CardiAid®

Automated External Defibrillator

Technical Service Manual

For Models: CT0207, CT0207RS, CT0207RF

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IMPORTANT!

- This technical service manual is intended ONLY for qualified personnel and it describes the maintenance and troubleshooting procedures of CardiAid Automated External Defibrillator models CT0207, CT0207RS and CT0207RF.

- Inspection, repair and other maintenance actions can be performed ONLY by Cardia International or a Cardia International authorized technical service provider. Any unauthorized attempt invalidates the warranty and may cause serious injuries and/or irreversible damage to the device.

- The supply of this manual does not in any event constitute permission or approval to modify or repair a device.

- All rights reserved for the devices, circuits, processes and names appearing in this manual.

- Cardia International, at its own discretion, reserves the right to make changes pertaining to the technical features and the accessories of the device.

- Cardia International, under no condition, shall be liable for any fault of spelling and/or writing in any and all instructive and informational data, documents, images given in this manual and any direct, indirect, accidental, secondary legal or penal loss or damages may arise from them.

1. INTRODUCTION

1.1. Introduction to CardiAid AED

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 (>25kg) with standard electrodes and patients 1 to 8 years old (<25kg) with special paediatric electrodes. Model CT0207 works only in adult mode. 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 versions (CT0207 and CT0207RS), the user is asked to press a button to release the shock.

• In the full-automatic version (CT0207RF), the device warns the user not to touch the patient and then proceeds to releasing the shock automatically.

For detailed information about CardiAid AED, please read carefully the CardiAid AED User Manual, Section 1: Introduction to the Device.

Report of analysis system of ECG can be found in Appendix 1.

1.2. Introduction for the Technical Service Provider

This manual is a guide for the Cardia International authorized service provider of CardiAid AED. It includes instructions about all after-sales technical service procedures including problem diagnosis, Return Material Acceptance (RMA) and maintenance.
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.

1.3. Authority and Responsibility of the Technical Service Provider

Inspection, repair and other maintenance actions can be performed ONLY by Cardia International or a Cardia International authorized technical service provider. A party can be "Cardia International authorized service provider" only after receiving training directly from Cardia International, signing the service provider agreement and receiving the service provider ID.

Technical service provider is responsible for the following:

- Technical service provider shall read this technical service manual, execute the maintenance and technical service of the CardiAid products with the CardiAid Monitor2 Technical Service Software according to the procedures in this technical service manual, and send all results of the maintenance to Cardia International.
- Technical service provider shall use the service provider ID during maintenance procedure.
- Technical service provider should have the necessary technical equipment defined by Cardia International. "The list of Technical Service Equipment" shall be found in **Appendix 2**. The technical service equipment should be kept in a good condition and ready to use. The necessary calibrations should be followed by the technical service provider.
- The technical service provider should keep enough stock of accessories and spare parts for periodical maintenance and/or repair. "The list of Spare Parts and Accessories" shall be found in **Appendix 3**.
  - o The quantity is determined according to the number of the AEDs which need the periodical maintenance.
  - o The needed items should be ready in stock of the service provider 2 months before the periodical maintenance time.
- The service provider should also keep a regular stock of accessories and spare parts for the After-Use Maintenance. The quantity of this stock is determined by Cardia International and the service provider together, being between 1% and 10% and provided that the amount is not less than the minimum order quantity of each item.

2. SAFETY INFORMATION

- In accordance with the requirements of Council Directive 93/42/EEC, CardiAid AED is marked as follows:

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- It fully meets the electromagnetic compatibility requirements of the standard IEC60601-1-2/EN60601-2 "Electromagnetic Compatibility of Medical Electrical Devices". The product has undergone interference suppression in accordance with the requirements of the standard EN50011, Class B.

2.1. Safety Rules for the Owner and User

For safety rules and important warnings, please read carefully the User Manual of CardiAid, Section 2.3: Safety Rules.

2.2. Safety Rules for the Technical Service Provider

CardiAid AED is a device containing a High-Voltage part on its mainboard and High-Voltage Capacitor. DO NOT TOUCH the mainboard while opening the device, replacing RTC Battery and taking off the main battery cable! ALWAYS USE the discharger to discharge the capacitor just after the device is opened before starting any action. The High-Voltage can result in serious injury or death.

While testing CardiAid AED, the patient may only be simulated with fixed high-voltage and high-power resistors that are well insulated from the ground or earth. Poorly insulated devices or devices with loose contacts or devices containing components such as spark arresters or electronic flash lamps should never be used as they could irremediably destroy the device.

The manufacturer shall only be liable for the safety, reliability and performance of CardiAid AED if:
- *Assembly, extensions, adjustments, modifications or repairs are performed by the manufacturer or by persons authorized by the manufacturer.*
- *The device is used in accordance with its instructions for use.*
- *The spare parts used are original parts from the manufacturer.*

Perform these steps in an antistatic environment. Wear antistatic wristband connected to cable and antistatic carpet before following the steps below. Not wearing antistatic wristband and not using antistatic carpet can cause damage to the CardiAid AED.

Use only original accessories and spare parts. Using incompatible accessories or spare parts can cause irreversible damage to the CardiAid AED 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.

3. PREPARATION FOR TECHNICAL SERVICE AND MAINTENANCE

Inspection, repair and other maintenance actions can be performed ONLY by Cardia International or a Cardia International authorized technical service provider.

After the receipt of the CardiAid AED the Cardia International authorized technical service provider shall do the following actions:

a. Check whether the warranty of the CardiAid AED is still valid according to the conditions written in the Section 3.2 "Warranty Conditions of CardiAid AED" of this technical service manual.
b. Check CardiAid AED very carefully if there is any damage at any part of the unit. See "Visual and Mechanical Check" in Section 4.6.4.
c. Check the status indicator lights of the CardiAid AED. See "Check Status Indicators" in Section 4.6.3. Also read Section 3.2. to learn "Error Management Concept" of CardiAid AED.

3.1. Warranty Conditions of CardiAid AED

CardiAid is a high quality product which is designed and manufactured with the highest medical standards. Cardia International guarantees that the device will perform properly for a period of 2 years after purchase. This period can automatically be extended to 6 years under the following conditions:

- The device should be registered on www.cardiaid.com/register
- The device may be used only as an automated external defibrillator; there is no compatibility at all with other equipment or peripherals.
- The device should be subjected to periodical maintenance at the end of 2nd and 4th years after purchase. The periodical maintenances should be performed on time and by an authorized technical service provider.
- CardiAid should also be subjected to maintenance after each use. The after-use maintenance should be performed by an authorized technical service provider.
- The device should not be unscrewed or back of the device should not be opened by another party. Inspection, repair and other maintenance actions can only be performed by an authorized service provider.
- Physical damage, fire or water damage and incompetent use will invalidate the warranty. This warranty does not cover the electrodes, protection bag or other accessories.
- The serial number on the device should be intact and legible.
- The original purchase invoice should be available for inspection.
- This guarantee does not cover the accessories such as electrode pads, and protection bag.

The warranty conditions of CardiAid AED are presented to the owner with the "Warranty Card" as seen in **Appendix 4.**

3.2. Error Management Concept

The error management in CardiAid has been designed to make the possible risks less probable and thereby CardiAid itself a safer equipment.

In order to tackle the risks, different monitoring- and self-tests-mechanisms have been designed. CardiAid uses the listed tests methods below to identify errors before or during an operation of the device:

- Daily self-test
- Monthly self-test
- Functional test on start-up
- Runtime test during operation

Depending on the results of these tests and monitoring activities CardiAid uses three different LEDs to signal the state of the device to the operator or the user.

3.3. Visual and Acoustic Failure Message

CardiAid has an intelligent error detecting system. Visual and acoustic failure messages inform the user about the type of the error and the necessary actions can be taken by the user. These failure messages are described in the User Manual of CardiAid CT0207 and the User Manual of CT0207RS & CT0207RF as follows:

3.3.1. Visual and Acoustic Failure Message of CT0207

	Failure Messages of CardiAid		Cause	Action
	Visual	**Acoustic**		
1	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 Cardia International or an authorized service provider immediately for battery replacement.
2	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 Cardia International or an authorized service provider for battery replacement.
3	Battery Symbol and Repair Symbol are flashing during stand-by.	Signal tone in every 4 minutes	Battery is empty. Device cannot be used.	Device cannot be used. Contact Cardia International or an authorized service provider immediately.
4	Battery and Repair Symbol are lighting continuously during operation.	"Device is not ready for use."	Battery is empty. Device cannot be used.	Device cannot be used. Contact Cardia International or an authorized service provider immediately.
5	Repair Symbol is flashing during stand-by.	Signal tone in every 4 minutes	There is a malfunction with the device.	Device cannot be used. Contact Cardia International or an authorized service provider immediately.
6	Repair Symbol is lighting continuously during operation.	"Device is not ready for use."	There is a malfunction with the device.	Device cannot be used. Contact Cardia International or an authorized service provider immediately.
7	None — Status indicators do not light or flash for a period of time during operation.	No acoustic message	There is a problem with LEDs.	CardiAid can be used only in emergencies. Contact Cardia International or an authorized service provider immediately.

		Visual message	Acoustic message	Cause	Action
8	Any	Any	"Stick electrodes on the patient's bare chest" even though the electrodes are sticked.	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 Cardia International or an authorized service provider immediately.
9	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.			
10	Any	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.
11	⊘	None	None	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.			
12	Any	Any	Any	Any	Contact Cardia International or an authorized service provider immediately.
		The device is not operating as indicated in the operating manual.			

As a service provider, if you will receive a device at least with one of the acoustic and visual messages listed above, please follow the instructions below:

Nr. 1 and 2: Battery Symbol and OK Symbol lights or flashes simultaneously.

- Open the cover of the device and check the device works (does start up self-test, switches on all LED lights and then starts voice prompts by switching on the LED lights of the first step). Then close the cover of the device and observe the status symbols. If the "Battery" and "OK" symbols are still active simultaneously, then follow the next step. If not, take action according to the status symbols.

- Follow the Maintenance Procedure which is described in the Section 4.6 : "Performing Maintenance" of

this technical service manual.

Nr. 3 and 4: Battery Symbol and Repair Symbol lights or flashes simultaneously.

- Open the cover of the device and check the device works (does start up self-test, switches on all LED lights and then starts voice prompts by switching on the LED lights of the first step). Then close the cover of the device and observe the status symbols. If the status symbols "Battery" and "Repair" are still active simultaneously, follow next step. If not take action according to the status symbols.

- Check whether the date of 2nd or 4th Year Maintenance is overdue. If yes, perform the necessary periodical maintenance. For further information, see Section 4.6 : "Performing Maintenance" in the Technical Service Manual.

- If the date of periodical maintenance is not passed, see **Problem A** in Section 6

Nr. 5 and 6: Repair Symbol lights or flashes simultaneously.

- Open the cover of the device and check the device works (does start up self-test, switches on all LED lights and then starts voice prompts by switching on the LED lights of the first step). Then close the cover of the device and observe the status symbols. If the "Repair" symbol is still active follow the steps in **Problem B** in Section 6 of Technical service manual. If not, take action according to the status symbols.

Nr. 7 : Status indicators do not light or flash for a period of time during operation.

- Open the cover of the device and check the device works (does start up self-test, switches on all LED lights and then starts voice prompts by switching on the LED lights of the first step). Then close the cover of the device and observe the status symbols. If any of the status indicators do not light or flash for a period of time follow the steps in **Problem C** in Section 6 of Technical Service Manual. If not, take action according to the status symbols.

Nr. 8 : The device indicates "Stick electrodes on the patient's bare chest" even though the electrodes are sticked.

- Check all points listed and observe the problem is solved or not. If the problem still exists, see Section 6.2 "RMA Procedure" of this technical service manual.

Nr. 9 None of the visual/acoustic messages are active; there is no sound or light when the device is opened.

- Check whether there is a problem with the main battery. So see **Problem D** in Section 6.

Nr. 10: The verbal instructions cannot be heard while CardiAid is operating.

- Check whether there is a problem with the main battery. Remove the battery and measure the voltage of the battery. If you determine a problem with the battery, replace it with a new one.
- If the problem is not caused by the battery, follow Section 6.2 "RMA Procedure" of this technical service manual.

Nr. 11 : Shock cannot be delivered even though shock button is pressed.

- Follow Section 6.3 "Testing Shock Button" in this manual.

Nr. 12 :The device is not operating indicated in the manual.

- Follow Section 6.2 "RMA Procedure" of this technical service manual.

3.3.2. Visual and Acoustic Failure Message of CT0207RS & CT0207RF

	Failure Messages of CardiAid			Cause	Action
	Visual		**Acoustic**		
1		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.
2		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 immediately for battery replacement.
3		Battery Symbol and Repair Symbol are flashing during stand-by.	Signal tone in every hour.	Battery is empty. Device cannot be used.	Device cannot be used. Contact Cardia International or an authorized service provider immediately.
4		Battery and Repair Symbol are lighting continuously during operation.	"Device is not ready for use."	Battery is empty. Device cannot be used.	Device cannot be used. Contact Cardia International or an authorized service provider immediately.
5		OK Symbol and Repair Symbol are flashing during stand-by.	No acoustic message	The electrodes are not connected to the device.	Plug the electrodes to the device.
6		OK Symbol and Repair Symbol are lighting continuously during operation.	"Plug electrodes into socket."	The electrodes are not connected to the device.	Plug the electrodes to the device.
				Wrong electrodes are connected	Be sure original CardiAid electrodes are used.
7		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.
8		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.
9	None	Status indicators do not light or flash for a period of time during	No acoustic message	There is a problem with LEDs.	CardiAid can be used only in emergencies. Contact Cardia International or an authorized service provider immediately.

#					
			operation.		
10	⊘ (OK)	Any	"Stick electrodes on the patient's bare chest" even though the electrodes are sticked.	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.
11	☒	Repair Symbol is lighting continuously during operation.	"Device is not ready for use."	There is a malfunction with the device.	Device cannot be used. Contact Cardia International or an authorized service provider immediately.
12	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.			
13	Any	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.
14	⊘ (OK)	None	None	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.			
15	Any	Any	Any	Any	Contact Cardia International or an authorized service provider immediately.
		The device is not operating as indicated in the operating manual.			

As a service provider, if you will receive a device at least with one of the acoustic and visual messages listed above, please follow the instructions below:

Nr. 1 and 2: Battery Symbol and OK Symbol lights or flashes simultaneously.

- Open the cover of the device and check the device works (does start up self-test, switches on all LED lights and then starts voice prompts by switching on the LED lights of the first step). Then close the cover of the device and observe the status symbols. If the "Battery" and "OK" symbols are still active simultaneously, then follow the next step. If not, take action according to the status symbols.

- Follow the Maintenance Procedure which is described in the Section 4.6 : "Performing Maintenance" of

this technical service manual.

Nr. 3 and 4: Battery Symbol and Repair Symbol lights or flashes simultaneously.

- Open the cover of the device and check the device works (does start up self-test, switches on all LED lights and then starts voice prompts by switching on the LED lights of the first step). Then close the cover of the device and observe the status symbols. If the status symbols "Battery" and "Repair" are still active simultaneously, follow next step. If not take action according to the status symbols.

- Check whether the date of 2nd or 4th Year Maintenance is overdue. If yes, perform the necessary periodical maintenance. For further information, see Section 4.6 : "Performing Maintenance" in the Technical Service Manual.

- If the date of periodical maintenance is not passed, see **Problem A** in Section 6

Nr. 5 and 6: OK and Repair Symbol lights or flashes simultaneously.

- Open the cover of the device and unplug the electrode to confirm the electrode installed is the correct electrode. If the electrode is not the correct electrode (the electrode with pins) replace it with the correct one and plug it on the socket to observe that "Repair" symbol is OFF. If the "Repair" symbol is still active follow the steps in Problem B in Section 6 of Technical service manual.

- If the electrode is the correct electrode then replug it on the socket. If there is no connection problem, the "Repair" symbol should be switched OFF. If not, follow the steps in in **Problem B** in Section 6 of Technical service manual.

Nr. 7, 8 and 11: Repair Symbol lights or flashes simultaneously.

- Open the cover of the device and check the device works (does start up self-test, switches on all LED lights and then starts voice prompts by switching on the LED lights of the first step). Then close the cover of the device and observe the status symbols. If the "Repair" symbol is still active follow the steps in in **Problem B** in Section 6 of Technical service manual. If not, take action according to the status symbols.

Nr. 9 : Status indicators do not light or flash for a period of time during operation.

- Open the cover of the device and check the device works (does start up self-test, switches on all LED lights and then starts voice prompts by switching on the LED lights of the first step). Then close the cover of the device and observe the status symbols. If any of the status indicators do not light or flash for a period of time follow the steps in **Problem C** in Section 6 of Technical Service Manual. If not, take action according to the status symbols.

Nr. 10 : The device indicates "Stick electrodes on the patient's bare chest" even though the electrodes are sticked.

- Check all points listed and observe the problem is solved or not. If the problem still exists, see Section 6.2 "RMA Procedure" of this technical service manual.

Nr. 12 None of the visual/acoustic messages are active; there is no sound or light when the device is opened.

- Check whether there is a problem with the main battery. So see **Problem D** in Section 6.

Nr. 13: The verbal instructions cannot be heard while CardiAid is operating.

- Check whether there is a problem with the main battery. Remove the battery and measure the voltage of the battery. If you determine a problem with the battery, replace it with a new one.

- If the problem is not caused by the battery, follow Section 6.2 "RMA Procedure" of this technical service manual.

Nr. 14 : Shock cannot be delivered even though shock button is pressed.

- Follow Section 6.3 "Testing Shock Button" in this manual.

Nr. 15 : The device is not operating indicated in the manual.

- Follow Section 6.2 "RMA Procedure" of this technical service manual.

