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CardiAid
Automated External Defibrillator

"Simple and Vital"

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WHAT IS CardiAid?

- CardiAid is an Automated External Defibrillator (AED); an easy-to-use device specially designed for public access use, to provide life-saving electroshock treatment for a patient having Sudden Cardiac Arrest.
- CardiAid can be used by any person with basic life support (CPR) knowledge.
- Having CardiAid in public places can save many lives.

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OVERVIEW of CardiAid

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Features of CardiAid

- Clear verbal and visual instructions from the beginning to the end of the whole process, including instructions reminding the user to call the emergency number and assisting the user through the reanimation process.
- One-button operation for providing immediate treatment and highest safety for the user
- The status indicator lights burn with universal colours: green and red, showing if there is any problem with the device, or not.
- Flashing lights of different colors and sound at the same time

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FEATURES of CardiAid

High level of safety for the user and the patient

- CardiAid is designed to provide the highest level of safety for the patient and the user.
- CardiAid performs self-check daily, monthly and when the cover of the device is opened. This function enables CardiAid to be in-use without a problem whenever needed.
- CardiAid is also equipped with features warranting both the patient's and the user's safety. CardiAid analyzes the heart rhythm of the patient with the most accurate technique and it is impossible to give shock if shock is not required. Using CardiAid is completely safe for the patient and the user.

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FEATURES of CardiAid

CardiAid was developed according to ILCOR 2005 ERC Reanimation Guideline.

ERC Reanimation Guideline advises;

- Electroshock values to be between 150j and 260j for biphasic defibrillators.
- CPR to be started with 30 heart massage immediately after electroshock.
- CPR to be started immediately when electroshock is not advised by AED.
- CPR to be done with a sequence of 30 chest compressions and 2 mouth-to-mouth breaths for 2 minutes before reanalyzing heart rhythm.
- CPR not to be interfered to check victim for signs of life during reanimation process.

International Liaison Committee on Resuscitation (ILCOR)

The International Liaison Committee on Resuscitation (ILCOR) was formed in 1992 to provide a forum for liaison between principal resuscitation organisations worldwide. Although the criteria for participation were not closely defined, member organisations were expected to have an accepted remit for creating resuscitation guidelines, preferably for more than one country, and to be multidisciplinary in membership. At present, ILCOR comprises representatives of

- American Heart Association (AHA)
- European Resuscitation Council (ERC)
- Heart and Stroke Foundation of Canada (HSFC)
- Australian and New Zealand Committee on Resuscitation (ANZCOR)
- Resuscitation Councils of Southern Africa (RCSA)
- Inter American Heart Foundation (IAHF)
- Resuscitation Council of Asia (RCA - current members Japan, Korea, Singapore, Taiwan).

International Liaison Committee on Resuscitation (ILCOR)

- ILCOR meets twice each year usually alternating between a venue in the United States and a venue elsewhere in the world. In collaboration with the AHA, ILCOR produced the first International CPR Guidelines in 2000 and an International Consensus on CPR and ECC Science with Treatment Recommendations in 2005. Once again, in collaboration with the AHA, ILCOR is now co-ordinating an evidence-based review of resuscitation science, which will culminate in a Consensus Conference in February 2010. The proceedings of this meeting, to be published in October 2010, will provide the material for regional resuscitation organisations, such as the ERC, to write their resuscitation guidelines.

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AED ALGORITHM OF ERC REANIMATION GUIDELINE

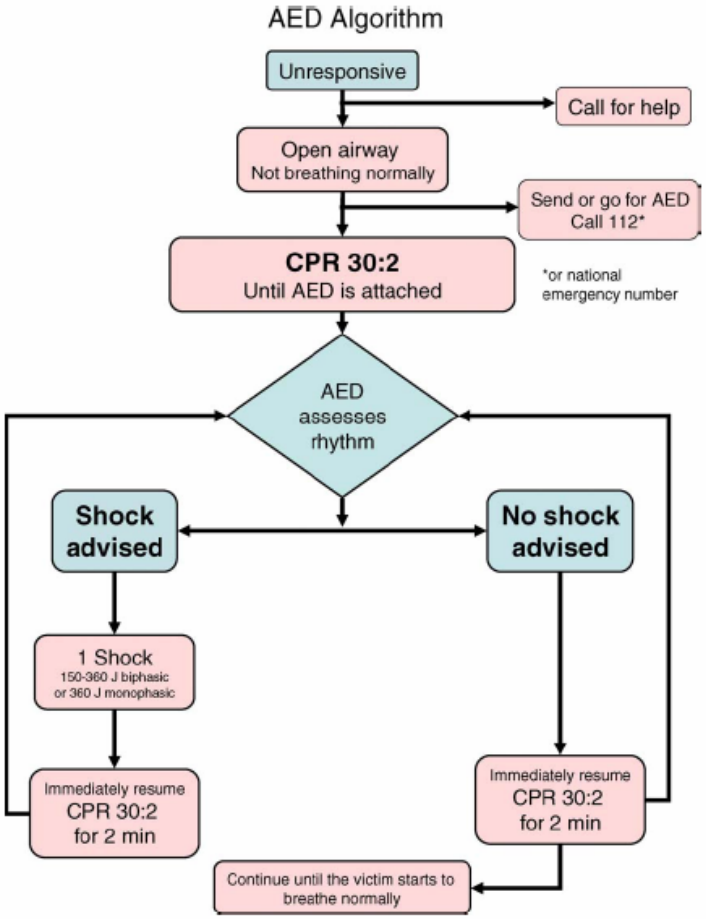

Figure 2.20 Algorithm for use of an automated external defibrillator.

