CardiAid®

Automated External Defibrillator

EN

User Manual and Introduction to the Device

For Models
CT0207RS Semi-Automatic Defibrillator
&
CT0207RF Fully Automatic Defibrillator

EN ENGLISH

CardiAid®

Public Access Defibrillator

User Manual
and
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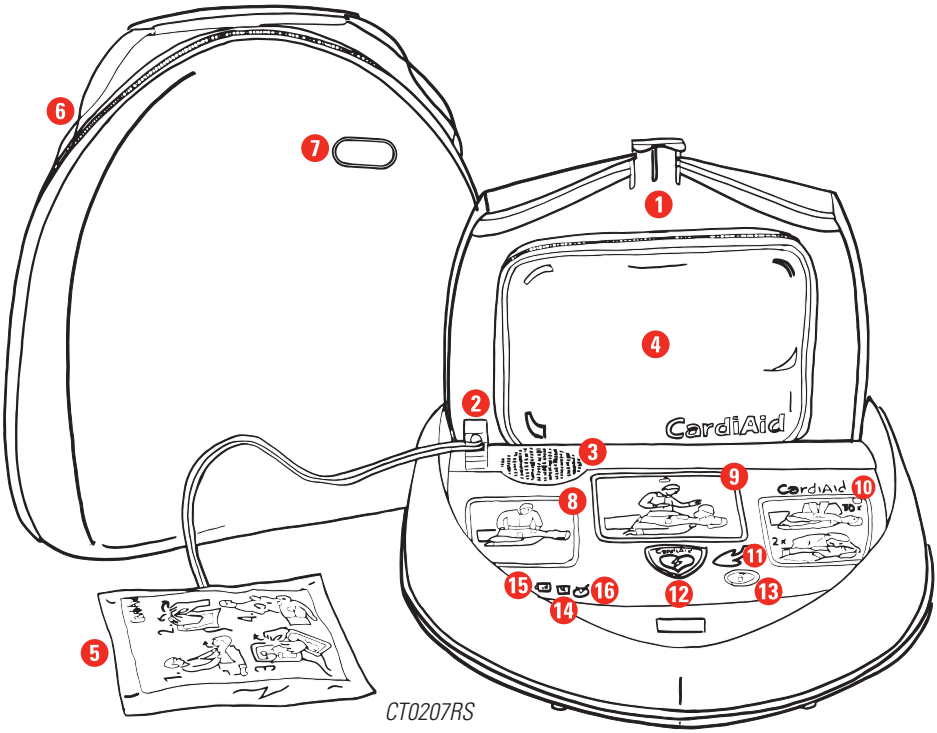
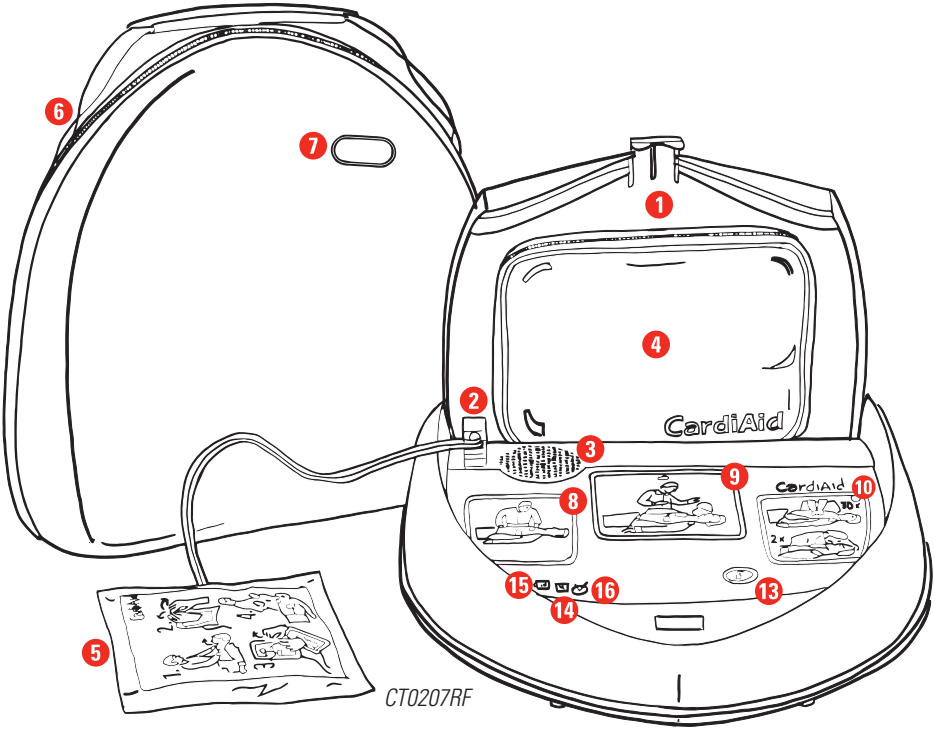
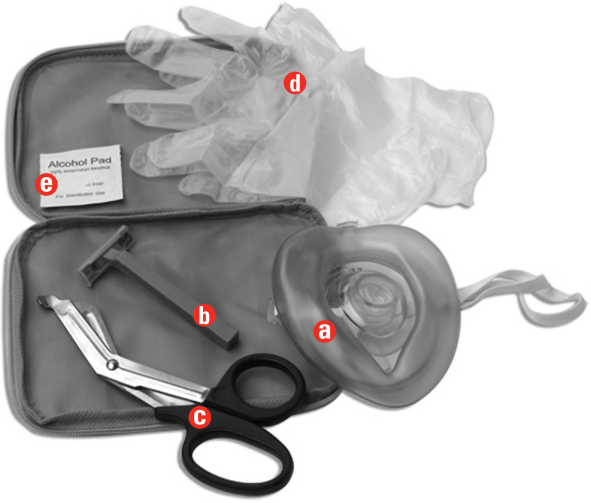


CT0207RS

1. Device Cover
2. Socket for Electrode Plug
3. Loudspeaker
4. Emergency Kit
5. Defibrillation Electrodes
6. Protection Bag
7. Indicator Window
8. Indicator: *"Remove clothing from chest and stick on electrodes"*
9. Indicator: *"Do not touch the patient from now on"*
10. Indicator: *"Patient may be touched"*
11. Indicator: *"Ready for Shock"* (only for CT0207RS)
12. Shock Button (only for CT0207RS)
13. Info-Button
14. Repair Symbol
15. Battery Symbol
16. OK Symbol



CardiAid Emergency Kit



a. CPR Mask
b. Razor
c. Scissors
d. Gloves
e. Alcohol Pad

1. Device Cover

CardiAid is switched on by opening the cover and switched off by closing the cover. Closing the cover will switch off the device only after the electrodes are disconnected.

2. Socket for Electrode Plug

Electrodes are connected to CardiAid through this socket. Electrodes supplied with the device are already connected to this socket.

3. Loudspeaker

Audio warnings of the CardiAid are heard through this loudspeaker.

4. Emergency Kit

Emergency kit includes scissors, razor, respiration mask, gloves and alcohol pad. Emergency kit should be replaced after use.

5. Defibrillation Electrodes

Electroshock is delivered to the patient through these electrodes. Electrodes should be replaced after each use.

6. Protection Bag

Protection bag is used to store, carry and protect the device.

7. Indicator Window

The status of the device can be observed through this window on the protection bag.

8. Indicator: *"Remove clothing from chest and stick on electrodes"*

When this indicator lights, you should stick the electrodes on patient's bare chest.

9. Indicator: *"Do not touch the patient from now on"*

Patient should not be touched when this indicator is flashing. For example: During heart rhythm analysis and shock application.

10. Indicator: *"Patient may be touched"*

While this indicator is lighting, patient may be touched. For example: During cardiopulmonary resuscitation.

11. Indicator: Ready for Shock (only for CT0207RS)

This indicator flashes when CardiAid is ready to deliver shock.

12. Shock Button (only for CT0207RS)

Shock button starts flashing after shock is prepared. This button is pressed to deliver electroshock.

13. Info-button

When pressed, an audible notification indicating the duration of use and number of shocks applied is heard.

14. Repair Symbol

The device should not be used, if the repair symbol is flashing or lighting. In this case, it should be repaired by Cardia International or an authorized service provider of Cardia International immediately.

15. Battery Symbol

The device is not ready for use, if the battery symbol is flashing or lighting. In this case, contact Cardia International or an authorized service provider of Cardia International immediately.

16. OK Symbol

CardiAid is ready for use, if the OK symbol is flashing while the device is switched off.

