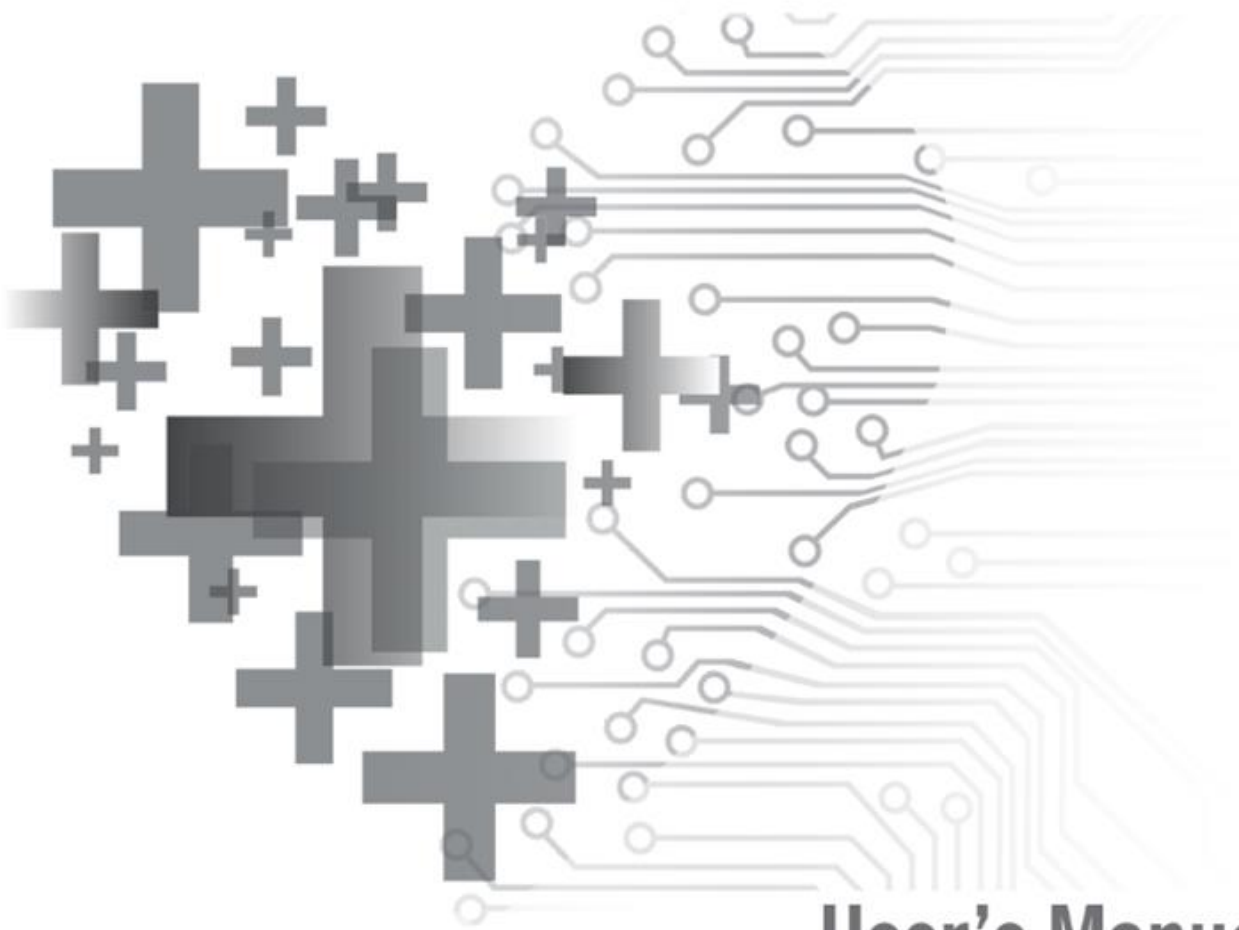
Cardio Light+



User's Manual

CE 1434

CARDIOS

VER 004 - 07/2025

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Summary

1. Presentation

Congratulations for purchasing your new Recorder!

The product on your hands was designed and produced with the highest technology and dedication. We hope it exceeds your expectations.

This is the instruction for use for the **CardioLight+**.

A printed version (hard copy) of this manual is also available.
To request a copy, please contact your Cardios Representative or local authorized distributor

Note on Terminology: Throughout this document, the product name is often shortened to **CardioLight+** for clarity and convenience. Unless otherwise specified, this term refers to the recorder name: **CardioLight+ Holter Recorder**.

1.1. Intended Use

CardioLight+ Holter System is a system composed of medical devices (software and ECG recorder device) that provides continuous recording and analysis of the ECG signal. The systems may first record and store the ECG and later analyze it on a separate computer with **CardioSmart CS550** software.

CardioLight+ is a portable digital Holter recorder. This instruction for use is specifically written for the **CardioLight+** recording device.

CardioSmart CS550 is a Software as a Medical Device (SaMD) used with the **CardioLight+** Holter System.

It performs several functions:

• **Prepares the Holter device:** Configures the device for a new patient examination.

• **Records and transfers data:** Transfers and saves the patient data (ECG signals) to a computer.

• **Analyzes data:** Processes the recorded data to identify key metrics (Heart rate, Heart rate variability, Arrhythmia detection, ST segments changes, QT interval measurement).

• **Generates reports:** Compiles the patient report summarizing the analysis.

The report includes statistics on normal and abnormal heartbeats, arrhythmias, and QRS morphologies. This information assists qualified physicians in making informed treatment decisions as part of a comprehensive patient evaluation.

CardioLight+ is an ambulatory Digital Holter Recorder intended for use in healthcare environments. While not exclusively for home healthcare, it is predominantly used in the ordinary home environment by healthcare providers and patients to screen for heartbeat rhythm disturbances.

The device records a three-channel ECG signal for 24 to 72 hours. Unlike cardiac monitors, **CardioLight+** is intended for temporary use and primarily aids in diagnosis.

Important Notes:

• **CardioLight+** is not indicated for self-monitoring.

• Use under the supervision of a healthcare professional.

• Some procedures require a microcomputer and a healthcare professional.

During use, **CardioLight+** (the device) continuously records and stores signals directly into its internal memory and captures infrequent or activity provoked heart rhythm abnormalities outside of the physician's office.

CardioLight+ is a portable device that is positioned on the patient's belt using its own clip (or a belt pouch) and using a proprietary 4-lead patient cable to carry the signal to the recorder. Patient cable is attached to patient's chest using four third-party electrodes.

See software user´s manual for more information on exam preparation.