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FEATURES of CardiAid

Design

- CardiAid has a design aimed to achieve simplicity which is very important for the user in a moment of emergency.

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FEATURES of CardiAid

- CardiAid comes to the user as a full rescue package:

1. CardiAid AED
2. CardiAid Protection Bag
3. CardiAid Emergency Kit
4. CardiAid Electrodes
5. CardiAid Manual
6. CardiAid Quick Reference Card

Always ready for use, ready to save...

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AVAILABLE LANGUAGES of CardiAid

- English
- German
- French
- Dutch
- Spanish
- Italian
- Turkish
- Danish
- Norvegian
- Swedish
- Portuguese
- Arabic
- Persian
- Chinese (Mandarin)
- Chinese (Cantoneese)

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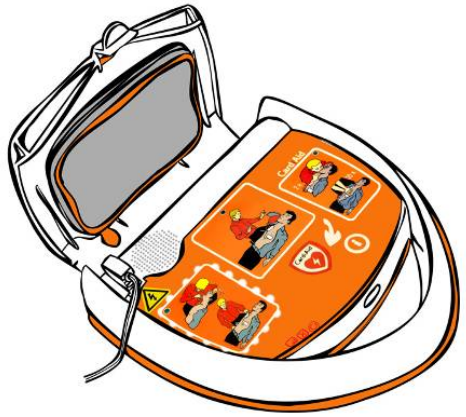
HOW TO USE CardiAid?

- Open the cover. CardiAid will switch on automatically.
- After opening the cover, CardiAid immediately starts self-test. All lights become active during this test. When the test is completed, follow the indicator lights:
  - CardiAid can be used if the green OK symbol is flashing.
  - CardiAid cannot be used when one of Maintenance or Battery Symbols is lighting continuously.



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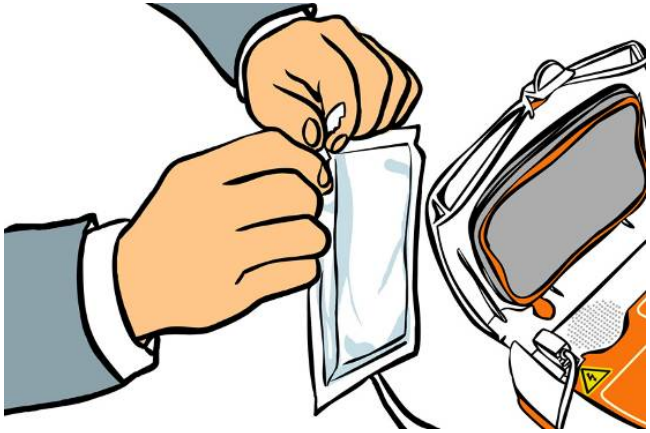
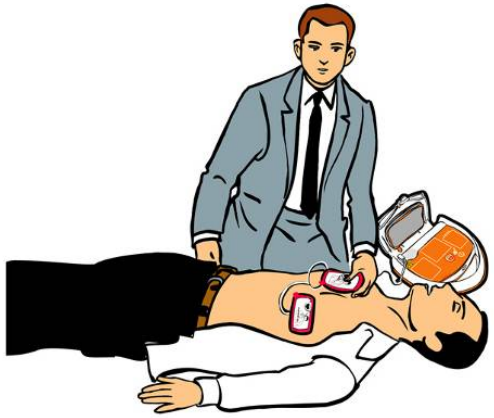
HOW TO USE CardiAid?

- Follow the instructions of CardiAid:
  1. “Phone alarm number. Open patient’s airway. If there are no signs of life, remove clothing from chest, and stick on electrodes.”
  - Check signs of consciousness and respiration. CardiAid can be used when the patient does not have any of these signs.
  - The chest of the patinet must be dry and not very hairy.
  - The patient should be on a dry and non-conductive surface.
  - CardiAid repeats the instruction “Stick electrodes on the patient’s bare chest.” until the electrodes are sticked properly.
  - During whole process, make sure that the electrodes are sticked firmly.





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HOW TO USE CardiAid?

2. “Do not touch the patient from now on. Analyzing heart rhythm.”

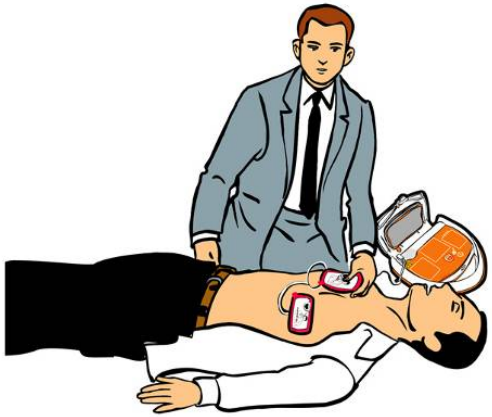
- Patient should not be touched or moved during analysis. Do not perform CPR during analysis. If CardiAid is unable to analyse the heart rhythm because of such movement, “Movement detected.” warning is heard.