1.1 Intended Use

CardiAid is a public access defibrillator (PAD), i.e. an automated external defibrillator (AED) which is available for public use. CardiAid can be used for the resuscitation of patients older than 8 years (>25 kg) with standard electrodes and patients 1 to 8 years old (<25 kg) with special paediatric electrodes. If a patient displays symptoms of a cardiac arrest due to ventricular fibrillation or ventricular tachycardia, CardiAid can be used to deliver the required defibrillation therapy directly on the site of the emergency. The user is guided through the resuscitation process with clear and comprehensible instructions. The device automatically records and analyses the ECG signal and, if required, prepares itself to deliver a shock to the patient.

The process by which the shock is delivered varies according to the version of CardiAid being used:

- In the semi-automatic version (CT0207RS), the user is asked to press a button to release the shock.
- In the fully-automatic version (CT0207RF), the device warns the user not to touch the patient and then proceeds to releasing the shock automatically.

Important! CardiAid should be used only for the purposes described above.

1.2 Intended Environment

Public use implicates that the AED can be used in Home Healthcare Environments but shall not be used inside RF shielded rooms or close to HF surgery equipments.

1.3 User Qualification

In most countries, public access defibrillators (PAD's) like CardiAid can be used by any rescuer who is present when a person has sudden cardiac arrest. In some countries, CardiAid can be used only by rescuers who are qualified with training in basic life support, use of automated external defibrillators and use of CardiAid.

1.4 Description of the Functions

CardiAid is used to deliver defibrillation to a person having sudden cardiac arrest due to ventricular fibrillation or ventricular tachycardia. It analyses the heart rhythm of the patient and decides whether an electroshock is necessary or not. If one is necessary, it prepares the shock automatically. The shock delivery method depends on the model used (semi-automatic or fully-automatic). After the shock (or when no shock is advised), CardiAid directs the rescuer to basic life support (CPR) and guides the user with verbal instructions and metronome. During the incident, duration of use and number of shocks delivered can be heard by pressing *"info-button"*. CardiAid also records the ECG and event data in its internal memory and this data can be obtained from the device as a report. Below, the functions of the devices are explained briefly, and also will be explained in further detail through this user manual.

Software:

- Windows XP Professional/Windows 7
- C/C++ Software
- Java

Electrodes: Electrodes are the components through which the defibrillator collects information for rhythm analysis and delivers energy to the patient's heart. Electro shock is delivered to the patient through these electrodes. Electrodes should be replaced after each use.

Info button: By pressing the Info-button during basic life support stage, duration of use and number of shocks delivered can be heard. During this time, the timer for basic life support continues in the background.

LED Status: The LED Fields that are integrated in the foil keyboard.

LEDs/LED fields integrated in the foil (white) + additional flashing LED for each field (green):

- Attach electrodes
- Do not touch the patient
- You can touch the patient
- Shock arrow (is on if shock is necessary and capacitor is charged)
- Shock arrow - flashing if shock is necessary and capacitor is charged

Status LEDs (Flash in standby, continuous during operation)

- Device OK (Green LED)
- Battery low (Red LED)
- Device error or battery empty (RED LED). Device cannot be used!

The status LEDs must be seen if the cover is closed.

Loudspeaker: Loudspeaker is used to generate the voice commands and beeps. The volume can be pre-configured via Bluetooth. Position of the loudspeaker in the casing must be analysed to avoid "acoustical short circuit. The loudspeaker openings must comply with the IP Code of the device.

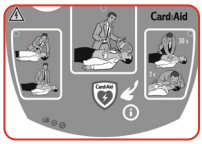
Shock: Shock button starts flashing after shock is prepared. This button is pressed to deliver electroshock.

Bluetooth: Bluetooth communication will be used instead of service connector to avoid problems with galvanic isolation. It used to read out results of the last self-test and saved ECG data. The self-test results can be read out only by service technician.

The following parameters can be also configured via Bluetooth interface.

- Language
- Voice prompts on/off
- CPR Time
- Impulse type
- Volume level of the voice prompts
- New Battery (must be performed after the battery is replaced)
- Time

Bluetooth interface is only available to the service technician, not to the device users. To change the settings or readout the data the device must be sent to the service centre.
In addition to that the Bluetooth port will be available for the Gateway after the daily selftest.



Visual and Acoustic Instructions for the User

CardiAid is designed to guide the user with verbal instructions together with pictures, flashing lights of different colours at the same time, thus maximizing the performance. CardiAid starts verbal instructions as soon as its cover is opened and guides the user step by step through the resuscitation process. Simultaneously, clear images support the verbal instructions. The pictures are simple and explanatory; the flashing lights are designed to emphasize the pictures and buttons, with white flashing light showing the stage of the process and red flashing light only indicating the shock button. In this way, all steps are ensured to be implemented accurately even if the user has limited knowledge or experience in resuscitation.

ECG Analysis and Recording
When electrodes are placed on the patient correctly, CardiAid immediately starts analysing and recording the ECG. According to the result of this analysis, CardiAid decides whether defibrillation is necessary or not; and informs the user accordingly. CardiAid continues analysing the heart rhythm until the device is turned off. The ECG analysis is continued also during shock charging of the device. The electroshock is aborted if the device detects a change in the rhythm. A change from *"Shock necessary"* to *"Shock not advised"* is the result of a change in patient's condition and is not a malfunction.

Attention!
CardiAid is turned off by unplugging the electrodes and closing the cover of the device. Closing the cover of the device when electrodes are still plugged in and connected to the patient does not stop the operation.

Defibrillation
If CardiAid detects a rhythm which requires defibrillation (Venticular Fibrillation (VF) or Venticular Tachycardia (VT)); it informs the user and prepares the electroshock. In semi-automatic model (CT0207RS), CardiAid instructs the user to press the shock button to deliver the electroshock. In the fully-automatic model (CT0207RF), the device warns the user and delivers the electroshock automatically.
The user cannot deliver an electroshock unless the device detects a shockable rhythm and prepares the electroshock.

CPR Guidance
In the basic life support phase, CardiAid guides the user according to the latest resuscitation guidelines. It provides metronome signals so that the user can perform chest compressions with the correct rhythm and number.
Adult Mode: After 30 signal tones, verbal instruction *"Now give 2 mouth to mouth breaths"* is heard, followed by a short silence for rescue breaths. Then, the user is directed to chest compressions with the verbal instruction: *"Now make 30 chest compressions"*. This cycle is repeated for 2 minutes according to the latest resuscitation guidelines.

Paediatric Mode: After 15 signal tones, verbal instruction *"Now give 2 mouth to mouth breaths"* is heard, followed by a short silence for rescue breaths. Then, the user is directed to chest compressions with the verbal instruction: *"Now make15 chest compressions"*. This cycle is repeated for 2 minutes according to the latest resuscitation guidelines.

Info-Button
By pressing the Info-button during basic life support stage, duration of use and number of shocks delivered can be heard. During this time, the timer for basic life support continues in the background.

Application Documentation
CardiAid records ECG and incident data in its internal memory. These data may be obtained from the device as a report to be analysed by specialists to define subsequent treatment.

Self-testing
CardiAid performs an automatic self-test daily, monthly and each time the cover is opened (i.e. when the device is switched on). The status of the device is indicated with flashing status symbols on the front side of the device.

1.5 Indications for Use

CardiAid is indicated to be used on victims of sudden cardiac arrest when;

- The patient is unconscious an unresponsive,
- The breathing is absent or not normal.

CardiAid CA-10ES Adult Defibrillation Electrodes should be used for patients older than 8 years or weighing more than 25 kg. CardiAid CR-13P Paediatric Electrodes should be used if the patient is 1 to 8 years old or weighs less than 25 kg. Therapy should not be delayed to determine the exact age or weight of the patient.

1.6 Contraindications for Use

CardiAid should not be used if any of the following signs are present:

- Consciousness and/or responsiveness
- Breathing

1.7 Important Points in an Emergency

If you suspect that a person is having sudden cardiac arrest, keep in mind the following points:

1. Keep calm and proceed rapidly
2. Check consciousness and breathing
   - Check the victim for a response. Gently shake the shoulders and ask loudly: *"Are you all right?"*
   - Check for normal breathing

Caution!
CardiAid should be used and defibrillation can be delivered only when the person is unconscious and the breathing is absent or not normal.

3. Phone emergency services and provide the following information:
   - Your name
   - Your current location
   - Number of patients
   - Type of emergency (suspicion of sudden cardiac arrest)
   - Presence of a defibrillator (PAD/AED)

Attention!
While starting resuscitation, make sure the emergency number is called without delay (preferably by other people around you).

4. Open the cover of CardiAid. The device will switch on automatically.
5. Follow the instructions exactly. See Section 4 *"Operation"* for detailed information regarding the verbal instructions.

Caution!
Note that the information in this user manual does not substitute a basic life support training.

