKER TACHOGRAM

The Extended Pacemaker Tachogram shows the pacemaker spikes representative points. These points have the characteristic color of the heartbeat in which the spike occurred, for example, in a Ventricular Capture, the color of the point representing the spike will be pink and in the case of the Supraventricular heartbeat, it will be green.

The figure on the left shows the Expanded Pacemaker Tachogram. The points in this chart refer to the Ventricular Captures (pink dots), and a Supraventricular Extrasystole that deflagrates a pacemaker spike with Ventricular Capture (green).

The Expanded Pacemaker Tachogram is represented by the relation between the values of the intervals between the pacemaker spikes, in milliseconds, and the time selected in the Compressed Tachogram. Thus, the selected point on the Compressed Pacemaker Tachogram is automatically displayed in the Extended Pacemaker Tachogram, enabling a more detailed view of the interval selection (specific pacemaker time and interval).



The figure on the left shows the Compressed and Expanded Pacemaker Tachograms. The selected time interval on the Compressed Pacemaker Tachogram (blue vertical line) appears expanded on the Extended pacemaker Tachogram.

9.12. EXPANDED PACEMAKER TACHOGRAM FEATURES

9.12.1. ZOOM - PRECISELY SELECTING A SPECIFIC POINT IN THE CHART

To better observe a period of the Compressed Tachogram, just select an area of it with the mouse. This will create the Extended Pacemaker Tachogram in the lower field of the chart.

If a greater definition is required, an Extended Tachogram excerpt can be selected with the mouse and pressing the [Enter] key; this will expand the selected area to the full chart width. This operation can be repeated as many times as necessary to identify the desired pacemaker time or interval (distinction between two consecutive pacemaker spikes).

The interval selected in the Compressed Tachogram in the figure above (gray excerpt identified by the mouse pointer) appears enlarged in the Expanded Tachogram Chart.

9.12.2. EXPANDED PACEMAKER TACHOGRAM SCALE

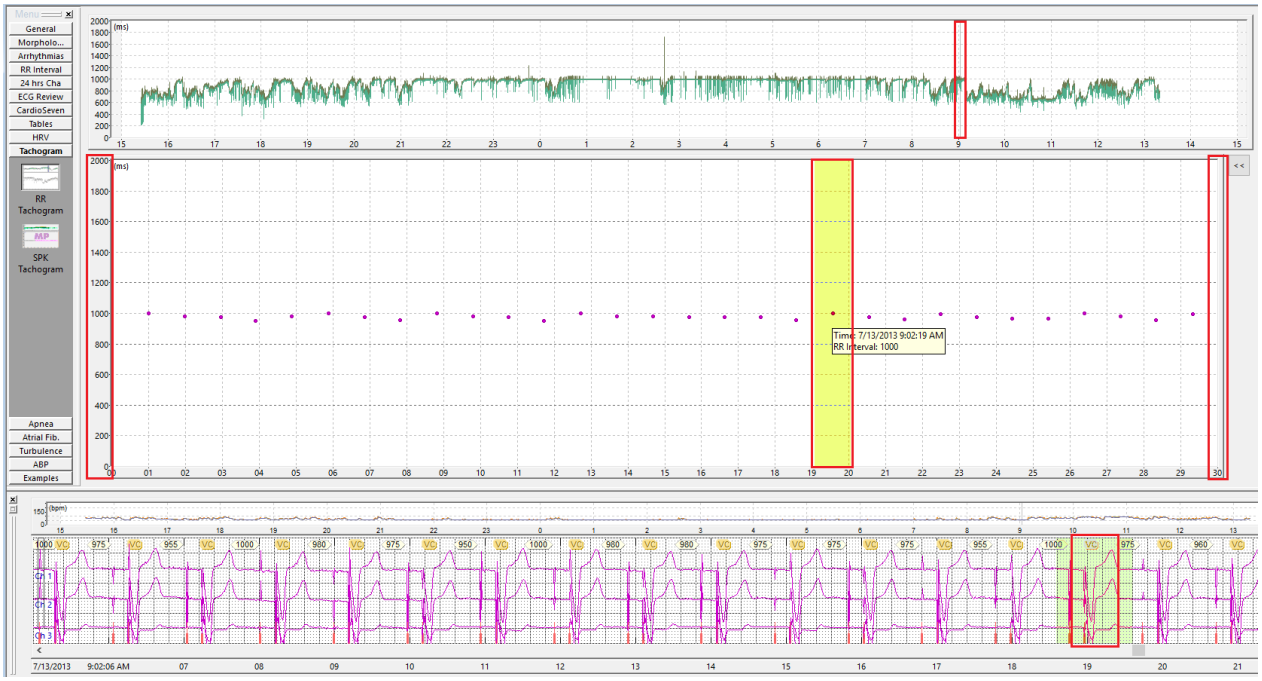
As in the Compressed Pacemaker Tachogram, in this chart the vertical scale change is also possible, using the same Compressed MP Tachogram features, which are the [+] and [-] shortcut screens.

9.12.3. HEARTBEATS RECLASSIFICATION

After reaching the Resolution Limit with the Zoom, the heartbeat reclassification occurs by choosing it with the mouse and then changing it by using the keyboard shortcut keys.

9.12.4. CURSOR NAVIGATION IN EXPANDED PACEMAKER TACHOGRAM

To optimize the user observation through the several hours represented in the Tachogram Chart, it presents the navigation feature between the screens; just click on the left and right edges of the Tachogram Chart.



The arrows on the Pacemaker Tachogram Chart in the figure above indicate the right and left limits on which the user should click to navigate along the chart.

Thus, in order to visualize the values of the intervals between the pacemaker spikes in an interval before the currently presented, the user can either use the keyboard left arrow or click on the chart left border indicated by the left arrow.

If the ECG Bar is active, the tracings times will follow those from the Tachogram.
The selected time interval on the Compressed Pacemaker Tachogram appears expanded on the Expanded Pacemaker Tachogram and highlighted (in green) on the ECG Bar.

10. ATRIAL FIBRILLATION

The evaluation of patients with atrial fibrillation is very important, since it is the most common sustained arrhythmia in clinical practice. It usually has a progressive evolution, defined by the presence of paroxysmal episodes, until it finally becomes persistent

Therefore, observing its behavior during continuous recording, or even detecting asymptomatic episodes, can bring important information, with prognostic and therapeutic implications.

Based on these criteria, Cardios developed a software capable of assisting the analyst physician in carrying out these studies.

The heart rate assessments at different day times, the behavior during sleep, as well as the presence of paroxysmal atrial fibrillation (AF) episodes, can be easily identified in a Holter, allowing the implementation of appropriate pharmacological therapy or even pacemaker implants.

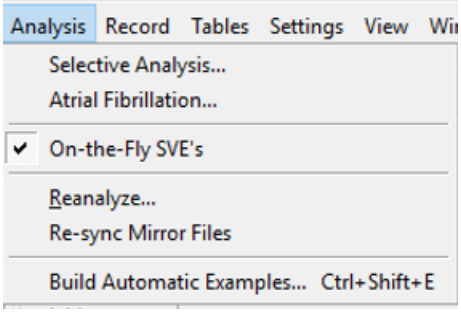
The basis of the developed algorithm is the detection of atrial fibrillation episodes, based on the statistics of NN intervals distribution. This will be another facilitator of this module to the analyst physician, because the elimination of supraventricular arrhythmias will be automatic in the periods detected by the software as atrial fibrillation.

In the figure to the left, there is the tab of the Atrial Fibrillation analysis component, highlighted in green, through the system navigation menu.

10.1. ATRIAL FIBRILLATION COMPONENT SETTING - INDIVIDUAL MODE

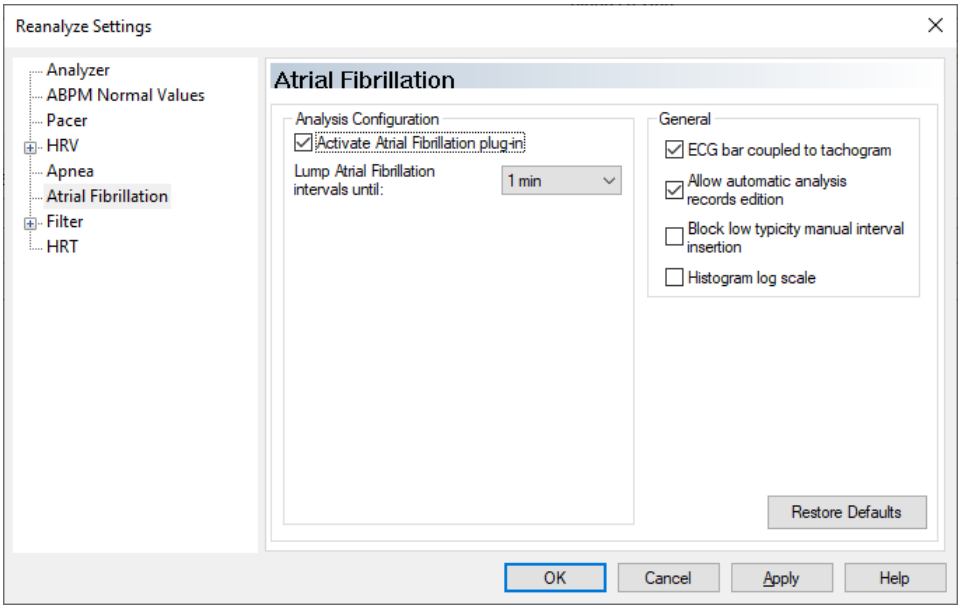
The user can setup the activation of the Atrial Fibrillation software individually, that is, it will not be standardized for all exams. The user will only activate this tool with the exam being analyzed opened, and whenever he/she wishes.

The AF software activation can be done by the user in two ways:

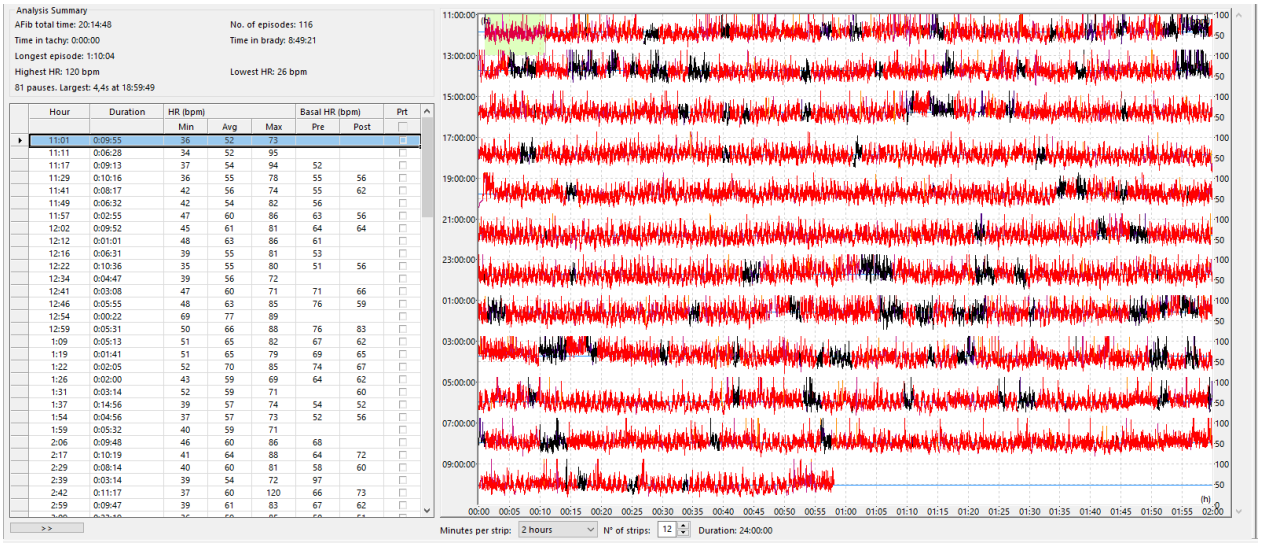


1. When detecting the presence of atrial fibrillation in the exam, the user should click on: [Analysis] [Reanalyze]

2. Click on the [Enable Atrial Fibrillation component] option and any other desired item within the module.
Click on [OK]

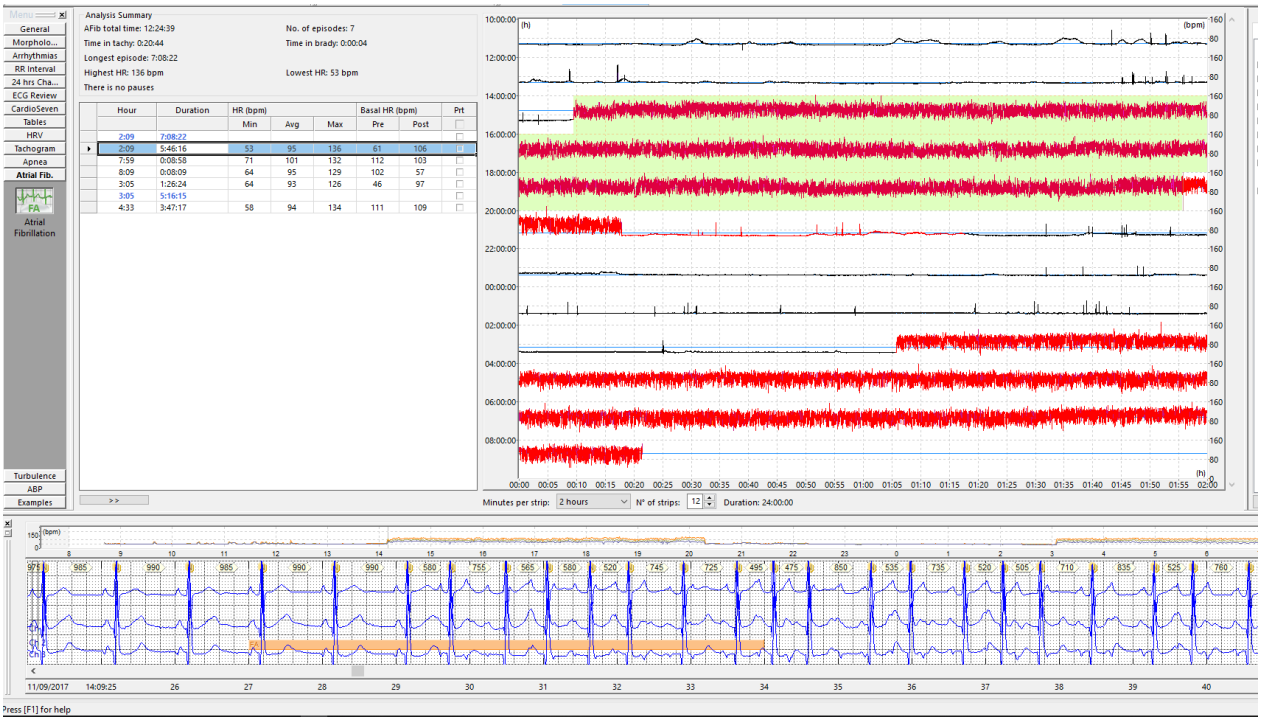


Immediately after this selection, it is possible to access the atrial fibrillation component in the navigation menu, and the episodes automatically detected by the software will be displayed according to table and tachogram exemplified below.



10.2. ATRIAL FIBRILLATION MODULE OVERVIEW

After the automatic analysis, a table showing the atrial fibrillation suggestive episode(s), detected by the AF software according to chart (table/tachogram), below will be displayed. We will look at each of these tools in detail.

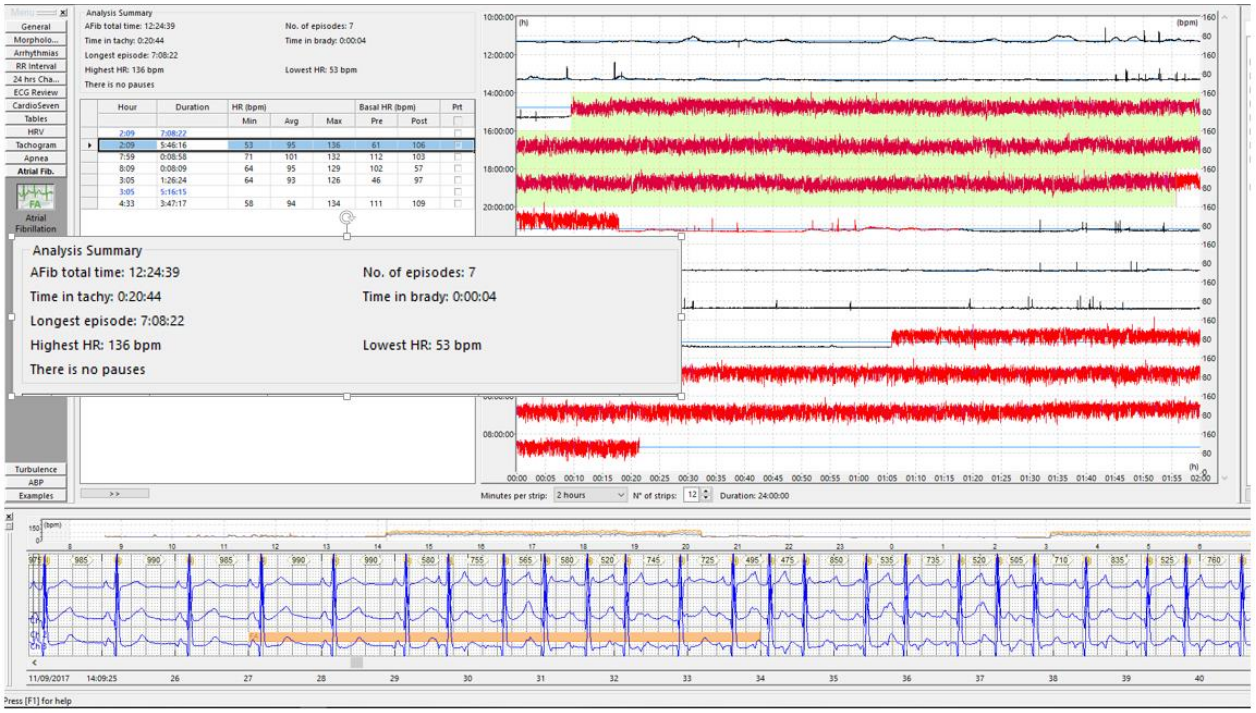


10.2.1. ANALYSIS SUMMARY

The information in this summary refers to the atrial fibrillation episodes detected by the software.

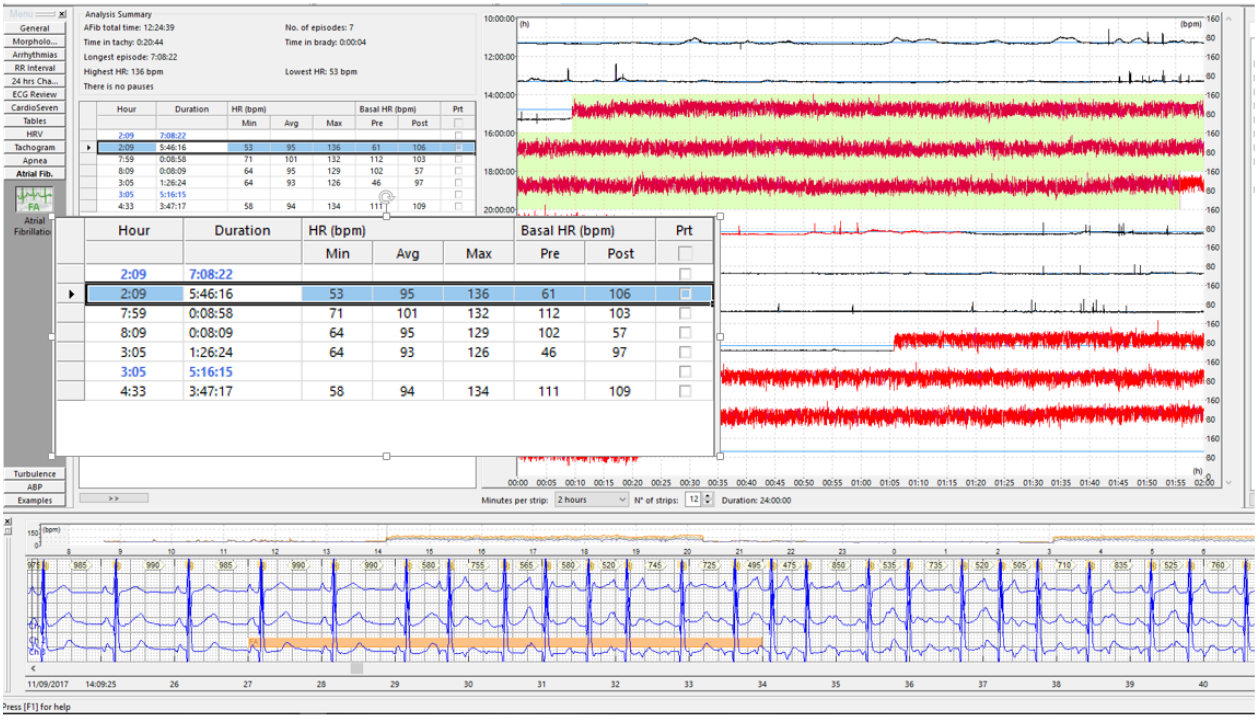
It includes:

- Total fibrillation time during the recorded period (which may be a single event in the case of persistent atrial fibrillation, or several episodes in the case of paroxysmal atrial fibrillation);
- How many AF episodes were detected during the exam;
- Total tachycardia and/or bradycardia (based on all detected events) based on system preconfiguration (bradycardia setting and default tachycardia, that is, standardized in CardioSmart CS550 software);
- The longest AF episode duration;
- The highest and lowest HR observed among the AF episodes detected by the software;
- Pauses during events, duration and time.



10.2.2. TABLE OF ATRIAL FIBRILLATION EPISODES DETECTED BY SOFTWARE

The fibrillation episodes detected by the software are listed below in an analyzed exam example:



In this table, it is possible for the analyst physician to verify detailed information of each detected episodes:

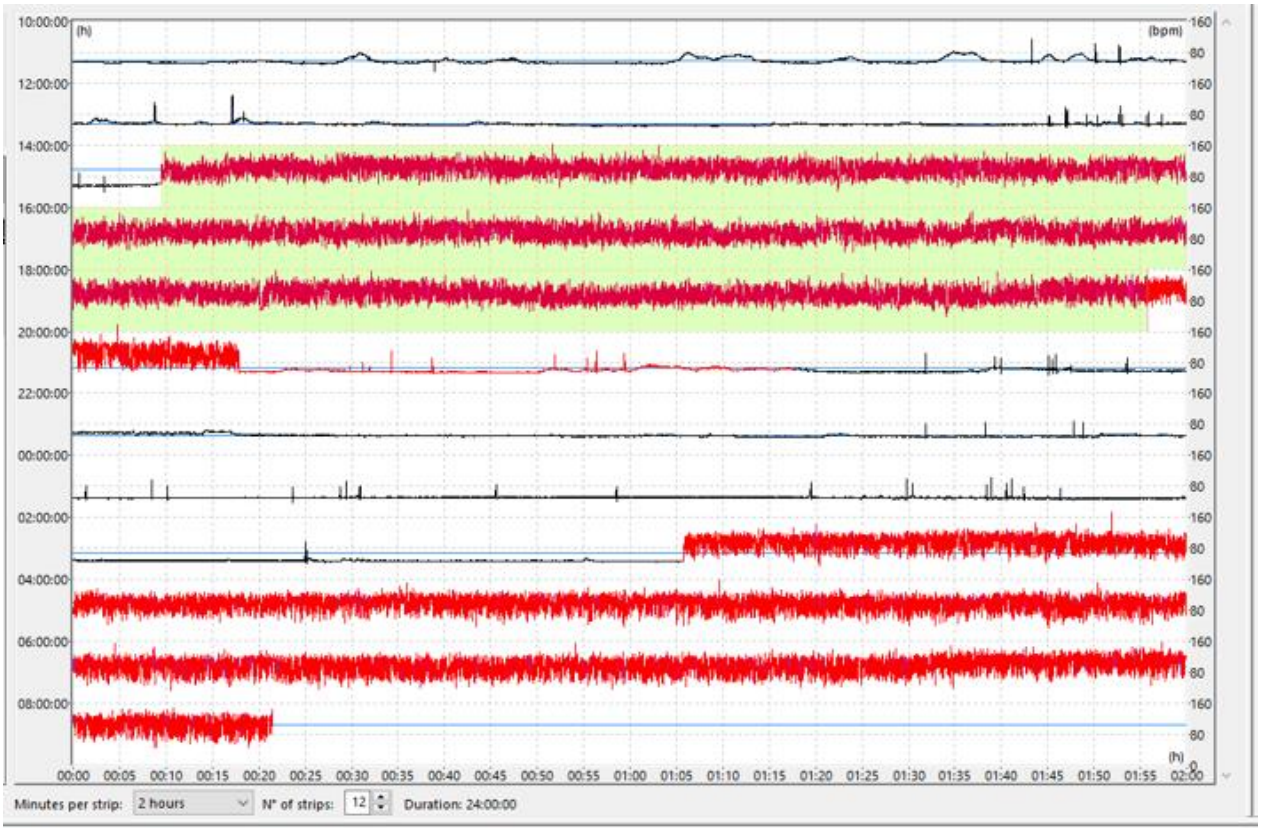
- Minimum, mean, and maximum HR and duration of the detected event.
- The previous HR (pre-basal HR) at the onset of atrial fibrillation, and HR (post-basal HR) immediately after the atrial fibrillation episode.

Each listed event can be selected individually (when clicked), and will be shown simultaneously on the tachogram (on the right side of the screen), and on the ECG bar (at the bottom of the screen) that will show the beginning and/or end of the electrocardiographic tracing corresponding to the episode.

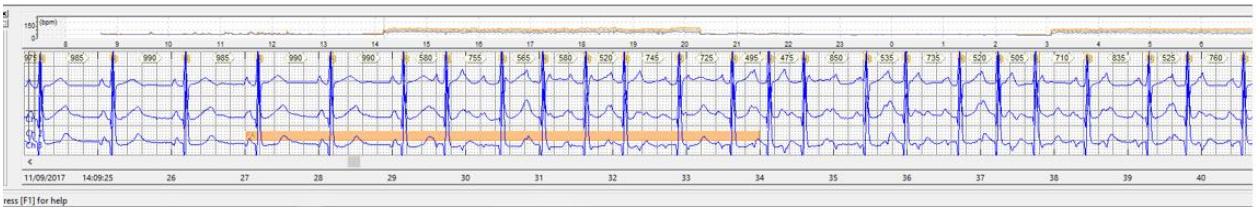
	Hour	Duration	HR (bpm)			Basal HR (bpm)		Prt
			Min	Avg	Max	Pre	Post	
	2:09	7:08:22						
▶	2:09	5:46:16	53	95	136	61	106	
	7:59	0:08:58	71	101	132	112	103	
	8:09	0:08:09	64	95	129	102	57	
	3:05	1:26:24	64	93	126	46	97	
	3:05	5:16:15						
	4:33	3:47:17	58	94	134	111	109	

NOTE: In order for the ECG to match the selected period, it should have been pre-configured (as we will see in the settings chapter).

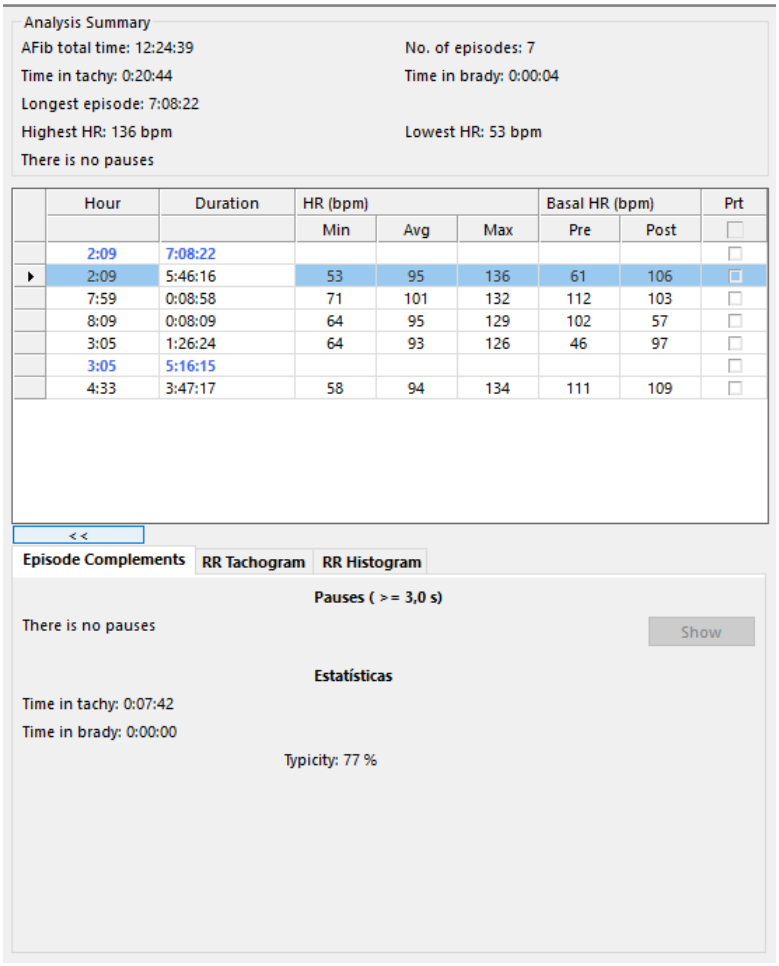
Tachogram



ECG bar



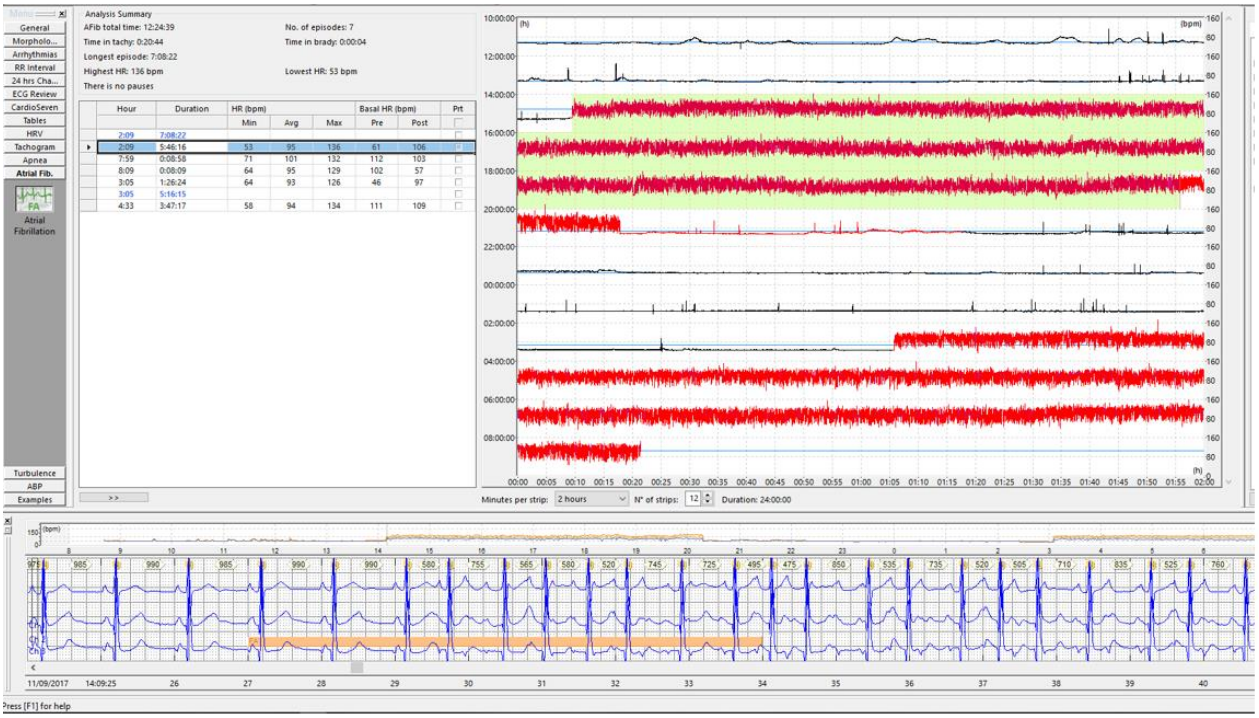
- The module will always display the atrial fibrillation episode start, that is, the suggestive transition moment of atrial fibrillation rhythm or vice versa



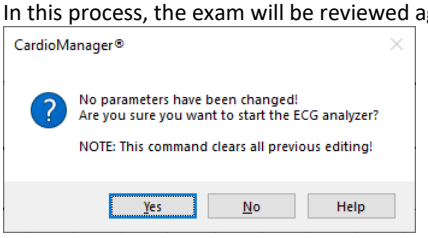
For visualization of these rhythm transition periods, just click once on a certain time of the table. The beginning of the episode is then displayed. With a new click on the time (side-header, on the symbol >), the program will locate the end of the episode, that is, the AF event reversal for sinus rhythm.

Still referring to the table, when a certain time is selected, the user can obtain an individualized statistical information of the episode, such as the total in tachycardia and/or bradycardia, the existence of pauses in that period, and the typicality, that is, how much this episode is approaching atrial fibrillation (with randomly varying RR intervals).

NOTE: The information displayed in each AF event, such as tachycardia, bradycardia, and pauses, are based on the General Setting (default) made in the Settings / System / CardioSmart item.

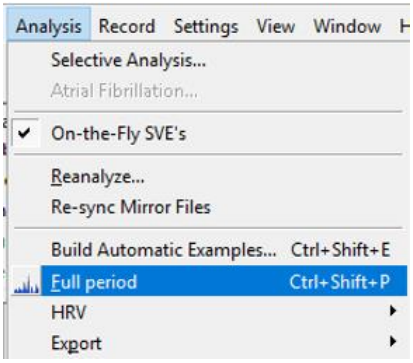


Attention in the need to revert the edits or change some data previously configured is necessary the data reanalysis data. (With the exam opened, the user will select <Analysis>, <Reanalyze>, <Atrial fibrillation>, and <OK>).
In this process, the exam will be reviewed again and the detected episodes suggestive of atrial fibrillation will be displayed.



If no parameter is changed, a warning will show informing that all edits made will be lost.

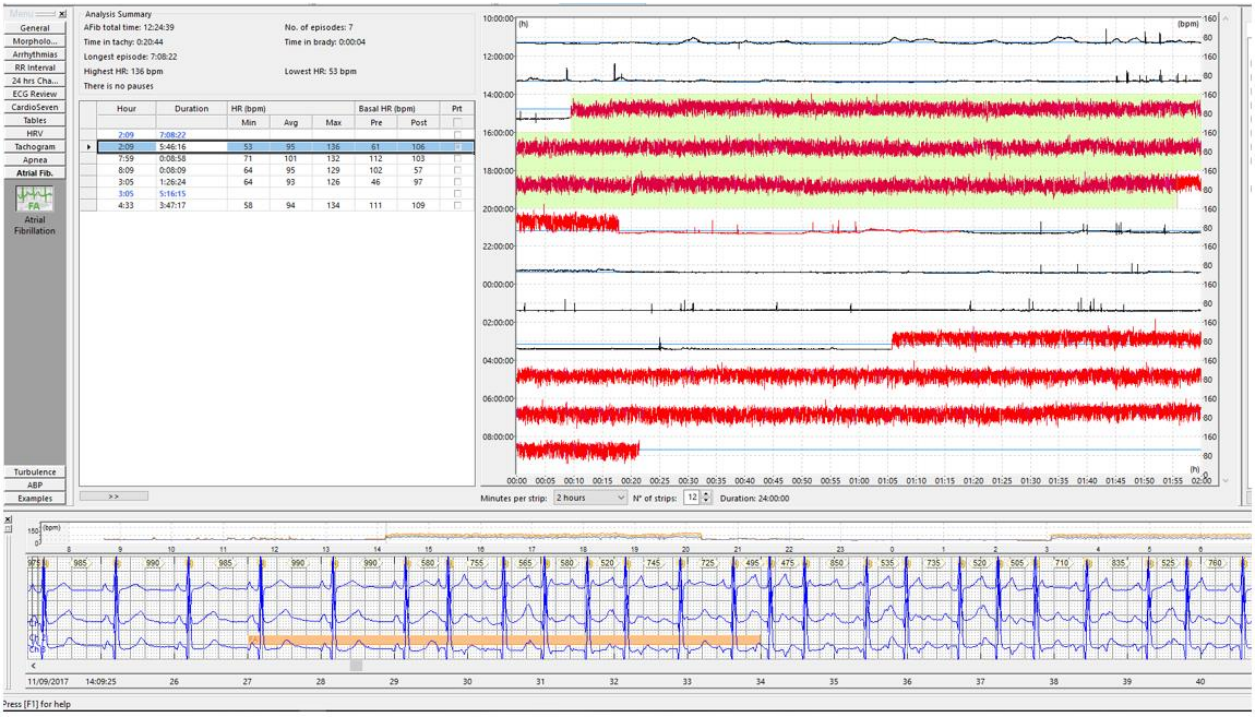
Unless there really is the analyst's intention to go back to the initial analysis state, click on the option <No>.



If the intention is only to reanalyze atrial fibrillation data without changing parameters, use the total period option from the analysis item in the main menu.

In this way, the software will reanalyze only the items related to atrial fibrillation.

NOTE: For the command to reflect only on the atrial fibrillation module, the user should have the atrial fibrillation window selected.



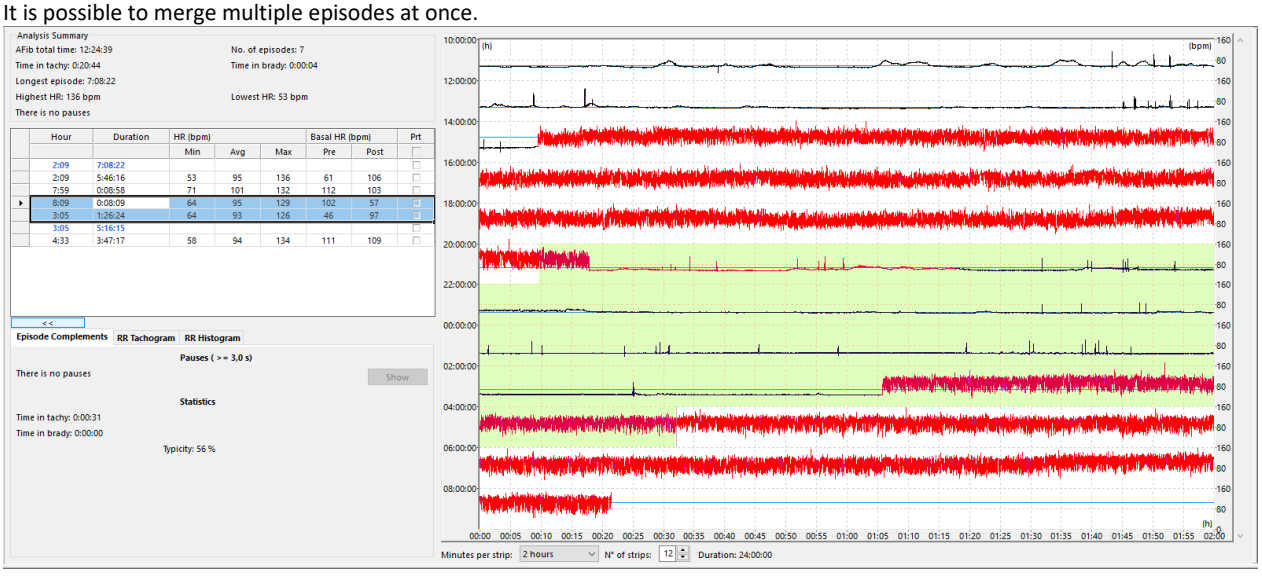
10.2.2.1. TABLE EDITING

MERGE EPISODES

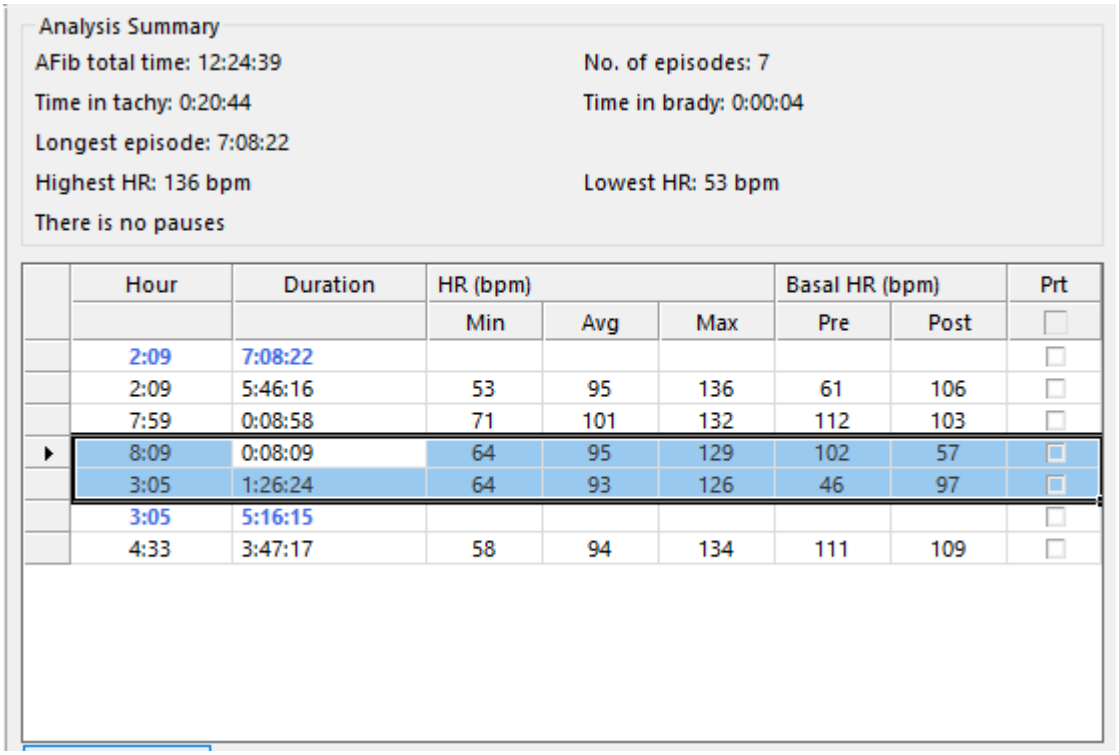
After the conference of the episode(s) identified and selected by the software, the user can merge episodes by turning two or more AF events into one.

This tool can be used in episodes that have been fragmented due to interference or periods of rhythmicity.

To perform this process, just click on the times the episodes were fragmented, drag them up or down, combining the periods pre-evaluated by the user as AF.
The selected events (which will be in distinct colors) will merge into one and will count as one single episode.
It is possible to merge multiple episodes at once.