CardioLight+ hardware has no capacity for automatic ECG analysis and consequently no capacity for automatically generating alerts to potentially critical cardiac conditions.

A qualified physician should review and interpret the summarized heartbeat report generated by the CardioSmart CS550 to assess the patient's condition.

CardioLight+ is intended for adult and infant patients (infants weighing less 10kg weight) and can be used on patients with pacemaker.

Final interpretation and diagnosis are the responsibility of a physician.

1.2. Intended Users

CardioLight+ is intended to be used by healthcare personal trained and qualified to setup and operate this Holter system and else to thoroughly instruct patients on how to proceed, telling what can and what cannot be done during exam recording.

Please contact Cardios representative for more information on training and tutorials.

Please carefully read Section 3 in this manual for Usage Restrictions before start using **CardioLight+**.

Please carefully read Section 5 in this manual for Important Information before start using **CardioLight+**.

1.3. Lifetime

CardioLight+ has an expected lifetime of 5 years.

1.4. Intended Patient Population

Intended for adult and pediatric (infants weighing less than 10 kg).

2. Product Identification

2.1. Packaging

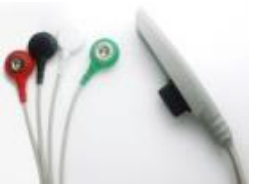
CardioLight+ package provides adequate product protection while not in use. If product demands repair, we recommend the use of the original package to accommodate **CardioLight+** and its accessories in their way to a repair center.

All parts included in the delivery package have been properly packed and checked for completeness and functionality.

ITEMS INCLUDED IN THE PACKAGE

Quantity	Item Description	Part Number
01	CardioLight+ Holter Recorder	02.1901.00013
01	4-lead Patient Cable	02.4600.00008
01	Pouch	01.7002.00003

If any item is missing or damaged, please contact Customer Support Service immediately (number indicated at the end of this manual) or your local authorized distributor.

CardioLight+ Holter Recorder	4-lead Patient Cable
	
User´s Manual (CD ROM)	**Pouch**
	

2.2. Spare parts

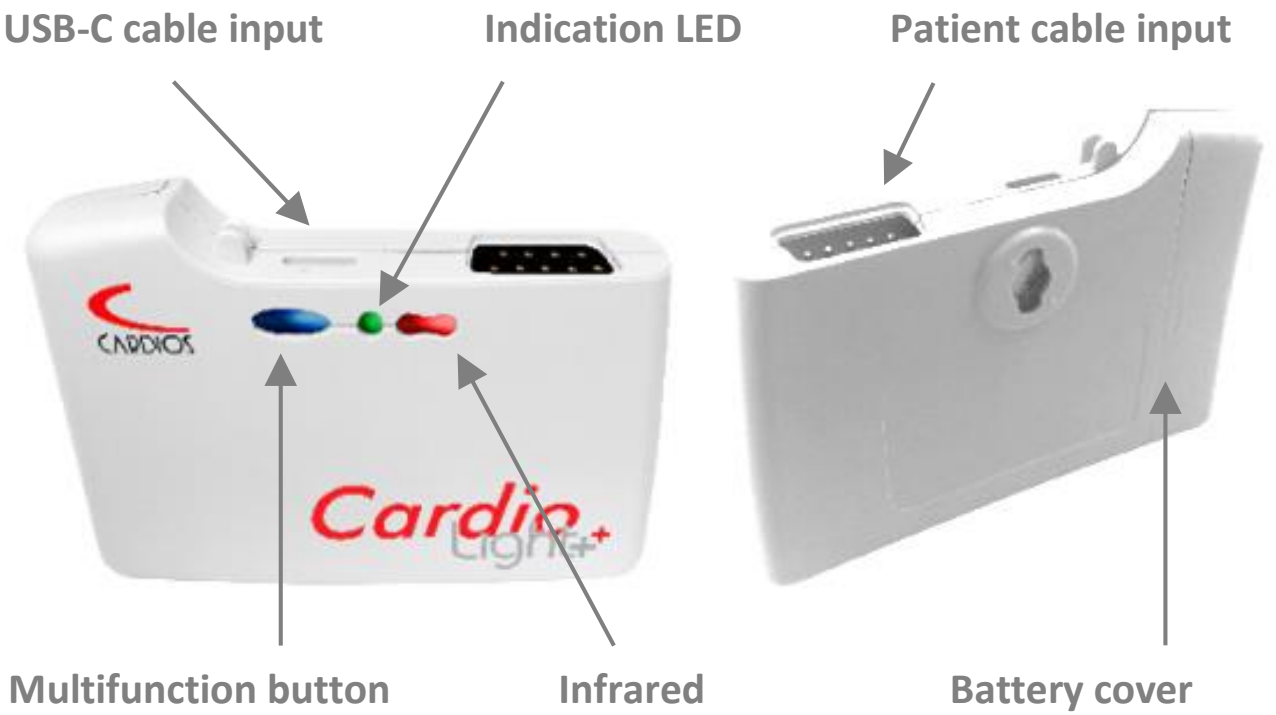
The following items are accessories for **CardioLight+**. If required any spares, these are available to be ordered separately:

Item Description
7-lead Patient Cable
4-lead Patient Cable
Pouch
Belt Clip

Only use accessories and spare parts provided by Cardios.

2.3. CardioLight+ Connections and Visual indication

The Recorder's LED visual indications and connections are shown below.



The presence of **CardioLight+** does not interfere specific investigations and/or treatments but usage restrictions must be observed (See 3. Usage Restrictions).

2.4. Multifunction button

The main functions of the multifunction button are:

Function	Sequence
Start ECG recording	Single Press
Mark event during the exam	Single Press
Stop infrared transmission	Single Press
Stop recording (power off)	Press three times and hold until a sound is emitted.

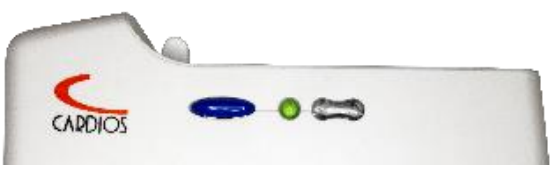
The multifunction button use is always accompanied by beeps and LED indications.

2.5. Sound and LED indicators

The LED visual indicators inform **CardioLight+** activities as follows:

Indication	Activity
Single GREEN flash	Recording in progress.
Three short GREEN flashes	Waiting for recording to begin. Press the button to start recording, otherwise **CardioLight+** will wait 5 min and automatically starts to record.
Alternating GREEN and YELLOW flashes accompanied by beep sound.	Self-test in progress.