4. MAINTENANCE

4.1. Introduction

This section describes the maintenance procedures recommended for **CardiAid CT0207, CT0207RS and CT0207RF AED models.**

CardiAid AEDs should be subjected to the following maintenances by an Authorized Technical Service Provider:

- 2nd Year Periodical Maintenance
- 4th Year Periodical Maintenance
- 6th Year Periodical Maintenance
- After-Use Maintenance

In addition to the periodical and after-use maintenances, the user / the owner is also liable to follow User Tests. The User and the owner of the CardiAid AEDs should follow the daily and semi-annual User Tests. The semi-annual User Test is named Function Check which should be performed every 6 months for ensuring that CardiAid is always ready for an emergency. This check may be performed by the owner. For The Daily Check and Function Check please read the User Manual of CardiAid, Section 6. The technical service provider should check the daily and semi-annual User Tests of the CardiAid AED completed by the user / the owner.

4.2. Periodical Maintenance

The periodical maintenances should be performed at the end of 2nd and 4th year after the purchase date of CardiAid AED. In some countries like Germany, legal period of Technical Safety Check (TSC) is 2 years according to the Medical Products Operation Regulation (Article 6).

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.

CardiAid AED should also be subjected to "6th Year Maintenance" and completely checked at the end of the 72 months period following the purchase date. The same procedure in "2nd Year Maintenance" can be fulfilled in the "6th Year Maintenance" by the Service Provider. The Service Provider cannot commit any additional warranties to the End User other than determined by Cardia International after 6th Year Maintenance.

The 6th Year Maintenance can also be performed by Cardia International in the factory. This Maintenance in the factory will include the full technical inspection. For this purpose, Service Provider is obliged to contact Authorized Distributor of CardiAid AED in the Territory or Cardia International, and the address to which the Product should be sent for this maintenance will be provided to the Service Provider.

4.3. 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 and 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.

4.4.   Before starting

Make sure that technical service provider will have the following ready   :

- Technical Service Equipments
- Spare parts needed
- The latest version of CardiAid Monitor2 Technical Service Software is already installed in computer and the Bluetooth connection of the computer is active

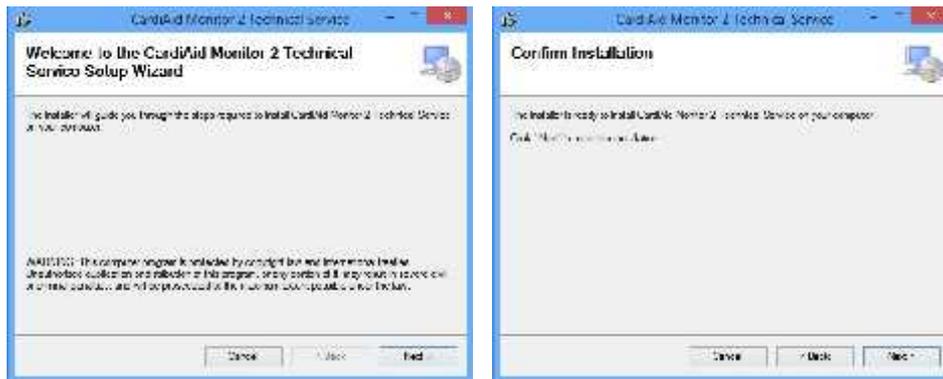The steps of all periodical and after-use maintenances can be found in Section 4.6. "Performing Maintenance".

4.5.   Installing the Software

CardiAid Monitor 2 Technical Service Software is the official technical service software* to check the "device settings", reset the "battery", set the date and time, save the "ECG data" of CardiAid AEDs CT0207, CT0207RS and CT0207RF and also manage the troubleshooting and problem diagnosis and solution.

CardiAid Monitor 2 Technical Service Software operates only on Windows XP, Windows Vista, Windows 7 and Windows 8 platforms and requires bluetooth dongle or built-in bluetooth hardware in your system.

- Double click on "setup.exe". The installation will start automatically. Follow the steps and complete the installation. There will be a shortcut on your desktop when the installation is completed.

CardiAid Monitor 2 Technical Service Software runs stable with Widcomm Stack (Belkin branded Bluetooth dongle) therefore please use a Bluetooth dongle or built-in bluetooth which uses Widcomm Stack to connect to CardiAid.*

*If you use another kind of bluetooth dongle, you may have problems with getting the ECG Data (some data may be lost during transfer). Please do not use Bluetooth dongle or built-in bluetooth with Toshiba stack.

4.6. Performing Maintenance

CardiAid Monitor 2 Technical Service Software shall be used to perform any of the periodical and after-use maintenances.

i. First make sure that you checked previously performed maintenances of the CardiAid AED. Note that previously performed maintenances, if there is any, can be tracked from the maintenance label on the device.

Periodical Maintenance Label   After-use Maintenance Label

ii. Make the Bluetooth connection of the computer active, and click the icon of CardiAid Monitor2 Technical Service Software to start.

4.6.1. Signing In CardiAid Monitor2 Technical Service Software

iii. Type service provider ID (username) and password; and then press sign-in to login CardiAid Monitor 2 Technical Service Software. Internet connection will be neccessary to login and continue!

Sign-Up Screen

If you have not received username and password press sign-up to fill the form below to contact Cardia International. You will receive the username and password from Cardia International if you have already been appointed Authorized Service Partner.

Limited OFF-Line Mode

If there is no internet connection available; you can still use the limited OFF-Line version to continue maintenance.

In Limited OFF-Line version, do not forget to lose, and to save the information (ECG Data, if any, device settings) and send them to Cardia International when you have internet connection available to complete service and maintenance action officially.

iv.   The next step after signing in the software you will be asked to select the purpose of using the software. Click "New Device" to start using the software for a new device.

Click "Send Maintenance Log File" in case you have unsent Maintenance Log Files of the devices you completed the maintenance in limited OFF-Line version. See Section 4.7 "Sending Maintenance Log File" to proceed to send maintenance log file.


If you use the limited OFF-Line Mode, you will not see this screen!

If you click on "Check Status of Pending Devices" anytime, you can always view the status of the devices you sent report to Cardia International about.


If you exit CardiAid Monitor 2 Software during the maintenance at any time and any window, you will be warned with the following message. If you want to save the last status do not forget to click "Yes". You will be automatically continue from the step you exit the software, the next time you use the software.
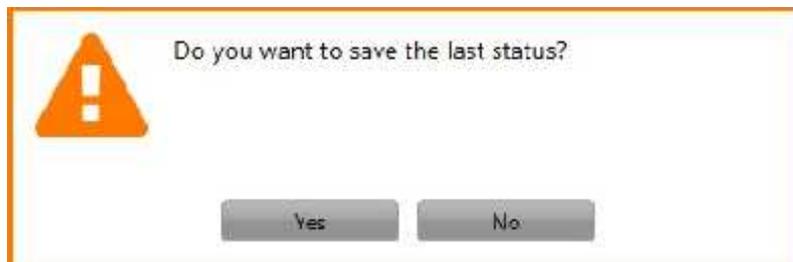
4.6.2. Filling serial number of CardiAid AED

v.   If you select "New Device" or Click "Next" in first screen of OFF-Line Mode you will be asked to fill the serial number of CardiAid AED. Type the serial number of the CardiAid AED on the screen and click "Next".
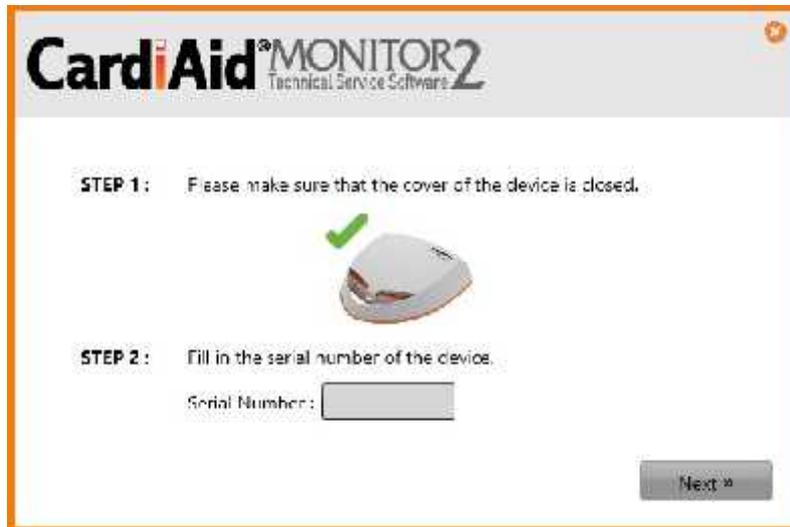
 The serial number of the CardiAid AED is found on backside of the device.
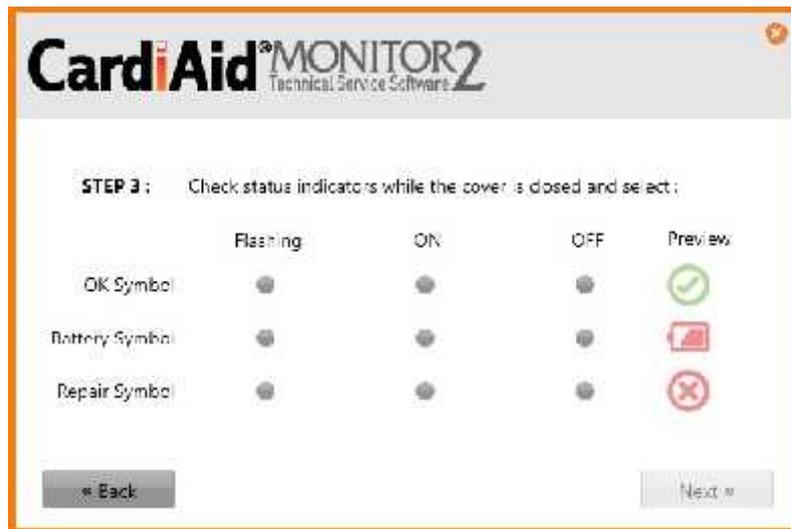
4.6.3. Check Status Indicators

vi. Check status indicators of CardiAid AED while the cover is closed and select "Flashing", "ON" or "OFF" for each status indicators and click "Next".

> ⚠ **According to the selected status indicators the device will be directed to "Problem Diagnosis Procedure" if there is a technical problem to be checked.**

4.6.4. Visual and Mechanical Check

vii. Check CardiAid AED very carefully if there is any damage at any part of the unit. If there is any damaged or broken part, the unit needs to be repaired or replaced. In this case you will be directed to follow "Problem Diagnosis Procedure" in CardiAid Monitor2 Technical Service Software. Select "Yes" or "No" to each question and then click on "Next"

> *If you click on "Yes" since there is any damage or any broken part on the device, and you click on "No" since the device does not stop the voice guidance, then the software will direct you to "Problem Diagnosis" . See Section 6.2.1., 6.2.2. and 6.2.3 of this manual.*

4.6.5. Connecting CardiAid

viii. Open the cover of the CardiAid AED to activate the Bluetooth module. Click "Search" to start searching the available devices to be connected.
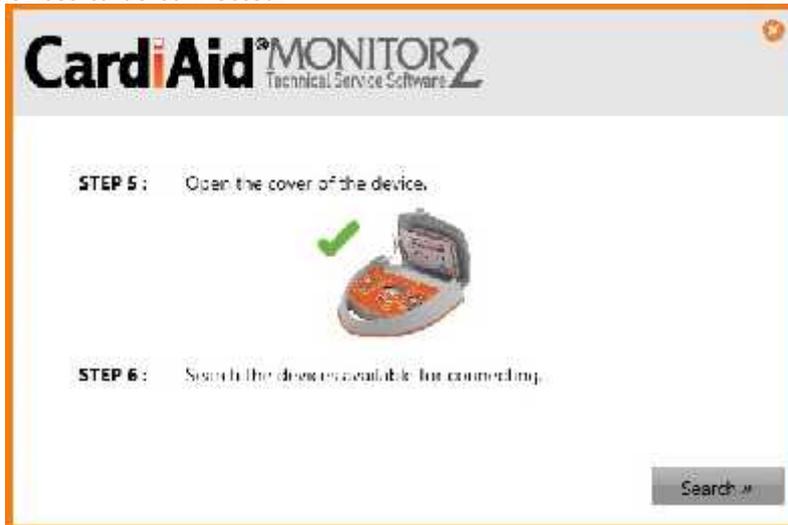
ix. CardiAid Monitor2 Technical Service Software will be connected automatically to the device with the serial number typed in "***Filling serial number of CardiAid AED***" to the software if the cover of the device is open and the serial number typed in is correct. If the connection to the device is failed, click "Search" once again to start searching the device(s) with the cover open.

x. The last step to establish the connection to the device is to type the connection password "4971" and click "Next".

> *When you connect to a CardiAid first time via CardiAid Monitor 2 Software, the device will ask for passkey. Please enter "4971" as passkey*

xi. The software will state "CONNECTED TO THE DEVICE" and show the status of CardiAid connected. At this stage click "Perform Maintenance" to continue with the maintenance.


Click "VIEW SETTINGS" to perform other settings. See section "VIEW SETTINGS" in Section 5 of this technical service manual.

4.6.6. Performing maintenance

**xii.** Select the type of the maintenance you would like to perform.

Click "2nd Year" to perform 2nd Year Maintenance

Click "4th Year" to perform 4th Year Maintenance

Click "6th Year" to perform 6th Year Maintenance

Click "After Shock" to perform maintenance after each usage

Click "Before Sales" in case the Battery Life Label of the device shows shelf life less than 24 months to perform maintenance to prepare the device for sales.
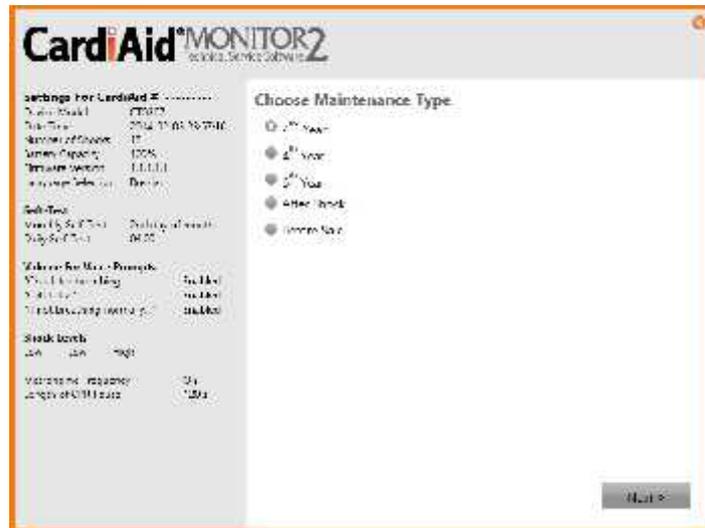
4.6.7. Checking memory and getting ECG Data recorded

xiii. After selecting the type of the maintenance, the memory of the device will be checked whether there is an ECG data recorded previously. If there is a record present in the memory, this record has to be saved and deleted before proceeding. Click "Next" to check the ECG Data
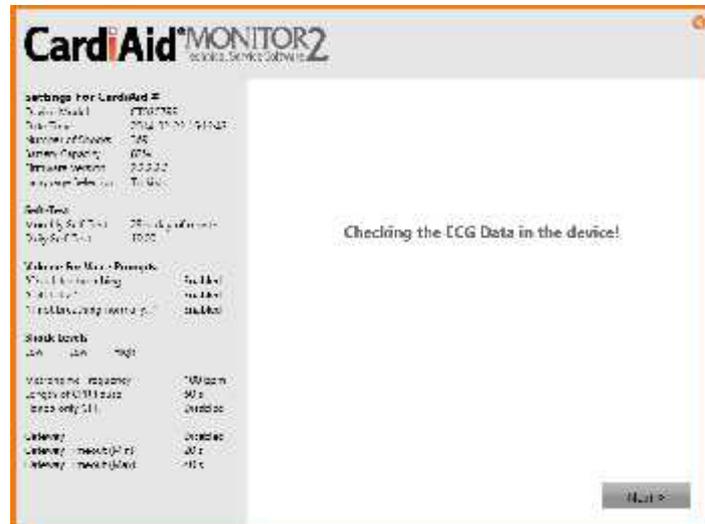
xiv. If there is an ECG Data recorded in the device you will be directed to the ECG Screen below. Perform all the steps below to continue.

 Reading ECG DATA will take almost 1 minute and then ECG screen will pop-up.

- o Save as CVF : Fill in patient information "Patient name", "Patient ID", "Patient Birth Date", "Place of Usage" and "Comments". Then click "Save as CVF" button and select the destination to save ECG data and report.

 There may be more than 1 record in device's memory. Make sure you saved all records before exiting the window.

- o Save as PDF : Click "Save as PDF" button to save the ECG report and the ECG Data

- o Delete ECG Data : The ECG Data(s) recorded in the device shall be deleted. The ECG Data(s) can only be deleted if saved to your computer. The software will direct you to save all the ECG Data(s) recorded in the device before deleting.