IMPORTANT: When performing this maneuver, carefully observe the context ECG, to make sure the involved episode is really an atrial fibrillation.



Analysis Summary

AFib total time: 12:24:39 No. of episodes: 7

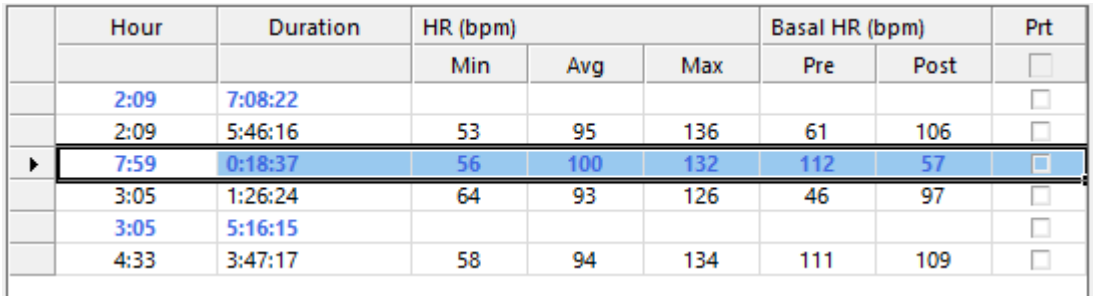
Time in tachy: 0:20:44 Time in brady: 0:00:04

Longest episode: 7:08:22

Highest HR: 136 bpm Lowest HR: 53 bpm

There is no pauses

Hour	Duration	HR (bpm)			Basal HR (bpm)		Prt
		Min	Avg	Max	Pre	Post	
2:09	7:08:22						
2:09	5:46:16	53	95	136	61	106	
7:59	0:08:58	71	101	132	112	103	
8:09	0:08:09	64	95	129	102	57	
3:05	1:26:24	64	93	126	46	97	
3:05	5:16:15						
4:33	3:47:17	58	94	134	111	109	



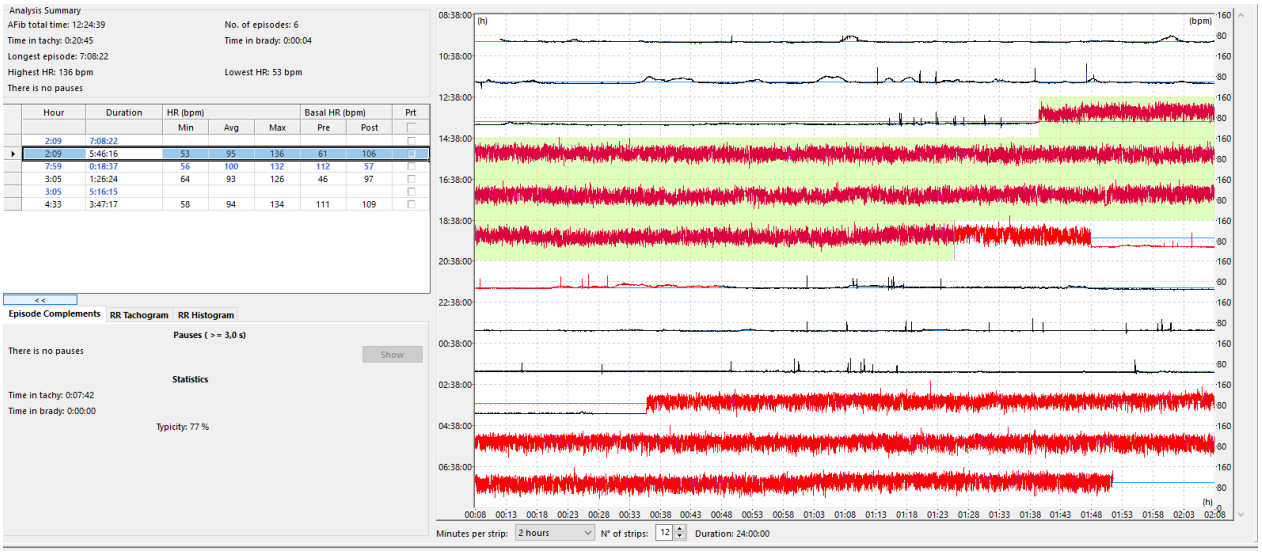
Hour	Duration	HR (bpm)			Basal HR (bpm)		Prt
		Min	Avg	Max	Pre	Post	
2:09	7:08:22						
2:09	5:46:16	53	95	136	61	106	
7:59	0:18:37	56	100	132	112	57	
3:05	1:26:24	64	93	126	46	97	
3:05	5:16:15						
4:33	3:47:17	58	94	134	111	109	

10.2.2.2. DELETE EPISODES

Still in relation to the table, by checking the episodes detected by the software, it is possible to delete events listed by mistake.

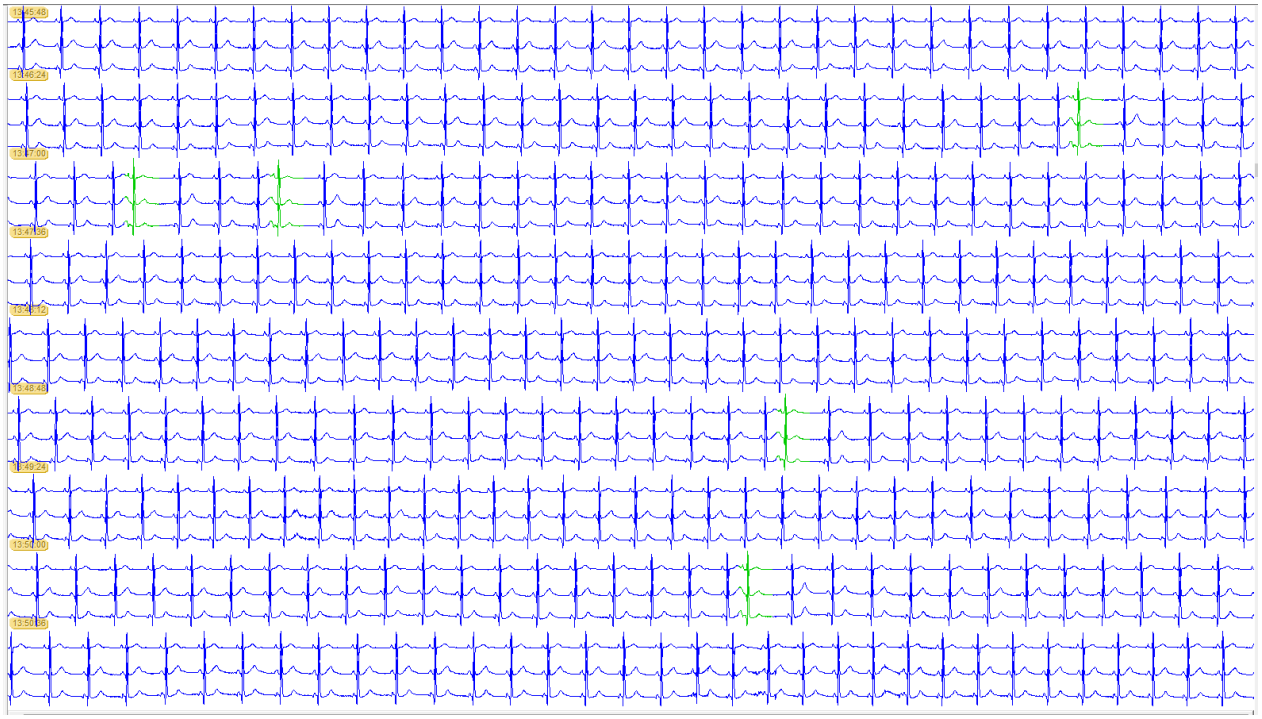
To delete a manual episode or an automatically detected by the software, just click on the desired time and press the delete key.

Just deleting an episode from the table causes the software to consider the period selected as NON ATRIAL FIBRILLATION. This excluded period will follow the editing performed in the conventional way.



ATTENTION: For this deletion to be performed directly in the table in episodes detected automatically, the option "Allow removal of automatic analysis records" should have been previously enabled in the AF software configuration. Otherwise, deleting episodes directly in the table will only work on manually selected events.

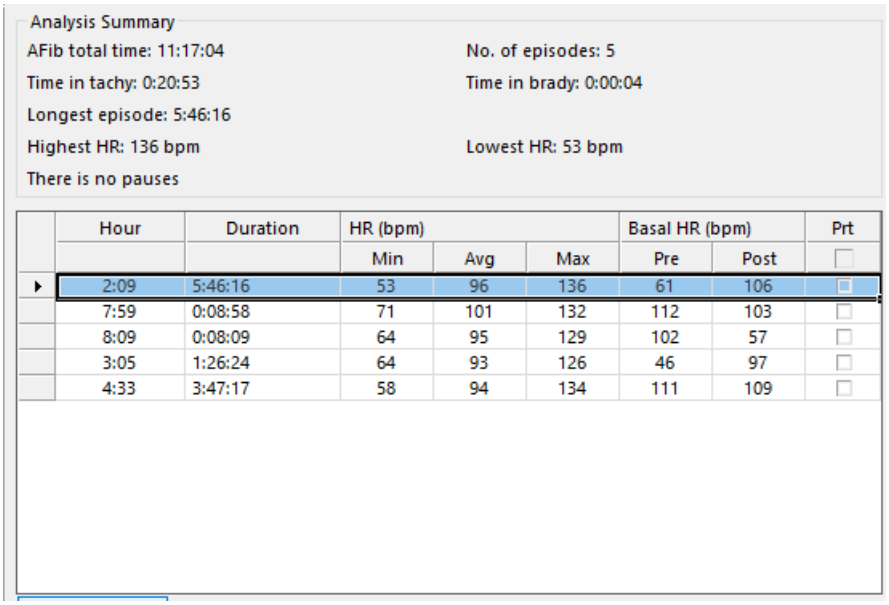
After deleting the desired episode from the table, the software will consider the supraventricular arrhythmias of the period (if any).

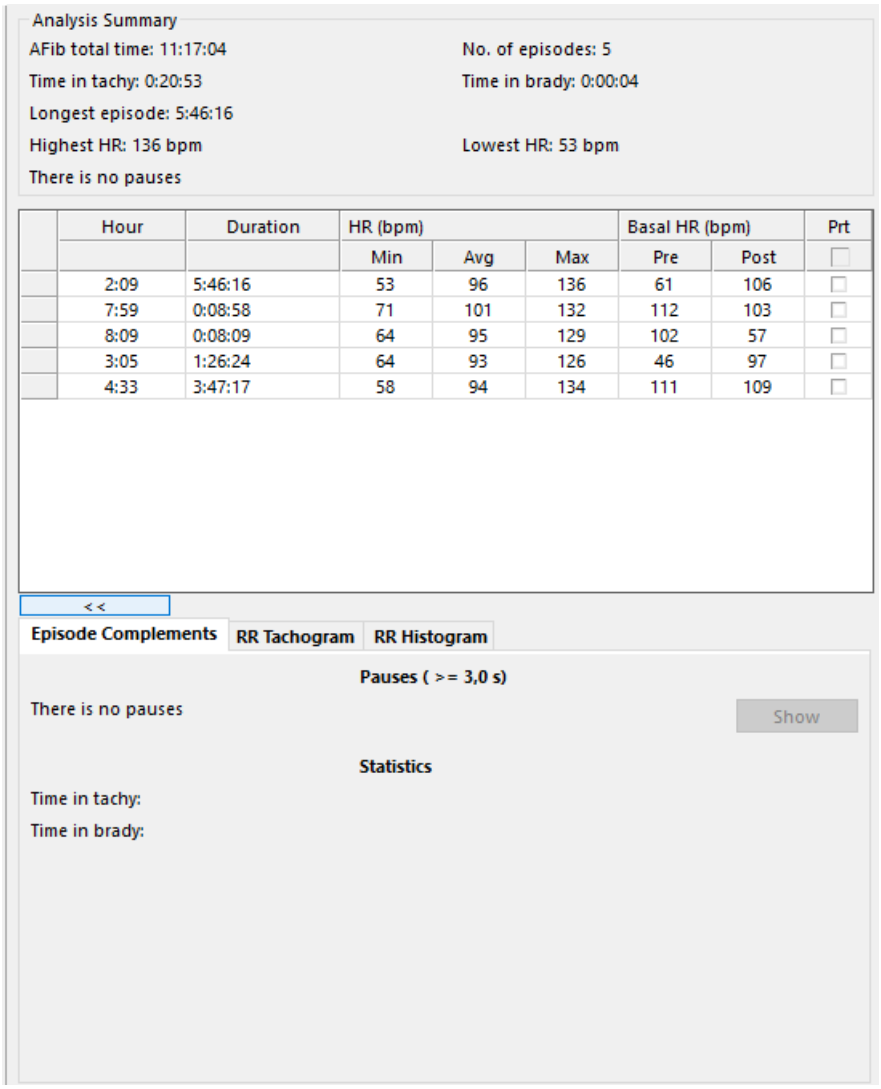


10.2.2.3. TABLE AND TOOLS

Below the table of detected atrial fibrillation times, a button allows you to expand the number of all episodes at once through the table vertical space.

For this expansion to be possible, the tabular control is hidden.
To show the tabular control again and reduce the table display, just click on the [>>] button again. This function is very useful in notebooks, which screen vertical resolution is usually low.





Analysis Summary

AFib total time: 11:17:04 No. of episodes: 5

Time in tachy: 0:20:53 Time in brady: 0:00:04

Longest episode: 5:46:16

Highest HR: 136 bpm Lowest HR: 53 bpm

There is no pauses

	Hour	Duration	HR (bpm)			Basal HR (bpm)		Prt
			Min	Avg	Max	Pre	Post	
	2:09	5:46:16	53	96	136	61	106	
	7:59	0:08:58	71	101	132	112	103	
	8:09	0:08:09	64	95	129	102	57	
	3:05	1:26:24	64	93	126	46	97	
	4:33	3:47:17	58	94	134	111	109	

<<

Episode Complements | RR Tachogram | RR Histogram

Pauses (>= 3,0 s)

There is no pauses Show

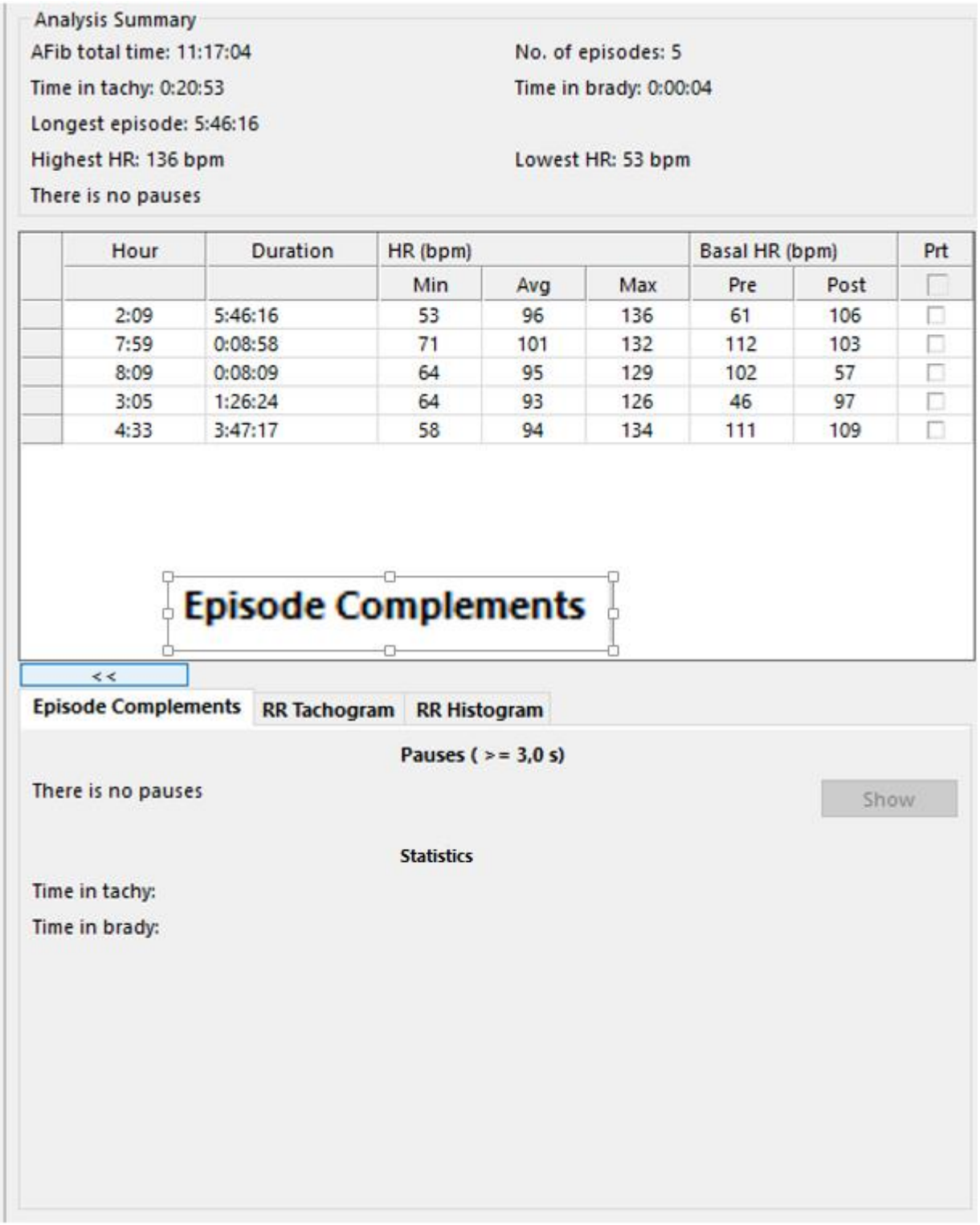
Statistics

Time in tachy:

Time in brady:

10.2.3. EPISODE COMPLEMENTS BAR

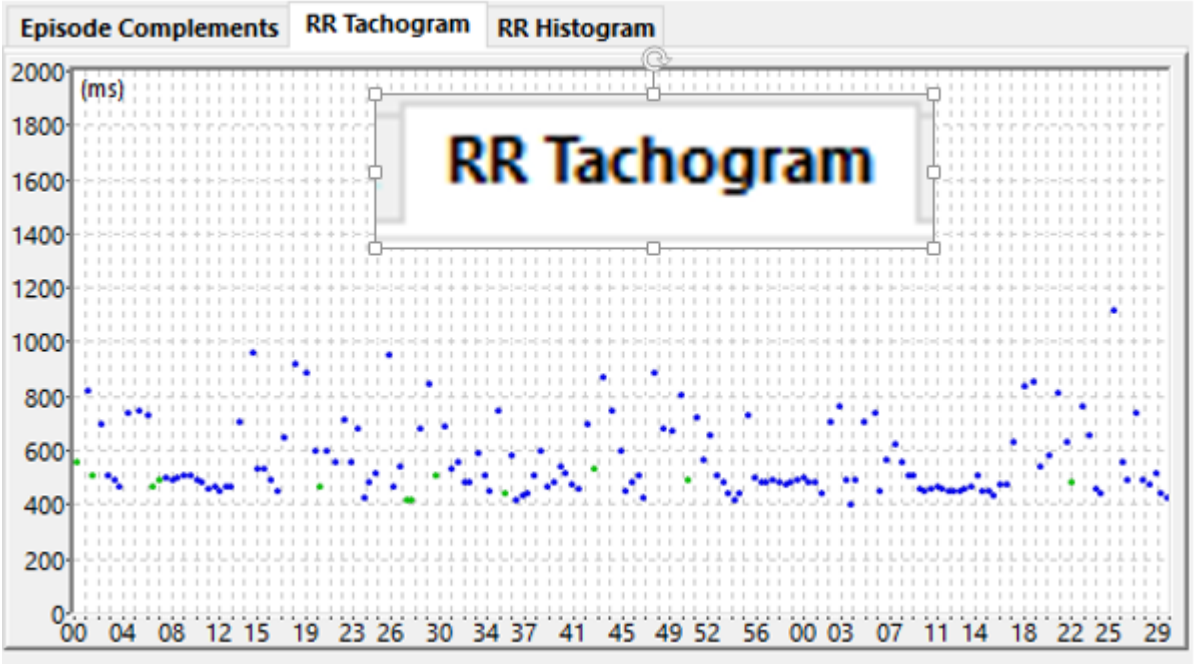
In episode complements, we find individual information about atrial fibrillation episodes detected by the software. That is, if there was a pause in that specific time, and the time in tachycardia and/or bradycardia (if any)



10.2.4. RR TACHOGRAM

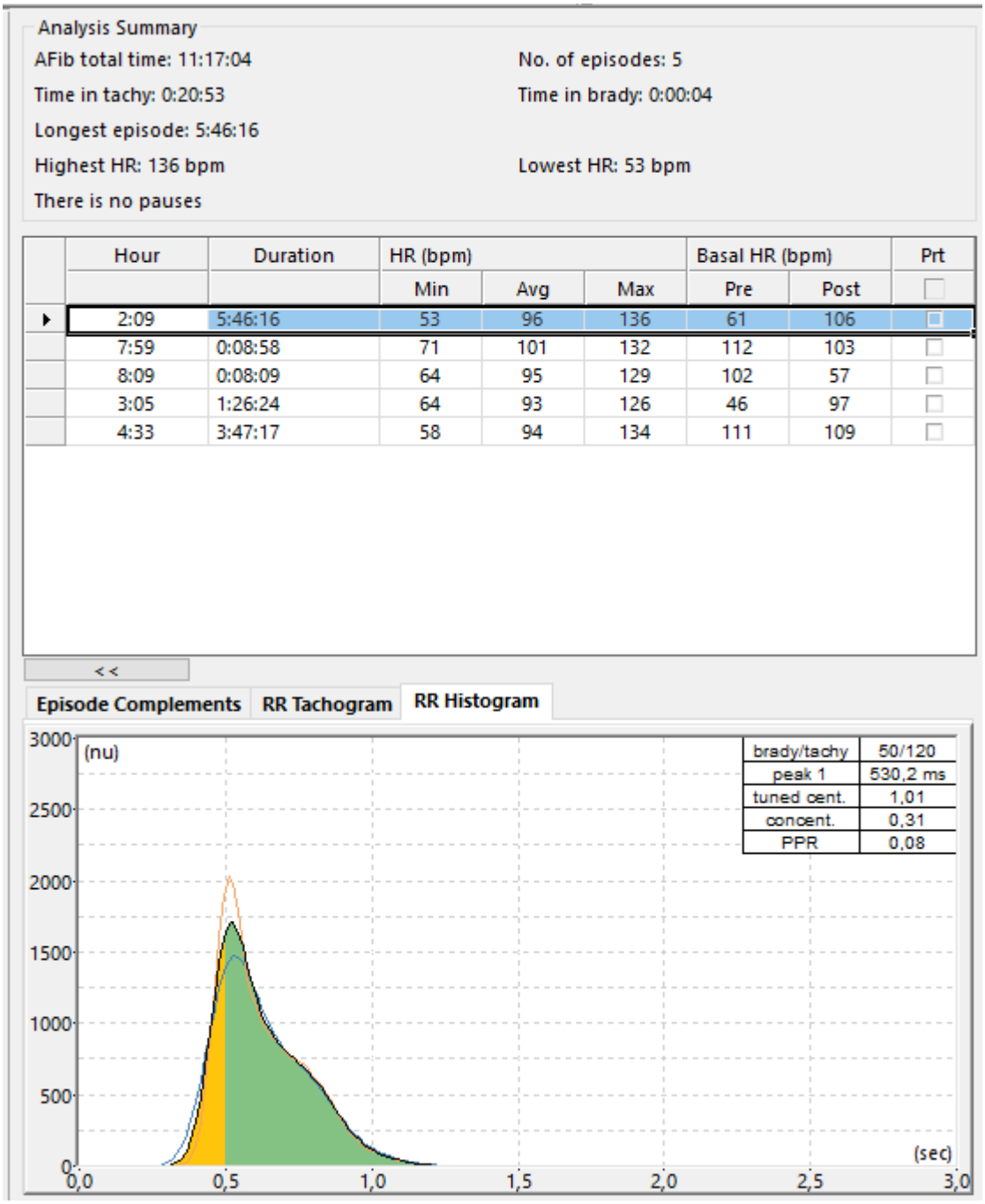
RR TACHOGRAM of a selected episode

The tachogram will display changes in the RR intervals of the selected period. In this tachogram, it is possible to visualize the extreme behaviors of HR variations typical of AF.



10.2.5. RR HISTOGRAM

HISTOGRAM of a selected episode.
The Histogram will show the incidence of RR intervals during the fibrillation period.



Yellow area
Tachycardia area (low RR)

Green area

Normal HR area

Blue area
Bradycardia area (high RR)

Peak 1
The first peak (greater occurrence of RR intervals)

Peak 2
The second peak (if any) (greater occurrence of RR intervals)

Turned cent.
Weighted number of peaks in three histograms with different smoothing levels

Concentration
How much the histogram is concentrated around the peaks: the greater this number, the more predictable the sequence of RR values is. In typical atrial fibrillation events, this value tends to be less than one.

PPR (Peak-to-Peak Ratio)
Ratio between the transformed peaks when there is more than one defined peak. This value is related to the regularity patterns found in the RR intervals variation, that is, when this value is greater than zero, the RR variability is not completely random.

10.3. TACHOGRAM EVALUATION

To the right of the screen we see a tachogram of the events detected by the atrial fibrillation software.
These events are highlighted in red and represent the large RR intervals variation in the AF periods.
The tachogram allows the user not only to view, but also to interact with the events detected by the software, allowing the union, addition, or removal of a specific episode.
Any change in the tachogram reflects simultaneously in the table.

All events selected directly in the tachogram are represented in the ECG bar.
To select any of the tools available (mentioned above), just click on any point in the tachogram with the mouse “right button” and it will present three options to execute the desired action:

Situation 1
In periods that have not been classified as atrial fibrillation due to external interference or by consecutive rhythmicity, causing the software to not classify an AF period.
Just drag the mouse over the episode you want to add, right-click the mouse, and select the [Save selected episode] option.

Situation 2
If an episode has been fragmented, it is possible to unite it by turning it into a single event.
Drag the mouse directly on the tachogram between one event and another and select the [Extend to contiguous episodes] option.

Situation 3
If the analyst disagrees for a selected period, just drag the mouse over the event and select [Remove the selected portion of the episode]. Note that, by selecting this option, the period will be interpreted by the software as NON atrial fibrillation, and will classify eventual supraventricular arrhythmias that may have occurred in the removed period

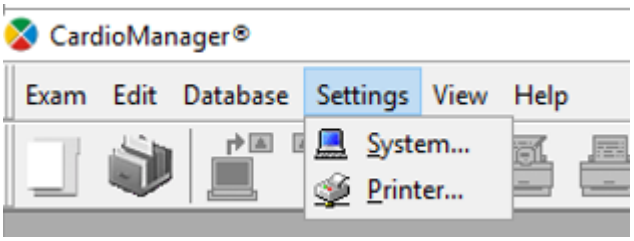
10.4. PRINTING SETUP

The user can choose two ways of printing.

10.4.1. 1ST PRINT OPTION - GENERAL SETUP

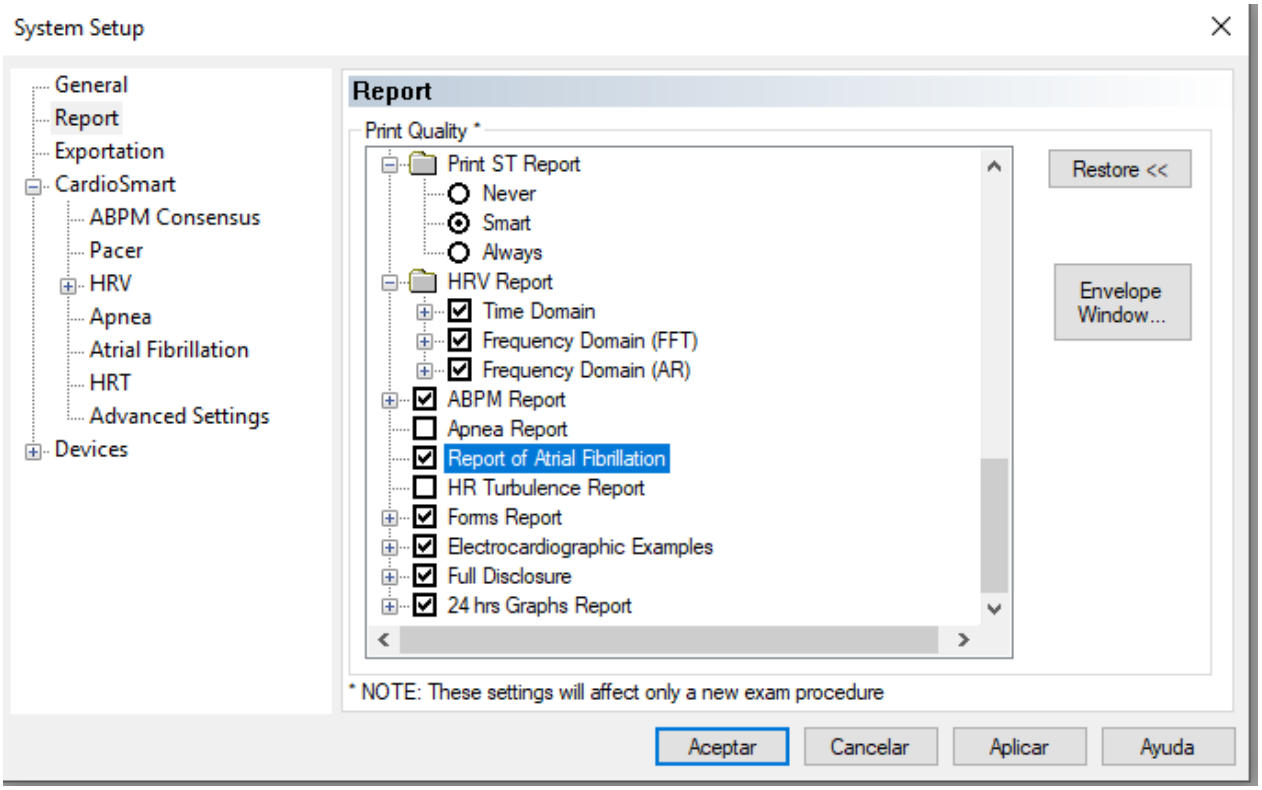
For printing the table of persistent and/or paroxysmal atrial fibrillation episodes, it is possible to leave it pre-configured as a permanent print item.

NOTE: It is worth noting that in this type of configuration, even in exams without AF, the table/tachogram will be printed.



With the Holter analysis software opened, select the option CardioSmart, [Settings] [System]

Click on [Report] option.
On the right of the screen, select the [Atrial Fibrillation Report] option.



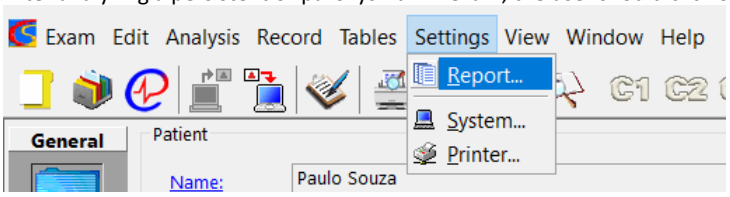
Click on [Apply] and [OK].

10.4.2. 2ND PRINTING OPTION - SINGLE

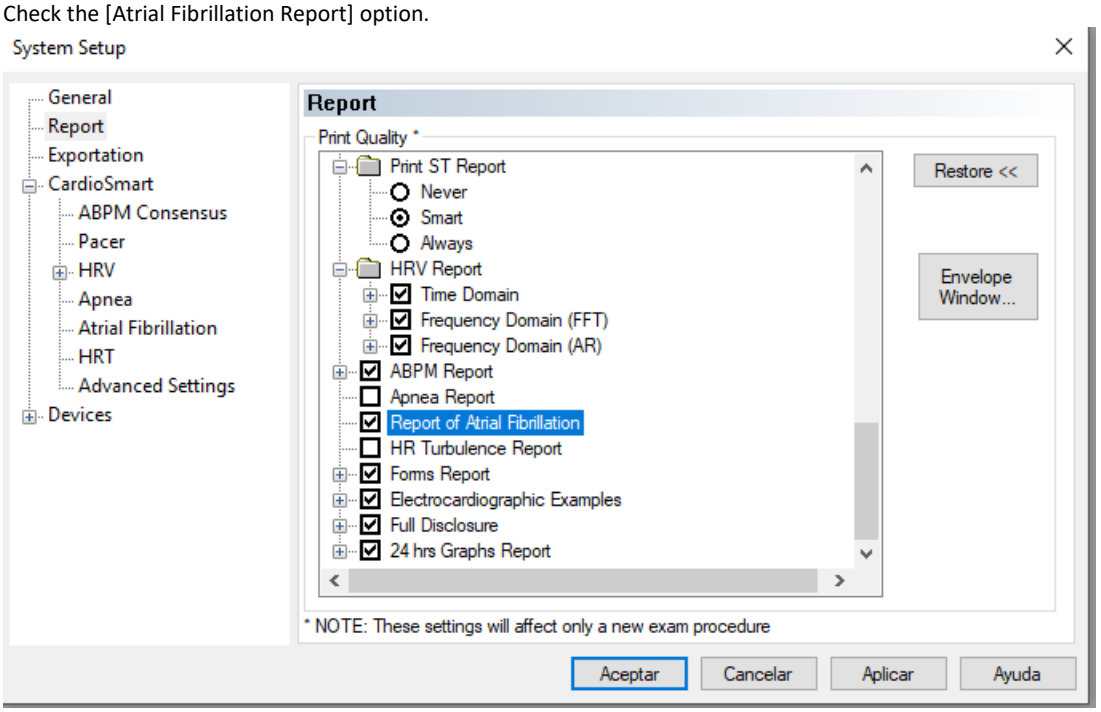
The user can leave the [Atrial Fibrillation Report] option (in the general configuration) unchecked and decide whether to print the table at the time of exam completion.

How to proceed in this second option:

After analyzing a persistent or paroxysmal AF exam, the user should click on [Settings] [Report], with the exam opened.



Check the [Atrial Fibrillation Report] option.



By clicking on this option, the table of the episodes suggestive of atrial fibrillation and the representative tachogram will be printed (either in the global or individual format).

The following two screens display the print pattern of Atrial Fibrillation Episodes detected and checked by the user.

Atrial Fibrillation Suggestive Episodes

Exam Number	Patient: P	Code:
213.872/66	Exam date: 11/09/2017 8:38:00	**4L8-00263**

Hour	Duration	HR Min. (bpm)	Mean HR (bpm)	HR Max. (bpm)	Time Brady	Time Tachy	Base HR Pre (bpm)	Base HR Post (bpm)	No. Pauses	Longest Pause (s)	Pause Start	Typi-cality
2:09	5:46:16	53	96	136	0:00:00	0:07:52	61	106	0			77
7:59	0:08:58	71	101	132	0:00:00	0:03:18	112	103	0			66
8:09	0:08:09	64	95	129	0:00:00	0:00:31	102	57	0			56
3:05	1:26:24	64	93	126	0:00:04	0:00:05	46	97	0			80
4:33	3:47:17	58	94	134	0:00:00	0:09:08	111	109	0			71

Totals

Estimated total time:	**11:17:04**
Number of episodes:	**5**
Longest episode:	**5:46:16**

Heart Rate

Max.:	**136 bpm**
Min.:	**53 pbm**
Time in tachycardia (>= 120 bpm):	**0:20:53**
Time in bradycardia (<= 50 bpm):	**0:00:04**

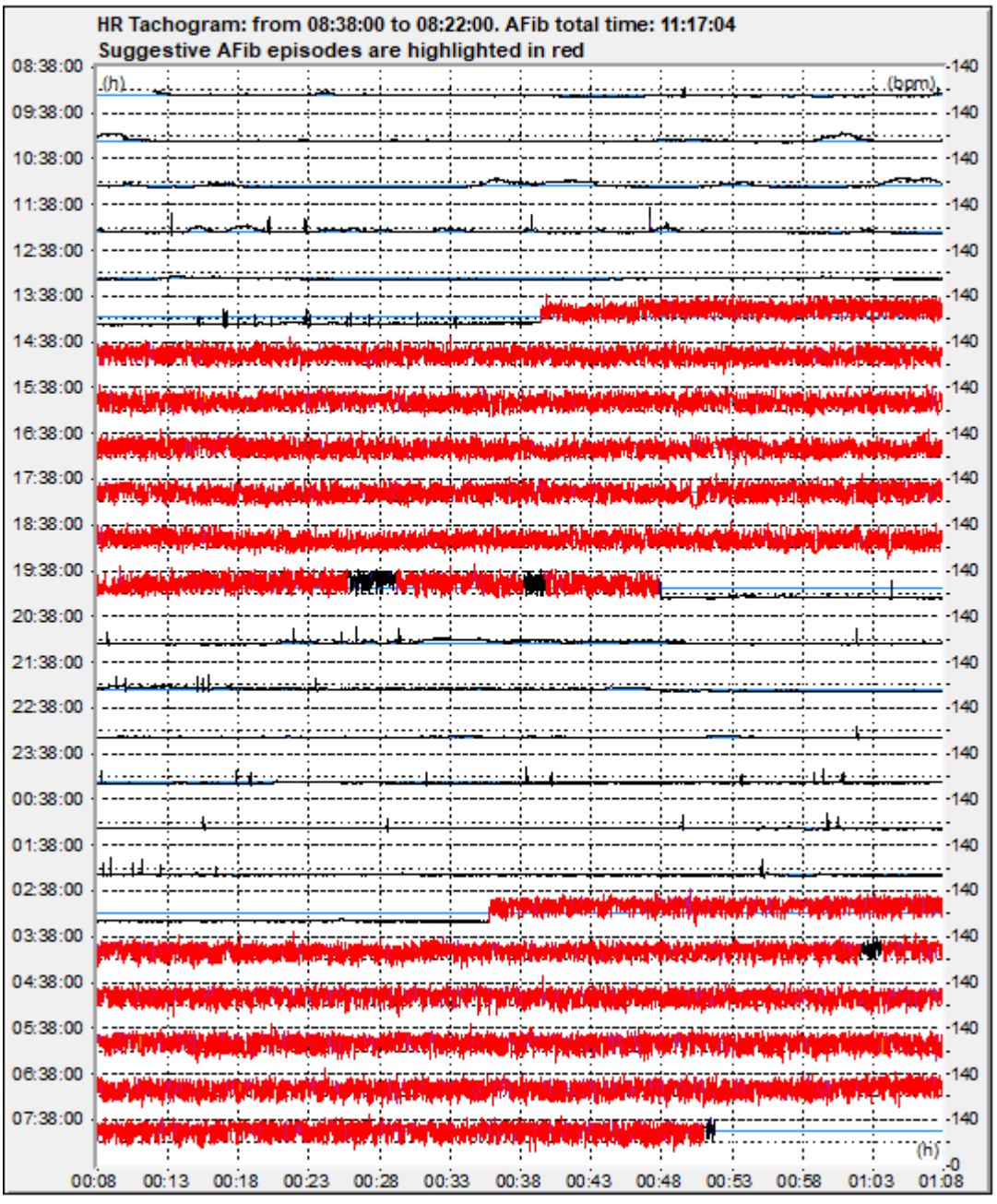
Pauses

0 Pauses (>= 3,0 s)

Criteria: *Agglutinate intervals between atrial fibrillations of up to: 1min; Block manual insertion of low frequency ranges: no.*

Atrial Fibrillation Suggestive Episodes

Exam Number	Patient: P	Code:
213.872/66	Exam date: 11/09/2017 8:38:00	4L8-00263



It is possible to print a few more tachogram screens for specific times. To do this, the times to be printed should be selected in the table, marked individually.

	Hour	Duration	HR (bpm)			Basal HR (bpm)		Prt
			Min	Avg	Max	Pre	Post	☑
	2:09	5:46:16	53	96	136	61	106	☐
	7:59	0:08:58	71	101	132	112	103	☑
	8:09	0:08:09	64	95	129	102	57	☐
▶	3:05	1:26:24	64	93	126	46	97	☑
	4:33	3:47:17	58	94	134	111	109	☑

When selecting a few more times for printing, the screens displayed are as follows:

Remember that the first two are standardized and the following two screens have been selected by the user according to the table above.