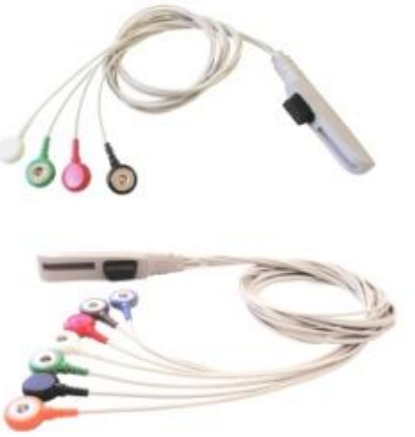
In addition to activities during normal operation, the LED and audible indicators also report **CardioLight+** error states, as shown at the end of this manual. Therefore, it is important to identify which color the LED is flashing.



Green LED

Yellow LED

2.6. Patient cable



CardioLight+ unique patient cable is composed of a 9-pin connector to connect to **CardioLight+**, and in the other end a 4-leads to connect to electrodes positioned on patient chest. (7-lead ECG patient cable is also available)

CARDIOS CABLE CONFIGURATION

	Polarity	4-lead	7-lead	7-lead TAB102*
C1 (Channel 1)	+	●	●	●
	-	○	○	○
C2 (Channel 2)	+	●	●	●
	-	○	●	●
C3 (Channel 3)	+	●	●	●
	-	●	●	●
GND (Ground)	⏚	●	●	●

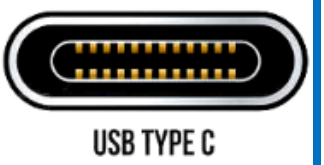
** IEC 60601-2-47*

Warning: CardioLight+ is designed for use with Cardios' Patient Cable only. The use of third-party ECG cables may lead to undesirable side effects such as noise or imprecision, and may expose the patient to risk.

2.7. USB-Type C cable

A USB Type-C data cable (not included with the product) is used to connect **CardioLight+** to the computer during the exam preparation and data transfer.

Use only USB Type C data Cable.



2.8. Applications

The table below shows the software that can be used as accessory with your **CardioLight+**.

CardioSmart® CS 550	Used for recorder preparation for new exam, recorded data verification and report generation.
CardioNet®	Used for recorder preparation for new exam, device data download and data transmission through the Internet.

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3. Usage Restrictions

CardioLight+: some restrictions need to be met for its correct functioning.

CardioLight+ can only be operated and connected to patient by trained and qualified health professionals.

Patient must be informed on how to proceed in case of alarms or misuse of device (sound alarms, visual information) and regarding what conditions need to be avoided showering (not waterproof device).

There is no evidence of contraindication or adverse effect or event reported from the Holter exam.

3.1. General Restrictions

Only trained and qualified health professionals should operate **CardioLight+**.

Do not expose **CardioLight+** to liquid **splashing** or **immersion**. The equipment is not sealed.

The operator must always instruct the patient how to act in case the device becomes wet or immersed in liquid:

- Immediately disconnect **CardioLight+**;
- Remove battery and send equipment, reporting what has happened, for immediate referral to an Authorized Technical Assistance.

Please refer to Technical Assistance contact at the end of this manual.

The equipment cannot be used in the immediate vicinity of an MRI scanner or near a microwave oven.

CardioLight+ is not used in conjunction with other equipment.
If a connection to mains is needed for any supporting equipment such as computers or battery charger, make sure not to connect to mains by means of coupling and/or using a portable multiple outlet.
There is a possible risk caused by the sum of the leakage currents when **several equipment** are connected together.

CardioLight+ is not suitable for use in the presence of an electronic scalpel.
CardioLight+ is designed to be used close to the patient body (belt clip or pouch).

CardioLight+ is not protected against **defibrillation**. Therefore, disconnect the cables and electrodes before using the defibrillator. If improper use occurs, the equipment may exhibit abnormal behavior, compromising the signal's subsequent analysis.
Avoid the use of **electrostimulators** along with **CardioLight+**. There is no risk to the equipment or patient but can interfere the recorded signal.

3.2. Electromagnetic Compatibility

CardioLight+ can be used even when exposed to electromagnetic fields as defined in IEC 60601-1-2. The tables below show the conditions under which the equipment can be exposed, and the values were taken from the test report issued by a competent laboratory.

Electromagnetic Emissions		
CardioLight+ is intended for use in the electromagnetic environment specified below. The customer or user of the CardioLight+ should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR11	Group 1	The **CardioLight+** uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The **CardioLight+** is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations, variations and flicker emissions IEC 61000-3-3	Not applicable	

CardioLight+ and its Patient Cable must not be used close to mobile or portable RF communication devices (mobile or cordless phones, or wireless modems) as they might interfere with the recorded signals and add noise (artifacts) to the recorded signal traces. A minimum distance of 30 cm is required for safe operation.

Electromagnetic Immunity			
CardioLight+ is intended for use in the electromagnetic environment specified below. The customer or user should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1 Test Level**	**Compliance Level**	**Electromagnetic environment - guidance**
IMMUNITY to Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air discharge	± 8 kV contact ± 15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
IMMUNITY to RF radiated electromagnetic fields IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	Portable and mobile RF communications equipment should not be used in close proximity to any part of the CardioLight+, including cables, with separation distance shorter than the recommended.
IMMUNITY to fast transient /burst IEC 61000-4-4		Not applicable.	Mains power quality should be that of a typical commercial or hospital environment.
IMMUNITY to surges IEC 61000-4-5		Not applicable.	Mains power quality should be that of a typical commercial or hospital environment.
IMMUNITY to disturbances conducted or inducted by RF fields IEC 61000-4-6		Not applicable.	Portable and mobile RF communications equipment should not be used in close proximity to any part of the **CardioLight+** including cables, with separation distance

			shorter than the recommended.
IMMUNITY to magnetic fields at mains frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields at mains frequency should be at levels typical of commercial or hospital environments.
Voltage dips, short interruptions and voltage variations on the power supply input lines. IEC 61000-4-11		Not applicable.	The quality of mains power supply should be that of a typical commercial or hospital environment. If user of the CardioLight+ requires continued operation during mains interruption it is recommended that the **CardioLight+** can be powered from an uninterruptible power supply or battery.