 To exit the ECG Screen, all the ECG Data(s) shall be saved and deleted.
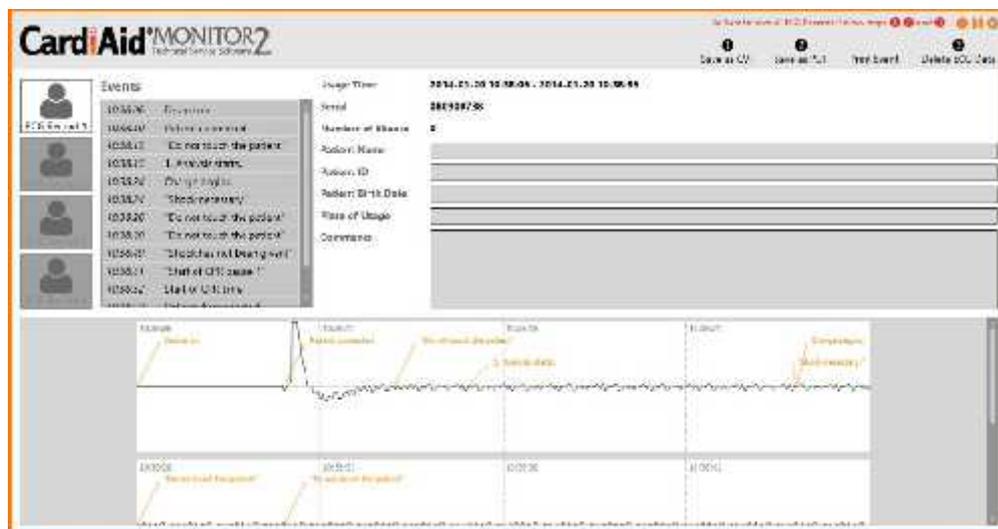
> ⚠️ ***If any event record is found in the memory of the device, the ECG data of the event(s) should be sent to Cardia International immediately.***

> ⚠️ ***If you use limited OFF-Line Mode, Make sure that you will send all saved ECG Data recorded in the device to Cardia International. The authorized technical service provider is responsible for loss of the recorded ECG Data(s) in the device.***

4.6.8. Removal of the old electrode set and the emergency kit

xv. After exiting the ECG Screen, CardiAid Monitor2 Technical Service Software will remind you to remove the old electrode set plugged in the device. Make sure the old electrode will not be reused if the expiry date will be earlier than the date of next maintenance (The shelf life of the electrode shall be more than 24 months)


xvi. Remove the emergency kit and check the existence and expiry date of the parts in the emergency kit.
xvii. Check whether any of the parts used. Then click "Next".

> ⚠️ ***Make sure to check each part in the emergency kit, and replace any of them if used or expired. The shelf life of the alcohol pad shall be at least more than 24 months.***

xviii. Close the cover of the device and then click "Next" to continue.
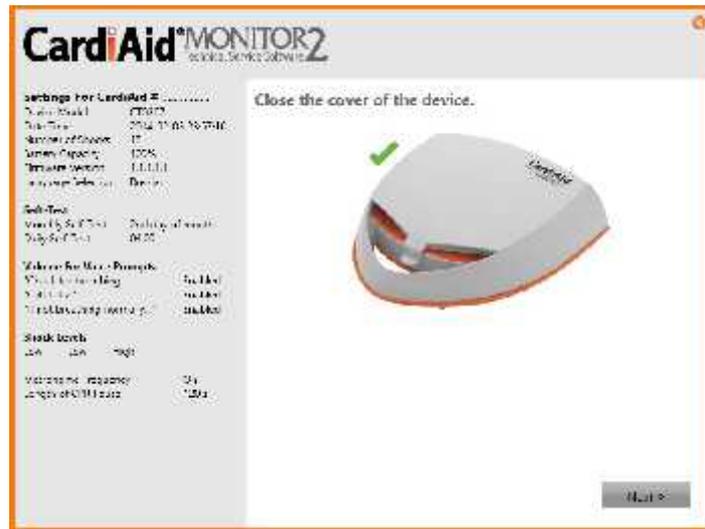
4.6.9. Electrode Detection Test (For CT0207RS and CT0207RF)

xix. You will be directed to the window showing the instructions for adult electrode test if the maintenance is performed for the AED models CT0207RS and CT0207RF.

xx. Make sure that the Defitester Adult Cable is not connected to the defitester and plug the Defitester Adult Cable to the socket of the AED.

xxi. Check the "Repair" status indicator is switched OFF and select "Yes" or "No"

The color of the Adult Cable is Grey and Orange and there are two pogo-pins on the plug of the cable.

If the "Repair" status indicator is not switched OFF and you click "No", you will be directed to "Problem Diagnosis".

xxii.   Unplug the Defitester Adult Cable and make sure the "Repair" status is switched ON again. Plug the Defitester Pediatric Cable to the socket of the AED.

xxiii. Check the "Repair" status indicator is switched OFF and select "Yes" or "No". Make sure "Pediatric electrodes connected" is played. Click "Next" to continue.
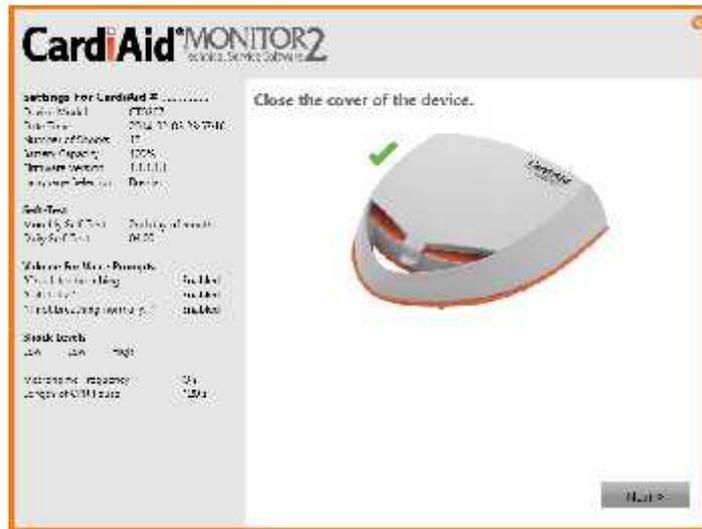
The color of the Pediatric Cable is Grey and Blue and there are two pogo-pins on the plug of the cable.

If the "Repair" status indicator is not switched OFF and you click "No", you will be directed to "Problem Diagnosis".

xxiv. Close the cover of the device and click "Next".

xxv.

Make sure you will not exit the software to follow the steps written in this technical manual. The screens of each step will assist you throughout the maintenance procedure.

4.6.10. Removal of old main battery

xxvi. Screw out the battery cover at the back of the unit and remove the battery compartment cover.

xxvii. Take the battery out from the battery compartment and plug off the battery connector.

4.6.11. Replacement of Lithium Button Cell Battery

This step is only applicable for CT0207. CardiAid Monitor2 Software will alert you the replacement time of the Lithium Button Cell Battery for models CT0207RS and CT0207RF

> **Perform these steps in an antistatic environment. Wear antistatic wristband connected to cable and use antistatic carpet before following the steps below.**

xxviii. Screw out all screws at the back of the unit.

xxix. Take off the back part of the housing from the orange separator, and be sure you do not separate it much.

xxx. Take off the battery cable as seen in the picture below.

> **DO NOT TOUCH the main board while taking off the battery cable!**

4.6.12. Removing old Lithium Button Cell

xxxi. After taking off the battery cable from the board, separate the back of the housing.

![Danger] **ALWAYS USE the discharger to discharge the capacitor just after the device is opened before starting any action. The High-Voltage can result in serious injury or death. Capacitor generally discharges itself automatically but be sure to discharge with discharger.**

xxxi. Remove the Lithium Button Cell Battery from the battery socket on the board and place the new one in the battery socket.

![Warning] **DO NOT USE this battery again! Make sure you will not mix the removed battery with the new one!**

![Warning] **USE ONLY CR2450 Lithium Button Cell Battery (RTC Battery) for CT0207RS and CT0207RF models!**

![Warning] **USE ONLY CR2032 Lithium Button Cell Battery (RTC Battery) for CT0207 models!**

xxxii. Connect the battery cable to the board; place the back of the housing and screw.

4.6.13. Installing new battery (Replacement of main battery)

xxxiii. Pick up a new battery pack. Check the battery production date and measure the voltage of the battery to make sure to use the battery.

> ⚠️ **Warning**
>
> *DATE OF REPLACEMENT ≤ PRODUCTION DATE OF THE BATTERY + 15 MONTHS*
> *USE only if the production date is appropriate.*

> ⚠️ **Warning**
>
> *The voltage measure should be more than or equal to 12.5 Volts. Use Only the battery if the battery voltage is more than or equal to 12.5 Volts.*

xxxiv. Type the serial number and the voltage level of the battery pack on the screen. Then connect the new battery to the battery connector and place the new battery in the battery compartment. After closing and screwing the cover of the battery compartment click "Next" to proceed.
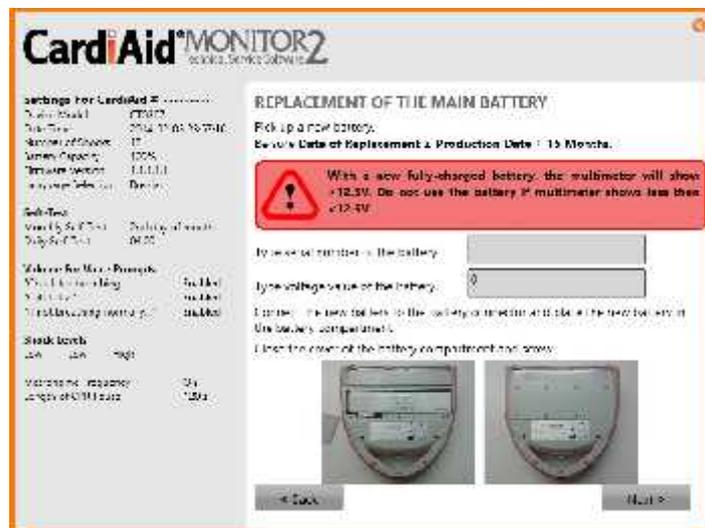
### 4.6.14. Setting Date and Time with CardiAid Monitor 2 Software

xxxv. Open the cover of the CardiAid to activate the Bluetooth module to connect to CardiAid by CardiAid Monitor 2 Software via Bluetooth and then Click "Search" to search and find the device under maintenance available for connecting.

CardiAid Monitor 2 Software can work with all Bluetooth devices if the driver of the Bluetooth will be changed to Microsoft Bluetooth device driver in Device Manager of your computer. (Cardia International recommends Belkin Bluetooth Dongle for the best communication performance.)
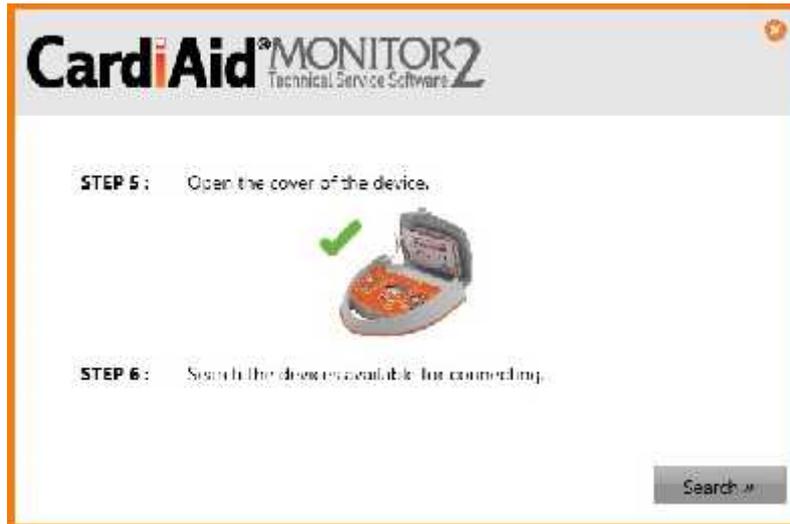
xxxvi. If the connection will be established the following screen to set date and time will be active. Click "Next" button. The date and time will be set automatically via internet. You can also set the time manually.
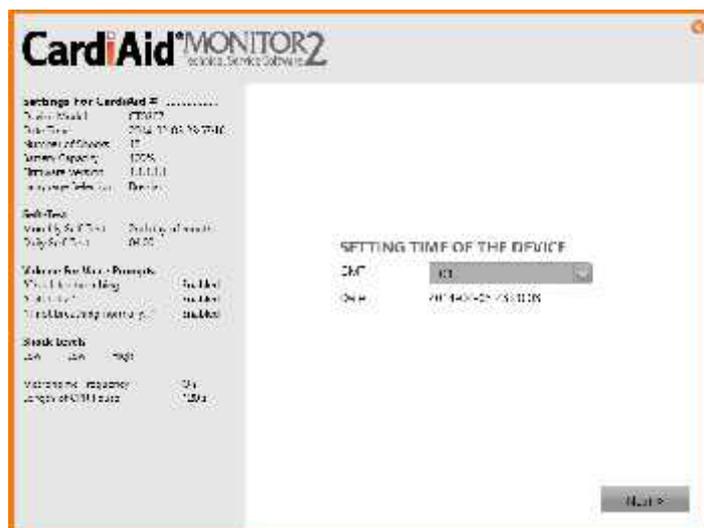
If the internet connection is lost or you are using limited OFF-Line mode, then the date and time should be set manually on the screen. In this case, Make sure that your computer's date and time settings are up to date; since the device will synchronise its date and time settings with your computer's date and time settings.

xxxvii.   Close the cover of the device and Click "Next" on the screen.
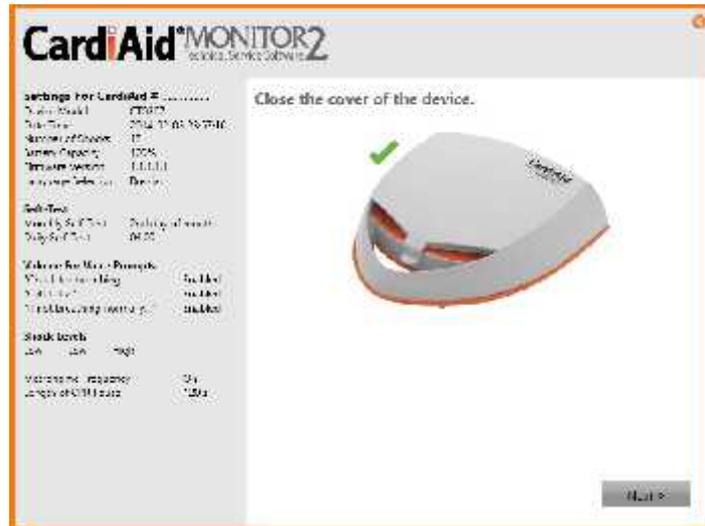
4.6.15. Measuring and Shock Test

It is recommended to check the shock level with the defitester (an electronic simulator of Ventricular Fibrillation and Ventricular Tachycardia, with an LCD Screen to show the energy consumed) before the replacement of the battery to check whether the functions of device are properly or not.

4.6.16. Testing Operation With Shock

xxxviii.   Open the cover to start CardiAid AED and switch ON the Defitester. Then click "Next" on the screen.
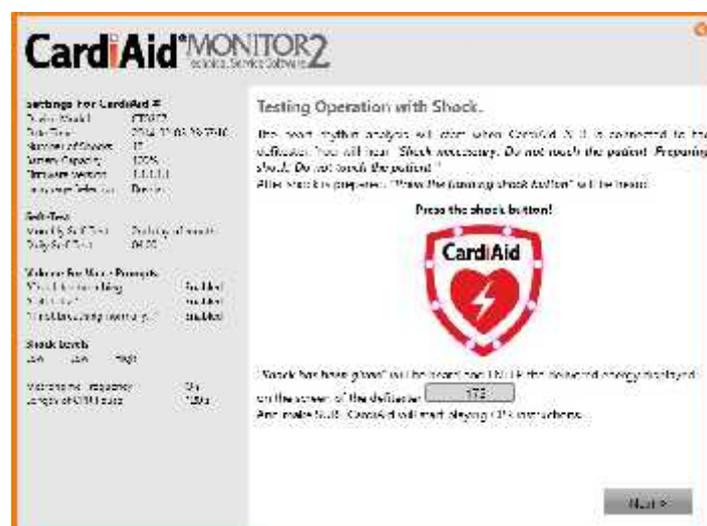
xxxix. Switch the defitester mode to a shockable rhythm (Press VFIB button of the defitester) and connect CardiAid AED to the defitester. Click "Next" to continue.

 For CT0207 and CT0207RS semi-automatic models only;

xl. Check if CardiAid AED operates as described below:

  - o The heart rhythm analysis will start when CardiAid AED is connected to the defitester.
  - o "Shock necessary. Do not touch the patient. Preparing shock. Do not touch the patient." will be heard.
  - o After shock preparation is completed, "Press the flashing shock button." will be heard.

xli. Press the shock button immediately and make sure CardiAid will behave as below:

  - o CardiAid will deliver the shock when the shock button is pressed. "Shock has been given." will be heard and CardiAid will go to CPR phase.

xlii. The energy value will be displayed on the screen of the defitester. Type the displayed energy value on the open screen of the CardiAid Monitor2 software and make sure CardiAid will assist the user with verbal instructions for 2 minutes of CPR (default setting). Click "Next" to proceed to the new step.

For CT0207RF full-automatic model the following screen will be displayed on the screen of the software. You will not be directed to press the flashing shock button. The shock will be applied automatically.

Check if CardiAid AED operates as described below:

- o The heart rhythm analysis will start when CardiAid AED is connected to the defitester.
- o "Shock necessary. Do not touch the patient. Preparing shock. Do not touch the patient." will be heard.
- o After shock preparation is completed, you will hear "Shock delivered"
- o CardiAid will deliver the shock automatically after this statement and "Shock has been given." will be heard and CardiAid will go to CPR phase.

Then enter the delivered energy on the screen displayed on the screen of the defitester. Disconnect the defitester and CardiAid AED. Close the cover of the AED and click "Next".

4.6.17. Testing Operation without pressing shock button (Only for models CT0207 and CT0207RS)

> ⚠️ **You will not be directed to this screen if you perform the maintenance for CT0207RF Full Automatic model**

xliii. Disconnect the defitester and CardiAid AED. Close the cover and then open again to restart CardiAid AED. Make sure the defitester is still ON.