2.1 Description of the User Manual

Please read this user manual carefully to ensure safe and effective use of CardiAid and to be prepared in case of an emergency. If you have additional questions about information in the user manual, you may contact the local distributor or Cardia International directly. Keep this manual where it can be reached easily.

The following safety warning icons are used throughout the manual:

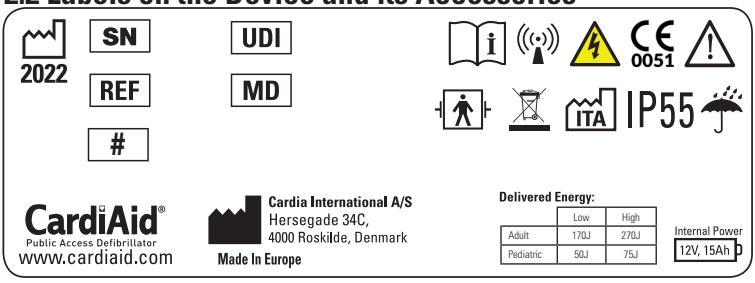
Danger!
The icon defines a danger which can result in serious injury or death

Caution!
The icon defines a possible danger which can result in serious injury or death

Warning!
The icon defines a possible danger which can result in simple - mild injury. This symbol is also used to indicate user errors which can result in damage to the device

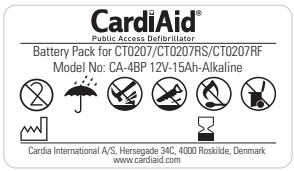
Attention!
This icon provides necessary additional information

2.2 Labels on the Device and its Accessories



Type Plate Label

Battery Life Label



Battery Product Label (on battery)

Electrode Product Label

SN	Serial number of the device
	Date of manufacture
	Do not dispose the device in common household waste
	Defibrillation protected, type BF patient connection
	Bluetooth
	Consult instructions for use
IP55	Dust protected, protected against water jet
	Manufacturer
	High voltage
	Replace battery before this date
	Caution: Further information in user manual
	Temperature limits
	Humidity limits
	Atmospheric pressure limits
	Operating temperature limits
#	Model number
UDI	Unique identification number
MD	Medical device

	Do not re-use
	Keep dry
	Avoid physical impact
	Avoid physical damage
	Keep away from fire
	Do not dispose in household waste
	Keep away from sunlight
	Do not use if package is damaged
	Use-by period after package opened
REF	Part/Reference number
	Use-by date
LOT	Batch code
	Transport and store this side up
	Fragile, handle with care
0051	IMQ S.p.A
ITA	Made in Italy
	Shock
	Battery Powered

2.3 Safety Rules

To ensure safety of the user, the patient and the bystanders, please pay attention to the following safety instructions which are the requirements of Regulation (EU) 2017/745:

General Rules

Danger!
To prevent danger of explosion, keep CardiAid away from oxygen sources, flammable anaesthesia gases and other flammable substance or gas mixtures.

Caution!
CardiAid can be used for the resuscitation of patients older than 8 years (>25 kg) with standard adult electrodes and patients 1 to 8 years old (<25 kg) with special paediatric electrodes.

Caution!
If you suspect that a person is having sudden cardiac arrest, check for signs of life, i.e. consciousness and breathing, before using the device. CardiAid should be used and defibrillation can be delivered only when the person is unconscious and the breathing is absent or not normal.

Caution!
Check CardiAid and its accessories for visual damage before using the device. If you observe damage on the device or its accessories, do not use it. Otherwise there may be functional errors resulting in the injury of both the patient and the user.

Caution!
Do not use the device if you observe differences in the procedures from the ones described in the user manual. In this case, immediately contact Cardia International or a Cardia International authorized service provider.

Caution!
CardiAid can be used only after self-test is completed successfully and any damage or misuse is not detected.

Caution!
Check periodically whether the device and its accessories are ready for use (See Section 6.2. Function Check for further details).

Caution!
CardiAid can be used to defibrillate a patient on either a wet or metal surface as long as the appropriate safety precautions are taken. During use of the CardiAid, please be sure that no one is touching the patient when the shock is being delivered.

Caution!
Do not attempt to deliver electroshock if defibrillation electrodes are in contact with each other or are not connected to the patient.

Danger!
Be sure that the electrode cable is not wedged when closing the cover of CardiAid. It may damage the electrode cables.

Caution!
Charging and delivering electroshock may affect the electronic devices nearby. Check the function of these devices before using CardiAid.

Warning!
Operation of CardiAid can be affected from electrical and magnetic fields. Keep CardiAid at least 2 meters away from electrical devices such as cellular phones, walkie-talkies, X-ray machines etc.

Warning!
Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning!
Do not immerse CardiAid or its accessories in any liquid. Liquid ingression may cause serious damage and the device can be unusable.

Warning!
Use only original accessories and spare parts. Using incompatible accessories or spare parts can cause irreversible damage to the device and serious injuries. Use of non-approved accessories and spare parts invalidates the warranty of your device and the manufacturer will not be responsible for any damages caused.

Warning!
Do not open and modify CardiAid. Opening and modifying CardiAid can cause irreversible damage to the device. This invalidates the warranty of your device and the manufacturer will not be responsible for any damages caused.

Caution!
Liquid ingressing in the holes for loudspeaker output can significantly reducethe audibility of voice prompts. Avoid ingress of liquids and position the device vertically in case liquids have already been ingressed.

Warning!
Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Defibrillation / Use

Caution!
Always observe national / regional laws and regulations in effect regarding the use of an automated external defibrillator.

Caution!
To prevent injuries of the user, the patient and any by-stander, make sure the patient is not being touched or moved during defibrillation. Do not touch metal objects or equipment which are in contact with the patient during defibrillation.

Caution!
Apply the electrodes on patient's bare chest as shown on the electrode pads. Applying electrodes incorrectly may cause faulty analysis of heart rhythm and/or faulty or inefficient defibrillation.

Caution!
In order to prevent faulty interpretation of ECG data, make sure that the patient is lying still, not being touched or moved while CardiAid is analysing heart rhythm. Do not perform basic life support (CPR) during rhythm analysis.

Warning!
Before delivering the electroshock, make sure the patient is disconnected from other medical devices which do not have defibrillation protection.

Warning!
Although CardiAid is one of the safest devices in its class, remember that wrong interpretation of heart rhythm may be possible.

Warning!
Make sure that the electrodes are placed firmly to the patient's chest. If not, air between the patient's skin and electrodes can cause burns.

Electrodes

Caution!
Only use original electrodes supplied with CardiAid. CardiAid CT0207RS and CardiAid CT0207RF should be used with CardiAid CA-10ES Adult Defibrillation Electrodes or CardiAid CR-13P Paediatric Electrodes.

Caution!
CardiAid CA-10ES Adult Defibrillation Electrodes should be used for patients older than 8 years or weighing more than 25 kg. CardiAid CR-13P Paediatric Electrodes should be used if the patient is 1 to 8 years old or weighs less than 25 kg. Therapy should not be delayed to determine the exact age or weight of the patient.

Caution!
Never use electrodes which have damage on the package and/or on the pads. Do not use electrodes after the expiry date written on the electrode package.

Caution!
Electrodes shall be disposed after every single use. After using adult / pediatric electrodes, follow your local clinical procedures for recycling. Reuse of Electrodes can cause insufficient contact with patient due to lack of adhesiveness inhibiting ECG analysis and shock delivery leading to failure of the device intended purpose.

Caution!
Open the electrode package only in case of an emergency and just before use.

Caution!
If the patient has an implanted pacemaker, do not stick the electrodes on the pacemaker. Using the defibrillator on a patient with implanted pacemakers can lead to incorrect analysis of the heart rhythm and to irreversible damage of the myocardium in case the electrodes are placed too close to the pacemaker.

Caution!
Do not place the electrode pad on the nipple.

Caution!
If there is excessive hair on chest, use the razor in the emergency kit of CardiAid (present inside the cover of the device) to clear the chest before applying electrode pads.

Caution!
Remove all clothing from upper body before applying electrode pads. Clothes or undergarments with metal parts may cause burns on skin.

Caution!
CardiAid defibrillation electrodes are for single-use only. After using CardiAid, immediately contact Cardia International or an authorized service provider for replacement of the electrodes.

Caution!
Pay attention to the operating and storage conditions of the device and its accessories, which are indicated in technical specifications.
The storage outside the specified temperature range will impact the electrode gel contact and therefore sometimes a 2nd or 3rd shock delivery maybe neccessary.

Caution!
Keep and store the device and its accessories away from children. Electrode cables may cause strangulation and suffocation.