Radiated Immunity		
Immunity Test	**ABNT NBR IEC 60601-1 test level**	**Compliance Level**
IMMUNITY to RF interference IEC 61000-4-3	380 to 390 MHz (Pulse Modulation 18 Hz - PM 50%) 27 V/m	380 to 390 MHz (Pulse Modulation 18 Hz - PM 50%) 27 V/m
	430 to 470 MHz (FM ± 5 kHz Senoidal 1 kHz - PM 50%) 28 V/m	430 to 470 MHz (FM ± 5 kHz Senoidal 1 kHz - PM 50%) 28 V/m
	704 to 787 MHz (Pulse Modulation 217 Hz - PM 50%) 9 V/m	704 to 787 MHz (Pulse Modulation 217 Hz - PM 50%) 9 V/m
	800 to 960 MHz (Pulse Modulation 18 Hz - PM 50%) 28 V/m	800 to 960 MHz (Pulse Modulation 18 Hz - PM 50%) 28 V/m
	1700 to 1990 MHz (Pulse Modulation 217 Hz - PM 50%) 28 V/m	1700 to 1990 MHz (Pulse Modulation 217 Hz - PM 50%) 9 V/m
	2400 to 2570 MHz (Pulse Modulation 217 Hz - PM 50%) 28 V/m	2400 to 2570 MHz (Pulse Modulation 217 Hz - PM 50%) 28 V/m
	5100 to 5800 MHz (Pulse Modulation 217 Hz - PM 50%) 9 V/m	5100 to 5800 MHz (Pulse Modulation 217 Hz - PM 50%) 9 V/m

Warning: In general, mobile and portable RF communication equipment can affect electromedical equipment. Keep **CardioLight+** away from mobile/cordless phones, radio communicators, etc.

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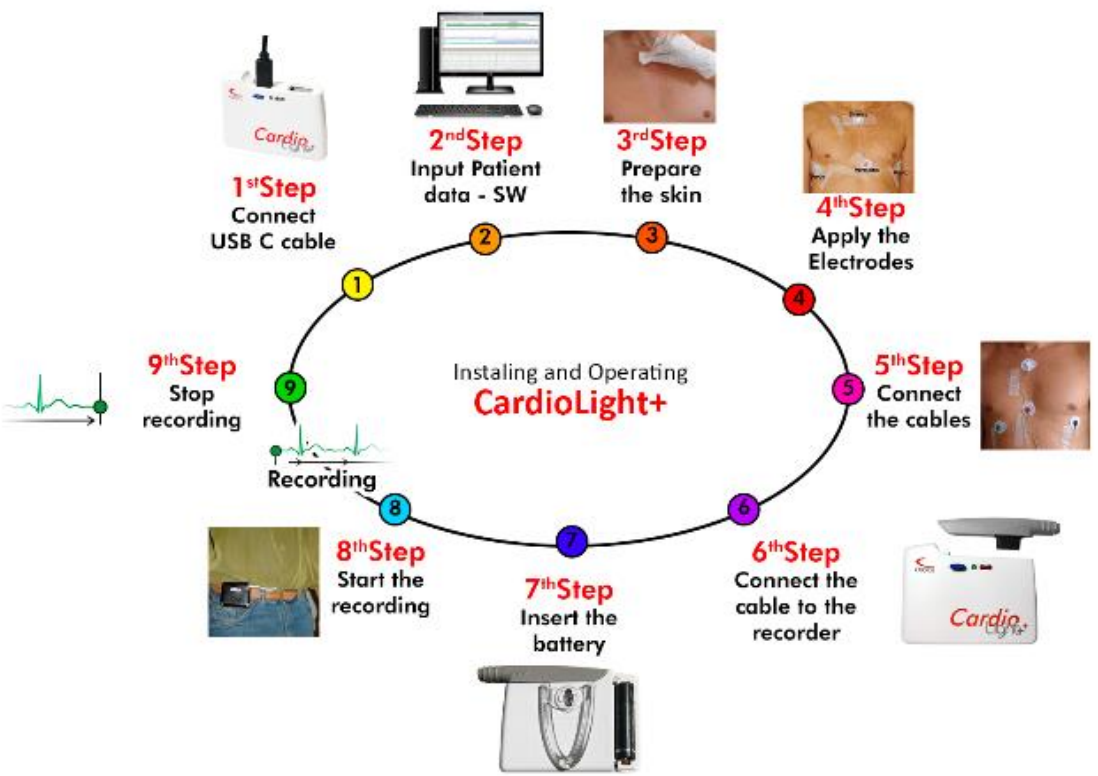
4. Recorder Operation

Follow these instructions carefully **every time** the equipment is used.

> Before you start using the Recorder, check if the patient cables and the USB-C cable are in **good condition** and if the battery is **fully charged**. These are basic requirements that should always be observed.

In addition, patients should be instructed by the Health Professional not to use any oil, lotion, moisturizer, or similar products on the body before and during the exam. These products can act as insulators and signal quality can be affected. **CardioLight+** should be used following the 9-step sequence as shown and explained below.



1st STEP: Cable Connection

The USB-C cable must be connected into the **CardioLight+** carefully to avoid physical damage, as this may damage either USB-C cable or **CardioLight+** USB-C connector.

Front view

Cable detail

Warning: To ensure compatibility with safety standards CardioLight+ must connect only to computers certified to IEC60950-1 or IEC62368-1. This will ensure that internal working voltages are controlled to only those levels guaranteed to exist in certified equipment.

2nd STEP: Recording Preparation

The USB-C cable must be connected to **CardioLight+** and to the USB port on the computer (**CardioSmart CS550** software must be installed on computer). New exam preparation can be done using **CardioSmart CS550** with the specific information of each exam.

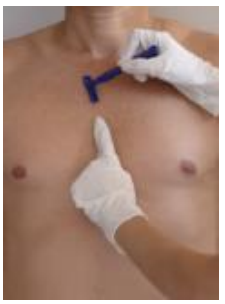
See software instruction for use for more information on exam preparation.

3rd STEP: Skin cleaning

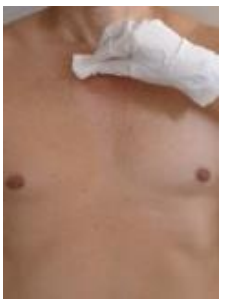
The quality of the recording is directly related to how well the electrodes are attached to the patient's skin. Therefore, it is essential to properly clean the patient's skin before applying the electrodes.

Cardios recommends the following procedures to get good skin contact:

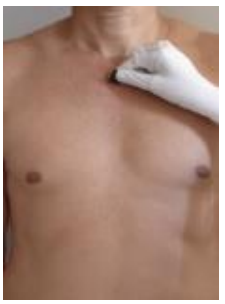
DEPILATION: guarantees the maximum electrical contact between the electrode and the patient's skin. It is a necessary step, even for a small amount of skin hair (even in female patients).



SKIN CLEANING: the skin superficial oil acts as an electrical insulator. Its removal can be done with gauze and 70% ethyl alcohol.