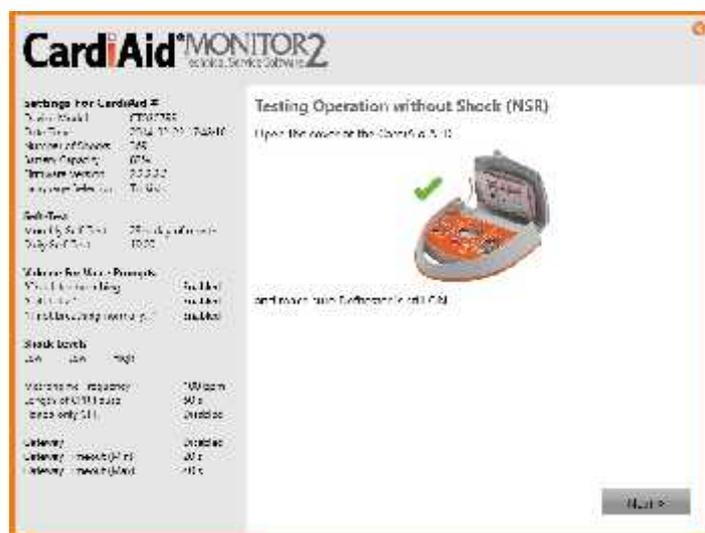**xxxi.** Plug the defitester cable to CardiAid AED. Check if CardiAid AED operates as described below:

- The heart rhythm analysis will start when CardiAid AED is connected to the defitester.
- "Shock necessary. Do not touch the patient. Preparing shock. Do not touch the patient." will be heard.
- After shock preparation is completed, "Press the flashing shock button." will be heard.

xxxii. To check "The shock will not be given", do not press the shock button and make sure you observe the following;

- o CardiAid will not deliver the shock when the shock button is pressed. "Shock not given." will be heard and CardiAid will go to CPR phase.
- o CardiAid will assist the user with verbal instructions for 2 minutes of CPR.

xxxiii. Disconnect the defitester and switch off CardiAid by closing the cover and then press "Next" to continue.

4.6.18. Testing Operation Without Shock

xxxiv. Open the cover and start CardiAid AED and make sure the defitester is still ON. Click "Next" to proceed.

xxxv. Switch the mode of the defitester to a non-shockable rhythm (Press NSR button of the defitester) and plug the defitester adult cable to CardiAid AED.

xxxvi. Check if CardiAid AED operates as described below:

- o The heart rhythm analysis will start when CardiAid AED is connected to the defitester.
- o "Shock not advised" will be heard and CardiAid will go to CPR phase.
- o CardiAid will assist the user with verbal instructions for 2 minutes of CPR.

xxxvii. Switch off CardiAid AED by closing the cover and click "Next" to continue.
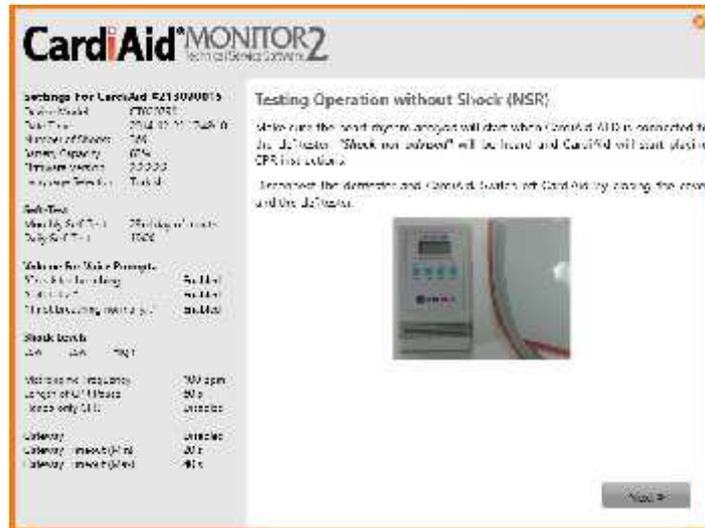
4.6.19. Testing Operation With Shock (Paediatric Mode of CT0207RS & CT0207RF)

 You will not be directed to this screen if you perform the maintenance for CT0207.

xxxviii. Open the cover to start CardiAid AED and make sure the Defitester is still ON. Then click "Next" on the screen.
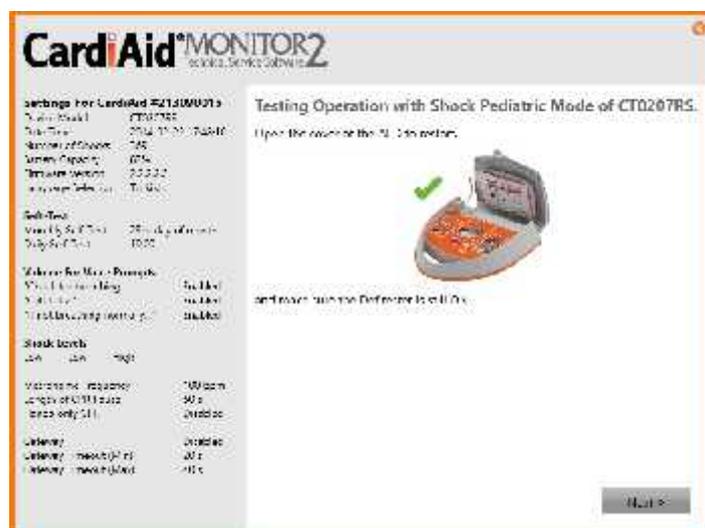
xxxix. Switch the defitester mode to a shockable rhythm (Press VFIB button of the defitester) and connect CardiAid AED to the defitester with defitester paediatric cable. Click "Next" to continue.
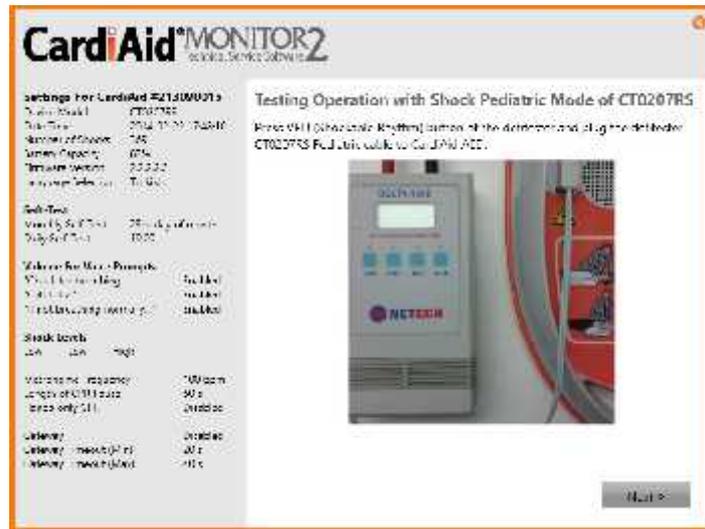
xliv. Check if CardiAid AED operates as described below:

- o The heart rhythm analysis will start when CardiAid AED is connected to the defitester.
- o "Shock necessary. Do not touch the patient. Preparing shock. Do not touch the patient." will be heard.
- o After shock preparation is completed, "Press the flashing shock button." will be heard.

xlv. Press the shock button immediately and make sure CardiAid will behave as below:

- o CardiAid will deliver the shock when the shock button is pressed. "Shock has been given." will be heard and CardiAid will go to CPR phase.

xlvi. The energy value will be displayed on the screen of the defitester. Type the displayed energy value on the open screen of the CardiAid Monitor2 software and make sure CardiAid will assist the user with verbal instructions for 2 minutes of CPR (default setting). Click "Next" to proceed to the new step.

For CT0207RF full-automatic model the following screen will be displayed on the screen of the software. You will not be directed to press the flashing shock button. The shock will be applied automatically.

Check if CardiAid AED operates as described below:
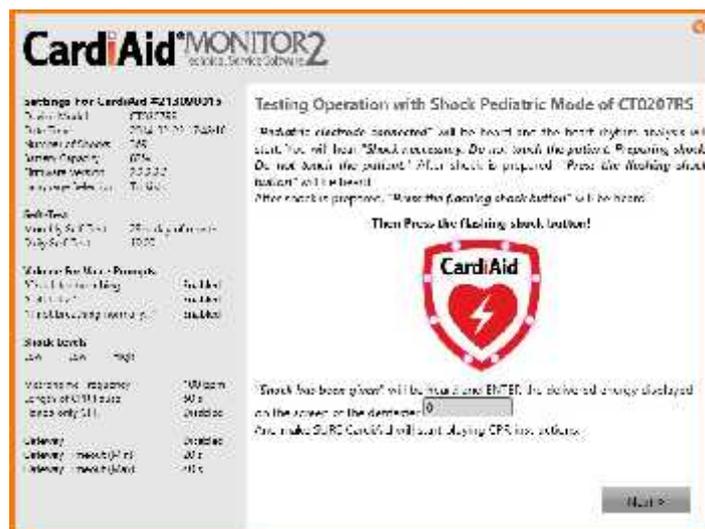
- o The heart rhythm analysis will start when CardiAid AED is connected to the defitester.
- o "Shock necessary. Do not touch the patient. Preparing shock. Do not touch the patient." will be heard.
- o After shock preparation is completed, you will hear "Shock delivered"
- o CardiAid will deliver the shock automatically after this statement and "Shock has been given." will be heard and CardiAid will go to CPR phase.

Then enter the delivered energy on the screen displayed on the screen of the defitester. Disconnect the defitester and CardiAid AED. Close the cover of the AED and click "Next".

xlvii. Disconnect the defitester and CardiAid AED. Close the cover of CardiAid AED and switch OFF the defitester.

4.6.20. Get & Delete ECG Data after testing operation

xlviii. You need to connect CardiAid AED again to get and delete the ECG Data of the testing operation. Open the cover of the AED and Click "Connect".

4.6.21. ECG Screen

Reading ECG DATA will take almost 1 minute and then ECG screen will pop-up.
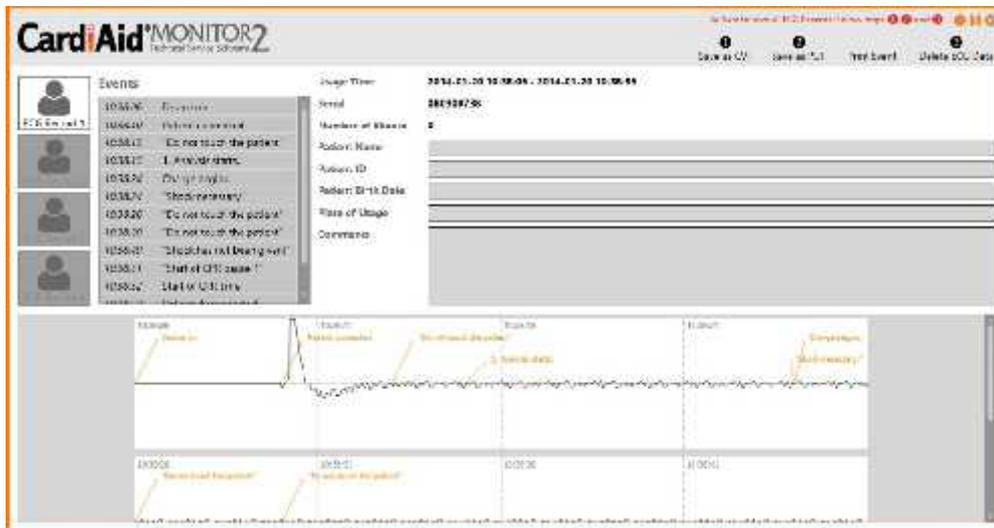
xlix. Fill in patient information: Patient name, Patient ID, Patient Birth Date, Place of Usage.

l. Then first (1) click on "Save as CVF" button, select the destination and save ECG data (there may be more than 1 record in device's memory. Make sure you saved all records before exiting the software).

li. Secondly (2) click on "Save as PDF" button to save the ECG Data in pdf.

lii. As a final step on this screen, click on "Delete ECG Data" to delete all the ECG Data(s) recorded in the device during testing operation. You can exit the screen if all ECG Data(s) are saved and deleted.

Make sure you will not exit the screen before saving the ECG Data(s) recorded in all 4 events.

4.6.22. Resetting Battery Counter

liii. After saving and deleting the ECG Data(s) and click "Exit" on the ECG Screen, the battery capacity needs to be set. Click on the "Next" button to reset the battery.
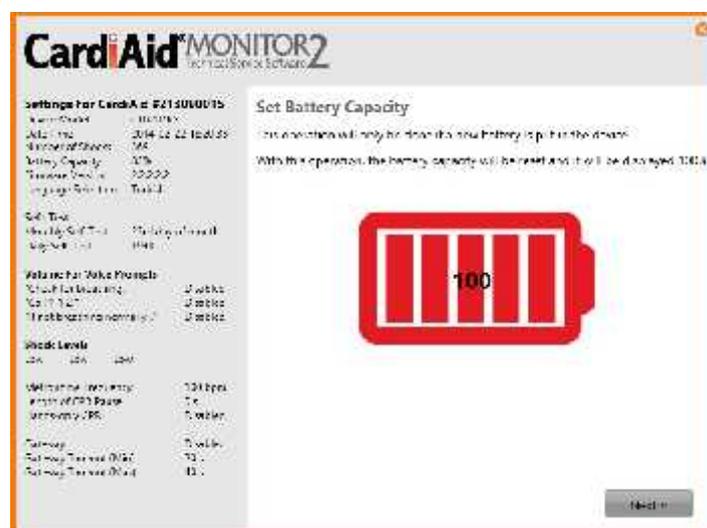
liv. Close and open the cover of the device to check the Battery Symbol is OFF. Click "Yes" if the Battery Symbol is OFF. If not click "No" to go to "Problem Diagnosis".

4.6.23. Save Device Settings

lv. Click "Save Device Settings" to save the settings of the AED to your computer.

4.6.24. Check of Emergency Kit

lvi. Check the content of the emergency kit and replace if the shelf-life of any part inside was expired or used. Click "Yes" or "No" to confirm if emergency kit replaced or not.

4.6.25. Replacement of Electrodes

lvii. Pick up a new electrode which should be suitable to the model of the CardiAid AED. Check the batch no and production date of the electrode, to type on the screen of the software.

lviii. Plug the electrode and then place the electrode pouch in front of the emergency kit bag.

lix. Make sure that the electrode is detected and the "Repair" status indicator is switched OFF. **(ONLY FOR CT0207RS and CT0207RF)**

⚠ *Warning* **DATE OF REPLACEMENT ≤ PRODUCTION DATE OF THE ELECTRODE + 12 MONTHS**
USE only if the production date is appropriate.

⚠ *Warning* **MAKE SURE CA-10ES Adult Electrode will be used for CT0207 and CR-13A Adult Electrode will be used for CT0207RS and CT0207RF.**

4.6.26. Stick the maintenance label

lx. Fill in the "2nd Year Maintenance" or "4th Year Maintenance", Service Provider ID, Date of the day maintenance will be performed and Date of Next Maintenance on the "Periodical Maintenance Sticker" and stick it on the back of the unit exactly as shown in the pictures below (First, remove the "Battery Sticker" on left-top side and stick the maintenance sticker at this place).

For After-Use Maintenance you have to use "After Use Maintenance Label".

For Before Sales Maintenance you have to use "Battery Label".

For After-Use Maintenance

Fill the Service Provider ID and Date of Maintenance on the after-use maintenance sticker. Stick the label on the right side of back of the AED.
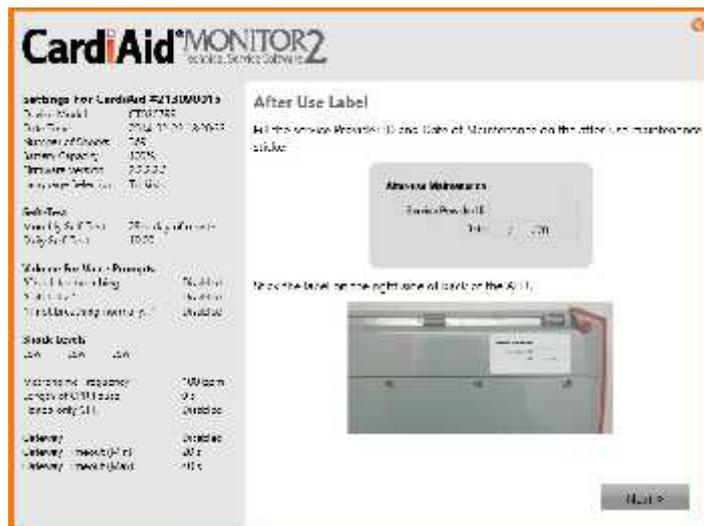
For Before Sales Maintenance

Fill the next battery replacement day on the empty Battery Label. Stick the label on the old battery label.
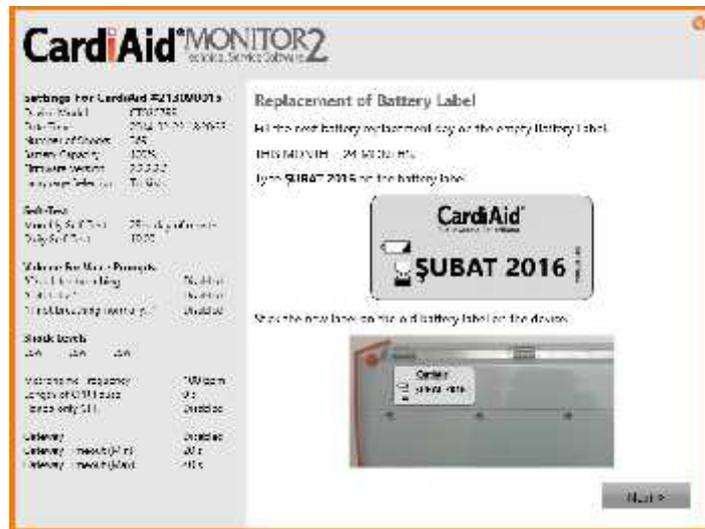
 The Battery Replacement Date should be THIS MONTH + 24 MONTHS

4.6.27. Labeling "Warranty Seal Sticker"

lxi. Stick the "Warranty Seal Sticker" on the battery cover of the device **<u>exactly</u>** as shown on the picture below and click on "Next".