2.4 Side Effects

The following adverse side effects may occur when CardiAid is used:

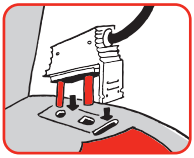
- Burns on skin
- Rashes on skin
- Delivering electroshock to a patient who has implanted pacemaker or is connected to other electronic devices can cause damage to these devices.
- Delivering electroshock to a patient having a non-shockable rhythm may cause fibrillation.

Unpacking the Device

Remove CardiAid from its packaging carefully. Check whether all parts are present according to *"Content of Delivery"* on Section 11. Check all components for any sign of damage. Contact your sales representative or Cardia International directly if there are any missing or damaged components.

Opening the Cover

Open the cover of CardiAid. The device will switch on automatically.



Connecting Electrode Plug

CardiAid is delivered with electrodes pre-connected to the device. Always keep the device in this condition to help save time in an emergency. If not connected already, connect the electrode plug to the socket on the device. Special design of the plug prevents user mistake. It can only be connected as required.

Placing Emergency Kit

CardiAid is delivered with an emergency kit placed inside the cover of the device and electrodes placed inside the package in front of the emergency kit. Always keep the device in this condition to help save time in an emergency.

Emergency kit includes a single-use razor, scissors, respiration mask, gloves and alcohol pad. The items in the emergency kit are for single-use only. After using CardiAid, contact Cardia International or an authorized service provider for replacement.

Closing the Cover

Close the cover of CardiAid carefully. The device will switch off automatically.

Danger!

Make sure that the electrode cable is not wedged while closing the cover of the device. It may damage the cable.

Installation

Different storage options are available for CardiAid. You can choose the product which suits your needs the best:

- CardiAid Wallmount: It provides practical storage for CardiAid AED. CardiAid Wallmount also provides storage for spare electrodes, if necessary.
- CardiAid Indoor Cabinet: Specially designed for CardiAid, they ensure that CardiAid AED is noticeable and easily reachable in case of an emergency while providing its safety.
- CardiAid Outdoor Cabinet: It provides climate protection and high visibility outdoors.

Installation instructions if applicable, and necessary parts are included in the packaging of the products.

4.1 Before Using CardiAid

Switching CardiAid On

Open the cover of CardiAid. Device will switch on automatically.

Self-testing

CardiAid immediately starts a self-test when switched on. During self-test, all indication and warning LEDs light up. When self-test is completed, indication symbols show the status of the device. Observe the status indicators before continuing to use CardiAid. Green "OK Symbol" flashing indicates that the device is ready to use. The combination of the status indicator lights have different meanings. See Section 7. Troubleshooting for further details.

Caution!
If the green "OK Symbol" is not flashing, the device is not ready to use. Immediately contact Cardia International or an authorized service provider.

Caution!
If any of the red "Battery Symbol" or "Repair Symbol" is flashing, immediately contact Cardia International or an authorized service provider. See Section 7. Troubleshooting for further details.

Caution!
If the red "Battery Symbol" is flashing, indicating a low battery, immediately contact Cardia International or an authorized service provider. The battery should be replaced when the device gives low battery warning.

Caution!
If one or more of the instruction lights does not light during self-test, the light diodes may be faulty. The device may be used in the current incident, if there is an emergency. Immediately contact Cardia International or an authorized service provider for repair.

4.2 Providing Reanimation

After opening the cover, verbal and visual instructions guide the user through the whole reanimation process. In this section, you may find details on how to act on each verbal and visual instruction given.

Caution!
Note that the information in this user manual does not substitute a basic life support training.

Caution!
The cover of the device should not be closed during operation.

Preparation of defibrillation

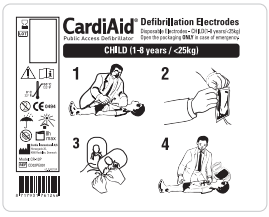
1. *"**Check for breathing**"* and "*__Phone emergency services__*" (This instruction may be differentiated to fit the national emergency number in your country). (These instructions can be deactivated by an authorized service provider) verbal instructions are heard immediately after opening the cover of CardiAid. The LEDs around the indicator of the first instruction field (on the left) light.
While starting resuscitation, make sure that the emergency number is called without delay (preferably by other people around you).

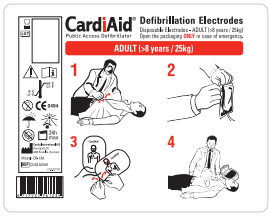
Check the patient for the following signs of life:

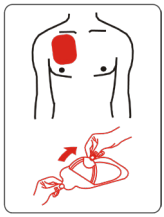
- Consciousness
- Normal breathing

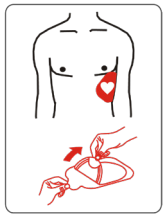
CardiAid should be used and defibrillation can be delivered only when the person is unconscious and the breathing is absent or not normal.

2. *"**If not breathing normally, remove clothing from chest and stick on electrodes**"*
(This instruction can be deactivated by an authorized service provider) instruction is heard. Position the patient on his back on a non-conductive and dry surface. Remove clothing from patient's chest. Patient's chest should be dry and not very hairy. If necessary, remove hair using the razor in the emergency kit.





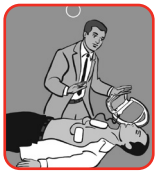




3. *"**Stick electrodes on patient's bare chest**"*
Open the package of the electrodes. Stick electrodes on patient's bare chest as shown on the electrode pads. Press the electrodes firmly to guarantee a good contact.
The instruction *"**Stick electrodes on patient's bare chest**"* is repeated every 8 seconds until electrodes are placed correctly to enable the heart rhythm analysis. If an electrode is detached or damaged, the instruction is repeated until the contact between the electrodes and the body is re-established.

Caution!
CardiAid CA-10ES Adult Defibrillation Electrodes should be used for patients older than 8 years or weighing more than 25 kg. CardiAid CR-13P Paediatric Electrodes should be used if the patient is 1 to 8 years old or weighs less than 25 kg. Therapy should not be delayed to determine the exact age or weight of the patient.

Caution!
During the whole process, make sure that electrodes are placed firmly on chest and are not damaged.



4. "***Do not touch the patient from now on. Analysing heart rhythm***"
These instructions are heard when electrodes are placed correctly, enabling the analysis of the heart rhythm (ECG). Simultaneously, the green light and LEDs around the second instruction field (in the middle) light, which indicates that the patient should no longer be touched or moved.

Caution!
Patient should not be touched or moved during heart rhythm analysis. Do not perform basic life support during the analysis. This may cause wrong interpretation of the ECG and delay in the defibrillation process which can be life threatening.

If the patient is touched or moved during analysis which cause interruption in the analysis, a signal tone and the warning "***Movement detected***" are heard.

Caution!
When warning "***Movement detected***" is heard, check for the cause of the interruption. If the patient is on a vehicle, stop the vehicle.

After the heart rhythm analysis, CardiAid decides whether shock is required. The device proceeds with verbal instructions according to the results of the analysis. These instructions will be explained in the following sections "***Shock Necessary***" and "***Shock Not Advised***".

Shock Necessary
5. If a shockable rhythm (Ventricular Fibrillation (VF) or Ventricular Tachycardia (VT)) is detected, instruction "***Shock necessary. Do not touch the patient from now on!***" is heard and CardiAid starts preparing the electroshock automatically. The instruction "***Preparing shock***" is heard next.

Attention!
The process by which the shock is delivered varies according to the version of CardiAid being used:

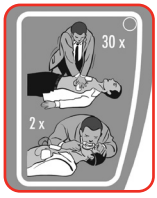
- In the semi-automatic version (CT0207RS), the user is asked to press a button to release the shock.
- In the fully-automatic version (CT0207RF), the device warns the user not to touch the patient and then proceeds to releasing the shock automatically.

For CT0207RS:
6a. When the device is ready for defibrillation, the instruction "***Press the flashing shock button***" is heard. At this moment, also the LEDs around the shock-button start flashing and the button is activated. This instruction is repeated with a signal tone until the shock button is pressed. Press the shock button to deliver the shock.

For CT0207RF:
6b. When the device is ready for defibrillation, the instruction "***Shock will be delivered***" is heard with a repeating signal tone until the device delivers the electroshock automatically.

7. After the shock delivery, the instruction *"**Shock delivered**"* is heard.
The device continues analysing heart rhythm while shock is being prepared. If the heart rhythm changes during this period, defibrillation is aborted.

Danger!
There is always a risk of electrocution for the user and the by-standers. Make sure that nobody touches the patient and there is no electrical connection in the surrounding or on the floor which may transmit electricity. Otherwise, life threatening injuries may occur for the user and the by-standers. You can touch the patient only after hearing the instruction *"**Patient may be touched**"*.



Basic Life Support
8. After delivering the electroshock, CardiAid proceeds to basic life support. The instruction *"**Patient may be touched. Carry on resuscitation: alternately make 30 chest compressions and give 2 mouth-to-mouth breaths**"* is heard. Simultaneously, the green light and LEDs around the third instruction field (on the right) light, which indicates that the patient can be touched from the moment. CardiAid also provides metronomic signals to guide the rescuer with the correct rhythm and number for the chest compressions.

Adult Mode: After 30 signal tones, verbal instruction *"**Now give 2 mouth to mouth breaths**"* is heard, followed by a short silence for rescue breaths. Then, the user is directed to chest compressions with the verbal instruction: *"**Now give 30 times chest compressions**"*. This cycle is repeated for 2 minutes according to the latest resuscitation guidelines.

Paediatric Mode: After 15 signal tones, verbal instruction *"**Now give 2 mouth to mouth breaths**"* is heard, followed by a short silence for rescue breaths. Then, the user is directed to chest compressions with the verbal instruction: *"**Now give 15 times chest compressions**"*. This cycle is repeated for 2 minutes according to the latest resuscitation guidelines.

Caution!
If you detect signs of life like consciousness or breathing during resuscitation, proceed as indicated in section *"**Signs of Life Present**"*.

Caution!
After basic life support, recheck the status of electrodes. If necessary, press the electrodes firmly on patient's chest to re-establish the contact.

After 2 minutes according to the current resuscitation guidelines, a new heart rhythm analysis starts (See Section 4) and second instruction field (in the middle) lights.

Shock Not Advised
After heart rhythm analysis; if CardiAid detects normal sinus rhythm, asystole or another rhythm which is inappropriate for defibrillation, the instruction *"**Shock not advised**"* is heard and CardiAid proceeds to *"**Basic Life Support**"* phase.

Analysis Result
If CardiAid cannot perform a clear heart rhythm analysis due to incorrect electrode connection or

inadequate signal level which is a result of touching or moving the patient, the warning *"**Movement detected. Do not touch the patient from now on**"* is heard. CardiAid will attempt another heart rhythm analysis. If the analysis is successful, device proceeds according to the results as explained in sections *"**Shock Necessary**"* or *"**Shock Not Advised**"*. If the second attempt is also unsuccessful, the device proceeds to *"**Basic Life Support**"* phase.

Signs of Life Present

If you detect signs of life like consciousness and normal breathing during operation of the device, place the patient in recovery position (lying on one side). Do not remove electrodes. CardiAid will continue operating normally. Heart rhythm analysis will be performed regularly.
If the patient loses consciousness again and *"**Shock necessary**"* instruction is heard, place the patient on his back again and follow CardiAid's instructions.

Information Function

During operation of CardiAid, information about the duration of use and the number of shocks delivered may be obtained. Press info-button to obtain this information. Information can only be provided while electrodes are not connected or the basic life support is being performed. The info-button is not active during heart rhythm analysis and shock delivery phase. If info-button is pressed at these stages, the information will be provided when CardiAid proceeds to basic life support phase, or the electrodes are disconnected.

4.3 After Using CardiAid

- Remove the plug of the electrodes from the socket.
- Close the cover of the device.
- Contact Cardia International or a Cardia International authorized service provider immediately after use.
- Remember that electrodes and the emergency kit are disposable and should be replaced after use.

4.4 Operation Documentation

Operation Data

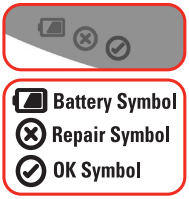
The following information is saved automatically in the internal memory of the device for every use:

- Date and time of use
- Patient's ECG
- Time of each voice prompt
- Time of important points in resuscitation like when the device starts and finishes the analysis, what the result of the analysis is and when the shock-button is pressed
- Time and number of shocks delivered

Contact Cardia International or a Cardia International authorized service provider immediately after use.

CardiAid can be cleaned by a piece of cloth which is moistened (but not saturated) with a simple disinfectant.

Caution!
Do not immerse CardiAid or its accessories in any liquid.
Liquid ingression may cause serious damage and the device can be unusable.



CardiAid performs an extensive self-test periodically on stand-by status (cover closed). Additionally, a self-test is performed at the start of each operation (when cover is opened). The result of the self-test is indicated with status indicators: battery symbol, repair symbol and OK symbol. In addition to these periodical self-tests, functions of CardiAid should be checked on a regular basis.

6.1 Periods of User Tests

Daily

Check the status indicator symbols of CardiAid daily. If the green "OK symbol" is flashing in stand-by position, CardiAid is ready for use. If the red "Battery Symbol" or "Repair Symbol" is flashing, see Section 7. Troubleshooting. If the problem persists, contact Cardia International or an authorized service provider immediately.

Semi-annual

Perform a function check every 6 months. (See Section 6.2. Function Check for details)

6.2 Function Check

Perform function check every 6 months as explained below. If you observe an error or discrepancy in the values, do not use the device and try to solve the problem by yourself by referring to Section 7. "Troubleshooting". If the problem cannot be solved, contact Cardia International or a Cardia International authorized service provider immediately.

1. Check the status indicator symbols while CardiAid is in stand-by mode (the cover is closed). If the OK symbol is flashing in stand-by mode, CardiAid is ready for use.
2. Open the cover of CardiAid. If the following conditions are met, the device is ready to use:
   - All lights and status indicator symbols light simultaneously for a short period of time.
   - Then, OK symbol lights continuously.
   - CardiAid starts giving verbal instructions.
3. Close the cover again and make sure that the device is in stand-by mode. If verbal instructions stop and OK symbol starts flashing, CardiAid is ready for use.
4. Inspect the appearance of the device. Check if the device has external damage. If the device is damaged, it shouldn't be used.
5. Check whether all accessories are complete and unused. Missing or faulty parts should be renewed immediately.
6. Check whether the electrode connector is plugged in the socket correctly. If the electrode plug is not connected correctly, press the plug firmly to the socket.
7. Check whether the electrode plug, electrode cables and the electrodes are in good condition. If the plug, cables or the pack is damaged, electrodes should be replaced immediately.
8. Make sure that the electrode pack has not passed its expiration date. If it is expired, the electrode pack should be replaced immediately.

Danger!

Inspection, repair and other maintenance actions can be performed only by Cardia International or a Cardia International authorized service provider. Do not attempt to unscrew the device. This invalidates the warranty, may cause serious injuries and/or irreversible damage on the device.

Failure Messages of CardiAid			Cause	Action
Visual		Acoustic		
	Battery Symbol and OK Symbol are flashing during stand-by	Signal tone in every hour	Battery is low. Battery can only supply a limited number of shocks	CardiAid can be used only in emergencies. Contact Cardia International or an authorized service provider immediately for battery replacement
	Battery Symbol and OK Symbol are lighting continuously during operation	"Battery low"	Battery is low. It can only supply a limited number of shocks	CardiAid can be used only in emergencies. Contact Cardia International or an authorized service provider for battery replacement
	Battery Symbol and Repair Symbol are flashing during stand-by	Signal tone in every hour	Battery is empty	Device cannot be used. Contact Cardia International or an authorized service provider immediately
	Battery Symbol and Repair Symbol are lighting continuously during operation.	"Battery low" or "Device is not ready for use"	Battery is empty	Device cannot be used. Contact Cardia International or an authorized service provider immediately
	Repair Symbol is flashing during stand-by	Signal tone in every hour	There is a malfunction with the device	Device cannot be used. Contact Cardia International or an authorized service provider immediately
	Repair Symbol is lighting continuously during operation	No acoustic message	There is a malfunction with the device	Device cannot be used. Contact Cardia International or an authorized service provider immediately

Failure Messages of CardiAid			Cause	Action
Visual		Acoustic		
None	Status indicators do not light or flash for a period of time during operation	Any	Problem with LEDs	CardiAid can be used only in emergencies. Contact Cardia International or an authorized service provider immediately
	OK Symbol is lighting continuously during operation	"Stick electrodes on the patient's bare chest" even though the electrodes are placed	Electrodes are not placed correctly	Press the electrodes firmly. Be sure that the chest is dry and not very hairy. Remove excessive hair, if necessary
			Electrodes are defective	Change electrodes
			There is a malfunction with the device	Contact Cardia International or an authorized service provider immediately
	Repair symbol is lighting continuously	"Device is not ready for use"	There is a malfunction with the device	Contact Cardia International or an authorized service provider immediately
None	No visual message	No acoustic message	There is a malfunction with the device	Close the cover and open the cover again. If the problem persists, contact Cardia International or an authorized service provider immediately
	CardiAid cannot be switched on			
Any		Verbal instructions cannot be heard while CardiAid is operating	There is a malfunction with the device	Contact Cardia International or an authorized service provider immediately
	Any	Any	There is a malfunction with the device	Contact Cardia International or an authorized service provider immediately
	Shock cannot be delivered, even though shock button is flashing			
Any	Any	Any	Any	Contact Cardia International or an authorized service provider immediately
	The device is not operating as indicated in the operating manual			

8. Disposal

Do not dispose the device to common household waste. For detailed information regarding disposal of the product and its accessories, visit **www.cardiaid.com**

For disposal of used electrical and electronic devices, refer to special collection system for these type of devices in European Union countries and other European countries.

The symbol on the product or its packaging indicates that this product cannot be disposed in common household waste. Electrical and electronic devices should be delivered to recycling facilities. With your contribution to disposal of this product, you can help protecting both the environment and its inhabitants. Incorrect disposal methods threaten the environment and health of the community. Material recycling reduces the use of raw materials.

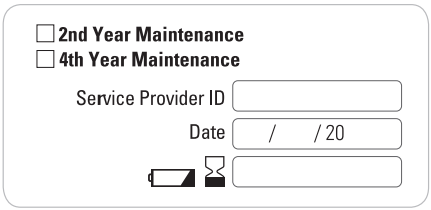
You may obtain additional information regarding the recycling of this product from municipal regional disposal facilities or from the dealer you purchased the product. Always consult a licensed analyser of electronic worn-out components for proper disposal of this device.

Always obey maintenance and function test schedule, regardless of whether the device is used rarely or stored for long periods. Device cannot be used if one of the maintenances is not performed on time. Always make sure maintenances and periodical controls are performed without delay.

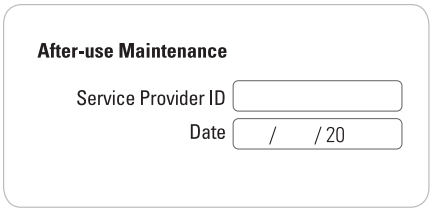
Pay attention to the storage condition requirements of CardiAid (see Section 12. Technical Information). Excessive ambient temperature can shorten the battery life considerably.

Do not keep CardiAid under direct sunlight. Store CardiAid in dry environment.

CardiAid is subject to maintenance periodically and after each use, as described below. Previously performed maintenances, if there is any, can be tracked from the maintenance label on the device.



Periodical Maintenance Label



After-use Maintenance Label

Danger!

Inspection, repair and other maintenance actions can be performed only by Cardia International or a Cardia International authorized service provider. Do not attempt to unscrew the device. This invalidates the warranty, may cause irreversible damage to the device and/or serious injuries.

10.1 After-Use Maintenance

CardiAid should be subject to maintenance by Cardia International or a Cardia International authorized service provider after every use. This ensures that CardiAid is in good condition and ready to use when needed again. During this maintenance, main battery capacity is analyzed, the electrodes are replaced, the incident data is obtained from the device and some function tests are performed. Also, the emergency kit is replaced if used. The next periodical maintenance should be performed at regular time. (See Section 10.2)

10.2 Periodical Maintenance

Periodical Maintenance:

CardiAid should be subject to periodical maintenance. The date of next maintenance is indicated on the battery life label on backside of the device. During this maintenance, main battery and electrodes are replaced; and some function tests are performed.

Caution!

The maintenances should be performed no later than the date on the battery life label. The device cannot be used unless the maintenances are performed on time.

In some countries like Germany, legal period of Technical Safety Check (TSC) is 2 years according to Medical Products Operation Regulation (Article 6). In these countries, CardiAid should be subjected to TSC during 2nd and 4th year periodical maintenance.

Caution!

Packaging material may cause suffocation. Keep away from children. Refer to local regulations for disposal of packaging material.

Warning!

Use only original accessories and spare parts. Using incompatible accessories or spare parts can cause irreversible damage to the device and serious injuries.

The standard package of CardiAid Semi-Automatic Defibrillator (CT0207RS) contains the following:

Description of the Item
CardiAid CT0207RS Semi-Automatic AED
CardiAid CA-10ES Adult Defibrillation Electrodes
CardiAid CA-4BP Battery Pack
CardiAid CT0207EK Emergency kit *(Containing CPR mask, razor, scissors, gloves, and alcohol pad)*
CardiAid CT0207P Protection Bag
User Manual for CardiAid AED
Quick Reference Card for CardiAid AED
Warranty Card for CardiAid AED
CardiAid CR-13P Paediatric Defibrillation Electrodes *(Optional)*

The standard package of CardiAid Fully-Automatic Defibrillator (CT0207RF) contains the following:

Description of the Item
CardiAid CT0207RF Fully-Automatic AED
CardiAid CA-10ES Adult Defibrillation Electrodes
CardiAid CA-4BP Battery Pack
CardiAid CT0207EK Emergency kit *(Containing CPR mask, razor, scissors, gloves, and alcohol pad)*
CardiAid CT0207P Protection Bag
User Manual for CardiAid AED
Quick Reference Card for CardiAid AED
Warranty Card for CardiAid AED
CardiAid CR-13P Paediatric Defibrillation Electrodes *(Optional)*

The following are the additional accessories are provided on a separate order:

Description of the Item
CardiAid CT0207RT Trainer (AED Training Unit)
CardiAid CT0207W Wallmount

The following are the service parts that can be ordered for the service purpose:

Description of the Item
CardiAid CA-10ES Adult Defibrillation Electrodes
CardiAid CA-4BP Battery Pack
CardiAid CT0207EK Emergency kit *(Containing CPR mask, razor, scissors, gloves, and alcohol pad)*
CardiAid CT0207P Protection Bag
CardiAid CR-13P Paediatric Defibrillation Electrodes

The information above might be subject to change. Please visit ***www.cardiaid.com*** for up-to-date information on all products and accessories.

12.1 Technical Specifications

DEVICE

Dimensions l x w x h (in mm)	301 x 304 x 112
Weight with battery and electrodes	3,0 kg
Product class according to Medical Product regulation or Regulation (EU) 2017/745	III

Operation:

Temperature limits	0°C - 50°C
Humidity	0% - 95%
Air pressure	572 - 1060 hPa

Transportation / Storage:

Temperature limits	0°C - 50°C
Temperature limits: Max. 2 weeks	-20°C - +70°C
Humidity	0% - 95%
Air pressure	500 - 1060 hPa
Protection class	EN 60529:1992+A2:2013 (Dust protected, protected against water jet)
Free drop	EN 60601-1:2006+A1:2013+AC: 2014+ A12:2014+A2:2020
Electromagnetic compatibility	EN 60601-1-2:2015+A1:2020
Norms	EN 60601-2-4:2011+A1:2019
Reanimation protocol	ERC, ILCOR 2020

SELF TEST

Schedule	Automatic daily, monthly and when the device is switched on
Timing	Can be programmed by factory settings
Scope	Battery, electronics, software, charging

DEFIBRILLATION ELECTRODES

Delivery status	Disposable, self-adhesive single use electrodes ready for use, sealed and packed with connector outside of the package
Polarization	Not polarized (Exchange is accepted)
Cable length	130 cm
Active surface area	200 cm^2 (adult), 80 cm^2 (paediatric)
Shelf Life	36 (adult / CA-10ES), 36 (paediatric / CR-13P) months from date of manufacture
Operating temperature limits	Between 0°C and 50°C
Transportation / Storage	Between 0°C and 35°C

ENERGY SOURCE

Type	Alkaline
Dimensions l x w x h (in mm)	260 x 59 x 30
Weight	930 g
Shock capacity *,**	Up to 210 shocks
Minimum capacity	100 shocks
Monitor capacity *,***	Up to 20 hours
Battery voltage	12 V
Nominal capacity	15 Ah
Battery replacement	Performed by Service Provider
Fuse	15 A
Stand-by Period *,*	42 months

* Measured with a new battery pack, 20°C. Values can vary within a non-significant tolerance and are dependent upon storage and environmental conditions, frequency of use, pre-configured settings and the shelf life of the product.
** at low energy setting
*** at lowest sound level

DEFIBRILLATION / ANALYSIS

Operating mode ..... Semi-Automatic (One-button operation) in CT0207RS, Fully-automatic in CT0207RF
Wave form ..... Biphasic, Current controlled
Delivered energy at 50 Ω (Adult Mode) ..... Low energy 170J ± 15%
..... High energy 270J ± 15%
Delivered energy at 50 Ω (Paediatric Mode) ..... Low energy 50J ± 15%
..... High energy 75J ± 15%
Maximum patient impedance ..... 250 Ω
Shock sequence ..... Constant or escalating, programmable (factory setting)
Cycle duration (Analysis and shock preparation) .....
With fully charged battery * ..... Max. 15 sec.
After 6 shocks * ..... Max. 15 sec.
After 15 shocks * ..... Max. 15 sec.
Cycle duration (Switch-on, analysis and shock preparation) .....
With fully charged battery * ..... < 32 sec.
After 6 shocks * ..... < 32 sec.
After 15 shocks * ..... < 35 sec.
CPR duration ..... 120 sec. (adjustable by factory settings)
* External disturbances or none-distinct analysis may impact the analysing time.

ECG ANALYSIS SYSTEM

Duration of analysis ..... < 10 sec.
Derivation II
Impedance measurement ..... Controlled by electrode contact
Movement detection ..... Checks the signal quality
..... Acoustic warning at patient movement
Reaction to implanted pacemaker ..... Normal cardiac pacemaker rhythm is not detected as being shockable
Asystole threshold ..... < 0,160 mV
Sensitivity VF / pVT * ..... > %90
Specificity NSR / Asystole * ..... > %95
* Report of analysis system can be found in Technical Service Manual, Appendix 1.

OPERATION

Operating elements ..... Automatic switch-on when the cover is opened, One-button Operation for CT0207RS,
..... fully-automatic operation for CT0207RF, Info-button
Information Mode ..... Announcement of the elapsed time and number of shocks since device started,
..... when info-button is pressed
Display Elements ..... Self-explanatory illuminated symbols (traffic light principle)
..... Device status indicator symbols (OK Symbol, Battery Symbol, Repair Symbol for self-test result)
Acoustic Signals ..... Verbal instructions
..... Signal tone (when in use)
..... Signal tone (in stand-by mode for device failure or low battery)
Data Transfer..... Bluetooth (Only for service provider)

BLUETOOTH

Class..... Class 2
Maximum Output..... 4 dBm

Warnings:

- Medical electrical equipment should be subjected to special precautions regarding EMC. The following EMC Guidelines must be observed during installation and operation of the device.
- Portable and mobile equipment using RF communications may affect medical electrical equipments.

Guidelines and manufacturer declaration – Electromagnetic emissions		
CardiAid is intended for operation in the electromagnetic environment specified below. The customer or user of the device or system should make sure that it is operated in such an environment.		
HF emissions according to CISPR 11	Group 1	CardiAid uses HF energy only for its internal functions. For this reason, its HF emissions are very low and it is not likely that it will interfere with neighbouring electronic devices.
HF emissions according to CISPR 11	Class B	CardiAid is suitable for use in all establishments, including residential establishments with similar purposes, which are directly connected to a public power supply, which also supplies buildings used for residential purposes.
Emissions of voltage fluctuations/flicker according to IEC 61000-3-2	N.A.	
Emissions of voltage fluctuations/flicker according to IEC 61000-3-3	N.A.	

Recommended safety distances between portable and mobile telecommunication devices (e.g. mobile telephones) and the measuring device			
Power rating of the HF-device in W	Safety distance depending on transmission frequency in m		
	150 kHz – 80 MHz	80 MHz – 800 MHz	800 MHz – 2,7 GHz
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1,17	1.17	2,33
10	3,69	3,69	7,38
100	11,67	11,67	23,33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: At 80 MHz and 800 MHz, higher frequency field is applicable.

NOTE: At 80 MHz and 800 MHz the separation distance for the higher frequency range is applicable.

NOTE: These guidelines may not apply in all situations. Electromagnetic transmission is affected by absorption of and reflection from structures, objects and people.

EMC information in acc. with EN 60601-1-2:2015+A1:2020

Guidelines and manufacturer declaration – Electromagnetic immunity			
CardiAid is intended for operation in the electromagnetic environment specified below The customer or user of CardiAid should make sure that it is operated in such an environment			
Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	The floor should be made of wood or concrete or be covered with ceramic tile. If the floor is covered with synthetic material, it must have a relative humidity of at least 30%
Fast transient electric noise / bursts in acc. with IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input/output lines	N.A.	
Surges in acc. with IEC 61000-4-5	± 1 kV series mode voltage ± 2 kV common-mode voltage	N.A.	
Voltage drops, short-term interruptions and fluctuations in the supply voltage in acc. with IEC 61000-4-11	< 5% UT (> 95% drop in UT) for ½ period 40% UT (60% drop in UT) for 5 periods 70% UT (30% drop in UT) for 25 periods < 5% UT (> 95% drop in UT) for 5 s	N.A.	
Magnetic field for supply frequency (50/60Hz) in acc. with IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields for the power-line should have values typical for business and hospital environments

Guidelines and manufacturer declaration – Electromagnetic immunity			
CardiAid is intended for operation in the electromagnetic environment specified below.			
The customer or user of CardiAid should make sure that it is operated in such an environment.			
Immunity tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment**
			Portable and mobile wireless devices should not be used at distance from CardiAid (including its power-line cables) smaller than the recommended safety distance. This is calculated according to the equation for the relevant transmission frequency. Recommended safety distance: d = (1.17 m/V) * √ P for 150 kHz - 80 MHz
Conducted HF noise in acc. with IEC 61000-4-6	3 Vrms 150 kHz – 80 MHz	10 Vrms	d = (1.17 m/V) * √ P for 80 MHz - 800 MHz
Radiated HF noise in acc. with IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz	10 V/m 80 MHz – 2.7 GHz	d = (2.33 m/V) * √ P for 800 MHz – 2.7 GHz P being the power rating of the transmitter expressed in W according to the specifications of the transmitter manufacturer, and d the recommended safety distance in m. The field strength of stationary wireless transmitters should be less than the compliance level for all frequencies according to an on-site investigation. Interference can occur in the environment of devices which are marked with the following symbol: 

REMARK 1: At 80 MHz and 800 MHz, the higher frequency range applies.

REMARK 2: These guidelines might not be applicable in all cases. The propagation of electromagnetic parameters is influenced by the absorption and reflection of buildings, objects and human beings.

a. Field strengths of fixed transmitters, such as base stations for mobile/portable communication devices, cannot be theoretically predicted with absolute certainty. In order to evaluate the electromagnetic environment based on fixed HF transmitters, an electromagnetic investigation on-site should be considered. If the measured field strength should exceed the HF compliance level specified above in the intended operating environment of the product, the product should be monitored to verify that it functions normally. If abnormal function should be observed, additional measures might be necessary, such as re-orienting or re-positioning the product.

b. Field strengths should lie under 10 V/m over the frequency range 150 kHz to 80 MHz.

Guidance and manufacturer's declaration - electromagnetic emissions			
CardiAid Public Access Defibrillator is intended for use in the electromagnetic environment specified below. The owner or the user of CardiAid should assure that it is used in such an environment.			
Immunity Test	IEC 60601-1 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Veff 150 kHz to 80 MHz outside ISM bands	not applicable for patient instructions according to EN 60601-2-4: 2011+A1:2019	Portable and mobile RF communications equipment should be used no closer to any part of the Public Access Defibrillator CardiAid, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. d= 4 * SQRT(P/W) for 80 MHz to 800 MHz For d = 7.67 * root (P/W), d= 7,67 * SQRT(P/W) for 800 MHz to 2,7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
Radiated RF IEC 61000-4-3	10 Veff 150 kHz to 80 MHz inside ISM-bands 10 V/m 80 MHz to 2,7 GHz	not applicable for patient instructions according to EN 60601-2-4: 2011+A1:2019 3 V/m	Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the symbol "nonionizing radiation".

NOTE: At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic transmission is affected by absorption and reflection from structures, objects and people.

Field strength from fixed transmitters, such as base stations for radio (Cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.

To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be made. If the measured field strength in the location which the CardiAid Public Access Defibrillator is used exceeds the applicable RF compliance level above, additional measures may be necessary, such as reorientation or relocating the CardiAid Public Access Defibrillator.

Above frequency fields between 150 KHz and 80 MHz, field strength should be less than 3 V/m.

Data Transmission: Serial Port Profile (SPP) based on Bluetooth 2.1 without EDR, class 2 (10m)

Wireless Transmission: Approved in accordance to RED (2014/53/EU) directive transmitter module marked by CE, manufactured by PANASONIC incorporated to OEM product.

Warning!

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Test specification compared to RF near fields of communication devices						
Test Frequency (MHz)	**Band** [a]	**Service** [a]	**Modulation** [b]	**Maximum Power** (W)	**Distance** (m)	**Immunity Test Level** (V/m)
385	380 - 390	TETRA 400	Pulse Modulation [b] 18 Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 - 787	LTE Band 13, 17	Pulse Modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse Modulation [b] 18 Hz	2	0,3	28
870						
930						
1720	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation [b] 217 Hz	2	0,3	28
1845						
1970						
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE band 7	Pulse Modulation [b] 217 Hz	2	0,3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse Modulation [b] 217 Hz	0,2	0,3	9
5500						
5785						

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME QUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a. For some services, only the uplink frequencies are included.

b. The carrier shall be modulated using a 50% duty cycle square wave signal.

c. As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Source: IEC 60601-1-2 / Edition 4.0 of 2014-02 - Chapter 8.10 *"Immunity to proximity fields from RF wireless communications euipment"*, table 9 *"test specifications for enclosure port immunity to RF wireless communications equipment*".

12.2 Pulse Form

The delivered shock is a biphasic current-based shock. Two different energy levels are implemented in the device, a low energy shock and a high energy shock. The current-based shock has the advantage that the delivered energy depends on the patient impedance. Myocardium damage caused by high electrical current applied to patient with low impedance is reduced considerably with this pulse form.

Pulse form / shock energy can only be configured by factory.

Factory setting is as follows:
1st Shock: Low, **2nd Shock:** Low, **3rd and Subsequent Shocks:** High

12.3 Essential Performance

Delivered Energy:

High-energy adult-impulse at 50 Ω	: 270J ± 15%
Low-energy adult-impulse at 50 Ω	: 170J ± 15%
High-energy paediatric-impulse at 50 Ω	: 75J ± 15%
Low-energy paediatric-impulse at 50 Ω	: 50J ± 15%

ECG ANALYSIS SYSTEM

Duration of analysis	< 10 sec.
Derivation	II
Impedance measurement	Controlled by electrode contact
Movement detection	Checks the signal quality
	Acoustic warning at patient movement
Reaction to implanted pacemaker	Normal cardiac pacemaker rhythm is not detected as being shockable
Asystole threshold	< 0,160 mV
Sensitivity VF / pVT *	> %90
Specificity NSR / Asystole *	> %95

* Report of analysis system can be found in Technical Service Manual, Appendix 1.

Functioning Principle

If the current exceeds the specified value, current transmission is interrupted. Current continues to flow to the patient with inductivity in connection path. However, the current falls gradually. If the specified current value exceeds 1 Amp, current transmission re-starts. In this way, current supplied to the patient rises again. This creates a saw tooth pulse. Proportion of supplied electrical current (integral of current in time) between 2nd (negative) and 1st (positive) phases is 0,38 on average. This value is determined as optimal in clinical studies.

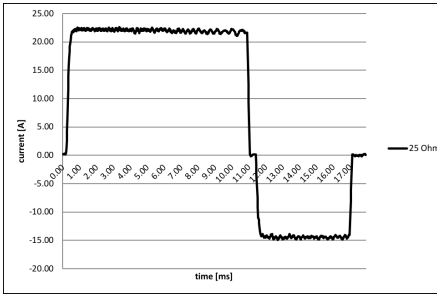
Impedance Dependence

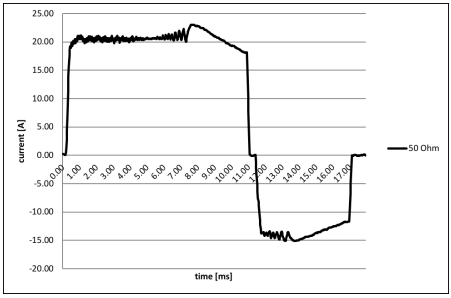
For safety reasons, a voltage of maximum 2.000 Volt is used. Resulting current as a function of patient impedance is shown in the graph.

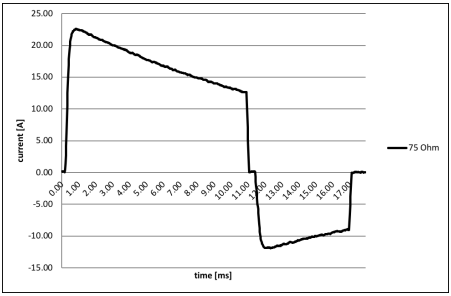
Energy Flow in High Patient Impedance

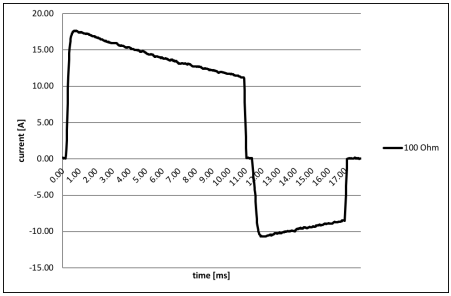
Supplying a fixed current has a determining effect on the energy applied to the patient. Ohm's law requires higher voltage with increasing impedance. Because the voltage enters the supplied energy quadratic; with increasing resistance, applied energy also rises considerably. This, in turn, provides a better treatment for patients with high impedance and has a positive effect on decreasing death rate in this patient group.

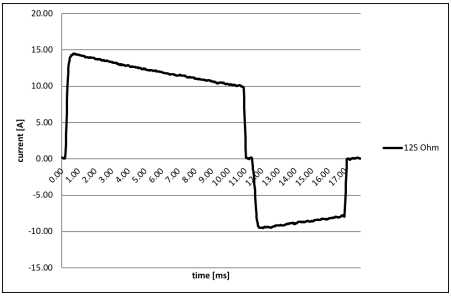
Current characteristics of high-energy adult-impulses for different patient impedances:

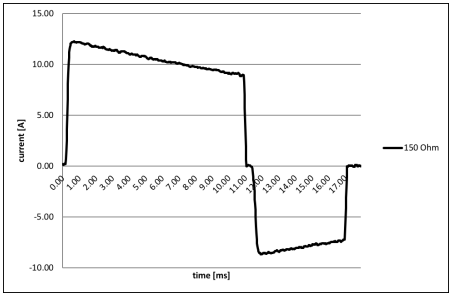


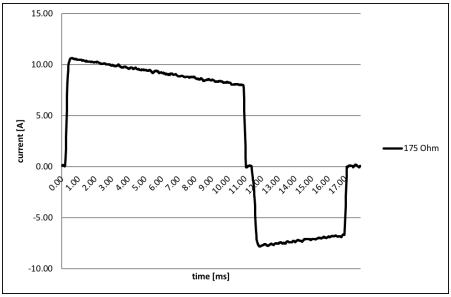


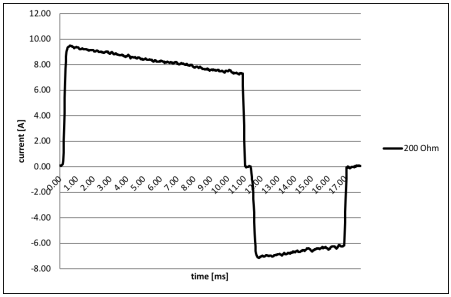












13.1 Clinical Benefits

a. Automated external defibrillators (AEDs) reduce the time to defibrillation.

b. AED can save a person whose cardiac rhythm slips to ventricular fibrillation mode.

c. This shock can help to stop abnormal electrical impulses in the heart and allow it to return to a normal beating rhythm.

d. An automated external defibrillator increases the chance of saving the life of an sudden cardiac arrest victim by 75%.

e. When care is provided within five to seven minutes, including early treatment with an AED, survival rates can improve dramatically.

f. Multiple studies and meta-analyses have demonstrated that early defibrillation improves survival for individuals with sudden cardiac arrest.

g. In case the sudden cardiac arrest victim is not close to Emergency Medical Services (EMS), an untrained person may intervene by just pressing a shock button on the automated external defibrillator.

h. The device offers a fully automated life-saving emergency therapy quickly and is operable by any lay person.

i. The machines are fully or semi automated, portable and can analyze the heart for shock rhythms.

j. They are designed to give shocks automatically in case of Fully Automatic, and the rescuer does not press any button.

k. The AED has an inbuilt communication that informs rescuers on the life-saving steps to follow. The rescuer will easily know when the sudden cardiac arrest victim needs a shock therapy.

l. AEDs have a proven track record of helping to save lives in public places as well as in the workplace.

13.2 Incident Reporting

If the user or patient needs to report any serious incidents in relation to the device, can contact the manufacturer and the competent authority of the Member State where the user and / or patient is established.

13.3 Information Available to The User

The user manual is provided with the device in a paper format additionally, electronic copy is available is available on the company website; **www.cardiaid.com**

The SSCP will be available on EUDAMED.

The quick reference guide is a concise note of the User Manual, however it does not replace this usermanual and does not impact the safety or performance of the device.

Registered Office / Legal Manufacturing Site:
Cardia International A/S
Hersegade 34C
4000 Roskilde
Denmark
info@cardiaid.com
www.cardiaid.com

Corporate Office / Operation Site:
Cardia International B.V.
Van der Burchstraat 40
2132RN Hoofddorp
The Netherlands
info@cardiaid.com
www.cardiaid.com

Notified Body:
IMQ S.p.A - Istituto Italiano del Marchio di Qualità
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