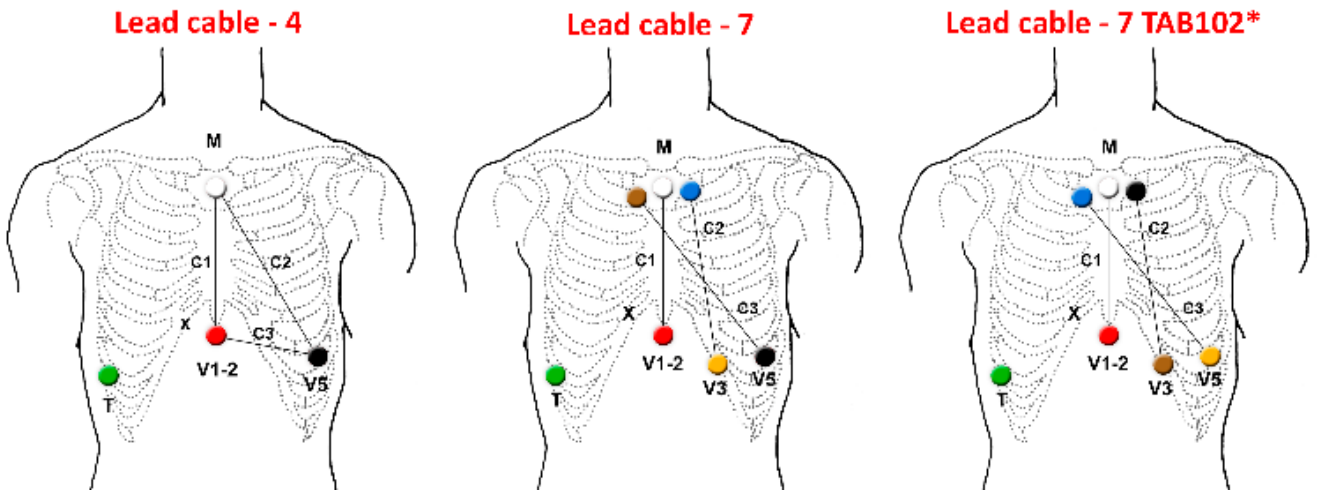


SKIN SCALIFICATION: ensures the removal of the dead skin cells layer and improves the skin conductivity. To do this, use a very fine sandpaper number 400, gently passing it to the points where the electrodes will be placed. It is recommended that the sandpaper is not passed more than 3 times on the same place.



4th STEP: Electrode Placement

CardioLight+ allows the recording of exams with four or seven leads, positioned as shown below:



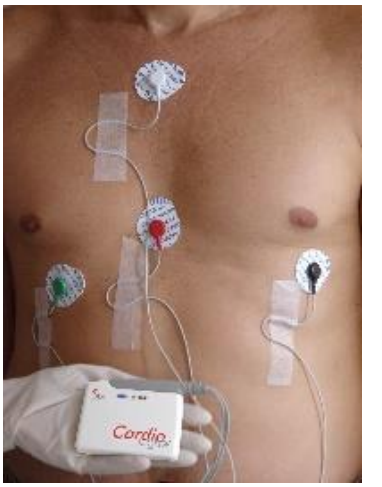
**IEC 60601-2-47*

C1 = Channel 01	*M = Sternal Manubrium*
C2 = Channel 02	*X = Appendix Xifoide*
C3 = Channel 03	

During electrode positioning, choose points supported by bone surfaces. Never place an electrode in the intercostal spaces or on skin folds.

5th STEP: Patient Cable Leads fixing

The leads must be well fixed, respecting the positions indicated in the previous figures.



During the exam, the leads can be stretched due the patient's movements. To prevent this from affecting the signal quality, it is recommended that small "loops" be made in the leads near the points where the electrodes are attached, as shown in the following figure.

Warning: Ensure the conductive (metal) parts of the electrodes are securely attached to prevent them from loosening and coming into contact with other conductive parts, including the ground wire.

6th STEP: Cable connection

The patient cable connector is designed for perfect and unique fit on **CardioLight+**, as shown below.

7th STEP: Inserting the Battery

First, place the battery negative pole (indicated by the negative **"-"** sign on the battery) and then the positive pole (plus **"+"** sign).

Negative pole

Fit the negative pole first

Then insert the positive pole

After the battery is inserted, **CardioLight+** will perform its self-test. The battery cover should be replaced as shown below.

Fit the bottom

Push the top

8th STEP: Start recording

After executing the self-test, the LED will indicate that **CardioLight+** waits for the multifunction button to start recording the exam. If it does not happen, the recording will start automatically after 5 minutes.

During the exam, **CardioLight+** acquires the signal and writes it to an internal memory. The green LED will flash once every 2 seconds approximately to indicate the recorder is operating normally.

The patient should be instructed by the Health Professional and encouraged to mark events that he/she considers relevant, especially those with symptoms of indisposition. **Event marking** is done when the multifunction button is pressed once.

During the exam, the patient can perform his/her activities normally. However, it is important that some instruction is given to the patient (or his/her companion) to ensure good signal recording quality.

The patient should **not** take a bath/shower **with CardioLight+**. If the equipment is wet (or soaked), the Health Professional should instruct the Patient to remove the equipment, turn it off, remove the battery and inform the responsible professional immediately.

Do not disconnect the Patient cable.
Do not turn off the **CardioLight+**.
In case of any of the above conditions, the professional responsible should be informed immediately.

Electrodes can NEVER be reused. A new set of electrodes is needed every day, or every time the equipment is placed into a new patient. It is recommended that some extra electrodes are supplied in case these are not properly fixed.

Before bathing, the patient should disconnect the patient cable and remove the electrodes, disclosing them properly.

After bathing, new electrodes will be placed in the **same chest location** as the previous ones after these areas are **thoroughly dried** *(see 4th Step – Electrode Placement)*. Fix the **leads** to the electrodes and make sure to provide loops on the lead, to avoid straining *(see 5th Step – Patient Cable Leads fixing)*.
Always refer to these instructions when placing the Patient cable!

In the case of **defibrillation**, the Patient cable and the electrodes must be removed from the patient, but it is recommended that the **CardioLight+** be removed completely. For a new exam, it is necessary to inform the professional responsible for the exam.

Eventually, some situations (usually while sleeping) may occur when the multifunction button is pressed **accidentally**. If held down, **CardioLight+** will beep continuously. This does not indicate malfunction, but the button needs to be released.

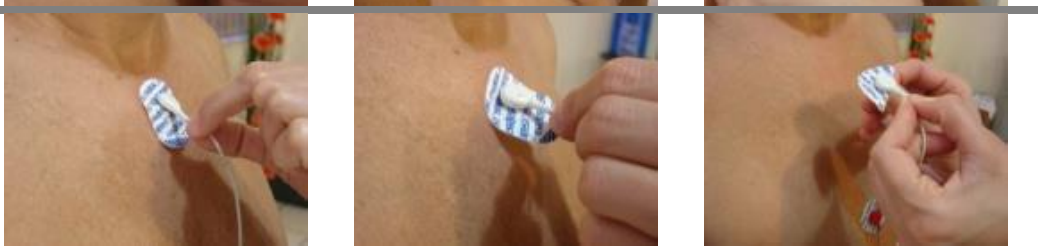
9th STEP: End of Recording

CardioLight+ is designed to perform the automatic shut-off at the end of the period set for the exam. In this situation, the equipment will sound an audible alarm, indicating the end of the recording, and it will not be possible to continue the exam or start a new one without new exam preparation procedure.

Once recording stops, the patient cable leads should be carefully withdrawn from the patient removing the electrodes from patient skin. Never pull on the cable leads! This can cause breakage, reducing the cable life.

✓ Correct

✘ Incorrect



CardioLight+ must be connected to the USB-C cable and to the computer so that the exam recording is transferred to the computer using either **CardioSmart CS550** software as described in its manuals.

Although the automatic shut-off is very useful, there are situations where it is necessary to switch off before the expected time. This can be done with the multifunction button, as indicated at the beginning of this manual.

Cardios recommends that patients return for device removal around the last hour of recording. This allows the correct equipment operation to be observed before it is switched off automatically. If the green **CardioLight+** LED is off or the yellow LED is blinking, there was a problem during recording. A list of possible errors is presented in this manual.

Warning: to avoid the poor quality of exams, always monitor the quality of electrode placement and provide regular training of staff.

No hazards are expected from the contact between cable leads and patient's skin, however, a good patient preparation would ensure leads are not stretched or tightly fit, so the patient can freely move.

5. Important information

5.1. For the physician

- Read this manual carefully before handling the equipment.
- Always position **CardioLight+** recorder on the patient´s belt either using the pouch or belt clip from Cardio Sistemas.
- Do not let liquids or chemicals wet the recorder or its parts / accessories. **CardioLight+** is not waterproof or water resistant (IPX0 device)
- Only replace parts and accessories supplied by Cardio Sistemas to avoid measurement errors and equipment damage.
- Do not subject the recorder to mechanical shock, fall or impact. Health Professional should clearly instruct the patient and users on care with the equipment.
- Always start an exam with a battery that is fully charged.
- Do not mix the batteries used in **CardioLight+** with batteries from other equipment.
- Make sure the battery compartment cover is firmly closed, preventing poor battery contact. If you notice the cover does not close properly or appears loose, contact your service representative.
- The recorder **cannot** be used in the immediate vicinity of a working magnetic resonance tomograph and microwave oven.

- Inform the patient not to stay close to RF transmitting equipment such as mobile phones, cordless phones, wireless communicators, transmitters, etc. A minimum of 30 cm is required between **CardioLight+** and most transmitters frequently found at domestic environments.
- Verify if the patient cable and the electrodes are securely in place.
- Health Professional should give instructions to patient on how to turn off the equipment if necessary.
- Inform the patient not to press the button unnecessarily.
- Always clean recorder and accessories used on the device for a new (or next) exam.
- The patient **cannot** take a bath (or shower) while using **CardioLight+**. If the device gets wet or soaked, the patient should be instructed by Health Professional to turn it off, remove the Patient cable and the battery, and inform the responsible professional as soon as possible. It is not a waterproof or water-resistant device (IPX0).
- Inform the patient that **before** bathing (or showering), he/she should disconnect the electrode cable and remove the electrodes, placing them away from other metal parts.
- Inform patient to fully dry the areas where the electrodes will be placed.

- Inform patient to position new electrodes and place them in the same locations as before.
- Connect the ECG leads to the correct locations.

WARNINGS

- If water has entered the recorder during cleaning or use, it can no longer be used: send the recorder for service, informing this condition.
- **Never** position electrodes in areas with injuries.
- **CardioLight+** is not suitable for simultaneous use with high-frequency surgical devices.
- **CardioLight+** complies with all electromagnetic compatibility standards requirements, however, it must not be exposed to strong electromagnetic fields outside the limits as it may be affected and cause anomalies.
- The recorder must **not** have contact with the patient during a defibrillator discharge, as it may be damaged and affect the recorded signal.

5.2. For the patient

The physician or professional responsible for the exam must inform the patient at the time of placement of Holter recorder about:

- During the exam, the recorder always flashes the indicator light. If this does not happen or if the indicator is turned to YELLOW, inform the professional responsible.
- Press the button only when something relevant patient condition or abnormal condition happens; the recorder will place a mark on the exam: record pertinent information in the patient's diary and report it to the physician or health care professional.
- If it is necessary to interrupt the exam, press the button 3 times and keep it pressed until an alarm is heard.
- Inform the patient the position of electrodes (position and lead color) to be placed after a bath, if necessary, provide the patient a drawing showing the positions/color of the individual ECG leads positioning. Before the bath, disconnect the cable leads from the electrodes and place the equipment away from metal parts and avoid contact to water/liquids.
- Dry thoroughly the areas where the electrodes will be placed.
- Stay away from mobile phones, cordless phones, RF communicators, etc. This may cause undesired noise into your exam. A minimum of 30 cm distance from these devices is recommended.

WARNINGS

- The recorder is not protected against the ingress of liquids (IPX0 device). Do not use the recorder during bathing (showering) and protect it from rain.
- If you notice the water entering the device, turn it off, remove the cable and electrodes, remove it from the pouch, remove the battery and inform the responsible professional.
- If a problem occurs during the exam, the recorder will emit an audible and luminous alarm. In this case, inform the responsible professional, who will help you solve the problem.

5.3. Rechargeable batteries

- The batteries recommended by Cardio Sistemas to use with your equipment are **Ni-MH** (Nickel-Metal Hydride) whose capacity is adequate to carry out the exam of 24, 48 or 72 hours. Batteries rated of 800mAh will work for 72h recording if fully charged.

Some precautions should be taken when using the batteries, so that their service life is extended and does not cause damage to the equipment:

- Polarity should **never** be reversed when the battery is placed in the battery compartment. Always observe the polarity label indication inside the compartment.
- **Never** use a battery with lower than 800mAh capacity because the exam total time may be reduced.

- **Never** insert or remove batteries from the charger connected as this may reduce their life and may damage the charger.
- The battery must be removed from the charger only to be inserted on the recorder. After the exam is done, remove the battery from the battery compartment and place it in the charger.
- In places where there is a lot of mains voltage oscillation or frequent energy drops, it is recommended to use an UPS to keep the chargers always powered.

Never leave the battery in the recorder when it is not in use, as the battery may leak and damage the recorder.

Battery leakage is NOT covered by warranty and maintenance contract.

6. Cleaning Guideline

CardioLight+ should be wiped with a **soft cloth** moistened with **ethyl alcohol at 70% concentration**. The cloth may be used around the plastic cabinet; however, the liquid inlet must be prevented especially at the USB-C connector, Patient cable and the battery compartment inputs.

The Patient cable and the USB-C cable can also be cleaned with ethyl alcohol 70%, taking care not to damage them (example: hold the cable at one end, wrap it with the cloth moistened and press it with great force, taking it to the other end, which will cause the cable to stretch).

No sterilization is required since **CardioLight+** is a non-invasive device.

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7. Error Signaling

CardioLight+ has a system that informs the occurrence of certain errors. This system consists of codes, which are blinked on the yellow LED with a beep, as indicated in the table below.

Number of blinks	Meaning
02 (Two)	Memory with exam already recorded or no more available space.
03 (Three)	Internal memory recovery. If during exam, the recorder tries to write over defective blocks or any abnormal operation is detected, the recorder will restart automatically and then continue recording. A continuous isoelectric signal will be shown on the ECG recorded data indicating the off-line period.
04 (Four)	Battery is not fully charged or is damaged.
06 (Six)	Internal equipment error - requires maintenance.

Note that it is very important to identify the flashing LED color. The figures below may help with this identification.

Green LED

Yellow LED

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8. Maintenance Information

If **CardioLight+** presents a defect or malfunction, it is necessary to provide corrective maintenance, or to send it to a repair center for verification and defect analysis.

CardioLight+ verification period is defined by the customer according to its own verification procedures.

CardioLight+ maintenance should be done only by Cardio Sistemas authorized repair center.

Patient cable must be replaced anytime that the professional using the recorder verifies the signal acquisition quality is not good enough for analysis.

NOTE: Unauthorized opening of **CardioLight+** results in the automatic loss of warranty, as well as this could damage it and generate incorrect recordings. In this case, Cardio Sistemas Coml. Indl. Ltda. **could not** be liable for any errors in the data integrity or signal quality of recordings.

The recorder must be shipped with all accessories to the authorized repair center.

It is necessary to send all parts to correctly identify defects.

It is recommended to use the **original** packaging to ensure that the recorder and accessories are protected against damage during transportation. If package is damaged upon repair center receiving, the customer will be informed.

Do not throw in regular trash. Please verify and follow local legislation and/or regulations regarding product (and accessories) disposal.

Warning: patients of product owner are not allowed to provide repair to the recorder or to its accessories. Therefore, no detailed product technical documentation is provided. If you require further information, please contact Customer Service.

9. Symbols

General warning sign

Text indicating a mandatory action

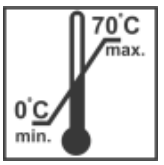
Follow instructions for use

Consult instructions for use

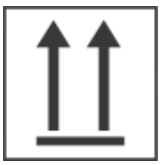
Text with prohibition

Disposable Material

Keep dry



Storage Temperature Limits



This Side Up

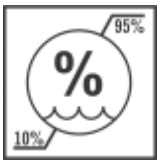
Applied Type BF Part

Fragile

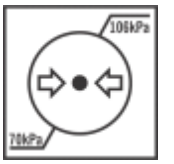
Maximum Stacking Limit

Do not throw in ordinary trash. Refer to local regulation for correct disposal

Recyclable Material



Humidity limitation



Atmospheric pressure limitation

Manufacturer

Date of Manufacture

Serial number

Batch number

Unique Device Identifier

Authorized representative in the European Community

Medical Device

CE Marking

https://ifu.cardios.com.br

Consult instructions for use

UDI-DI + UDI-PI (AIDC* format)

(01)00051901000118 UDI-DI (HRI** format)

(10)...(11)……(21)……. UDI-PI (HRI** format)

**AIDC Automatic identification and data capture*

***HRI Human Readable Interpretation*

10.Specifications

Recorder	
Model	CardioLight+
Dynamic Input Range	± 5 mVp
Minimum amplitude(1)	50 µVp
Tolerance per channel	± 10%
Sample Resolution	12 bits/channel
Sampling Rate	800 samples/sec per channel
Pacemaker (PM)	Pacemaker Spike Detector in 1 Channel
Storage	Built-in memory
Interfaces	
Visual	Bicolor LED: green and yellow
Electrode connection	Patient cable with 4 (standard) or 7 (optional) leads with DB9 connector and plugs to connect to the electrodes
General Features	
Power Supply	1 AAA battery (1.2V 800mAh) rechargeable Ni-MH, or 1 Alkaline AAA (1.5V)
Power Consumption	25 mW (max)
Mechanical Specification	
Dimensions	82 x 60 x 14 mm
Cabinet	High Impact ABS
Weight	47g
Assembling Technology	High density SMD

Environmental Characteristics	
Operating Temperature	5°C to 40° C
Relative Humidity	10% to 95% non-condensing
Atmospheric pressure	70kPa to 106kPa
Storage Conditions	0°C to 70°C - RH 15% to 95%
Rating	
Type of protection against electric shock	Internally energized
Degree of protection against electric shock of the applied part	Type BF
Degree of protection against harmful penetration of water	IPX0
Degree of application safety in the presence of flammable anesthetics	Not suitable
Operation mode	Continuous
Reference to Standards	
IEC 60601-1	IEC 62366-1
IEC 60601-1-2	ISO 10993-1
IEC 60601-1-6	ISO 15223-1
IEC 60601-2-47	ISO 14971

Intended Use Environment

Locations:

- Healthcare environments (hospitals, clinics)
- Home healthcare settings
- Ordinary home environment (with healthcare provider)

Purpose:

- Screening for heartbeat rhythm disturbances
- Recording a three-channel ECG signal for 24 to 72 hours
- Primarily aids in diagnosis; temporary use only

Important Notes: • Not for self-monitoring • Requires supervision of a healthcare professional • Some procedures require a microcomputer and a healthcare professional
Classification
Body Worn IIa Rule 10 (MDR Article 51, Annex VIII, Chapter III 6.2
User Manual Format
Electronic(PDF)/printed file
Product Lifetime
5 years
Records
Technical Responsible: Eng. Rubens Paulo Silva CREA # 0600572553

**** Equipment operation with amplitudes below this limit may produce inaccurate results.***

11.Contacts

Manufacturer		
Name		Cardio Sistemas Coml. Indl. Ltda
Address		Av. Paulista, 509 1st Floor Bela Vista
		01311-910 São Paulo -SP Brasil
Phones	General	+55 (11) 3883-3000
	Fax	+55 (11) 3883-3060
	Sales	+55 (11) 3883-3030
	SSC	+55 (11) 3883-3010 (customer Support)
Website		www.cardios.com.br
CNPJ (Brazilian tax ID)		51.961.258/0001-95

Customer Support

Name		Cardio Sistemas Coml. Indl. Ltda
Address		Av. Paulista, 509 21st Floor Bela Vista
		01311-910 São Paulo – SP Brasil
Phones	General	+55 (11) 3883-3000
	Fax	+55 (11) 3883-3060
	Sales	+55 (11) 3883-3030
	SSC	+55 (11) 3883-3010
Website		www.cardios.com.br
CNPJ (Brazilian tax ID)		51.961.258/0001-95

Cardio Sistemas Repair Center

Name		Cardio Sistemas Coml. Indl. Ltda
Address		Av. Paulista, 509 3rd Floor Cj. 309
		01311-910 São Paulo – SP Brasil
Phones	General	+55 (11) 3883-3000
	Fax	+55 (11) 3883-3060
	Sales	+55 (11) 3883-3030
	SSC	+55 (11) 3883-3010
Website		www.cardios.com.br
CNPJ (Brazilian tax ID)		51.961.258/0001-95

Legal Representative

Name		Obelis S.A.
Address		Bd. Général Washis 53
		1030 Brussels Belgium
Phones	General	+32 (2) 732 59 54
	Fax	+32 (2) 732 60 03
E-mail		mail@obelis.net

12.Glossary

Pouch

Pouch to be placed on the patient´s belt to protect the recorder during exam.

Firmware

Equipment embedded software, not accessible to the user, which determines its normal operation.

Recorder

CardioLight+, it is a Digital Holter Recorder.

Ni-MH

Nickel-Metal Hydride - rechargeable batteries internal composition.

SLC NAND

Flash memory digital technology.

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13.Composition

13.1. Equipment

Product	
CardioLight+ Digital Holter Recorder	05.1901.00011
Product Parts	
CardioLight+ Holter Recorder	02.1901.00013
Patient Cable CL 4 leads	02.4600.00008
Pouch CardioLight	01.7002.00003
Parts Sold Separately	
Patient Cable CL 4 leads	05.1950.00013
Patient Cable CL 7 leads	05.1950.00014
Patient Cable CL 7-lead TAB102	05.1950.00025
Battery Cover	01.3210.00012
Accessories	
Pouch (CardioLight)	01.7002.00003
Black Belt 115x3cm	01.7002.00005
Accompanying Documents	
CardioLight User's Manual (Internet)[1]	01.2900.00066

[1] - Printed version available upon request. Please contact the Cardios representative.

Note: Cardios does not include electrodes with its products. However, Cardios recommends using high-quality 'solid gel' type electrodes from a reputable source. Users must always check the expiration date of the electrode batch and follow the manufacturer's instructions.

14.Change History

Version	Revision	Comments
001	MAR23	**Initial release**
002	JAN24	• Inclusion of specifications regarding intended patient population • Inclusion of lifetime declaration • Inclusion of change history • Removed the term "accreditation" from the CE symbol • Changing the term "Always" to "Only" in the following sentence in item 5.1 For the physician. "Only replace parts and accessories supplied by Cardio Sistemas to avoid measurement errors and equipment damage."
003	Nov24	• The text from the last paragraph of page 5 to the 4th paragraph of page 6 was revised for clarity. • Pg. 7, paragraph 2: Revised for clarity. • Pg. 10: The part number has been corrected to 02.1901.00013. • Pg. 10: corrected the code and the information about the local authorized distributor was added. • Pg. 29: first paragraph revised for better understanding. • Pg. 30: first paragraph revised for better understanding. • Pg. 31: warning message revised for better understanding.

		• Pg. 49 first warning message: symbol and text updated. • Pg. 51: UDI symbol added. • Pg. 53: Specifications table updated • Pg. 54, 55, 56: updated address • Pg. 60: CS550 and CardioNet removed • Pg. 65: Correction of the warranty period: from 2 to 3 years
004	Jul25	• Symbols: ▪ added **MD**, **UDI** and "electronic instructions for use" symbols and the website address for the Instructions for Use (IFU). ▪ Added an explanation about the presentation of UDI-DI & UDI-PI information2.1 – user manual removed from the list. • 1. Presentation: removed the 2nd paragraph and added text to the "Note on Terminology"; updated the text regarding the printed manual. • 10.1 – manual format changed to "Electronic (PDF)/printed file" • Note added after table 13.1. • User manual removed from table 13.1 – Product Parts • User manual added to **Accompanying Documents** on table 13.1. • Updated address • Corrected minor typos and wording issues.

WARRANTY CERTIFICATE CardioLight+

Cardios Total Warranty

Cardio Sistemas Coml. and Indl. Ltda guarantees through this certificate the CardioLight+WARRANTY for the period of 02 (two) years, from the date of the invoice. This warranty fully covers service for specific CardioLight+ components (does not include accessories and parts sold separately) provided by Cardio Sistemas, subject to the terms listed below.

Technical Assistance services will be provided by the authorized representative in the country upon the owner sending the equipment or components requested by the Technical Support representative, following their instructions, securely and appropriately packaged, with freight and insurance expenses to be borne by the owner.

Warranty Term

The equipment must only be sent to Technical Assistance after consulting the TechnicalSupport representative, who will define which components should be sent.

This warranty covers, during the period of validity, parts supplied by Cardio Sistemas that have manufacturing defects, premature wear of components, and misadjustments, provided that they are used under normal conditions, in accordance with the instructions in the user manual and Cardios Support & Service guidelines.

THIS WARRANTY DOES NOT COVER separately sold accessories and parts (batteries, charger, hood, patient cable, USB-C cable).

The warranty will be automatically canceled if the equipment is repaired or modified by unauthorized personnel or when it is misused, not following the technical guidelines given by Cardio Sistemas.

The warranty does not cover damage caused by liquid entering the equipment (water, battery leakage), use of unsuitable cleaning product, parts damaged by negligence or misuse of the equipment without Cardio Sistemas technical guidance, use of non-original parts as well as damage caused during shipping for maintenance due to improper packaging.

CARDIOS
A Halma company

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AUTHORIZED DISTRIBUTOR

EC REP

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