4.6.28. Final Check

lxii. Open and close the cover once more and Make sure

- The Battery Symbol is off.
- The opening "Beep" sound is played.
- All LEDs are ON and OFF.
- The first step on the front foil is active and GREEN OK status indicator is ON.

lxiii. Check the box to confirm if everything is OK.

lxiv. Check CardiAid very carefully if there is any damage at any part of the unit once more. Click "Confirm" if everything is Ok. Then Click on "Next" to continue.

![Warning triangle] ***If the Repair Symbol is flashing and/or any damage is found on CardiAid, follow Problem Diagnosis Procedure.***

![Warning triangle] ***Make sure all filled forms (Maintenance Form, Printed Device Settings, Usage Form, Maintenance Report etc.) and "Incident Report" (if a record is found in the memory) are sent to Cardia International immediately after completing the maintenance.***

xxxi. The software will display "Maintenance Completed" screen. At this stage, the maintenance is completed and the authorized technical service provider is asked to click on the buttons on the screen to receive the maintenance files.

Maintenance Report : The maintenance report shows the actions completed in maintenance and issued for each device tested and checked in maintenance. This report is prepared to be presented to the customers. The example of this report may be found in ***Appendix 5***.

Maintenance Check List : The checklist showing all steps covered and completed during the maintenance. The technical service provider is asked to keep the checklist for each device for future maintenances. The example of this report may be found in ***Appendix 6***.

Device Settings : Settings of the device. It is important to save the device settings after setting the device settings. See ***Appendix 7***.

Usage Form : This report is only active in after-use maintenance. The technical service provider is asked to fill this form and share with Cardia International. The example of this report may be found in ***Appendix 8***.

Archive **:** This button is used to save all active reports in zip file.
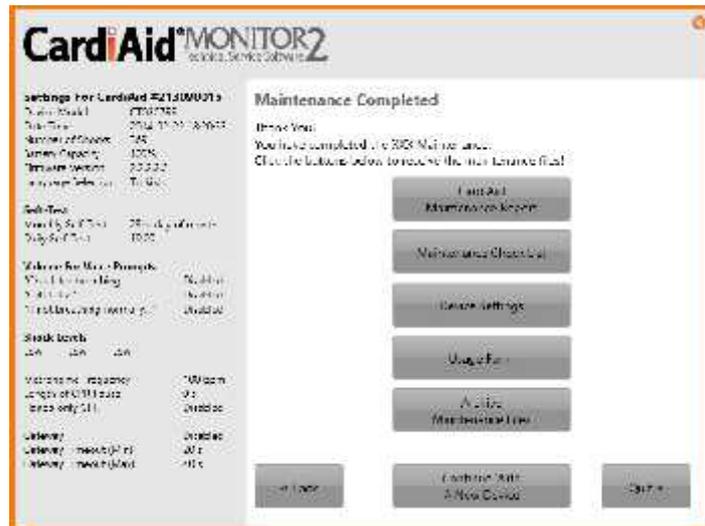
This screen is not active in Limited OFF-Line Mode. The following two screens will be seen in Limited OFF-Line Mode after completing the Final Check!
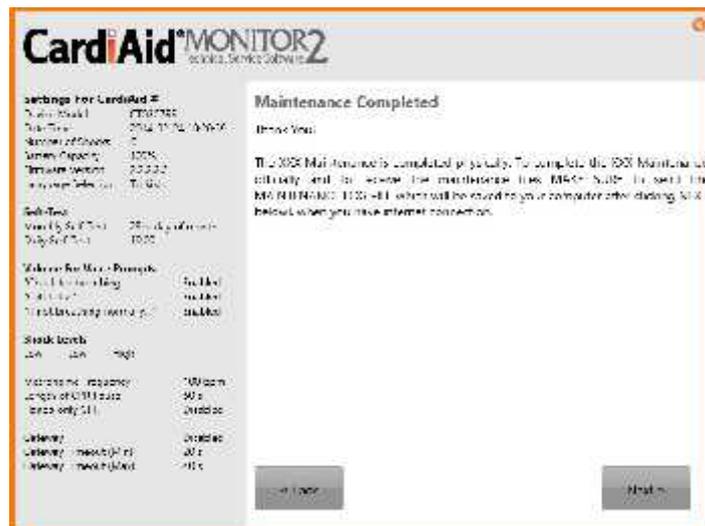
In this "Maintenance Completed" Screen in limited OFF-Line Mode, the technical service provider will be asked to click on "Next" to save the maintenance log file automatically to the computer. Make sure you will forget the location of the file saved in your computer!

Make sure you will send the maintenance log file by email to Cardia International when there is internet connection to complete the maintenance officially. If the maintenance log file will be sent to Cardia International, you will be receiving all official maintenance files for each device from Cardia International!

The maintenance log file can also be sent using the CardiAid Monitor 2 software when you will have internet connection.

xxxii. After downloading all maintenance files click on "Quit" to complete the maintenance. You can click on "Continue with new device" if you will have to perform maintenance to other devices.

4.6.29. Sending Maintenance Log File

The maintenance log file, saved at the end of maintenance in limited OFF-Line mode, can also be sent using the CardiAid Monitor 2 Technical Service Software when you will have internet connection.

a. Log in with CardiAid Monitor 2 Technical software and follow the steps as described in Section 4.6 "Performing Maintenance".

b. Select "Send Maintenance Log File" in Step "iv" of "Periodical Maintenance". After clicking "Send Maintenance Log File", the browser of your computer will be swiched ON. Find and select the maintenance log file of the device.

![Attention icon] **Make sure you will find the location of the maintenance log file saved for the correct serial number.**

c. Open the file selected. Then you will see the following screen of the Technical Service Software. This is process of sending "Maintenance Log File" and receiving "Maintenance Reports" of the device. Following this screen, you will see the zip files on your computer where you will find all maintenance reports of the device that you completed the maintenance. At this stage the maintenance is completed officially in limited OFF-Line mode.

5. VIEW SETTINGS

CardiAid Monitor 2 Technical Service Software shall be used to view and change the settings of CardiAid AED. The software will state "CONNECTED TO THE DEVICE" and show the status of CardiAid connected. At this stage if you click on "VIEW SETTINGS" the following screen will be displayed.


If you change any settings, "Settings will be changed" will be displayed.

You can change the volume level, enable/disable voice prompts, change metronome frequency and length of CPR pause, enable/disable Gateway function and Hands Only CPR/Mode.

To change volume level, click on drop down menu on **volume level tab** and select "Soft", "Normal", "Loud" and "Very Loud". To save the settings make sure you click on "Save Device Settings" before exit. The default setting is "Very Loud".
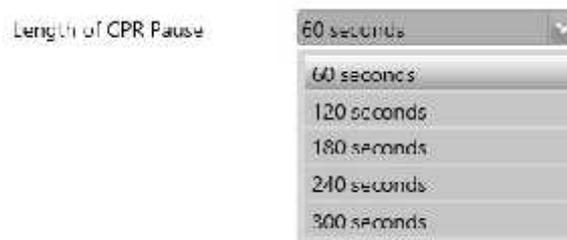
Voice Settings

Language Selection	Turkish
Volume Level	Very Loud
	Soft
	Normal
	Loud
	Very Loud
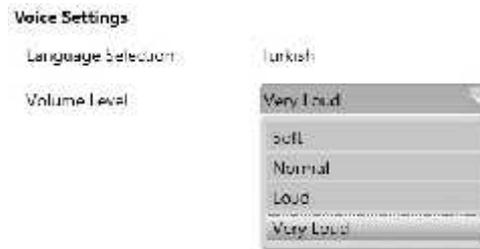
To enable/disable voice prompts, click on drop down menu on each voice prompts tab and select "On" or "OFF". To save the settings make sure you click on "Save Device Settings" before exit. The default setting is "ON".

Voice Prompts

"Check for breathing."	On
"Call 1 1 2."	On
"If not breathing normally…"	On
	Off
	On

⚠️ **The settings below cannot be performed in limited OFF-Line Mode. You need to have internet connection to proceed with the following actions.**

To change length of CPR Pause, click on drop down menu on **Length of CPR Pause tab** and select "60 seconds", "120 seconds", "180 seconds", "240 seconds" and "300 seconds". To save the settings make sure you click on "Save Device Settings" before exit. The default setting is "180 seconds".

Length of CPR Pause	60 seconds
	60 seconds
	120 seconds
	180 seconds
	240 seconds
	300 seconds

To change metronome frequency, click on drop down menu on **metronome frequency tab** and select "OFF", "100 bpm", "110 bpm" and "120 bpm". To save the settings make sure you click on "Save Device Settings" before exit. The default setting is "100 bpm". If you select "OFF", then the metronome will not be played.

Metronome Frequency

| 100 bpm ▼ |
| Off |
| 100 bpm |
| 110 bpm |
| 120 bpm |

To enable/disable Gateway function, click on drop down menu on **Gateway tab** and select "ON" or "OFF". To save the settings make sure you click on "Save Device Settings" before exit. The default setting is "OFF".
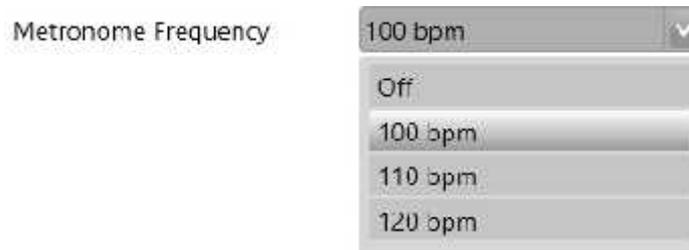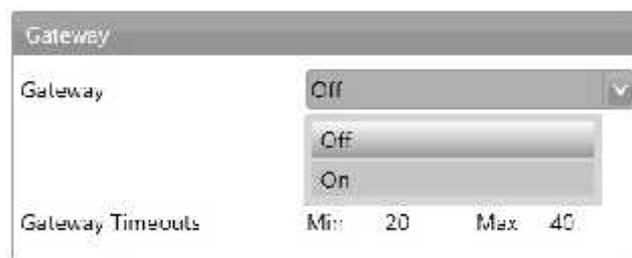
Gateway

Gateway	Off ▼	
	Off	
	On	
Gateway Timeouts	Min: 20	Max 40

To enable/disable Hands-only CPR function, click on drop down menu on **Hands-only CPR tab** and select "ON" or "OFF". To save the settings make sure you click on "Save Device Settings" before exit. The default setting is "OFF".

Hands-only CPR

| Off ▼ |
| Off |
| On |

6. PROBLEM DIAGNOSIS

6.1. Problems and Solutions

A. Problem A: Battery Symbol and Repair Symbol lights or flashes simultaneously, and the maintenance date is not overdue. (For CT0207, CT0207RS and CT0207RF models!)

You have to use CardiAid Monitor 2 Technical Software to check the problem of the CardiAid AED. Make sure that you will have internet connection in your computer to use the online version of the software.

a. Log in with CardiAid Monitor 2 Technical software and follow the steps as described in Section 4.6 "Performing Maintenance".

b. Please select "New Device" in Step "iv" of "Periodical Maintenance" and continue till Step "x".

c. You will be directed to the screen below to state that "Device is not ready to use". To plug a test battery click on "Next".

d. Screw out the battery cover at the back of the unit and take the main battery off.

e. Take the battery out from the battery compartment and take out the battery connector. Click on "Next" to proceed.

f. Measure the voltage of the battery removed. If the voltage of battery removed is less than 11.5 Volts, use a test battery. Click on "Next" to proceed.

 Make sure to use the battery if the voltage of the battery is more than 11.5 Volts. Otherwise pick up a test battery which is more than 11.5 Volts to install.

g. Connect the battery to the battery connector and place the battery in the battery compartment. Close the battery compartment cover and screw. Click on "Next" to proceed.

h. Check status indicators of CardiAid AED once again while the cover is closed and select "Flashing", "ON" or "OFF" for each status indicators and click on "Next".
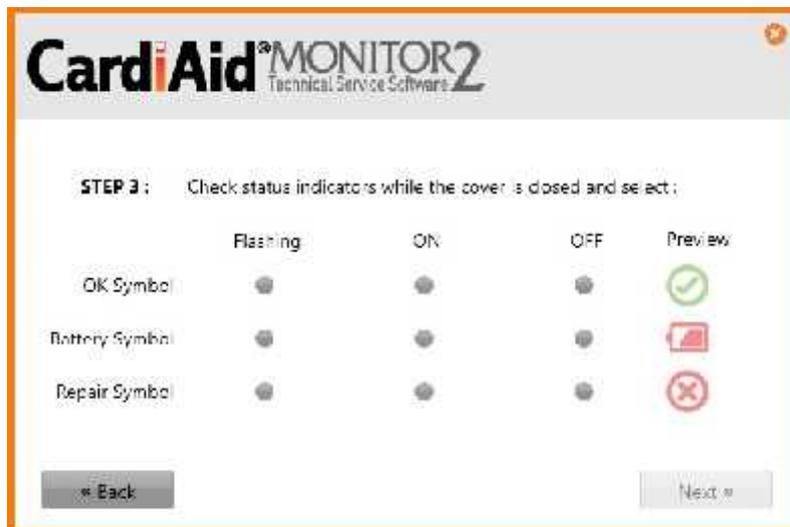
i. Open the cover of the CardiAid AED to activate the Bluetooth module. Click on "Next" to connect to the device again.

j. CardiAid Monitor2 Technical Service Software will be connected automatically to the device with the serial number typed in "***Filling serial number of CardiAid AED***" to the software if the cover of the device is open and the serial number typed in is correct. If the connection to the device is failed, click "Search" once again to start searching the device(s) with the cover open.

> ***Make sure that the cover of the device is not closed. If the cover is closed, the connection cannot be established.***

k. At this stage, the software will show the status of the device. The software will instruct you to proceed according to "Not Ready to Use" or "Ready to Use".

Ready To Use

If the problem is due to the voltage of the battery, the status of the device will be "Ready to Use". You will be directed to the screen below. At this stage you can also perform the maintenance.

Not Ready To Use

1. If the status of the device is "Not Ready to Use.", the following screen will instruct you to report the problem to Cardia International for diagnosis and action. Please click on "Report to Cardia International" to proceed.

2. When the report was sent to Cardia International, the software will inform you with the following screen. Click on "OK".

3. At this stage the software will display the screen to check the status of the device.

 Make sure you do not click on "Check Status" immediately after sending report to Cardia International. If Cardia International has not completed the process of checking the report, the software will display the following screen :

 Make sure you wait for the email from Cardia International with the subject "Your product status has been changed: serial number of the device" to proceed.

4. Wait for the email to continue or Click on "Exit" to quit the software or click on "New Process" to perform an action with a new device. If you wait, you can keep the cover of the device open or closed!

5. You will receive the following email with the subject "Your product status has been changed: serial number of the device" from Cardia International.

   Please login CardiAid Monitor2 Technical Service Software and click on "Check Status of Pending Devices" to proceed.

6. Click on "Check Status" at this stage, if the screen is still active on your desktop. The software will instruct you to proceed according to the analysis of the problem reported.
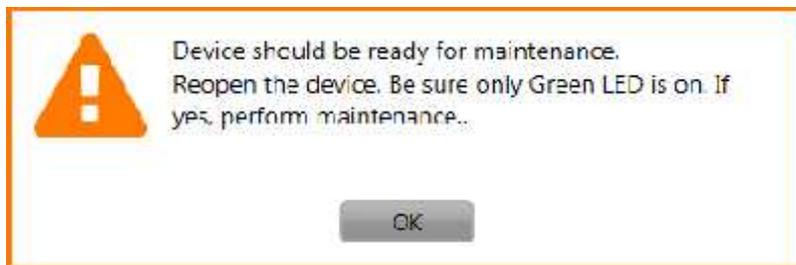
If the problem is related with the late maintenance or battery

The software will display the following screen to instruct you to unlock the device. First make sure that the cover of the device is open and then Click on "Unlock" to unlock the device to proceed. The software will connect to the device to unlock the device.

⚠ ***If the cover of the device is not open the software will warn you that connection cannot be established. Make sure that you open the cover of the device before you click on "Unlock"***

The software will inform you that "Device should be ready for maintenance". At this stage the battery or late maintenance status should be settled and Only the Green LED should be ON. You will be instructed to close and reopen the cover of the device again to check the status indicators. If ONLY Green Led is ON, click on "OK" to proceed with maintenance.

If the device needs to be sent back to Cardia International for further check and repairing,

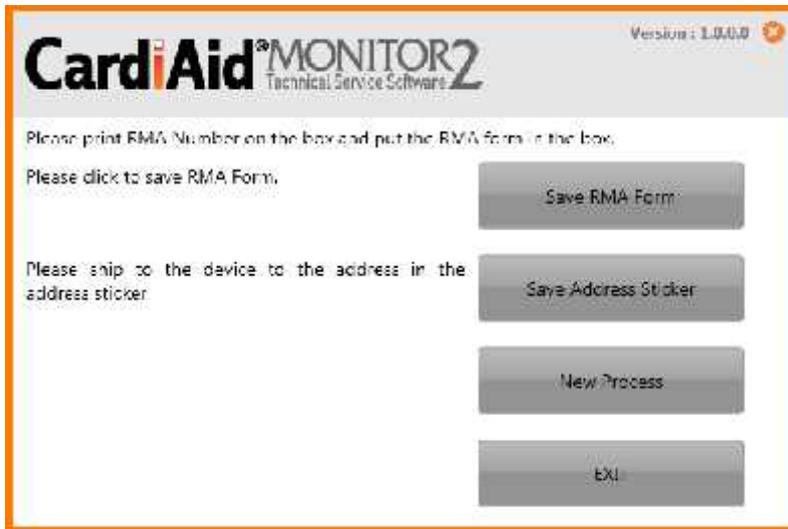The software will display you the RMA number assigned for the device and asks you to fill in the questions in the following screen.