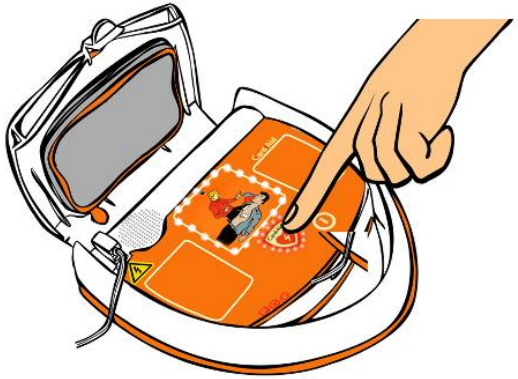
CardiAid informs the user about the result of the analysis: “Shock is necessary.” or “Shock not advised.”

- If shock is necessary, “Shock necessary. Do not touch the patient from now on. Preparing shock.Do not touch the patient.” is heard.

When the electroshock is ready, “Press the flashing shock button.” is heard. CardiAid delivers electroshock, when the shock button is pressed, and CardiAid informs the user: “Shock has been given.” CardiAid proceeds to the CPR process.

- Make sure that nobody touches the patient before pressing the shock button.





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HOW TO USE CardiAid?

3. If shock is not necessary, “Shock not advised.” is heard and CardiAid proceeds to the CPR process.

– “Patient may be touched. Carry on resuscitation.Alternately give 30 chest compressions and 2 mouth-to-mouth breaths.”

- CardiAid assists the user with metronomic signals when making heart massage.
- After 30 metronomic signals, “Now give 2 mouth-to-mouth breaths.” is heard.
- After 2 mouth-to-mouth breaths, “Now give 30 times chest compressions.” is heard.

5. After 2 minutes of CPR, CardiAid reanalyzes the heart rhythm and prepares shock, if needed.

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HOW TO USE CardiAid?

- After CPR, recheck the status of electrodes. If necessary, press the electrodes on patient's chest firmly.
- If you detect signs of life during operation of the device, place the patient into recovery position. Do not remove the electrodes. CardiAid will continue analyzing heart rhythm, in case another shock is needed. If "Shock necessary" instruction is heard, place the patient on his back again and follow the verbal instructions.

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AFTER USING CardiAid

- Contact Cardiatech authorized service partner immediately.
- ECG and event data can be obtained via bluetooth connection with CardiAid Monitor Software, by an authorized service partner.
- CardiAid should be controlled by an authorized service partner after each use with shock application.
- Remember that the electrodes and the emergency kit should be changed after each use.
- Authorized service partner changes the battery, if necessary.

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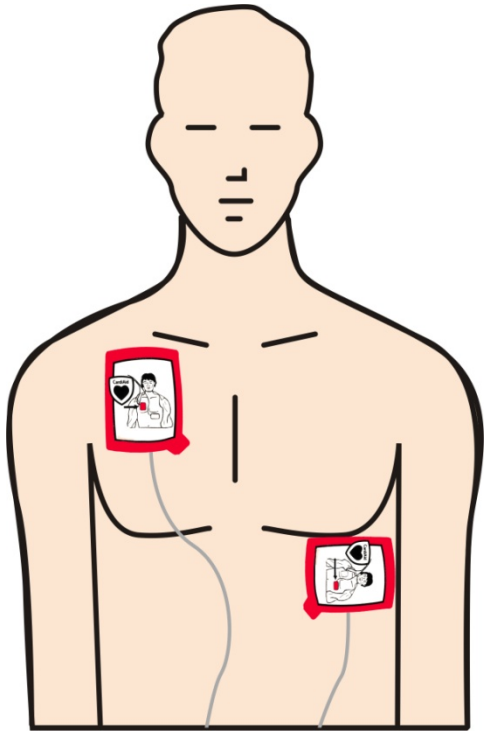
BATTERY CONCEPT of CardiAid

- Battery has to be exchanged after the first complete defibrillation
- Complete defibrillation:
  - 1 complete service: electrodes attached to a patient and device shut down by closing the lid
  - 1 shock delivered
- On the next self test the device will report a weak battery.
- If no complete defibrillation: Internal counter will count down the capacity and report a weak battery after 2 ½ years or if the device was running so long that only 10 more shocks are possible.
- CardiAid can give 9 more shocks after the battery signal lights continuously because of low battery.
- The battery should be changed by an authorized service partner every 24 months.

CardiAid ELECTRODES

- Only use CardiAid Defibrillation Electrodes with CardiAid.
- CardiAid Electrodes are disposable and should be replaced after each use.
- Electrodes are sticked on the patient's chest as shown in the picture.
- Electrodes should be changed by a CardiaTech authorized service partner.



TECHNICAL SERVICE FOR CardiAid AFTER USE

- The following actions are mandatory to be able to continue using CardiAid:
  - The product should be checked by a CardiaTech authorized service partner after each use with shock delivery.
  - Electrodes and main battery should be replaced by a CardiaTech authorized service partner at the end of the 2nd year after purchase.
  - Electrodes, main battery and the lithium button cell battery should be replaced by a CardiaTech authorized service partner at the end of the 4th year after purchase.

CardiAid **CANNOT** be used if any of these procedures are not undertaken by an authorized service partner.

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DESCRIPTION OF THE FUNCTIONS

- **Visual and Acoustic Instructions for the User**
  - Application images
  - Verbal Instructions
  - Lights

  CardiAid starts giving verbal instructions as soon as its cover is opened, and directs the user in the resuscitation procedure step by step. At the same time, lights indicate clearly the stages of the process.

- **Metronome Function**

  CardiAid provides a metronome signal with a frequency of 100 pulses/sec during the Basic Life Support process. This metronome signal provides the most efficient heart-massage with correct rhythm and number.

- **Self-Test**

  CardiAid performs automatic self-tests daily, monthly and when the device is swithced on. The result of the analysis is shown by indicator lights.

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DESCRIPTION OF THE FUNCTIONS

- **ECG Analysis**

  CardiAid starts analyzing heart rhythm when the electrodes are sticked correctly. ECG analysis and record continues until the device is switched off.

- **Defibrillation**

  If CardiAid detects a shockable rhythm (i.e. Ventricular Fibrillation (VF) or Ventricular Tachcycardia (VT)), it prepares electroshock automatically. When the shock is ready, CardiAid warns the user to press the shock button to deliver shock.

- **Documentation**

  CardiAid records ECG data and event data in its internal memory. These data can be obtained by CardiAid Monitor Software for future analysis.

- **Event Information**

  Information about how long the device is operating and the number of shocks applied is given to the user audially when the “info-button” is pressed.

  - Info-button can be used only when electrodes are not connected or during CPR process.

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AUTOMATIC SELF-TEST

- CardiAid performs automatic self-test daily, monthly and when it is switched on.

- During self-test when the device is switched on, all indicator and warning lights light up. When self-test is completed, the indicator LEDs show the status of the device.

Caution!

warning led is lit continuously then the device should not be used., because the device is not ready for use. In this case you should get the device repaired by Cardiatech or an authorized service centre.

Caution!

If one or more than one of the instruction led's is not lit during self-testing, it means that there are faulty light diodes. Use the device for that application only and get the device repaired by Cardiatech or an authorized service centre immediately after use.

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STATUS SYMBOLS ON CardiAid

	Battery Symbol
	Maintenance Symbol
	OK Symbol

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VISUAL AND ACOUSTIC FAILURE MESSAGES

Visual	Acoustic	Cause	Action
Battery Symbol and OK Symbol are flashing during stand-by.	Signal tone in every 4 minutes	Battery is low. Battery can only supply a limited number of shocks.	CardiAid can be used only in emergencies. Contact authorized service partner immediately.
Battery Symbol and OK Symbol are lighting continuously during operation.	"Battery is almost empty."	Battery is low. It can only supply a limited number of shocks.	CardiAid can be used only in emergencies. Contact authorized service partner for battery replacement.
Battery Symbol and Maintenance Symbol are flashing during stand-by.	Signal tone in every 4 minutes	Battery is empty. Device cannot be used.	Device cannot be used. Contact authorized service partner immediately.
Battery Symbol and Maintenance Symbol are lighting continuously during operation.	-	Battery is empty. Device cannot be used.	Device cannot be used. Contact authorized service partner immediately.
Maintenance Symbol are flashing during stand-by.	Signal tone in every 4 minutes	There is a malfunction with the device.	Device cannot be used. Contact authorized service partner immediately.
Maintenance Symbol are lighting continuously during operation.	-	There is a malfunction with the device.	Device cannot be used. Contact authorized service partner immediately.
Status indicators do not light or flash for a period of time during operation.	-	There is a problem with LEDs.	CardiAid can be used only in emergencies. Contact authorized service partner immediately.

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VISUAL AND ACOUSTIC FAILURE MESSAGES

Visual	Acoustic	Cause	Action
-	"Stick electrodes on the patient's bare chest" when the electrodes are sticked already.	Electrodes are not connected to the plug correctly.	Plug electrodes firmly.
		Electrodes are not sticked correctly.	Press the electrodes firmly. Be sure that the chest is dry and not very hairy. Remove excessive hair, if necessary.
		Wrong electrodes are being used.	Be sure that special defibrillation electrodes are being used. Only use CardiAid Defibrillation Electrodes CA10-ES with CardiAid.
		Electrodes are defective.	Change electrodes.
		There is a malfunction with the device.	Contact authorized service partner immediately.
Maintenance symbol is lighting continuously.	"Device is not ready for use."	There is a malfunction with the device.	Contact authorized service partner immediately.

SPECIAL MARKINGS ON CardiAid

Type Plate on the bottom of the device

SPECIAL MARKINGS ON CardiAid

	Serial Number of the Device
	Production Date
	Do not dispose the device in common household waste.
	Attention, refer to operating manual.
	Resistant to water spray
	Manufacturer
	Protection Class BF
	Bluetooth
	High Voltage

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SAFETY WARNINGS

To assure safe and effective use of CardiAid, the neccessary safety warnings according to EN 60601-1-4 are described in the user manual

	Describes a danger that can result in serious injury or death.
	Defines a possible danger that can result in serious injury or death.
	Defines a possible danger that can result in simple – mild injury. This symbol is also used to indicate user errors that can result in damage to the device.
	Provides necessary additional information.

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GENERAL RULES

Danger!

- To prevent danger of explosion, keep CardiAid away from oxygen sources, flammable gases and other flammable substances.

Caution!

- Never use the device on patients with weight of less than 20 kgs. This may cause life threatening injuries.

Caution!

- If you are suspecting a sudden heart failure, check the following signs of life before using CardiAid:
  - Consciousness
  - Breathing

  CardiAid can only be used when both of the above signs are missing.

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GENERAL RULES

Caution!

- Check the device and accessories for visual damages before using CardiAid. If you observe damages, do not use the device. It may cause injuries of both the patient and the user.

Caution!

- Do not use the device, if you observe differencies in the procedures than it is described in the user manual. In this case, contact an authorized service partner immediately.

Caution!

- CardiAid can be used only after self-test is completed successfully.

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GENERAL RULES

Caution!

- Perform “Function Check” periodically.

Caution!

- Use CardiAid only in dry and non-conductive environments. It may cause injuries of the patient, user and / or the by-standers.

Danger!

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

Caution!

- Delivering electoshock may affect the electonic devices nearby. Check the function of these devices before using.

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GENERAL RULES

Attention!

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

Attention!

- Do not immerse CardiAid or its accessories in any liquid.

Attention!

- Use only special accessories of CardiAid. Products of other producers may be incompatible and can cause damage or malfunction.

DEFIBRILLATION / USE

Caution!

- Always observe national / local regulations regarding use of an automated external defibrillator.

Caution!

- To prevent injuries of the user and by-standers, make sure the patient is not being touched during defibrillation. Do not touch metal objects or equipment which are in contact with the patient duritn defibrillation. Do not perform defibrillation in very humid and wet environment.

Caution!

- Sticke the electrodes on the 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.

DEFIBRILLATION / USE

Caution!

- Make sure that the patient is not being moved or touched during heart rhythm analysis. It may cause faulty interpretation of ECG data.

Caution!

- Do not stick the electrode pad on an implanted pacemaker, if the patient has one.

Attention!

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

Attention!

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

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DEFIBRILLATION / USE

Attention!

- CardiAid does not have defibrillation protection. When you need to use another defibrillator, make sure CardiAid electrodes are disconnected from patient's chest. It may damage the device.

Attention!

- Make sure that the electrodes are firmly sticked to the chest. Air between the electrodes and the skin may cause burns.

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ELECTRODES

Caution!

- Only use electrodes supplied with CardiAid. CardiAid CT0207 should be used with CardiAid Defibrillaiton ELectrodes CA-10ES.

Caution!

- Never use electrodes which has damage on the package and / or on the pads. Never use electrodes after expiry date.

Caution!

- CardiAid Defbirillation Electrodes are for single-use only. After using CardiAid, contact an authorized service for replacement of the electrodes.

ELECTRODES

Caution!

- Pay attention to the operating and storage conditions of the device and its accessories, which are indicated in technical specifications.

Caution!

- Store CardiAid away from children. Electrode cable can cause suffocation.

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SIDE EFFECTS

- Following side effects may occur when CardiAid is used:
  - Burns on skin
  - Rashes on skin
- Delivering electroshock to a patient who has implanted pacemakers 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.

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CardiAid
Automated External Defibrillator

Technical Specifications

DIMENSIONS / ENVIRONMENT / NORMS

- Weight with battery and electrodes — 3,1 kg
- Product Class according to Medical Product Regulation No. 93/42/EEC — IIb
- Operational Limits
  - Temperature — between 0ºC and +50ºC
  - Humidity — between 30% and 75%
  - Air pressure — between 800 and 1160 h/Pa
- Transportation / Storage Temperature Range — between 0ºC and +50ºC
- Temperature Limits : Max. 2 weeks — between -20ºC and +60ºC
- Protection Class — IEC 529 : IPX4 (protection against splash water)
- Free Drop — IEC 601-1:1998+A1: 1991+A2:1995

APPROVALS & NORMS

CE 0494

- The SLG Prüf- und Zertifizierungs declare that :
  - CardiAid CT0207 has a valid EC Type-Examination Certificate SLG 103954N1, issued by the Notified Body (0494) SLG Prüf- und Zertifzierungs GmbH in accordance with the European Medical Device Directive 93/42/EEC (MDD), Annex III
  - Each product of CardiAid CT0207 has been subjected to an EC-Verification according to MDD, Annex IV. Certificates based on valid EC-Verifications were issued for several single batches.

- Electromagnetic Compatibility — EN 60601-1-2 : 2001
  EN 55011
  EN 61000-4-3:2002/A1:2002
  EN 61000-4-8:1993+A1:1001
- Norms — EN 60601-2-4:2003
- Reanimation Protocol — ERC / AHA ; 2005

DEFIBRILLATION ELECTRODE / ENERGY SOURCE

ELECTRODES

- Self-adhesive single use electrodes, packed by leaving the connection plug outside
- No polarization (exchange is accepted)
- Length of the cable is 130 cm.
- Electrode size is 125 cm2 each.
- Transportation and Storage temperature limits : between 0ºC and +50ºC

ENERGY SOURCE

- Alkaline Battery Pack
- Shelf Life of the battery pack 5 years
- Standby Life Time 2 years
- Shock Capacity (Max. at low energy settings with new batteries) 210 shocks
- Monitor Capacity (Max. at lowest sound level with new batteries) 20 hours

DEFIBRILLATION

- The Operating Mode of CardiAid is semi-automatic (one-push button)
  - The operator needs to push the shock button to give shock to the patient after the device analysed and suggested shock,
  - If the operator will not push the button for 8-10 seconds , the Cardiaid will consume shock inside and go on for next step.

- The Wave form of CardiAid is Biphasic ;
  - Biphasic waveforms are the latest development in external defibrillation. Instead of sending electrical current through the heart in only one direction, the current now also reverses direction and passes back through the heart a second time. Biphasic waveforms were first used in implantable defibrillators in the early 1980s, where research showed that the use of these waveforms offered the same effectiveness while using less energy and less current, which is ultimately better for the heart.

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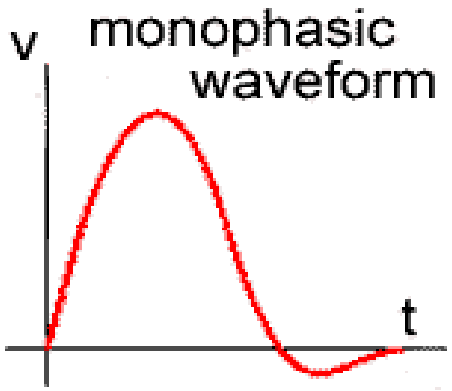
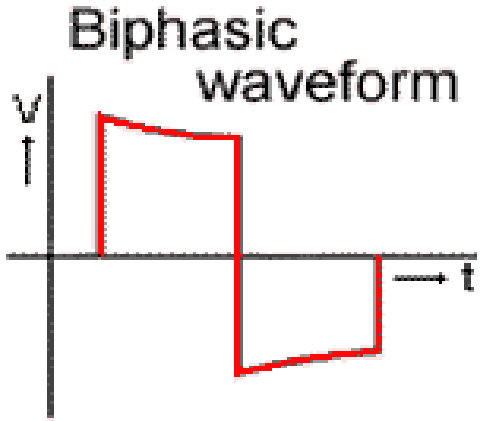
DEFIBRILLATION - BIPHASIC vs MONOPHASIC WAVEFORM





- Several studies in animals and humans have shown that defibrillators using biphasic waveforms are more effective for terminating ventricular fibrillation (VF) than those using monophasic waveforms. The biphasic waveforms delivered by the biphasic defibrillators have different waveform characteristics and impedance compensation schemes and, most importantly, different recommended energy levels. The optimal biphasic waveform, energy level and shock sequence (escalating energy versus fixed dose) has not been determined.

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DEFIBRILLATION - BIPHASIC TECHNOLOGY

- Originally, defibrillators used only a monophasic damped sine waveform; a single-directional form of energy passed through the heart. Biphasic damped sine waveforms, in which current travels in one direction and then reverses polarity to travel in the opposite direction, can achieve defibrillation using less energy than the monophasic waveform Lower energy requirements could lead to miniaturized devices with smaller capacitors and batteries. To deliver a 360 J monophasic damped sine wave, 5200 volts of electricity are needed. Only 1600 to 1750 volts are needed to deliver a 150 J biphasic truncated waveform.
- In clinical trials, biphasic shocks of 150 J converted VF in 93 per cent of cases in 1 or 2 attempts. Also, low-energy, impedance-compensating biphasic waveforms are more successful than high-energy shocks at terminating VF of long duration in out-of-hospital cardiac arrest. Biphasic technology is emerging as the standard in newer AED models.

DEFIBRILLATION

- Delivered Energy;
  - Low Energy Level : max. 181 Joules at 75 Ohm
  - High Energy Level : max. 237. Joules at 75 Ohm

The international guidelines and studies say the following :

ILCOR/ ERC guidelines recommends to defibrillate (biphasic) with 150 - 200J in first shock and either 200J or higher in the second and subsequent shocks.

The 360J are only for the old mono phasic shocks. Newer studies show that it is not recommended to shock with Energy greater 300J with a biphasic defibrillator.

- Current based defibrillation shock

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DETAILED TECHNICAL INFORMATION

- CardiAid has a current based defibrillation shock (nearly rectangular current) and this fulfils automatically the restriction more impedance more energy, and less impedance less energy, cause with a constant current and time there is E=I^2*t*R rising and falling with reference to R. So the shock of CardiAid is same as an adjustable Energy based shock. And also the adjustable energy shocks have a max energy at a specific Impedance.

- There are more advantages that the shock of CardiAid have : In CardiAid there is no huge current at beginning of the shock that all normal Energy based shocks have. This current can cause damages of the tissue. The constant current shock is automatically current limited.

- Many people confuse current and energy. This distinction is important in defibrillation, since defibrillators are often described in terms of energy (e.g., 200J) but it is their current - not the energy - that defibrillates. Successful defibrillation requires that enough current be delivered to the heart muscle during the shock.

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DETAILED TECHNICAL INFORMATION

- VF and other cardiac arrhythmias can be terminated by electric shock when sufficient current passes through the myocardium. A promising alternative approach to defibrillation is the use of electric current (amperes) instead of energy (joules). This approach would prevent attempts to deliver inappropriately low energy levels to a patient with high impedance. Current-based therapy would also prevent high-energy shocks to patients with low impedance, which result in excessive current flow, myocardial damage, and failure to defibrillate.

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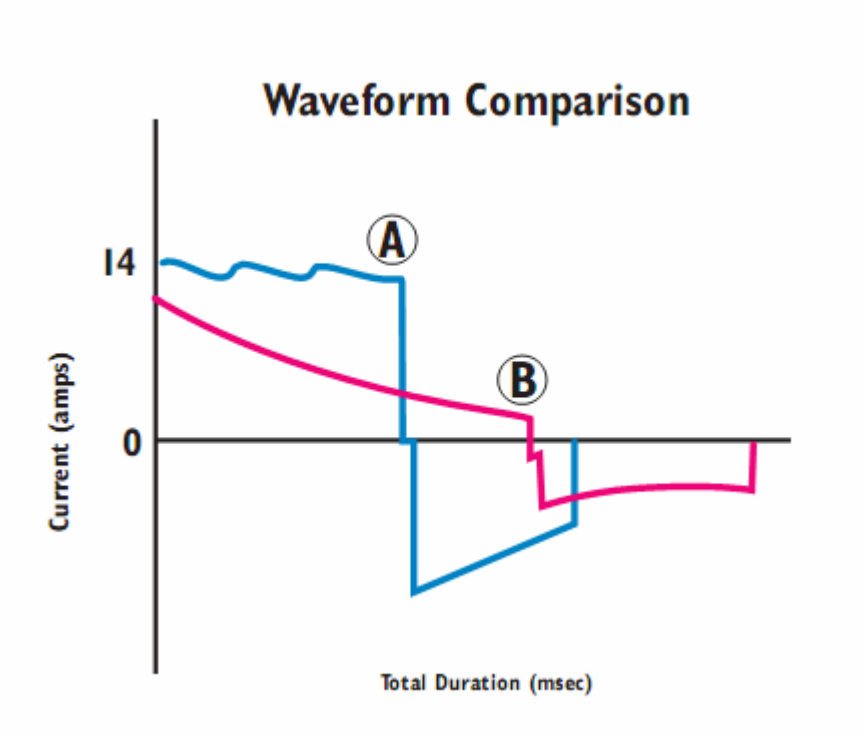
CURRENT – NOT THE ENERGY – DEFIBRILLATES THE HEART

- In the diagram on the right, Waveform "B" has more energy than Waveform "A," but actually delivers less current. Here's why: Energy (joules) is simply the work required to get current to the heart; it's the product of three variables:

  Joules = Voltage x Current x Time

- By extending duration (time), as in Waveform "B," you can deliver more energy. But you only create

  the illusion of more capability because you have not necessarily delivered more current—or more efficacy.



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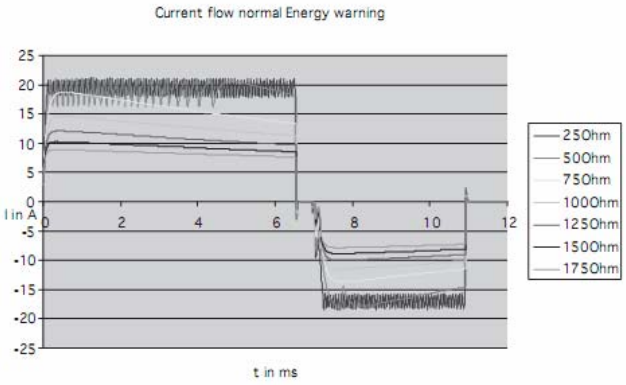
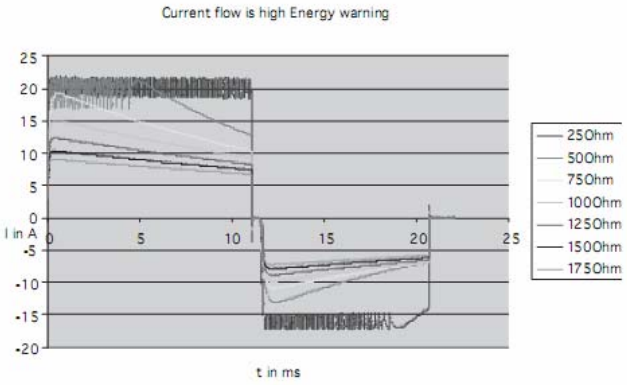
PULSE FORM

- A pulse form is drawn by applying a fixed maximum current. Myocardium damage typically caused by high electric currents, with low patient's impedance are reduced considerably with this pulse form.

- Pulse form / shock energy can only be configured by service. Pre-adjustment is as follows:
  1. Shock to be applied : low
  2. Shock to be applied : low
  3. And other shocks to be applied : high





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TELEMEDICINE DEVICES

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PULSE FORM

- Impedance Dependence

  For safety reasons, a current of maximum 2000 Volt are used.

- Energy flow in high patient resistance

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

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ECG ANALYSIS SYSTEM

- Duration of ECG Analysis — less than 10 sec.
- Impedance measurement — controlled by electrode contact
- Precision VF/pVT — > % 90
- Specified NSR / Asystolic — > % 95
- The last 4 events are stored up to 4 hours in the device. And with connecting the CardiAid Monitor Software through bluetooth interference ECG data can be obtained from the CardiAid.

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FAQ - WHAT SHOULD BE DONE AFTER THE ANNOUNCEMENT OF ILCOR 2010?

- First of all there is no obligation for any end-user to upgrade the AED's produced according to the former ILCOR guidelines. ILCOR only recommends the end-users to upgrade their AED's for the new guidelines. (For example, today it is possible to find AED's in the field, not upgraded to the new guidelines.)
- The manufacturer should announce the upgrade solutions of the devices in the field to the new guidelines for the end-user who are willing to upgrade their devices.
- Depending on the changes; the way how to upgrade CardiAid will be different.

  For example; if the only change will be in CPR like cancelling the –mouth to mouth breathing-; then the solution is the replacement of the SD Card by Cardiatech Service Partner. The device has to be opened and the SD Card has to be replaced. And then CardiAid has to be tested like it is tested during the 2nd and 4th year maintenance.

  if the only change is to change the length of the CPR; this will be done by CardiAid Monitor Software running on a computer connected to CardiAid through Bluetooth. For safety this also needs to be done by trained people, which means Cardiatech Service Partner.
- If an end-user would like to upgrade their AED's to the new guidelines; then this will be an up-sell for Cardiatech Service Partner. This is not different than the management of 2nd and 4th year maintenance. Therefore like Cardiatech Service Partner will charge 2nd and 4th year maintenance to the enduser; Cardiatech Service Partner will be able to charge the upgrades if requested.

FAQ- WHY DOES CardiAid HAVE a LOW POWEVR of 181 J and HIGH POWER of 237 J WHILE THE OTHER COMPETITORS IN THE MARKET HAVE 200 J / 340 J. ?

- CardiAid AED is a biphasic defibrillator with current based defibrillation shock. It is clear that biphasic waveforms offer improvement in patient outcomes however there is sometimes confusion about energy settings. That's why you will receive several questions about energy settings of CardiAid. That is because all biphasic waveforms are different from each other, so each manufacturer uses different energy settings to deliver the necessary amount of current to defibrillate a heart. Comparisons of energy settings between different devices are no longer applicable. One company's setting of 360 J could deliver the same amount of current as another company's setting of 200 J. This is a very important distinction, because electrical current is what actually defibrillates the heart – not energy.
- The international guidelines and studies say the following :

  ILCOR/ ERC guidelines recommends to defibrillate (biphasic) with 150 - 200J in first shock and either 200J or higher in the second and subsequent shocks.

  The 360J are only for the old mono phasic shocks. Newer studies show that it is not recommended to shock with Energy greater 300J with a biphasic defibrillator.
- Therefore CardiAid is in the well Energy range.

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FAQ

- **If ECG is flat, what will CardiAid do?**
- If ECG is flat, i.e. there is no rhythm (asystole), CardiAid will say “Shock not advised.” and direct the user to resuscitation phase. This is an obligation according to the ILCOR 2005. ILCOR does not allow to shock if ECG is flat.

- **How can you explain the difference between 181 and 237 Joules in the same resistivity?**
- There are two different shock levels (low and high level). These levels are chosen by factory settings. CardiAid AED gives first & second shocks “low”; third, forth and the rest at “high” level. In addition to that, CardiAid chooses which energy value to deliver according to the impedance of the patient. 181 j refers to the maximum shock value which can be delivered by CardiAid to a patient with 75 ohm impedance at “low” level shock. 237 j refers to the maximum shock value which can be delivered by CardiAid to a patient with 75 ohm impedance at “high” level shock.

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FAQ

- **What happens if the two electrodes are swapped?**
- Actually if you check our electrode pair you will see that we put sign on the electrode where to stick because in case of emergency people can be scared or can mix where they have to stick the electrodes. On the other hand since the electrodes are non-polarized, nothing will happen if the electrodes are swapped.

- **Do the electrodes for children exist ?**
- No, CardiAid does not have pediatric electrodes. CardiAid can be used for patients over 20 kg, which is averagely the weight of a 7-year-old child.

- **Can the AED be used safely if the victim is on a metal surface such as a bleacher or stretcher?**
- Yes. AEDs can be used safely as long as the electrode pads do not come into contact with the metal surface.

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FAQ

- **Are there special considerations when placing electrodes on a female victim?**
- If the victim is wearing a bra, remove it before placing electrodes.

- **What if the victim has a medication patch, such as nitroglycerin?**
- Never place electrodes directly on top of medication patches. If the patch is in the way of the AED pads, remove it and wipe off the area with the victim's shirt. Then apply the pads to the clean, bare skin.

- **What if the victim has an implantable pacemaker or defibrillator?**
- If the victim has a pacemaker or internal defibrillator with a battery pack (visible as a lump under the skin about two inches long), avoid placing pad directely on top of the implanted medical device.

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FAQ

- **Can CardiAid be used on a wet surface, for example near a swimming pool?**
- Drowning is one of the main reasons for SCA. Thus, swimming pools should have an AED. CardiAid can be used near a swimming pool if is used properly. Using CardiAid on a wet surface is not recommended. This may cause the current to change direction and not go through the heart, decreasing the effectiveness of the treatment. If a person has SCA in this environment, the procedure is that lying the patient on a towel and drying the upper body with another towel before sticking the electrodes.

- **Can CardiAid be used on a wet person?**
- Using CardiAid on a wet person is not recommended. This may cause the current to change direction and not go through the heart, decreasing the effectiveness of the treatment. Also the electrodes may not be sticked properly. The patient must be dried with a towel or cloth before sticking the electrodes.

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FAQ

- **Can CardiAid analyze the heart rhythm on a plane?**
- CardiAid cannot analyze the heart rhythm only if there is vibration and/or the patient is being moved. When the plane is flying, there does not become such vibration which can disable the analyzing. Only if the plane flies in a turbulence at that moment, that may cause a problem. In that case, the procedure is that the pilot is informed about the situation and he flies the plane out of the turbulence as soon as possible.

- **Why does CardiAid not have a screen?**
- CardiAid was designed specially for public access use. Thus, any item which can confuse the user or cause loss of time was avoided. CardiAid does not have any feature which is not proper for public access use.

- **Does CardiAid store data about the patient?**
- CardiAid saves the following data at every use:
  - Date and time of use
  - Patient's ECG
  - The number and time of shocks delivered

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