Atrial Fibrillation Suggestive Episodes

Exam Number	Patient: P	Code:
213.872/66	Exam date: 11/09/2017 8:38:00	**4L8-00263**

Hour	Duration	HR Min. (bpm)	Mean HR (bpm)	HR Max. (bpm)	Time Brady	Time Tachy	Base HR Pre (bpm)	Base HR Post (bpm)	No. Pauses	Longest Pause (s)	Pause Start	Typi-cality
2:09	5:46:16	53	96	136	0:00:00	0:07:52	61	106	0			77
7:59	0:08:58	71	101	132	0:00:00	0:03:18	112	103	0			66
8:09	0:08:09	64	95	129	0:00:00	0:00:31	102	57	0			56
3:05	1:26:24	64	93	126	0:00:04	0:00:05	46	97	0			80
4:33	3:47:17	58	94	134	0:00:00	0:09:08	111	109	0			71

Totals

Estimated total time:	**11:17:04**
Number of episodes:	**5**
Longest episode:	**5:46:16**

Heart Rate

Max.:	**136 bpm**
Min.:	**53 pbm**
Time in tachycardia (>= 120 bpm):	**0:20:53**
Time in bradycardia (<= 50 bpm):	**0:00:04**

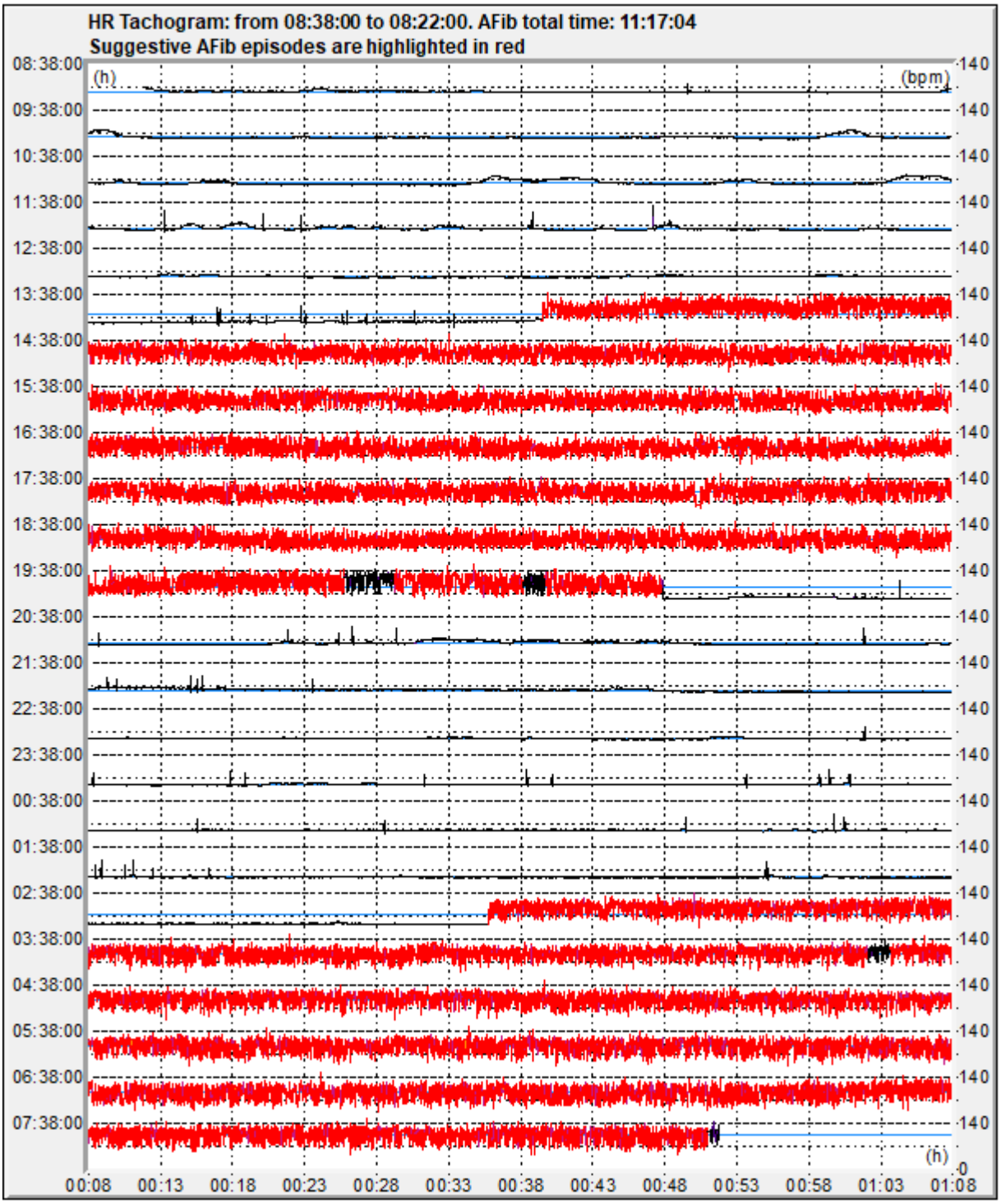
Pauses

0 Pauses (>= 3,0 s)

Criteria: *Agglutinate intervals between atrial fibrillations of up to: 1min; Block manual insertion of low frequency ranges: no.*

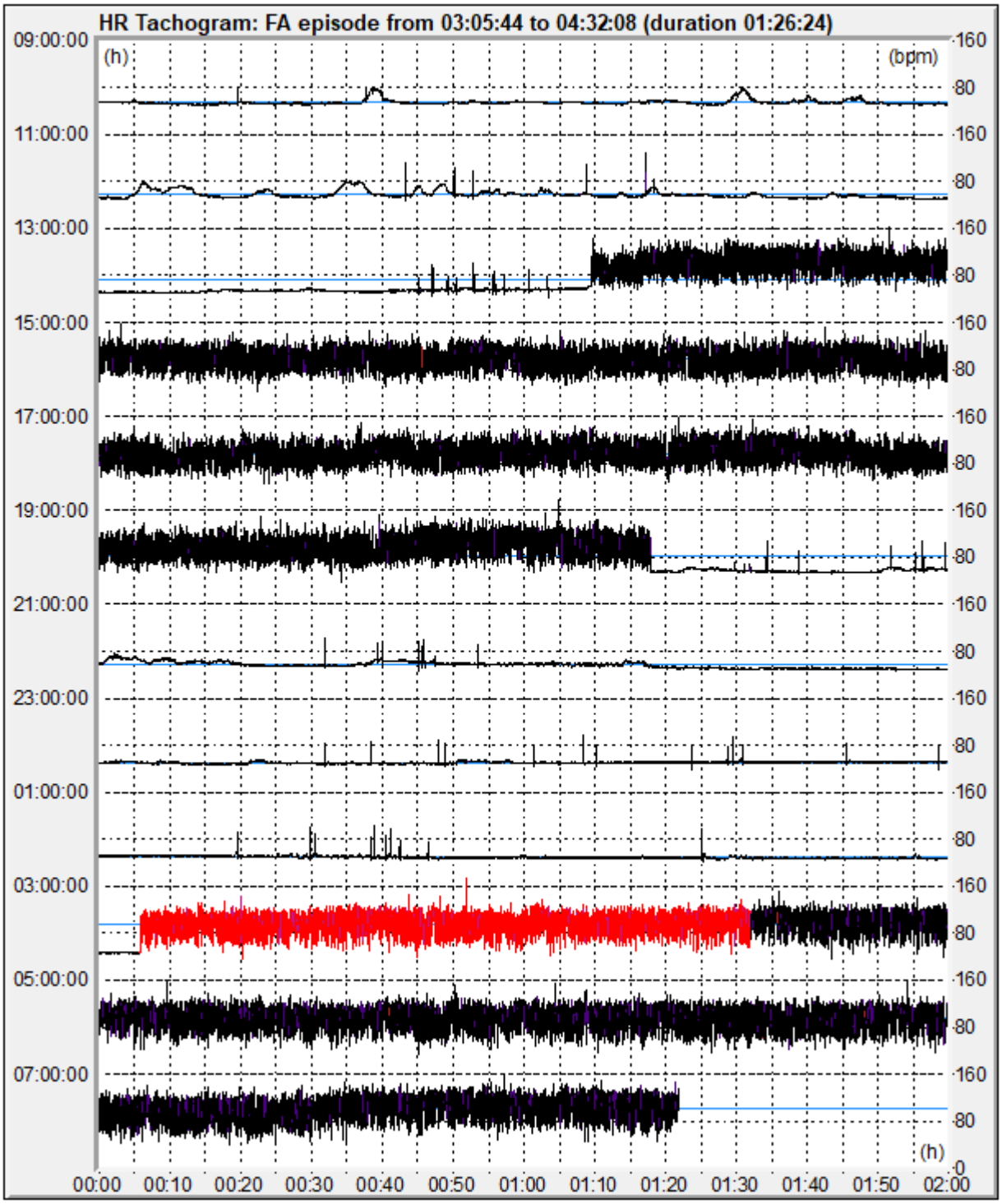
Atrial Fibrillation Suggestive Episodes

Exam Number	Patient: P	Code:
213.872/66	Exam date: 11/09/2017 8:38:00	**4L8-00263**



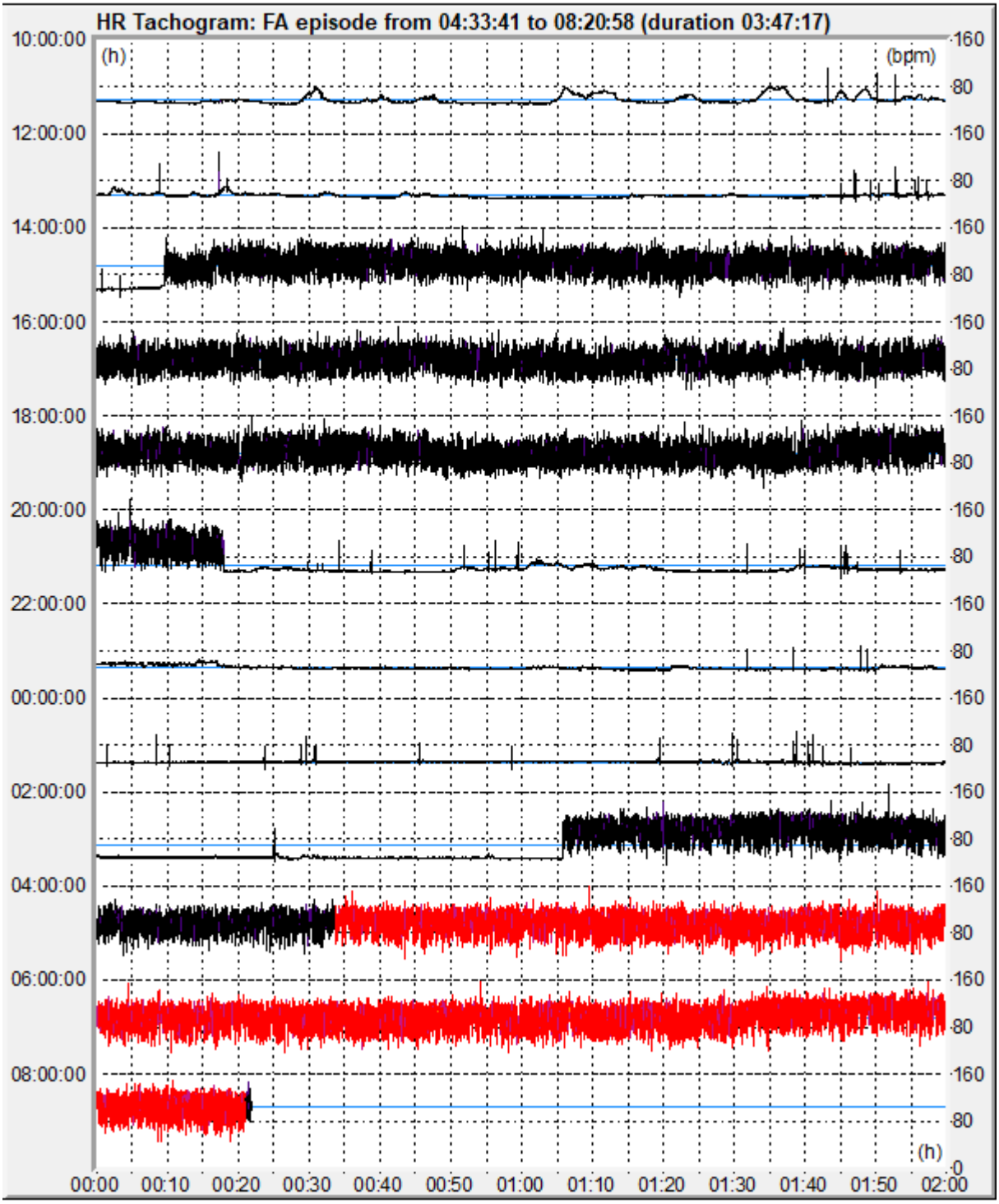
Atrial Fibrillation Suggestive Episodes

Exam Number	Patient: P	Code:
213.872/66	Exam date: 11/09/2017 8:38:00	4L8-00263



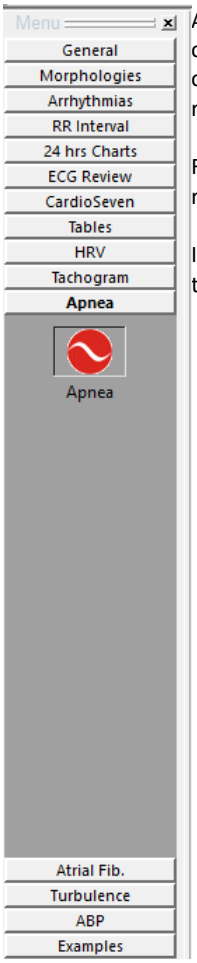
Atrial Fibrillation Suggestive Episodes

Exam Number	Patient: P	Code:
213.872/66	Exam date: 11/09/2017 8:38:00	4L8-00263



11. SLEEP APNEA ANALYSIS COMPONENT

Intended Use / Technical Information



An apnea/hypopnea period is defined as a set of CVHR (Cyclical Variation of Heart Rate). Each CVHR consists of a bradycardia phase during apnea, followed by an abrupt tachycardia phase after the end of this apnea. In order to determine an OSA period, at least three CVHRs and a minimum variation of 5 bpm in heart rate are required.

For the detection of OSA periods, the RR intervals are extracted from the graded heartbeats and an algorithm composed of several steps is used, some of which using the HRV analysis.

In the figure to the left, we see the Apnea analysis component guide highlighted in red in the system navigation menu.

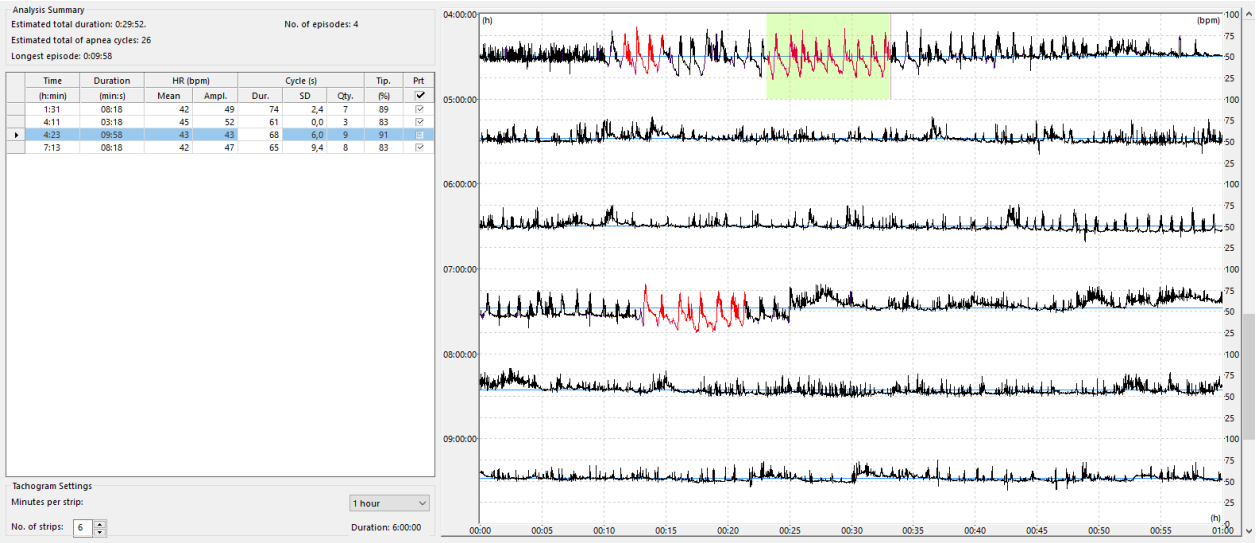
11.1. OVERVIEW

The Apnea Analysis component is composed of four basic tools:

1. A Heart Rate Tachogram
2. A table of detected suggestive episodes
3. A Summary of Quantified Episodes
4. A Tachogram Display Configuration Section

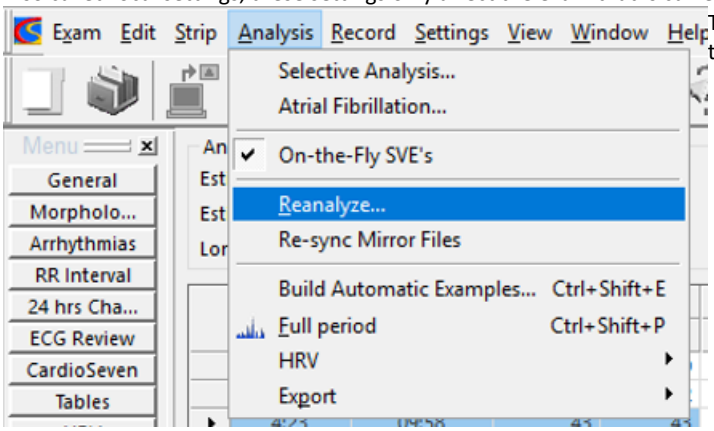
Additionally, in the component screen, the ECG bar is used to visualize the electrocardiographic tracings corresponding to the episodes detected in the analysis, as well as to navigate through the context.

The analysis component tools usage will be described in detail in the corresponding topics. Its visualization and functionalities depend on the system global settings (applicable to any new exams) and can be changed through the configurations.



11.2. REANALYSIS SETTINGS

Also called local settings, these settings only affect the exam that is currently open in the system.

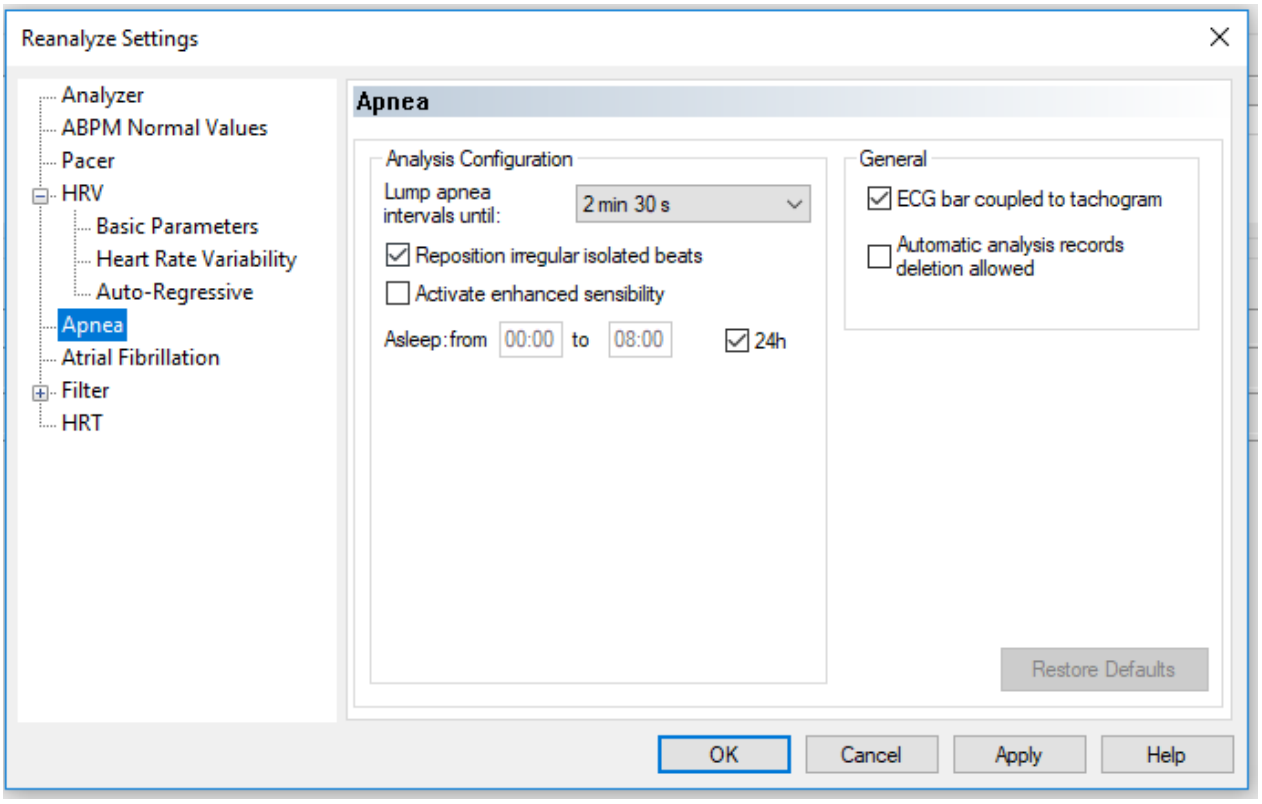


To access these settings, click on [Analysis] option on the main menu, and select [Reanalyze...].

The system displays the reanalysis settings window. In the left side panel, select the [Apnea] component.

The options available for the reanalysis setup in the Apnea component do not include the tachogram configuration, as these are available on the component's own screen.

The configurable items in the reanalysis, except for the tachogram configuration, are the same items available in the global settings, but affect only the currently open exam. For details on each configuration item, see the previous topic (Global Settings).


Reanalyze Settings
Analyzer
ABPM Normal Values
Pacer
HRV
Basic Parameters
Heart Rate Variability
Auto-Regressive
Apnea
Atrial Fibrillation
Filter
HRT
Apnea
Analysis Configuration
Lump apnea intervals until:
2 min 30 s
Reposition irregular isolated beats
Activate enhanced sensibility
Asleep: from
00:00
to
08:00
24h
General
ECG bar coupled to tachogram
Automatic analysis records deletion allowed
Restore Defaults
OK
Cancel
Apply
Help

11.3. ANALYSIS TOOLS

The apnea analysis component consists of a heart rate tachogram and a table of episodes suggestive of apnea/hypopnea, synchronized with each other.
The tachogram display is configurable and both (table and tachogram) can be attached to the ECG bar tool, enabling integrated navigation throughout the entire exam duration.

11.3.1. EPISODES TABLE

Episodes suggestive of apnea/hypopnea are detected by the system through cyclicity analysis of heart rate variations and are inserted into the episodes table in chronological order.

	Time	Duration	HR (bpm)		Cycle (s)			Tip.	Prt
	(h:min)	(min:s)	Mean	Ampl.	Dur.	SD	Qty.	(%)	☑
	1:31	08:18	42	49	74	2,4	7	89	☑
	4:11	03:18	45	52	61	0,0	3	83	☑
▸	4:23	09:58	43	43	68	6,0	9	91	☑
	7:13	08:18	42	47	65	9,4	8	83	☑

In the table, the columns describe the relevant data on each episode detected, namely:

Time
Onset time of the episode suggestive of apnea/hypopnea;

Duration
Episode duration, in minutes;

HR (bpm)
Mean
Mean heart rate during the episode detected, in heartbeats per minute;

Ampl. (HR amplitude)
Difference between the maximum and minimum HR during the detected episode;

Cycle(s)
Dur.
Mean duration of the variation cycles of HR during the episode detected, in seconds;

SD
Standard deviation of the cycle duration within the episode, in seconds;

Qty.
Number of HR rise/fall cycles within the episode;

Typ. (Typicality)
Percentage probability of the detected episode being an apnea/hypopnea, in relation to the system classification criteria.

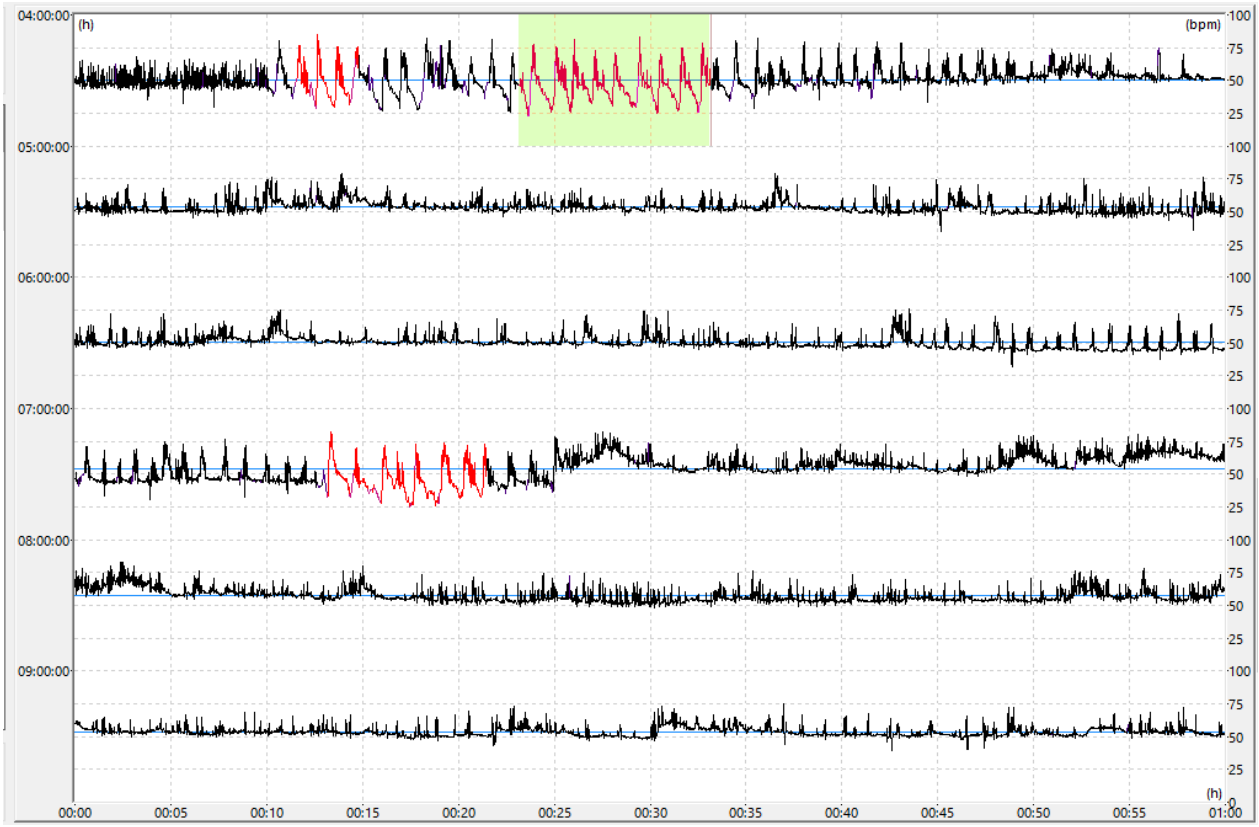
The last column of the table allows you to select the episodes to be printed on the report.

11.3.2. HEART RATE TACHOGRAM

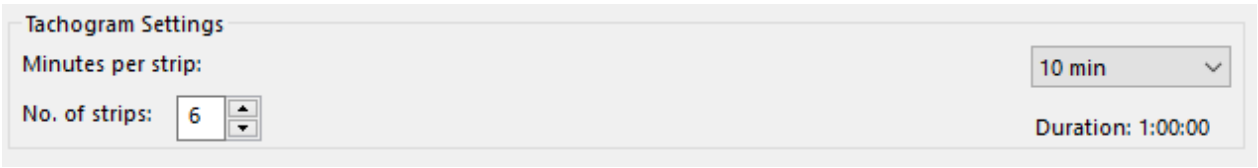
The heart rate tachogram allows the HR behavior visualization throughout the exam duration. Through the HR tachogram, we can observe the heart rate cycling patterns found in the episodes classified by the system as suggestive of apnea/hypopnea.

Episodes classified in the table are highlighted in the tachogram in red color.
The episode selected in the table is highlighted with a shading in the tachogram.

The tachogram is composed of two components: the tachogram itself and the visualization control.
Below we see the various informative tachogram elements.



The configuration control of the tachogram visualization, seen below, is self-explanatory.
It allows the configuration of the time ranges number to be displayed, as well as its duration. The combination of these two values allows us to observe from a single range with 5 minutes duration, until the total 24-hour period (12 ranges of 2 hours each).



The tachogram time scales adjust according to these display settings, where the largest divisions of the displayed time are represented in the vertical scale, while the time subdivisions of each range are represented in the lower area of the tachogram.
According to the configuration, the scroll bar will allow to go through the entire duration of the exam with the tachogram
The heart rate scale of each range viewed is dynamic. Its values will be set by the system according to the maximum frequency value to be displayed in the ranges.

11.3.3. ECG BAR

The ECG Bar tool is the same as seen in other CardioSmart CS550 software windows. Its role in the analysis of apnea/hypopnea episodes is to facilitate navigation through the entire exam period and to allow the detailed visualization of the electrocardiographic tracings at the selected moments.

The ECG Bar has its own controls and settings that allow you to select which information to display and its display format. For details on these controls and settings, refer to the corresponding section in the CardioSmart CS550 manual.

11.3.4. EPISODES ANALYSIS

The use of the apnea analysis component is divided into four stages:

1. Detection of episodes suggestive of apnea/hypopnea (automatic analysis);
2. Viewing the detected episodes ("browsing");
3. Data editing (inclusion and/or exclusion and/or merging of episodes);
4. Selection of examples for the report.

Although the apnea analysis component works virtually independently of the other software analysis tools, it is convenient to perform the conventional Holter exam analysis before using this component.
In this way, any events related to the ECG (arrhythmias, pauses, bradycardias/tachycardias, etc.) that may be correlated with the apnea events detected by the software, will already be previously known.

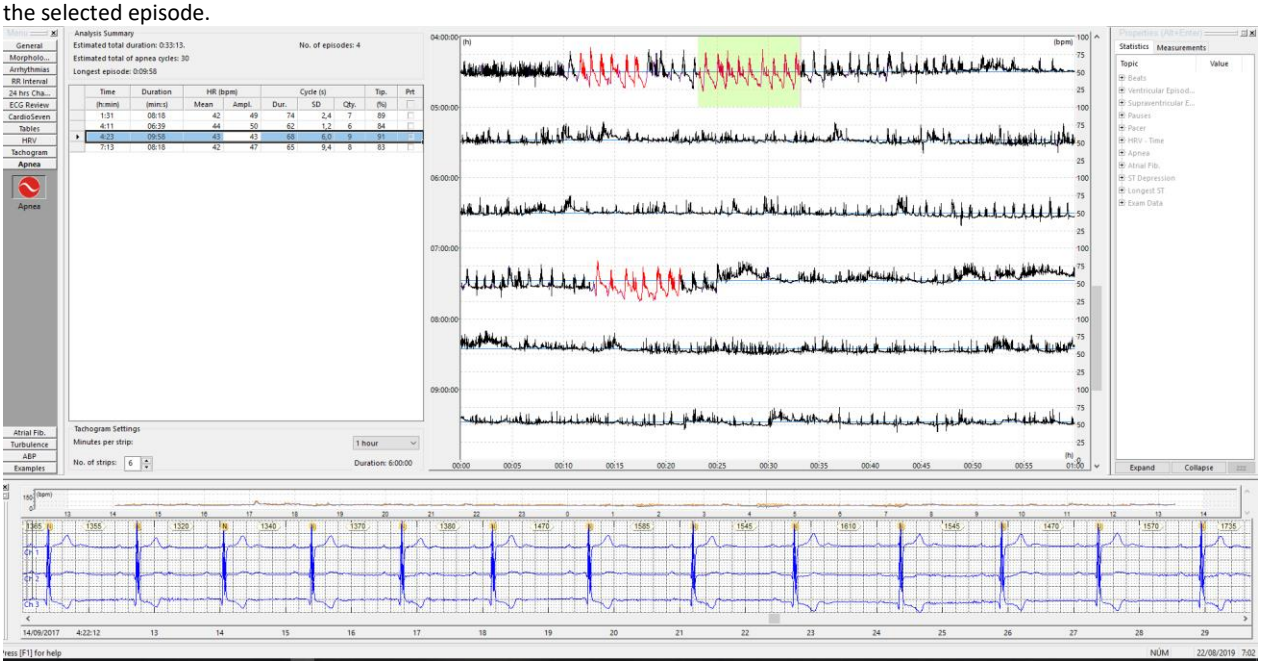
11.3.4.1. EPISODES DETECTION

When accessing the apnea analysis component for the first time, in an exam in which this analysis has not yet been performed, the software will automatically process a "scan" throughout the recorded tracing and select any episodes suggestive of apnea/hypopnea that it detects.
During this analysis, the software displays a progress bar at the bottom of the analysis component window. This bar is located on the left side of the CardioSmart CS550 status bar.

This detection will cover the entire exam period or only the sleep period, according to the general software settings (see corresponding topic). Each episode suggestive of apnea/hypopnea detected will automatically be inserted into the table, to be then evaluated by the analyst.

11.3.4.2. EPISODES VIEW

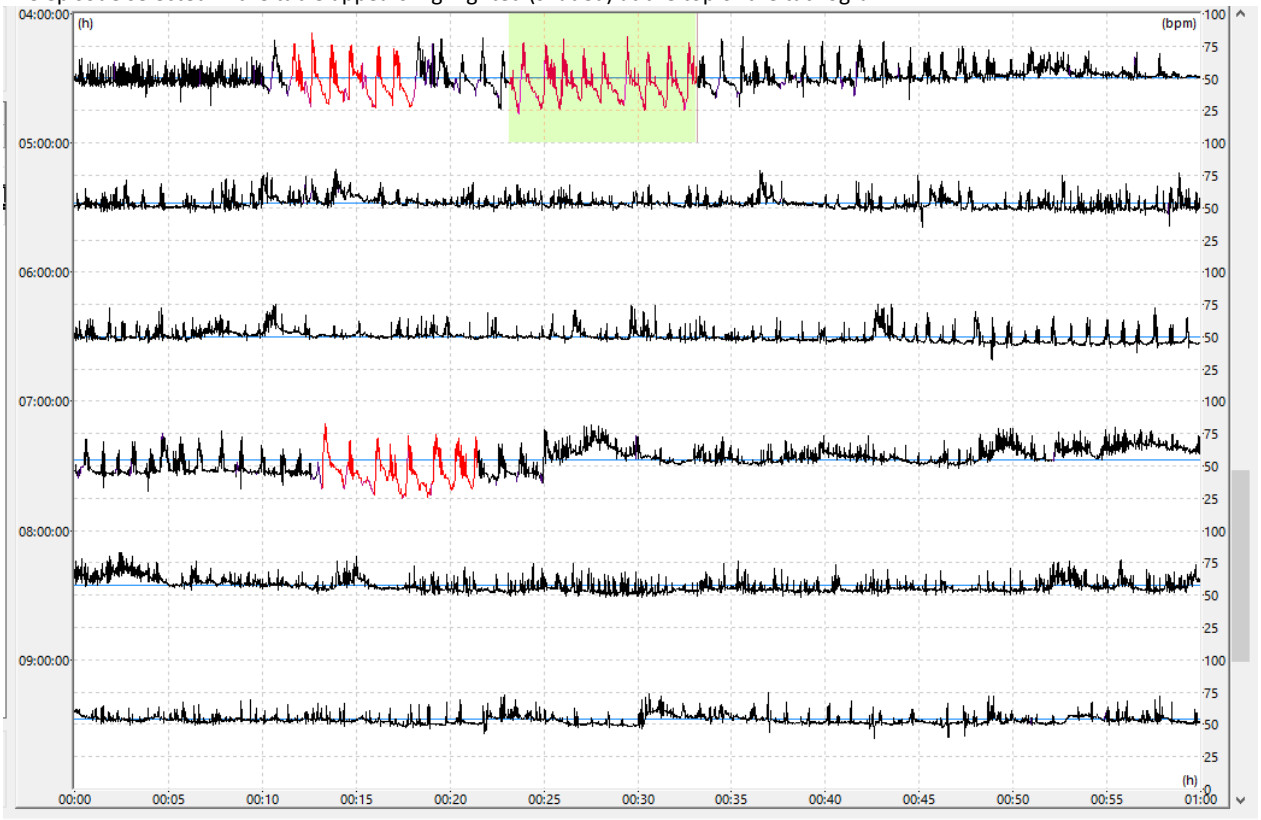
By default, when selecting any episode from the table, the tachogram and the ECG Bar will automatically be synchronized with the selected episode.



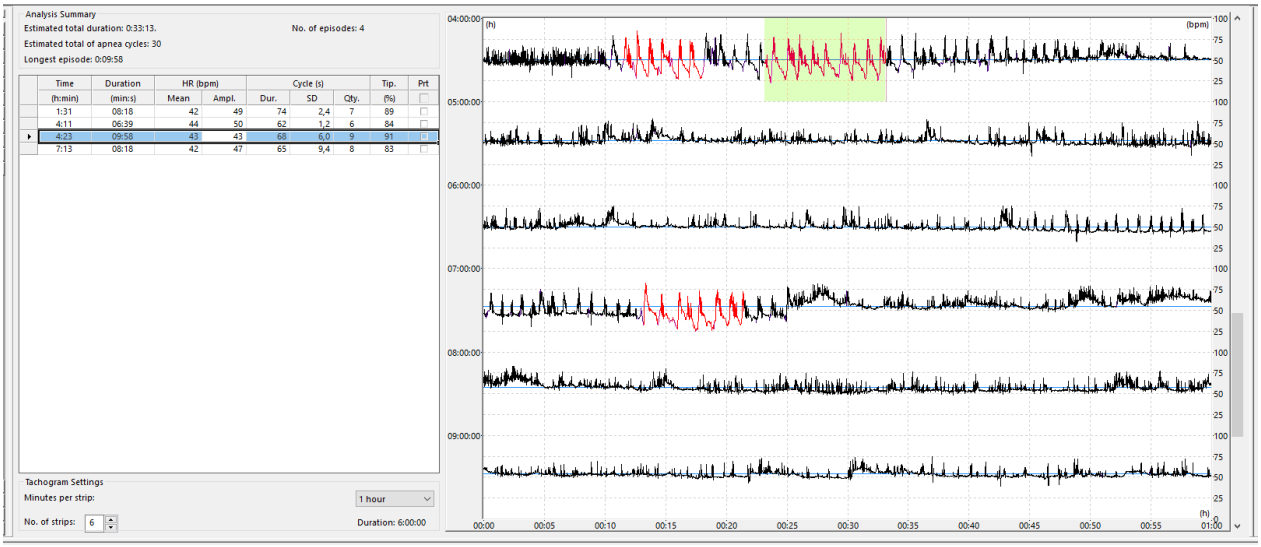
To select any episode of the table, just click with the mouse on it. The software places a highlight border on the line corresponding to the selected episode.

Time	Duration	HR (bpm)		Cycle (s)			Tip.	Prt
(h:min)	(min:s)	Mean	Ampl.	Dur.	SD	Qty.	(%)	
1:31	08:18	42	49	74	2,4	7	89	
4:11	06:39	44	50	62	1,2	6	84	
4:23	09:58	43	43	68	6,0	9	91	
7:13	08:18	42	47	65	9,4	8	83	

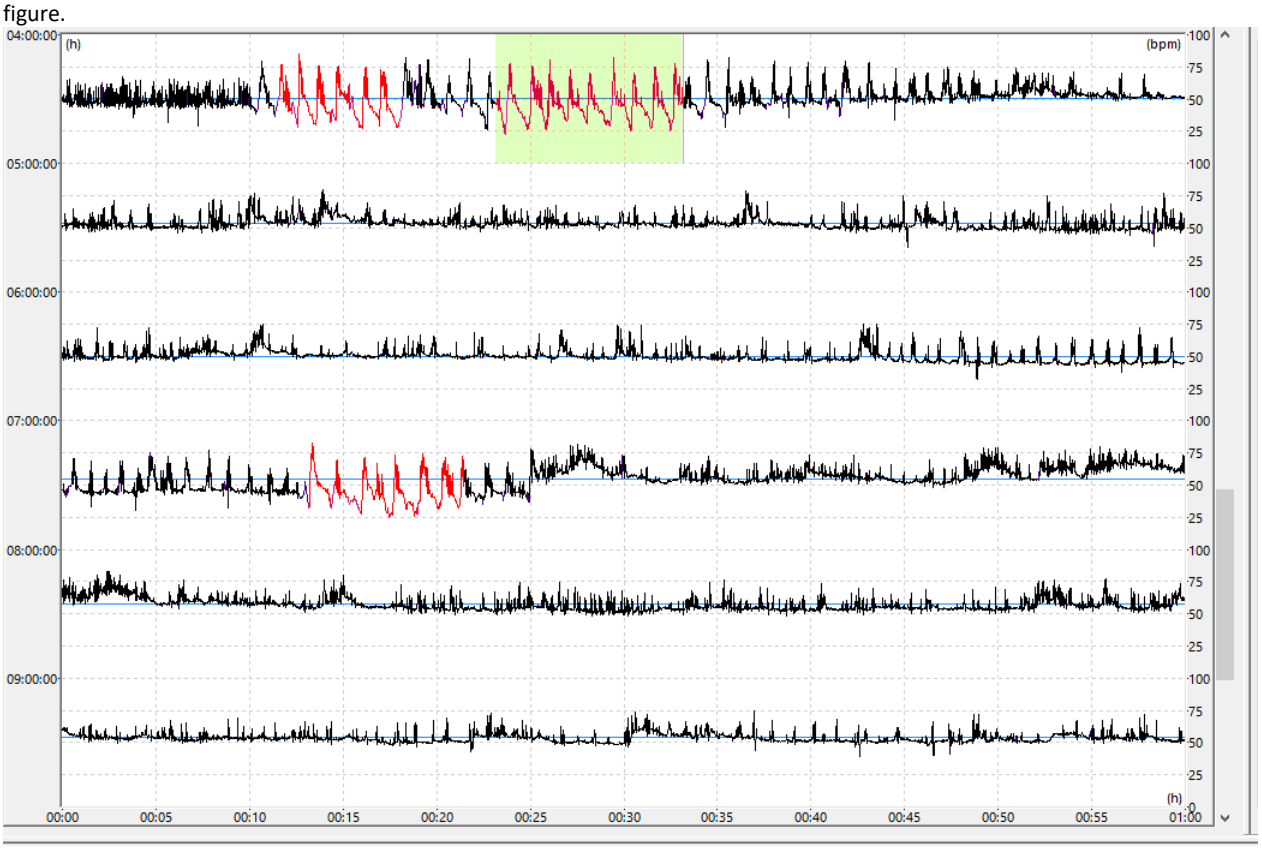
The episode selected in the table appears highlighted (shaded) at the top of the tachogram.



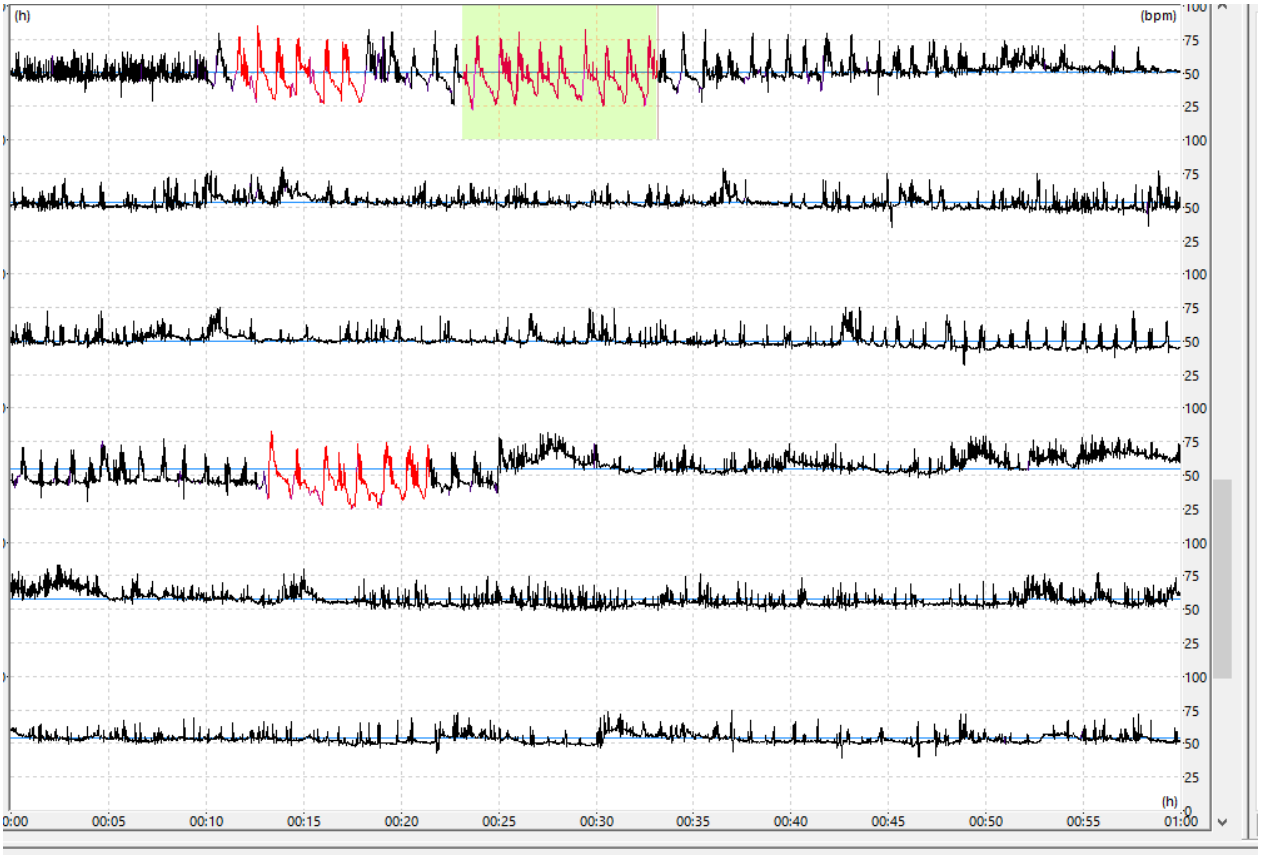
If the tachogram setting allows it, you can view several episodes simultaneously. The display order is in the same order as the table. The number of episodes viewed simultaneously also depends on the time distance between them.



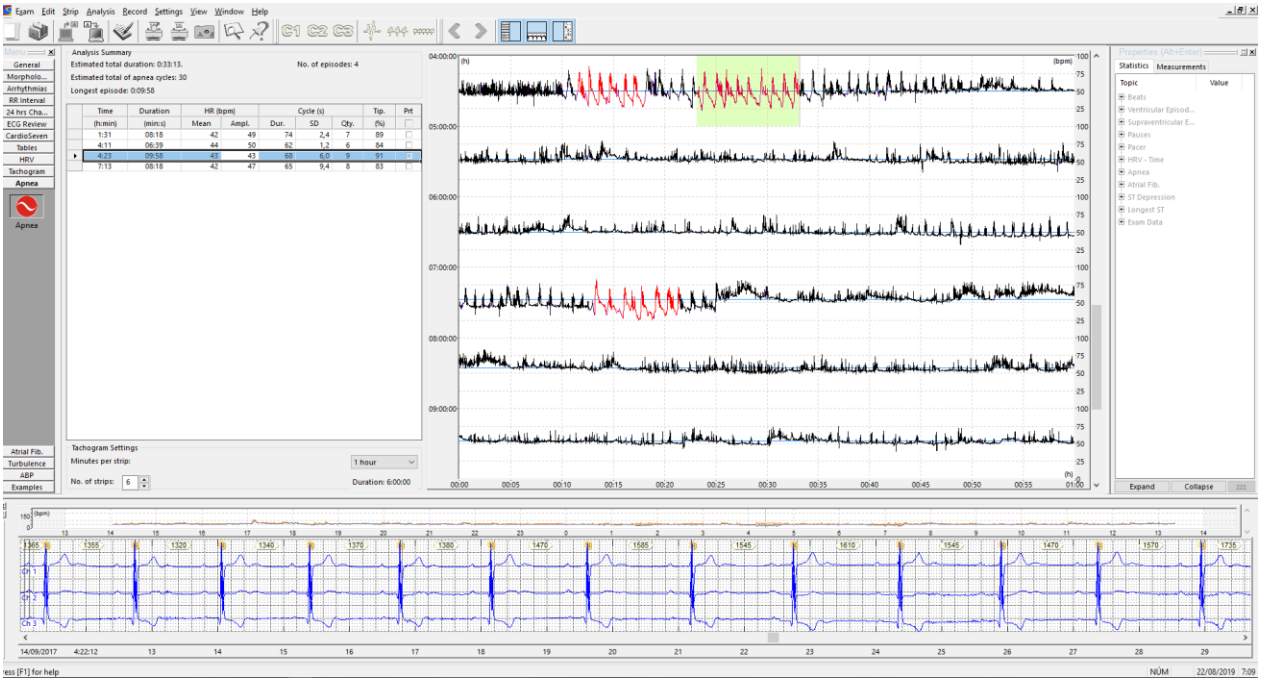
To scroll through the tachogram for the entire recording period, use the vertical scroll bar, highlighted in red in the following figure.



If you setup the tachogram display with a suitable "number of ranges" and "minutes per track" combination, you can accommodate viewing the entire sleep period (or even the entire duration of the exam) on the screen.
The episodes can be easily viewed because they are highlighted in red. The episode currently selected in the table (the first in the following figure) will be highlighted with a shadow.



The navigation is also synchronized to the ECG bar for the tachogram. Just click anywhere on the ECG bar and the tachogram will be moved to the corresponding time.



Note that in this case, the table will not highlight episodes that coincide with the time selected in the ECG Bar tool. Only the tachogram will be synchronized. Additionally, the software will not highlight in shadowing any episodes found, but the red marking remains.

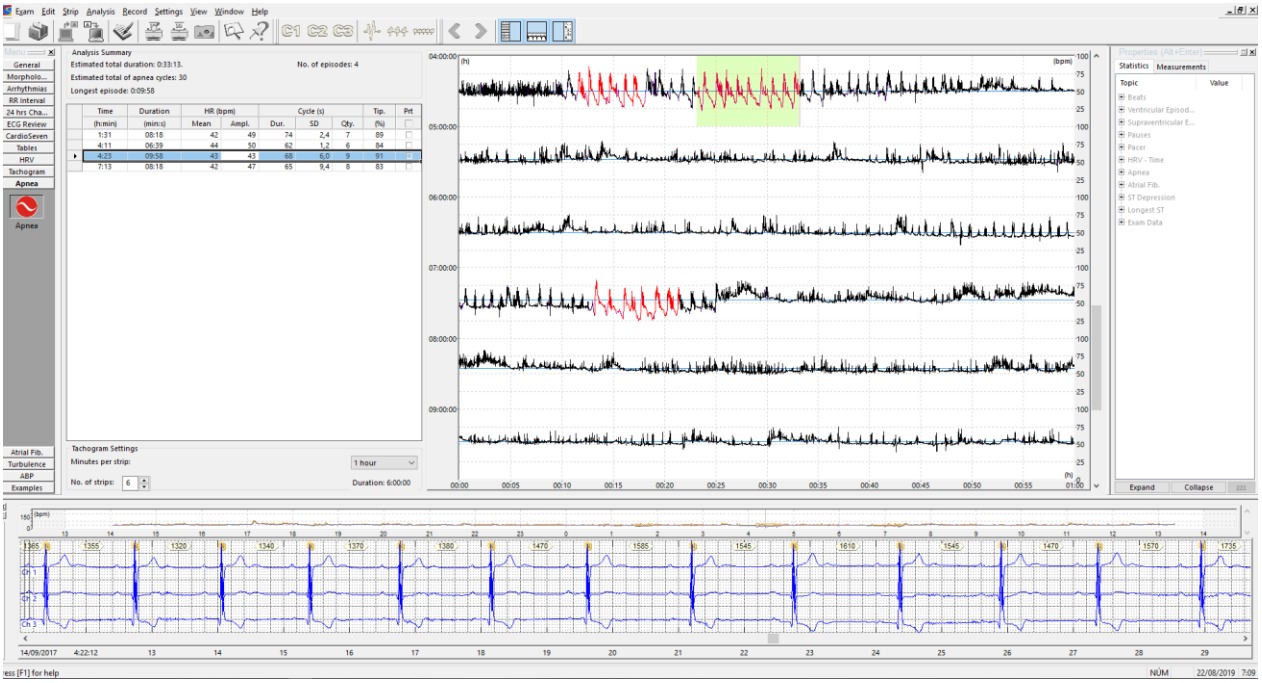
11.3.4.3. EDITING DATA

The editing of the analyzed data is very important to validate or rectify the automatic analysis results. It is always up to the analyst physician to critically assess the data of the episodes selected by the software (or their absence...) to ensure it assists the correct diagnosis and conduct to be adopted, along with additional patient information (risk factors that contribute to apnea/hypopnea occurrence).

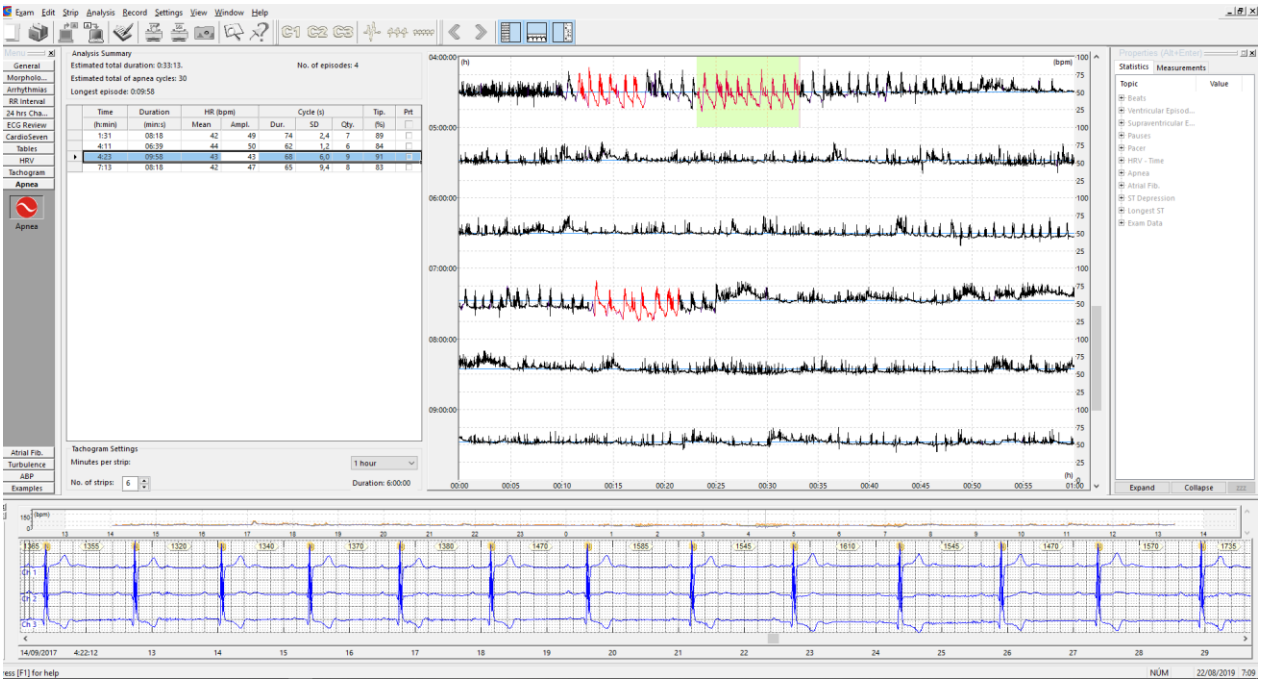
11.3.4.4. EPISODES INCLUSION

The software allows the episodes inclusion that may not have been detected by the automatic analysis and that the analyst physician considers characteristic of apnea/hypopnea.

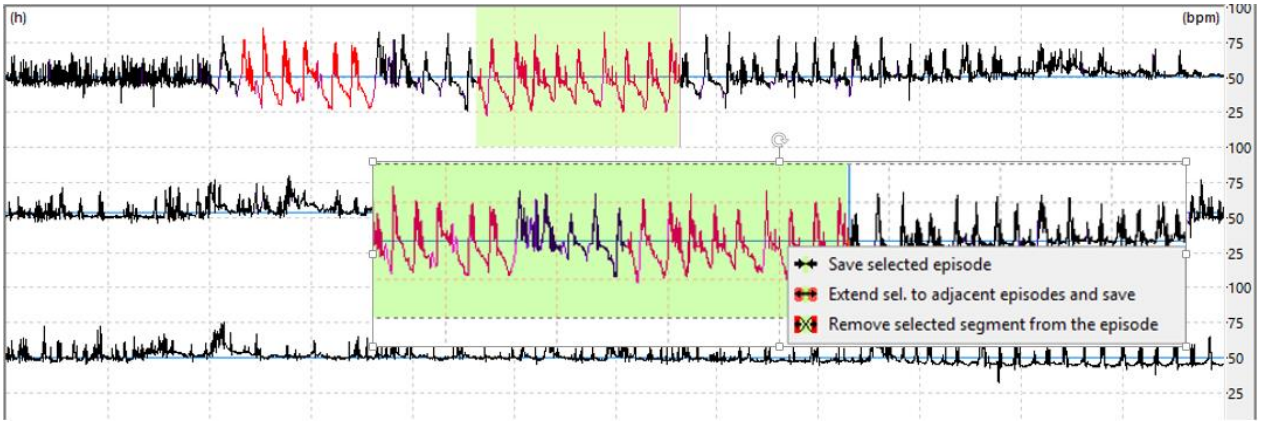
To include an episode, position the mouse cursor over its starting point on the tachogram and drag the mouse to mark the desired extension. The software will mark the episode with a shading, initially in ocher color (roughly corresponds to the “dark yellow” color). This color means the selected period length has not yet met the minimum duration criteria for inclusion as an episode suggestive of apnea/hypopnea.



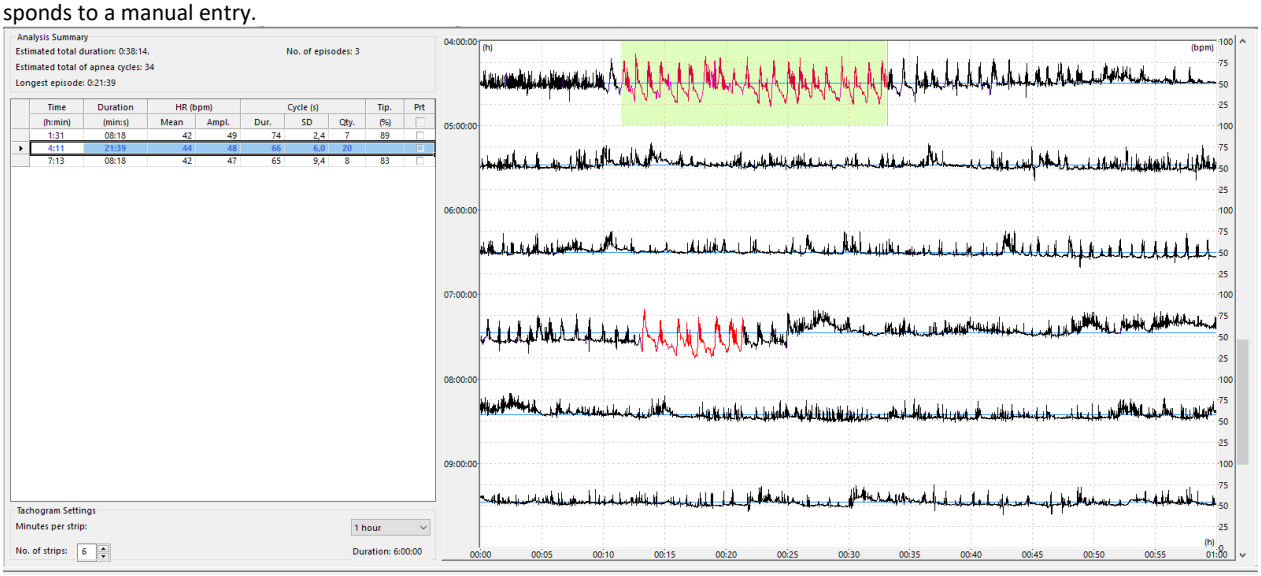
If you continue dragging the mouse, the color of the shading will change to green, meaning the period has already reached the minimum required duration. Continue until you have selected the entire period you want to include as an episode.



Right-click and the software displays a [Save Selected Period] control. To complete the include operation, click on this control.



The episode will then be included in the table. The blue highlight indicates the episode was edited by the user, that is, it corresponds to a manual entry.

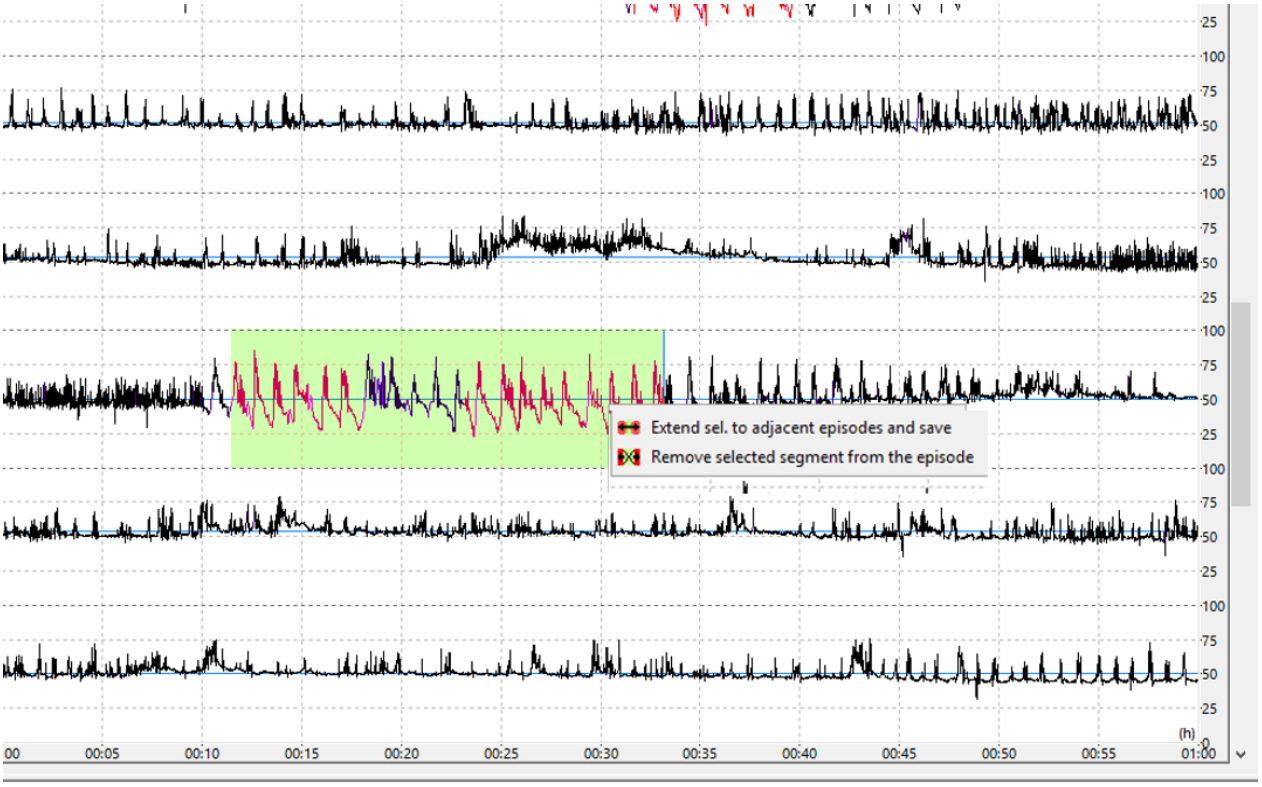


For manually entered episodes, the software will attempt to calculate the values of the columns for apnea/hypopnea cycle data. If this is possible, these values are automatically entered in the corresponding row in the table.

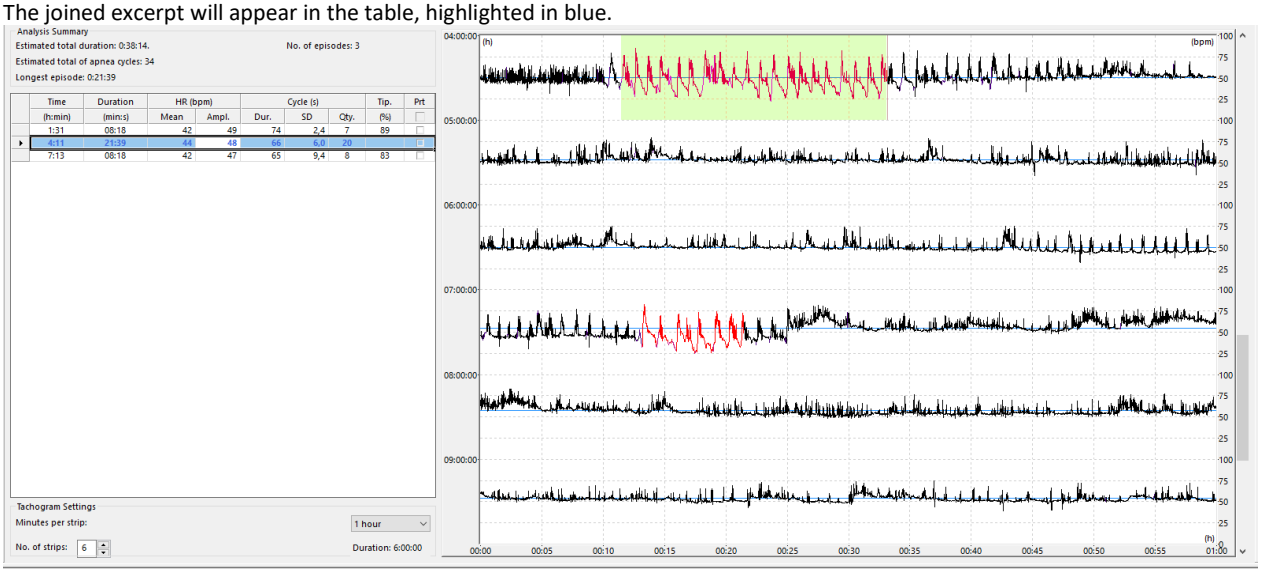
	Time	Duration	HR (bpm)		Cycle (s)			Tip.	Prt
	(h:min)	(min:s)	Mean	Ampl.	Dur.	SD	Qty.	(%)	☐
	1:31	08:18	42	49	74	2,4	7	89	☐
▶	4:11	21:39	44	48	66	6,0	20		☐
	7:13	08:18	42	47	65	9,4	8	83	☐

If the calculated values do not meet the cyclicity criteria used by the algorithm to typify the episodes, the corresponding field(s) in the table will be left blank.

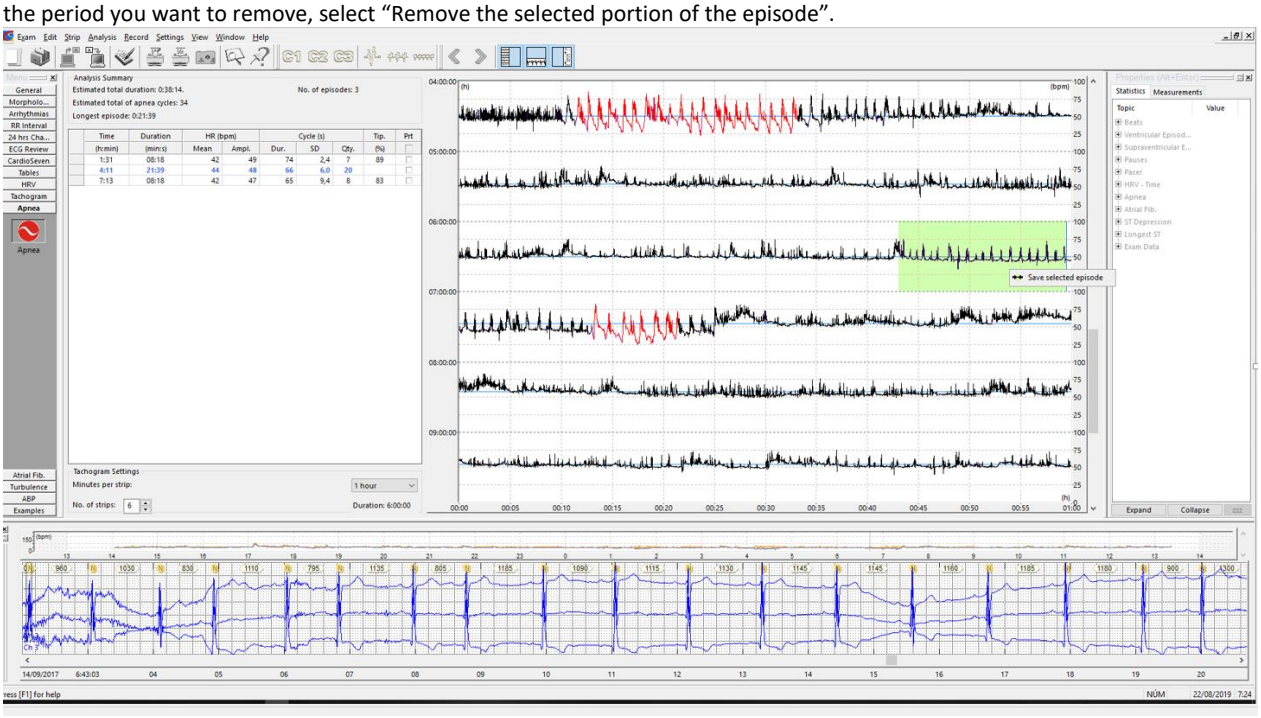
In case an episode has been fragmented (due to the presence of some artifact, for example) it is possible to unite them directly in the tachogram selecting the option to extend the contiguous episodes.



The joined excerpt will appear in the table, highlighted in blue.

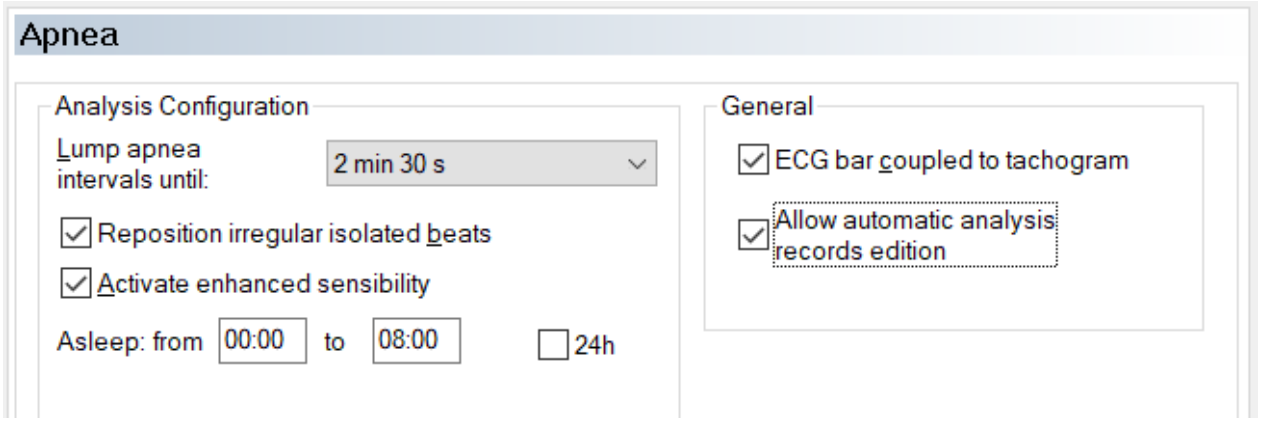


If the physician disagrees with any detected event, it is possible to remove it directly in the tachogram. Just drag the mouse over the period you want to remove, select “Remove the selected portion of the episode”.



11.3.4.5. EPISODES EXCLUSION

In the same way that the manual episodes inclusion may be necessary, it may also be necessary to exclude examples the software may have considered significant, but with which the analyst disagrees. In this case, episodes that result from automatic analysis can be manually deleted, as long as the manual deletion permission option is enabled.



To delete an episode, just click on it in the table and press the [Delete] key. The selected episode will be marked with a bold border and will be deleted as soon as the key is pressed.

	Time	Duration	HR (bpm)		Cycle (s)			Tip.	Prt
	(h:min)	(min:s)	Mean	Ampl.	Dur.	SD	Qty.	(%)	
	1:31	08:18	42	49	74	2,4	7	89	
	4:11	21:39	44	48	66	6,0	20		
▶	6:43	16:25	47	21					
	7:13	08:18	42	47	65	9,4	8	83	

The software allows the selection of multiple episodes, using the Microsoft Windows selection rules.

To select multiple consecutive episodes, click on the first episode and, holding down the [Shift] key, drag the mouse to the last episode you want to delete. The selected episodes will be highlighted, as shown in the following figure.

Once selected, press the [Delete] key and they will be deleted from the table.

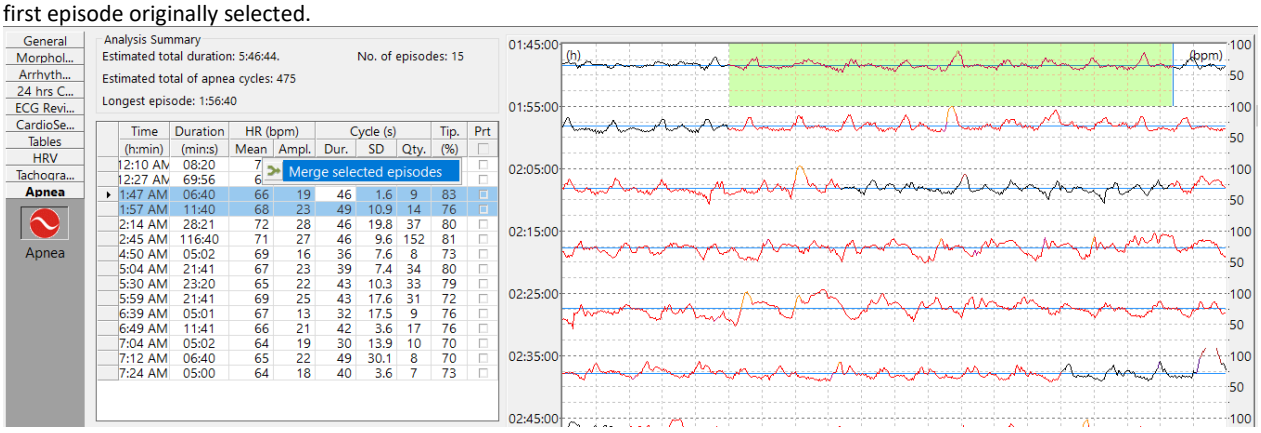
	Time	Duration	HR (bpm)		Cycle (s)			Tip.	Prt
	(h:min)	(min:s)	Mean	Ampl.	Dur.	SD	Qty.	(%)	
	1:31	08:18	42	49	74	2,4	7	89	
	4:11	21:39	44	48	66	6,0	20		
▶	6:43	16:25	47	21					
	7:13	08:18	42	47	65	9,4	8	83	

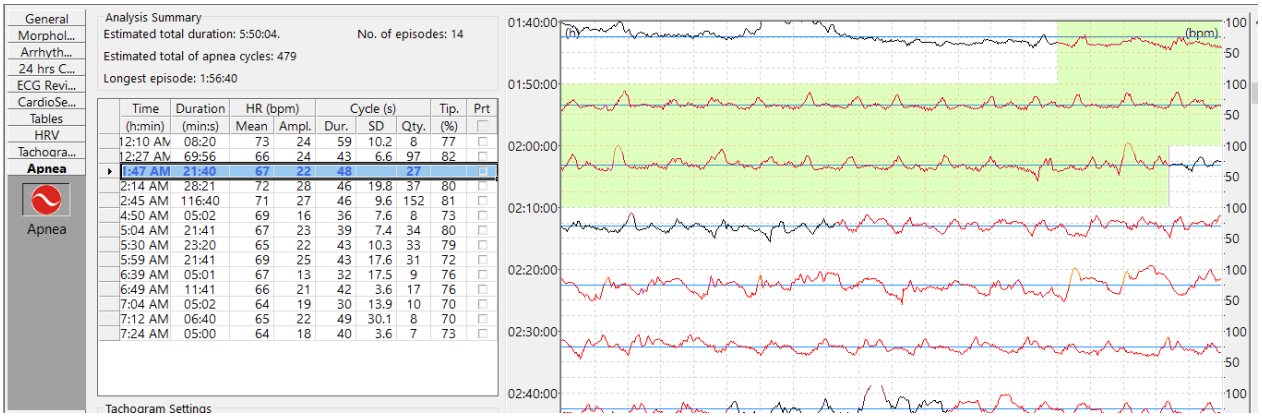
11.3.4.6. EPISODES MERGING

Due to the mathematical characteristics of the parsing algorithm, it is possible for the software to separate an episode into one or more segments.
This is due to changes in heart rate behavior that do not fit the mathematical criteria by which the software determines the HR behavior cyclicity.
Other factors, such as arrhythmias, may determine a discontinuity in these cycles.

When two consecutive episodes automatically sorted by the software are temporarily close to each other, it may be convenient to merge them into a single episode.
To perform this merge, select the episodes to be merged in the table and right-click on them.

Click on the [Merge selected periods] control. The software will merge them into a single episode, starting at the time of the first episode originally selected.

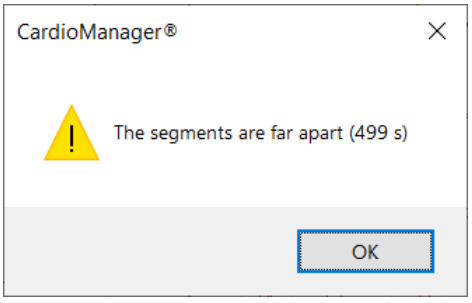




It is important to note that, as they were not considered in the automatic analysis as a single episode, the software may not calculate the value of any (or even none) cyclicity parameter, leaving it blank in the table.

Time	Duration	HR (bpm)		Cycle (s)			Tip.	Prt
(h:min)	(min:s)	Mean	Ampl.	Dur.	SD	Qty.	(%)	
12:10 AM	08:20	73	24	59	10.2	8	77	
12:27 AM	69:56	66	24	43	6.6	97	82	
1:47 AM	21:40	67	22	48		27		
2:14 AM	28:21	72	28	46	19.8	37	80	
2:45 AM	116:40	71	27	46	9.6	152	81	

NOTE: If the selected episodes are “temporarily” set aside beyond a maximum limit, the software will issue a warning message and refuse to merge. This maximum limit is proportional to the current value selected in the “Agglutination of Intervals” combo box described in item 11.2.3.

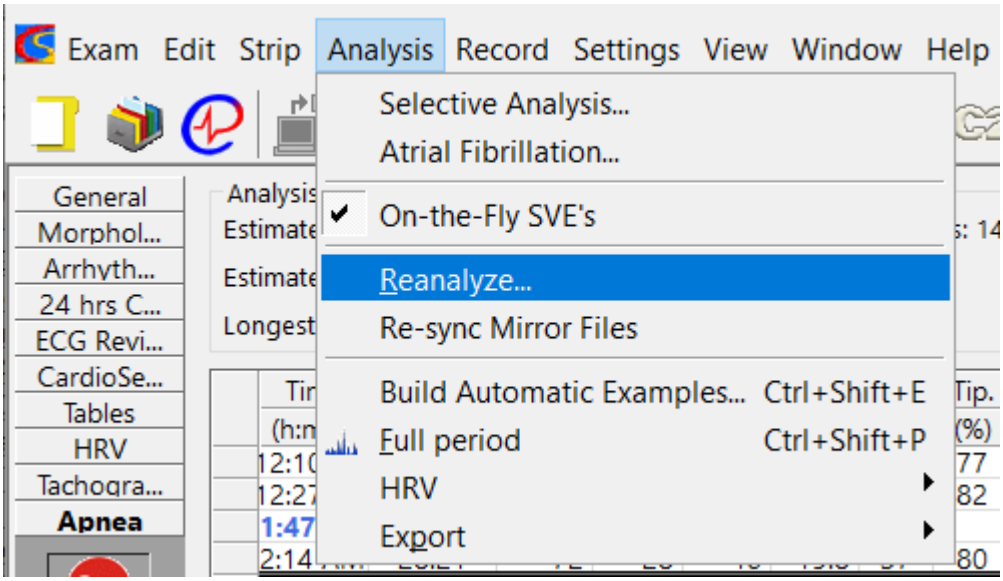


The value shown in the message represents the time, in seconds, corresponding to the time distance between the selected segments.

11.3.5. REANALYSIS

Sometimes, to revert edits or revise the approach to analysis by changing configuration parameters, you need to perform a data reanalysis.

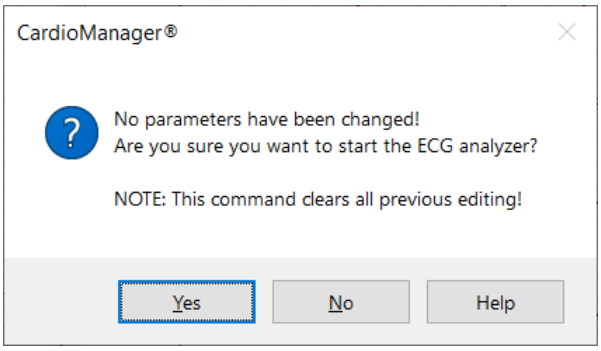
In the reanalysis, the software reviews the entire exam duration and again detects episodes suggestive of apnea/hypopnea according to the configuration parameters.



To change the analysis parameters, click on the [Analysis] option in the main menu and select [Reanalyze].

The software displays the exam local settings window, as seen in the Reanalysis Settings topic. If you change any parameters or restore the default settings, as soon as you click on the [OK] button, the software will reanalyze the entire recording signal, returning to the component analysis window.

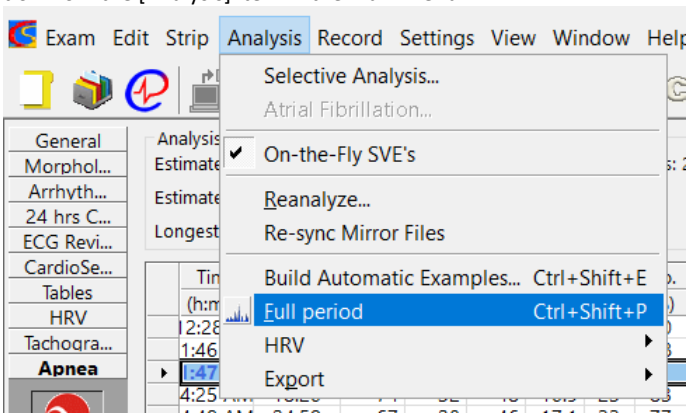
It is very important to note that, if the reanalysis is accessed and no parameters have been changed, when returning to the component window, the software will prompt with a warning message informing that all edits made will be lost.



Unless you want to “clear” the analysis status of the entire exam, click on the [No] button.

IMPORTANT: If you accept the exam reanalysis without changing any parameters, all exam editions, including those on the other analysis tools, will be permanently DELETED, forcing the analyst to do the entire analysis again.

If you need to reanalyze only the apnea/hypopnea data without changing configuration parameters, use the [Total period] option from the [Analysis] item in the main menu.



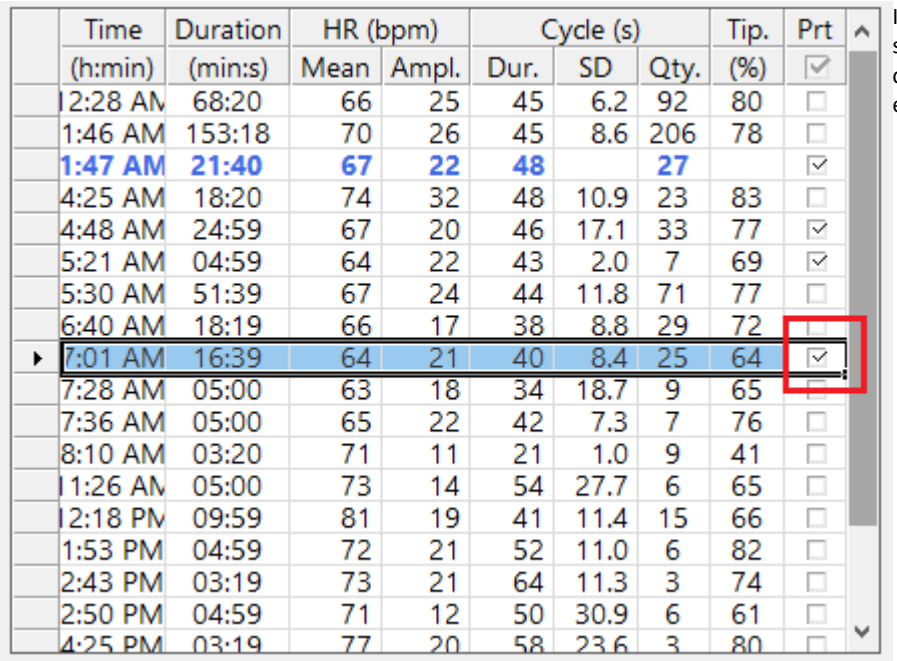
NOTE: User edits such as episode merges and inclusions are retained. In case of merges, the software will preserve the episodes resulting from the merge operations, but the original episodes that were detected automatically will be inserted again in the table.

11.3.6. SELECTION OF EXAMPLES FOR THE REPORT

Also, in the editing stage, the user should select, in the episode table, the ones to be included in the final report.

Time	Duration	HR (bpm)		Cycle (s)			Tip.	Prt
(h:min)	(min:s)	Mean	Ampl.	Dur.	SD	Qty.	(%)	✔
12:28 AM	68:20	66	25	45	6.2	92	80	
1:46 AM	153:18	70	26	45	8.6	206	78	
1:47 AM	21:40	67	22	48		27		
4:25 AM	18:20	74	32	48	10.9	23	83	
4:48 AM	24:59	67	20	46	17.1	33	77	
5:21 AM	04:59	64	22	43	2.0	7	69	
5:30 AM	51:39	67	24	44	11.8	71	77	
6:40 AM	18:19	66	17	38	8.8	29	72	
7:01 AM	16:39	64	21	40	8.4	25	64	
7:28 AM	05:00	63	18	34	18.7	9	65	
7:36 AM	05:00	65	22	42	7.3	7	76	
8:10 AM	03:20	71	11	21	1.0	9	41	
11:26 AM	05:00	73	14	54	27.7	6	65	
12:18 PM	09:59	81	19	41	11.4	15	66	
1:53 PM	04:59	72	21	52	11.0	6	82	
2:43 PM	03:19	73	21	64	11.3	3	74	
2:50 PM	04:59	71	12	50	30.9	6	61	
4:25 PM	03:19	77	20	58	23.6	3	80	

You can select all table episodes by clicking on the corresponding field in the table header.



Time	Duration	HR (bpm)		Cycle (s)			Tip.	Prt
(h:min)	(min:s)	Mean	Ampl.	Dur.	SD	Qty.	(%)	☑
12:28 AM	68:20	66	25	45	6.2	92	80	☐
1:46 AM	153:18	70	26	45	8.6	206	78	☐
1:47 AM	**21:40**	**67**	**22**	**48**		**27**		☑
4:25 AM	18:20	74	32	48	10.9	23	83	☐
4:48 AM	24:59	67	20	46	17.1	33	77	☑
5:21 AM	04:59	64	22	43	2.0	7	69	☑
5:30 AM	51:39	67	24	44	11.8	71	77	☐
6:40 AM	18:19	66	17	38	8.8	29	72	☐
7:01 AM	16:39	64	21	40	8.4	25	64	☑
7:28 AM	05:00	63	18	34	18.7	9	65	☐
7:36 AM	05:00	65	22	42	7.3	7	76	☐
8:10 AM	03:20	71	11	21	1.0	9	41	☐
11:26 AM	05:00	73	14	54	27.7	6	65	☐
12:18 PM	09:59	81	19	41	11.4	15	66	☐
1:53 PM	04:59	72	21	52	11.0	6	82	☐
2:43 PM	03:19	73	21	64	11.3	3	74	☐
2:50 PM	04:59	71	12	50	30.9	6	61	☐
4:25 PM	03:19	77	20	58	23.6	3	80	☐

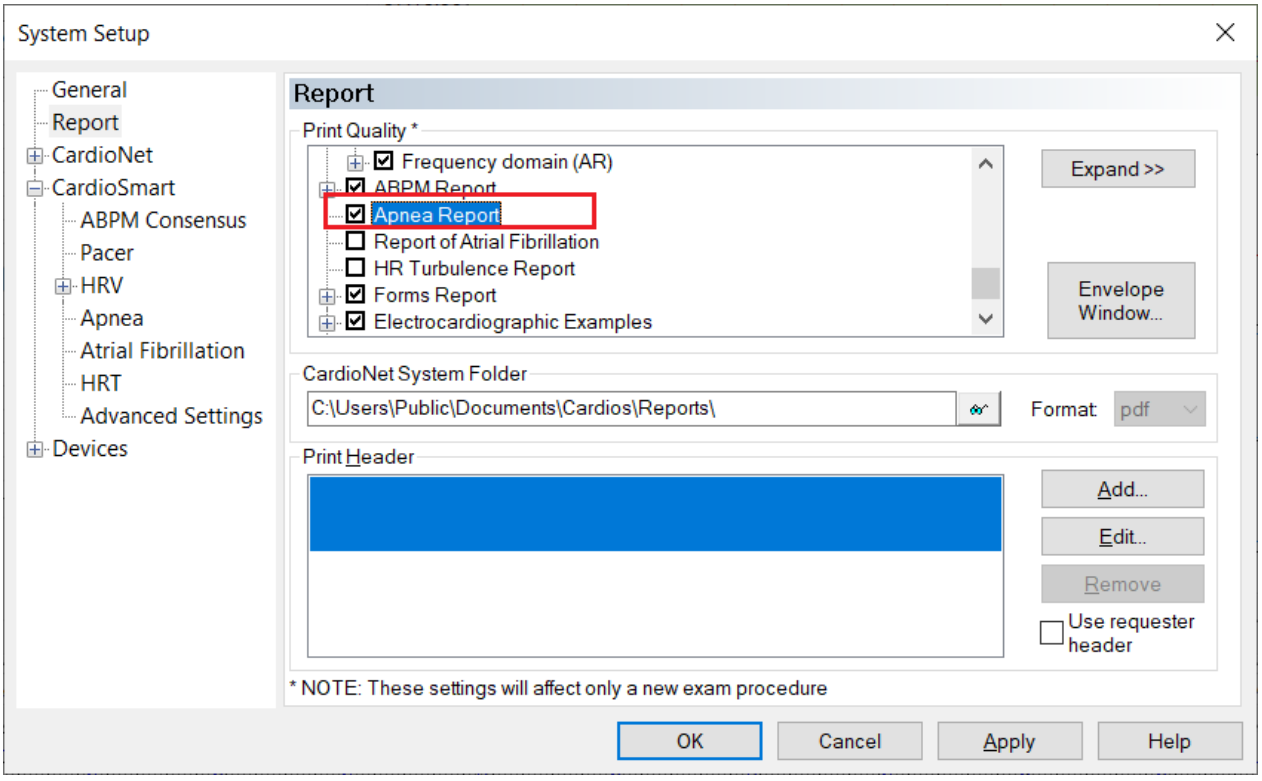
If you want to select only a few episodes to be included in the report, click on the selection fields for each episode you want to include.

For each episode selected for printing, a page will be included in the final report, containing the corresponding tachogram. The tachogram to be printed will follow the configuration of the currently configured view in the analysis window.

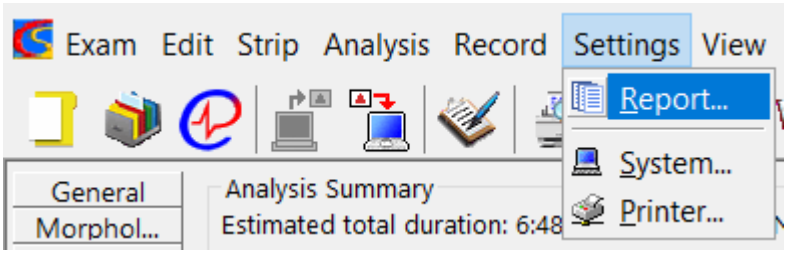
11.3.7. REPORT OF EPISODES SUGGESTIVE OF APNEA/HYPOPNEA

To allow the final report to include a report of episodes suggestive of apnea/hypopnea, the report setting should include this component.

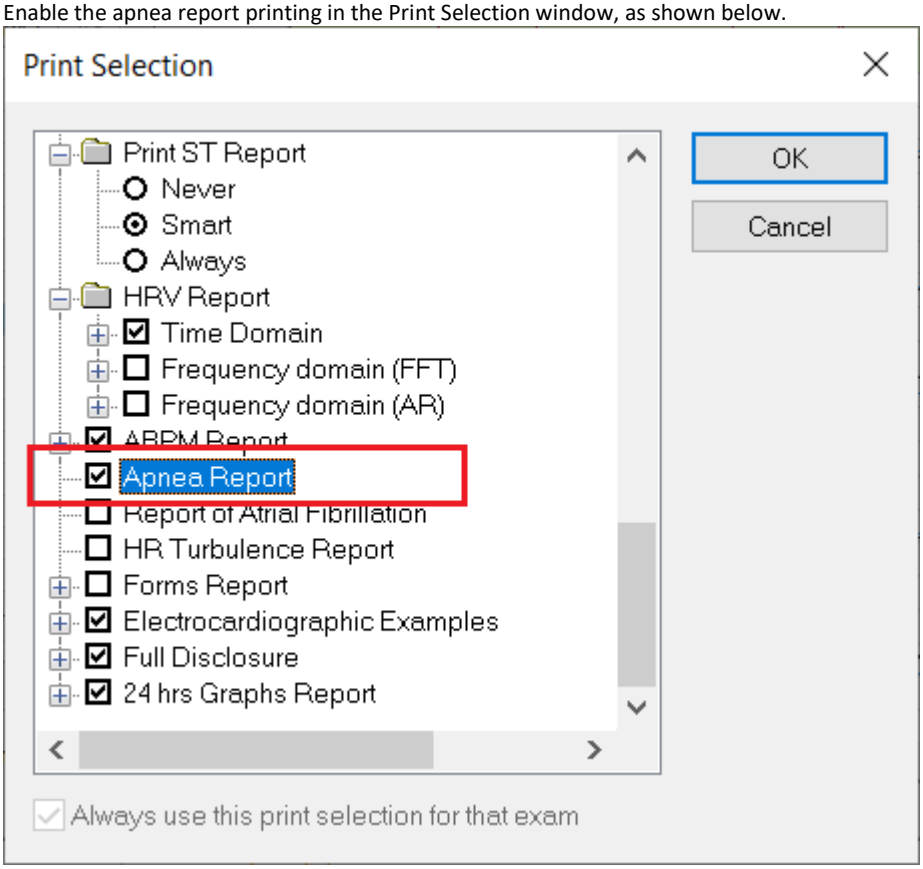
If in the global system setting, the apnea report option is enabled, as in the following figure, it will automatically be included in the final report.



If it is not enabled in the global settings, it should be done in the settings of the currently open exam report. To do this, select the [Settings] option in the main menu and click on [Report].



Enable the apnea report printing in the Print Selection window, as shown below.



The report of episodes suggestive of apnea/hypopnea, once enabled, will include at least two components: the episodes chart and a general analysis tachogram.

The report table will contain all the analysis component episodes and will have, in its lower portion, an estimated time summary of apnea/hypopnea occurrences, as well as the estimated number of apnea/hypopnea cycles.

Apnea/Hypopnea Suggestive Episodes

Exam Number	Patient: D	Code:
213.981/89	**Exam date:** 13/09/2017 13:59:00	**1EE-05269**

Hour	Duration (min)	HR (bpm)	HR Amplit. (bpm)	Cycle Duration (s)	Cycle Std. Dev. (s)	Cycles Qty.	Tipicality (%)
1:31	08:18	42	49	74	2,4	7	89
4:11	21:39	44	48	66	6,0	20	
6:43	16:25	47	21				
7:13	08:18	42	47	65	9,4	8	83

Totals

Estimated apnoea total time:	**0:54:39**
Number of episodes:	**4**
Estimated quantity of cycles:	**34**
Longest episode:	**0:21:39**

Criteria: *Period of analysis: total; Agglutinate intervals between apneas up to: 2min 30s; Repositioning irregular isolated beats: yes; Enhanced sensitivity activation: no.*

Note that for episodes with user edits, whether they are period's addition or merge not detected by the automatic analysis, they will be highlighted in the report table by a shadow, as seen in the example above.

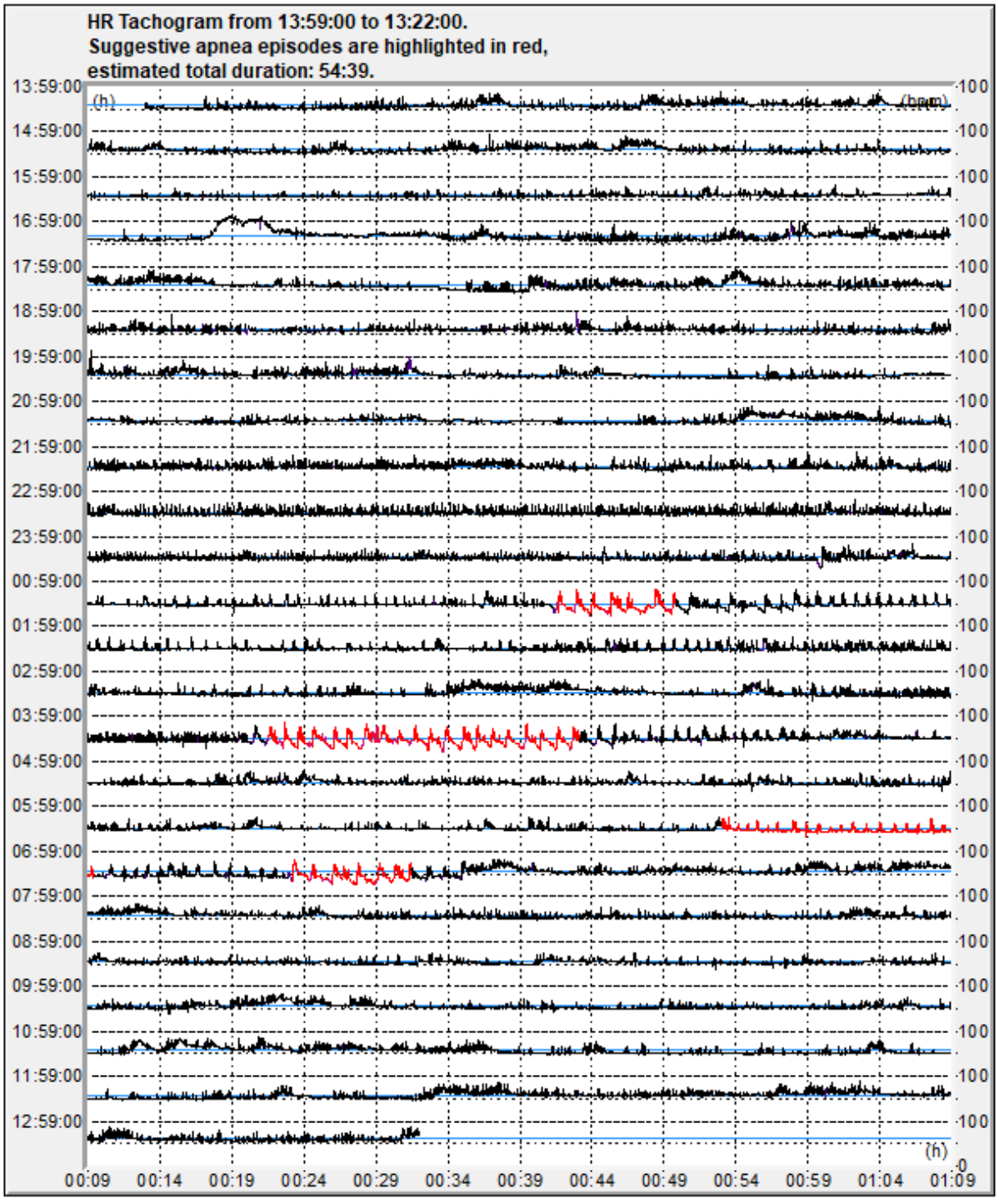
The total estimated time, in hours, corresponds to the sum of all the periods in which HR variation cycles suggestive of apnea/hypopnea were detected.

The estimated number of episodes summarizes the cycles detected, which would potentially correspond to an “arousal” event in a polysomnography.

The general tachogram of episodes suggestive of apnea/hypopnea covers the period set for the analysis.

Apnea/Hypopnea Suggestive Episodes

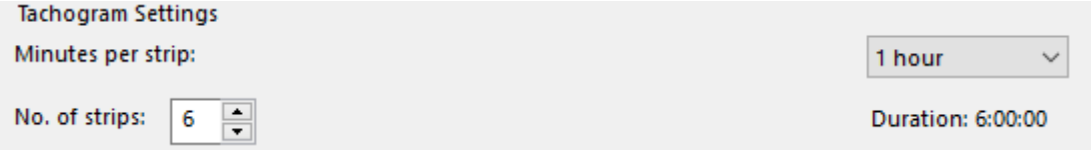
Exam Number	Patient: D	Code:
213.981/89	Exam date: 13/09/2017 13:59:00	1EE-05269



If the setting is selected for the total exam period, the tachogram will correspond to that period.

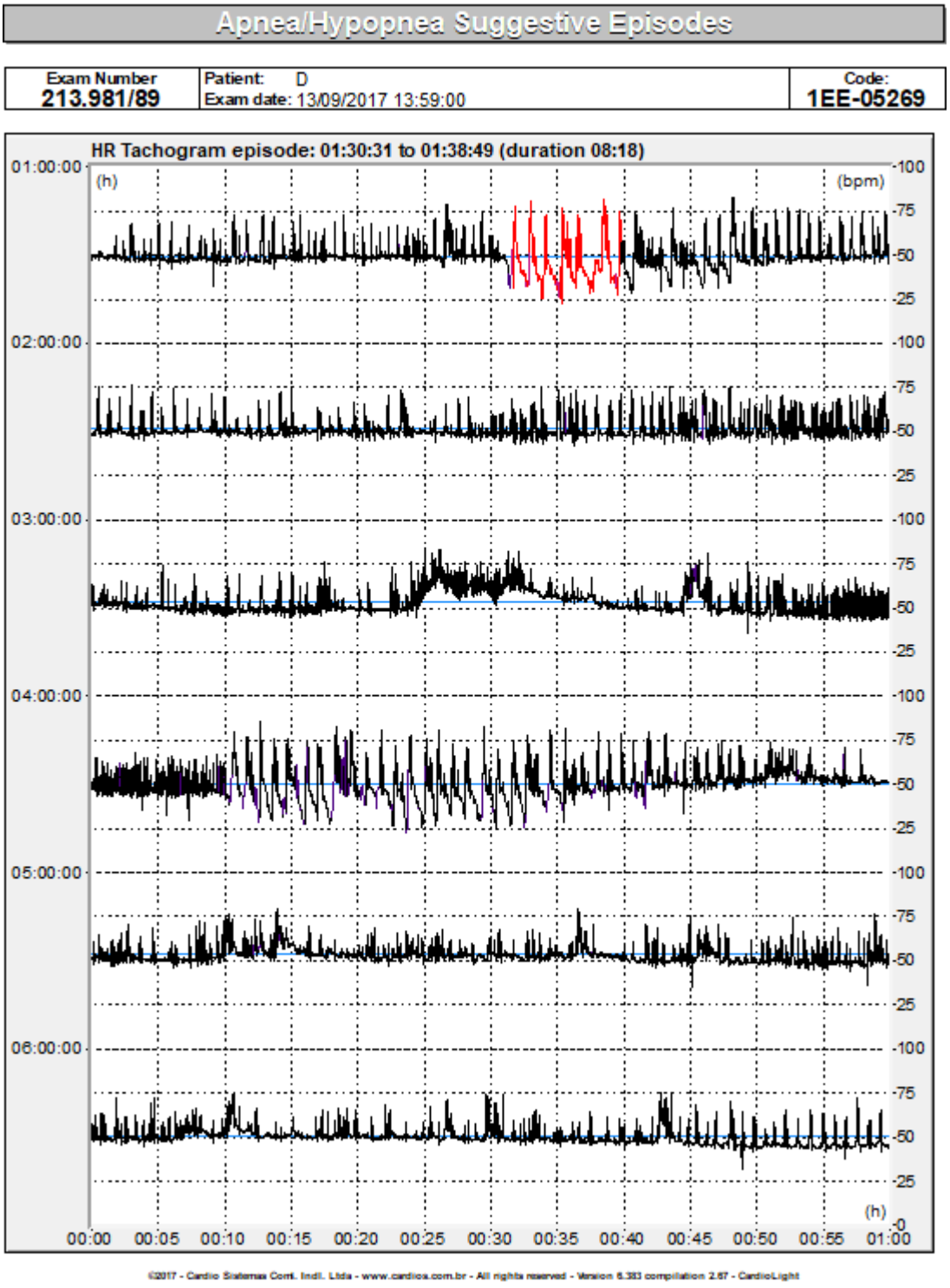
If the analysis is only set for the sleep period, the scope of this tachogram will be limited to this period (as in the previous example, with sleep setting between 00:00 and 08:00).

For each example the user selects for inclusion in the report, a tachogram page will be added, and these will follow the ranges number and length settings on the analysis window.



In the example above, we see a configuration of three ranges, each with a 10-minute duration.

The tachogram included in the report for each example selected by the user will meet this setting, as seen below.



12. CARDIONET

The CardioNet® module enables the transmission and reception of exams, as reported in the topic "Technical Compatibility with Other Devices" via Internet. Using this method eliminates the time required for exams to reach the analysis center, which receives the data, processes it and returns the report also via Internet, which can be printed by the requesting service.

It is thus possible, in one day:
- Remove the device from the patient after recording;
- Transfer the recording to the computer;
- Check if there is adequate signal for the analysis;
- Send the exam via Internet to the analysis center;
- Send an notification email to the analysis center that a new exam has been submitted;
- Prepare and install the device on the next patient;
- Receive the laudable report of the exam sent (depends on the analysis service);
- Print the report.

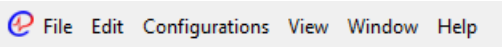
The analytics service center may, as available, receive, analyze, report and issue the report within hours of withdrawing the patient exam. The report is sent back via the system itself (or via email) in PDF format and printed by the exam-generating center itself.

12.1. SCREEN DESCRIPTION

The main screen is composed of several areas, each with its specific function, as described below.

12.1.1. MAIN MENU

Located at the top of the main screen is where we can command and configure the software.



12.1.2. TOOLBAR

It functions as a shortcut to activate the most common software operations.

Icon function description

Create a exam - used to create a new exam

Referring Doctor - open the referring doctors list

Transfer a recording - used to acquire recorded data

Send E-mail - used to send a exam file attached to an e-mail message

Settings - used to access general system settings

Help

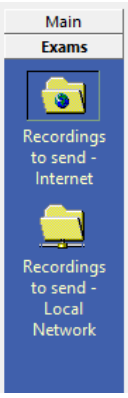
12.1.3. SIDE MENU BAR

It allows navigation between the main screens. By clicking on each of the icons, the corresponding screen is accessed.

In this window, there are three tabs for the software windows.

On the Main tab, we have the software initial screen, with the configured exam and report folders.

On the Exams tab, we can access the exam manager window.
Analogously, we use the Reports tab to manage software reports.
The Exam and Report areas, are divided into specific accesses to the local network or to the internet.



When we access the Exams area, we noticed two subdivisions in the menu:

Recordings to send - Internet: Access to the control window of exams in the Remote area, where the exam files are posted.

Recordings to send - Local Network: Control window of exams in the Local Network. This network may possibly be a wider network (WAN, VPN, etc.).

When we accessed the Reports area, we see two subdivisions in the menu:

Reports to send - Internet: Access to the report control window in the Remote area, where the PDF files of the analyzed exam are posted.

Reports to send - Local Network: Report control window in the Local Network. Like the exams, this network may possibly be a wider network (WAN, VPN, etc.).

In the Local Network and Internet windows, other information and controls will be available in the lower area of the screen under the patient list. This information and controls are described in the exam and report sending sections.

12.1.4. WORKSPACE

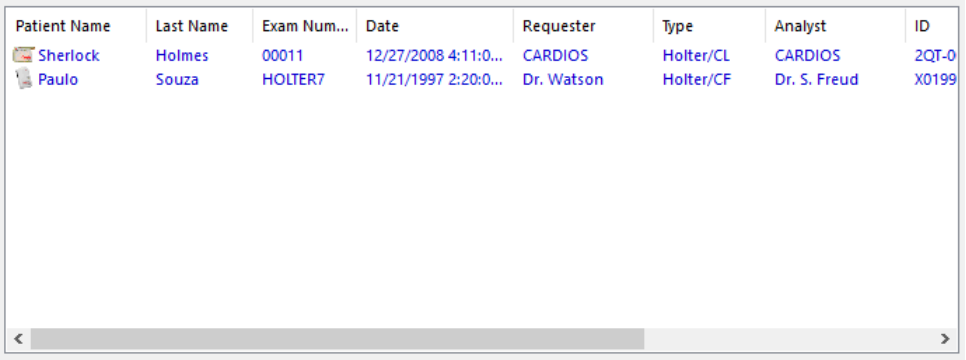
For each selected window (as commented in the previous item), it will have a specific format, but its basic function is to list the exam files present in the software. The information display format can be configured in two ways:

Icon display: The software displays an icon corresponding to the type of examination.

Exam recorded with **CardioLight+®**

The information for each exam is initially "truncated". To check them completely, click once on the corresponding icon and you will be able to see the patient's full name and date of the examination.

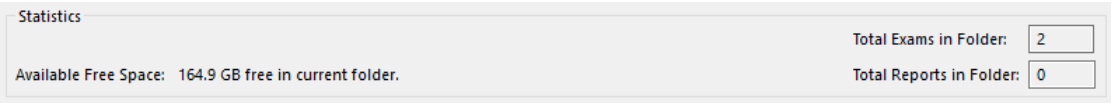
List view: The software displays a detailed list of the data for each exam, adding a colored mark to the exams already sent.



Patient Name	Last Name	Exam Num...	Date	Requester	Type	Analyst	ID
Sherlock	Holmes	00011	12/27/2008 4:11:0...	CARDIOS	Holter/CL	CARDIOS	2QT-0
Paulo	Souza	HOLTER7	11/21/1997 2:20:0...	Dr. Watson	Holter/CF	Dr. S. Freud	X0199

12.1.5. STATISTICS - MAIN WINDOW

In the lower area of the main window, under the workspace, there is a software statistics window, which shows us some useful data:



Available Free Space: Reports how much disk space remains (in megabytes or gigabytes).

Total Exams in Folder: Reports the number of exams found in the standard exam folder.

Total Reports in Folder: Indicates the number of reports found in the default reports folder.

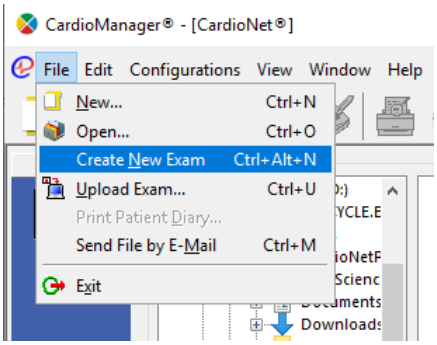
The number of exams or reports found refers to the folder that is currently selected in the software. If the software is viewing any folder other than the default folder, and in which exams or reports are found, the number indicated will be that of the folder currently being "selected".

12.2. PREPARING EXAM

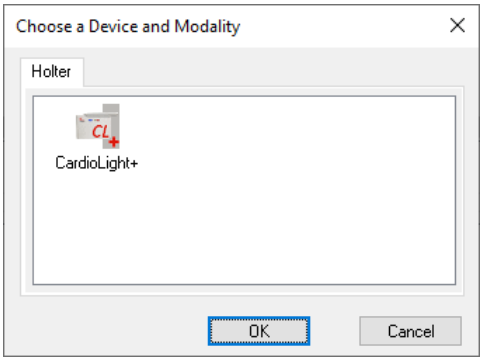
When using a digital recorder to record a Holter or Event exam, you must first prepare the device.

It is imperative that the recorder is programmed for the exam to be performed before being installed on the patient. This causes the software to insert the identification of the patient to be examined on the memory of the recorder. In this way, it is ensured that an exam of a particular patient is not inadvertently transferred as if from another patient.

To do so, select the [File] option in the main menu, then select [Create new exam]. This can also be done by combining the [Ctrl] + [Alt] + [N] keys.



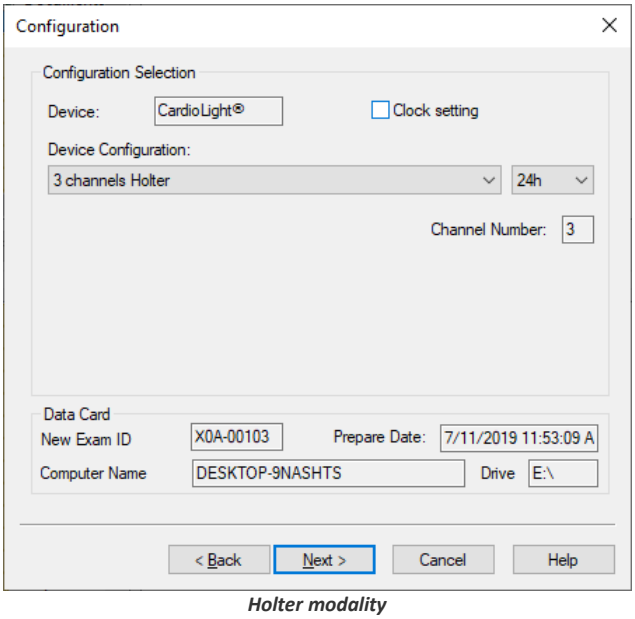
The software will display a window, where we must select the mode and the recording device to be used in the exam.



In the Holter modality, it supports the exam preparation of the digital recorder **CardioLight+**®

When selecting a digital recording device, the software will automatically search for the its presence. If not connected, the software will display a message asking you to connect the device.

Once the device is located, the next step is to set the configuration.

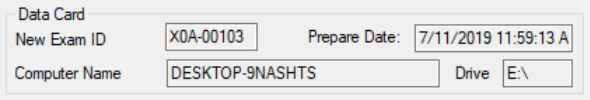


Holter modality

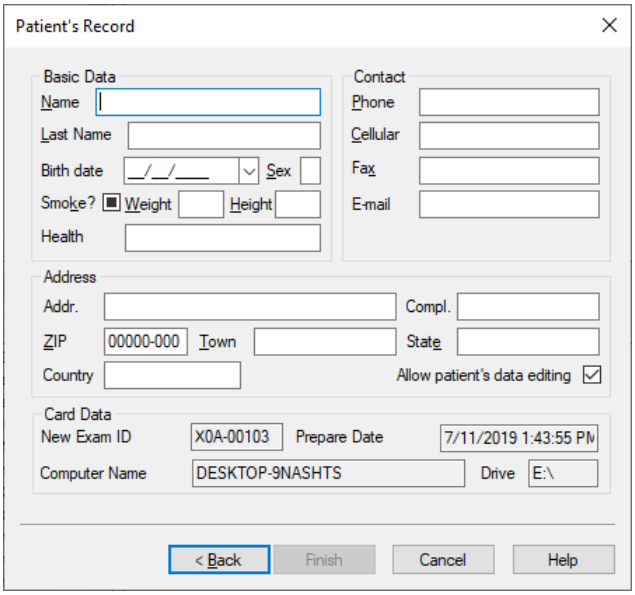
The "Clock Setting" option allows you to set the internal clock of the recorder according to the time of the computer that is preparing the exam.

The correct start time of the exam is fundamental to the analysis. The time used to set the internal clock is determined by the time of the computer programming it. Always make sure your computer's time is correct before selecting the time setting option.

At the bottom of the window, there are some information regarding the configuration of the exam.

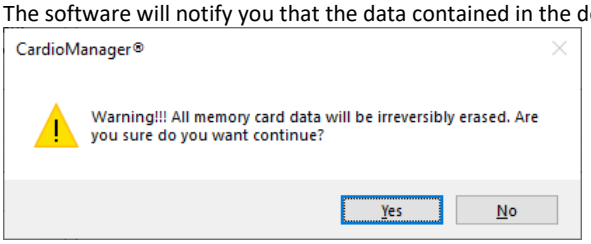


The next step is to fill in the patient data. Try to fill in the data as completely as possible. This helps a lot the medical analyst. At least the patient's first and last name must be filled out, information without which the software does not proceed in the creation of the examination.

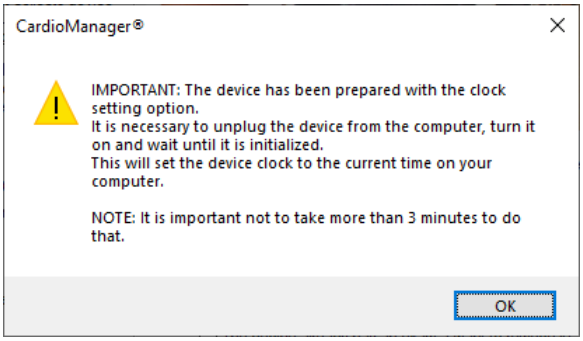


After completing this data, click on the [Finish] button.

The software will notify you that the data contained in the device will be erased and will ask for confirmation to continue.



If you selected the "Clock setting" option, the software will issue a warning that it is necessary to start the exam within a maximum of 3 minutes. This will ensure that there will be no significant delay between the time set on the device and the actual time.



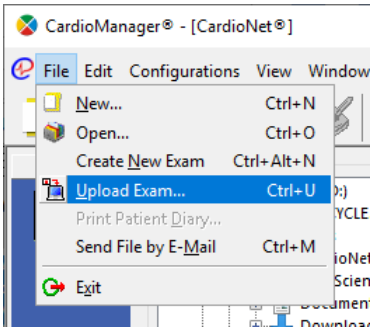
Now install the device on the patient and instruct him on how to behave during the examination and how to operate the event button.

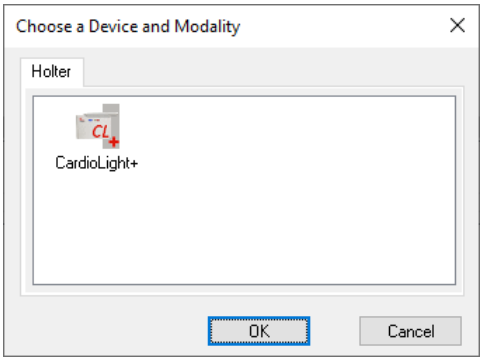
The success of the exam depends essentially on the quality of the electrodes installation in the patient and the understanding of the same regarding the operation of the device and the behavior to be adopted during the examination.

For details, refer to the operation manual of the digital recorder.

12.3. READING THE DIGITAL RECORDER

After recording an exam with a compatible digital recorder, you must transfer the recorded data to the software. To do this, click on the corresponding icon in the software toolbar. You can also trigger data transfer via the [Files] menu by selecting the [Upload Exam] item.





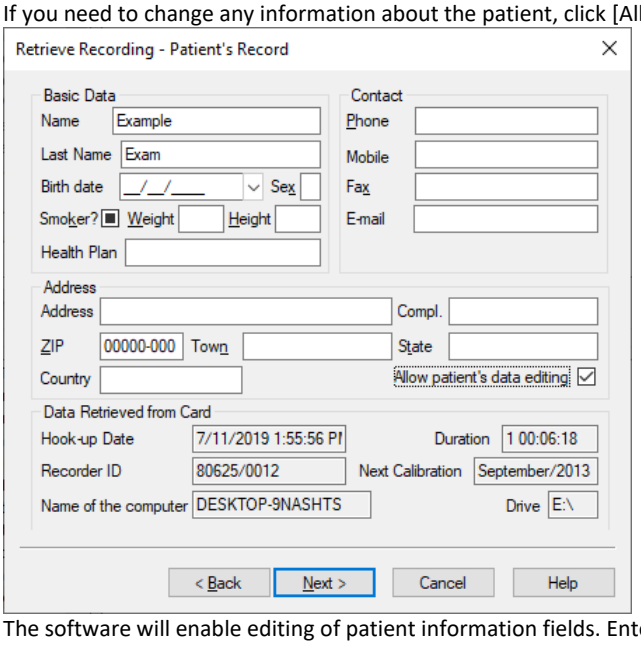
Select the modality and type of device that recorded the exam.

If the device connected to the software has different data from what is expected, the software will display a warning screen comparing device data with software data.

Review the information presented and take corrective action if necessary. Press [Next>] to display the patient data.

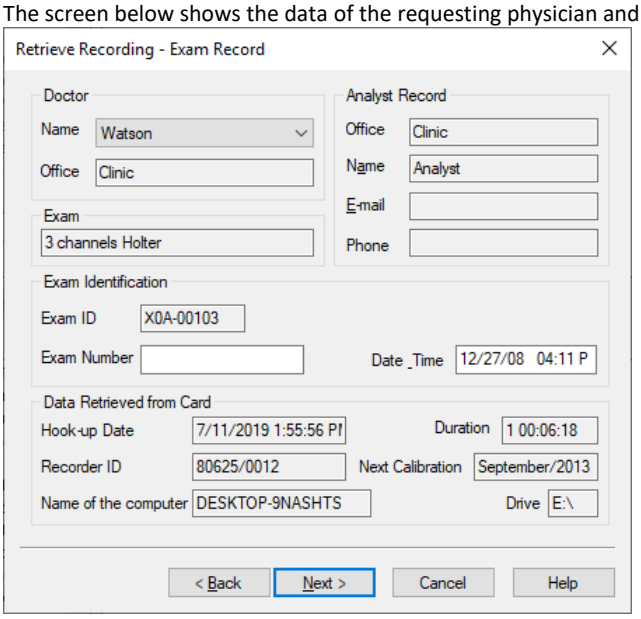
The software will scan the connected device and display the exam data screen.

Note that the patient data fields are grayed out, inaccessible for editing.
If you need to change any information about the patient, click [Allow patient´s data editing].



The software will enable editing of patient information fields. Enter the correct data in the fields you want to change or complete. When finished, click on the [Next] button.

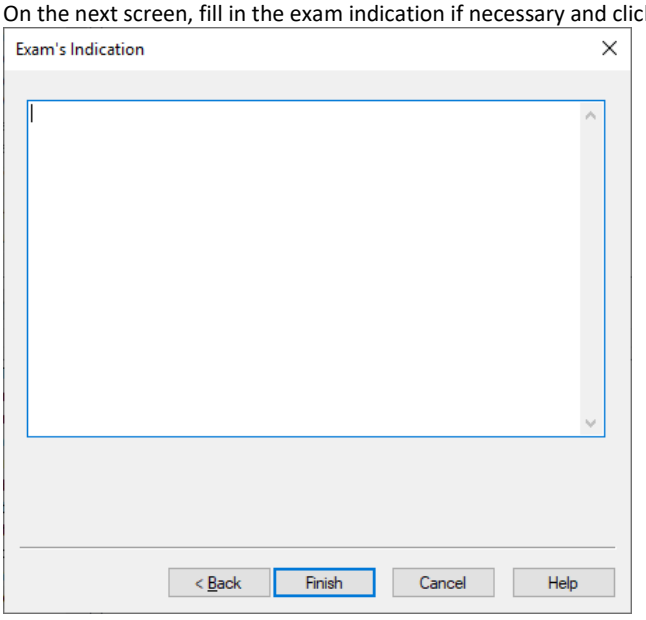
The screen below shows the data of the requesting physician and the analysis service for which the examination will be sent.



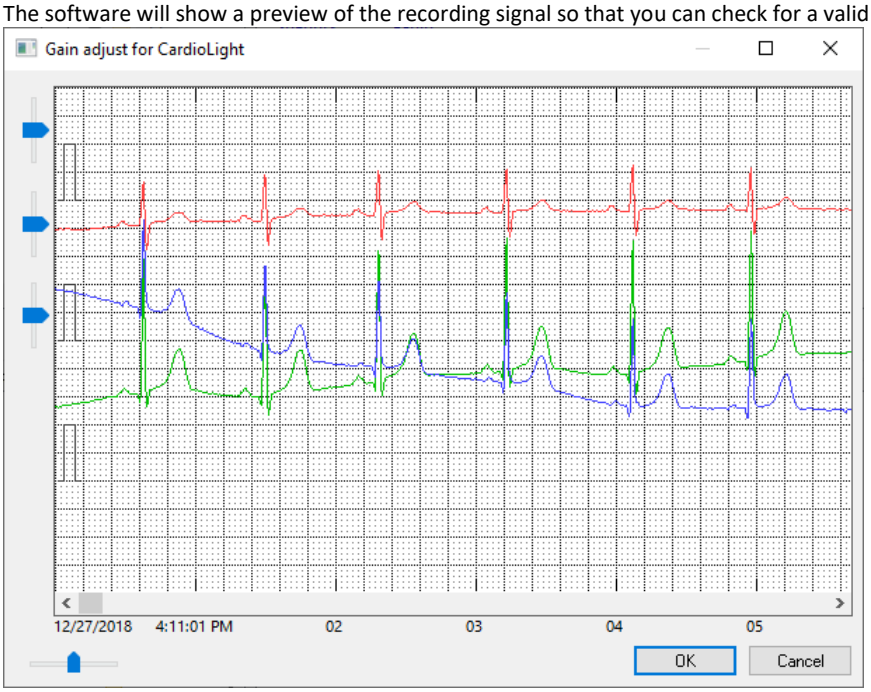
You can at this point change the identification data of the exam by simply entering the new data about the old ones in the corresponding spaces:

If everything is correct, click the [Next] button.

On the next screen, fill in the exam indication if necessary and click the [Finish] button.



The software will show a preview of the recording signal so that you can check for a valid ECG signal on the device.



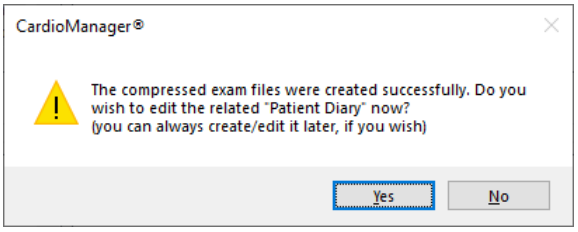
There is the option to change the gain on the side window controls and the graph density on the control located in the lower left corner of the window.

At the beginning of each ECG strip there is a signal, which was called a calibration signal. Despite being a recorder that stores the exam in digital memory, this signal is displayed to facilitate visualization of the ECG chart, by improving the usability of the tool to the Operator/Medical. This pulse, in the form of a square wave of 1mV amplitude, can be used as the amplitude reference for the ECG signal.

It is important to check whether the signal is suitable or not, because if there is no analysis signal, it will be necessary to repeat the examination. It is convenient to perform this check before dispensing the patient and, if further examination is necessary, as take the opportunity to reschedule.

If there are recorded signal and it is appropriate, click the [OK] button.

After transferring data from the device memory to the PC, the software will display a screen giving you the opportunity to fill in the patient's diary. If you wish to do so, read the section corresponding to the Patient Journal item.

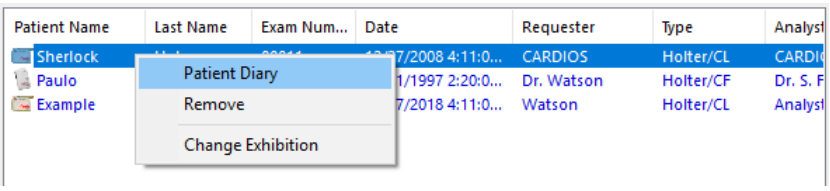


12.3.1. PATIENT DIARY

Allows the creation of a patient diary, which can be filled after the record transfer of the exam data, or later.
This diary is a kind of spreadsheet, with predefined areas for typing times, description of activities and symptoms.

The exam identification data, containing the patient's name, exam file identification, start time and date are taken directly from the ECG data file, and can not be changed. Therefore, it is important that you properly record these data when creating the exam.

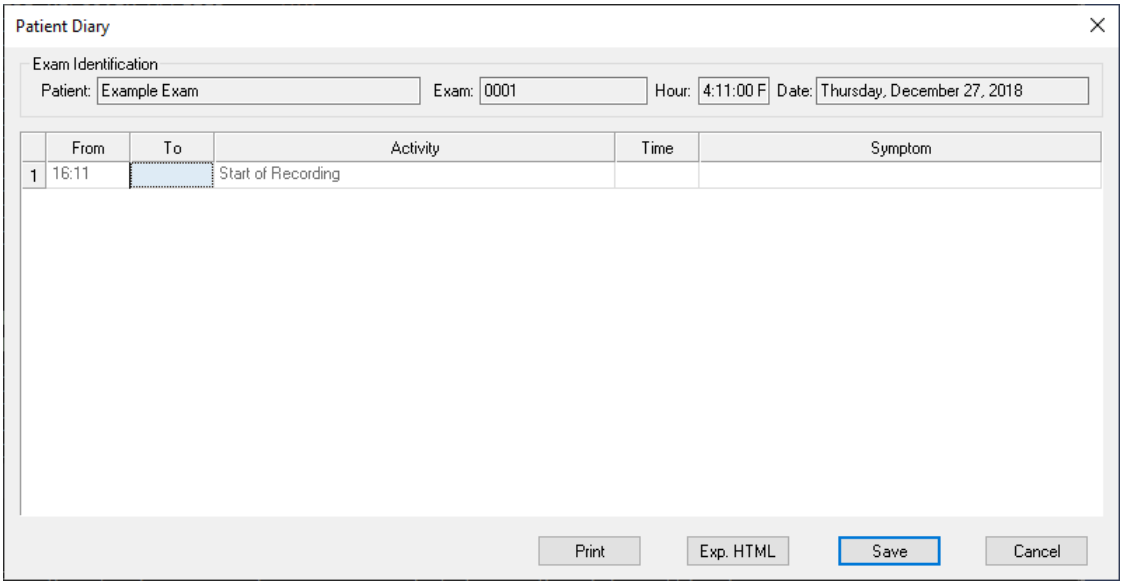
To access the patient diary editor, select any screen where the local examination area is displayed. Right-click the exam for which you want to enter the diary data. A menu will appear.



Select the [Patient Diary] option. A window will open.

In this window, the start time of the recording is already filled with the time of the exam file.

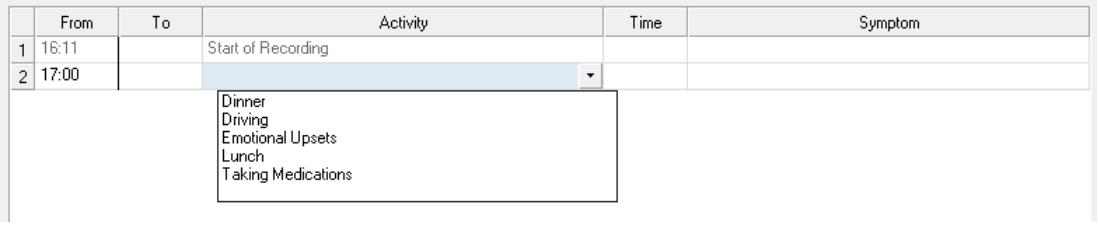
Just below, we have the first cell of the diary previously filled, containing the start time of the recording. To access the other cells, we can "navigate" through the diary with the [Tab] key to advance to the next cell or with the combination [Shift] + [Tab] to go back to the previous cell. With the mouse, we can point to any available cell in the worksheet. To enter text or time, simply "focus" the desired cell and type directly inside it.



The times must be filled in with 4 digits, and the hour and minute separators are placed automatically.

Also note that when filling in a symptom (or event), the editor automatically advances to the next cell and fills in the next time. If any cell fill is incorrect or does not match the one you want, just select its contents and press [Delete].

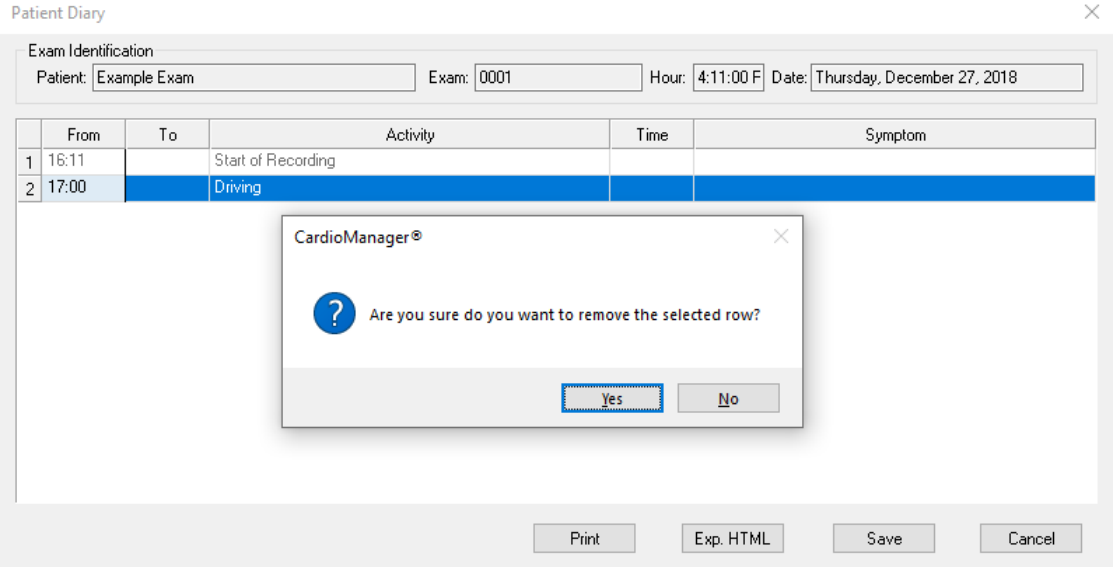
In the cells corresponding to the activities and symptoms, there are pre-filled lists, which can be used to facilitate the diary. Just click with the mouse on the cell, which a button will appear to the right of the text area.



Click on this button and a list of phrases or words will be displayed. Select the desired text by locating it in the list and clicking on it. If you do not find what you want to describe in the list, just type the text and it will be incorporated into the list and can be used whenever necessary.

If you want to delete a diary line, click on the check mark corresponding to the line number and press the [Delete] key.

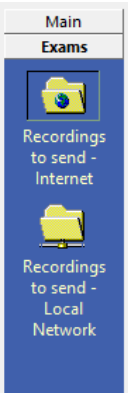
The software will ask you to confirm the operation. If you are sure that you really want remove it, click the [Yes] button.



After finishing editing the diary, click on the [Save] button. The data will be stored together with the exam and the analyst doctor will be able to see it after importing the exam into your software.

12.4. SENDING EXAMS

CardioNet® has all the tools you need to manage Holter exams sent by analysis clients via the Internet or a local network. The software sends files exams or reports via the HTTPS protocol, which is widely used on the Internet for transferring files. CardioNet® works in a similar way to other HTTPS transfer software, but also incorporates the content identification features of the exams, checking the files download integrity and other features.

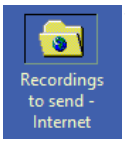


To send exams, first we must access through the navigation menu the Exams area.

In the area of exams, we can select the option to send via Internet or through a local network. The last option accessed will open automatically when you access the exam area. Click on the desired option in the navigation menu.

12.4.1. SENDING EXAMS VIA INTERNET

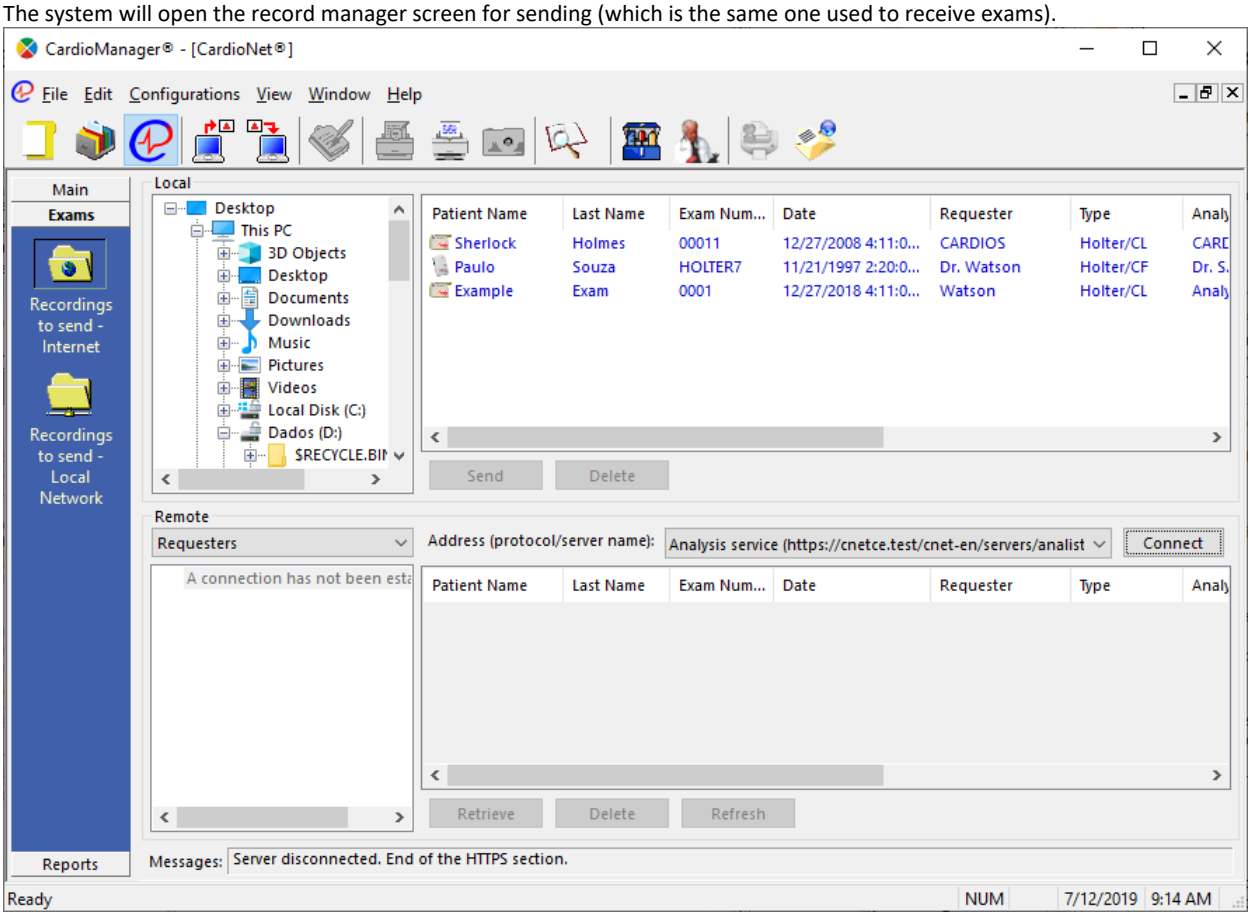
Sending exams via the Internet through the CardioNet® System is the way that best exploits the potential of CardioNet®, since the exams posted on the CardioNet® System can be received by another CardioNet® system anywhere in the world where there is access the Internet.



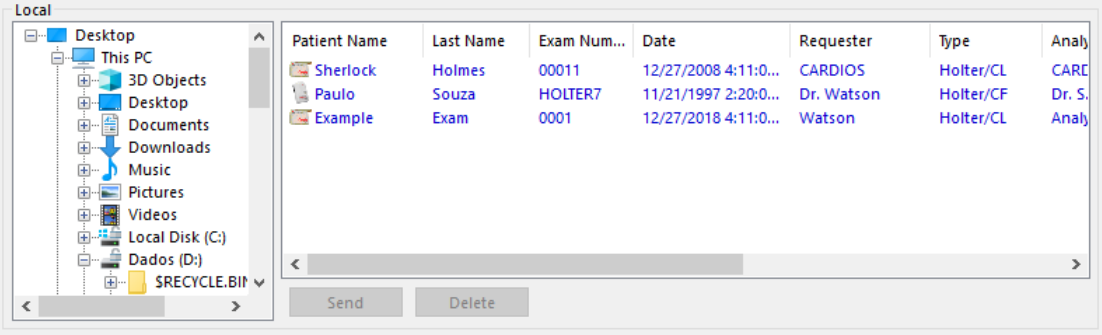
To send exams to the Internet, select the Exams tab in the navigation menu and click on the "Recordings to send - Internet" icon.

Remember that exam viewing windows (Local or Remote) can be configured to display the exams in the form of icons (as seen in the following figure) or in list format, the latter being the most suitable. In list mode, we have more visible information about the exams, making it easier to identify the file (s) you want. To change the display format, right-click on the area you want to configure and select the desired display format.

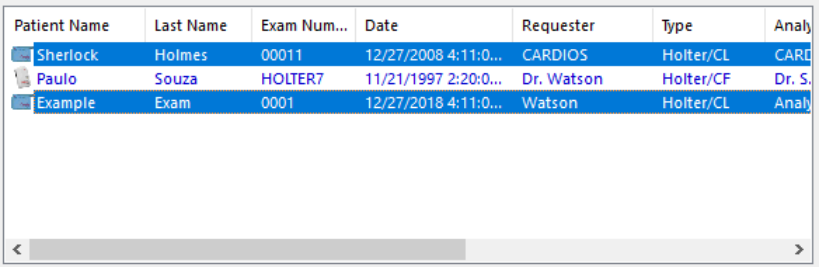
The system will open the record manager screen for sending (which is the same one used to receive exams).



In the upper area of the screen we will see the Local window, where we have the list of stored exams on the computer.



To select an exam, simply click on it, which will then appear highlighted in blue. To select multiple exams randomly, hold down the [Ctrl] key while clicking on each of the exams you want.

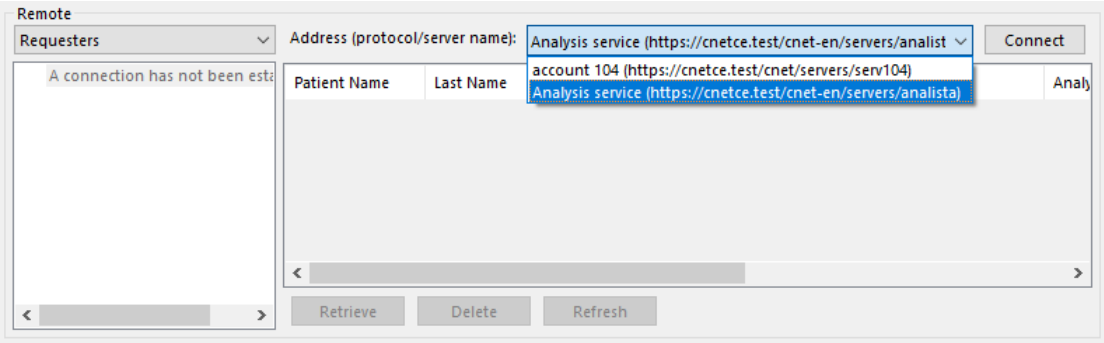


To select a sequence of exams, click on the first one of them and, holding down the [Shift] key, click on the last exam of the sequence.

The lower area of the (Remote) screen will initially be empty because the system is not yet connected.

The connection control will show the account set to "default" in the settings area. We can have several accounts configured, and we must select the account to which we wish to send the exam file (s).

To select an account already configured, just click the connection control on the small arrow to the right of the address. Select the address to which you want to send the exam (s).

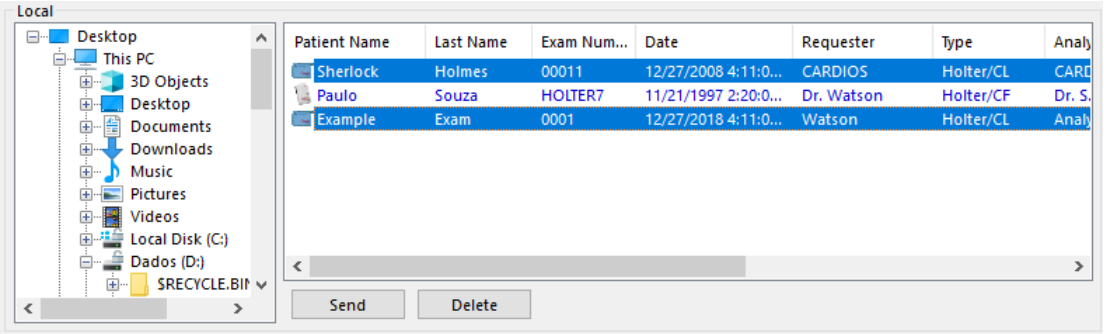


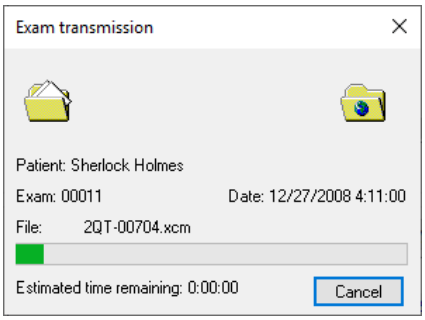
After selecting the desired address, click on the [Connect] button. The system will initiate the connection with the CardioNet® System, displaying on the status line a series of messages regarding the operation in progress.

When finished building the list and retrieve the information, the system displays the status line a message that the operation is complete and the system is ready to work.

The duration of each of these phases depends on the connection conditions and the number of files that is stored in the remote area. The higher the number of files in the Remote area, the longer the connection time is required.

Once you have the exams selected for sending, click on the [Send] button at the bottom of the Local window.

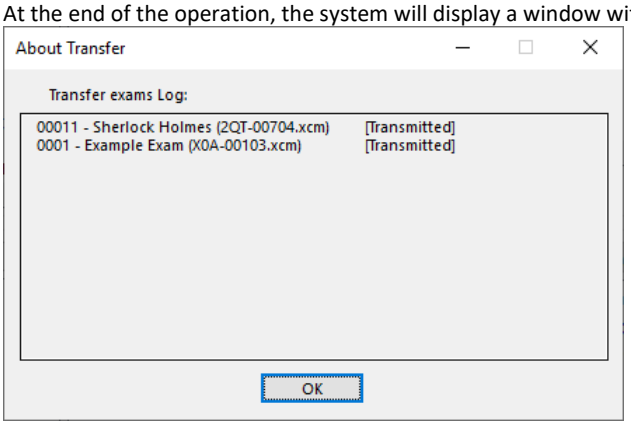




The system will start the transmission of the selected file(s), showing a progress screen.

This will repeated for each file, and the transmission time will depend on the speed and the Internet traffic conditions.

At the end of the operation, the system will display a window with the operation summary



The CardioNet, if configured to do so, will send a message via email to the recipient of the exams, advising you which files have been posted for analysis.

On some systems, depending on your e-mail settings, you may receive a system warning that a program is trying to send messages using a particular identity. This is a feature of Windows that aims to prevent programs from accessing messaging services automatically.

The recipient of the notification message is the e-mail address configured on the analyst physician's tab.

The body of the message contains text similar to the following:

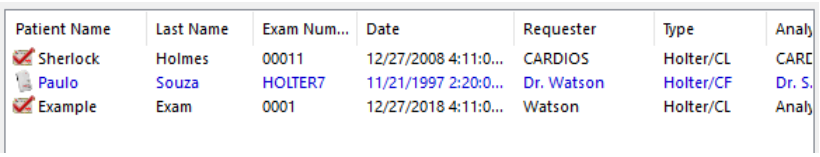
```
From:  Requesting physician
To:    Analyst physician

       This e-mail was automatically sent in order to notify you about
the transmission via CardioNet of the following exam:
       2QT-00704 - Sherlock Holmes (2QT-00704.xcm)
```

```
Yours very truly,

       Requesting physician
```

In your system, when in the "list" view, files already transmitted will be highlighted by a small colored mark on the left side of the data:

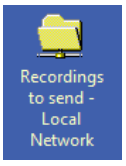


Patient Name	Last Name	Exam Num...	Date	Requester	Type	Analy
Sherlock	Holmes	00011	12/27/2008 4:11:0...	CARDIOS	Holter/CL	CARD
Paulo	Souza	HOLTER7	11/21/1997 2:20:0...	Dr. Watson	Holter/CF	Dr. S.
Example	Exam	0001	12/27/2018 4:11:0...	Watson	Holter/CL	Analy

The files will be available for download from the analysis center to which they were sent, which will be notified via email notification.

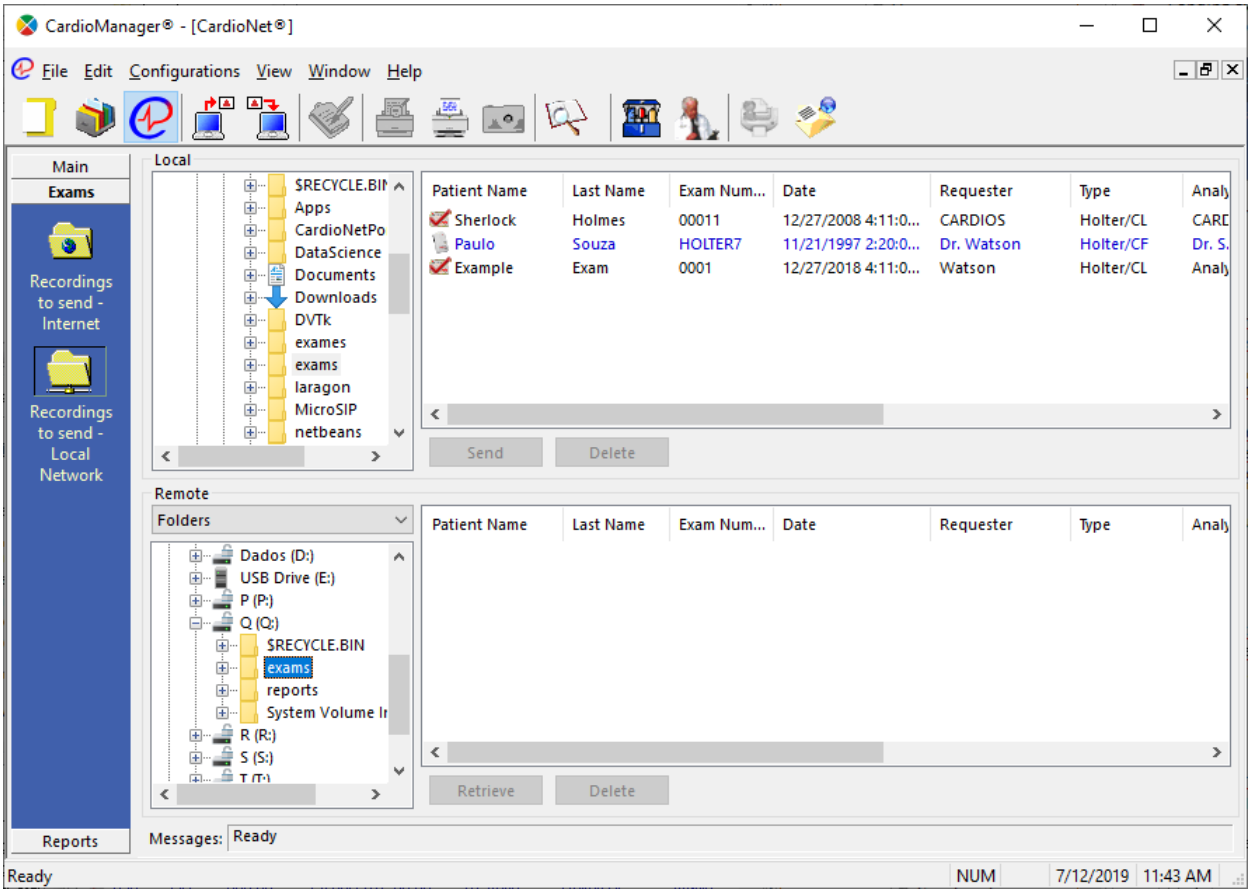
12.4.2. SENDING EXAMS VIA LOCAL NETWORK

Sending exams via Local Area Network allows CardioNet® to send through a private network, whose scope can be literally local (same room or even building) or geographically distributed in several locations.



To send exams to the Local Network, select the Exams tab in the navigation menu and click on the "Recording to send - Local Network" icon.

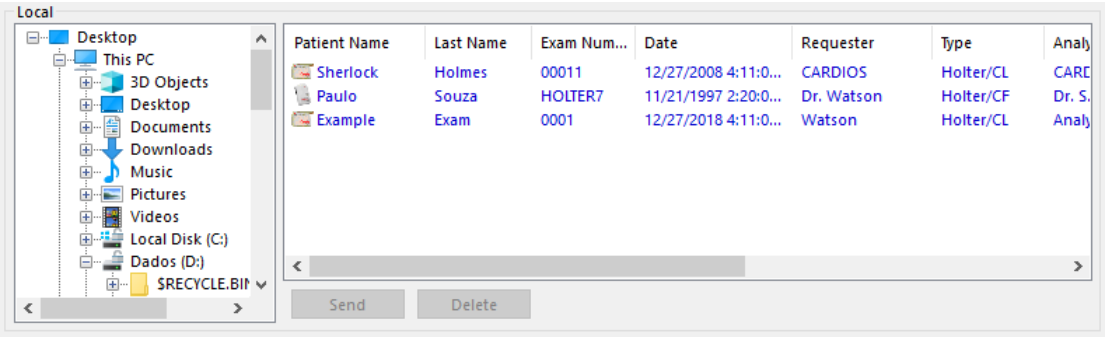
The system will open the record manager screen for sending (which is the same one used to receive exams).



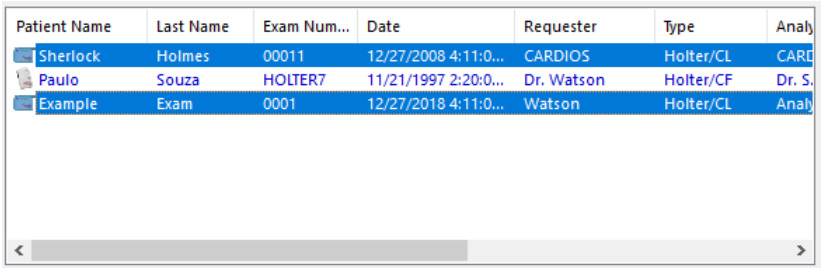
Unlike the Send window to the Internet, in the Local Area window there is no connection control, and the connection is automatically made if the Local Area Network folder is available.

Remember that exam viewing windows (Local or Remote) can be configured to display the exams in the form of icons (as seen in the following figure) or in list format, the latter being the most suitable. In list mode, we have more visible information about the exams, making it easier to identify the file (s) you want. To change the display format, right-click on the area you want to configure and select the desired display format.

In the upper area of the screen we will see the Local window, where we have the list of the exams stored in the computer.

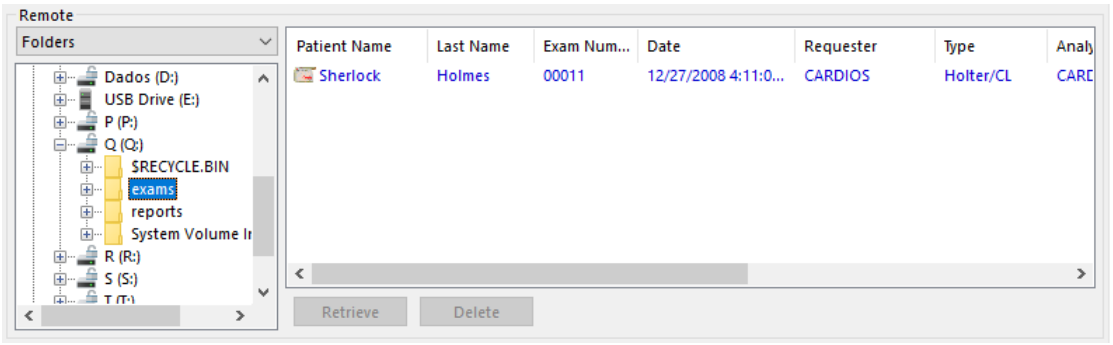


To select an exam, simply click on it, which will then appear highlighted in blue. To select multiple exams randomly, hold down the [Ctrl] key while clicking on each of the exams you want. All selected exams will be highlighted in blue.



To select a sequence of exams, click on the first one of them and, holding down the [Shift] key, click on the last exam of the sequence.

The bottom area of the screen (Remote) will display the exams that are already in the network folder.

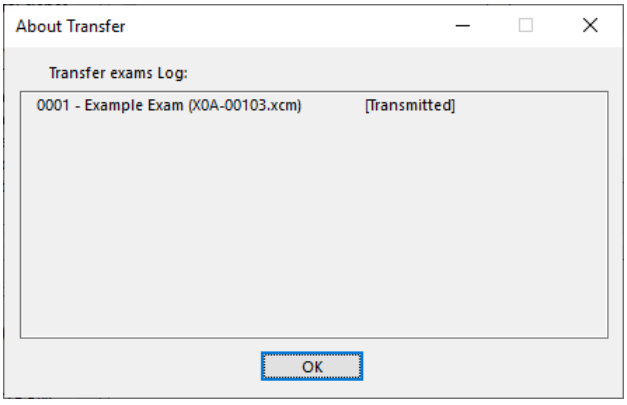


With the exams you want to transfer selected, click on the [Send] button.

Under the Remote window there is a Message line, where we can follow each step of the file transfer operation.

Upon completion, the system will send a message to the designated address on the analyst register. On some systems, depending on your e-mail settings, you may be asked to explicitly confirm the operation.

A screen containing the summary of the operation will be displayed, as shown below.



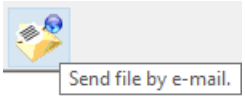
12.4.3. SENDING EXAMS VIA E-MAIL

CardioNet® also makes it possible to send exams attached to e-mail messages. This method should be considered when examining small files, since most ISPs limit the size of files attached to e-mails in 5MB, making it difficult to use them for Holter exam files. Even so, we recommend that your use be limited to instances where the HTTPS connection is unavailable.

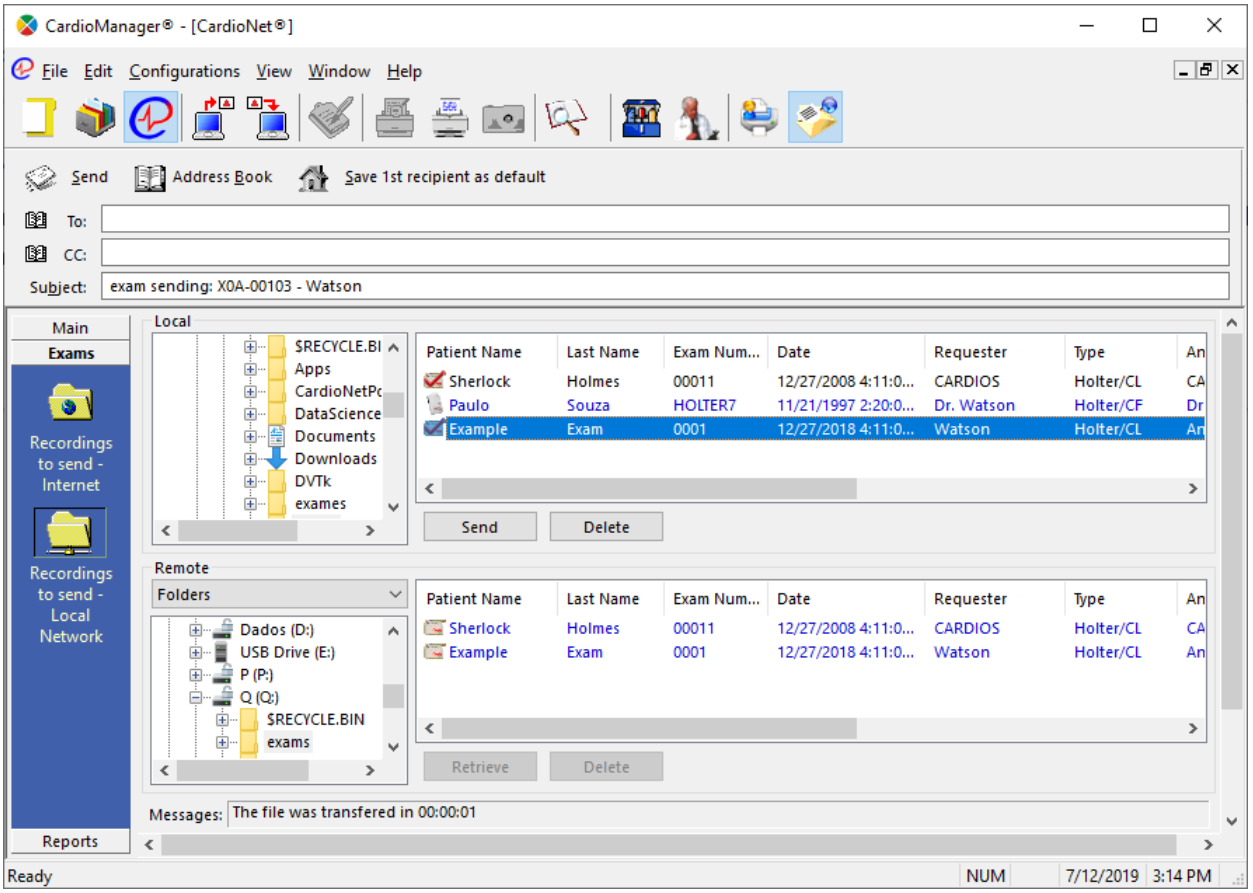
To send e-mail with exam, select the desired file in the same way as previously described for sending over the Internet or via the local network.

In email submission mode, only one exam can be sent at a time.

Having already selected the file, click on the email button, located on the system toolbar.



The screen will change the format for sending email, displaying lines to fill the recipient's data and others.



After completing the data, click on the [Send] button.

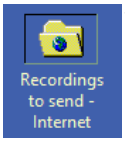
On some systems, depending on your e-mail settings, you may receive a system warning that a program is trying to send message using a particular identity. This is a feature of Windows that aims to prevent programs from accessing messaging services automatically. As in this case this is a desirable feature, click on the [Send] button if this message appears.

The recipient will receive the exam attached to an email and can import it into the CardioSmart CS550 System for analysis.

12.5. RETRIEVING EXAMS

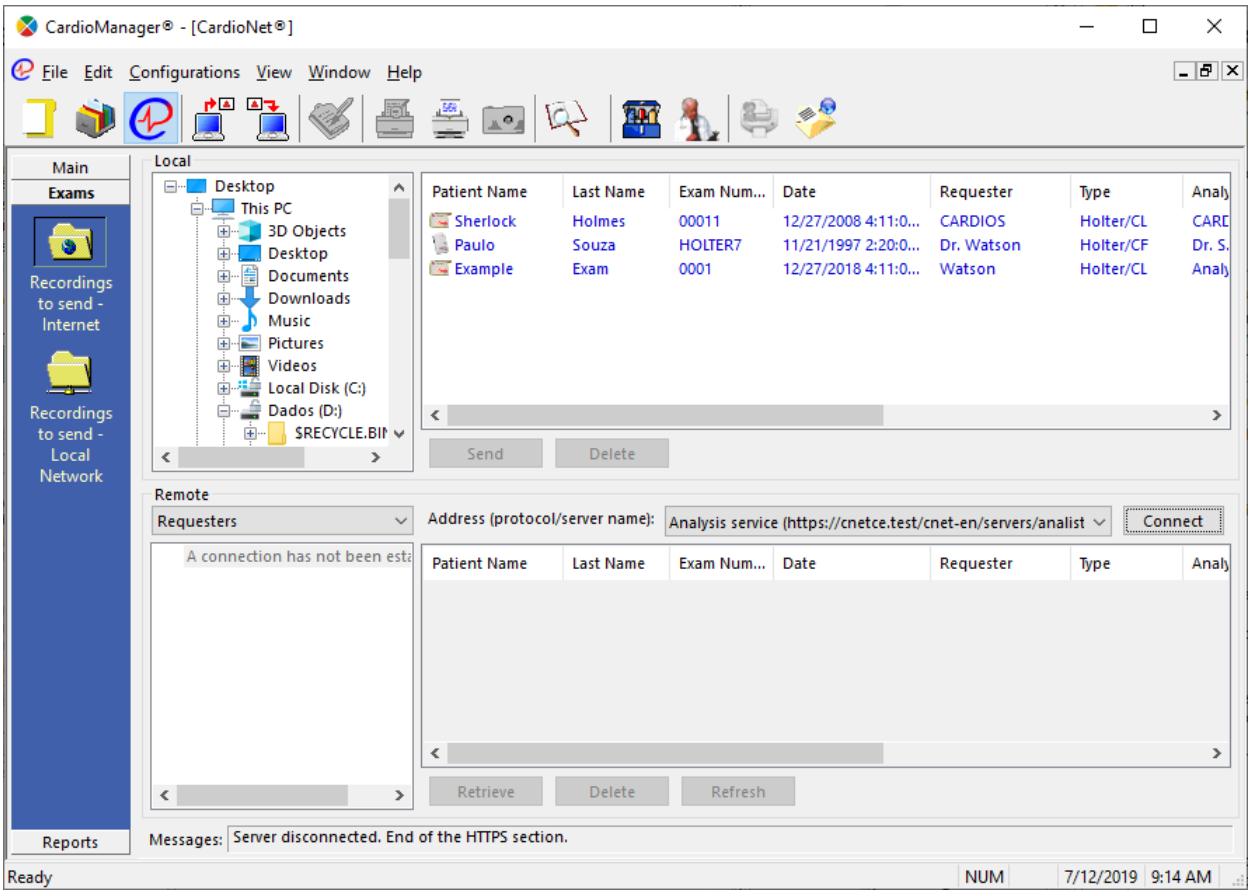
To retrieve exams, we must access the Exams area.

12.5.1. RETRIEVING EXAMS VIA INTERNET

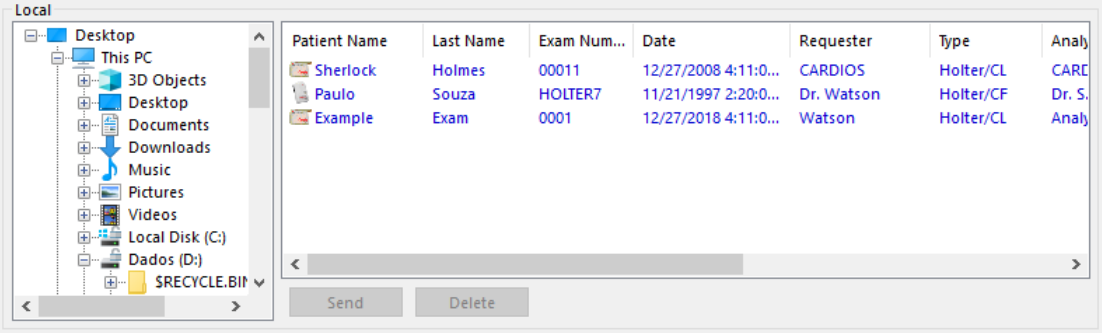


To receive exams via the Internet, select the Exams item in the Navigation Menu and click on the "Recordings to send - Internet" icon.

The exam manager window is displayed, where you can see the Local and Remote areas.



The Local window displays the list of exams that are in the local folder defined in the settings.



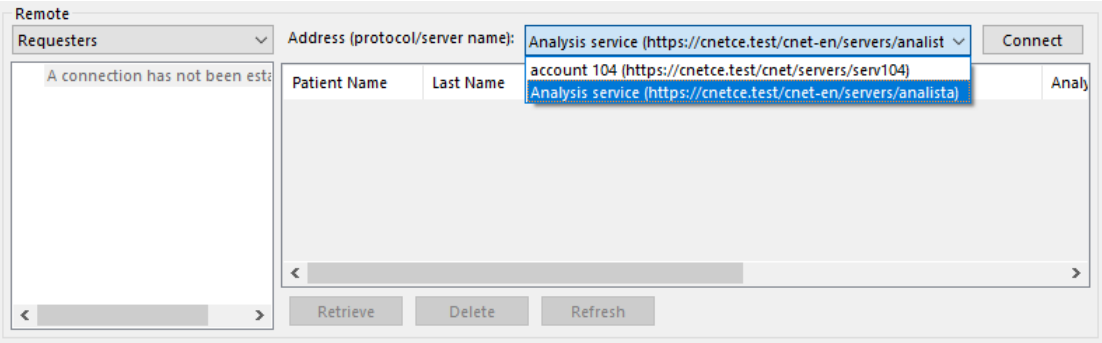
The display can be set to list format (as in the example above) or the icons format. To change the display format, use the right mouse button.

The bottom (Remote) window will initially be empty because the system is still disconnected from the Internet.

There is, in the region between the Local and Remote windows, a connection control, which should initially be showing the connection set as the default in the settings area.

Note that the connection control is a "combo box" type, that is, when you click the small arrow to the right of the text box that contains the connection name, a list with all available configured connections is displayed.

We can easily establish a connection with any of the Internet addresses added in the settings area by simply clicking on the desired address in the list of available connections.

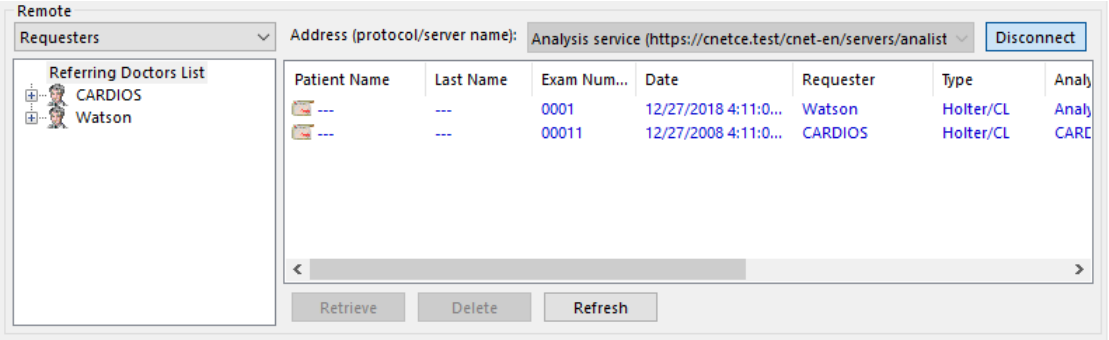


After selecting the desired address, click on the [Connect] button. The system will initiate the connection with the CardioNet® System, displaying on the status line a series of messages regarding the operation in progress.

When finished building the list and retrieve the information, the system displays the status line a message that the operation is complete and the system is ready to work.

The duration of each of these phases depends on the connection conditions and the number of exams that is stored in the remote area. The higher the number of exams in the Remote area, the longer the connection time is required.

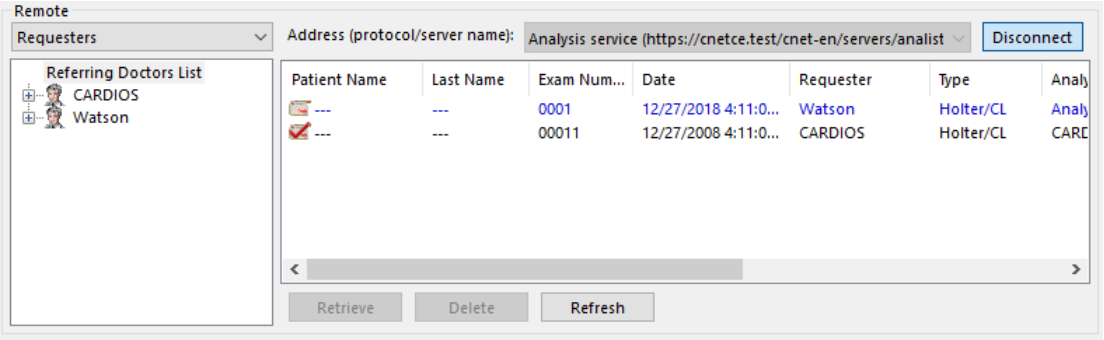
After connected, the Remote window will list all exams that are stored in the remote area.
The list will be updated every 10 minutes (configurable), and the user can also update manually by clicking the "Refresh" button.



Note, in the list above, that the system identifies with specific colors and markings the status of each exam that are in the storage area.

When a transmitted exam has already been "downloaded" on any system (whatever it is), CardioNet® will identify it in black and place a check mark in the device icon.

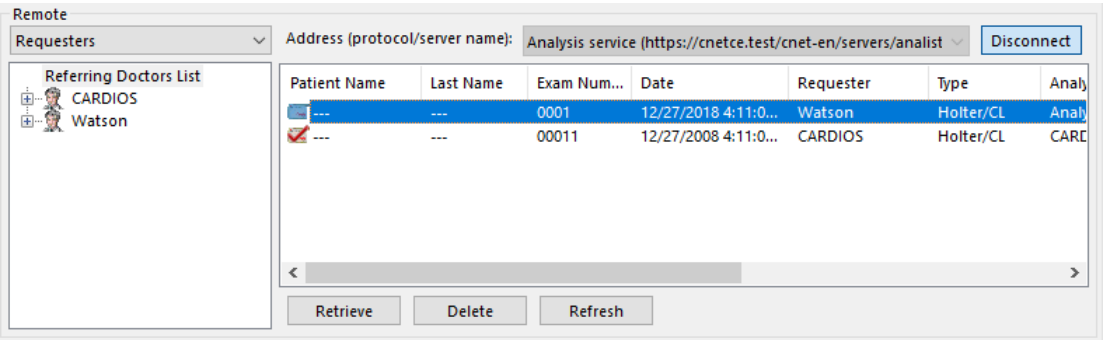
Exams identified in blue are those that were successfully transmitted to the Internet area, but have not yet been "downloaded".



The system identifies when a file is corrupted by highlighting in red the file and placing a question mark in front of it. A corrupted file can not be analyzed, therefore requiring a retransmission.

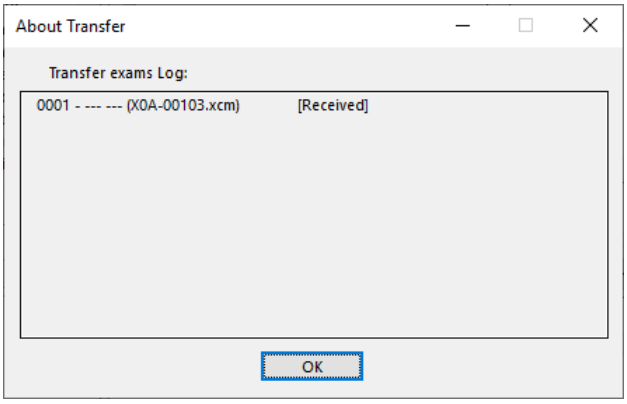
An exam whose identification is highlighted in ocher indicates that the transmission has failed. In this case, it is possible to try to analyze the exam, although it will probably not be complete. It is advisable to ask the analysis client to retransmit the exam file. If after the resubmission the system insists on displaying the file with the identification in the ocher color, we can conclude that the original file (stored on the computer where the exam was uploaded) is corrupted, allowing only partial data analysis.

The next step is to select the exams you wish to receive. To select an exam, simply click on it, which will then appear highlighted in blue. To select multiple exams randomly, hold down the [Ctrl] key while clicking on each of the exams you want. All the selected exams will be highlighted. To select a sequence of exams, click on the first one of them and, holding down the [Shift] key, click on the last exam of the sequence.



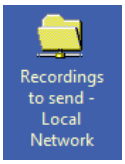
After selecting the desired exams, click on the [Retrieve] button. The system will start to download the exam(s) from the remote area (Internet).

When it finishes downloading the files, the system will display a summary of the operation.



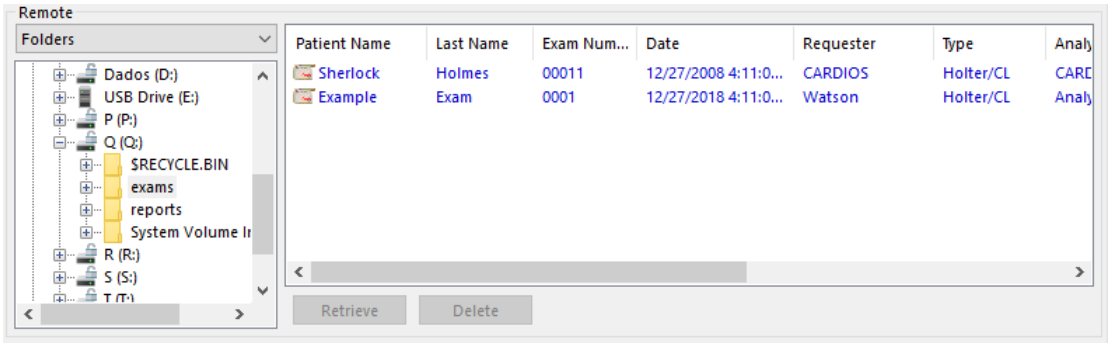
12.5.2. RETRIEVING EXAMS VIA LOCAL NETWORK

CardioNet® can also transfer exam files over a local area network on which the computer is connected. Despite the term "local", the scope of this type of network can go far beyond the physical environment where the system is located. In a private network, the system will work with a "local network folder", which is nothing more than a shared directory, located on some network machine. This is very useful, for example, in situations such as a hospital or a clinical laboratory where exams are prepared and collected in different locations and sent to an area on the local network.



To retrieve exams from the Local Network, select the Exams tab in the navigation menu and click on the "Recording to send - Local Network" icon.

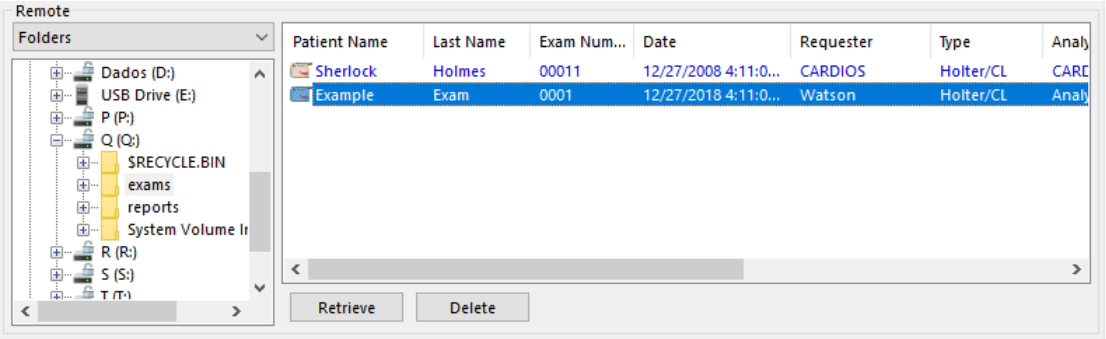
In the window of the exam manager, we will see the Remote area, which in this case corresponds to the local network folder, defined in the system configuration.



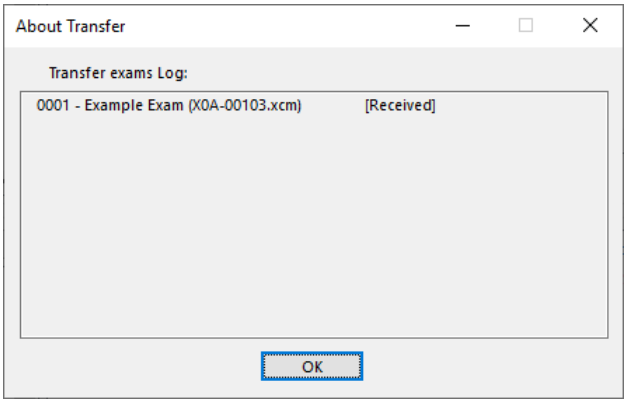
The next step is to select the exams you wish to receive. To select an exam, simply click on it, which will then appear highlighted in blue.

To select multiple exams randomly, hold down the [Ctrl] key while clicking on each of the exams you want. All selected exams will be highlighted in blue.

To select a sequence of exams, click on the first one of them and, holding down the [Shift] key, click on the last exam of the sequence.



When you finish downloading the files, the system will display a summary of the operation.



The downloaded exams will be ready to be imported and analyzed on the CardioSmart CS550.

12.5.3. COLOR CODING IN LISTS

The system identifies, with specific colors and markings, the status of each of the files that are in the storage area.

For exams not transferred (that is, not yet posted or collected):

	In the "local" context, it means that the exam has not yet been posted. In the context of Internet or network, it means that the exam was never collected.
	In the "local" context, it means that the exam has already been posted at least once. In the Internet or network context, it means that the exam was collected at least once.
	Corrupted exam file.
	Try the last command again (extremely rare).
	The exam contains some kind of defect (eg missing some important data). Missing medical report extension file 'rbd' file (PDF or RPK file).

If the exam has already been transferred, it is worth the same color code, but with slightly dark tones.

Check marks color code:

✔	The exam has already been posted (transferred).
✔	The exam has already been posted and the report is already present (i.e., collected).

12.6. SENDING REPORTS

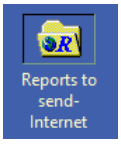
The CardioNet can either send or receive reports via the local network or the Internet.

In order to use the CardioNet system in the management of reports, they must have been generated in CardioSmart CS550 through the option "CardioNet System" and "Report only".

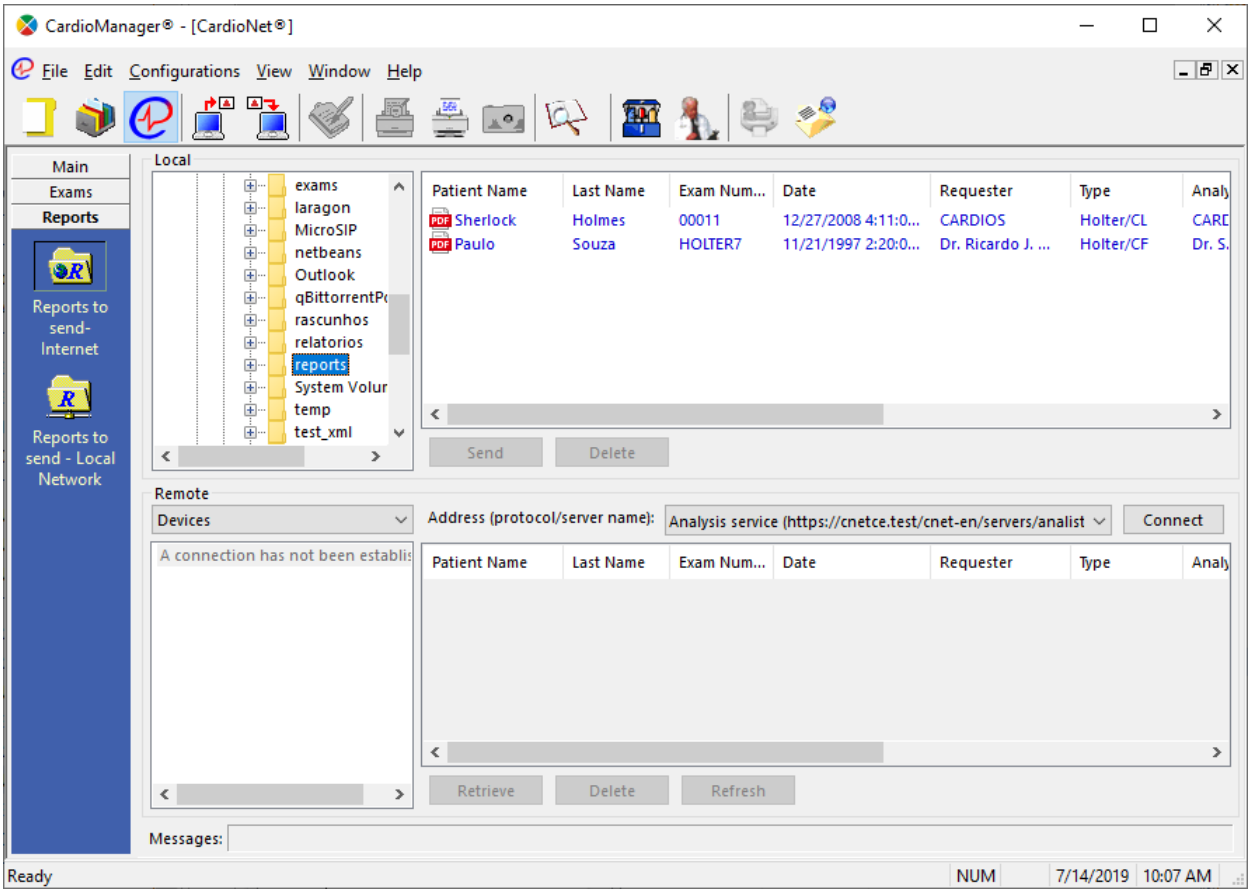
To send reports, access the menu Reports area.

If there is any report file in the local listing whose information appears incomplete (or with question marks), it may mean that the report was not generated correctly for transmission.

12.6.1. SENDING REPORTS VIA INTERNET

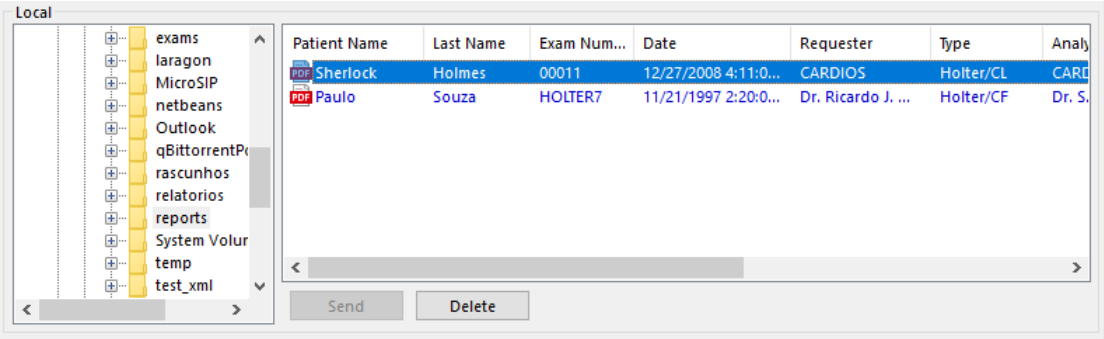


To send reports via the Internet, select the Reports tab in the navigation menu and click on the "Reports to send - Internet" icon.



In the Local window, reports that have not yet been sent the text appears in blue.

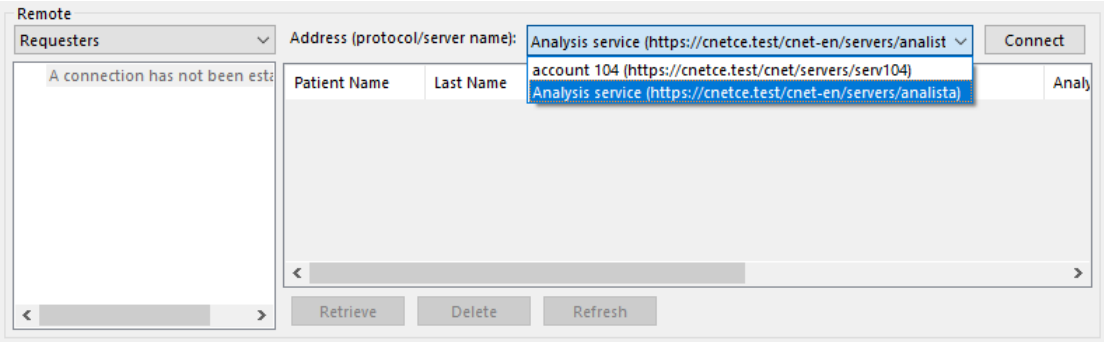
To send reports via the Internet, we must first select the desired files in the Local window. To do this, click on the reports you want to send. The file will be highlighted with a blue stripe, as shown in the figure below.



To select multiple files randomly, hold down the [Ctrl] key while clicking on each of the exams you want.

To select a sequence of files, click on the first one of them and, holding down the [Shift] key, click on the last file of the sequence.

Next we will have to connect to the Internet. The connection control will be showing the account set to "default" in the settings area. We can have several accounts configured, and we must select the account to which we wish to send the file(s).



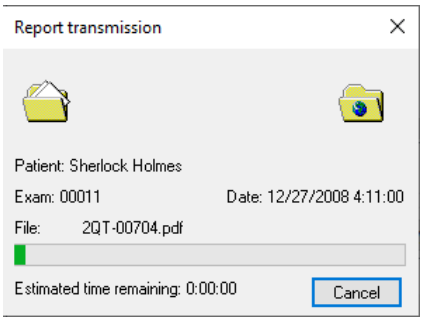
After selecting the desired address, click on the [Connect] button.

The system will initiate the connection with the CardioNet® System, displaying on the status line a series of messages regarding the operation in progress.

When finished building the list and retrieve the information, the system displays the status line a message that the operation is complete and the system is ready to work.

The duration of each of these phases depends on the connection conditions and the number of files that is stored in the remote area. The higher the number of files in the Remote area, the longer the connection time is required.

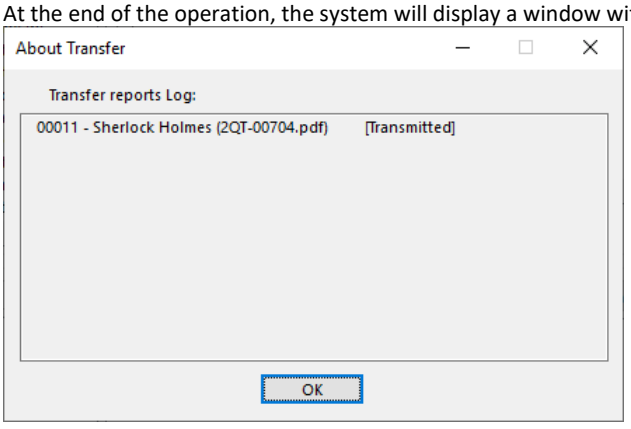
Once you have selected reports for sending, click on the [Send] button at the bottom of the Local window.



The system will start the transmission of the selected file(s), showing a progress screen.

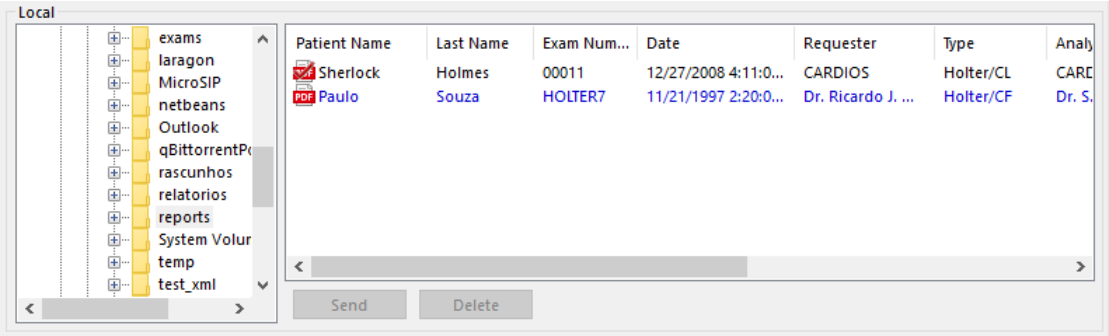
This will repeated for each file, and the transmission time will depend on the speed and the Internet traffic conditions.

At the end of the operation, the system will display a window with the operation summary

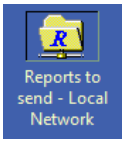


Sent reports will be available in the remote account to be retrieved by the recipient.

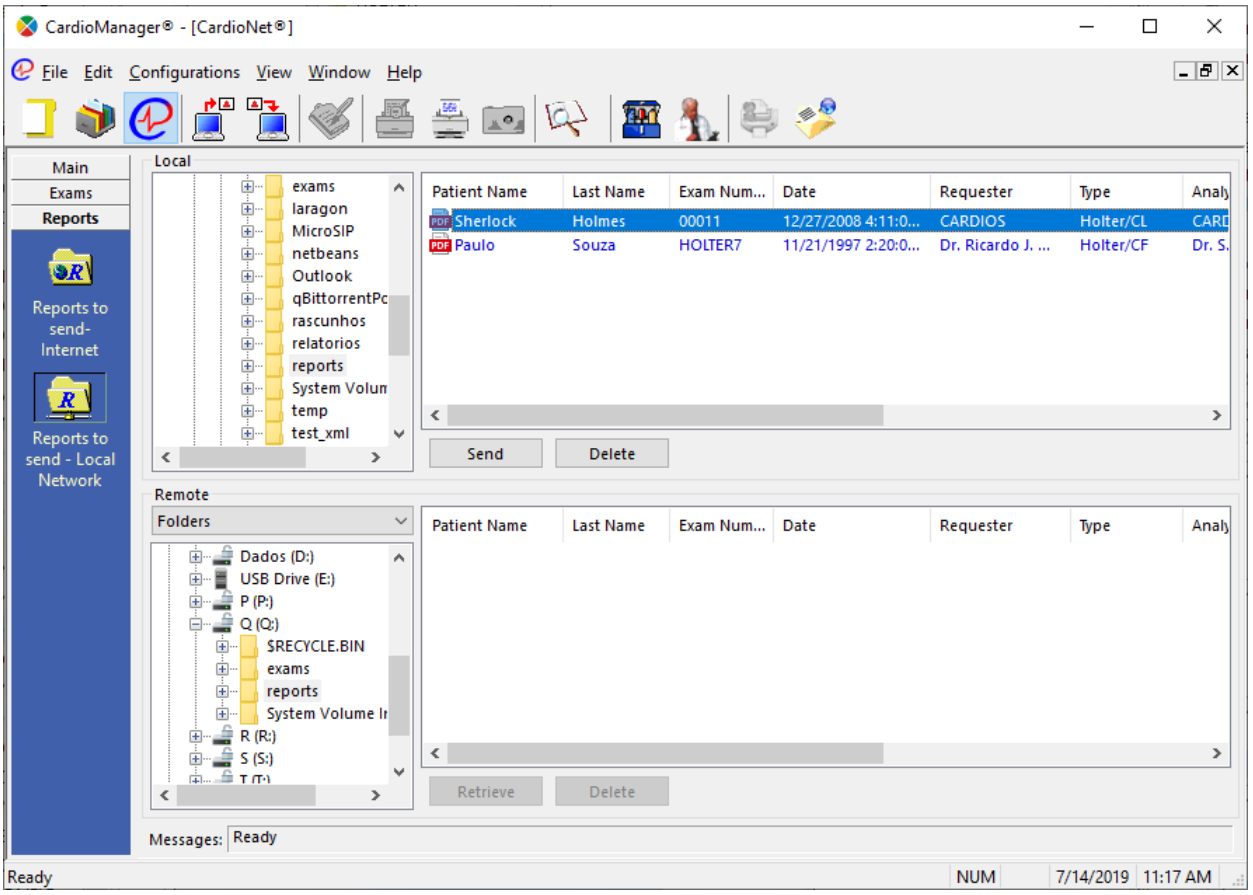
In the Local window, reports that have already been sent will be identified by a tag and appear in black. Reports in blue are those that have not yet been sent.



12.6.2. SENDING REPORTS VIA LOCAL NETWORK



To send reports via the local network, select the Reports tab in the navigation menu and click on the "Reports to send - Local Network" icon.



To send reports over the local network, we must first select the desired files in the Local window. To do this, click on the reports you want to send. The file will be highlighted in blue. To select multiple files randomly, hold down the [Ctrl] key while clicking on each of the exams you want.

To select a sequence of files, click on the first one of them and, holding down the [Shift] key, click on the last file of the sequence.

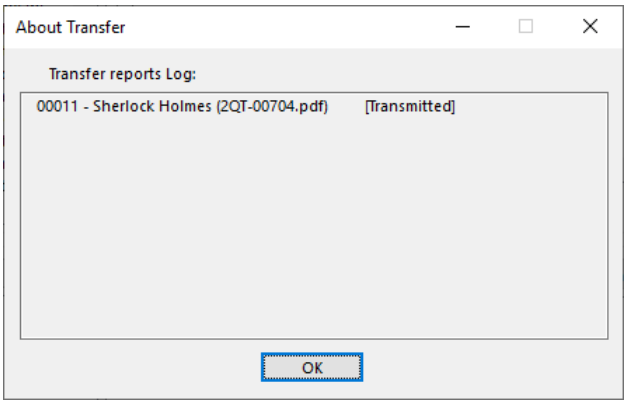
With the files you want to transfer selected, click on the [Send] button.

The system will start transferring the files. For each file, a progress screen will be displayed.

Under the Remote window there is a Message line, where we can follow each step of the file transfer operation.

Upon completion, the system will send a message to the designated address on the analyst register. On some systems, depending on your e-mail settings, you may be asked to explicitly confirm the operation.

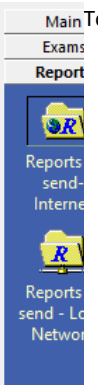
A screen containing the summary of the operation will be displayed, as shown below.



Sent reports will be available in the remote folder to be retrieved by the recipient.

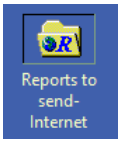
In the Local window, reports that have already been sent will be identified by a tag and appear in black. Reports in blue are those that have not yet been sent.

12.7. RETRIEVING REPORTS



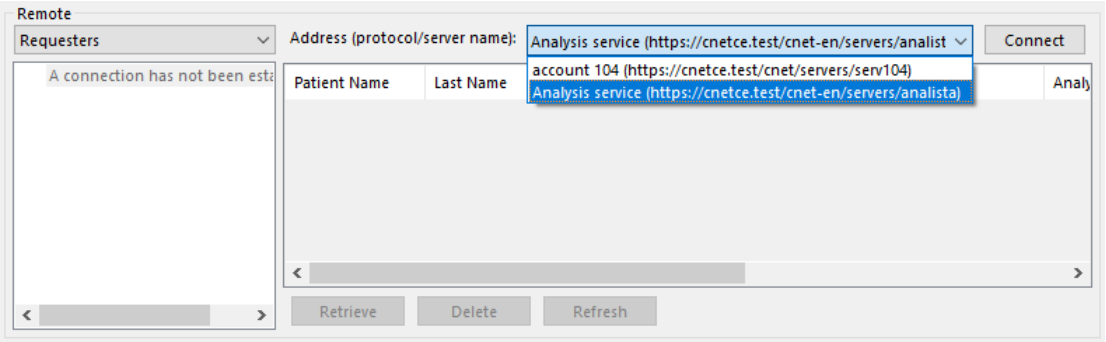
To retrieve reports, access the menu Reports area.

12.7.1. RETRIEVING REPORTS VIA INTERNET



To receive reports via the Internet, select the Reports item in the Navigation Menu and click on the "Reports to send - Internet" icon.

Select in the connection control the Internet account to which you want to retrieve reports. We can have several accounts configured, and we must select the account to which we wish to retrieve the file(s).

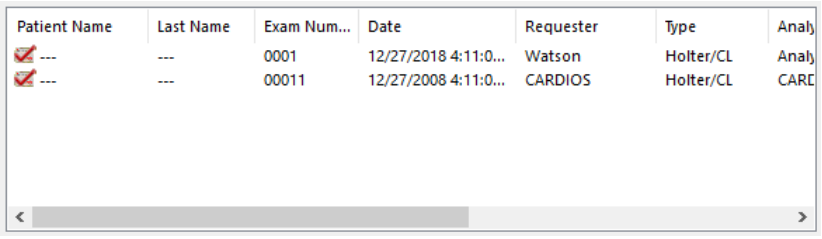


After selecting the desired address, click on the [Connect] button. The system will initiate the connection with the CardioNet® System, displaying on the status line a series of messages regarding the operation in progress.

When finished building the list and retrieve the information, the system displays the status line a message that the operation is complete and the system is ready to work.

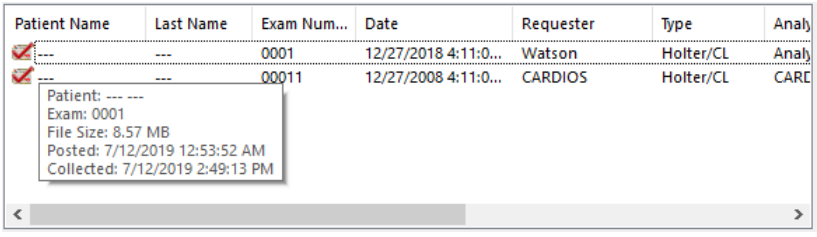
The duration of each of these phases depends on the connection conditions and the number of exams that is stored in the remote area. The higher the number of exams in the Remote area, the longer the connection time is required.

After connected, the Remote window will list all reports that are stored in the remote area.
The list will be updated every 10 minutes (configurable), and the user can also update manually by clicking the "Refresh" button.



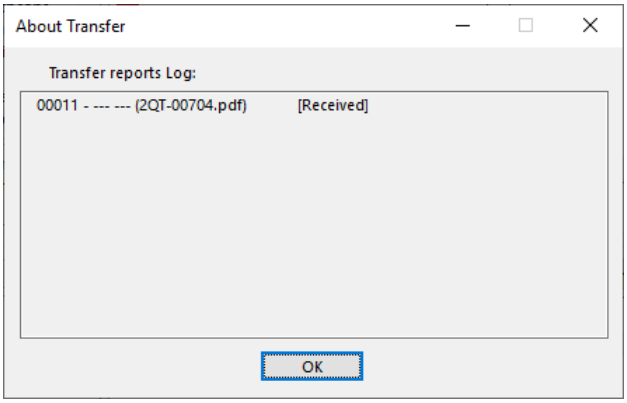
Note in the figure below the tool tip, the small frame that opens when we hover over an record, allows us to observe some information about the report, including the date and time it was made available on the Internet and whether or not it has already been collected.

Select the reports you want to retrieve, multiple (holding down the [Ctrl] key) or sequentially (by pressing [Shift]).

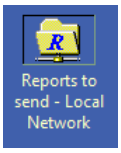


After selecting the desired files, click on the [Retrieve] button. The system will start to download the exam(s) from the remote area (Internet).

When it finishes downloading the files, the system will display a summary of the operation.

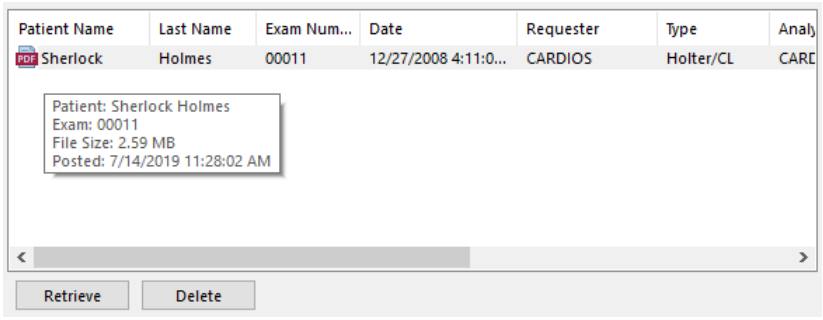


12.7.2. RETRIEVING REPORTS VIA LOCAL NETWORK



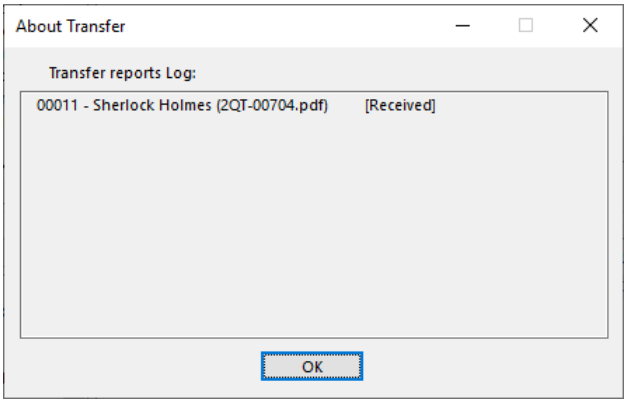
To retrieve reports from the Local Network, select the Reports tab in the navigation menu and click on the "Reports to send - Local Network" icon.

To receive a report available in the "Remote" window, click on it to select it. Note that by hovering the mouse on a line or a report icon, the system returns additional information about that element, as shown in the figure below.

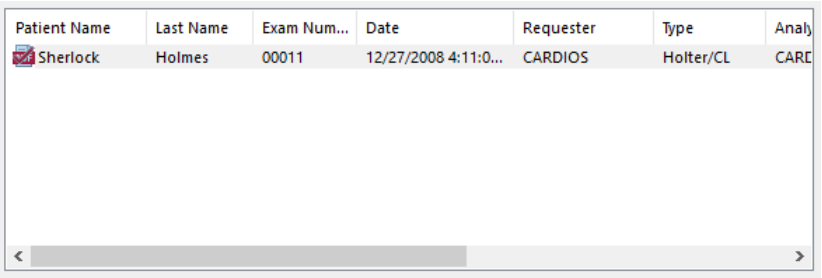


After selecting one or more reports, click the [Retrieve] button.
The system will start transferring the report file from the remote area to the local area. The transfer speed will depend on the bandwidth of the network, and the system will display a window showing the progress of the operation.

At the end of the transfer a window will display the result of the process.



Note that in order to identify the report as already received by your system, a red mark will be placed on the icon corresponding to the report information as indicated by the cursor arrow in the following figure.

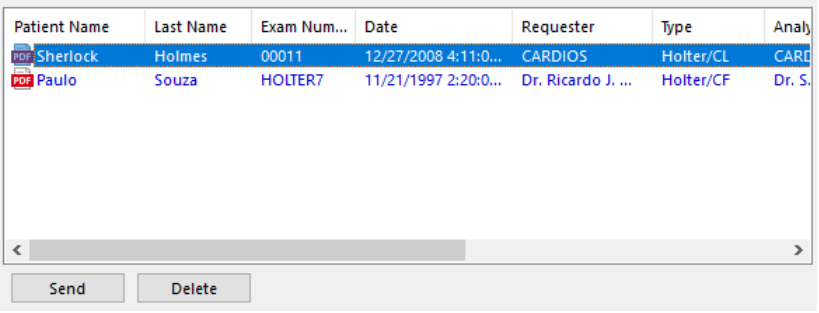


12.8. DELETING FILES

To delete files in any of the windows (Local or Remote), select the reports you want and click on the [Delete] button corresponding to that window.

Check your users permission to delete files in your operation system, network and CardioNet System before proceed.

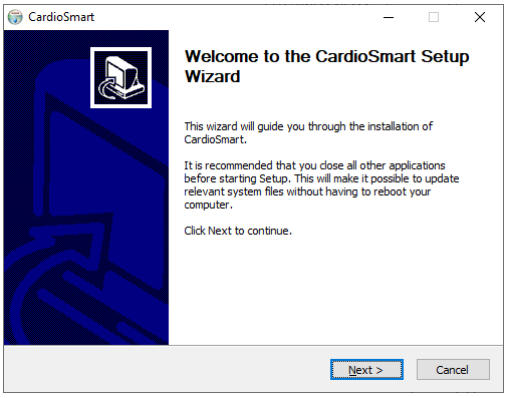
In the CardioNet System, account type client can not delete exam files in the remote area.



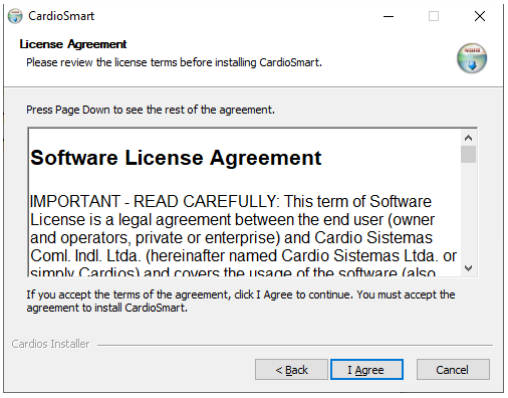
Files deleted from the system CAN NOT BE RECOVERED. Therefore, it is convenient to make a backup of the exams and / or reports that are to be excluded, guaranteeing the preservation of the data.

13. INSTALLING CARDIOSMART CS550 ON YOUR COMPUTER

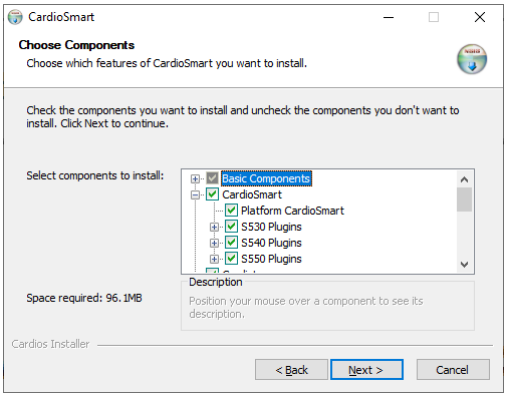
Download the CardioSmart CS550 installer



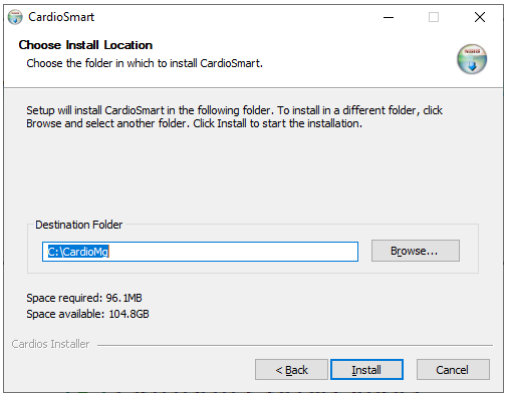
1. Double-click on the installer to run it
2. Click on [Next]



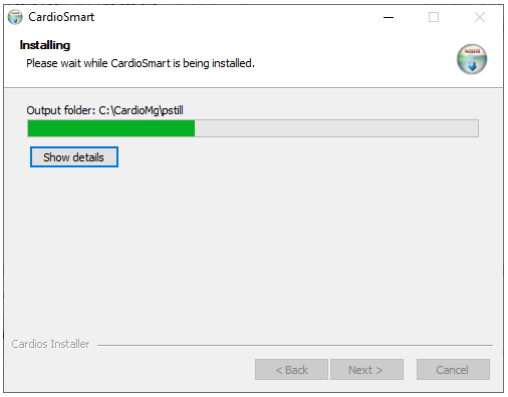
3. Read the agreement and if you agree, click on [Agree].



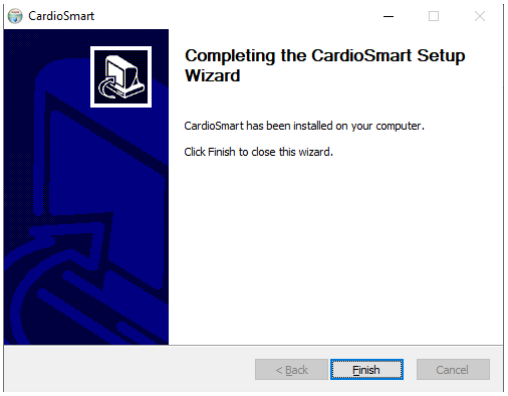
4. Click on [Next]



5. Click on [Install]



6. **[Next]**



7. [Finish]

14. TROUBLESHOOTING

When operating the CardioSmart CS550, problems, and messages may occur. The table below shows the expected messages, as well as more information about them and possible solution in case of problem.

Message	Possible Solution
[Device] is still sending data. Press the event button to stop data transmission.	Please follow the instructions in the message. If it is not possible, or if you have any questions, please contact Cardios Customer Service.
A connection has not been established	Try to access some site or transfer some file to another service. If you can't, contact your Internet service provider
A full disk error occurred during file compression/decompressing.	You should clean other files on the disk. Please contact your IT support or Cardios Customer Service.
A generic Internet error has occurred.	A communication failure has occurred. Check for available Internet connection. If not, please contact your ISP. If any, please contact Cardios Customer Support Service.
Ambiguous recipient	There is more than one recipient to register for this account. Please check.
An attachment could not be located at the specified path	A missing file, bad path, or access right error may have occurred. Please check and if it persists, please contact Cardios Customer Support Service.
An attachment could not be written to a temporary file. Check directory permissions.	A missing file, bad path, or access right error may have occurred. Please check and if it persists, please contact Cardios Customer Support Service.
An error occurred reading the input XML file, please make sure the file is valid.	You may need to correct the structure of the input XML file. Contact Cardios Customer Support If you have questions about the configuration.
An error occurred while creating the tachogram (subcode [subcode]).	An error occurred during signal processing. Write down the error message, the operation being performed, and the exam. Please contact Cardios Customer Service as soon as possible.
An error occurred while loading the heartbeat sequence.	An unexpected error occurred while loading the heartbeat sequence. Write down the error message, the operation being performed, and the exam. Please contact Cardios Customer Service as soon as possible.
An error occurred while reading the heartbeat sequence.	An unexpected error occurred while reading the heartbeat sequence. Write down the error message, the operation being performed, and the exam. Please contact Cardios Customer Service as soon as possible.
An error occurred while recording the heartbeat sequence.	An unexpected error occurred while recording the heartbeat sequence. Write down the error message, the operation being performed, and the exam. Please contact Cardios Customer Service as soon as possible.
An error occurred while registering the component [component name]. Check the component installation or contact technical support.	There may have been an error installing the software. Please contact your IT support or Cardios Customer Service.
An exception was generated during parallel processing.	Internal error occurred during parallel processing. Write down the exam, the operation being performed, and its sequence. Please contact Cardios Customer Service as soon as possible.

Message	Possible Solution
Attention! The Cardionet will run in "demo mode".	A compatible software license (USB dongle) or in perfect working condition was not found.
Attention! This record is related to another record. To preserve the database integrity, you cannot remove it.	The master record should be removed first. If in doubt, please contact Cardios Customer Service.
Automatic records cannot be removed unless "automatic record removal" mode is enabled	Please follow the instructions in the message. If it is not possible, or if you have any questions, please contact Cardios Customer Service.
Bad recipient type	Check the settings of the registered email. If they are correct, please contact the Cardios Customer Support service.
Cannot import file [file] that contains an [exam type] exam type. Install the corresponding module on your system in order to import this exam.	There was a problem installing the program. Please contact your IT technical support or Cardios Customer Service.
Cannot open an Internet Session. Please check your Internet configuration.	A communication failure has occurred. Check for available Internet connection. If not, please contact your ISP. If any, please contact Cardios Customer Support Service.
Can't open file: [file]	A file error has occurred, which may have been deleted or corrupted. Please contact Cardios Customer Support Service.
CFDAS environment variable has not been configured correctly.	Please contact Cardios Customer Service.
Connection may be decayed dealing with protocol [name]. Please reconnect before continuing.	A communication failure has occurred. Check for available Internet connection. If not, please contact your ISP. If any, please contact Cardios Customer Support Service.
Could not activate the Holter Analysis component. Verify if the Holter module installation is correct or contact technical support.	A software installation error occurred. Contact your IT support or Cardios Customer Service.
Could not create directory [directory name] to store CardioManager® files. Cannot continue. Restart your computer and try again. If the problem persists, contact Cardios Technical Support.	Please follow the instructions in the message. If it is not possible, or if you have any questions, please contact Cardios Customer Service.
Could not detect license device. Please check the device installation as well as the drivers' installation.	Connect the license device, if the error persists, contact the Cardios Customer Service.
Could not find morphologies and forms file, or none of them was identified in the signal.	Exam check needed. Please contact Cardios Customer Service.
Could not find valid heartbeats to be grouped. Please check the recording quality on the compressed ECG screen.	Exam check needed. Please contact Cardios Customer Service.
Could not open serial port [port]. Check the possibilities: - Some program/module is already accessing this device. - Reconfigure your system to use an available serial port.	Please contact your IT support. If the error persists, please contact Cardios Customer Service.

Message	Possible Solution
Device version is higher than expected. Contact Technical Support.	Contact Cardios Customer Service.
Do not inform more than one day.	Please follow the instructions in the message. If it is not possible, or if you have any questions, please contact Cardios Customer Service.
Download file has failed.	A communication failure has occurred. Check for available Internet connection. If not, please contact your ISP. If any, please contact Cardios Customer Support Service.
ECG monitoring capabilities via infrared cable are disabled. Use the [Module] menu and the [System Setup] option to enable infrared monitoring.	Please follow the instructions in the message. If it is not possible, or if you have any questions, please contact Cardios Customer Service.
E-mail address seems incorrect (check @ and .)	You need to check the email address you typed. If you are, please contact Cardios Customer Support Service.
E-mail error (MAPI system)	A generic error occurred in the e-mail service. Please write it down, as well as the operation being performed and its sequence, and contact Cardios Customer Service.
Error [number] (code: [code])	A generic error occurred. Please write it down, as well as the operation being performed and its sequence, and contact Cardios Customer Service.
Error accessing files... Error code: [code] Message: [message]	A generic error occurred. Please write it down, as well as the operation being performed and its sequence, and contact Cardios Customer Service.
Error closing file. Check for any restrictions to disk access, such as user privilege, disk error, or other user using the ECG data.	Please follow the instructions in the message. If it is not possible, or if you have any questions, please contact Cardios Customer Service.
Error during "Flash Memory Card" initialization.	An error occurred in the operation with the card. Check that it is inserted and keep it in operation. If the error persists, please contact Cardios Customer Support Service.
Error during [process] domain analysis (subcode [subcode]).	An error occurred during signal processing. Write down the error message, the operation being performed, and the exam. Please contact Cardios Customer Service as soon as possible.
Error during power spectrum calculation through autoregressive (AR) analysis (subcode [subcode]).	An error occurred during signal processing. Write down the error message, the operation being performed, and the exam. Please contact Cardios Customer Service as soon as possible.
Error during signal resampling.	An error occurred during signal processing. Write down the error message, the operation being performed, and the exam. Please contact Cardios Customer Service as soon as possible.
Error on file access... Error Code: [code] Description: [Message]	A missing file or access right error may have occurred. Please check and if it persists, please contact Cardios Customer Support Service.
Error opening analysis file. Check the file access attributes or if there is another user using it.	Please follow the instructions in the message. If it is not possible, or if you have any questions, please contact Cardios Customer Service.
Error processing QRS data. Please check the recording quality on the compressed ECG screen.	The recording quality is probably not adequate for data processing. It will be necessary to perform a new exam, following the equipment installation instructions and checking the cables and electrodes condition. Please see additional instructions on Cardios website. If in doubt, please contact Cardios Customer Service.

Message	Possible Solution
Error reading file. Check for any restrictions to disk access, such as user privilege, disk error, or other user using the ECG data.	Please follow the instructions in the message. If it is not possible, or if you have any questions, please contact Cardios Customer Service.
Error while executing WFDB package tool.	A generic error occurred. Please write it down, as well as the operation being performed and its sequence, and contact Cardios Customer Service.
Error while reading "Flash Memory Card" data.	There was an error related to the card communication. It is necessary to check the reader, the cables, and the installation. Contact your IT support or Cardios Customer Service.
Error while reading data from the Memory Card	An error occurred in the card reading, which may be missing or corrupted. Please contact Cardios Customer Support Service
Error while reading the tips file.	A generic error occurred. Please write it down, as well as the operation being performed and its sequence, and contact Cardios Customer Service.
Error: could not complete Internet operation!	A communication failure has occurred. Check for available Internet connection. If not, please contact your ISP. If any, please contact Cardios Customer Support Service.
Error: Could not create folder [folder]	There was a problem accessing the requested resource. Please verify your access credentials or contact your IT support. If you cannot, contact Cardios Customer Service.
Error: could not get the remote list...	It is necessary to verify the connection to the location where the exams/reports are.
Error: HTTP Request Header creation failed.	A communication failure has occurred. Check for available Internet connection. If not, please contact your ISP. If any, please contact Cardios Customer Support Service.
Error: module [name] returned code [code]	A generic error occurred. Please write it down, as well as the operation being performed and its sequence, and contact Cardios Customer Service.
Error: The attempt to configure the connection has failed.	A communication failure has occurred. Check for available Internet connection. If not, please contact your ISP. If any, please contact Cardios Customer Support Service.
Error: The attempt to connect to the Internet has failed.	A communication failure has occurred. Check for available Internet connection. If not, please contact your ISP. If any, please contact Cardios Customer Support Service.
Error: The attempt to disconnect to the Internet has failed.	A communication failure has occurred. Check for available Internet connection. If not, please contact your ISP. If any, please contact Cardios Customer Support Service.
Error: The file name you are trying to send is invalid	The file name is not valid. The file name should contain only alphanumeric characters (A-Z, 0-9), not accented, no space, and must contain from 4 to 96 characters.
Error: the process [process] is not responding.	A process crash error occurred, or communication failure between the system and it. Please try again and if the problem persists, contact Cardios Customer Service.
Exam export not supported by the active export version.	A generic error occurred. Please write it down, as well as the operation being performed and its sequence, and contact Cardios Customer Service.
Exam exportation not supported by the active export version	Need to check the version. Please contact Cardios Customer Support Service.
Exam file invalid or corrupted	Exam file transmitted to the service provider is corrupted or is not a valid exam file. Generate the export file and download it again.

Message	Possible Solution
Exception not supported!	A failure has occurred that cannot be retrieved. Please contact Cardios Customer Support Service, reporting the situation where the error occurred.
Failed to copy file to temporary files folder.	A generic error occurred. Please write it down, as well as the operation being performed and its sequence, and contact Cardios Customer Service.
Failed to setup GUC (Generator Unit Code), caused by an invalid directory. For a network configuration, verify if share point has write privileges.	The GCE code appears to be invalid or incorrectly configured. It is necessary to verify the GCE provided by the Cardios Customer Support service.
Failed to write GUC (Generator Unit Code) record. Please check that the configuration Folder has write permission. This procedure must be performed by a privileged user account.	The GCE code appears to be invalid or incorrectly configured. It is necessary to verify the GCE provided by the Cardios Customer Support service.
Failed to write into Windows Registry Key. This task must be performed by an user with administrator privileges. Contact your network administrator to continue the setup procedure.	You must perform the operation by having administrator rights on the computer. Look for your network administrator.
Feature not implemented in program version [version number]. Please contact support for an update.	Contact Cardios Customer Service.
File download [file] has been rejected.	The file could not be fully received. Repeat operation required. If the error persists, check for communication as a remote location and contact the Cardios Customer Support service.
File download [file] has failed.	The file could not be fully received. Repeat operation required. If the error persists, check for communication as a remote location and contact the Cardios Customer Support service.
If you want detailed information about the error, please send us the following information: [error]	A generic error occurred. Please write it down, as well as the operation being performed and its sequence, and contact Cardios Customer Service.
Import dictionary is missing. Please check your importer setup.	The XML dictionary file was not found. Contact Cardios Customer Support Service.
Import Incomplete! One or more signals belonging to the exam set are missing: [number of expected signals] was expected but [number of signals found] were found.	A signal processing error occurred. Exam check needed. Please contact Cardios Customer Service.
IMPORTANT: The memory card has been prepared with the clock setting option. It is necessary to put the card in the recorder, turn it on and wait until it is initialized. This way, the clock will be set to your computer's current time. NOTE: It is important not to take more than 3 minutes to do that.	Please follow the instructions in the message. If it is not possible, or if you have any questions, please contact Cardios Customer Service.
Incorrect number of arguments.	A generic error occurred. Please write it down, as well as the operation being performed and its sequence, and contact Cardios Customer Service.

Message	Possible Solution
Insufficient ECG signal duration! The analyzer requires at least [n] minutes of ECG signal to accomplish any results. Please check if the ECG signal acquisition has been correctly performed.	The exam is too short for analysis. There may have been some problem in recording or transmitting the data, or simply the recorder has been erroneously configured. Contact Cardios Customer Support service for verification.
Internal Error	A failure has occurred that cannot be retrieved. Please contact Cardios Customer Support Service, reporting the situation where the error occurred.
Internal error! The exam requested for transfer cannot be found on the database. Please contact the technical support to verify if all installed modules are of compatible versions.	There may have been incompatibility between the installed modules, or the exam has been deleted or is corrupted. Contact Cardios Customer Support Service.
Invalid directory size... For details, enter: CFCard -?X	The recommended specification should be followed. If you have any questions, please contact Cardios Customer Service.
Invalid formatting mode: [Formatting mode]	The card appears to have been formatted in an incompatible manner. Need to contact Cardios Customer Support Service to reorder it.
Invalid input file.	The file format is not as expected. Please check the format and try the operation again. If this is not possible, please contact Cardios Customer Service.
Invalid or bad specified XML file.	Necessary to correct the structure of the input XML file. Contact Cardios Customer Support If you have questions about the configuration.
Invalid Parameters Number. NOTE: There is likely to be incompatibility between the versions of the installed components. Please reinstall this software!	A software installation error occurred. Contact your IT support or Cardios Customer Service.
Invalid report file	The report file transmitted to the service provider does not have the corresponding "RBD" file and the file name is not a valid exam code.
It is not possible to delete the exam code "[code]" because the module that created this exam could not be found. Install the corresponding module on your system in order to remove this exam.	Please follow the instructions in the message. If it is not possible, or if you have any questions, please contact Cardios Customer Service.
It is not possible to verify transfer integrity of [file].	The file could not be transmitted in a full way. Repeat operation required. If the error persists, check for communication as a remote location and contact the Cardios Customer Support service.
It is only possible to store 999 exams with compressed ECG. This unit is wasting space.	You need to backup your exams as instructed in the user manual. Then exclude exams and proceed to the desired operation again. If in doubt, please contact Cardios Customer Service.
It was not possible to extract a segment with the required minimum length ([time] s) from the heartbeat sequence.	Try a longer interval and repeat the operation. If this is still not possible, please contact Cardios Customer Service.
Lack of memory space	Exam interrupted due to lack of card space. Please contact Cardios Customer Service.
Low battery	Shutdown of the recorder due to low battery. Need to recharge or replace the battery.
MAPI (e-mail system) failure	Check the settings of the registered email. If they are correct, please contact the Cardios Customer Support service.

Message	Possible Solution
Measurement error [Code]	A measurement error has occurred. Please refer to the table [MAP error table].
Memory Exception!	A failure has occurred that cannot be retrieved. Please contact Cardios Customer Support Service, reporting the situation where the error occurred.
Memory is full	Shutdown of the recorder due to lack of memory space. It is necessary to check the available memory in the equipment.
Missing quotation mark (") in user part	The username is incomplete, apparently missing completing it with quotation marks. If the error persists, please contact Cardios Customer Service.
No CAM input parameter <HdrFile> <PacerFile> [/C<Chans>] [/D <database>] [/T <TempFolder>]	Please follow the instructions in the message. If it is not possible, or if you have any questions, please contact Cardios Customer Service.
No exam or report was found on server.	There are no files in the remote location.
No message was sent.	Check the settings of the registered email. If they are correct, please contact the Cardios Customer Support service.
One of the 'SIG' lines indicates an invalid channel number. The number must be between 1 and 3. NOTE: Support for more than 3 channels will be provided in future versions.	The file format is incompatible with the expected. Check the version of the file used and if the error persists, please contact the Cardios Customer Support service.
Operation canceled: An integrity failure was detected in the exam [exam code] export process.	Please contact Cardios Customer Service.
Out of Memory!	The memory available on the computer is insufficient to run the software. Please check the minimum recommended setting.
Part of the compressed data is corrupted. Do you want to try to continue the importation of the exam?	An error occurred reading the data. There may have been a problem with the card or the exam. Please contact Cardios Customer Support Service
Please set up the Holter module before transferring an exam. To do this, select the "Module" menu and the "Configure system..." option.	Necessary to configure the system to work with Holter exams.
Printer [printer] could not be found	Please check the connection to the printer. Please contact your IT support.
Problems opening the serial port. Check the configuration.	Please contact your IT support. If the error persists, please contact Cardios Customer Service.
Processing error	A generic error occurred. Please write it down, as well as the operation being performed and its sequence, and contact Cardios Customer Service.
Recipient not recognized [recipient]	The message recipient was not found. Please make sure that no typos have occurred and try again. If you cannot, please contact Cardios Customer Service.

Message	Possible Solution
Remote object not found	The file could not be fully received. Repeat operation required. If the error persists, check for communication as a remote location and contact the Cardios Customer Support service.
Remote object remains not collected	The file could not be fully received. Repeat operation required. If the error persists, check for communication as a remote location and contact the Cardios Customer Support service.
Resource ("resource") failure.	A software installation error occurred. Contact your IT support or Cardios Customer Service.
Some required parameter is incorrect: CAM <HdrFile> <PacerFile> [/C<Chans>] [/D <database>] [/T <TempFolder>]	Contact Cardios Customer Service.
Some standard CardioSmart CS550 components could not be loaded. Please check the product installation and try again.	There was a problem installing the program. Please contact your IT technical support or Cardios Customer Service.
Sorry! You cannot continue without a valid database.	An error occurred while creating the system database. Please contact your IT technical support or Cardios Customer Service.
Source with low voltage	Shutdown of the recorder due to low voltage. Need to recharge or replace the battery, please contact Cardios Customer Support Service.
Tachogram segment duration limits are incorrect	Please correct the duration limits of the tachogram segment. If the error persists, please contact Cardios Customer Service.
The "analyst record" must have the doctor's name and office fulfilled.	Please fill in the fields of the physician analyst. If already completed, please contact Cardios Customer Support Service.
The "complementary channel" parameter is invalid.	You need to correct the supplemental channel parameter. If you are correct, please contact Cardios Customer Support Service.
The "Flash Memory Card" seems to be corrupted. Remove and reinsert the card, then try again. If the error persists then contact our technical support.	An error occurred in the operation with the card. Check that it is inserted and keep it in operation. If the error persists, please contact Cardios Customer Support Service.
The "Flash Memory Card" seems to be damaged or corrupted. Please try again. If the problem persists contact our technical support.	The card is possibly corrupted. Repeat the operation again. If the problem persists please contact Cardios Customer Support Service.
The "Flash Memory Card" was not found. Note: If the card is inserted, consider the following: - The card reader is not correctly installed; - The card is corrupted and requires a rebuild procedure in our factory.	The reader's configuration problem has occurred or the card is corrupted. Please check the configuration of the player. If correct, replace the card. If the problem persists, please contact the Cardios Customer Support service.
The "user name" doesn't seem to be valid. Are you sure you want to continue?	You need to check the email address you typed. If you are, please contact Cardios Customer Support Service.
The ABPM exam has not yet been prepared	An ABPM exam should be prepared first. If in doubt, please contact Cardios Customer Service.

Message	Possible Solution
The active version of the software is not compatible.	Please contact Cardios Customer Support Service.
The 'ADCBits' line supports only the 8 value. Currently, this product version cannot handle different values.	The file format is incompatible with the expected. Check the version of the file used and if the error persists, please contact the Cardios Customer Support service.
The 'AmpCalibratedFlag' line of the header file contains a value different from 'TRUE'. This software can only handle calibrated signals.	The file format is incompatible with the expected. Check the version of the file used and if the error persists, please contact the Cardios Customer Support service.
The analysis channel selected is invalid.	Please try another channel.
The backup file containing the list of Referring Doctors is corrupted! Do you wish remove it?	An error occurred reading in the file backup of the requesting physicians. If you wish, you can delete it. Please contact Cardios Customer Support Service for file analysis.
The 'BitPackedFlag' line of the header file must have the 'TRUE' or 'FALSE' value. All other values will be rejected.	The file format is incompatible with the expected. Check the version of the file used and if the error persists, please contact the Cardios Customer Support service.
The card does not contain data. You should insert this card into a compatible recorder and make a complete exam procedure before we can start reading data.	The card is empty. It may have been formatted incorrectly or there is no write on it.
The card is being used by another program... Please close the other program and try again...	Please follow the instructions in the message. If it is not possible, or if you have any questions, please contact Cardios Customer Service.
The card is empty.	The card is empty or something has failed to read it. Please contact Cardios Customer Support Service.
The CardioFlash® version is newer than expected. You must upgrade the "RECORDER.CMM" file to the latest version to support this new format. Please contact our Technical Support.	Need to update the CardioNet application. Please contact Cardios Customer Support Service.
The CardioManager Database could not be updated. Contact technical support.	Please contact Cardios Customer Service.
The CardioSeven® version is higher than expected. You will need to upgrade the "CardioSeven.cmm" device manager to a newer version. Contact Technical Support.	Contact Cardios Customer Service.
The CardioVista module does not support the total channels reported by the device ([number of channels] ECG channels). Verify if the communication with the device is OK and try again.	Please follow the instructions in the message. If it is not possible, or if you have any questions, please contact Cardios Customer Service.

Message	Possible Solution
The Card's ID record has been created by a newer version of this software Contact our technical support and check for current upgrade conditions.	There was some incompatibility between the exam card and the control. Please contact Cardios Customer Support Service.
The Card's ID record has been created by an older version of this software.	Exam created in previous version of software. Please contact Cardios Customer Support Service.
The Card's ID record is corrupted. Consider the possibility of virus!	A card ID error has occurred. Please contact Cardios Customer Support Service.
The card's recording doesn't match the selected exam.	There was some incompatibility between the exam card and the control. Check if the recording belongs to the exam.
The channel [channel] option is not supported.	This setting is not allowed. Please correct the exam setup. If it is not possible to correct it, please contact Cardios Customer Service.
The chosen entry does not represent a valid dial string! The valid characters are: 1-9, space, dash, comma, !, P, T, W, and A-D.	You need to check the dialing settings.
The complementary ECG interval must be from 0 to 30 seconds.	Necessary to correct the supplementary ECG parameter. If you are correct, please contact Cardios Customer Support Service.
The compressed data is irrecoverably corrupted.	An error occurred reading the data. There may have been a problem with the card or the exam. Please contact Cardios Customer Support Service
The 'CompressionMode' line of the header file must have 'NOCOMPRESSION' or 'TP' value. All other values will be rejected.	The file format is incompatible with the expected. Check the version of the file used and if the error persists, please contact the Cardios Customer Support service.
The current range Exam number is out of the valid range	It is necessary to check the valid numbering for exams and correct it.
The data import failed, check the import file and try again.	An error occurred during the import. You need to try again, and if the error persists, contact Cardios Customer Support Service.
The description already exists. Please change it.	Another description should be used.
The destination IP address is invalid	You need to verify that the IP address you have entered is correct. If you are, contact Cardios Customer Support Services.
The device used for this exam has been disabled and the exam cannot be opened. You may need to update the manager module for the installed devices.	There may have been an error installing the software. Please contact your IT support or Cardios Customer Service.
The disk is full and cannot support the specified number of files. It is advisable to reduce the number of files to free up disk space.	You need to backup your exams as instructed in the user manual. Then exclude exams and proceed to the desired operation again. If in doubt, please contact Cardios Customer Service.
The doctor's record is not filled! In order to create a new exam, that record must have critical information previously filled.	Required to complete the registration of requesting physician. If it is already completed and the error persists, please contact the Cardios Customer Support service.

Message	Possible Solution
The domain name does not seem to be valid	It is necessary to verify that the reported domain is correct. If you are, contact Cardios Customer Support Services.
The dynamic component library (DynaCom.dll) could not be loaded. Check the installation of this library or contact Cardios technical support.	A software installation error occurred. Contact your IT support or Cardios Customer Service.
The e-mail address field is empty	Please fill in the e-mail address correctly.
The e-mail address is empty	You need to check the email address you typed. If you are, please contact Cardios Customer Support Service.
The e-mail address(es) seems to be not typed correctly. Are you sure you want to continue?	You need to check the email address you typed. If you are, please contact Cardios Customer Support Service.
The essential exportation key [name] is missing.	Please inform the desired export key.
The exam [exam number] cannot be exported until it is opened at least once.	Open and close the exam and perform the export again.
The exam code you have entered is invalid. It is possible that the GUC (Generator Unit Code) record is not properly installed.	The GCE code of the exam appears to be invalid or incorrectly configured. It is necessary to verify the GCE provided by the Cardios Customer Support service.
The Exam ID sequence generator has been exhausted. You must contact the Analyst in order to continue.	You need to start a new number of exams. Please contact Cardios Customer Support Service.
The Exam ID sequence generator hasn't been initiated yet.	Set up exam numbering. Please contact Cardios Customer Support Service.
The exam number is higher than the current control exam number.	There was some incompatibility between the exam card and the control. Please contact Cardios Customer Support Service.
The exportation archive [file] has at least an essential field not filled.	There was a problem in the generation of the export file, which may have been caused by a registration error. Please check. If you persist, please contact Cardios Customer Support Service.
The 'ExtractedFlag' line of the header file must have the 'TRUE' or 'FALSE' value. All other values will be rejected.	The file format is incompatible with the expected. Check the version of the file used and if the error persists, please contact the Cardios Customer Support service.
The field doesn't accept the amount of characters you attempted to add. Try inserting or pasting less characters.	Please follow the instructions in the message. If it is not possible, or if you have any questions, please contact Cardios Customer Service.
The file [filename] was not found during the compression/decompression operation.	There was an error reading files. Please try again and if the error persists, contact Cardios Customer Service.

Message	Possible Solution
The file [name] at the remote site seems to be incomplete an interrupted upload of the local file. Do you wish complete it (""Yes"") or restart from the beginning (""No"")?	The file could not be fully received. Repeat operation required. If the error persists, check for communication as a remote location and contact the Cardios Customer Support service.
The file containing the list of Network Connections is corrupted. Do you wish remove it and recover data from the backup file?	An error occurred reading the network Connections file. If desired, you can replace it with the backup.
The file containing the list of Referring Doctors is corrupted. Do you wish remove it and recover data from the backup file?	An error occurred reading the file from requesting physicians. If desired, you can replace it with the backup.
The file is truncated or not in EDF format.	Please check the file. If the error persists, please contact Cardios Customer Service
The 'Format' line of the header file supports only the 'AOB' value. No other option is currently supported.	The file format is incompatible with the expected. Check the version of the file used and if the error persists, please contact the Cardios Customer Support service.
The full disclosure file indication on the header file could not be found. Do you want to select it manually?	A failure occurred in the load or transmission of the specified file. Need to locate it manually.
The GUC (Generator Unit Code) was never used.	The GCE code appears to be invalid or incorrectly configured. It is necessary to verify the GCE provided by the Cardios Customer Support service.
The GUC (Generator Unit Code) was not correctly setup for this application. Run the "Generator Unit Code Setup" utility, provided with your software installation.	The GCE code appears to be invalid or incorrectly configured. It is necessary to verify the GCE provided by the Cardios Customer Support service.
The Holter Analysis component returned an error code [error code]. Try to analyze again; if error persists, write down all error messages, and contact Cardios technical support.	Please follow the instructions in the message. If it is not possible, or if you have any questions, please contact Cardios Customer Service.
The hostname is missing on the e-mail address!	Please complete the email address, with the part following the "@" symbol
The import file is configured for one type of exam and you are trying to import a different type.	Necessary to change the configured exam.
The importation archive is related to an unknown exam device (ID = [id]).	There was a problem in the generation of the export file, which may have been caused by a registration error. Please check. If you persist, please contact Cardios Customer Support Service.
The just created LOCAL exam file [filename] is probably corrupted! So, I already removed it for you. Obs: The remote exam file was not affected by this operation, so it remains OK.	If you have any questions, please contact Cardios Customer Support Service.

Message	Possible Solution
The just created REMOTE exam file [name] is probably corrupted! Please, replace it as soon as possible. Obs: the local exam file was not affected by this operation, so it remains OK.	Need to retransmit the file.
The line [line] of the header file cannot be recognized. Check if the header file is compatible with the system.	The file format is incompatible with the expected. Check the version of the file used and if the error persists, please contact the Cardios Customer Support service.
The line [line] will be lost because it is incorrect. Do you want to continue?	The ABPM protocol configuration was not populated correctly. If you continue, the exam will be prepared without this data.
The memory card does not contain a [type] exam.	Verify that the desired card has been inserted. If so, please contact Cardios Customer Support Service.
The memory card does not contain a 12-lead ECG exam.	Verify that the desired card has been inserted. If so, please contact Cardios Customer Support Service.
The Memory Card does not contain any data.	Data loss has occurred or the card has never been used. Verify that this is the correct card and if the error persists, please contact the Cardios Customer Support service.
The Memory Card has probably been removed. The Card MUST be kept inserted during all the upload operation!	An error occurred in the operation with the card. Check that it is inserted and keep it in operation. If the error persists, please contact Cardios Customer Support Service.
The memory card is possibly corrupted. Repeat the operation again. If the problem persists contact Cardios technical support.	The card is possibly corrupted. Repeat the operation again. If the problem persists please contact Cardios Customer Support Service.
The memory card you are reading contains less procedures than the selected exam. This operation is invalid!	An error occurred reading the data. There may have been a problem with the card or the exam. Please contact Cardios Customer Support Service.
The 'Millivolts' line of the header file supports only 'Millivolts' units. No other units are supported.	The file format is incompatible with the expected. Check the version of the file used and if the error persists, please contact the Cardios Customer Support service.
The module does not work with the supplied configuration.	You need to correct the informed configuration. If in doubt, please contact Cardios Customer Support Service.
The module you are using is misconfigured. Or its installation did not complete correctly, or it is out of specification. Contact the software provider. Function: [function name]	There may have been an error installing the software. Please contact your IT support or Cardios Customer Service.
The network is incomplete! In order to create a new connection, that record must have the required information previously filled.	Necessary to correctly populate the network connection master. If completed, please contact Cardios Customer Support Service.
The 'NumSamps' line of the header file has an invalid value. NOTE: This value is a positive integer and greater than 2.	The file format is incompatible with the expected. Check the version of the file used and if the error persists, please contact the Cardios Customer Support service.

Message	Possible Solution
The operation cannot be performed due to an internal error.	The CardioSmart CS550 reserves disk space on the customer's computer to store the complete recordings performed by Cardios Digital Holter recorders. Without the allocation configuration, it is not possible to import exams or read the device's memory card data. To create the allocation, click on System, in the Settings menu. Click on the “+” icon next to the CardioSmart item in the menu tree to the left to expand the group. Select the Advanced Settings option. In this window, the system shows the current allocation value. Set the value to a sufficient number of exams performed by the client or available disk space on the computer, since each number added to the counter will reserve approximately 25MB of disk space. The allocation limit is 999 exams. If this number is already being used, it will be necessary to backup the current exams and delete them, to free up space. It is recommended that the client routinely perform the exams backup by exporting data to an external disk.
The operation failed.	The file could not be fully received. Repeat operation required. If the error persists, check for communication as a remote location and contact the Cardios Customer Support service.
The other point doesn't respond [command]	A communication failure has occurred. Check for available Internet connection. If not, please contact your ISP. If any, please contact Cardios Customer Support Service.
The pacer detection parameter must be between 1 (max) and 7 (off).	Necessary to correct the parameter for pacemaker detection. If you are correct, please contact Cardios Customer Support Service.
The post-event parameter must be from 10 up to 300 seconds.	Necessary to correct the post-event parameter. If you are correct, please contact Cardios Customer Support Service.
The pre-event parameter must be from 0 up to 100 seconds.	Need to correct the pre-event parameter. If you are correct, please contact Cardios Customer Support Service.
The recorder was incorrectly shutdown and may cause data loss or card malfunction. Get more info in the user's guide.	If the error persists even after the appropriate measures are taken in the manual, please contact the Cardios Customer Support service.
The registry does not contain a valid key (error: [code]).	A generic error occurred. Please write it down, as well as the operation being performed and its sequence, and contact Cardios Customer Service.
The remote site is not responding the command [command] or became unavailable.	A communication failure has occurred. Check for available Internet connection. If not, please contact your ISP. If any, please contact Cardios Customer Support Service.

Message	Possible Solution
The resources of ECG Monitoring through infrared cable are disabled. Use the menu [Module] and the option [Configure System] to enable the infrared monitor.	You need to enable infrared cable monitoring if it is available in system configuration.
The 'SampFreq' line of the header file must have a value between 50 and 1000. Other values aren't of practical use by ECG systems.	The file format is incompatible with the expected. Check the version of the file used and if the error persists, please contact the Cardios Customer Support service.
The sample rate parameter is not valid for the [mode] mode. You should also verify if some installed module may require an upgrade.	Need to contact Cardios Customer Support Service.
The section [section] was not found!	An internal error occurred. Please try the operation again, and if it does not work, please contact Cardios Customer Service.
The selected device does not have any configuration to operate and does not support adding configuration. It is likely that the device should be reinstalled to work properly.	There may have been an error installing the software. Please contact your IT support or Cardios Customer Service.
The selected diagnostic record is related to some other record in the register. To preserve the Database integrity, it cannot be removed as long as there are references to it.	The master record should be removed first. If in doubt, please contact Cardios Customer Service.
The selected file is not a valid WFDB/MIT file.	The file format is not as expected. Please check the format and try the operation again. If this is not possible, please contact Cardios Customer Service.
The selected folder contains unknown files. Please select another one.	The selected folder does not contain the expected files. Please try another folder. If this is not possible, please contact Cardios Customer Service.
The selected window size is incompatible with the current tachogram processing type, given the maximum segment time specified. To change the window size, go to the 'HRV - Basic Parameters' page and change 'Process:' in the 'Segment Data' group.	Please follow the instructions in the message. If it is not possible, or if you have any questions, please contact Cardios Customer Service.
The specified drive is not removable. Verify if the drive is not a network connection or hard disk.	You should select a removable drive (for example, flash drive, or CD-R). If you are selecting correctly and still receive this message, please contact Cardios Customer Service.
The 'StartDate' line of the header file has an invalid date value. NOTE: This date must agree to the locale settings or the US date standard.	The file format is incompatible with the expected. Check the version of the file used and if the error persists, please contact the Cardios Customer Support service.
The 'StartTime' line of the header file has an invalid hour. NOTE: This value must be formatted according to the locale settings or the US Format.	The file format is incompatible with the expected. Check the version of the file used and if the error persists, please contact the Cardios Customer Support service.

Message	Possible Solution
The system cannot locate the Flash Memory Card on your system. A valid card must be present on a compatible Card Reader.	Prepare the card and leave it connected to a reader to perform the operation. If the error persists, please contact the Cardios Customer Support service.
The system has found many memory cards of the CardioLight type. Please remove the undesired cards from the reader.	There is a limit to the number of cards of type CardioFlash2. It is necessary to remove the unwanted card (s) from the reader.
The system has not located an available serial port for infrared communication. Devices such as 'mouse' and 'modem' also use serial ports. For the use of some features, it will be necessary to have at least one serial port.	Please contact your IT support. If the error persists, please contact Cardios Customer Service.
The total pre and post event intervals cannot be greater than 300 seconds.	Please check the selected time interval. If it is within the expected and still does not work, please contact Cardios Customer Service.
The unlock key you entered is not correct. Check the digits carefully, as instructed by the technical support.	The key should be entered correctly. If you are sure it is correct and are still receiving this message, please contact Cardios Customer Service.
There are no more full disclosure files available. You should delete undesired exams from the catalog before uploading more Holter exams.	The disk exam limit has been reached. Increase the limit or back up and remove exams from the disk.
There at least one octet number invalid in the IP address	You need to verify that the IP address you have entered is correct. If you are, contact Cardios Customer Support Services.
There is missing a "[" or a "]" in domain	It is necessary to verify that the reported domain is correct. If you are, contact Cardios Customer Support Services.
There is no memory card space available for an exam of such duration.	Please contact Cardios Customer Support Service.
There is not channel information available on this header file. Cannot proceed with import operation.	The file format is incompatible with the expected. Check the version of the file used and if the error persists, please contact the Cardios Customer Support service.
There was a management error of the signal file system.	Please contact Cardios Customer Service.
There was a socket error.	A communication failure has occurred. Check for available Internet connection. If not, please contact your ISP. If any, please contact Cardios Customer Support Service.
There was an error during reading ECG file. Please verify if the media is correctly inserted.	A card read error has occurred, which may be missing or corrupted. Please check and contact Cardios Customer Support Service.
There was an error on this application! It will not work reliably until you restart your computer. Call our technical support if the problem persists.	This is an unexpected error. Please contact Cardios Customer Support Service to report it.
There was an error while moving the export file to its destination [error]	A generic error occurred. Please write it down, as well as the operation being performed and its sequence, and contact Cardios Customer Service.

Message	Possible Solution
This address doesn't end in a three-letter domain, or two letter country. Do you still want to save it as is?	You need to check the email address you typed. If you are, please contact Cardios Customer Support Service.
This address is missing a "host name"	You need to check the email address you typed. If you are, please contact Cardios Customer Support Service.
This command is not available in demo mode, or the software license has expired.	Please follow the instructions in the message. If it is not possible, or if you have any questions, please contact Cardios Customer Service.
This operation needs to change the size of your files, but it cannot proceed because they are associated with some exam. Release the access to the files by deleting all exams and repeat this operation.	You need to backup your exams as instructed in the user manual. Then exclude exams and proceed to the desired operation again. If in doubt, please contact Cardios Customer Service.
This program version has restrictions and does not allow the data recovery from the card. The data can only be retrieved through "CardioManager®".	Please contact Cardios Customer Service.
Time already used.	Please follow the instructions in the message. If it is not possible, or if you have any questions, please contact Cardios Customer Service.
Unable to detect the Card's exam because it was created in another machine.	There was some incompatibility between the exam card and the control. Please contact Cardios Customer Support Service.
Unable to identify the Card's Exam because it was created using another database installation.	The card is empty, there was some failure in the reading of the same or the exam created in previous version of software. Please contact Cardios Customer Support Service.
Unable to locate the card on the specified drive.	A card read error has occurred, which may be missing or corrupted. Please check and contact Cardios Customer Support Service.
Unable to locate the Card's ID record.	There was some incompatibility between the exam card and the control. Please contact Cardios Customer Support Service.
Unable to update the remote buddy file.	The file could not be transmitted in a full way. Repeat operation required. If the error persists, check for communication as a remote location and contact the Cardios Customer Support service.
Unknown	Unknown recorder type. Need to contact Cardios Customer Support Service.
Unknown cause	Shutdown of the recorder for unknown cause. Need to contact Cardios Customer Support Service.
Unknown event (code: [code])	A generic error occurred. Please write it down, as well as the operation being performed and its sequence, and contact Cardios Customer Service.
Unknown recipient	Check the settings of the registered email. If they are correct, please contact the Cardios Customer Support service.
Upload [name] file has failed.	The file could not be transmitted in a full way. Repeat operation required. If the error persists, check for communication as a remote location and contact the Cardios Customer Support service.
Upload not supported by active export version.	Need to check the version in use. Please contact Cardios Customer Support Service.
Warning! The service date is expired!	It is suggested that the recorder be sent to the technical assistance authorized for verification.

Message	Possible Solution
WARNING! There are no supported "Monitor" devices configured on your system. To use this module you must install at least one "Monitor Mode" capable device.	There was a problem installing the program. Please contact your IT technical support or Cardios Customer Service.
Warning! This module only be used with exams records x,y e z orthogonal derivations, and 7 ways.	The recommended specification should be followed. If you have any questions, please contact Cardios Customer Service.
Warning: The transfer notification will not effectively set, due to the fact there is no analyst e-mail defined in the "Analyst Record."	Need to correct the email address in the medical analyst's Register.
You did not select a report to print. Configure at least some part of the report in the Report Settings menu.	Please follow the instructions in the message. If it is not possible, or if you have any questions, please contact Cardios Customer Service.
You have canceled the creation of this exam. In the meantime, someone else has already created one more exam. As a result, the canceled exam code will be unavailable and will be ignored.	Unable to reuse exam code. Please repeat the operation. If this is not possible, please contact Cardios Customer Service.
You should configure the amount of compressed ECG files before using the module. Select [Modules], [System Setup], and the [Holter] folder to configure this parameter.	The recommended configuration should be performed. If you have any questions, please contact Cardios Customer Service.
Your analyzer installation is not correct. The analysis module version is not returning the expected version. It is likely that the exam can still be opened, but do not edit it.	A software installation error occurred. Contact your IT support or Cardios Customer Service.

Note: words within brackets [] mean messages with variable content.

15. SOFTWARE LICENSE AGREEMENT

IMPORTANT – READ CAREFULLY: This term of Software License is a legal agreement between the end user (owner and operators, private or enterprise) and Cardio Sistemas Coml. Indl. Ltda. (hereinafter named Cardio Sistemas Ltda. or simply Cardios) and covers the usage of the software (also referred as “software application”, “software system” or “system”) that is currently being activated.

By installing, re-installing, activating or using this software application, you automatically agree on respecting all the terms of this license, in its entire extension and with no exclusions. If you do not agree on these terms, please contact the Cardio Sistemas Ltda. authorized local dealer or representative from which you have purchased the system and request instructions on how to proceed.

Special care must be taken in regards to preserving the integrity and security of the device. In case the device gets lost, replacement policy depends on a written communication assuming responsibility over the missing device and a deep analysis of each individual situation. A new protection device, in any situation, will be supplied under charge

1 Definitions

1.1 LICENSOR: Refers to Cardio Sistemas Coml. Indl. Ltda., manufacturer of the CardioLight+® systems (CardioLight+® Digital Holter recorder and CardioSmart CS550 analysis software + complimentary modules).
1.2 CUSTOMER: Represents the end user (owner or operator) of the systems.
1.3 SOFTWARE: Refers to the application (also referred to as “software application”, “software system” or “system”), in its executable Binary code form, together with its complimentary modules and all the accompanying documentation (manuals, guides, technical data, etc.).
1.4 USE LICENSE: Refers to the non-exclusive right to use any legally purchased and activated software application produced by Cardio Sistemas Ltda. and commercialized by the manufacturer or its authorized dealers.
1.5 PROTECTION DEVICE: Refers to the hardware device (also called “hard lock” or “dongle”) destined to control and protect the license usage for all Cardios’ software applications that you install. This device contains the license information and represents it “physically”, so that it is mandatory to have the device connected to the PC where the system is going to run.
1.6 ESSENTIAL SERVICES: Refer to the installation, re-installation, configuration or customization of any legally purchased and activated software application produced by Cardio Sistemas Ltda. and commercialized by the manufacturer or its authorized dealers.
1.7 OPERATIONAL TRAINING: Refers to the instructions provided to the end user (owner and/or operators) of the systems by one or more than the different means made available by Cardio Sistemas Ltda. or its authorized dealers. That includes, but not restricts to, printed material (manuals, “quick-steps guides”, leaflets, etc.), electronic (video, audio, text, “on-line help files”, etc.) or alive (workshops, training sessions, open courses, seminars, “in-loco” training, etc.).
1.8 BASIC REQUIREMENTS: Refer to the physical layer (hardware) and the OPERATING SYSTEM under which the software applications will be installed, considering that both shall be compatible to the specific requirements of each system configuration and intended use (IT infrastructure, volume of exams to be processed, communications, Internet, trained operators, etc.).

2 License Agreement Terms

The usage license granting will obey to all the following terms:

2.1 The LICENSOR hereby grants to the CUSTOMER, upon payment in full of the agreed license fee, a personal, non-exclusive and non-transferable license to use the SOFTWARE in the version existing on the date of the acceptance of this agreement (registered by the acceptance term).
2.2 All the SOFTWARE updates, whether described as updates, new releases, new versions, modifications or corrections, shall be subject to the terms of this AGREEMENT.
2.3 The CUSTOMER may not assign or transfer any of its rights and obligations pursuant to this AGREEMENT to others, unless agreed with and under a written consent of Cardio Sistemas Ltda.
2.4 The CUSTOMER is authorized to make duplicate copies of the SOFTWARE installer for backup purposes. This duplication right, however, is not extensive to the PROTECTION DEVICE that accompanies the application software installer.
2.5 The CUSTOMER shall not decompile or disassemble the SOFTWARE, nor analyze or otherwise examine the SOFTWARE for the purpose of reverse engineering.
2.6 The CUSTOMER is not entitled to perform by any means changes or modifications in the SOFTWARE without a written agreement with the LICENSOR.
2.7 The CUSTOMER agrees on using the SOFTWARE solely for its declared intended use.
2.8 The CUSTOMER understands that the results delivered by the SOFTWARE depend on the operator’s medical knowledge and training to validate and interpret the information processed by it.

3 Title

3.1 Title to the SOFTWARE remains, at all times, the property of Cardio Sistemas Coml. Indl. Ltda. The CUSTOMER shall have no right, title or interest therein, except the license to use the SOFTWARE according to the conditions set forth herein.

4 Warranty

4.1 Cardio Sistemas Coml. Indl. Ltda. disclaims any warranty that the SOFTWARE is error-free. The CUSTOMER agrees that the existence of such errors shall not constitute a breach of this agreement.
4.2 Cardio Sistemas Coml. Indl. Ltda. warrants the SOFTWARE for a 90-day period, commencing upon the acceptance of this agreement. Cardio Sistemas Coml. Indl. Ltda. warrants, during the warranty period, that the SOFTWARE when used properly and according to the operators manual, shall execute correctly the tasks required by the intended use.

4.3 During the warranty period, Cardio Sistemas Coml. Indl. Ltda.'s sole liability to the CUSTOMER will be the resolution of errors (bugs) in the SOFTWARE, which are not in conformance with the SOFTWARE specification, by correcting or by providing a workaround, and the rendering of a telephone and/or e-mail support for the resolution of problems related to the SOFTWARE.

4.4 The SOFTWARE is declared by the LICENSOR not to be fault-tolerant or intended to be used under conditions that require fail-safe operation. Also, the SOFTWARE is declared by the LICENSOR to require operation by trained and skilled personnel, with the ability and knowledge to validate or interfere with the processed data under a specialized medical point of view.

4.5 The above warranty does not apply to conditions resulting from improper use or operation of the SOFTWARE, from causes external to the SOFTWARE after delivery or from modifications/configurations made to the SOFTWARE other than those performed or recommended by Cardio Sistemas Coml. Indl. Ltda. The CUSTOMER assumes full responsibility for the use of the SOFTWARE and for any information/data entered, used, stored or processed thereon.

5 Limitation of Liability

5.1 Cardio Sistemas Coml. Indl. Ltda. will bear no liability for any damages which may be caused to the CUSTOMER or to any third party whatsoever resulting from data loss and/or for any indirect, incidental or consequential damages which may be caused resulting from improper use of the SOFTWARE and/or inability of the operators, including loss of profits, time or excessive consumption of computational resources.

16. REVISION HISTORY

Version	Revision	Comments
001	APR/2021	Initial release
	APR/2025	• Added Symbols Manufacturer Electronic instructions for use Medical Device Unique Device Identifier Authorized representative in the European Community CE Marking • Cardio Sistemas address update • Corrections to the usage of the name CardioSmart CS550 • Added 16. Revision History

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