Click on if you observe any of them, and type in if you observe other problems additionally. Click on "Next" to proceed.

The software will display the following screen to instruct you to select the accessories included in the RMA-device. Select the accessories and click on "Confirm".

The next screen will display the commands to save the RMA Form. Click on "Save RMA Form" to save the RMA form to your computer. Please print the RMA form that you have to put inside the box of the device. If you click on "Save Address Sticker" you will receive "ship to address" and make sure you stick the "address sticker" on the box and ship the device to the "ship to address" written on the sticker!

If you click on "New Process" you can continue with a new process and exit the software by clicking on "Exit".

Checking Status of Pending Devices

If you exit the software or the screen to wait for the email from Cardia International, you have to login CardiAid Monitor2 Technical Software again to check the status of the device(s)

You can send the report for more than one device and login the software to check the status of the devices when you receive the email about all devices you sent report for.

a. Log in with CardiAid Monitor 2 Technical software and follow the steps as described in Section 4.6 "Performing Maintenance".

b. Please click on "Check Status of Pending Devices" in Step "iv" of "Periodical Maintenance"

c. The software will display the following screen showing the status of your pending devices. Select the device which you received the "Check Status" email from Cardia International.

If the status is "Waiting for your action"

If the status is "Waiting for your action", and you will select the device with "Waiting for your action" and then click on "Next", the software will display the following screen to instruct you to unlock the device. First make sure that the cover of the device is open and then Click on "Unlock" to unlock the device to proceed. The software will connect to the device to unlock the device.

If the cover of the device is not open the software will warn you that connection cannot be established. Make sure that you open the cover of the device before you click on "Unlock"

The software will inform you that "Device should be ready for maintenance". At this stage the battery or late maintenance status should be settled and Only the Green LED should be ON. You will be instructed to close and reopen the cover of the device again to check the status indicators. If ONLY Green Led is ON, click on "OK" to proceed with maintenance.

If the status is "Click for RMA"

If the status is "Click for RMA", and you will select the device with "Click for RMA" and then click on "Next", the software will display you the RMA number assigned for the device and asks you to fill in the questions in the following screen.

Click on if you observe any of them, and type in if you observe other problems additionally. Click on "Next" to proceed.

The software will display the following screen to instruct you to select the accessories included in the RMA-device. Select the accessories and click on "Confirm".

If the status is "Click for RMA"

The next screen will display the commands to save the RMA Form. Click on "Save RMA Form" to save the RMA form to your computer. Please print the RMA form that you have to put inside the box of the device. If you click on "Save Address Sticker" you will receive "ship to address" and make sure you stick the "address sticker" on the box and ship the device to the "ship to address" written on the sticker!

If you click on "New Process" you can continue with a new process and exit the software by clicking on "Exit".

If the status is "Under Process"

You cannot click on "Under Process" at this screen but you can observe the status of your devices anytime if you click on "Check Status of Pending Devices".

B. **Problem B: Repair Symbol lights or flashes simultaneously. (For CT0207, CT0207RS and CT0207RF models!)**

Follow **Problem A**.

C. Problem C: Status indicators do not light or flash for a period of time during operation. (For CT0207, CT0207RS and CT0207RF models!)

You have to use CardiAid Monitor 2 Technical Software to check the problem of the CardiAid AED. Make sure that you will have internet connection in your computer to use the online version of the software.

a. Log in with CardiAid Monitor 2 Technical software and follow the steps as described in Section 4.6 "Performing Maintenance".

b. Please select "New Device" in Step "iv" of "Periodical Maintenance" and continue till Step "iv". Select "OFF" for all indicators and click on "Next"

c. The following screen will be active. Open the cover of the device and check there is a voice guidance or not. Select "Yes" if you hear the voice prompts.

d. The software will display you the RMA number assigned for the device and asks you to fill in the questions in the following screen. Click on if you observe any of them, and type in if you observe other problems additionally. Click on "Next" to proceed.
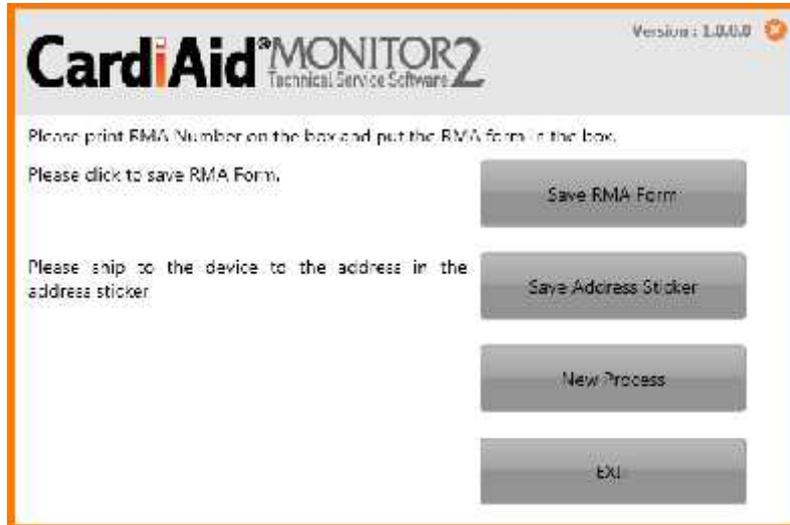

e. The software will display the following screen to instruct you to select the accessories included in the RMA-device. Select the accessories and click on "Confirm".

f.   The next screen will display the commands to save the RMA Form. Click on "Save RMA Form" to save the RMA form to your computer. Please print the RMA form that you have to put inside the box of the device. If you click on "Save Address Sticker" you will receive "ship to address" and make sure you stick the "address sticker" on the box and ship the device to the "ship to address" written on the sticker!

g.   If you click on "New Process" you can continue with a new process and exit the software by clicking on "Exit".

D. None of the visual/acoustic messages are active; there is no sound or light when the device is opened. (For CT0207, CT0207RS and CT0207RF models!)

You have to use CardiAid Monitor 2 Technical Software to check the problem of the CardiAid AED. Make sure that you will have internet connection in your computer to use the online version of the software.

a.   Log in with CardiAid Monitor 2 Technical software and follow the steps as described in Section 4.6 "Performing Maintenance".

b.   Please select "New Device" in Step "iv" of "Periodical Maintenance" and continue till Step "iv". Select "OFF" for all indicators and click on "Next"

c. The following screen will be active. Open the cover of the device and check there is a voice guidance or not. Select "No" if you do not hear the voice prompts to test the device with test battery.

d. There is no power on the AED. Screw out the battery cover at the back of the unit and Make sure the battery is connected. If the battery is connected unplug it and take the main battery off.

e. Take the battery out from the battery compartment and take out the battery connector. Click on "Next" to proceed.

f. Measure the voltage of the battery removed. If the voltage of battery removed is less than 11.5 Volts, use a test battery. Click on "Next" to proceed.

⚠️ **_Make sure to use the battery if the voltage of the battery is more than 11.5 Volts. Otherwise pick up a test battery which is more than 11.5 Volts to install._**

g.   Connect the battery to the battery connector and place the battery in the battery compartment. Close the battery compartment cover and screw. Click on "Next" to proceed.

h.   After closing the cover, open the cover of the AED again to observe the device starts operation or not. Click "Yes" if the device starts operation.

Clicking "Yes"
If you Click "Yes" the following screen will be displayed. Select the status indicators and click on "Next".
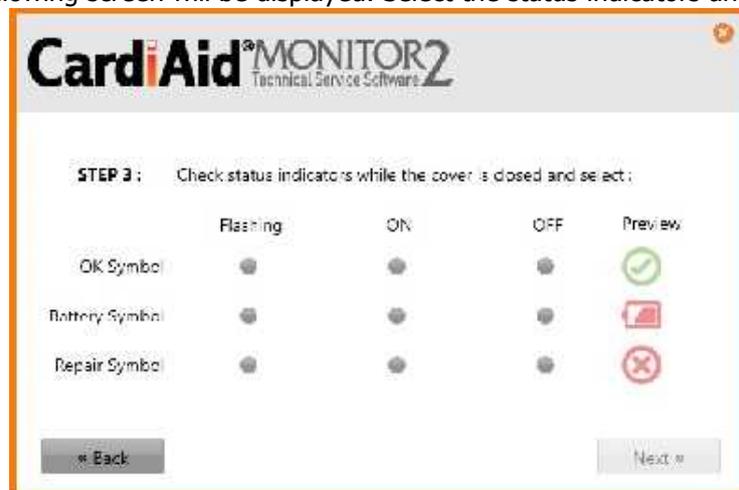
When you will click on "Next", the software will connect to the device informing you the status of the device. Proceed with the screens according to the status.
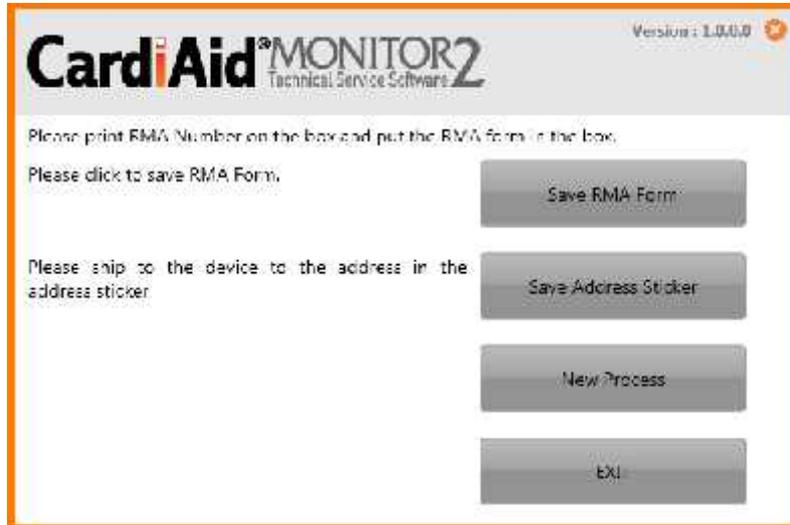
Clicking No

If you Click "No" ;

    a. The software will display you the RMA number assigned for the device and asks you to fill in the questions in the following screen. Click on if you observe any of them, and type in if you observe other problems additionally. Click on "Next" to proceed.

    b. The software will display the following screen to instruct you to select the accessories included in the RMA-device. Select the accessories and click on "Confirm".

c. The next screen will display the commands to save the RMA Form. Click on "Save RMA Form" to save the RMA form to your computer. Please print the RMA form that you have to put inside the box of the device. If you click on "Save Address Sticker" you will receive "ship to address" and make sure you stick the "address sticker" on the box and ship the device to the "ship to address" written on the sticker!
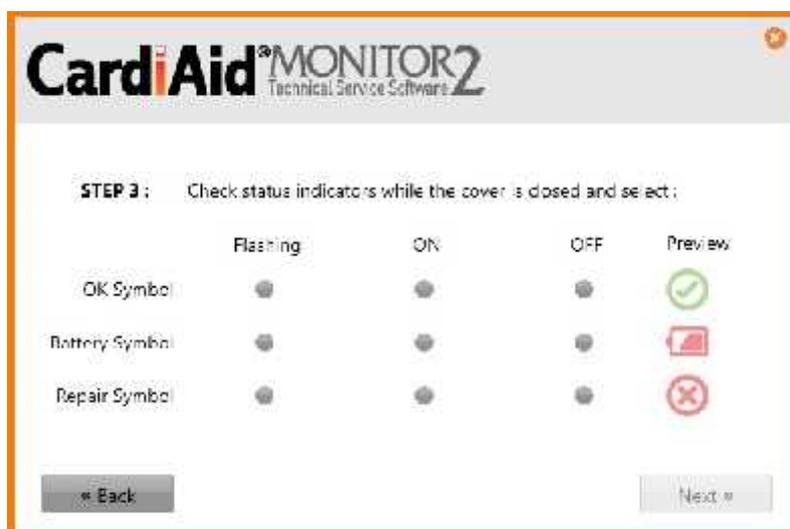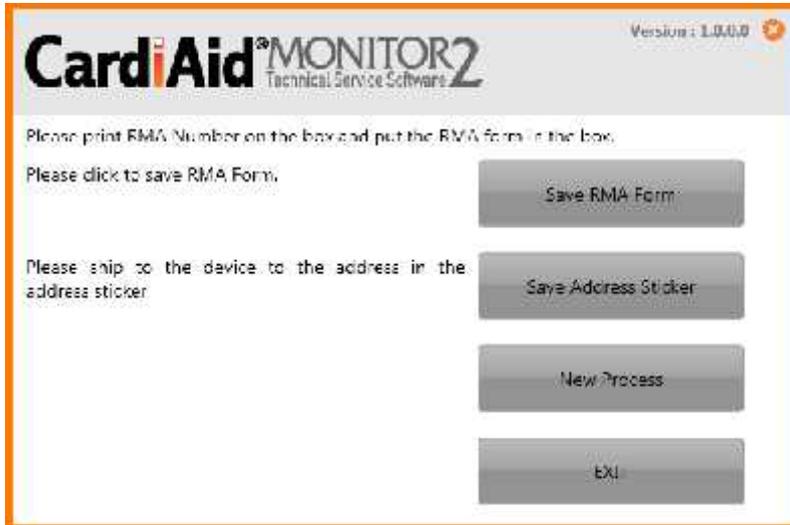

d. If you click on "New Process" you can continue with a new process and exit the software by clicking on "Exit".

6.2. RMA Procedure

If you observe a visual or mechanical problem, or problems with a CardiAid AED device which cannot be settled with CardiAid Monitor2 Technical Service Software, follow the steps below:

- Go to servicepartners.cardiaid.com
- Log in with your Service Provider ID and Password.
- Fill in the descriptive form.

According to the problem, you will be directed by the system.

You may also be asked to visit servicepartners.cardiaid.com if you report the problems below while using CardiAid Monitor2 Technical Service Software;

6.2.1. Damage on the device

If you select "Yes" when you find a damage on the device, you will be asked to describe the damage on the device. If this damage is unimportant and the device still works, or you can repair it, Type in the description and select the answers of other questions and click on "Next".

Make sure the damaged or broken part was repaired or replaced before proceeding

If you cannot repair or replace the damaged or broken part, go to
servicepartners.cardiaid.com

6.2.2.   Broken part on the device

If you select "Yes" when you find a broken part on the device, you will be asked to describe the damage on the device. If this damage is unimportant and the device still works, or you can repair it, Type in the description and select the answers of other questions and click on "Next".
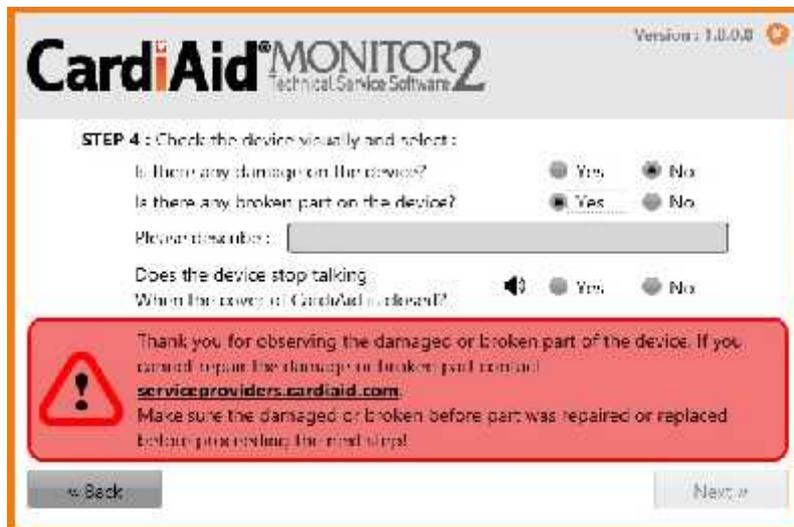
Make sure the damaged or broken part was repaired or replaced before proceeding

If you cannot repair or replace the damaged or broken part, go to servicepartners.cardiaid.com

6.2.3. "Voice Guidance Not Stopped"

If you select "No" if the device does not stop voice guidance when the cover is closed and click on "Next", the main reason might be the absence of the magnet. So you will be questioned with the following screens after clicking on "Next".
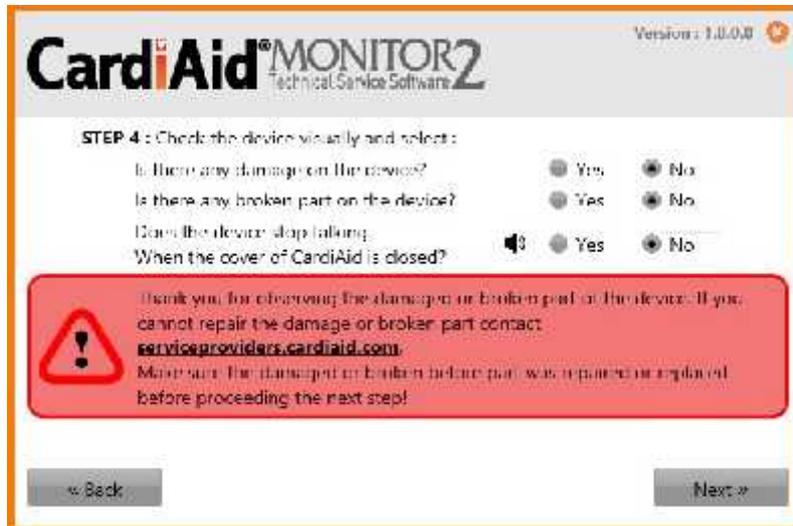
Click on "Yes" in you are sure that the device stops talking or "No" if the voice guidance is still active.
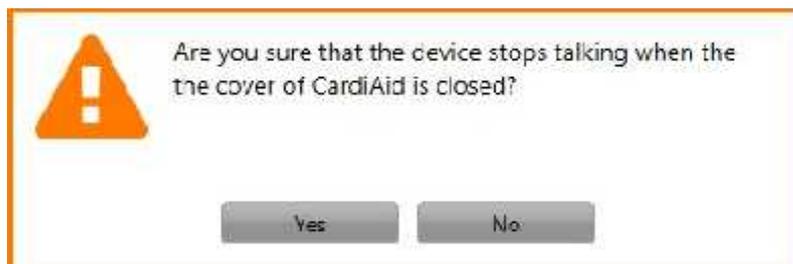
If you click on "No", then this means the device still works (voice is heard) even the cover is closed. Please follow the screen to open the cover of the AED and make sure the magnet is on the cover as shown in the picture. Click "No" if the magnet is not at its location.

You confirmed that there is no magnet on the cover. Pick up a new magnet and place it on the housing. To make it installed and stay stable, put silicone on the empty space for the magnet as shown in the picture and place the magnet on it. Click on "Next" after the process is completed to proceed.

Close the cover of the device when you are sure that the silicone under the magnet is dry. If the voice guidance is stopped, click "No" to the question "Does the device still operate?"

6.3. Testing Shock Button (For CT0207 and CT0207RS only)

Plug the defitester cable both the defitester jack and the socket of the device. Switch On the defitester and press "VFIB" button.

Make sure that the device will start analysing the heart rhythm by stating "Analysing hearth rhythm".

The device will state "Shock necessary." and please press the shock button to test shock will be given.

If shock cannot be given by pressing the button, please servicepartners.cardiaid.com to report.

Appendix 1

Category: **Test report**
Report No.:   **CS V260-13**
Purpose: **Evaluation of sensitivity and specificity of the VF/VT algorithm**

CardiAid®

Table of contents

1 Test Purpose

The aim of the test is to qualify sensitivity and specificity of the algorithm for the recognition of VF/VT for the current hardware. This test is meant to show that the hardware change does not have a negative influence on the specificity and sensitivity.

2 Device under Test

Hardware

The test on specificity and sensitivity is performed by using a PCB of the device CardiAid with the PCB CS-No.: 10571
Serial number: 13030014.

Firmware version:

DOK MSP:AE04
SPE MSP: AE01
CTR MSP: AE04
PLD: AE02
DSP : C

3 Test Setup / Test Equipment

3.1 Test setup

3.1.1   Test stand

- PC with measuring card PCI-MIO-16E-4 (E20)
- Connection box SCB 68
- LabView programme "Teststand_Cardiaid.vi"
- Power supply unit Manson (E52)
- Relay for the switching of the 12 V supply voltage
- Voltage divider 1:1000
- IRF7811

The PCB is operated in a defibrillator test box. The electrode inputs were linked to the connectors „Defi-Pads". The supply voltage of the defibrillator was applied via the relay input, so that the relay can switch the PCB on and off.

The relay is controlled via the channel DO3 of the measuring card.

With the help of the LabView program a 20-second ECG segment of the database is output at the analogue outlput of the measuring card (AO0) during the defibrillator analysis. After that it is passed on to the PAD connectors plugged to the test circuit via a voltage divider at a relation of 1:1000.

The pins "*Schockpfeil*" and "*Ablauf_3*" are monitored via the inputs AI0 and DI2. In case one of these pins is TRUE, the voltage supply is shut down by means of setting the DO3 to FALSE. Afterwards a new run is started. The decision shockable/ not shockable/ ambiguous is registered in a file for each data record and each 20-second segment. Specificity and sensitivity are determined by using the log file.
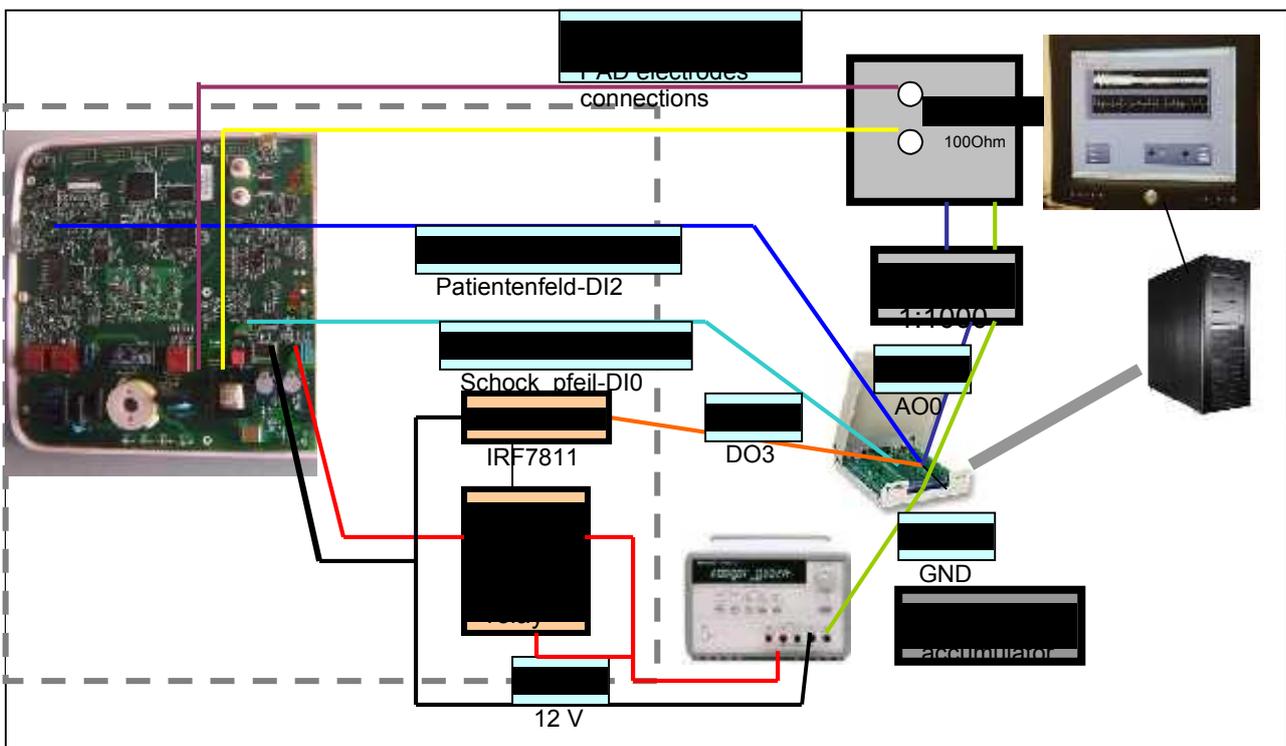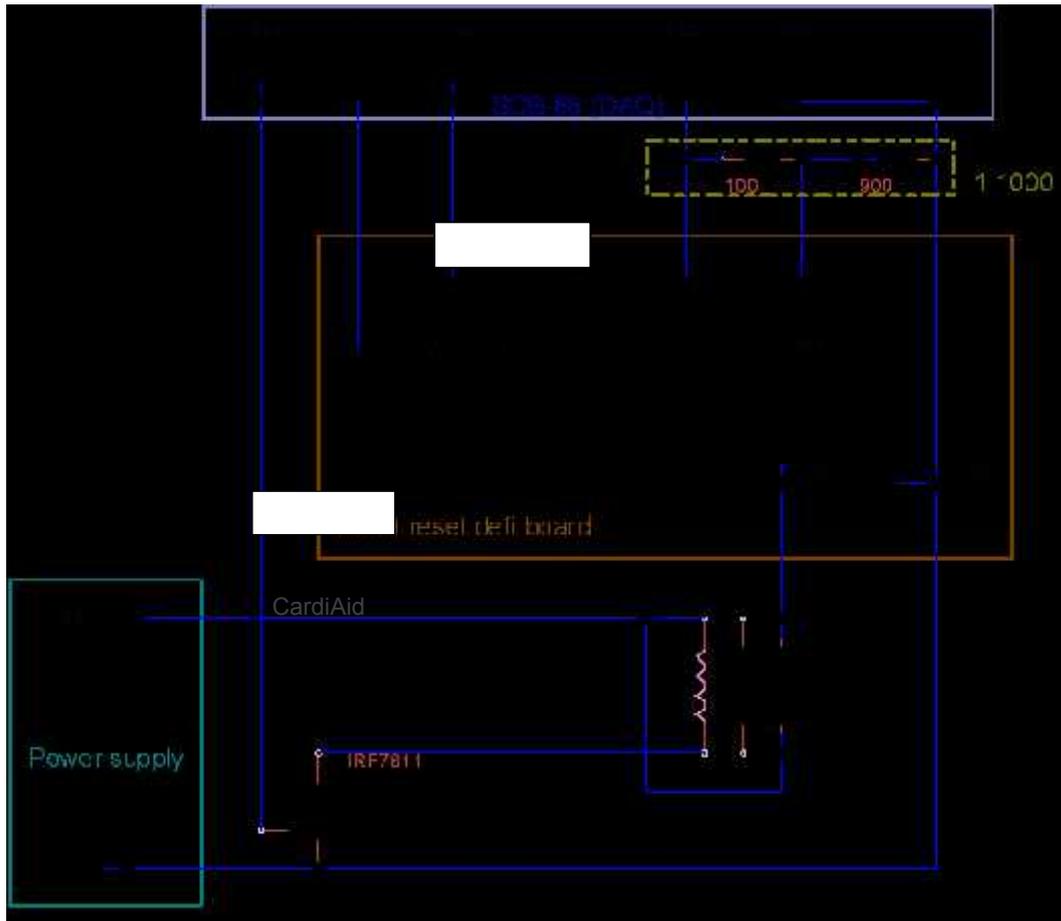
Figure 1 - Test setup

3.2 Test Equipment

- Measuring card NI E113
- Function generator Keithley E110
- Oscilloscope Agilent E104

3.2.1 Creighton University database

Unambiguous time periods were cut out of all 35 ECG files of the CU (Creighton University Ventricular Tachyarrhythmia) database and divided into two groups „shockable" and „not shockable". The non-shockable part contains 80 signals and the shockable part consists of 40 signals (see Tables 1 and 2). The files Cu 12,14,20,25,28,31 and 34 merely contain non-shockable rhythms.

Appendix 1

Original CU-Database No.	Start time	End time	Duration (minute)	Time (second)	Modified CU-Database No.
cu01	00:00:00	00:03:30	00:03:30	210	ns_cu01
cu02	00:00:00	00:00:40	00:00:40	40	ns_cu02
	00:01:10	00:04:00	00:02:50	170	ns_cu03
	00:04:30	00:06:30	00:02:00	120	ns_cu04
	00:06:50	00:08:10	00:01:20	80	ns_cu05
cu03	00:00:00	00:04:20	00:04:20	260	ns_cu06
	00:04:30	00:07:40	00:03:10	190	ns_cu07
cu04	00:00:00	00:02:30	00:02:30	150	ns_cu08
	00:05:49	00:06:09	00:00:20	20	ns_cu09
	00:07:57	00:08:27	00:00:30	30	ns_cu10
cu05	00:00:00	00:01:30	00:01:30	90	ns_cu11
	00:01:40	00:02:20	00:00:40	40	ns_cu12
	00:02:30	00:03:10	00:00:40	40	ns_cu13
	00:03:50	00:05:50	00:02:00	120	ns_cu14
	00:07:28	00:08:28	00:01:00	60	ns_cu15
cu06	00:00:00	00:03:00	00:03:00	180	ns_cu16
	00:05:44	00:08:24	00:02:40	160	ns_cu17
cu07	00:00:00	00:03:00	00:03:00	180	ns_cu18
cu08	00:00:00	00:00:20	00:00:20	20	ns_cu19
	00:01:20	00:02:30	00:01:10	70	ns_cu20
	00:03:00	00:03:40	00:00:40	40	ns_cu21
	00:03:50	00:04:20	00:00:30	30	ns_cu22
	00:05:40	00:06:10	00:00:30	30	ns_cu23
	00:06:20	00:07:00	00:00:40	40	ns_cu24
cu09	00:00:00	00:03:50	00:03:50	230	ns_cu25
	00:05:00	00:07:10	00:02:10	130	ns_cu26
	00:07:17	00:07:47	00:00:30	30	ns_cu27
	00:07:57	00:08:27	00:00:30	30	ns_cu28
cu10	00:00:00	00:05:10	00:05:10	310	ns_cu29
cu11	00:00:00	00:06:10	00:06:10	370	ns_cu30
cu12	00:00:00	00:04:20	00:04:20	260	ns_cu31
	00:07:42	00:08:22	00:00:40	40	ns_cu32
cu13	00:00:00	00:06:20	00:06:20	380	ns_cu33
	00:08:08	00:08:28	00:00:20	20	ns_cu34
cu14	00:00:00	00:00:30	00:00:30	30	ns_cu35
	00:00:40	00:07:10	00:06:30	390	ns_cu36
	00:07:20	00:07:40	00:00:20	20	ns_cu37
	00:07:50	00:08:20	00:00:30	30	ns_cu38
cu15	00:00:00	00:06:40	00:06:40	400	ns_cu39
cu16	00:00:00	00:04:10	00:04:10	250	ns_cu40
	00:05:54	00:07:44	00:01:50	110	ns_cu41

Original CU-Database No.	Start time	End time	Duration (minute)	Time (second)	Modified CU-Database No.
	00:08:02	00:08:22	00:00:20	20	ns_cu42
cu17	00:00:00	00:06:20	00:06:20	380	ns_cu43
	00:07:39	00:08:19	00:00:40	40	ns_cu44
cu18	00:00:00	00:05:30	00:05:30	330	ns_cu45
	00:06:08	00:08:28	00:02:20	140	ns_cu46
cu19	00:00:00	00:06:40	00:06:40	400	ns_cu47
cu20	00:00:00	00:01:30	00:01:30	90	ns_cu48
	00:01:45	00:03:55	00:02:10	130	ns_cu49
	00:05:40	00:08:20	00:02:40	160	ns_cu50
cu21	00:00:14	00:00:54	00:00:40	40	ns_cu51
	00:01:41	00:03:11	00:01:30	90	ns_cu52
	00:03:40	00:04:00	00:00:20	20	ns_cu53
	00:04:52	00:05:22	00:00:30	30	ns_cu54
	00:06:14	00:07:24	00:01:10	70	ns_cu55
	00:07:32	00:08:22	00:00:50	50	ns_cu56
cu22	00:00:00	00:05:30	00:05:30	330	ns_cu57
	00:07:38	00:08:28	00:00:50	50	ns_cu58
cu23	00:00:00	00:05:30	00:05:30	330	ns_cu59
	00:08:07	00:08:27	00:00:20	20	ns_cu60
cu24	00:00:00	00:05:50	00:05:50	350	ns_cu61
	00:07:34	00:08:24	00:00:50	50	ns_cu62
cu25	00:00:00	00:07:00	00:07:00	420	ns_cu63
	00:07:50	00:08:20	00:00:30	30	ns_cu64
cu26	00:00:00	00:02:10	00:02:10	130	ns_cu65
	00:04:54	00:07:54	00:03:00	180	ns_cu66
cu27	00:00:20	00:05:00	00:04:40	280	ns_cu67
	00:05:42	00:07:22	00:01:40	100	ns_cu68
cu28	00:00:00	00:08:10	00:08:10	490	ns_cu69
cu29	00:00:00	00:06:10	00:06:10	370	ns_cu70
cu30	00:00:00	00:00:20	00:00:20	20	ns_cu71
	00:05:48	00:06:48	00:01:00	60	ns_cu72
cu31	00:00:00	00:08:10	00:08:10	490	ns_cu73
cu32	00:00:00	00:07:20	00:07:20	440	ns_cu74
cu33	00:00:00	00:06:40	00:06:40	400	ns_cu75
cu34	00:00:00	00:01:50	00:01:50	110	ns_cu76
	00:02:12	00:06:22	00:04:10	250	ns_cu77
	00:07:11	00:08:21	00:01:10	70	ns_cu78
cu35	00:00:20	00:06:40	00:06:20	380	ns_cu79
	00:07:00	00:08:00	00:01:00	60	ns_cu80

Table 1: CU not shockable part

Original CU-Database No.	Start time	End time	Duration (minute)	Time (second)	Modified CU-Database No.
cu01	00:03:35	00:08:25	00:04:50	290	s_cu01
cu02	00:08:06	00:08:26	00:00:20	20	s_cu02
cu03	00:07:46	00:08:26	00:00:40	40	s_cu03
cu04	00:02:36	00:03:26	00:00:50	50	s_cu04
	00:03:44	00:04:04	00:00:20	20	s_cu05
	00:04:15	00:05:45	00:01:30	90	s_cu06
	00:06:10	00:07:50	00:01:40	100	s_cu07
cu05	00:05:59	00:07:19	00:01:20	80	s_cu08
cu06	00:03:05	00:04:35	00:01:30	90	s_cu09
cu07	00:03:02	00:08:22	00:05:20	320	s_cu10
cu08	00:07:07	00:07:57	00:00:50	50	s_cu11
cu09	00:04:00	00:04:20	00:00:20	20	s_cu12
cu10	00:05:17	00:07:57	00:02:40	160	s_cu13
	00:08:07	00:08:27	00:00:20	20	s_cu14
cu11	00:06:11	00:07:11	00:01:00	60	s_cu15
cu13	00:06:20	00:07:00	00:00:40	40	s_cu16
	00:07:08	00:07:58	00:00:50	50	s_cu17
cu15	00:06:46	00:08:26	00:01:40	100	s_cu18
cu16	00:04:15	00:05:45	00:01:30	90	s_cu19
cu17	00:06:23	00:06:53	00:00:30	30	s_cu20
cu18	00:05:35	00:05:55	00:00:20	20	s_cu21
cu19	00:06:50	00:07:10	00:00:20	20	s_cu22
cu21	00:00:57	00:01:27	00:00:30	30	s_cu23
	00:04:05	00:04:35	00:00:30	30	s_cu24
cu22	00:05:38	00:05:58	00:00:20	20	s_cu25
	00:06:08	00:07:18	00:01:10	70	s_cu26
cu23	00:05:34	00:05:54	00:00:20	20	s_cu27
	00:06:01	00:06:31	00:00:30	30	s_cu28
cu24	00:05:56	00:06:56	00:01:00	60	s_cu29
cu26	00:02:26	00:02:46	00:00:20	20	s_cu30
	00:02:50	00:03:20	00:00:30	30	s_cu31
cu27	00:05:10	00:06:00	00:00:50	50	s_cu32
	00:07:32	00:07:52	00:00:20	20	s_cu33
cu29	00:06:19	00:07:19	00:01:00	60	s_cu34
cu30	00:00:28	00:00:58	00:00:30	30	s_cu35
	00:07:20	00:08:20	00:01:00	60	s_cu36
cu32	00:07:23	00:08:03	00:00:40	40	s_cu37
cu33	00:06:45	00:07:35	00:00:50	50	s_cu38
	00:07:40	00:08:10	00:00:30	30	s_cu39
cu35	00:08:04	00:08:24	00:00:20	20	s_cu40

Table 2: CU shockable part

3.2.2 Extract of the MIT/BIH arrhythmia database

Five patient data with each containing a 30-minute sequence of the MIT arrhythmia database were selected from

http://www.physionet.org/physiobank/database/mitdb/

for being tested. All selected data have to be classified as „not shockable".

Record 119 (MLII, V1; female, age 51)

Medications: Pronestyl

Beats	Before 5:00	After 5:00	Total
Normal	246	1297	1543
PVC	80	364	444
Total	326	1661	1987

Ventricular ectopy

- 444 isolated beats

Rhythm	Rate	Episodes	Duration
Normal sinus rhythm	61-84	49	22:36
Ventricular bigeminy	52-91	37	3:55
Ventricular trigeminy	56-77	17	3:34

Signal quality	Episodes	Duration
Both clean	3	29:35
Lower noisy	2	0:30

Notes:
    The PVCs are uniform.

Points of interest:

1:55	PVC
2:38	Ventricular trigeminy
4:51	Ventricular bigeminy
8:42	Normal sinus rhythm
20:05	Noise
25:33	Noise

Record 104 (V5, V2; female, age 66)

Medications: Digoxin, Pronestyl

Beats	Before 5:00	After 5:00	Total
Normal	65	98	163
PVC	1	1	2
Paced	197	1183	1380
Pacemaker fusion	104	562	666

		13	18
Unclassifiable	5		
Total	372	1857	2229

Ventricular ectopy

- 2 isolated beats

Rhythm	Rate	Episodes	Duration
Normal sinus rhythm	69-82	22	3:52
Paced rhythm	70-78	23	26:13

Signal quality	Episodes	Duration
Both clean	13	26:46
Upper noisy	5	0:24
Lower noisy	8	0:46
Both noisy	12	2:09

Notes:

    The rate of paced rhythm is close to that of the underlying sinus rhythm, resulting in many pacemaker fusion beats. The PVCs are multiform. Several bursts of muscle noise occur, but the signals are generally of good quality.

Points of interest:

3:42	PVC
5:13	Noise
5:52	Transition from paced to normal sinus rhythm
6:17	Noise
8:22	Noise in lower signal
26:51	Paced, normal, and pacemaker fusion beats
29:10	Paced, normal, and pacemaker fusion beats

Record 108 (MLII, V1; female, age 87)

Medications: Digoxin, Quinaglute

Beats	Before 5:00	After 5:00	Total
Normal	279	1461	1740
APC	1	3	4
PVC	3	13	16
Fusion PVC	-	2	2
Junctional escape	-	1	1
Blocked APC	2	9	11
Total	285	1489	1774

Supraventricular ectopy

- 4 isolated beats

Ventricular ectopy

- 14 isolated beats
- 2 couplets

Rhythm	Rate	Episodes	Duration
Normal sinus rhythm	44-78	1	30:06

Signal quality Episodes Duration

Signal quality	Episodes	Duration
Both clean	19	24:05
Upper noisy	3	0:16
Lower noisy	12	2:45
Both noisy	8	3:01

Notes:

There is borderline first degree AV block and sinus arrhythmia. The PVCs are multi-form. The lower channel exhibits considerable noise and baseline shifts.

Points of interest:

0:22	PVC, blocked APC, noise
4:51	Interpolated PVC
7:41	Axis shift
8:13	PVC, blocked APC, fusion PVC
10:55	Sinus arrhythmia
18:08	Fusion PVC-PVC couplet
20:05	Junctional escape beat
24:20	Blocked APC, APCs
28:10	Noise
29:00	Noise

Record 114 (V5, MLII; female, age 72)

Medications: Digoxin

Beats	Before 5:00	After 5:00	Total
Normal	261	1559	1820
APC	-	10	10
Junctional premature	1	1	2
PVC	13	30	43
Fusion PVC	-	4	4
Total	275	1604	1879

Supraventricular ectopy

- 7 isolated beats
- 1 run of 5 beats

Ventricular ectopy

- 45 isolated beats
- 1 couplet

Rhythm	Rate	Episodes	Duration
Normal sinus rhythm	51-82	2	30:01
SVTA	102-122	1	0:05

Signal quality	Episodes	Duration
Both clean	4	29:18
Upper noisy	4	0:47

Notes:

The PVCs are uniform.

Points of interest:

0:00	Normal sinus rhythm
1:20	PVC
3:39	PVC
3:56	Late-cycle PVC
4:35	Late-cycle PVC
5:36	Ventricular couplet
8:31	PVCs
9:26	PVC, muscle noise
11:37	SVTA, PVC, junctional premature beat
20:02	Noise
29:29	Baseline artifact

Record 124 (MLII, V4; male, age 77)

Medications: Digoxin, Isordil, Quinidine

Beats	Before 5:00	After 5:00	Total
Right BBB	238	1293	1531
APC	-	2	2
Junctional premature	14	15	29
PVC	-	47	47
Fusion PVC	-	5	5
Junctional escape	-	5	5
Total	252	1367	1619

Supraventricular ectopy

- 2 isolated beats
- 1 run of 3 beats
- 2 runs of 6 beats
- 1 run of 14 beats

Ventricular ectopy

- 18 isolated beats
- 1 run of 6 beats
- 1 run of 8 beats
- 1 run of 20 beats

Rhythm	Rate	Episodes	Duration
Normal sinus rhythm	47-64	6	28:36
Nodal (junctional) rhythm	56-64	2	0:30
Ventricular trigeminy	51-59	2	0:22
Idioventricular rhythm	53-61	3	0:37

Signal quality Episodes Duration

Signal quality	Episodes	Duration
Both clean	2	29:53
Lower noisy	1	0:13

Notes:

The PVCs are multiform. The junctional escape beats follow PVCs.

Points of interest:

4:43	Accelerated junctional rhythm
5:09	Accelerated idioventricular rhythm, 20 beats
5:21	Accelerated idioventricular rhythm (continued from previous strip)
9:05	Noise in lower signal
10:27	Accelerated idioventricular rhythm
17:38	Accelerated idioventricular rhythm
20:13	APC
23:22	Ventricular trigeminy
26:03	PVC
27:41	PVC, junctional escape beats

3.2.3 Paediatric ECG

The database was collected at the *Kinder- und Jugendklinik Universitätsklinikum* in Erlangen. The database includes 10 s-long recordings from 52 subjects (age 25 days to 20 years, average age 10.4 years) and with a non-shockable rhythm.

4 Test Execution

Attempts are made with the aim of optimizing the parameters that are responsible for the shock decision. In order to optimize the results, the parameter „THRPARAM" is adjusted.
In each of the following tests a corresponding data record is analysed as follows:
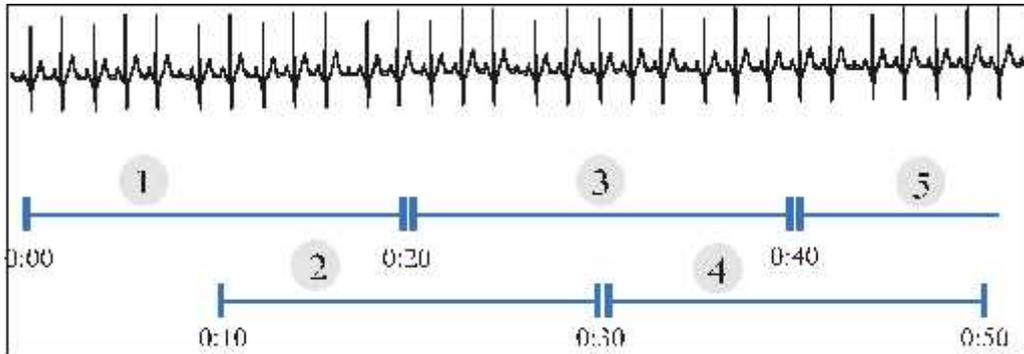
All ECG signals are subdivided into 20-second blocks which overlap. In the following, the known performance parameters are calculated according to the classifications.

$$Se = A / (A+C)$$

$$Sp = D / (B+D)$$

$$+P = A / (A+B)$$

$$-P = B / (B+D)$$

with:

	VF/VT (shockable)	NSR (not shockable)
Shock recommended	A (TP)	B (FP)
Shock not recommended	C (FN)	D (TN)

4.1.1 Test stand calibration with test ECG

On the test stand, a 5 Hz sinus signal (amplitude ±1 mV) is stored on a PCB. The flash is read and it is checked if 1 mV were actually measured by the ADC.

4.1.2 Validation of the determined tendency on the test stand

All ECG signals from the modified CU (Creighton University Ventricular Tachyarrhythmia) and the MIT database were divided into 20-second segments. The time period of 20 seconds was chosen in order to fulfil the lead and follow-up time of the analysis (voice outputs and analysis period). For the reason of not losing too many signals there is a 10-second overlap between two segments. The 20-second ECG segments were stored with an ECG amplitude in the defibrillator via a DAQ card and the decision on the pins "*HV_laden*" and "*Patientenfeld*" registered.

5 Test Result

5.1.1 Test stand calibration

The amplifying factor is **0,002454**

The factor was set in a way that a database extract with the size of 1 mV corresponds exactly to 1 mV at the ECG input of the PCB.

5.1.2 Test stand

The results of the test stand on the basis of the tested databases are summarized below:

results

adult electrodes:

database	TP	TN	FP	FN	Se	Sp	+P	-P
CU	194	1164	23	6	0,97	0,98	0,89	0,019

MIT database (not shockable) **TN:**900, **FP:**0

child electrodes:

database	TP	TN	FP	FN	Se	Sp	+P	-P
Paediatric	-	1171	16	-	-	0,98	-	0,0134

Paediatric database:

TN: 91
FP: 2

6 Assessment

Requirement	Description	Result	Comment	Pass/fail	Tester	Test date
>0,95	specificity adult specificity child	0,98 0,98		PASS	KSE	2013-06-11
>0,9	sensitivity adult	0,97		PASS	KSE	2013-06-11

7 Next Steps

8 Remarks

9 Attachments

Log Data in project folder

Appendix 2

The List of Technical Service Equipment

Model Nr.	Description	Picture
CS-DFT01	Defitester	
CS-DFT01C	Spare Cable for Defitester	-
CS-DCH01	Discharger	
CS-BTA01	Bluetooth Dongle	
-	T10 x 100mm Screwdriver	-
-	Antistatic Protection Equipment	-

The List of Spare Parts and Accessories

1. CardiAid CA-4BP Battery Pack
2. CardiAid CA-10ES Defibrillation Electrodes (for CT0207)
3. CardiAid CR-13A Adult Defibrillation Electrodes (for CT0207RS/ CT0207RF)
4. CardiAid CR-13P Paediatric Defibrillation Electrodes (for CT0207RS/ CT0207RF)
5. CardiAid CT0207EK Emergency Kit
6. CardiAid CT0207P Protection Bag
7. Lithium Button Cell Battery CR-2032
8. Lithium Button Cell Battery CR-2450

Appendix 4

CardiAid®
Public Access Defibrillator

Warranty Card

Date of Sale: _____/_____/_____

Model: ☐ CT0207RS ☐ CT0207RF

SN

CardiAid is a high quality product which is designed and manufactured with the highest medical standards. Cardia International guarantees that the device will perform properly for a period of 2 years after purchase. This period can automatically be extended to 6 years under the following conditions:

- The device should be registered on ***www.cardiaid.com/register***
- The device should be subjected to periodical maintenance at the end of 2nd and 4th years after purchase. The periodical maintenances should be performed on time and by an authorized technical service provider. (For information on authorized technical service providers, go to: www.cardiaid.com/servicepartners).
- CardiAid should be subjected to maintenance after each use. The after-use maintenance should be performed by an authorized technical service provider. (For information on authorized technical service providers, go to: www.cardiaid.com/servicepartners).
- The device should not be unscrewed or back of the device should not be opened by another party. Inspection, repair and other maintenance actions can be performed by an authorized service provider.
- The serial number on the device should be intact and legible.
- The original purchase invoice should be available for inspection.

⚠ **IMPORTANT!**
- The warranty is valid only if the device is registered on ***www.cardiaid.com/register***
- Do not attempt to unscrew the device. Any intervention by unauthorized parties invalidates the warranty and may cause serious injuries and/or irreversible damage to the device.
- Physical damage, fire or water damage and incompetent use will invalidate the warranty. This warranty does not cover the electrodes, protection bag or other accessories.
- The device may be used only as an automated external defibrillator; there is no compatibility at all with other equipment or peripherals.
- The periodical maintenances should be performed no later than the date on the battery life label, and after-use maintenance should be performed immediately after use. The device cannot be used unless the maintenances are performed on time.
- In the unlikely event of experiencing problems with the device, please contact your local service provider or Cardia International directly.

CD02GC003-EN v.3.0.40403

(EN)

Appendix 5

CardiAid®
Automated External Defibrillator

CardiAid Maintenance Report

SERIAL NUMBER   :

MODEL NO   :

INFORMATION OF THE OWNER

Company   :

Contact Person   :

Telephone Number   :

E-Mail Address   :

Installation Address :

TYPE OF MAINTENANCE

☐   2nd Year Periodical Maintenance

☐   4th Year Periodical Maintenance

☐   6th Year Periodical Maintenance

☐   After-Use Maintenance

ACTIONS TAKEN

- Visual check was performed.   ☐

- Accessories were checked.   ☐

- Internal memory was checked.   ☐

- ECG and Incident Data were obtained from memory.   ☐

- Main battery was replaced.   ☐

- Lithium button cell battery was replaced.   ☐

- Emergency Kit was replaced.   ☐

- Electroshock test was performed.   ☐

- Function test was performed.   ☐

Notes:

_____

_____

_____

_____

Maintenance Performed by

Service Provider ID:

Technician Name:

Date:

Signature:

CardiAid®
Automated External Defibrillator

Date:

Device Information		Owner Information	
Serial Number		Company	
Model Number		Contact Person	
Language		Telephone Number	
		e-Mail Address	
		Installation Address	

#	Action	Status	Description
1	Status Indicators		
2	Visual Check		
3	Getting, Saving & Deleting ECG Data		
4	Electrode Detection Test		
5	RTC Replacement		
6	Battery Replacement		
7	Setting Time		
8	Testing Operation With Shock		
9	Testing Operation Without Pressing Shock Button		
10	Testing Operation Without Shock		
11	Testing Operation with Shock Pediatric Mode		
12	Getting, Saving & Deleting ECG Data		
13	Setting Battery		
14	Print Device Setting		
15	Emergency Kit Replacement		
16	Electrode Replacement		
17	Filling and Sticking Maintenance Sticker		
18	Warranty Seal Sticker		
19	Final Check		

Next Maintenance Date Before

Filled By:
Service Provider ID:
Signature:

Settings For CardiAid

Device Model	:
Serial Number	:
Date	:
Time	:
Number of Shocks	:
Battery Capacity	:
Firmware Version	:
Auto Monthly Self-Test	:
Language Selection	:
Volume For Voice Prompts	:
"Check for breathing." Voice Prompt	:
"Call 1 1 2." Voice Prompt	:
"If not breathing normally..." Voice Prompt	:
First Shock Level	:
Second Shock Level	:
Third Shock Level	:
Metronome Function in CPR Pause	:
Length of CPR Pause	:
Hands-only CPR during CPR	:
Gateway	:
Gateway Timeout (Min)	:
Gateway Timeout (Max)	:

CardiAid®
Automated External Defibrillator

CardiAid AED Usage Form

This form aims to assist the authorized service providers of Cardia Intl. while obtaining information about the incident after a CardiAid AED is used. CardiAid AED saves information about the incident and the ECG record of the patient. This information should be saved and immediately sent to Cardia International. CardiAid AED can store the data of 4 different events in its internal memory. In some cases, more than one event record may be present in the memory due to reasons such that the product may be used and not taken to service provider afterwards before the current incident, or the device may save the data as 2 separate events because the electrodes may be detached and the cover of the device may be closed (this will switch the device off.), and then the product may be used on the patient again. As a result, the service provider technician should analyze the event in detail in order to understand which record belongs to that incident. The following questions aims this analysis.

Serial Number of the Device :
Date and Time of Usage :
Place of Usage :

Were the electrodes disconnected during the incident?   YES   NO

If yes; please explain:

Please explain in detail how the incident happened:

Filled By:
Service Provider ID:
Signature: