DefiMonitor XD

Operating instructions
English

24050 | GB | I

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Masthead

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Table of contents

1 Glossary

Term / abbreviation	Description
AED	Automated external defibrillator
AHA	American Heart Association
AkuPak LITE XD	Rechargeable energy module
bpm	“beats per minute”
EAR	Used Electronic Appliances Register
ECG	Electrocardiogram
ElektroG	German Electrical and Electronic Equipment Act
ERC Guidelines	European Resuscitation Council guidelines on cardiopulmonary resuscitation (CPR)
HF	High frequency
CPR	Cardiopulmonary resuscitation
Internal buffer battery	Internal buffer battery for continued running of DefiMonitor XD real-time clock if no energy module is inserted.
MDD	Medical Device Directive
MIT	Massachusetts Institute of Technology
ms	millisecond
ÖRE	Public law
Patient impedance	Patience resistance between the SavePads
SaveCard	Memory card for data transfer
s	second
SavePads	Self-adhesive multifunction electrodes for defibrillation, stimulation, monitoring, cardioversion
WEEE	Waste of Electrical and Electronic Equipment

2 Introduction

2.1 Foreword

Dear User,

You are faced with the task of using the DefiMonitor XD on human beings in a medical emergency!

To ensure that you can react quickly and correctly in this special situation and can optimally use the options given with the device, it is necessary for you to read through these operating instructions in your own time beforehand to familiarise yourself with the device, its functions and the areas of application.

Keep these instructions for use near the device so that you consult them for any queries which may arise.

If you have any questions regarding the start-up, use or maintenance of the DefiMonitor XD please do not hesitate to contact us.

In case of unexpected device behaviour or events, please contact us.

The instructions given on the device are no substitute for reading these operating instructions.

Serious incidents related to the defibrillator must be reported. If the defibrillator has not performed as expected, contact the manufacturer and the appropriate local authority.

A "serious incident" means an event that has had, could have had, or may have had, directly or indirectly, any of the following consequences

- the death of a patient, user or other person
- the temporary or permanent serious deterioration of the health status of a patient, user or other person
- a serious risk to public health.

You will find our contact address on the masthead at the start of these instructions for use.

2.2 Validity

The descriptions in these operating instructions refer to all models in the DefiMonitor XD range of defibrillators made by Metrax GmbH.

These operating instructions describe the software version ARM 1.XX, DSP 4.XX.

Please note that, depending on the model, your DefiMonitor XD may not have all the features described in these operating instructions. Refer to the start dialogue of your DefiMonitor XD to determine which model you have.

The DefiMonitor XD is run using an AkuPak LITE XD. This item will also be referred to as an energy module in this document.

SavePads are self-adhesive multifunction electrodes which can be used for defibrillation, stimulation, monitoring and cardioversion. For statements in these operating instructions concerning all SavePads models, they will be referred to simply as SavePads. If there are specifics for using individual models, the item description will be given in full (e.g. SavePads Connect).

The content of this document can be changed without prior notice.

2.3 Disclaimers

Liability claims for personal injury and damage to property are excluded if they are attributable to one or more of the following causes:

- Using the device in a manner for which it was not intended.
- Improper use and maintenance of the device.
- Operating the device with the protective covers removed or if there is obvious damage to the cables and/or electrodes.
- Non-observance of the advice given in these instructions for use with regard to operation, maintenance and repair of the device.
- Customer intervention, repairs or constructional changes to the device.
- Autonomous exceeding of the performance limits.
- Lack of monitoring of parts that are subject to wear and tear.
- Treating patients without prior indication.

2.4 Symbols used in these instructions for use

Note

This symbol indicates text which contains important information.

Follow the instructions in the order in which they are given in the instructions for use. The instructions are structured as follows:

Procedure:

- First instruction
- Second instruction

➢ Possible interim result

- etc.

✓ Possible final result

■ This symbol indicates a list.

Numbers in brackets, e.g. (3), refer to items in figures.

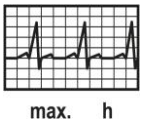
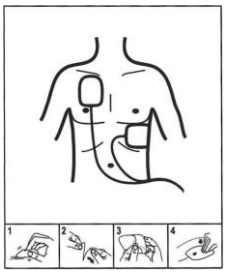
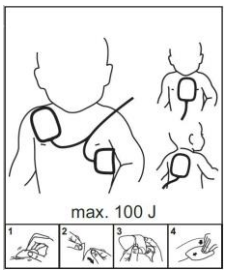
Voice messages or voice instructions are in **bold** in these instructions for use. In some instances, they will be shown as text messages on the monitor at the same time.

Settings options will be placed in “ “.

2.5 Pictograms

Symbol	Meaning
	Serial number
	CE symbol for the notified body
	CE symbol
	HIBC / UDI code (example)
	GOST R symbol
	EAC symbol
	Medical device
	Applied part, defibrillation-proof, type CF
	Protection class II
	Do not dispose of device in household waste
IP33	Protected against solid foreign objects larger than 2.5 mm and against spraying water
	Manufacturer and production date if necessary YYYY-MM-DD
	Follow the instructions for use
	"General warning” safety symbol – the individual meanings are explained in the operating instructions
	Dangerous electrical voltage (high voltage)

Symbol	Meaning
	Caution
	Service life of the internal battery YYYY-MM-DD
	Do not short-circuit energy module
	Do not open or disassemble energy module
	Protect energy module from fire
	For adults and children more than 8 years old and with a bodyweight greater than 25 kg
	For children aged 1 – 8 and with a bodyweight up to a maximum of 25 kg
	Infants up to the age of 1
	SavePads Connect can only be used in conjunction with a coded Save-Pads Connect cable
	Contains no hazardous substances and can be recycled
	Open packaging here
	Do not use if packaging is damaged
	Do not bend or fold the electrodes and do not store beneath heavy items
	Recycling code for low-density polyethylene
	Do not reuse
	non sterile
	Can be used a maximum of 24 hours after opening
	Observe the instructions for use
	Not made from natural latex

Symbol	Meaning
	Batch code
	Article number
	Global Trade Item Number
	Can be used until YYYY-MM-DD
	Maximum frequency of use for 1 pair of multifunction electrodes (SavePads) for defibrillation
	Maximum duration of use for 1 pair of multifunction electrodes (SavePads) for monitoring Maximum duration of use for ECG electrodes
	Maximum duration of use for 1 pair of multifunction electrodes (SavePads) for pacing
	Positioning and handling the SavePads 1. Dry skin 2. Open the packaging of the electrodes 3. Pull off protective foil 4. Attach SavePads and smooth out
	Positioning and handling the SavePads Mini 1. Dry skin 2. Open the packaging of the electrodes 3. Pull off protective foil 4. Attach SavePads and smooth out
	Prescription only
	Silver / Silver Chloride
	Remove chest hair
	Dry skin
	Connect the ECG cable to the ECG electrodes

Symbol	Meaning
	Remove protections foil
	Attach the ECG electrode to the skin and press down with circular movements
	Store remaining ECG electrodes in their original packaging. Close the packaging by folding the opening twice
	This side up
	Fragile goods
	Protect from heat (solar radiation)
	Protect from moisture
	Air pressure in hPa
	Humidity specification in %
	Permissible temperature range in Celsius and Fahrenheit

3 Purpose

3.1 Functionality

The DefiMonitor XD is a portable defibrillator / monitor that is intended for use of trained medical personnel in indoor and out-of-doors emergency care setting with environmental condition specified in the technical data. DefiMonitor XD is designed to be used during ground transportation. DefiMonitor XD is battery powered and can be powered by mains. The battery has to be inserted for operation. DefiMonitor XD may only be used on one patient at a time.

For additional intended use information see below.

Function	Availability
ECG monitoring	Standard
Async manual defibrillation	Standard
Sync manual defibrillation	Standard
AED-Mode	Option
Pacing	Option
Pulse oximetry (SpO2)	Option

3.2 Operational principle

ECG

The electrocardiogram (ECG) records the electrical activity of the heart. The ECG allows the interpretation and identification of cardiac rhythm, dysrhythmias and calculation of heartrate. The ECG is

captured by multifunction electrodes or ECG electrodes on the patient's skin what allows the electrical activity to be monitored and recorded. ECG monitoring is used in addition to assess the patient, do not rely solely on the ECG monitor, care should be taken to assess the patient at all time.

Asynchronous Defibrillation

DefiMonitor XD applies a high-intensity current pulse to the patient to treat life-threatening cardiac arrhythmia.

The high-intensity current pulse is called defibrillation. DefiMonitor XD will apply high-intensity current pulse in biphasic waveform. In adult mode, DefiMonitor XD will apply up to 360J, in pediatric mode up to 100J.

DefiMonitor XD DefiMonitor XD provides asynchronous manual defibrillation using multifunction electrodes or paddles.

Synchronous Defibrillation (Cardioversion)

DefiMonitor XD applies a high-intensity current pulse synchronized to R-wave of the ECG to the patient to treat cardiac arrhythmia.

The high-intensity current pulse is called defibrillation. DefiMonitor XD will apply high-intensity current pulse in biphasic waveform. In adult mode, DefiMonitor XD will apply up to 360J, in pediatric mode up to 100J.

DefiMonitor XD DefiMonitor XD provides synchronous manual defibrillation using multifunction electrodes or paddles.

Pacemaker therapy

Pacemaker therapy mode generates electrical impulses delivered by multifunction electrodes on the patient’s chest to contract the heart muscle and regulate the electrical conduction system of the heart. By this the heart rate of the patient can be controlled by the pacemaker therapy.

The electrical stimulus is applied from one electrode to the other electrode.

AED-Mode

AED-Mode is intended for treating patients with symptoms of sudden cardiac arrest. AED-Mode provides treatment protocol using voice and visual guidance to operator. After the multifunction electrodes are attached the patient’s chest or upper back DefiMonitor XD analyses the patient’s heartbeat. DefiMonitor XD will deliver a high-intensity current pulse to the patient. The high-intensity current pulse is delivered by the multifunction electrodes. The high-intensity current pulse is delivered when the operator presses the shock button

The high-intensity current pulse is called defibrillation. DefiMonitor XD will apply high-intensity current pulse in biphasic waveform. In adult mode, DefiMonitor XD will apply up to 360J, in pediatric mode up to 100J.

SpO2

SpO2 Monitoring uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying a Nellcor™ sensor to tissue regions with rich presence of capillaries and arterioles, such as a finger or toe. The sensor contains a dual light source and a photodetector.

Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The vascular bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO2).

Ambient conditions, sensor application, and patient conditions can influence the ability of the monitoring cable to accurately measure SpO2.

Pulse oximetry is based on two physical principles: oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (measured using spectrophotometry), and the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (registered using plethysmography). A monitoring system determines SpO2 by passing red and infra-red light into a vascular bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the sensor serve as light sources; a photo diode serves as the photo detector.

Since oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infra-red light absorbed by blood is related to hemoglobin oxygen saturation.

The monitoring cable uses the pulsatile nature of arterial flow to identify the oxygen saturation of arterial hemoglobin. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The monitoring cable bases its SpO2 measurements on the difference be-tween maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of non-pulsatile absorbers such as tissue, bone, and venous blood.

3.3 Intended use

ECG

Monitor the electrical activity of the heart.

Asynchronous Defibrillation

Treatment of life-threatening cardiac arrhythmia applying high-intensity current pulse to patient's chest or upper back.

Synchronous Defibrillation (Cardioversion)

Treatment of cardiac arrhythmia applying high-intensity current pulse to patient's chest or upper back.

Pacemaker therapy

Treatment of cardiac arrhythmia applying an electrical stimulus to patient's chest or upper back.

AED-Mode

Treatment of life-threatening cardiac arrhythmia applying high-intensity current pulse to patient's chest or upper back.

SpO2

SpO2 monitoring included in DefiMonitor XD is a portable pulse oximeter intended as a continuous non-invasive monitor of arterial oxygen saturation (SpO2) and pulse rate of adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused. The monitoring system is intended for use in hospitals, hospital-type facilities, and during intra-hospital transport.

3.3.1 Medical indications

ECG

ECG monitoring is indicated for recognition of the heart rhythm and to monitor the heart rate of the patient.

Asynchronous defibrillation

Manual asynchronous defibrillation is indicated for the termination of certain potentially fatal arrhythmias, such as ventricular fibrillation and ventricular tachycardia.

Synchronous defibrillation (cardioversion)

Manual synchronous defibrillation (Cardioversion) is indicated for the treatment of atrial fibrillation, atrial flutter paroxysmal supraventricular tachycardia and in relatively stable ventricular fibrillation.

Pacemaker therapy

DEMAND / FIX: Pacemaker therapy in DEMAND or FIX pacer mode is intended for treatment of symptomatic bradycardia with pulse.

OVERDRIVE: Pacemaker therapy in OVERDRIVE pacer mode is intended for suppression of tachycardia.

AED-Mode

AED-Mode should be used when the patient has all of the following symptoms:

- Unconsciousness
- Absence of normal breathing
- Absence of signs of circulation

SpO2

Nellcor OxiMax™ technology allows the use of different types of SpO2 sensors. The indications of the sensors are listed in the instructions for use of the sensors.

3.3.2 Medical contraindications

ECG

No contraindications known.

Asynchronous defibrillation

Manual asynchronous defibrillation is contraindicated in the treatment of Pulseless Electrical Activity (PEA) and in the treatment if asystole. Defibrillation is unintended for patient who show signs of circulation.

Synchronous defibrillation (cardioversion)

Synchronous defibrillation (Cardioversion) is contraindicated in the treatment of Pulseless Electrical Activity (PEA), such as idioventricular or ventricular escape rhythms, and in the treatment of asystole.

AED-Mode

AED-Mode should not be used if the patient shows one of following symptoms:

- Consciousness
- Breathing
- Signs of circulation

Pacemaker therapy

DEMAND / FIX: Pacemaker therapy in DEMAND or FIX pacer mode is unintended for treatment of ventricular fibrillation or asystole.

OVERDRIVE: Pacemaker therapy in OVERDRIVE pacer mode is unintended for treatment of ventricular fibrillation or asystole.

SpO2

Nellcor OxiMax™ technology allows the use of different types of SpO2 sensors. The contraindications are listed in the instructions for use of the sensors.

3.3.3 Intended patient group

ECG

Patients older than one year where heart rate and heart rhythm recognition is indicated.

Asynchronous defibrillation / synchronous defibrillation (Cardioversion)

Patients where asynchronous or synchronous defibrillation is indicated.

Patients older than one year but with less body weight than 25kg shall be treated with SavePads Mini in pediatric mode or child paddles and a maximum energy of 100J.

Pacemaker therapy

Patients older than one year where pacemaker therapy is indicated.

SpO2

Nellcor OxiMax™ technology allows the use of different types of SpO2 sensors. The intended patient group is specified in the instruction for use if the SpO2 sensor.

AED-Mode

Patients older than one year that show symptoms of sudden cardiac arrest.

Patients older than one year but with less body weight than 25kg shall be treated with SavePads Mini in pediatric mode.

3.3.4 Probable body part

ECG electrodes

ECG electrodes are attached to the patient's chest.

Multifunction electrodes

SavePads Connect, SavePads Mini Connect, SavePads, SavePads PreConnect, SavePads Mini are attached to the patient's chest or upper back.

Paddles

Adult / Pediatric paddles are attached to the patient's chest.

SpO2

Nellcor OxiMax™ technology allows the use of different types of SpO2 sensors. The applied part depends on the sensor used. The applied part is defined in the instructions for use of the sensor itself.

3.3.5 Intended use environment

The DefiMonitor XD will be used on scene of emergency. The DefiMonitor XD can be used in road ambulances as well. The limitations for temperature, humidity and air pressure are specified in chapter 11.7.

3.3.6 Intended user profile

The DefiMonitor XD is intended to be used by trained medical personnel who are familiar with basic monitoring, vital sign assessment, resuscitation situations and trained on the use of DefiMonitor XD. While using the DefiMonitor XD, the patient has to be attended by trained medical personnel constantly.

4 General safety advice

Read the operating instructions carefully before using the DefiMonitor XD for the first time. Only use the DefiMonitor XD as described in the instructions for use.

Consider the environmental conditions mentioned in the technical specifications when storing and operating the device.

Install the DefiMonitor XD so that you can separate the device from the supply network at any time.

Follow the instructions of the DefiMonitor XD.

Use the DefiMonitor XD on a non-conductive base only. Do **not** use the DefiMonitor XD in standing water or in the rain.

Do not use the DefiMonitor XD in the presence of flammable materials.

The DefiMonitor XD and its accessories are safe when used as intended and when following the descriptions and information detailed in these operating instructions. Despite this, if used incorrectly, the DefiMonitor XD and its accessories can be dangerous to the user, the patient or third parties!

Do not touch the contacts on the DefiMonitor XD or on the energy module.

The use of several medical devices simultaneously may present a danger to the patient as a result of the cumulation of patient currents.

Keep the device away from children!

Only the use of original accessories specified in these instructions for use provides defibrillation protection.

The warnings in the following chapters indicate dangers and must be heeded to avoid the dangers. They are divided into various escalation levels, see the following warnings.

⚠ DANGER

Texts marked DANGER indicate an extraordinarily serious immediate danger which will definitely lead to serious injury or even death if no preventative measures are adopted! It is imperative that you pay attention to these texts!

⚠ WARNING

Texts marked WARNING indicate an extraordinarily serious potential danger which could lead to serious injury or even death if no preventative measures are adopted! It is imperative that you pay attention to these texts!

⚠ CAUTION

Texts marked CAUTION indicate a potentially dangerous situation which could lead to minor injuries! It is imperative that you pay attention to these texts!

5 Description of device

5.1 General description

The DefiMonitor XD is an external defibrillator with integrated 6-channel ECG. The ECG can be recorded either via the SavePads, the defibrillation paddles or the four-pin patient cable with self-adhesive ECG electrodes. The DefiMonitor XD is available in various models. The respective model will be shown on the monitor when the defibrillator is turned on.

The DefiMonitor XD is available in the following models:

Model	Product designations so far	Basic device	AED option	PACER option	SPO2 option
DefiMonitor XD	DefiMonitor XD1 / DefiMonitor XD1xe	X			
DefiMonitor XD SPO2	DefiMonitor XD3 / DefiMonitor XD3xe	X			X
DefiMonitor XD PACER	DefiMonitor XD10 / DefiMonitor XD10xe	X		X	
DefiMonitor XD PACER, SPO2	DefiMonitor XD30 / DefiMonitor XD30xe	X		X	X
DefiMonitor XD AED	DefiMonitor XD100 / DefiMonitor XD100xe	X	X		
DefiMonitor XD AED, PACER	DefiMonitor XD110 / DefiMonitor XD110xe	X	X	X	
DefiMonitor XD AED, SPO2	DefiMonitor XD300 / DefiMonitor XD300xe	X	X		X
DefiMonitor XD AED, PACER, SPO2	DefiMonitor XD330 / DefiMonitor XD330xe	X	X	X	X

For all models, energy is provided by the AkuPak LITE XD or via the mains. For further information regarding the AkuPak LITE XD, please refer to the separate operating instructions.

A wide range of accessories are available. The handling of the accessories is described in separate operating instructions in-part.

The lifetime of DefiMonitor XD is 10 years.

5.2 Scope of delivery

After delivery, first of all check the packaging and the device for transport damage.

If you notice any damage to the device, immediately contact your transport company or dealer, or directly contact the technical service at Metrax GmbH, stating the device number and describing the damage to the device.

Satisfy yourself that the scope of delivery is complete in accordance with the enclosed delivery note (standard accessories).

Article	Article no.	Further information
DefiMonitor XD	model dependent language dependent	
AkuPak LITE XD	97311	
Power supply cord M290 SK II EU black 2,5 m or Power supply cord M290 SK II USA black 2,5 m	23955 24026	only for Latin America
SavePads Connect cable coded	97384	Cable length 3.6 m
SavePads Connect (1 pair)	96516	
Paddle set XD	96591	
ECG patient cable 4-pole coded IEC	97386	Cable length 3.6 m
ECG electrodes, 1 pack = 30 pcs.	-	
Printer paper, 1 roll	-	
Contact gel, 1 tube	-	
SaveCard	20770	
Instructions for useDefiMonitor XD	language dependent	
Instructions for use AkuPak LITE XD	language dependent	
only for devices with SPO2 option:		
Nellcor SpO2 finger sensor FLEXMAX	97802	reusable, patient weight >20 kg
Nellcor SPO2 interface cable DOC10	97221	Cable length 3 m

Subject to change without notice.

5.3 Description of device details

Fig. 1 DefiMonitor XD – front view

1 Carry handle
2 Paddle
3 Paddle cable, detachable
4 Membrane keypad (option-dependent, here: DefiMonitor XD AED, PACER, SPO2)
5 Monitor
6 Status display

Fig. 2 DefiMonitor XD – rear view (similar to illustration)

1 Opening for single-hand release hook
2 Identification plate
3 Quality seal

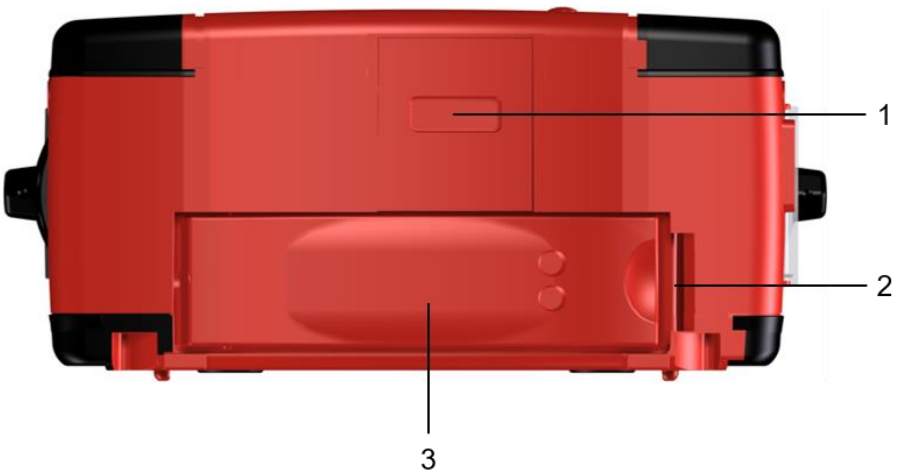


Fig. 3 DefiMonitor XD – bottom view

1 SaveCard cover
2 Release button (to remove the energy module)
3 Energy module AkuPak LITE XD

Fig. 4 DefiMonitor XD – left-hand side view

1 Slot for paddle
2 Loudspeaker
3 Socket for electrode connector
4 Socket for paddle connector
5 Socket for SpO2 sensor (optional)
6 Attachment point for bag

Fig. 5 DefiMonitor XD – right-hand side view

1 Slot for paddle
2 Release lever for printer cover
3 Printer cover
4 Power supply socket
5 Attachment point for bag

Fig. 6 Paddle set

1 STERNUM paddle button
2 APEX paddle button
3 Paddle connector

5.3.1 Controls

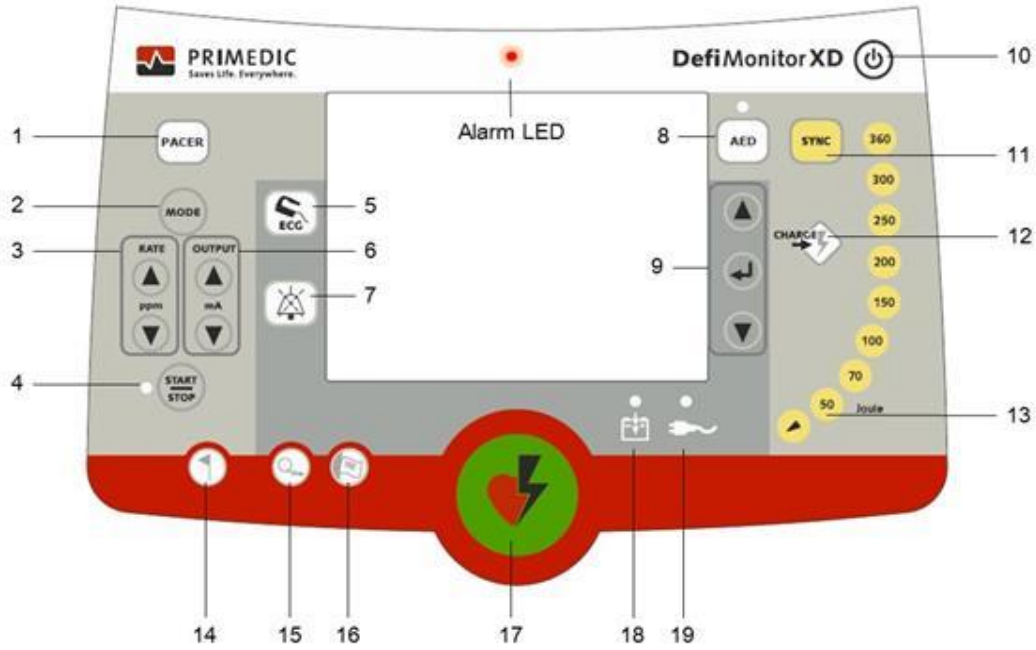


Fig. 7 DefiMonitor XD controls

1 Pacer on/off (only for the Pacer option)

2 Pacer mode DEMAND / FIX / OVERDRIVE (only for the Pacer option)

3 Stimulation frequency +/- (only for the Pacer option)

4 Pacer Start/Stop with LED (only for the Pacer option)

5 ECG source

6 Stimulation intensity +/- (only for the Pacer option)

7 Alarm acknowledgement button

8 AED button with LED (only for the AED option)

9 Settings keys

Key to scroll upwards in Settings, to increase parameters, or to select upper ECG curve lead

Enter key to select or confirm

Key to scroll downwards in Settings, to decrease parameters, or to select lower ECG curve lead

10 On / Off button

11 SYNC button

12 Charging button for use with the multifunction electrodes (SavePads)

13 Energy level in joules

14 Event button

15 Paper feed

16 Printer button

17 Shock button for use with the multifunction electrodes (SavePads)

18 LED display - battery charging

19 LED display - connected to mains

5.3.2 Monitor display

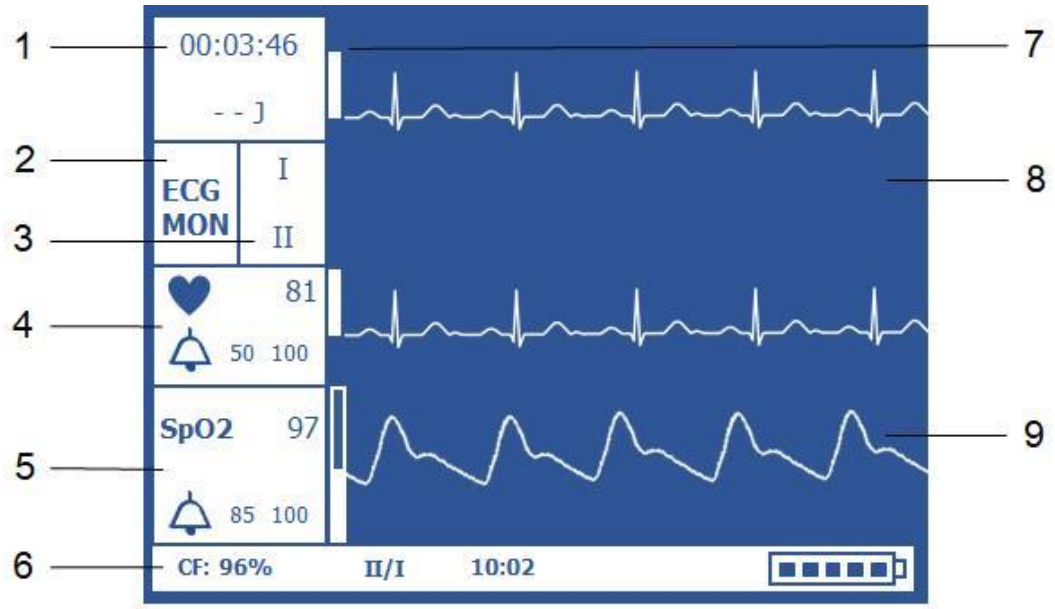


Fig. 8 Monitor display

1 Period since device started / energy level / progress of charging process / pacer

2 Mode: AED / MAN / SYNC / PACE / ECG MON

3 ECG channel display / number of shocks

4 Heart rate and alarm limits display

5 Plethysmogram and alarm limits display

6 Status bar for displaying SaveCard storage capacity, patient contact status, time, pediatric mode, pacer status, printer status, paper status, battery capacity

7 Calibration peak, height corresponds to 1 mV

8 ECG channels display (max. 2)

9 SpO2 curve, notes, information (SpO2 option)

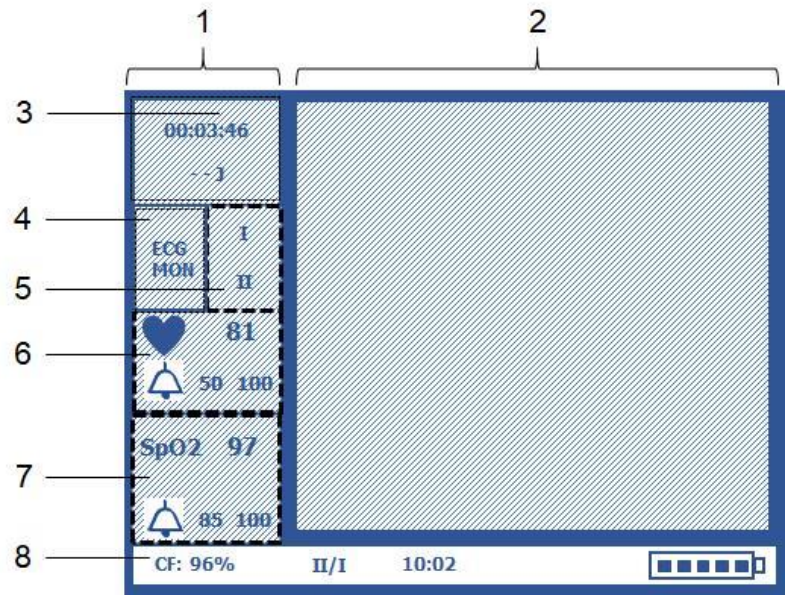


Fig. 9 Monitor area

1 Information column
2 Display area
3 Information area 1
4 Information area 2
5 Information area 3
6 Information area 4
7 Information area 5
8 Status bar

5.3.3 Monitor symbols

Symbol	Meaning
	Pacer passed self-test
	Pacer failed self-test
	No paper
	Printer error
	Paddle
	Heart rate
	Alarm limits / Alarm activated
	Alarm deactivated

Symbol	Meaning
	Pediatric mode activated
	Charge level of energy module, see chapter 6.1.5

Patient contact status

The following tables show the patient contact status. The symbols are displayed in the status bar.

Display when using ECG electrodes

ECG lead I	ECG lead II	Display
valid	valid	II / I
valid	invalid	- / I
invalid	valid	II / -
invalid	invalid	- / -
		with ECG patient cable, 4-pin, coded (97386)

Display when using SavePads or Paddles

Patient contact	Display
valid	II
invalid	-

Note

You can find more information about ECG leads in chapter 7.9.

6 Preparatory measures before (initial) start-up

Note

Should the device have been stored or transported under extreme environmental conditions (see Chapter 11.7), allow the device acclimatise for at least 2 hours before turning it on.

Prior to initial use, the device must be fully commissioned.

Daily testing of the DefiMonitor XD

Note

We recommend carrying out visual inspection of the DefiMonitor XD, its accessories and the MMI test daily.

Conduct the daily testing of the DefiMonitor XD according to the following checklist.

Check expiration dates

- Check the expiration date
  - ➢ Of the SavePads
  - ➢ Of the ECG electrodes
  - ➢ Of the electrode gel
  - ➢ Of the AkuPak LITE XD
- Replace the parts if necessary!

Check device

- Check whether
  - ➢ The status display “OK” is shown
  - ➢ You can switch on the device
  - ➢ The device automatically carries out the self-test after being switched on
  - ➢ The slot for the energy supply is clean
  - ➢ The device is fully equipped
  - ➢ The cables and plugs show no signs of damage
- Check the cleanliness of paddles and children’s paddles.
- Carry out the MMI test, see Chapter 7.14.1.

Pay attention to the following

- Check whether the SavePads’ case is undamaged. Replace the SavePads if necessary.
- If parts of the housing, the insulation or accessories are damaged, they must be repaired or replaced immediately.
- If parts of the housing, the insulation or accessories are damaged, do not commission the device or switch it off immediately!

Testing the AkuPak LITE XD every 4 - 6 weeks

- Disconnect the defibrillator from the mains.
- Switch the defibrillator on in battery mode.
- Allow the defibrillator to operate for approx. 5 minutes.
- Reconnect the defibrillator to the mains power network.
  - ✓ The charge level of the AkuPak LITE XD is reassessed and displayed.

6.1 Power supply

⚠ WARNING

The device can only be used if the AkuPak LITE XD is inserted

Treatment or monitoring not possible

- ➢ Make that sure than an AkuPak LITE XD has been inserted.
- ➢ If the device reports during use that AkuPak LITE XD needs to charged, charge the AkuPak LITE XD.
  If you are unable to charge the AkuPak LITE XD, the device can be operated until it switches itself off.
- ➢ Regularly check whether the AkuPak LITE XD has sufficient charge. Charge the AkuPak LITE XD if necessary.

⚠ DANGER

Defective cells in the energy module

Danger due to the emission of fluids, gases or flying parts

- ➢ Do not damage battery cells mechanically.
- ➢ Wear personal protective equipment when handling burst cells.
- ➢ Do not inhale any fumes which arise.
- ➢ Do not inhale any gas which is emitted.
- ➢ Keep the energy module away from sources of ignition.

The DefiMonitor XD has two power supply options:

- ■ Energy module AkuPak LITE XD energy module (see attached operating instructions)
- ■ Running from the mains with a power cable.

Note

When the AkuPak LITE XD is delivered, the energy module is in “shipping mode” and must be activated before the first use. The activation process is described in Chapter 6.1.2 .

6.1.1 Removing the energy module

Note

When the DefiMonitor XD is delivered, there is a film between the energy module contacts and the device contacts. This film must be removed before use.

Note

Only change the power module when the device is switched off and the mains plug has been disconnected.

Remove the electrode connector before changing the energy module.

Wait at least 5 seconds after switching off before removing the energy module.

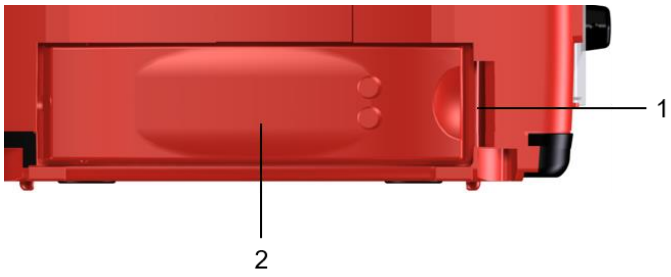


Fig. 10 DefiMonitor XD – removing the energy module

Procedure:

- Lay the DefiMonitor XD on its back.
- Press the release mechanism button, fig. 10 (1) to the right until the energy module (2) is released and protrudes from the slot.
- Pivot the energy module (2) to the front and remove it.

6.1.2 Activate the AkuPak LITE XD

The AkuPak LITE XD is put into a special energy saving mode – "shipping mode” – before being despatched, ensuring maximum storage time for the battery. You therefore need to take the AkuPak LITE XD out of this mode before operating a defibrillator with it for the first time.

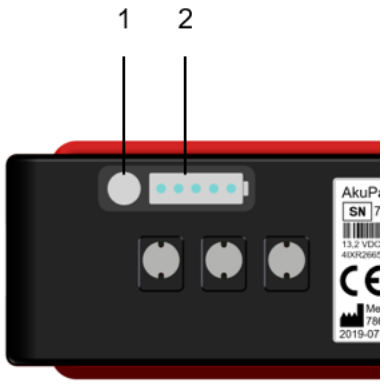


Fig. 11 AkuPak LITE XD charge level display

1 Button to activate charge level display

2 Charge level display

Procedure, Fig. 11:

- Press the charge level display button (1) for several seconds.
- Watch the charge level display (2)
  - ✓ If the LEDs start to light up from the middle LED and then also go out again starting from the middle, the AkuPak LITE XD has been activated.

Checking the AkuPak LITE XD charge level, Fig. 11

If an AkuPak LITE XD is stored outside the device, its charge level can be checked by briefly pressing the button (1).

Charge level display	Meaning
● ● ● ● ●	81 % - 100 % charged
● ● ● ●	61 % - 80 % charged
● ● ●	41 % - 60 % charged
● ●	21 % - 40 % charged
●	1 % - 20 % charged
	0 % charged

6.1.3 Inserting the energy module

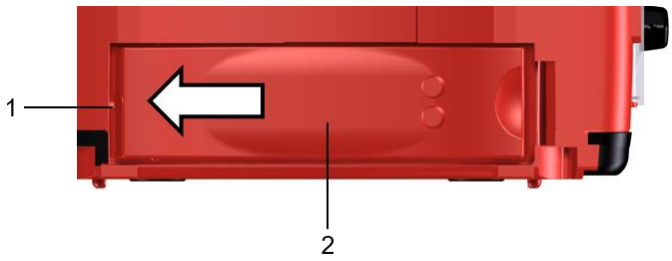


Fig. 12 DefiMonitor XD – inserting the energy module

Procedure:

- Lay the DefiMonitor XD on its back.
- Push the energy module, fig. 12 (2) into the device in the direction of the arrow until it rests against the stop position (1) in the energy module slot.
- Press the energy module (2) into the energy module slot until it audibly clicks into place and it is flush with the device housing.
  - ➢ The DefiMonitor XD switches on automatically when the AkuPak LITE XD is inserted and performs an automatic self-test.
  - ✓ If the status display shows the message "OK", the device is ready to use.
- Switch the DefiMonitor XD off (if required) by pressing the On/Off button, fig. 7 (10).

6.1.4 Charging the AkuPak LITE XD

Procedure

- Insert the AkuPak LITE XD into the DefiMonitor XD (see chapter 6.1.3).
- Connect the DefiMonitor XD to the mains using the power cable.
  - ➢ The LED to indicate the device is connected to the mains lights up, Fig. 7 (19). It signals that the DefiMonitor XD has been connected to the mains.
  - ✓ The battery charging LED (18) on the front of the equipment signals that the battery is charging. It goes out when the AkuPak LITE XD is fully charged.

Note

The AkuPak LITE XD can **not** be charged with the Charger Basis or the ClipCharger as there are no contacts on the bottom.

The AkuPak LITE XD must be charged before being used for the first time. The process for this is as described above.

6.1.5 Battery capacity display on the monitor

On the DefiMonitor XD the charge status of the energy module is displayed as a bar chart in the status bar on the monitor. Examples of what might be displayed are explained below:

Shown on the monitor	Meaning
	100 % charged
	80% charged
	60% charged
	40% charged
	20% charged
	0 % charged (device will keep going until it is forced to shut down)
	Communication with AkuPak LITE XD interrupted or AkuPak LITE XD has reached the end of its service life.

To ensure optimum capacity, the AkuPak LITE XD is monitored using electronic charge regulation.

In addition to this display, the DefiMonitor XD also plays a voice message if the charge level of the rechargeable battery is too low and it is about to shut down imminently. This voice message will be repeated every three minutes during operation.

Voice message	Display on monitor
Charging status battery low, please recharge	**Charging status battery low, please recharge**

Note

When the voice message **Charging status battery low, please recharge** is played for the first time, the capacity in the energy module will still be sufficient for at least 3 defibrillations at full energy or 90 minutes' monitoring (ECG and SpO2) or 60 minutes' pacer operation with maximum output.

Note

Make sure to protect the AkuPak LITE XD from moisture as soon as you have removed it from the defibrillator. Otherwise moisture can penetrate inside the battery via the interface and cause damage.

6.1.6 Connection to the supply network

Procedure:

- Insert the power cable connector into the power supply socket, Fig. 5 (4) at the device.
- Plug the mains plug into an socket with the correct voltage.
  - ✓ The LED, Fig. 7 (19) lights up. This signals that the DefiMonitor XD has been connected to the mains power supply.

Note

Ensure that the AkuPak LITE XD is inserted in the energy module slot. This is vital to ensure use of the DefiMonitor XD using the mains power supply. The power cable provided must be used.

Should the DefiMonitor XD monitor show a broken energy module and the mains plug be removed, operation of the DefiMonitor XD cannot be guaranteed.

6.1.7 Separation from the supply network

Procedure:

- Separate the power cable connector from the power supply socket, Fig. 5 (4) at the device.
- Separate the mains plug from the socket.
  - ✓ The LED, Fig. 7 (19) goes out. This signals that the DefiMonitor XD has been separated from the supply network.

7 Using the DefiMonitor XD

⚠ DANGER

Damaged device or accessories

Treatment not possible, injury to patient, user or third party due to electric shock

- ➢ Do not use the device or its accessories if it is damaged.
- ➢ Check the status display before using the device.

⚠ DANGER

Danger of electric shock and too little energy for the patient

Triggering cardiac arrhythmia and burns caused by electric shock

- ➢ Do not touch the patient during defibrillation.
- ➢ Warn third parties about the dangers of defibrillation.
- ➢ Do not touch any conductive items (metal, blood, water, other liquids, etc.) connected to the patient during defibrillation.

⚠ WARNING

Incorrect use of the device

Treatment with incorrect level of energy, defibrillation at the wrong point in time, no treatment possible, not identifying critical condition of a patient

- ➢ Make sure that they meet the qualifications for proper use.
- ➢ Make sure that they have been trained in using the device before using the device.
- ➢ Read the operating instructions carefully before using the device for the first time.
- ➢ Monitor the patient continuously while the device is in use.
- ➢ Only actuate the device if the charging process is complete.

⚠ WARNING

Defibrillation in environments where there is a risk of fire or explosion

Danger of fire or explosion, burn injuries

- ➢ Do not use the defibrillator in areas where there is a risk of fire.
- ➢ Do not use the defibrillator in the presence of flammable substances
- ➢ Do not use the defibrillator in areas where there is a risk of explosion
- ➢ Do not use the defibrillator in oxygen-enriched atmospheres.

⚠ WARNING

Accessories from third party providers

It may be the case that the device specifications (e.g. the energy emitted does not correspond the energy selected, measurement inaccuracies, electromagnetic radiation) are not adhered to if a non-original accessory is used.

- ➢ Only use original accessories.

⚠ WARNING

Interference from external influences

Defibrillator may not be working as intended

- ➢ Do not use the defibrillator for therapy at the same time as high-frequency surgical devices (manual asynchronous/synchronous defibrillation, AED-Mode, pacer).
- ➢ Do not use the defibrillator in areas in which high levels of electromagnetic interference occur (e.g. near MRI scanners).
- ➢ Do not use portable high-frequency communication devices (radio equipment and accessories) closer than 30 cm to the defibrillator or accessories connected to the defibrillator.

⚠ WARNING

Injury due to incorrectly secured defibrillator

Injuries to patients, users or third parties

- ➢ Secure the DefiMonitor XD to the wall bracket during transport.
- ➢ Secure the accessories before transport.

⚠ WARNING

DefiMonitor XD can not be turned on

No use of the DefiMonitor XD is possible

- ➢ After use, check the power supply contacts of the energy module and the defibrillator for damage.

⚠ WARNING

Incorrect cable laying

Strangulation of the patient

- ➢ Lay the cables on the patient in such a way that it cannot result in strangulation.

⚠ WARNING

Other devices interfering with the defibrillator

Potential incorrect operation

- ➢ Avoid using the defibrillator in the immediate vicinity of other devices.
- ➢ Do not use the defibrillator stacked on top of other devices.
  If it is nevertheless necessary to use the device in this way, this device and the other devices should be monitored to make sure that they are working properly.

⚠ WARNING

Improper lifting of DefiMonitor XD

DefiMonitor XD could fall down.

- ➢ Do not lift DefiMonitor XD by the cables.
- ➢ Do not lift DefiMonitor XD by the paddles.
- ➢ Carry DefiMonitor XD only on the carry handle.

⚠ WARNING

The alarm volume is quieter than the ambient noise

A critical patient condition may not be recognised.

- ➢ Select an alarm volume which is audible despite the ambient noise

⚠ WARNING

Improper use of accessories designed for single use

Reduced liability, transmission of pathogens between patients

- ➢ Do not use disposable accessories if they have expired or are damaged.
- ➢ Do not use disposable accessories when they have dried out.
- ➢ Use disposable accessories only once.

Select your position to the DefiMonitor XD so that you can see the monitor at all times and operated the device.

7.1 Switching on / off

7.1.1 Switching on

The device is switched on by pressing the On / Off button, Fig. 7 (10). Directly after switching it on, an internal self-test is carried out to check important functions and signal devices. The device will go into manual mode after passing a self-test.

Standby is confirmed by a beep.

7.1.2 Switching off

You can switch off the device in different ways:

- By pressing the On / Off button for approx. 2 seconds, Fig. 7 (10). A continuous warning beep will sound simultaneously.
- The device switches off automatically if it does not detect any signal source for 30 minutes, or if no key is pressed over that same period. A continuous warning beep will sound simultaneously.
- If the device detects an error, it will automatically switch off to avoid injuries. A continuous warning beep will sound simultaneously.

7.2 Device self-test

⚠ WARNING

Reduced charge level of the energy module due to repeated extended self-tests

The device may not be ready for use.

- ➢ Regularly check the status display.
- ➢ Resolve technical faults if possible.

⚠ WARNING

Only check pacer functionality if the device if switched on

Pacer may not be ready for use.

➢ Check the information in the status bar.

⚠ WARNING

Only check SpO2 module functionality if the device is switched on

SpO2 module may not be ready for operation

➢ Check the display on the monitor

Note

Pacer and SpO2 module functionality are not part of the self-test and must be checked by the user.

7.2.1 Self-test after switching on

The self-test is activated by turning the DefiMonitor XD on or by inserting the AkuPak LITE XD into the device. The self-test checks all important functions and signalling devices.

If an error is detected, an extended self-test (LONG) is automatically carried out. If the error is not resolved, all subsequent self-tests will be extended (LONG). This can lead to the charge level of the AkuPak LITE XD decreasing more quickly than expected.

7.2.2 Automatic, periodic self-tests

The device carries out automatic self-tests at 8:00 pm device time to ensure that it is always ready for operation. Self-testing is only possible if the DefiMonitor XD is either connected to the mains or if a charged battery has been inserted.

Frequency	Self-test	Scope of test
Daily	SHORT	Software, membrane keypad, ECG calibration, clock, internal voltage supply and HV unit at 0 V, impedance measurement
First day of the month	MEDIUM	Software, membrane keypad, ECG calibration, clock, internal voltage supply and HV unit at 300 V, impedance measurement
On 1st July and 1st January every year	LONG	Software, membrane keypad, ECG calibration, clock, internal voltage supply and HV unit at 1600 V, impedance measurement

Note

Automatic printout of the results of the self-test can be activated. For more information on this, see chapter 7.16.2

7.2.3 DefiMonitor XD status display

Note

The status display is always viewable even if the device is switched off. Regular checking of the display status is vital for ensuring that the DefiMonitor XD is ready for operation.

Fig. 13 Status display

Ensuring readiness for operation

- Check the status display, Fig. 13 regularly.

The following table lists the possible displays in the status display and their meanings.

Energy module status display	Status display DefiMonitor XD	Energy module meaning	Meaning DefiMonitor XD	Availability for use	Measure
	OK	Energy module capacity is sufficient	Self-test passed	DefiMonitor XD Ready for use	None
	OK	Energy module discharged	Self-test passed	DefiMonitor XD Ready for limited use	Charge or replace the energy module
	OK	Energy module use-by date exceeded	Self-test passed	DefiMonitor XD Ready for limited use	Check use-by date, replace the energy module.
	OK	No energy module inserted	Self-test passed	DefiMonitor XD Not ready for use	Insert energy module
Battery symbol flashes during operation	OK	Internal buffer battery empty	Self-test passed	DefiMonitor XD Ready for limited use	Contact the technical services team for replacement of the internal buffer battery
		Energy module capacity is sufficient	Self-test failed	DefiMonitor XD Not ready for use	Carry out a major self-test by reinserting the energy module or by switching the DefiMonitor XD on again. If the status remains, contact the technical services team
		Communication error between DefiMonitor XD and the energy module	Self-test failed	DefiMonitor XD Not ready for use	Carry out a major self-test by reinserting the energy module or by switching the device on again Charge or replace the energy module

Energy module status display	Status display DefiMonitor XD	Energy module meaning	Meaning DefiMonitor XD	Availability for use	Measure
		Energy module deeply discharged			If the status remains, contact the technical services team

7.2.4 Internal error

If the DefiMonitor XD detects an internal error, voice message **Internal error** will be played. The error code will be displayed on the monitor while the voice message is playing. The DefiMonitor XD will shut itself down independently immediately afterwards.

The error code will be stored on the SaveCard and can be read for servicing purposes.

Note

It may be the case that this error is only temporary or that it is reversible. After receiving the **Internal error** error message you should turn the device back on after waiting for about 30 seconds and await the results of the self-test started up after the device was turned on. If this is completed successfully, the unit can be used without any problems. If the error continues to occur, contact the technical service.

7.3 Settings

Note

You can close the settings menu at any time by changing the mode or by selecting an energy level, Fig. 7.

The device is configured in the factory.

You can change certain parameters in the settings menu. The new configuration remains stored until it is changed again, irrespective of whether the device is switched off or the power module replaced.

General navigation, Fig. 7 (9):

- To open the settings menu during operation, press the enter key ↵.
- Press the ▲ (up) key or the ▼ (down) key to navigate in the settings menu and to increase or decrease a selected parameter.
- Press the ↵ key to select a parameter and to confirm the changed value.

7.3.1 Changing settings – time

Procedure:

- To open the settings menu during operation, press the enter key ↵, Fig. 7 (9).
- Press the ▲ key until the field "To page 2" is highlighted.
- Change the page by pressing the ↵ key several times until “Settings page 3” is displayed.
- Move the cursor upwards by pressing the ▲ key until "Time" is highlighted.
- Select the highlighted parameter “Time” by pressing the ↵ key.
  - ➢ The hour value is highlighted.
- Change the hour by pressing the ▲ key or ▼ key.
- Confirm the correct value by pressing the ↵ key.
  - ➢ The minute value is highlighted.
- Change this entry as described above. Confirm the selected value by pressing the ↵ key.
  - ➢ The parameter "Time" is highlighted.

- If required, you can change the other parameters in the same way.
- To exit the settings menu, use the ▲ key or ▼ key to move the cursor to “Exit” and confirm by pressing the ↵ key.
  ✓ The device is now ready for operation again.

7.3.2 Basic settings

The following table shows the settings of a fully-equipped DefiMonitor XD with AED, PACER and SPO2 options. With the other device variants only entries corresponding to existing options are displayed.

Settings	Value	Basic setting
SpO2 alarm limits	lower alarm limit: 70 - 99 % upper alarm limit: 71 - 100 %	85 100
SpO2 alarm volume	0 %, 25 %, 50 %, 75 %, 100 %	100 %
ECG alarm limits	lower alarm limit: 30 - 150 bpm upper alarm limit: 31 - 300 bpm	50 100
ECG alarm volume	0 %, 25 %, 50 %, 75 %, 100 %	100 %
ECG sensitivity	5 mm/mV , 10 mm/mV , 15 mm/mV	10 mm/mV
AED rescue breaths	On, Off	On
AED pediatric mode	15:2, 30:2	15
To page 2	-	End

Settings page 2	Value	Basic setting
Print format	1-channel, 3-channel, 6-channel	3-channel
Print speed	25 mm/s, 50 mm/s	25 mm/s
Print on shock	On, Off	Off
Self-test report	On, Off	Off
Print events	-	
QRS volume	0 %, 25 %, 50 %, 75 %, 100 %	25 %
Metronome volume	0 %, 25 %, 50 %, 75 %, 100 %	100 %
Master volume	0 %, 25 %, 50 %, 75 %, 100 %	100 %
To page 3	-	End

Settings page 3	Value	Basic setting
Date	-	DD/MM/YYYY
Time	-	hh:mm
MMI Test	-	
Language	-	depends on language package
Contrast	60 - 180	120
To page 4	-	End

Settings page 4	Value	Information
ARM SW	-	Version
	-	Checksum
	-	Date

Settings page 4	Value	Information
DSP SW	-	Version check-sum
	-	Date
MSP SW	-	Version check-sum
	-	Date
ULF	-	Checksum
To page 5	-	End

Settings page 5	Value	Information
BQ type	-	Model
BQ SN	-	Serial number
Ext. MSP SW	-	Version check-sum
Ext. MSP HW	-	Version
SpO2 module	-	PMB05N
Pacer SW	-	Version check-sum
Pacer HW	-	Version check-sum
Device SN	-	Serial number
To page 1	-	End

Note

The values "SpO2 alarm volume" and "ECG alarm volume" are always set to 100 % after the device is switched on.

7.4 Positioning the electrodes on the patient

⚠ WARNING

Placing multifunction electrodes or paddles above active implants

Faulty readings due to active implants or damage to the active implants

- ➢ Make sure that there is no active implant in the path of the current.
- ➢ Do not stick the multifunction electrodes directly over an active implant (pacemaker or similar).
- ➢ Do not place the paddles directly over an active implant (pacemaker or similar).

Make sure that the conductive parts of the electrodes and the connectors of the parts being used are not in contact with conductive parts or the earthing.

Note

Use the electrodes on intact (uninjured) skin.

Note

The electrodes may cause redness in the area to which they are applied.

7.4.1 Undressing the patient

Undress the patient's upper body so that you can place the multifunction electrodes (SavePads).

7.4.2 Removing chest hair

Remove any chest hair present in those areas where the multifunction electrodes (SavePads) are to be placed.

7.4.3 Drying the skin

If the patient's chest is damp, dry the skin in those areas where the multifunction electrodes (SavePads) are to be placed. You can use the patient's clothing as a drying material.

7.4.4 SavePads

⚠ WARNING

Using SavePads Mini / child paddles on adults

Energy output too low for patients with a bodyweight >25 kg

- For patients with a bodyweight >25 kg, use the multifunction electrodes for adults or the adult paddles.

⚠ WARNING

Improper usage of multifunction electrodes meant for one-off usage

Irritation or burning of the skin in the area to which the multifunction electrodes are applied, disrupted ECG analysis, reduced treatment functions due to multifunction electrodes drying out, transmission of pathogens between patients

- Do NOT use the SavePads if they are out-of-date or damaged.
- Do NOT use the SavePads if they have dried out.
- Use the SavePads only once.

SavePads are self-adhesive multifunction electrodes which can be used for defibrillation, stimulation, monitoring and cardioversion.

SavePads are available in various models, see chapter 12.5. The DefiMonitor XD is delivered with SavePads **Connect** as standard. The SavePads Connect are connected to the DefiMonitor XD using the SavePads Connect cable.

Note

Heed the use-by date. The SavePads are to be replaced once they have expired.

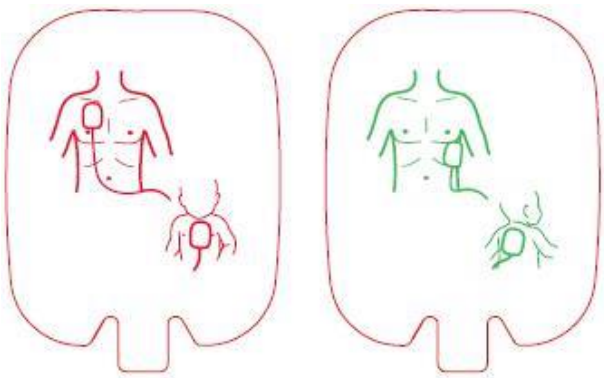


Fig. 14 SavePads Connect (unpacked)

7.4.4.1 SavePads Mini / Pediatric mode

When the DefiMonitor XD detects that SavePads Mini are connected, the energy is limited to max. 100 joules. The DefiMonitor XD is in Pediatric Mode. This applies for asynchronous and synchronous defibrillation. Also in AED mode the energy is automatically reduced. The ratio of chest compression to ventilation is adjusted to the setting.

TheDefiMonitor XD plays the voice prompt **Pediatric Mode**. As long as the DefiMonitor XD is in Pediatric Mode, the status bar shows the icon .

When the SavePads Mini are removed from DefiMonitor XD, the voice prompt **Adult Mode** will sound.

7.4.5 Paddles

⚠ DANGER

Damaged device due to defibrillation with short-circuited paddles

Treatment not possible, injury to patient, user or third party due to electric shock

- ➢ Do not trigger defibrillation if the electrode areas of the two paddles are touching (short circuit)

⚠ WARNING

Short-circuit via electrode gel

Treatment not possible, injury to patient, user or third party due to electric shock

- ➢ Make sure that no short-circuiting can occur via a gel bridge.
- ➢ Make sure that the user is not connected to the patient via electrode gel.

⚠ CAUTION

High contact resistance between paddles and patients

Irritation or burning of the skin in the area the paddles are applied, disrupted ECG analysis, reduced treatment functions

- ➢ Apply a sufficient amount of electrode gel to the contact surfaces of the paddles before usage.

Note

If the paddles are used, the contact surfaces must be furnished with sufficient electrode gel.

The DefiMonitor XD has paddles with integrated child paddles for the defibrillation of children. There is a button for triggering defibrillation on each paddle.

To treat patients aged 1-8, proceed as follows:

- Unscrew the large electrodes on both paddles by turning them anticlockwise.
  - ✓ You now have a reduced electrode surface suitable for children.

Note

Deliver a maximum of 100 joules using the reduced electrode surface!

Fig. 15 Locking the adult paddles in place over the child paddles

Locking the adult paddles in place over the child paddles

- Place an adult paddle on top of a child paddle.
- Tighten the adult paddle by turning it clockwise.
- Repeat the process for the second paddle.

7.4.6 Positioning the SavePads and/or paddles on adults

⚠ WARNING

Increased patient resistance

Danger of skin burns and too-low energy output

- ➢ Remove chest hair in those areas where the electrodes are to be positioned.
- ➢ If necessary, dry the skin before attaching the electrodes.
- ➢ Attach the electrodes directly to the skin. Remove any plasters or anything similar.
- ➢ Do not contact any metallic parts with the multifunction electrodes which are connected to the patient.
- ➢ Keep a distance between multifunction electrodes and other electrodes.

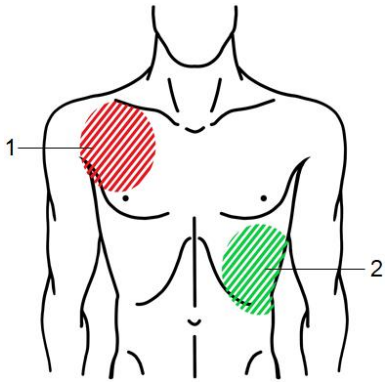


Fig. 16 anterior - anterior position for adults

For the anterior - anterior position, the SavePads / paddles are positioned:

- on the right side of the chest, below the collar bone (1)
- on the left side of the chest, above the apex of the heart on the axillary line (2)

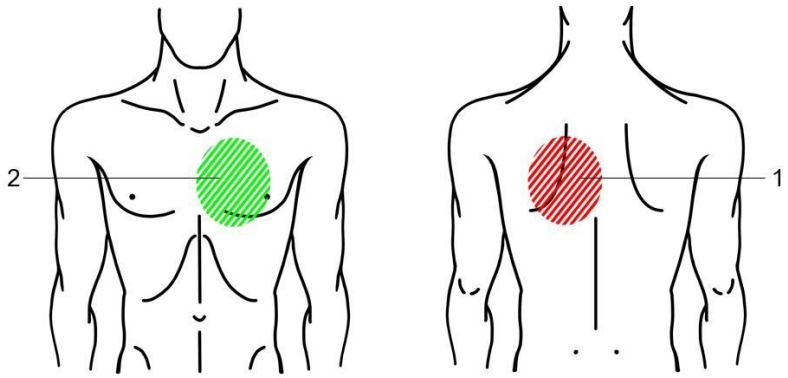


Fig. 17 anterior - posterior position for adults

For the posterior - anterior position, the SavePads are positioned:

- at the back left of chest, between tip of shoulder blade and spine (1)
- at the front left of chest, between sternum and left nipple (2)

Incorrectly positioned electrodes can lead to faulty readings.

Note

Plasters must be removed before using the SavePads.

7.4.7 Positioning the SavePads and/or paddles on children

⚠ WARNING

Using adult electrodes on children

Energy output too high for patients aged 1 – 8 (bodyweight <25 kg)

- ➢ For patients aged 1 – 8 (bodyweight <25 kg), use the SavePads **Mini**.
- ➢ If no SavePads **Mini** are available, the device can be used on patients aged 1 – 8 (bodyweight <25 kg) by using multifunction electrodes for adults.
- ➢ Do not delay the treatment due to not knowing the patient's exact age or weight.

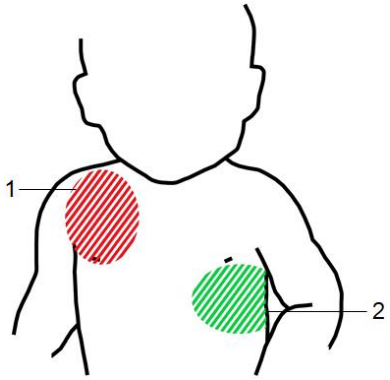


Fig. 18 anterior - anterior position for children

For the anterior - anterior position, the SavePads / paddles are positioned:

- on the right side of the chest, below the collar bone (1), red SavePad
- on the left side of the chest, above the apex of the heart on the axillary line (2) green SavePad

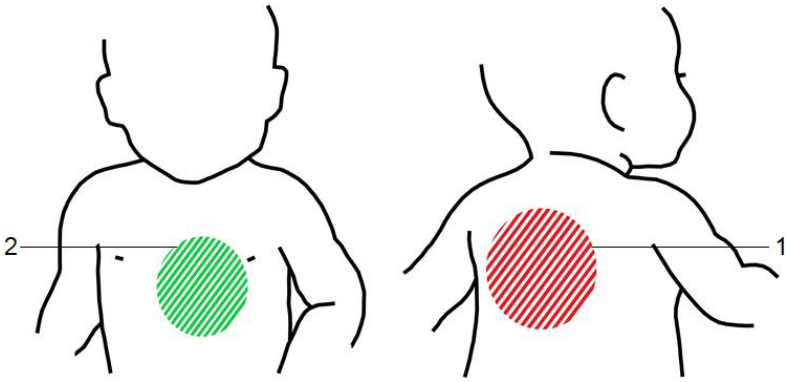


Fig. 19 anterior - posterior position for children

For the posterior - anterior position, the SavePads are positioned:

- at the back left of chest, between tip of shoulder blade and spine (1), red SavePad
- at the front left of chest, between sternum and left nipple (2) green SavePad

Incorrectly positioned electrodes can lead to faulty readings.

Note
Plasters must be removed before using the SavePads.

7.4.8 Opening and attaching SavePads

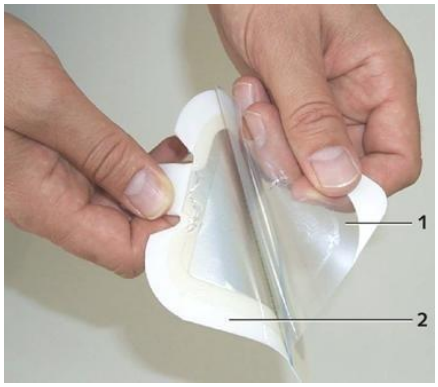


Fig. 20 Removing the protective foil from the electrodes (illustration similar)

1 Protective foil

2 Electrode with a layer of gel

Note
The SavePads themselves are coloured so that they can be placed in their correct positions more easily.

Proceed as follows to attach the SavePads to the patient, Fig. 20:

- Open the SavePads bag by tearing along the red-coloured groove.
- First, remove the protective foil (1) from one of the electrodes (2) and then place the electrode in the position specified previously (see chapter 7.4.6 and 7.4.7)
- Remove the protective foil from the second electrode and place it in its position.
- Smooth the electrodes onto the patient ensuring there are no pockets of air under the electrodes.
- If you are using the SavePads **Mini** , insert the electrode connector into the socket of the DefiMonitor XD.
- If you are using the SavePads **Connect** or SavePads **Mini Connect**, it is imperative that you follow the procedure described below.

Note

Do not touch the floor, objects, clothing or other body parts with the opened Save-Pads. This could remove the conductive layer of gel on the electrodes.

Connecting SavePads Connect / Mini Connect

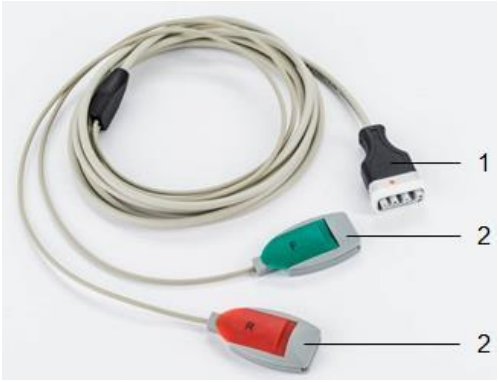


Fig. 21 Coded SavePads Connect cable

1 Connector

2 Connecting clips for SavePads Connect / Mini Connect

Pay attention to the following sequence for attaching the SavePads Connect / Mini Connect, Fig. 21 :

- Attach the SavePads Connect / Mini Connect as in Chapter 7.4.6 or 7.4.7 described onto the upper body of the patient.
- Connect the SavePads Connect cable to the SavePads Connect / Mini Connect attached to the patient. To do this, open the connecting clips (2) in turn and plug the multifunction electrode connection tabs into the respective slit on the connecting clips.
- Make sure that the coloured clips are facing upwards.
- Snap the upper part of the clips back in place to fix the connection.
- Plug the connector of the SavePads Connect cable (1) into the socket on the switched-on DefiMonitor XD. Make sure that the markings match up.

7.4.9 Positioning the ECG adhesive electrodes

Fig. 22 ECG patient cable, 4-pin IEC

1 Connector

2 Electrode clips (green, black, red, yellow)

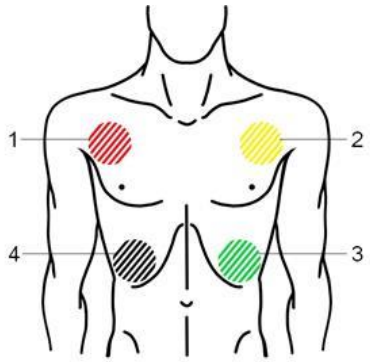


Fig. 23 Positions of the ECG adhesive electrodes on the patient

The positions of the ECG adhesive electrodes are:

(1) red (R)	directly below the centre of the right collar bone (medioclavicular)
(2) yellow (L)	directly below the centre of the left collar bone (medioclavicular)
(3) green (F)	directly below the left chest muscle on the medioclavicular line
(4) black (N)	directly below the right chest muscle on the medioclavicular line

7.5 Removing the electrodes from the patient

Proceed as follows to separate the patient from the DefiMonitor XD:

- Remove the connector for the SavePads or ECG electrodes from the DefiMonitor XD.
- Slowly remove the electrodes from the patient's skin.
- Dispose of the electrodes in the residual waste.

7.6 Fitting an SpO2 sensor

The approval of the DefiMonitor XD was carried out using the Nellcor™ SpO2 finger sensor FLEXMAX and the Nellcor™ interface cable DOC10. Nonetheless, the option exists to insert all Nellcor™ sensors with OxiMax™ technology. Information regarding the use, warnings, precautionary measures and further information can be found in the operating instructions for the respective Nellcor™ sensor.

To attach the FLEXMAX sensor models, proceed as follows:

- Insert the patient's index finger into the sensor

Note
If possible, use the sensor on the patient's index finger. Depending on its size, the sensor can also be attached to a different finger (with the exception of the thumb).

  - ➢ Ensure that the fingertip has contact with the inner end of the sensor.
  - ➢ Guide the sensor cable along the surface of the hand.

Note
Ensure that the sensor is attached the right way round and that the finger doesn't protrude out of the sensor.

- Connect the sensor cable to interface cable DOC10.
- Insert the interface cable connector into the socket, Fig. 4 5) of the DefiMonitor XD.
  - ✓ The measurement values are displayed on the DefiMonitor XD monitor.

Note
Check the sensor measurement site at least every 6 hours. Pay attention to pressure injuries and the skin condition. If necessary, place the sensor elsewhere.

7.7 Removing an SpO2 sensor

Removing sensor model FLEXMAX

- Press the sides of the sensor together to open the sensor.
- Remove the sensor from the finger.
- Disconnect the sensor cable from the interface cable.
- Remove the interface cable plug from the DefiMonitor XD.
- Clean and disinfect the sensor. Please also observe the operating instructions for the sensor.
  - ✓ Store the sensor until it is next used.

The expected shelf life of the sensor is 1 year.

7.8 Alarms and alarm limits

⚠ WARNING

Extremely set alarm limits

No alarm in case of a patient's critical state.

The patient's critical state is not recognised.

➢ Select purposeful alarm thresholds.

The DefiMonitor XD has an intelligent alarm system. High, medium and low priority alarms exist and also informative notifications and error notifications. If several alarms are triggered simultaneously, all the alarms are displayed on the monitor. However, only the heart alarm signal (heart frequency and VF/VT) is played back. Alarm signalling takes place for all alarms in less than 10 seconds.

Physiological alarms

Physiological alarms are triggered by patient monitoring. Different alarm signals exist for alarms which are triggered via heart monitoring (heart frequency and VF/VT) and for alarms which are triggered via the SpO2 monitoring.

Technical alarms

Technical alarms are triggered by the monitoring of the DefiMonitor XD, e.g. battery charge level low. These alarms are signalised acoustically and optically.

Informative notifications and error notifications

Informative notifications and error notifications are signalised acoustically and optically. If your Defi-Monitor XD has SpO2, the notifications will be displayed instead of the SpO2 curve. The notifications will be shown until the cause is resolved.

7.8.1 Alarms with high priority

A high-priority alarm indicates that it is necessary for the user to react immediately.

Parameter	Status	Notification	Mode
ECG, SpO2 (physiological alarm)	Upper alarm limit for heart rate exceeded	Blinking heart rate value	ECG MON
		Blinking alarm bell	MAN
		Blinking alarm LED	SYNC
		Alarm signal	PACE
		Blinking heart rate value	AED
		Blinking crossed-out alarm bell	
	Fallen below lower alarm limit for heart rate	Blinking heart rate value	ECG MON
		Blinking alarm bell	MAN

Parameter	Status	Notification	Mode
		Blinking alarm LED	SYNC
		Alarm signal: High-priority alarm	PACE
		Blinking heart rate value	AED
		Blinking crossed-out alarm bell	
VF/VT (physiological alarm)	A life-threatening cardiac arrhythmia has been detected	Alarm signal: High-priority alarm	ECG MON
		Text message: **VF/VT possible, check patient**,	
		Blinking alarm LED	
SpO2 (physiological alarm)	Upper ECG alarm limit exceeded for SpO2	Blinking SpO2 value	ECG MON
		Blinking alarm bell	MAN
		Blinking alarm LED	SYNC
		Alarm signal: High-priority alarm	PACE
	Upper ECG alarm limit exceeded for SpO2	Blinking SpO2 value	AED
		Blinking crossed-out alarm bell	
	Fallen below lower SpO2 alarm limit	Blinking SpO2 value	ECG MON
		Blinking alarm bell	MAN
		Blinking alarm LED	SYNC
		Alarm signal: High-priority alarm	PACE
	Fallen below lower SpO2 alarm limit	Blinking SpO2 value	AED
		Blinking crossed-out alarm bell	
SpO2 sensor no longer attached to the patient (physiological alarm)	The SpO2 sensor was correctly connected but is no longer attached to the patient. If the condition persists for longer than 10 seconds:	Alarm signal	ECG MON
		Blinking alarm LED	MAN
		Text notification **Check SpO2 Sensor** (omitted when in AED mode)	SYNC PACE AED
		"- - -" instead of the SpO2 value	
		No SpO2 curve	
		No pulse amplitude display	
		No SpO2 alarm bell	
		No SpO2 alarm limits	
		The following symbol is displayed in the SpO2 area: 	

- Check the SpO2 sensor's connection to the patient. Correct it if necessary.

7.8.2 Alarms with medium priority

The following table provides an overview of the alarms with medium priority.

Parameters	Status	Notification	Mode
Battery charge level low (technical alarm)	The AkuPak LITE XDs charge level is low.	The following icon is displayed in the status line:  The following icon is displayed in the status display: 	ECG MON MAN SYNC PACE AED
		Voice message **Charging status battery low, please recharge** After each CPR cycle	AED
		Voice message **Charging status battery low, please recharge** Every 2 minutes	ECG MON MAN SYNC PACE

- Charge the AkuPak LITE XD as soon as possible. Connect the DefiMonitor XD to the mains if possible.

7.8.3 Alarms with low priority

The following table provides an overview of the alarms with low priority.

Parameters	Status	Notification	Mode
Time interval for data update is longer than 30 s (technical alarm)	The measurement of the SpO2 value may be incorrect.	“?” displayed next to the SpO2 value	ECG MON MAN SYNC PACE AED

- Contact the technical services team if necessary.

7.8.4 Informative messages

The following table provides an overview of the informative notifications.

Parameters	Status	Notification	Mode
Key is disabled	ECG electrodes are used and an attempt to change to a therapy mode is made.	Information signal	ECG MON

Shock method via SavePads:

- Connect the patient to the DefiMonitor XD using SavePads.

Shock method via paddles:

- Select ECG lead via paddles to switch to MAN mode.

SpO2 module notifies faulty SpO2 signal SpO2 or pulse rate may be incorrect	The measurement of the SpO2 value may be incorrect.	“?” displayed next to the SpO2 value	ECG MON MAN SYNC PACE AED

Parameters	Status	Notification	Mode
• Check the SpO2 sensor. • Check the SpO2 sensor's connection to the patient • Ensure that the SpO2 sensor is safely connected to the DefiMonitor XD.			
SpO2 sensor not connected to the DefiMonitor XD	The SpO2 sensor is not connected to the DefiMonitor XD.	Text notification **Check SpO2 Sensor** (omitted when in AED mode) "- - -" instead of the SpO2 value No SpO2 alarm bell No SpO2 alarm limits No SpO2 curve No pulse amplitude display The following symbol is displayed in the SpO2 area: 	ECG MON MAN SYNC PACE AED
SpO2 sensor not attached to the patient	The SpO2 sensor has not been attached to the patient.	"- - -" instead of the SpO2 value No SpO2 alarm bell No SpO2 alarm limits	ECG MON MAN SYNC PACE AED
	If the condition persists for longer than 10 seconds:	Text notification **Check SpO2 Sensor** (omitted when in AED mode) The following symbol is displayed in the SpO2 area:  No SpO2 curve No pulse amplitude display	ECG MON MAN SYNC PACE AED
SpO2 sensor no longer attached to the patient	The SpO2 sensor was correctly connected but is no longer attached to the patient.	Text notification **Check SpO2 Sensor** (omitted when in AED mode) "- - -" instead of the SpO2 value No SpO2 curve, no empty pulse amplitude display No SpO2 alarm bell No SpO2 alarm limits	ECG MON MAN SYNC PACE AED

Parameters	Status	Notification	Mode
		The following symbol is displayed in the SpO2 area: 	
	If the condition persists for longer than 10 seconds:	Alarm signal Blinking alarm LED Text notification **Check SpO2 Sensor** (omitted when in AED mode) "- - -" instead of the SpO2 value No SpO2 curve No pulse amplitude display No SpO2 alarm bell No SpO2 alarm limits The following symbol is displayed in the SpO2 area: 	ECG MON MAN SYNC PACE AED

- Check the SpO2 sensor's connection to the patient. Correct it if necessary.

Pacer treatment was stopped	Pacer treatment was stopped as the energy specified differs from the set value.	Voice message: **Pacing stopped** Information signal	PACE

The DefiMonitor XD cannot achieve the set parameter in PACE mode and automatically switches to MAN mode. Pacer treatment is interrupted.

- Check the multifunction electrodes.

Pacer treatment was stopped	The pacer treatment was stopped as the patient's connection to the DefiMonitor XD was interrupted.	Voice message: **Pacing stopped** Information signal	PACE

The patient cannot be treated using PACE mode as the patient's connection to the DefiMonitor XD was interrupted.

- Check the connection between the patient and the DefiMonitor XD.
- Re-establish the connection between the patient and the DefiMonitor XD if necessary.

Pacer self-test not passed	PACE mode is unavailable.	PACE mode cannot be activated. The following icon is displayed in the status line: 	PACE

Parameters	Status	Notification	Mode
ECG interrupted during rhythm analysis	The patient moved during the rhythm analysis.	Voice message: **Patient movement detected** Restart the rhythm analysis	AED
• Ensure that the patient is not moved during the rhythm analysis. • Cease chest compressions during rhythm analysis.			
Information signal, that the mode has changed from MAN to SYNC or vice-versa.	Mode change from MAN to SYNC. Mode change from SYNC to MAN.	Information signal	MAN SYNC
The DefiMonitor XD is in manual asynchronous or manual synchronous mode and the energy for defibrillation has been fully charged. An attempt is made to change between these two modes.	The energy required for defibrillation is fully charged. No change from MAN to SYNC and vice-versa possible	Information signal Notification: **No shock delivered**	MAN SYNC
The DefiMonitor XD is in manual asynchronous or manual synchronous mode and the energy for defibrillation has been fully charged. Defibrillation should be made via the paddles.	No valid patient connection at the point in time of defibrillation.	Information signal Notification: **No shock delivered**	MAN SYNC
DefiMonitor XD is switched on.	DefiMonitor XD is switched on and ready for operation.	Information signal	ECG MON MAN SYNC AED
DefiMonitor XD is switched off.	DefiMonitor XD is switched off	Information signal	ECG MON MAN SYNC AED

Error Messages

The following table provides an overview of the error notifications.

Internal error	An internal error has been detected. The DefiMonitor XD is not ready for use.	Voice message: **Internal error**	ECG MON MAN SYNC PACE AED

The DefiMonitor XD has detected an internal error and is not ready for operation. The DefiMonitor XD turns itself off independently.

- Switch the DefiMonitor XD back on.
  - ✓ If the self-test is successful, the DefiMonitor XD can be used. If not, please contact the technical services team.

Parameters	Status	Notification	Mode
ECG in invalid range	The ECG is in the saturation region or cannot be displayed.	Dashed line instead of ECG curve	ECG MON MAN SYNC PACE AED

- Wait until the ECG signal returns to a valid region.

DefiMonitor XD is ready for defibrillation.	The energy required for defibrillation is fully charged to the DefiMonitor XD.	Information signal	MAN AED

Shock via SavePads

- Press the Shock button to trigger defibrillation.

Shock via paddles

- Press the paddles on the patient’s chest and press both paddle buttons simultaneously.

Internal discharge after 15 seconds

If defibrillation is not triggered within 15 seconds, the energy is discharged internally.

DefiMonitor XD is ready for defibrillation.	The energy required for defibrillation is fully charged to the DefiMonitor XD.	Information signal	SYNC

Shock via SavePads

- Press the Shock button to trigger defibrillation. The pitch changes during synchronisation.

Shock via paddles

- Press the paddles on the patient’s chest and press both paddle buttons simultaneously. The pitch changes during synchronisation.

Internal discharge after 15 seconds

If defibrillation is not triggered within 15 seconds, the energy is discharged internally.

No connection between the patient and the DefiMonitor XD	The ECG electrodes are not attached to the patient or the ECG cable is not connected to the DefiMonitor XD. The ECG electrodes used are defective. The ECG electrodes have short-circuited.	Voice message: **Plug in electrode cable** **Apply electrodes one after the other to patient's bare chest**	ECG MON

- Check the ECG electrodes and ensure there is a connection between the patient and the DefiMonitor XD.

No connection between the patient and the DefiMonitor XD	The connection between the patient and the DefiMonitor XD has been interrupted.	Voice message: **Check electrodes** **Apply electrodes one after the other to patient's bare chest**	AED MAN SYNC PACE

Parameters	Status	Notification	Mode
• Check the SavePads and ensure there is a connection between the patient and the DefiMonitor XD.			
Printer not ready for operation	An internal error has been detected in the printer.	The following icon is displayed in the status line: 	ECG MON MAN SYNC PACE AED
• Please contact the technical services team.			
Printer not ready for operation	There is not enough printer paper in the printer.	The following icon is displayed in the status line: 	ECG MON MAN SYNC PACE AED
• Refill with printer paper.			
Data recording not possible	The SaveCard in the DefiMonitor XD is full.	“CF:FULL” displayed in the status bar	ECG MON MAN SYNC PACE AED
• Archive the data on the SaveCard externally. • Insert an empty SaveCard into the DefiMonitor XD.			
Data recording not possible	There is no SaveCard in the DefiMonitor XD. The SaveCard in the DefiMonitor XD is defective.	“NO CF” displayed in the status bar	ECG MON MAN SYNC PACE AED
• Insert a SaveCard into the DefiMonitor XD.			
Error in the SpO2 module	An error has been detected in the SpO2 module.	No SpO2 curve “- - -” instead of the SpO2 value Text message:**SpO2 error**	ECG MON MAN SYNC PACE AED
Error in the SpO2 sensor	An error has been detected in the SpO2 sensor.	“- - -” instead of the SpO2 value Text message:**Replace SpO2 Sensor** The following symbol is displayed in the SpO2 area: 	ECG MON MAN SYNC PACE AED
• Please contact the technical services team.			

7.8.5 Messages in AED-Mode

The DefiMonitor XD issues voice messages. The corresponding text version of the message will be shown in the lower area of the monitor. For devices with SpO2 option, the plethysmogram will not be shown in AED mode.

Status / Action	Notification	Voice message
The patient must be connected to the DefiMonitor XD.	**Apply electrodes one after the other to patient's bare chest**	**Apply electrodes one after the other to patient's bare chest**
An internal error has been detected. The DefiMonitor XD is not ready for use.	**Internal error**	**Internal error**
The patient must not be touched.	**Stand clear of patient**	**Stand clear of patient**
The energy required for defibrillation has been charged. Trigger defibrillation by pressing the shock button.	**Deliver shock now**	**Deliver shock now**
The ECG analysis has revealed that there is no heart rhythm requiring defibrillation.	**No shock advised**	**No shock advised**
The ECG analysis has revealed that there is a heart rhythm requiring defibrillation.	**Shock advised**	**Shock advised**
Carry out cardiopulmonary resuscitation.	**Cardio pulmonary resuscitation**	**Cardio pulmonary resuscitation**
No correct electrode contact. Check whether there are any pockets of air between the electrodes and the skin.	**Check electrodes**	**Check electrodes**
The patient may neither be touched nor moved.	**Do not touch the patient**	**Do not touch the patient**
An ECG analysis is being carried out	**Analysing rhythm**	**Analysing rhythm**
Message from the MMI test. This notification will not appear while the device is being used on the patient.	**If you hear this message, press the shock button**	**If you hear this message, press the shock button**
Call emergency services.	**Call emergency services**	**Call emergency services**
Ventilate the patient twice.	**Give 2 rescue breaths**	**Give 2 rescue breaths**
Perform 30 chest compressions.	**Give 30 chest compressions**	**Give 30 chest compressions**
Perform 15 chest compressions.	**Give 15 chest compressions**	**Give 15 chest compressions**
Insert the SavePads connector or the coded SavePads Connect cable.	**Plug in electrode cable**	**Plug in electrode cable**
The AkuPak LITE XD charge level is low. Charge the AkuPak LITE XD if possible.	**Charging status battery low, please recharge**	**Charging status battery low, please recharge**
Use the SavePads.	**Electrodes not suitable. Please change to defibrillation electrodes.**	**Electrodes not suitable. Please change to defibrillation electrodes.**
Switch to AED mode or assess the ECG. There may be a heart rhythm requiring defibrillation.	**VF/VT possible, check patient**	**VF/VT possible, check patient**

Status / Action	Notification	Voice message
Perform chest compressions.	**Chest compressions**	**Chest compressions**
Patient movement has been detected. Ensure that the patient is not moved.	**Patient movement detected**	**Patient movement detected**
The device is in adult mode.	**Adult Mode**	**Adult Mode**
The device is in Pediatric Mode.	**Pediatric Mode**	**Pediatric Mode**
The electrodes seem to be out of order technically. Replace the electrodes if possible.	**Invalid electrodes. Please use different electrodes**	**Invalid electrodes. Please use different electrodes**
No defibrillation was delivered to the patient.	**No shock delivered**	**No shock delivered**

7.8.6 Alarm volume

The alarm volume can be adjusted as follows:

Parameter	Area	Resolution	Basic setting
ECG alarm volume	0-100%	25%	100%
SpO2 alarm volume	0-100%	25%	100%

Changing the alarm volume

- To start the settings menu during operation, press the enter key ↵, Fig. 7 (9).
- Move the cursor upwards by pressing the ▲ key several times until the desired parameter is highlighted.
- Select the highlighted parameter “ECG alarm volume” or “SpO2 alarm volume” by pressing the ↵ key.
- Change the alarm volume by pressing the ▲ key or ▼ key.
- Confirm the selected value by pressing the ↵ key.
- To exit the settings menu, use the ▲ key or ▼ key to move the cursor to “Exit” and press the ↵ key.
  - ✓ The device is now ready for operation again.

The volume of the acoustic alarm can be changed as described in the table.

7.8.7 Alarm limits

The alarm limits can be adjusted as follows:

Parameter	Area	Resolution	Basic setting
ECG alarm limits Lower alarm limit	30 – 300 bpm	1 bpm	50 bpm
ECG alarm limits Upper alarm limit	Lower alarm limit - 300 bpm	1 bpm	100 bpm
SpO2 alarm limits Lower alarm limit	70 - 99 %	1 %	85 %
SpO2 alarm limits Upper alarm limit	Lower alarm limit - 100 %	1 %	100 %

Changing the alarm limits

- To start the settings menu during operation, press the enter key ↵, Fig. 7 (9).
- Move the cursor upwards by pressing the ▲ key several times until the desired parameter is highlighted.

- Select the highlighted parameter “ECG alarm limits” or “SpO2 alarm limits” by pressing the ↵ key.
  - ➢ The lower alarm limit is highlighted.
- Change the lower alarm limit by pressing the ▲ key or ▼ key.
- Confirm the selected value by pressing the ↵ key.
  - ➢ The upper alarm limit is highlighted.
- Change this entry as described above. Confirm the selection by pressing the ↵ key.
  - ➢ The parameter "ECG alarm volume" is highlighted.
- To exit the settings menu, use the ▲ key or ▼ key to move the cursor to “Exit” and press the ↵ key.
  - ✓ The device is now ready for operation again.

7.8.8 Muting the alarm

The alarms are always activated when the DefiMonitor XD is switched on. The alarm limits can be adjusted in the settings menu.

If an alarm occurs, it can be muted for 60s using the alarm acknowledgement button, Fig. 7 (7). The visual alarms will continue to be displayed during this time.

- Check the patient and initiate the appropriate measures.

7.9 ECG monitoring (ECG MON)

The ECG shows the electrical activity of the patient’s heart. An ECG can be used to determine the patient’s heart rate or heart rhythm, and detect any arrhythmias. For an ECG, electrodes are placed on the patient’s skin to determine the ECG.

The ECG signal may be briefly disrupted by defibrillation.

Make sure that neither the ECG electrodes nor the conductive parts of the electrode clips contact other conductive parts or the ground.

The DefiMonitor XD can record the patient ECG using the following sensors:

- 4-pin ECG cable
- SavePads
- Paddles

ECG leads I, II, III, aVR, aVF and aVL can be represented by the 4-pin ECG cable. Lead II can be represented by the SavePads and the paddles.

Lead	Lead formation
I	R - L
II	R - F
III	L - F
aVR	$R - \frac{L+F}{2}$
aVF	$F - \frac{R+L}{2}$
aVL	$R - \frac{L+F}{2}$

It is not possible to switch off pacemaker rejection.

If the patient has a pacemaker implanted, the stimulation signal will be shown as follows:

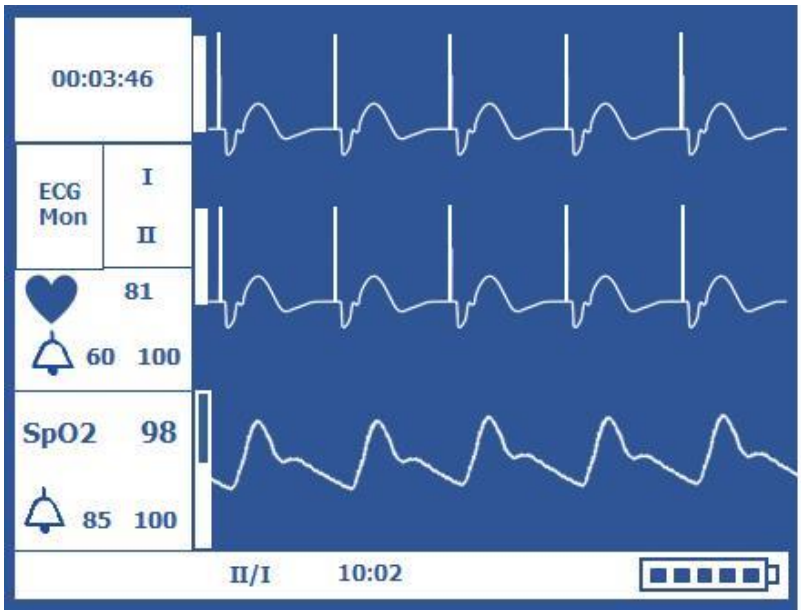


Fig. 24 Display of the suppression of pacemaker pulses

7.9.1 Connecting the ECG electrodes

Note

Do not use any dried-out or out-of-date electrodes.

Note

Attach all four ECG electrodes to the patient's chest to perform ECG monitoring, see chapter 7.4.9.

Connection for ECG adhesive electrodes Fig. 4 (3)

- Insert the 4-pin ECG cable connector into the socket, Fig. 4 (3)
- Connect the ECG electrodes with the electrode clips.

7.9.2 Changeover of ECG source

The ECG can be recorded via the paddles or via the adhesive electrodes. Pressing the ECG source button, Fig. 7 (5) alternates between the paddles and multifunction electrodes.

7.9.3 Switching the leads on the monitor

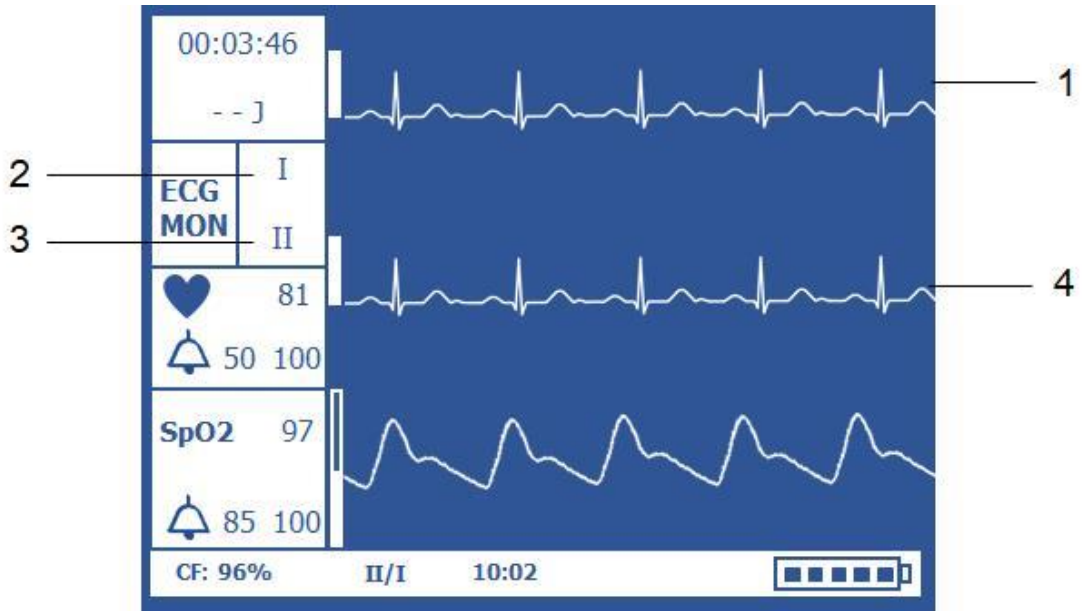


Fig. 25 Display leads

If the 4-pin ECG cable is used, the leads of the ECG curves can be selected independent of each other.

- By pressing the ▲ (up) key, fig. 7 (9) several times, the upper ECG curve lead (1) can be changed (I, II, III, aVR, aVF, aVL) during operation. The selected lead is displayed in information area 3 (2).
- By pressing the ▼ (down) key (9) several times, the second ECG curve lead (4) can be changed (I, II, III, aVR, aVF, aVL) during operation. The selected lead is displayed in information area 3 (3).

7.10 Manual asynchronous / synchronous defibrillation (MAN / SYNC)

Side-effects

The following side-effects may be incurred during or after defibrillation:

Frequently

- Muscle contractions

Likely

- Irritation or burning of the skin in the area of the electrodes

Occasionally

- Cardiac arrhythmia (atrial fibrillation or atrial flatter)
- Damage to the heart muscle
- Chest pain

Note

Separate the patient from other electrical medical devices which are not defibrillation-proof for the defibrillation.

Note

If the settings view is active, you can switch to MAN mode directly by pressing one of the energy levels or the ECG source button.

7.10.1 Energy selection

⚠ DANGER

Energy too high for children

Skin burns, current density too high

➢ Select 100 joules at most for treating children (bodyweight < 25 kg).

⚠ WARNING

Unintentional energy selection

Treatment with incorrect energy

➢ Check the energy selection before triggering defibrillation.

Various energy levels are available for manual defibrillation.

In adult mode, the following energy levels are avaiable by button selection: 50 J, 70 J, 100 J, 150 J, 200 J, 250 J, 300 J, 360 J.

In pediatric mode, the following energy levels are avaiable by button selection: 50 J, 70 J, 100 J.

By pressing the arrow button, in adult and pediatric mode, you can select the energy levels 2 J, 5 J, 7 J, 10 J, 20 J, 30 J. The selection is repeated from the beginning again after 2 J.

The selected energy level is shown in information area 1 in Fig. 9.

7.10.2 Charging

- First choose the shock method.

Note

It is possible to correct the selected energy level using the keypad, Fig. 7 (13).

Shock via paddles

- Charge up the selected energy by pressing the paddle button, Fig. 6.
  - ➢ The energy charging progress is shown on the monitor.
  - ➢ The energy level shown on the monitor will quickly be available to be delivered as defibrillation.
  - ➢ If the charging process is complete, a warning sound will be played.
  - ➢ The selected charge is available for 15 seconds. If defibrillation does not occur during this period, the energy will be discharged internally.

Shock via SavePads

- Charge up the selected energy by pressing the charge button, Fig. 7 (12).
  - ➢ The energy charging progress is shown on the monitor.
  - ➢ The energy level shown on the monitor will quickly be available to be delivered as defibrillation.
  - ➢ If the charging process is complete, the green shock button (17) lights up and a warning sound will be played.
  - ➢ The selected charge is available for 15 seconds. If defibrillation does not occur during this period, the energy will be discharged internally.
  - ➢ If SYNC mode was activated beforehand, the defibrillator switches to MAN mode from SYNC mode.
- The energy can also be discharged internally by pressing the charge button (12) again.

7.10.3 Triggering defibrillation

Note

The DefiMonitor XD carries out automatic impedance measurement. If it doesn't detect the patient, the electrodes and the adhesive contact on the skin need to be checked. Defibrillation can only be carried out if the DefiMonitor XD detects the patient.

Note

Triggering defibrillation can temporarily disrupt the ECG and SpO2 measurement.

7.10.3.1 MAN (manual mode)

After switching the device on and successfully carrying out the self-test, all DefiMonitor XD models will automatically go into manual mode (MAN).

"MAN" mode will be shown in information area 2 of the monitor.

Shock via paddles

- Select energy level and charge up as described in chapter 7.10.1 and 7.10.2.
- Press the paddles on to the patient's chest with at least 60 N (6 kg) of force.
- Wait until the ECG is visible on the monitor.
- Press the two paddle buttons simultaneously to trigger defibrillation, which occurs immediately after the button is pressed.
- Hold the buttons down until the shock has been administered.
- Avoid contact with the sockets on the device during defibrillation.
  - ➢ The number of shocks applied is shown in information area 3 of the monitor for 8 seconds.

Shock via SavePads

- Select energy level and charge up as described in chapter 7.10.1 and 7.10.2.
- Press the lit-up, green shock button, Fig. 7 (17) to trigger defibrillation, which occurs immediately after the button is pressed.
- Hold the button down until the shock has been administered.
- Avoid contact with the sockets on the device during defibrillation.
  - ➢ The number of shocks applied is shown in information area 3 of the monitor for 8 seconds, Fig. 9.

If the defibrillation energy is not delivered to the patient, the corresponding message will be shown in display area 3. (see Fig. 9)

When defibrillation is triggered, the display on the monitor looks like this:

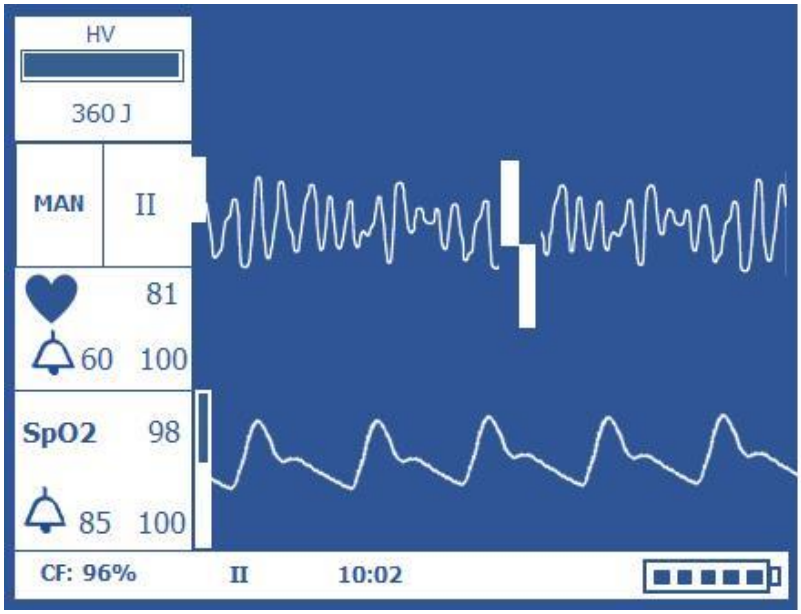


Fig. 26 Manual defibrillation MAN

7.10.3.2 SYNC mode (cardioversion)

⚠ WARNING

Incorrect R waves detection

No treatment possible, delivering a shock at the wrong time may lead to ventricular fibrillation

➢ Make sure that the R wave detection is correct before charging up the energy.

⚠ WARNING

Pressing button for too short a time when triggering synchronous defibrillation

No treatment possible

➢ **Shock via paddles:** Press the paddle buttons on both paddles until synchronous defibrillation has been carried out.

➢ **Shock via SavePads:** Press the shock button until synchronous defibrillation has been carried out.

Synchronisation only occurs via ECG lead II and is conducted via the selected shock method if the DefiMonitor XD detects the R waves and marks them with triangles.

SYNC mode can only be activated via MAN mode.

The delay time between detecting a QRS complex (synchronous pulse) and the energy transfer is less than 60 ms.

Defibrillation in SYNC mode:

- Press the SYNC button to get to SYNC mode from MAN mode.
  - ➢ Information area 2 on the monitor now shows SYNC.

Shock method via paddles:

- Select the energy level as described in Chapter 7.10.1 .
- Press the paddles on to the patient's chest with at least 60 N (6 kg) of force.
- Wait until the ECG is visible on the monitor.
  - ➢ The DefiMonitor XD now highlights the R waves of the ECG.
- Make sure that the ECG is free of artefacts.
- Charge up the energy level as described in Chapter 7.10.2 .

➢ As long as there is disposition to shock, a beep sounds.

- Trigger defibrillation:
  Keep both paddle buttons pressed until the defibrillation output at the next marked QRS complex is completed.
  ➢ Until defibrillation is triggered, a changed beep will sound.
  ✓ If the energy is delivered to the patient, the DefiMonitor XD displays this.

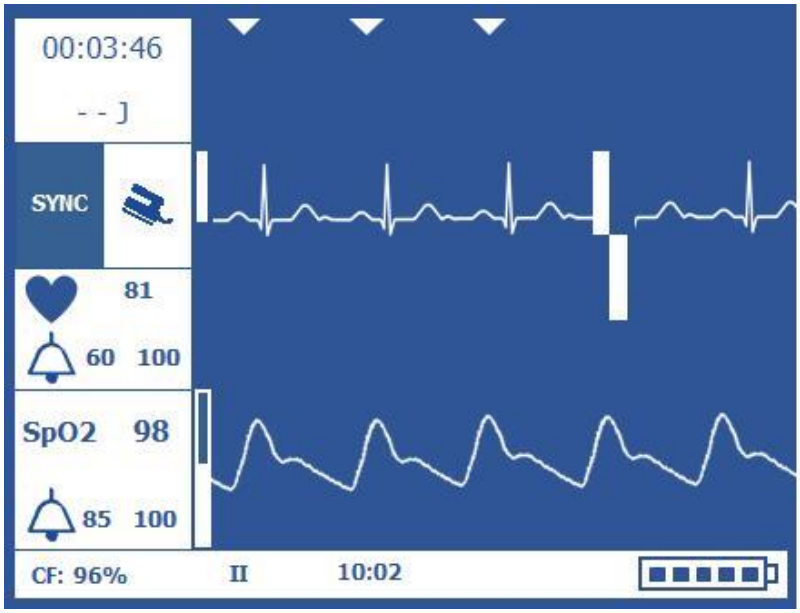


Fig. 27 Display for synchronous defibrillation (SYNC) via paddles

Shock method via SavePads:

- Wait until the ECG is visible on the monitor.
  ➢ The DefiMonitor XD now highlights the R waves of the ECG.
- Make sure that the ECG is free of artefacts.
- Select energy level and charge up as described in Chapters 7.10.1 and 7.10.2 .
  ➢ As long as there is disposition to shock, a beep sounds.
- Trigger defibrillation:
  Press and hold the shock button until defibrillation is carried out.
  ➢ Until defibrillation is triggered, a changed beep will sound.
  ✓ If the energy is delivered to the patient, the DefiMonitor XD displays this.

Note

If no R waves have been found for synchronising within 15 seconds, the DefiMonitor XD will discharge the energy internally.

When synchronous defibrillation is triggered, the monitor looks like this:

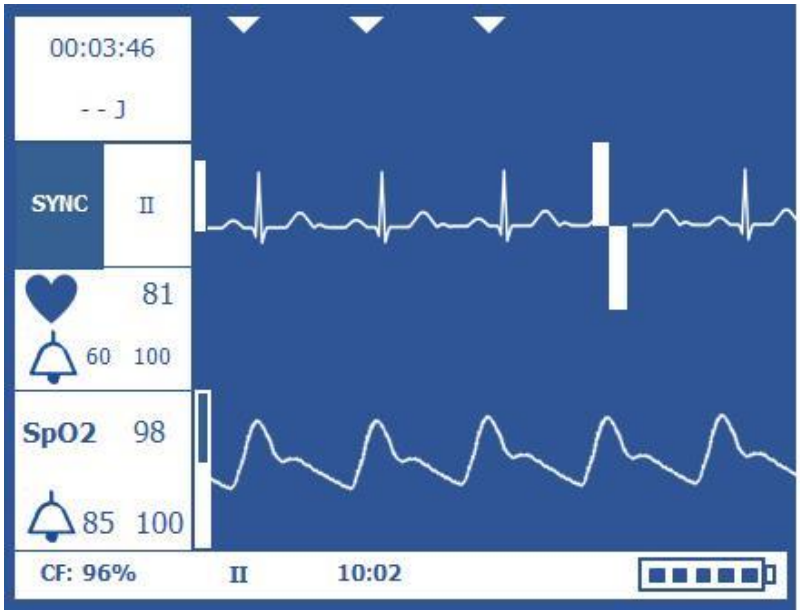


Fig. 28 Display for synchronous defibrillation (SYNC) via SavePads

Note

The DefiMonitor XD automatically switches back to MAN mode following synchronous defibrillation. This is displayed on the monitor accordingly.

Changing from SNYC mode into MAN mode:

- Press the SYNC button once again to get to MAN mode.
  - ➢ Information area 2 on the monitor shows MAN.
  - ✓ The DefiMonitor XD is in manual mode (MAN).

7.11 SpO2 measurement

⚠ WARNING

Only check SpO2 module functionality if the device is switched on

SpO2 module may not be ready for operation

- ➢ Check the display on the monitor

⚠ WARNING

Incorrect use of a sensor

Tissue damages

- ➢ Observe the instructions for use of the sensor.
- ➢ Inspect the measuring point of the sensor regularly.
- ➢ Pay attention to the maximum duration of use of the sensor.

⚠ WARNING

Strong magnetic fields

Mutual interference from MRI equipment

- ➢ Do not use the device near MRI equipment

⚠ WARNING

Ambient light

Inaccurate measurement of the SpO2 value

- ➢ Check the environmental conditions. Cover the sensor, if necessary.
- ➢ Check sensor is connected to the patient correctly.

⚠ WARNING

Moving the patient, medical measures, external influences such as dysfunctional haemoglobin, arterial dyes, low perfusion, dark pigmentation and dyes applied externally such as nail polish or pigment cream

Impairment of pulse oximetry signal quality

- ➢ Eliminate the cause if possible.

⚠ WARNING

Constriction of the extremity the SpO2 sensor is on

Potential incorrect measurement due to blood stasis

- ➢ Do not use blood pressure cuffs or other constricting instruments on the extremities the SpO2 sensor is placed on.

⚠ WARNING

Use of incompatible accessories

Injury to the patient, no SpO2 measurement possible, incorrect SpO2 measurement results

- ➢ Check the compatibility of the DefiMonitor XD, the interface cable and the sensor.

⚠ CAUTION

Do not attach any cable intended for computer use to the sensor port connector.

Note

Only the pulse amplitude display is active in AED mode, in case of high-priority and technical alarms. The SpO2 curve is not displayed.

Note

Triggering defibrillation can temporarily disrupt SpO2 measurement.

SpO2 measurement can be used to determine functional oxygen saturation. The sensor can also be used to determine the pulse rate. If the patient is not connected to the DefiMonitor XD with ECG electrodes or via SavePads, the pulse rate will be displayed on the monitor instead of the heart rate. As soon as the heart rate can be determined via the ECG signal (ECG electrodes or SavePads), the source automatically switches back to ECG.

Delivery includes a reusable Nellcor™ SpO2 finger sensor FLEXMAX, which is connected to the DefiMonitor XD via the Nellcor™ SpO2 interface cable DOC10.

7.11.1 General SpO2 safety advice

- Please observe the instructions for use for the SpO2 sensor, including all warnings, risks and instructions.
- Do not use damaged sensors or cables. Do not use sensors whose optical components are exposed.
- While using the SpO2 sensor, check the signal path on the monitor or the pulse amplitude display before considering the measurement values as correct measurement data.

- Do not use blood pressure cuffs or other constricting instruments on the arm the SpO2 sensor is placed on.
- Make sure that you do not touch the connector system and the patient at the same time.
- Do not use the SpO2 measurement equipment near high-frequency surgical equipment.
- Regularly check the sensor and cable for damage. Only use undamaged cables and sensors.

Long cables (sensor or extension cables) may lead to strangulation if they are laid improperly.

SpO2 measurement signal quality may be affected during defibrillation or by other electromagnetic interference.

7.11.2 Shown on the monitor

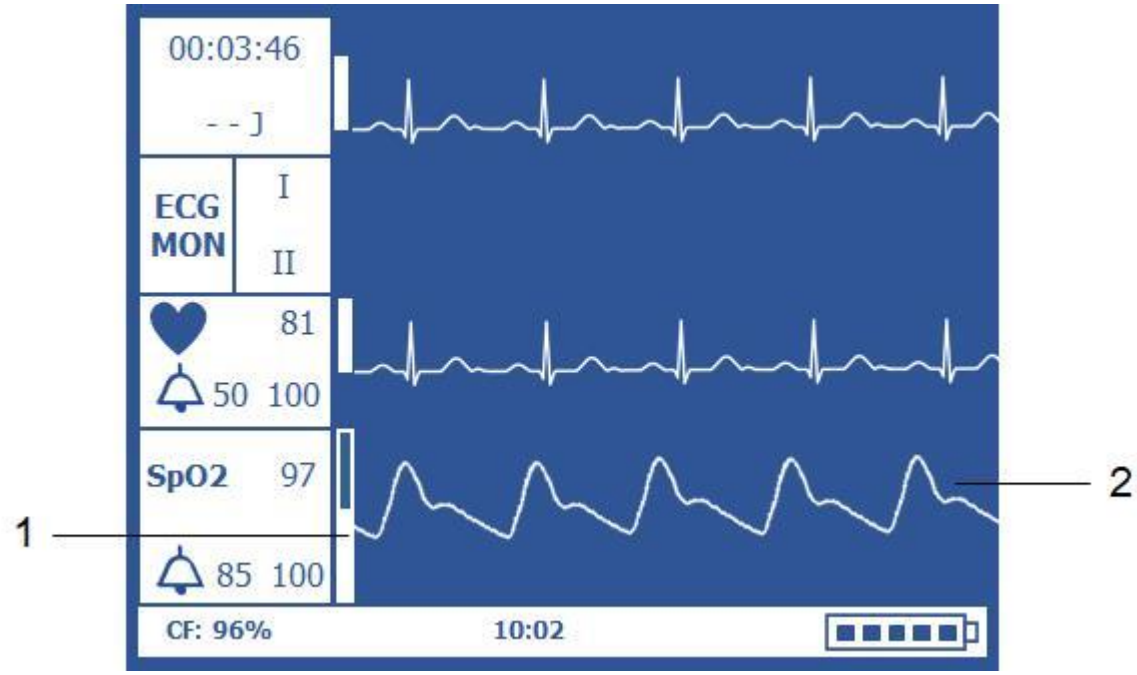


Fig. 29 SpO2 signal display

1 Pulse amplitude display
A bar showing the pulse rate and relative pulse amplitude. If the detected pulse becomes stronger, the bar is filled further.

2 SpO2 curve, plethysmographic (pleth) curve
This unnormalized curve uses real-time sensor signals which reflect the relative pulse strength of the input signals.

7.12 Pacer (PACE)

⚠ DANGER

Too great a deviation (± 30 %) from the selected intensity, treatment automatically stopped

Selected treatment is stopped

- ➢ Check the multifunction electrodes being used
- ➢ If necessary, replace the multifunction electrodes

⚠ WARNING

Inappropriate stimulation intensity or stimulation frequency

Ineffective or faulty stimulation

- ➢ Regularly check whether the stimulation is effective.
- ➢ Do not leave patient unattended with pacer activated.
- ➢ Comply with the time limit for pacemaker operation on the SavePads packaging.

⚠ WARNING

Only check pacer functionality if the device if switched on

Pacer may not be ready for use.

- ➢ Check the information in the status bar.

Side-effects

The following side-effects may be incurred during or after defibrillation:

Frequently

- Muscle contractions

Likely

- Irritation or burning of the skin in the area of the electrodes

Occasionally

- Cardiac arrhythmia (atrial fibrillation or atrial flatter)
- Damage to the heart muscle
- Chest pain

Note

Defibrillation has priority ahead of treatment with a transcutaneous pacemaker. If an energy level is selected during active pacer treatment and the energy has been charged up, pacemaker treatment is stopped and the DefiMonitor XD switches to MAN mode.

Pacer mode can only be activated when the DefiMonitor XD is in MAN mode and multifunction electrodes are connected.

Positioning the multifunction electrodes is described in chapter 7.4 .

When the pacer is switched-on, information areas 1 and 2 (see Fig. 9) may show “Pacemaker Init” together with a progress bar. This indicates that the Pacer is currently performing an internal self-test routine. After a few seconds, the Pacer is ready for configuration.

The result of the pacer self-test is shown in the status bar as follows:

Pacer passed self-test

Pacer failed self-test

Note

If it should become necessary to defibrillate the patient during stimulation (pacing), defibrillation can be carried out via the SavePads multifunction electrodes.

Note

If more than 3 minutes elapse without the pacer being operated, it switches off automatically.

The pacer has three modes:

- DEMAND (basic setting)
- FIX
- OVERDRIVE

Mode	Meaning
DEMAND (basic setting)	Stimulation is only carried out “as required”. I.e. only if the spontaneous heart rate falls below the set DEMAND rate.
FIX	Fixed-frequency stimulation. A fixed heart rate is imposed independently of the spontaneous heart rate.
OVERDRIVE	Overstimulation of the heart with high-frequency fixed-rate stimulation (max. 250 1/min) to stop, for example, ventricular tachycardia.

DEMAND is automatically activated when the pacer is switched on. The mode is displayed as text on the monitor.

The default settings are reactivated after the pacer is turned off and on again.

7.12.1 Setting the pacer modes

Switching mode:

- Push the MODE button, Fig. 7 Press the MODE button, Fig. (2) until the desired mode is displayed on the monitor.
  - ➢ No stimulation pulse will be administered during mode selection.

Note

The mode cannot be changed while the stimulation is being administered via the pacer. To change the mode, the pacer must first be stopped.

Note

Limited duration of stimulation in OVERDRIVE mode:
To prevent dangerous, excessively long stimulation in OVERDRIVE mode, stimulation time without intervention by the user is limited to 15 seconds.

7.12.2 Setting stimulation frequencies

Various stimulation frequencies (number of pacer pulses per minute) are available depending on the pacer mode:

DEMAND, FIX	30 to 180 1/min (beats per minute)
OVERDRIVE	30 to 250 1/min

The following frequency values are preset when the respective modes are activated:

DEMAND, FIX	70 1/min
OVERDRIVE	200 1/min

Procedure:

- Using the RATE ppm ▲ (+) and ▼ (-) keys, Fig. 7 (3), the stimulation frequency can be increased or decreased by increments of 5 units (5 1/min) each time the key is pressed. In the ranges shown above.
  - ➢ The stimulation frequency can also be changed during pacing.

7.12.3 Setting stimulation intensities

Various stimulation intensities (current strengths) are available depending on the pacer mode:

DEMAND, FIX, OVERDRIVE	10 to 180 mA

The following current strengths are preset when the respective modes are activated:

DEMAND, FIX, OVERDRIVE	10 mA

Procedure:

- Using the OUTPUT mA ▲ (+) and ▼ (-) keys, Fig. 7 (6), the stimulation intensity can be increased or decreased by increments of 5 mA each time the key is pressed.
  - ➢ The stimulation intensity can also be changed during pacing.

The level of stimulation intensity depends on the patient's physical constitution. The current selected should result in the effect of the stimulation being clearly visible on the monitor.

Pacing results in a contraction of the skeletal muscles. This is not a sign of effective heart stimulation. Watch the ECG on the monitor and the patient’s reaction to the treatment to determine when the intensity is sufficient.

7.12.4 Starting and stopping stimulation in pacer mode (PACE)

Pacer mode must be selected before pacing is started. The mode cannot be changed once pacing has started. The set mode is displayed on the monitor.

Starting stimulation, fig. 7:

- Press the Start/Stop button (4). Stimulation is started with the preset values.
  - ➢ A beep is issued to confirm this.
  - ✓ The mode display text on the monitor starts to flash. Delivered stimulation pulses are shown by the LED next to the Start/Stop button (4) lighting up.
    The stimulation pulses are illustrated as follows:

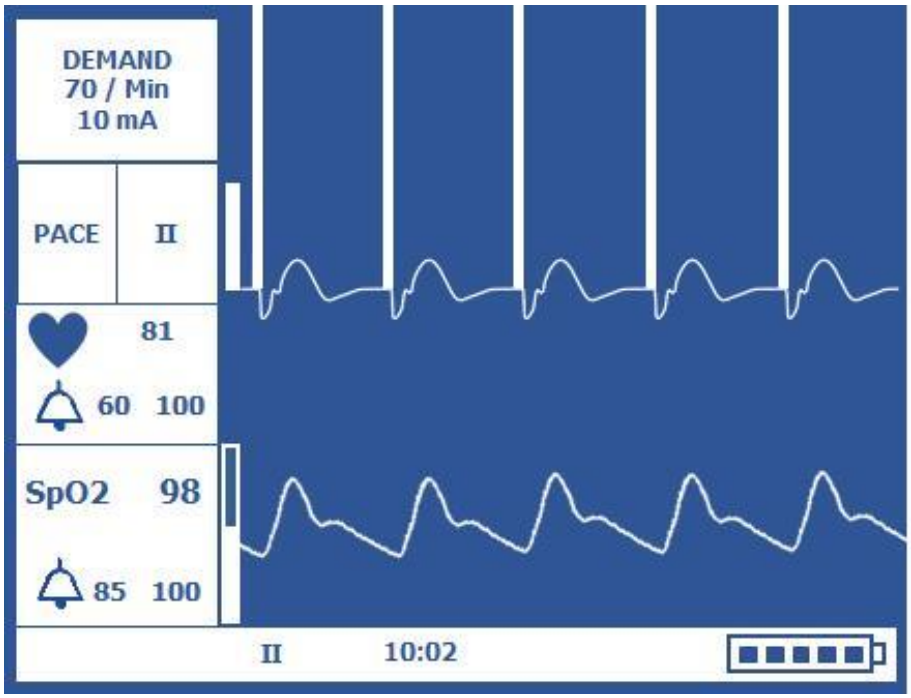


Fig. 30 Display of activated pacer with stimulation

Stopping stimulation, fig. 7:

- Press the Start/Stop button (4). This is confirmed by an acoustic signal.
  - ➢ The display text stops flashing.

Stimulation in overdrive mode ends after 15 seconds if neither the pacer intensity (6) nor the pacer rate (3) are changed. If one of these keys is pressed, the 15 seconds are restarted.

Stimulation can be stopped before the 15 seconds have elapsed by pressing the Start/Stop button (4).

7.12.5 Defibrillation during pacing / Defibrillation via multifunction electrodes

Pacer treatment is automatically interrupted when selecting the energy level. Proceed as described in chapter 7.10. Defibrillation can be performed without modifying the SavePads. Alternatively, the paddles can also be used to carry out defibrillation.

7.13 AED-Mode (AED)

⚠ DANGER

Disrupted ECG analysis due to movement of the patient

Defibrillation for a non-shockable ECG or no shock recommendation for a shockable ECG

- ➢ Ensure that the patient is not touched during the ECG analysis.
- ➢ If an ECG analysis is being conducted in transit, the vehicle must be stopped and the motor switched off.
- ➢ Switch off the chest compression device for the ECG analysis if one is being used.
- ➢ Cease chest compressions during ECG analysis.

⚠ DANGER

Danger of electric shock and too little energy for the patient

Triggering cardiac arrhythmia and burns caused by electric shock

- ➢ Do not touch the patient during defibrillation.
- ➢ Warn third parties about the dangers of defibrillation.
- ➢ Do not touch any conductive items (metal, blood, water, other liquids, etc.) connected to the patient during defibrillation.

⚠ WARNING

Using adult electrodes on children

Energy output too high for patients aged 1 – 8 (bodyweight <25 kg)

- ➢ For patients aged 1 – 8 (bodyweight <25 kg), use the SavePads **Mini**.
- ➢ If no SavePads **Mini** are available, the device can be used on patients aged 1 – 8 (bodyweight <25 kg) by using multifunction electrodes for adults.
- ➢ Do not delay the treatment due to not knowing the patient's exact age or weight.

Side-effects

The following side-effects may be incurred during or after defibrillation:

Frequently

- Muscle contractions

Likely

- Irritation or burning of the skin in the area of the electrodes

Occasionally

- Cardiac arrhythmia (atrial fibrillation or atrial flatter)
- Damage to the heart muscle
- Chest pain

Note

Separate the patient from other electrical medical devices which are not defibrillation-proof for the defibrillation.

In AED-Mode, the ECG is analysed via an implemented algorithm. This is only possible when using the SavePads.

If heart rhythms potentially requiring defibrillation are detected, the device recommends defibrillation and generates the necessary electric shock for resuscitation when enabled by the user. An electrical shock is not generated if the device does not detect a rhythm requiring defibrillation. The device recommends cardiopulmonary resuscitation.

The resuscitation procedure should be carried out in accordance with the current guidelines of the European Resuscitation Council (ERC) or of the American Heart Association (AHA).

If you have a device with AED-Mode, you must – after switch-on, fig. 7 (10) – start the AED-Mode using the AED button (8). This state is indicated by the illuminated LED above the button.

In AED-Mode, the DefiMonitor XD only enables defibrillation to be triggered after it has detected a shockable rhythm.

In adult mode the energy levels 290J, 340J, 360J are delivered, in pediatric mode the energy levels 50J, 70J, 100J.

7.13.1 Voice messages

You will be asked to examine the patient while the voice messages are played.

After the device has successfully carried out the self-test and switched over to the AED-Mode, the following instructions will be given:

Call emergency services

Apply electrodes one after the other to patient's bare chest

Plug in electrode cable

The message **Plug in electrode cable** is only played if the electrode connector is not plugged in.

The last two voice instructions are repeated for a period of one minute. If the device cannot recognise a patient impedance/patient at that time, the device will give instructions for cycle of cardiopulmonary resuscitation:

Adult mode	Pediatric mode
Give 30 chest compressions	**Give 15 chest compressions**
Give 2 rescue breaths	**Give 2 rescue breaths**

Afterwards, the device will give instructions for attaching the electrodes for a maximum of one minute. This procedure will continue until the device recognises a valid patient impedance / patient and begins the rhythm analysis.

Note

If the patient is connected to the DefiMonitor XD , an ECG analysis will be carried out immediately. In this case, the other voice messages will be skipped.

In basic state, a dashed line appears on the display and the acoustic message **Check electrodes** is played if the electrodes are not connected. As soon as a circuit is made between the electrodes, the ECG signal appears on the monitor.

7.13.2 Carrying out ECG analysis in AED-Mode

⚠ DANGER

Disrupted ECG analysis due to movement of the patient

Defibrillation for a non-shockable ECG or no shock recommendation for a shockable ECG

- ➢ Ensure that the patient is not touched during the ECG analysis.
- ➢ If an ECG analysis is being conducted in transit, the vehicle must be stopped and the motor switched off.
- ➢ Switch off the chest compression device for the ECG analysis if one is being used.
- ➢ Cease chest compressions during ECG analysis.

If the SavePads (multifunction electrodes) have been applied correctly, the device will start the first ECG analysis automatically. Automatic analysis can only be carried out using the multifunction electrodes

The patient must now be put in an immobile position and may no longer be touched.

The device notifies **Do not touch the patient**, **Analysing rhythm**.

The DefiMonitor XD will then analyse the ECG. If the device detects a cardiac rhythm requiring defibrillation, it will recommend defibrillation. No further ECG analysis is made during energy charging. If the device detects a cardiac rhythm not requiring defibrillation, it will recommend no defibrillation.

The ECG analysis is repeated after 2 minutes of cardiopulmonary resuscitation.

7.13.3 Defibrillation required

⚠ WARNING

Pressing the shock button early results in the energy being discharged internally

Delayed treatment

➢ Only trigger defibrillation when the shock button lights up and the device prompts you to do so.

Note

In AED mode, the energy for defibrillation is charged up automatically.

If the device detects a heart rhythm requiring defibrillation, it will recommend defibrillation, for which automatic preparations are made inside the device.

The device announces:

Shock advised

Chest compressions

Metronome

To reduce the time without chest compressions, the metronome is activated during the charging phase. This time span may vary depending on the charge level of the energy module. Carry out the chest compressions until the metronome tone stops.

Once the capacitor is charged internally, power for the defibrillation pulse is available for 15 seconds. This is signalled by a continuous acoustic warning, the voice message

Stand clear of patient

Deliver shock now

a continuous tone and the shock button lighting up in "green".

Options for leaving the status of readiness to shock

If the DefiMonitor XD looses the connection to the patient in the status of readiness to shock, the energy is discharged internally. The status of readiness to shock will remain for 15 seconds. If no shock delivery takes place within this period, the energy is discharged internally.

Triggering defibrillation:

- Warn those around you loudly before applying the defibrillation!
- Press the shock button – lit up green – to apply the shock.

Note

Triggering defibrillation can temporarily disrupt the ECG and SpO2 measurement.

The number of defibrillations carried out will be shown in information area 3 for 10 seconds.

Defibrillation and cardiopulmonary resuscitation (CPR) will be repeated on an alternating basis.

The charge time of the capacitor for defibrillation depends on the available battery capacity. Charging may take longer if the power module is partly discharged.

The device notifies:

Give 30 chest compressions

Give 2 rescue breaths

Furthermore, during the chest compressions, you will be supported by a metronome which will give you the correct frequency for the chest compressions (100 compressions/min).

Note

Once the CPR time has expired (2 mins.), the device returns to ECG analysis.

If the shock is not triggered within 15s,

- An internal safety discharge of the defibrillation energy takes place.
- the DefiMonitor XD outputs the message **No shock delivered**
- the DefiMonitor XD instructs for cardiopulmonary resuscitation.

7.13.4 Defibrillation not required

If the device cannot find a rhythm requiring defibrillation, it will recommend cardiopulmonary resuscitation (CPR).

No shock advised

Cardio pulmonary resuscitation

Give 30 chest compressions

Give 2 rescue breaths

Furthermore, during the chest compressions, you will be supported by a metronome which will give you the correct frequency for the chest compressions (100 compressions/min).

Note

Once the CPR time has expired (2 mins.), the device returns to ECG analysis.

7.14 Keeping the defibrillator ready for use

⚠ DANGER

Damaged device or accessories

Treatment not possible, injury to patient, user or third party due to electric shock

- ➢ Do not use the device or its accessories if it is damaged.
- ➢ Check the status display before using the device.

⚠ WARNING

Defibrillator contamination

Defibrillation not possible, patient infection

- ➢ Clean the defibrillator after every use.
- ➢ Clean the accessories after every use.
- ➢ Disinfect the defibrillator and accessories if necessary.
- ➢ Clean the paddles after use.

⚠ WARNING

No treatment / monitoring possible

Empty or faulty energy module

- ➢ Check the status display regularly.
- ➢ Do not use any faulty or deeply discharged energy modules.

Procedure:

- After each use, check the DefiMonitor XD and accessories for damage.
- Clean the DefiMonitor XD and accessories after each use.
- Disinfect the DefiMonitor XD and the accessories if there is a risk of infection, see chapter 9.1.
- Replace disposable accessories.
- Check the expiry date of the disposable accessories and replace them if necessary.
- Charge or replace the power module if necessary.
- Check the expiry date of the internal battery (sticker in the power module slot).
  - ➢ Contact the technical service for replacement.
- Perform the MMI test to check the visual and audible alarm signals, see chapter 7.14.1.
- In the event of any faults or anomalies, contact our technical service as soon as possible.

7.14.1 MMI test (Man-Machine-Interaction)

The MMI test checks the function of the loudspeaker, the alarm LED and the buttons on the membrane keypad of the DefiMonitor XD.

Procedure:

- Start the MMI test via the settings on page 3, see paragraph 7.3.2.
- Follow the instructions on the monitor.
  - ✓ After the MMI test is successfully completed, the DefiMonitor XD switches back to the settings.

7.15 Event button

By pressing the event button, Fig. 7 (14), a mark is placed on the ECG which causes the ECG to be stored for the 5 seconds before and the 5 seconds after the mark. This ECG sequence can then be printed out later from the event memory.

The printing format for the ECG sequence is always 2-channel print. The signal curves on the monitor at the time of the event are printed out.

7.16 Operating the printer

7.16.1 Inserting paper into the printer

Fig. 31 DefiMonitor XD – right-hand side view

1 Slot for paddle
2 Release lever for printer cover
3 Printer cover
4 Power supply socket
5 Attachment point for bag

Procedure, Fig. 31:

- Push down the release lever (2).
- Open the printer lid (3) forwards.
- Remove the adhesive strip on the roll of paper.
- Unwind the paper by approx. 5 cm.
- Insert the roll of paper into the printer slot with the chequered side facing up.
- Close the printer lid (3).

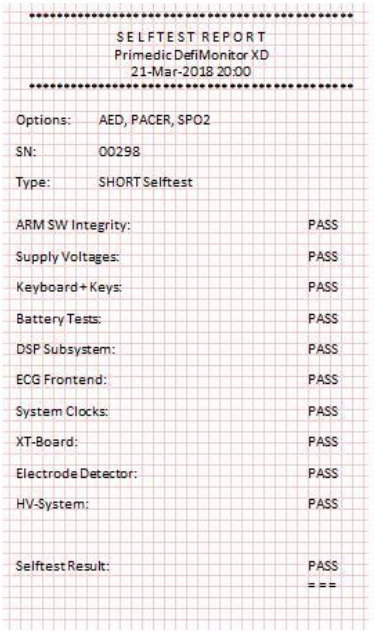
Note
The printer can only be operated or used in manual mode.

7.16.2 Automatic self-test printout

The self-test printout contains the following parameters:

- Model, serial number
- Date, time
- The selection (off / short / detailed)
- Result of the test

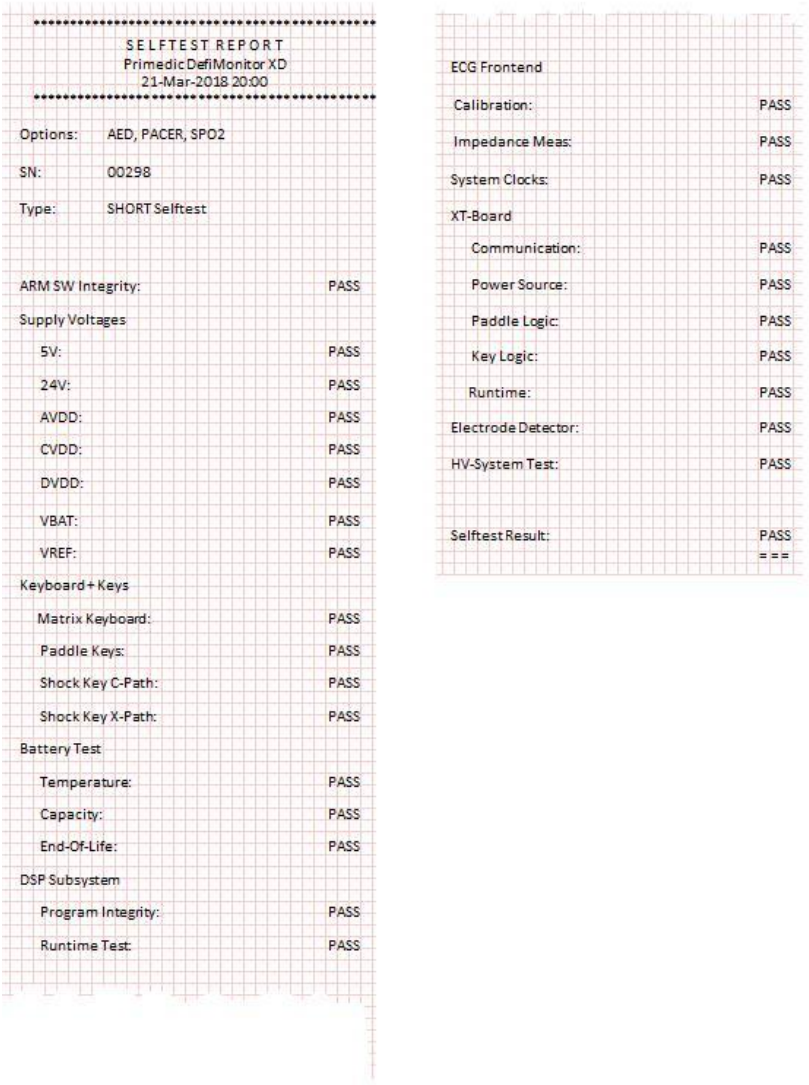
If the test was completed successfully, the test will be receive the grade PASS.
If the test was not completely successfully, the DefiMonitor XD will turn itself off automatically. No printout will be possible.



SELFTEST REPORT
Primedic DefiMonitor XD
21-Mar-2018 20:00

Options:	AED, PACER, SPO2
SN:	00298
Type:	SHORT Selftest
ARM SW Integrity:	PASS
Supply Voltages:	PASS
Keyboard+Keys:	PASS
Battery Tests:	PASS
DSP Subsystem:	PASS
ECG Frontend:	PASS
System Clocks:	PASS
XT-Board:	PASS
Electrode Detector:	PASS
HV-System:	PASS
Selftest Result:	PASS

Fig. 32 Self-test printout (similar to illustration)



SELFTEST REPORT
Primedic DefiMonitor XD
21-Mar-2018 20:00

Options:	AED, PACER, SPO2
SN:	00298
Type:	SHORT Selftest
ARM SW Integrity:	PASS
Supply Voltages	
5V:	PASS
24V:	PASS
AVDD:	PASS
CVDD:	PASS
DVDD:	PASS
VBAT:	PASS
VREF:	PASS
Keyboard+Keys	
Matrix Keyboard:	PASS
Paddle Keys:	PASS
Shock Key C-Path:	PASS
Shock Key X-Path:	PASS
Battery Test	
Temperature:	PASS
Capacity:	PASS
End-Of-Life:	PASS
DSP Subsystem	
Program Integrity:	PASS
Runtime Test:	PASS
ECG Frontend	
Calibration:	PASS
Impedance Meas:	PASS
System Clocks:	PASS
XT-Board	
Communication:	PASS
Power Source:	PASS
Paddle Logic:	PASS
Key Logic:	PASS
Runtime:	PASS
Electrode Detector:	PASS
HV-System Test:	PASS
Selftest Result:	PASS

Fig. 33 Detailed self-test printout (similar to illustration)

7.16.3 ECG signal log

The DefiMonitor XD has a printer. ECG printout of 1 to 6 channels simultaneously is possible. Feed speeds of 25 and 50 mm/s can be selected.

Logging the ECG curve during monitoring:

- Pressing the printer button, Fig. 7 (16), causes the log printout to start.
- The log printout is stopped by pressing the printer button (16) again.

ECG printout is made with the parameters selected in the settings. The following settings can be selected:

Printing parameter	Meaning	ECG sensitivity
Print format: 1-channel	Prints the upper ECG channel displayed on the monitor.	5, 10, 15 mm/mV
Print format: 3-channel	Prints the two ECG channels displayed on the monitor. If an SpO2 sensor is connected to the patient, the plethysmogram is also printed.	10 mm/mV
Print format: 6-channel	Prints the leads I, II, III, aVR, aVL, aVF simultaneously, depending on the electrodes attached, with a maximum of 3 leads, 5 seconds before and the 5 seconds after pressing the button.	5 mm/mV

Printing parameter	Meaning
25 mm/s printout speed	Printout is produced at 25 mm/s.
50 mm/s printout speed	Printout is produced at 50 mm/s.

The following relevant parameters are printed out in a header:

- Date, time
- Speed
- Scale
- Heart rate
- Energy (joules)
- Mode
- SpO2 value (option: SpO2)

There is a time lag of 7 seconds between the monitor display and the printout, i.e. events which occurred before activation of the printout function can be displayed. If the printout is stopped, printout also ends with data recorded 7 seconds previously.

Use the integrated cutting edge on the printer cover to tear off the ECG log printout. Tear off the strip upwards and to the side.

Note

Every printout disrupts energy charging up before defibrillation.

If the ECG lead is changed during printout:

- The printing process stops immediately.
- The header is rewritten.
- The printout then continues.

Data still stored at the time of the changeover is discarded, the new printout starts at the time of the changeover.

7.16.4 Automatic printout after each shock

The DefiMonitor XD allows you to record the event automatically each time defibrillation or cardioversion is performed. Data from 5 seconds before and 5 seconds after the shock was administered is recorded.

The “printout on shock” feature can be turned on or off on page 2 of the settings. When the device is delivered, the function is switched off.

The selection remains active after the device is switched off or the battery is changed.

7.16.5 Printing out the event memory

DefiMonitor XD automatically stores the last 30 defibrillations / cardioversions / events in an event memory. For this purpose, the ECG (the 5 seconds before and the 5 seconds after each shock) and the following parameters are stored.

- Date, time
- Speed
- Scale
- Heart rate
- Energy (joules)
- Mode
- SpO2 value (option: SpO2)

The contents of the memory will be printed out, beginning with the last event logged.

Procedure, Fig. 7:

- Select the parameter “Print events” on page 2 in the settings menu.
- Press the enter key ↵ (9).
  - ➢ The Memo Print function is activated.
- To stop the printout, press the printer button (16).
  - ✓ Printout is produced at 25 mm/s.

The data remains in the event memory after printout and after switching off the DefiMonitor XD. It can be printed out as often as required.

Error messages on the monitor:

Symbol on the monitor	Cause
	No paper
	Printer error

8 SaveCard data management

The DefiMonitor XD all usage data on a removable SaveCard.

The saved data can be displayed using a PC / laptop.

Internal errors are stored on the SaveCard in the file “syserr.txt.”. The file is also available after switching the DefiMonitor XD off.

Note

If the memory space on the SaveCard is full, no more data can be stored on the SaveCard.

The device can be operated with full memory space and without a SaveCard.

- The data saved on the SaveCard should be externally archived after every use.
- Delete the data every time you archive the SaveCard.

The SaveCard supplied with the device is already formatted and can be used straight away. If you have problems with the SaveCard, or with new memory cards, it must be formatted using the FAT 16 or FAT 32 file system.

Proceed as follows for Windows 2000, Windows XP, Windows Vista, Windows 7, Windows 8 and Windows 8.1:

- Insert the SaveCard into the memory card slot on the PC / laptop.
- Start a command line window using "Start->Run" and enter "cmd.exe" in the entry field.
  - ➢ The command line window will then open.
- Now enter the following:
  - ➢ for SaveCards up to 2 GB= format f: /U /FS:FAT /X /V:savecard
  - ➢ for SaveCards above 2 GB= format f: /U /FS:FAT32 /X /V:savecard
  - ➢ where f: stands for the drive letter of the card reading device – you may need to adjust this.

When starting the device for the first time after formatting a SaveCard, it will take considerably longer because the device performs various self-tests. The device then resumes normal operation again.

8.1 Inserting / replacing the SaveCard

Fig. 34 DefiMonitor XD – open bottom view

1 Slot for SaveCard

2 SaveCard eject button

3 Cover

8.1.1 Inserting SaveCard

Procedure inserting SaveCard, Fig. 34:

- Lay the device on its back.
- Remove the energy module if inserted. See chapter 6.1.1.
- Open the slot by sliding the cover down towards the energy module slot (3).
- Push the SaveCard as far as possible into the slot (1).
  - ➢ The ejector (2) sticks out of the opening.
- Close the slot by sliding the cover (3) over the shaft until the cover audibly clicks into place.
- Insert the energy module again.
  - ➢ The device starts and performs a self-test.
- Check the status bar.
  - ➢ The message "CF:" indicating the card capacity in % is displayed:
    The SaveCard is inserted correctly.

➢ The message "NO CF" is displayed:
The SaveCard probably has no contact with the unit.

- In this case, press the ejector (2) and remove the SaveCard.
- Insert the SaveCard again as described above.
- If the message "NO CF" is still displayed, contact the technical service.

8.1.2 Changing SaveCard

Procedure, Fig. 34:

- Lay the device on its back.
- Remove the energy module, see chapter 6.1.1.
- Open the slot by sliding the cover towards the energy module slot (3).
- To remove the SaveCard, press the eject button (2) in fully, which makes the SaveCard protrude from the slot (1) a little. The SaveCard can now be removed.
- Push the SaveCard as far as possible into the slot (1).
  ➢ The ejector (2) sticks out of the opening.
- Close the slot by sliding the cover (3) over the shaft until the cover audibly clicks into place.
- Insert the energy module again.
  ➢ The device starts and performs a self-test.
- Check the status bar.
  ➢ The message "CF:" indicating the card capacity in % is displayed:
  The SaveCard is inserted correctly.
  ➢ The message "NO CF" is displayed:
  The SaveCard probably has no contact with the unit.
- In this case, press the ejector (2) and remove the SaveCard.
- Insert the SaveCard again as described above.
- If the message "NO CF" is still displayed, contact the technical service.

9 Cleaning, maintenance and shipping

9.1 Cleaning and disinfection

⚠ WARNING

Warning: physical harm to user

Risk of electrocution

➢ Only clean the device when switched off.
➢ Clean the accessories after every use.
➢ Clean the child paddles before screwing on the adult paddles.
➢ Use damp cloths to clean.

Clean the device and all its accessories with soap and water solution. Use a slightly damp, clean cloth.

Use isopropyl alcohol to disinfect it.

For cleaning and disinfecting the SpO2 sensor, please observe the separate instructions for use for the sensor.

9.2 Servicing

⚠ WARNING

Defibrillator not ready for use due to permanent connection to the mains

Status display indicates device is ready for use even though it is not

- Disconnect the defibrillator from the mains.
- Switch the defibrillator on in battery mode.
- Allow the defibrillator to operate for approx. 5 minutes.
- Reconnect the defibrillator to the mains.
  The charge level of the AkuPak LITE XD will be re-evaluated and displayed.
- Repeat this test every 4 – 6 weeks.

Note

During service or maintenance, the DefiMonitor XD must not be used on a patient.

Note

If fluid leaks from the housing, do not touch the fluid.

Note

The device does not have any parts which can be modified by the user.

Testing after each use

- Check your defibrillator, energy module and accessories for damage.

Please contact the technical service for further maintenance.

9.3 Shipping

Observe the current valid dangerous goods guidelines for shipping lithium batteries.

If you are shipping the DefiMonitor XD together with the energy module, break the contact between the energy module and the DefiMonitor XD for shipment. This prevents the device from switching on during transport.

10 Disposal

In accordance with the founding principles of Metrax GmbH, your product has been developed and made using high-quality materials and components which are recyclable.

At the end of its service life, recycle the device via your public waste disposal company. Proper disposal of this product is in the interest of protecting the environment.

Through the registration of Metrax GmbH with the responsible authorities, we ensure that the disposal and utilisation of electronics devices brought to the market by us is secure in accordance with the EU directive on the disposal of electronic and electrical equipment (WEEE-directive).

In Germany, in accordance with legislation on the sale, return and environmentally friendly disposal of electrical and electronic devices (Elektro- und Elektronikgerätegesetz – ElektroG), Metrax is registered with EAR under the number 73450404.

For business customers in the European Union

Please contact your dealer or supplier if you want to dispose of electrical and electronic equipment.

11 Technical Data

11.1 Monitor

Model	LCD monitor
Dimensions	115 x 86 mm (diagonal 144 mm, 5.7“)
Resolution	320 x 240 pixels
Displays	Heart rate, SpO2

11.2 Alarms

LED alarm indicator

Alarm category	Colour	Frequency	Duty cycle
High priority	red	2 Hz	56:44

Alarm signal delay

Signal	Delay
High-priority alarm	< 10 s
Alarms with medium priority	< 10 s
Information signal	< 10 s

Sound level range of the audible alarm signals

Volume	Sound level range
25 %	52 ± 6 dBA
100 %	71 ± 6 dBA

11.3 Physical properties

Dimensions	33 x 16 x 29 cm (W x D x H)
Weight	approx. 5.3 kg (without energy module) approx. 5.8 kg (with energy module)
Protection class of applied parts	defibrillation-proof, type CF
Protection class of casing	
Ingress of foreign matter	IP3X protection against solid foreign matter with diameter of 2.5 mm
Ingress of liquid	IPX3 protection against spraying water
Operating mode	Continuous
Classification	Class IIb (MDD Annex IX Rule 09)

11.4 Printer

Model	Thermal printer
Number of channels	1 to 3 channels
Type of paper	Thermal paper
Paper width	58 mm
Printing speed	25 mm/s, 50 mm/s

11.5 Memory

Model	Compact Flash Card 2GB

11.6 Voltage supply

Built-in power supply	110 - 240 V, 50 - 60 Hz
Power consumption	110W
Protection class	II for mains usage
AkuPak LITE XD	Lithium ion battery internally provided with current
Lithium-ion technology	Lithium iron phosphate (LiFePO4)
Nominal operating voltage	13.2 V DC
Charging voltage	14.4 V
Max. charging current	5.1 A
Charging cycles	> 1000 (100% SOC)
Periodic replacement of battery	4 years from date of manufacture
Maximum storage period before re-charging	Outside the DefiMonitor XD: 3 months Inserted in the DefiMonitor XD: maximum 1 month
Nominal capacity	2500 mAh
Energy content (100 % SOC)	33 Wh
Charge time (0 – 90% SOC)	Approx. 3h in the DefiMonitor XD All details refer to an ambient temperature of 20°C ± 5°C
Number of shocks at 200J	160
Number of shocks at 360J	95
Operating time (monitoring)	at least 5:00 h (for AkuPak LITE XD in a DefiMonitor XD after three initial shocks in AED mode, ECG/SpO2 monitoring until device is switched off at 20°C ± 5°C)
Operating time (pacing)	at least 3:20 h hours 20 minutes (for AkuPak LITE XD in a DefiMonitor XD after three initial shocks in AED mode, ECG/SpO2 monitoring and pacing in FIX mode at 70 ppm/100 mA until device is switched off at 20°C ± 5°C)

Note

Please note that the storage conditions have a direct effect on the potential service life of the AkuPak LITE XD and make a considerable contribution to the decision when it needs to be recharged in order to avoid deep discharge.

- If possible, store the AkuPak LITE XD at a temperature range of 15°C – 35°C. These conditions will provide for maximum storage capacity and service life.
- Always be sure to charge the AkuPak LITE XD fully after longer storage before possible use.

All details are for a fully-charged, new AkuPak LITE XD and a temperature of 20 degrees Celsius ± 5 degrees Celsius.

AkuPak LITE XD: The service life of an AkuPak LITE XD is usually up to 4 years or 1,000 charge cycles – depending on which occurs first – if the following conditions are met: The AkuPak LITE XD is inserted into the device, the device is only ever in standby mode and is not used, only the regular self-tests recommended by Metrax are carried out, and the ambient temperature is consistently around 23 degrees Celsius (± 2 degrees Celsius). Storing the device outdoors significantly reduces the service

life of the AkuPak LITE XD. As a wide variety of factors can influence the service life of the AkuPak, Metrax accepts no liability for the service life of the AkuPak LITE XD.

11.7 Environmental conditions

Operating conditions

Conditions during continuous operation

Temperature	DefiMonitor XD with energy module	0 °C to +45 °C +32 °F to +113 °F
	SavePads	0°C to +50°C +32 °F to +122 °F
	ECG electrodes	5°C to +30°C +41 °F bis +86 °F
	Printer paper	0°C to +40°C +32 °F to +104°F
	SpO2	0 °C to +40 °C +32 °F to +104°F
Humidity	15 % to 95 % non-condensing	
Air pressure	620 hPa to 1060 hPa	

Transient operating conditions

The DefiMonitor XD can be operated for at least 20 minutes with the conditions specified as follows.

Temperature	DefiMonitor XD with energy module	-20 °C to +50 °C -4 °F to +122 °F
Humidity	15 % to 95 % non-condensing	

Storage conditions

Temperature	-20 °C to +50 °C -4 °F to +122 °F
Humidity	15 % to 95 % non-condensing
Air pressure	620 hPa to 1060 hPa

Transport conditions (max. 10 days)

Temperature	-25 °C to +50 °C -13 °F to +122°F
Humidity	15 % to 95 % non-condensing
Air pressure	500 hPa to 1060 hPa

Environmental conditions Nellcor™ SpO2 finger sensor FLEXMAX

Operating temperature range	0 °C to +40 °C 32 °F to 104 °F
Transient operating conditions	The sensor can be operated for 20 minutes at temperatures from -20 °C (-4 °F) and +50 °C (122 °F).
Temperature range for storage and transport	-40 °C to +70 °C (-40 °F to 158 °F)
Humidity	15 % to 95 % non-condensing
Air pressure	620 hPa to 1060 hPa

Stabilisation time (from storage to operation)	Up to 20 minutes

11.8 Sound definitions

Alarm signal for high-priority alarms

Volume levels	Can be set to 0 %, 25 %, 50 %, 75 %, 100 %
Pitch	398 Hz – 796 Hz
Pulse width	120 ms
Number of pulses	10 pulses every 2.5 s
Repeated	Every 15 s

Information signal

Volume levels	Can be set to 0 %, 25 %, 50 %, 75 %, 100 %
Pitch	696 Hz
Pulse width	75 ms – 1000 ms
Number of pulses	1 or 2 pulses
Repeated	Not repeated

11.9 Monitoring

11.9.1 ECG

Heart rate

Measurement range	From 30 to 300 bpm
Resolution	1 bpm
Valid QRS amplitude range	0.5 mV to 5 mV
Valid QRS duration range	40 ms to 120 ms
Note: No differentiation is made between adults and children for QRS recognition. The DefiMonitor XD displays a valid heart frequency if the QRS complexes have a duration of 10ms and an amplitude of 1mV.	
Display update rate	1 s
Accuracy	± 10 % or ± 5 bpm, depending on which is larger
Suppression of large T waves	maximum T wave amplitude 5 mV
Heart rate average determination	The heart frequency displayed on the monitor is an average which is based on the time from a QRS complex peak to the next peak. Normally, this average is based on the data from the previous 10 seconds, however at higher heart frequencies only the pervious 10 times between the QRS peak values are taken into account. The initial heart frequency value appears after some 5 seconds (a maximum of 10 seconds) after the ECG signal is available. The heart frequency is updated after each new QRS complex, however not more often than every 0.5s.
SpO2 value average determination	7 to 20s
Accuracy of the heart frequency display and behaviour in case of irregular rhythms (IEC 60601-2-27:2011+Cor.:2012)	The following values will be displayed after 20 seconds: A1, ventricular bigeminies: 80 bpm A2, slowly changing ventricular bigeminies: 60 bpm

	A3, fast changing ventricular bigeminies: 118 bpm A4, bidirectional systoles: 90 bpm
Time until alarm in the event of tachycardia Upper alarm limit set to 100 bpm Lower alarm limit set to 60 bpm (IEC 60601-2-27:2011+Cor.:2012)	B1, ventricular tachycardia 1 mV peak to valley: 4 s B1, ventricular tachycardia 2 mV peak to valley: (doubled amplitude): 4 s B1, ventricular tachycardia 0.5 mV peak to valley (halved amplitude): 6 s B2, ventricular tachycardia 2 mV peak to valley: 3 s B2, ventricular tachycardia 4 mV peak to valley (doubled amplitude): 3 s B2, ventricular tachycardia 1 mV peak to valley (halved amplitude): 5 s
Response time for heart rate display after change in heart rate	HR change from 80 to 120 bpm: 9 s HR change from 80 to 40 bpm: 13 s

ECG signal

Leads	I, II, III, aVR, aVL, aVF
Impedance	500 to 2500 Ohms
Power output for the measurement of electrodes which have fallen off	4 µA RMS, 30 kHz, sinusoidal
Detection of electrodes that fell off	Detected and shown
Pacemaker suppression region	**Effective pacemaker pulses** For individual pacemaker pulses and a normally stimulated QRS and T peak, pulses between ±10 mV and ±700 mV amplitude, with a pulse width between 0.1ms and 2ms and overshooting from 0 to 100ms. For double pacemaker pulses with 150 ms gaps and a normally stimulated QRS and T peak, pulses between ±10 mV and ±700 mV amplitude, with pulse widths between 0.1 ms and 2 ms and overshooting from 0 to 20ms. For double pacemaker pulses with 250 ms gaps and a normally stimulated QRS and T peak, pulses between ±10 mV and ±700 mV amplitude, with pulse widths between 0.1ms and 2 ms and overshooting from 0 to 4 ms. **Pacemaker pulses with a stimulated QRS pattern ineffectively stimulated by the pacemaker** For pacemaker pulses with an ineffective QRS pattern, pulses between ±10 mV and ±700 mV amplitude, with pulse widths between 0.1 ms and 2 ms and overshooting from 0 to 10ms. For pacemaker pulses and double pacemaker pulses with gaps of 150 ms and 250 ms and an ineffectively simulated QRS pattern, pulses between ±10 mV and ±700 mV amplitude, with pulse widths between 0.1 ms and 2 ms and overshooting from 0 to 4 ms. **Pacemaker pulses without a QRS** For single pacemaker pulses and double pacemaker pulses with gaps of 150 ms and 250 ms alone, pulses between ±10 mV and ±700 mV amplitude, with pulse widths between 0.1 ms and 2 ms and overshooting from 0 to 10 ms.
Input	
Dynamic input range	± 5 mV AC, ± 300 mV DC

Voltage range for detecting QRS complexes	± 0.5 mV ~ ± 5 mV
QRS complex signal width	40 to 120 ms (Q to S)
Output	
Frequency response (monitor)	0.67 to 40 Hz
ECG sensitivity (monitor)	5, 10, 15 mm/mV
Spot velocity	25.0 mm/s
Pacing pulse detection	On
Alarm for electrode separation	Voice message
ECG/paddle input classification	CF, defibrillation-proof
Signal recording via	ECG electrodes, multifunction electrodes or paddles

11.9.2 SpO2

Measurement Range

Pulse oximetry saturation SpO2	1 % - 100 %
Pulse rate measurement range	
Source SpO2	20 – 250 bpm
Wavelength red	660 nm
Output power[1]	< 5 mW
Wavelength infrared	885 nm focus
Output power[1]	< 5 mW
Power dissipation	52,5 mW
SpO2 input classification	CF, defibrillation-proof

SpO2 measurement accuracy

Adult [2, 3]	70 - 100 % ± 2 digits
Adult and Neonate Low Sat [2, 3, 4]	60 - 80 % ± 3 digits
Neonate [4, 5]	70 - 100 % ± 2 digits
Low Perfusion[6]	70 - 100 % ± 2 digits
Adult and Neonate with Motion [2, 7]	70 - 100 % ± 3 digits

Pulse rate measurement accuracy

Adult and Neonate [2, 3, 4]	20 - 250 ± 3 bpm
Low Perfusion [6]	20 - 250 ± 3 bpm
Adult and Neonate with Motion [2, 7]	48 - 127 ± 5 bpm

[1] Saturation accuracy varies by sensor type. Refer to the Sensor Accuracy Grid at www.covidien.com/rms.

[2] Accuracy specifications were validated using measurements of healthy non-smoking adult volunteers during controlled hypoxia studies spanning the specified saturation ranges. Subjects were recruited from the local population and comprised both men and women ranging in age from 18-50 years old, and spanned a range of skin pigmentations. Pulse oximeter SpO2 readings were compared to SaO2 values of drawn blood samples measured by hemoximetry. All accuracies are expressed as ±1 SD. Because pulse oximeter equipment measurements are statistically distributed, about two-thirds of the measurements can be expected to fall in this accuracy (ARMS) range (refer to the Sensor Accuracy Grid for more details).

[3] Adult specifications are shown for OxiMax MAXA and MAXN sensors with the Nellcor™ Bedside Respiratory Patient Monitoring System.

[4] Neonate specifications are shown for OxiMax MAXN sensors with the Nellcor™ Bedside Respiratory Patient Monitoring System.

[5] Clinical functionality of the MAXN sensor has been demonstrated on a population of hospitalized neonate patients. The observed SpO2 accuracy was 2.5% in a study of 42 patients with ages of 1 to 23 days, weight from 750 to 4,100 grams, and 63 observations made spanning a range of 85% to 99% SaO2.

[6] Specification applies to Nellcor™ Bedside Respiratory Patient Monitoring System oximeter performance. Reading accuracy in the presence of low perfusion (detected IR pulse modulation amplitude 0.03% - 1.5%) was validated using signals supplied by a patient simulator. SpO2 and pulse rate values were varied across the monitoring range over a range of weaksignal conditions and compared to the known true saturation and pulse rate of the input signals.

[7] Motion performance was validated during a controlled hypoxia blood study. Subjects performed rubbing and tapping movements 1-2 cm in amplitude with aperiodic intervals (randomly changing) with a random variation in frequency between 1-4 Hz. Applicability: OxiMax MAXA, MAXAL, MAXP, MAXI, and MAXN sensors.

11.10Treatment parameters

Charging time (in accordance with IEC 60601-2-4)

Manual mode	
Maximum time until ready for defibrillation of 360J	12 ± 3 s when run at rated voltage from mains
	12 ± 3 s when operating at 90 % rated voltage
	12 ± 3 s when run with fully charged, new AkuPak LITE XD
	12 ± 3 s when run with an AkuPak LITE XD after discharge of energy for 15 shocks
Maximum time from switching on until ready for defibrillation of 360J	≤ 25 s when operated at rated voltage from the mains
	≤ 25 s when operated at 90 % of rated voltage
	≤ 25 s when operated with a fully charged, new AkuPak LITE XD
	≤ 25 s when operated with an AkuPak LITE XD after discharge of energy for 15 shocks
AED-Mode	
Maximum time between the start of analysis and readiness for defibrillation of 360J	≤ 30 s when operated at rated voltage from the mains
	≤ 30 s when operated at 90 % of rated voltage
	≤ 30 s when operated with a fully charged, new AkuPak LITE XD
	≤ 30 s when operated with an AkuPak LITE XD after discharge of energy for 15 shocks
Maximum time between switching on and readiness for defibrillation of 360J	≤ 33 s when operated at rated voltage from the mains
	≤ 33 s when operated at 90 % of rated voltage
	≤ 33 s when operated with a fully charged, new AkuPak LITE XD
	≤ 33 s when operated with an AkuPak LITE XD after discharge of energy for 15 shocks

11.10.1 Biphasic curve properties

Pulse length	Positive phase 11.25 ms, negative phase 3.75 ms
Pulse shape	Biphasic, current-regulated

Output energy in AED mode (adult mode) for	Patient impedance	1st stage	2nd stage	3rd stage	Tolerance
	25 Ohm	150J	220J	290J	± 15 %
	50 Ohm	290J	340J	360J	± 15 %
	75 Ohm	330J	340J	340J	± 15 %
	100 Ohm	320J	320J	320J	± 15 %
	125 Ohm	296J	296J	296J	± 15 %
	150 Ohm	274J	274J	274J	± 15 %
	175 Ohm	250J	250J	250J	± 15 %
Output energy in AED mode (paediatric mode) for	Patient impedance	1st stage	2nd stage	3rd stage	Tolerance
	25 Ohm	41J	55J	81J	± 15 %
	50 Ohm	50J	70J	100J	± 15 %
	75 Ohm	49J	64J	96J	± 15 %
	100 Ohm	44J	60J	89J	± 15 %
	125 Ohm	42J	56J	83J	± 15 %
	150 Ohm	39J	51J	77J	± 15 %
	175 Ohm	36J	48J	71J	± 15 %

Output energy in manual mode (adult)depending on patient impedance	Energy to:	25 Ω	50 Ω	75 Ω	100 Ω	125 Ω	150 Ω	175 Ω	Tolerance
	2J	2J	2J	2J	2J	2J	2J	1J	0,5J - 5J
	5J	4J	5J	5J	4J	4J	4J	4J	± 3 J
	7J	6J	7J	7J	6J	6J	5J	5J	± 3 J
	10J	8J	10J	9J	9J	8J	8J	7J	± 3 J
	20J	16J	20J	19J	18J	17J	15J	14J	± 3 J
	30J	25J	30J	29J	27J	25J	23J	21J	± 15 %
	50J	41J	50J	49J	44J	42J	39J	36J	± 15 %
	70J	55J	70J	64J	60J	56J	51J	48J	± 15 %
	100J	81J	100J	96J	89J	83J	77J	71J	± 15 %
	150J	122J	150J	143J	134J	123J	115J	106J	± 15 %
	200J	165J	200J	192J	179J	166J	153J	143J	± 15 %
	250J	205J	250J	239J	224J	208J	192J	178J	± 15 %
	300J	244J	300J	287J	268J	249J	230J	214J	± 15 %
	360J	288J	360J	337J	315J	291J	269J	250J	± 15 %

Output energy in manual mode (paediatric) depending on patient impedance	Energy to:	25 Ω	50 Ω	75 Ω	100 Ω	125 Ω	150 Ω	175 Ω	Tolerance
	2J	2J	2J	2J	2J	2J	2J	1J	0,5J - 5J
	5J	4J	5J	5J	4J	4J	4J	4J	± 3 J
	7J	6J	7J	7J	6J	6J	5J	5J	± 3 J
	10J	8J	10J	9J	9J	8J	8J	7J	± 3 J
	20J	16J	20J	19J	18J	17J	15J	14J	± 3 J
	30J	25J	30J	29J	27J	25J	23J	21J	± 15 %
	50J	41J	50J	49J	44J	42J	39J	36J	± 15 %
	70J	55J	70J	64J	60J	56J	51J	48J	± 15 %
	100J	81J	100J	96J	89J	83J	77J	71J	± 15 %

Note: With SavePads Mini you cannot select more than 100J.

11.10.2 Manual defibrillation (asynchronous / synchronous)

Impedance range	23 Ω – 200 Ω
Measurement frequency impedance	30 kHz
Energy levels adult mode	2 J, 5 J,7 J, 10 J, 20 J, 30 J, 50 J, 70 J, 100 J, 150 J, 200 J, 250 J, 300 J, 360 J
Energy levels pediatric mode	2 J, 5 J,7 J, 10 J, 20 J, 30 J, 50 J, 70 J, 100 J
Time until internal discharge	15 s
Maximum delay time between synchronisation pulse and energy output This delay time is the time from the R-wave to the onset of the defibrillation impulse.	60 ms
Time until charged up to 360 J	12 s
Shock method	Paddles or multifunction electrodes SavePads (Connect), for pediatric patients: multifunction electrodes SavePads Mini

11.10.3 Pacer

Impedance range	23 Ω – 200 Ω
Measurement frequency impedance	30 kHz
Modes	FIX, DEMAND, OVERDRIVE
Stimulation frequency	
Fix, Demand	30 ppm – 180 ppm
Overdrive	30 ppm – 250 ppm
Stimulation frequency accuracy	± 0.5 %
Energy output via	Multifunction electrodes
Stimulation intensity	10 mA – 180 mA
Stimulation intensity accuracy	± 10 % or + 3/-1 mA
Pulse width	20 ms

Pulse width accuracy	± 100 µs
Refractory period	340 ms for a stimulation frequency < 100 bpm 240 ms for a stimulation frequency ≥ 100 bpm

11.10.4 AED-Mode

Impedance range	23 Ω – 200 Ω
Measurement frequency impedance	30 kHz
Shock method	Multifunction electrodes for adults or children
Asystole threshold	≥ 200 µV.
Analysis duration	4 - 20 s
Adult mode energy stages to 50 Ω	290J, 340J, 360J
Pediatric mode energy stages to 50 Ω	50J, 70J, 100J
Sensitivity	> 90 %
Specificity	> 95 %
Real predictive value	> 90 %
False positive rate	< 5 %

ECG rhythm for determining whether a shock should be delivered

- Ventricular fibrillation at an amplitude greater than or equal to 0.2 mV
- Ventricular tachycardia at a heart rate greater than or equal to 160 bpm

Subject to change without notice.

11.11Multifunction electrodes (SavePads)

SavePads Connect

- Max. 50 shocks at 360 J
- Max. 24 hours of monitoring
- Max. 1 hour of pacing at 140 mA / 120 ppm (pulse duration 20 ms)
- Max. 8 hour of pacing at 70 mA / 60 ppm (pulse duration 20 ms)
- Check the multifunction electrodes every 30 minutes

Electrode shape	Rectangular
Total surface area	Approx. 125 cm²
Adhesive surface area	Approx. 121 cm²
Gel surface area / active surface area	Approx. 87 cm²
Gel thickness	0.60 ± 0.10 mm
Pieces / bag	1 set (2 pieces)
Carrier material	Adhesive PE foam
Conductive material	Tin
Gel	Adhesive hydrogel
Separating film	Siliconised PET film
Packaging material	PET, Al, PE
Cable length	N/A

SavePads Mini Connect

Developed for patients with a maximum bodyweight of 25 kg and maximum age of 8 years.

- Max. 25 shocks at 100 J
- Max. 8 hours of monitoring
- Max. 1 hour of pacing at 140 mA / 140 ppm (pulse duration 20 ms)
- Check the multifunction electrodes every 30 minutes

Electrode shape	Rectangular
Total surface area	Approx. 80 cm²
Adhesive surface area	Approx. 75 cm²
Gel surface area / active surface area	Approx. 42 cm²
Gel thickness	0.60 ± 0.10 mm
Pieces / bag	1 set (2 pieces)
Carrier material	Adhesive PE foam
Conductive material	Tin
Gel	Adhesive hydrogel
Separating film	Siliconised PET film
Packaging material	PET, Al, PE
SavePads Mini Connect cable length	N/A

SavePads PreConnect

- Max. 50 shocks at 360 J
- Max. 24 hours of monitoring
- Max. 1 hour of pacing at 140 mA / 120 ppm (pulse duration 20 ms)
- Max. 8 hour of pacing at 70 mA / 60 ppm (pulse duration 20 ms)
- Check the multifunction electrodes every 30 minutes

Electrode shape	Rectangular
Total surface area	Approx. 148 cm²
Adhesive surface area	Approx. 145 cm²
Gel surface area / active surface area	Approx. 87 cm²
Gel thickness	0.60 ± 0.10 mm
Pieces / bag	1 set (2 pieces)
Carrier material	Adhesive PE foam
Conductive material	Tin
Gel	Adhesive hydrogel
Separating film	Siliconised PET film
Packaging material	PET, Al, PE
SavePads PreConnect cable length	2 m

SavePads Mini

Developed for patients with a maximum bodyweight of 25 kg and maximum age of 8 years.

- Max. 25 shocks at 100 J
- Max. 8 hours of monitoring
- Max. 1 hour of pacing at 140 mA / 140 ppm (pulse duration 20 ms)
- Check the multifunction electrodes every 30 minutes

Electrode shape	Oval
Total surface area	Approx. 75 cm²
Adhesive surface area	Approx. 74 cm²
Gel surface area / active surface area	Approx. 43 cm²
Gel thickness	0.60 ± 0.10 mm
Pieces / bag	1 set (2 pieces)
Carrier material	Adhesive PE foam
Conductive material	Tin
Gel	Adhesive hydrogel
Separating film	Siliconised PET film
Packaging material	PET, Al, PE
SavePads Mini cable length	Approx. 1.2 m

12 Appendix

12.1 Illustration of time-current curves

The following diagrams show the graphs for the defibrillation pulse displayed depending on the load resistance:

Maximum output

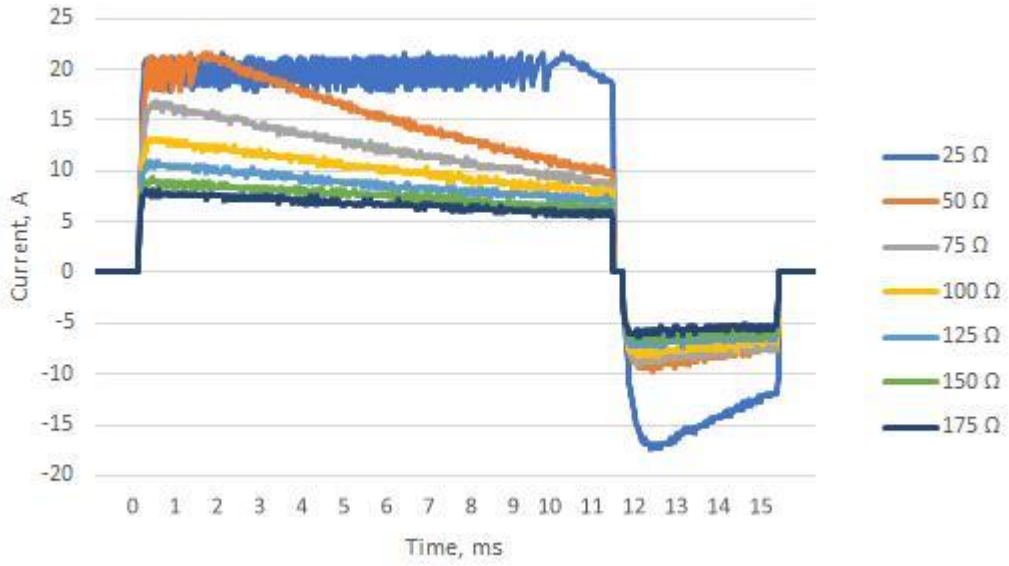


Fig. 35 Defibrillation with a maximum output of 360 joules

AED adult mode

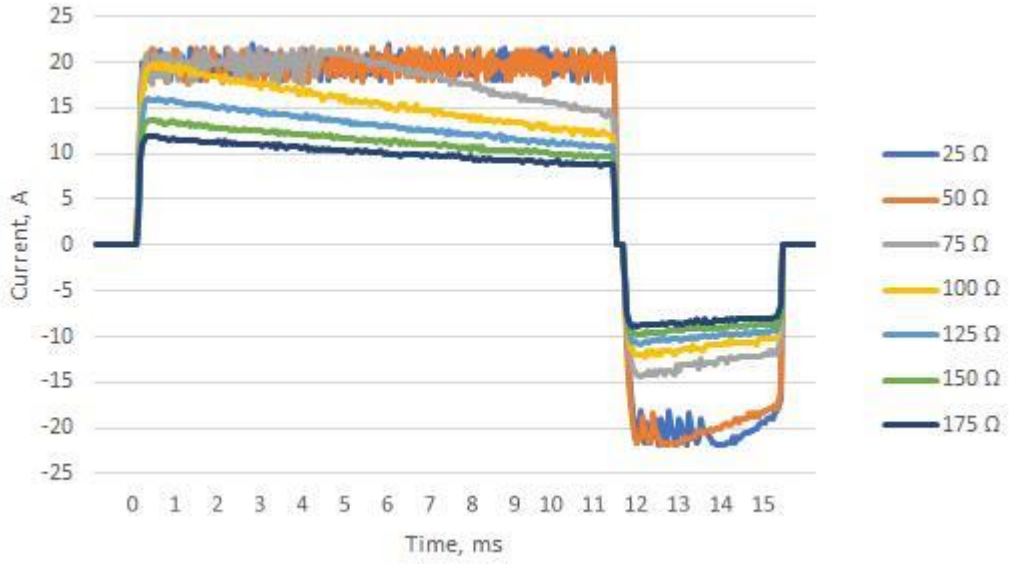


Fig. 36 First defibrillation in AED adult mode

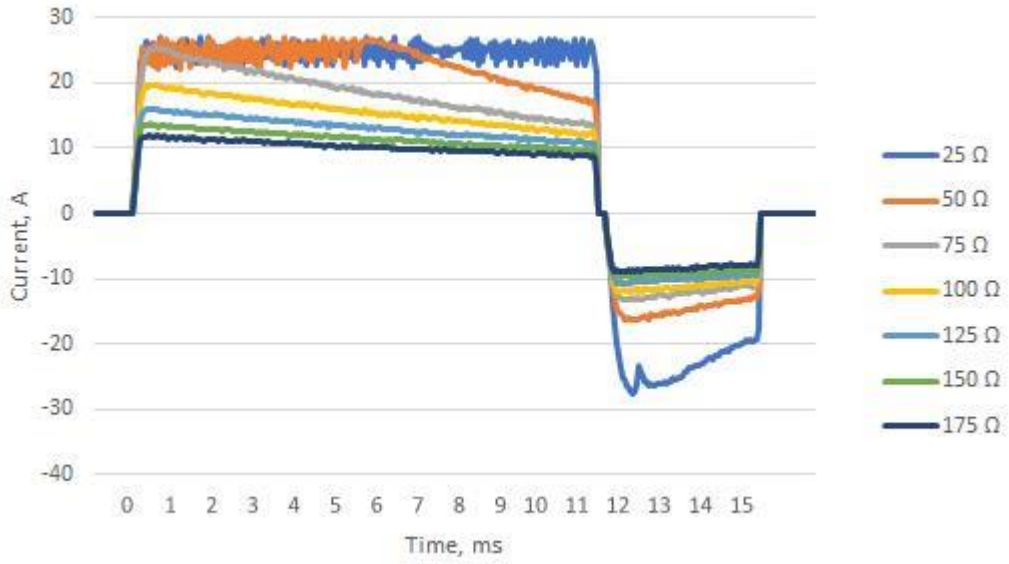


Fig. 37 Second defibrillation in AED adult mode

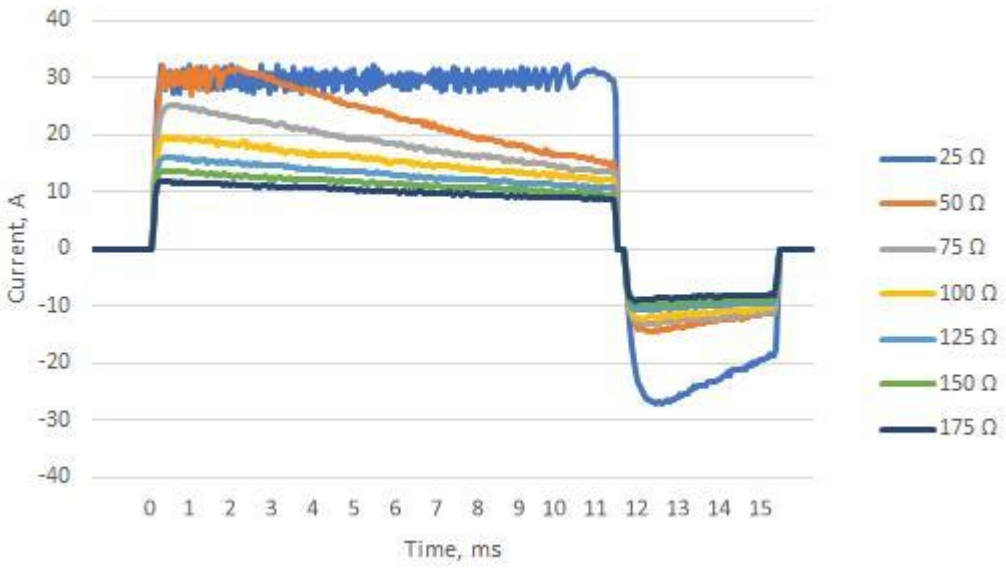


Fig. 38 Third and subsequent defibrillations in AED adult mode

AED pediatric mode

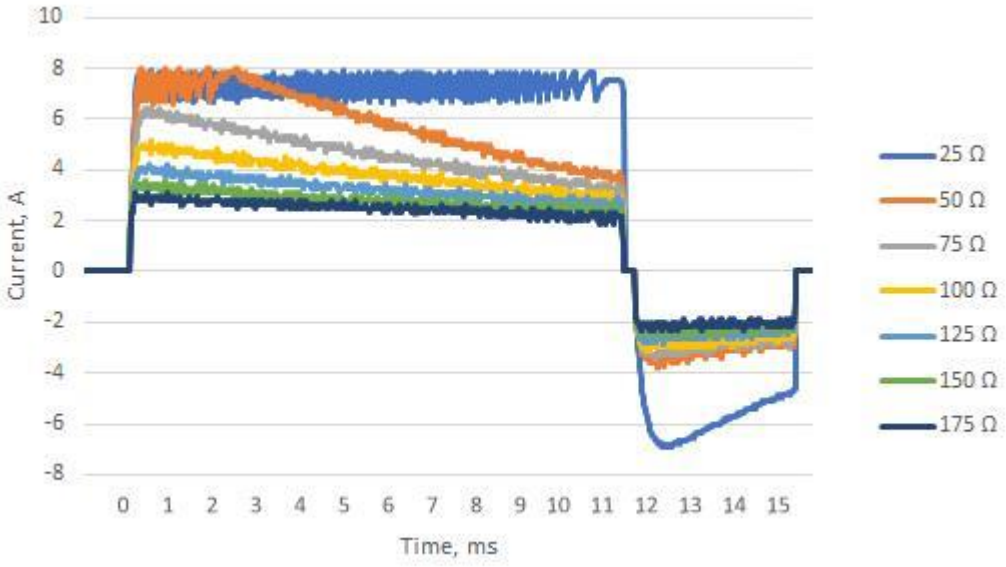


Fig. 39 First defibrillation in AED pediatric mode

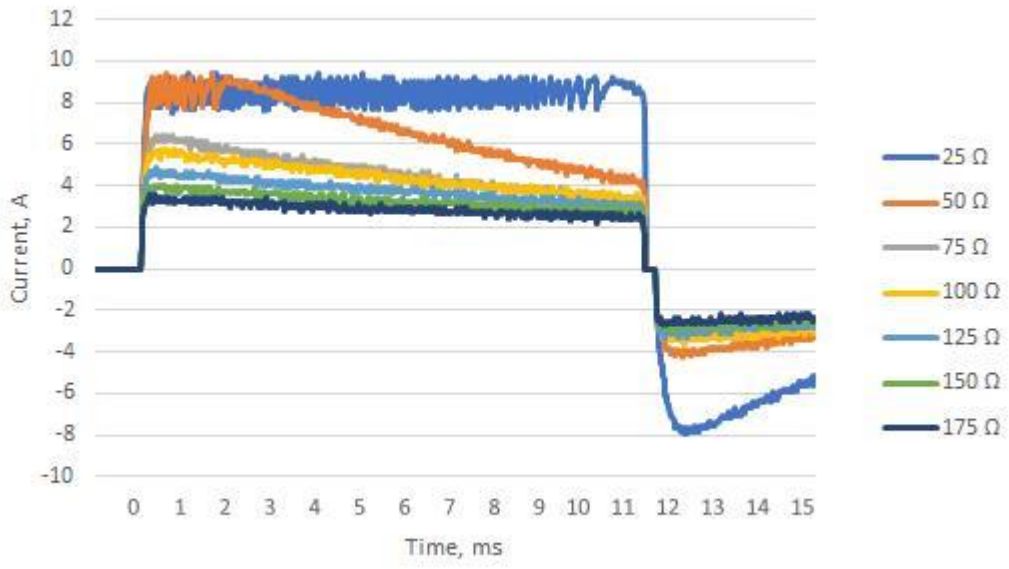


Fig. 40 Second defibrillation in AED pediatric mode

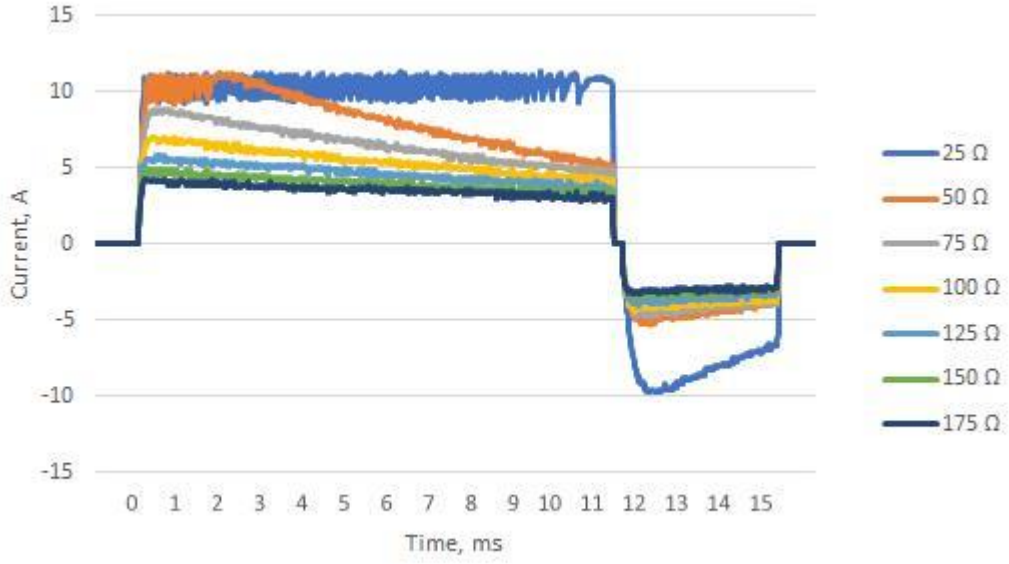


Fig. 41 Third and subsequent defibrillations in AED pediatric mode

12.2 General advice for using pulse oximeters

12.2.1 Data Update Period, Data Averaging, and Signal Processing

The advanced signal processing of the OxiMax™ algorithm automatically extends the amount of data required for measuring SpO2 and pulse rate depending on the measurement conditions. The OxiMax™ algorithm automatically extends the dynamic averaging time required beyond seven (7) seconds during degraded or difficult measurement conditions caused by low perfusion, signal artifact, ambient light, electrocautery, other interference, or a combination of these factors, which results in an increase in the dynamic averaging to 20 seconds.

12.2.2 Functional versus Fractional Saturation

This monitoring system measures functional saturation where oxygenated hemoglobin is expressed as a percentage of the hemoglobin that can transport oxygen. It does not detect significant amounts of dysfunctional hemoglobin, such as carboxy-hemoglobin or methemoglobin. In contrast, hemoximeters such as the IL482 report fractional saturation where oxygenated hemoglobin is expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobins. To compare

functional saturation measurements to those from a monitoring system that measures fractional saturation, fractional measurements must be converted using the listed equation.

$$\Phi = \frac{\varphi}{100 - (\eta + \Lambda)} \times 100$$

Φ functional saturation	η % carboxyhemoglobin
φ fractional saturation	Λ % methemoglobin

12.2.3 Performance Considerations

This section contains information for optimizing the performance of the monitoring system.

Prior to initial installation in a clinical setting, have a qualified service technician verify the performance of the monitoring system per the Service Manual.

Patient Conditions

Application issues and certain patient conditions can affect the measurements of the monitoring system and cause the loss of the pulse signal.

- Anemia — Anemia causes decreased arterial oxygen content. Although SpO2 readings may appear normal, an anemic patient may be hypoxic. Correcting anemia can improve arterial oxygen content. The monitoring system may fail to provide an SpO2 reading if hemoglobin levels fall below 5 gm/dl.
- Dysfunctional hemoglobins — Dysfunctional hemoglobins such as carboxyhemoglo-bin, methemoglobin, and sulphemoglobin are unable to carry oxygen. SpO2 readings may appear normal; however, a patient may be hypoxic because less hemoglobin is available to carry oxygen. Further assessment beyond pulse oximetry is recommended.
- Additional possible patient conditions may also influence measurements.
  - Poor peripheral perfusion
  - Excessive patient movement
  - Venous pulsations
  - Dark skin pigment
  - Intravascular dyes, such as indocyanine green or methylene blue
  - Externally applied coloring agents (nail polish, dye, pigmented cream)
  - Defibrillation

Sensor Performance Considerations

Inaccurate Sensor Measurement Conditions

A variety of conditions can cause inaccurate Nellcor™ pulse oximetry sensor mea-surements.

- Incorrect application of the pulse oximetry sensor
- Placement of the pulse oximetry sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- Ambient light
- Failure to cover the pulse oximetry sensor site with opaque material in high ambient light conditions
- Excessive patient movement
- Dark skin pigment
- Intravascular dyes or externally applied coloring, such as nail polish or pigmented cream

Signal Loss

Loss-of-pulse signal can occur for several reasons:

- Pulse oximetry sensor applied too tightly
- Inflation of a blood pressure cuff on the same extremity as the attached pulse oximetry sensor
- Arterial occlusion proximal to the pulse oximetry sensor
- Poor peripheral perfusion

Recommended Usage

Select an appropriate Nellcor™ pulse oximetry sensor, apply it as directed, and observe all warnings and cautions presented in the Instructions for Use accompanying the sensor. Clean and remove any substances such as nail polish from the application site. Periodically check to ensure that the sensor remains properly positioned on the patient.

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of a Nellcor™ pulse oximetry sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material.

If patient movement presents a problem, try one or more of the following remedies to correct the problem:

- Verify the Nellcor™ pulse oximetry sensor is properly and securely applied.
- Move the sensor to a less active site.
- Use an adhesive sensor that improves patient skin contact.
- Use a new sensor with fresh adhesive backing.
- Keep the patient still, if possible.

If poor perfusion affects performance, consider using the Nellcor™ forehead SpO2sensor (MAXFAST).

12.2.3.1 Sensor Performance Considerations

Inaccurate Sensor Measurement Conditions

A variety of conditions can cause inaccurate Nellcor™ pulse oximetry sensor measurements.

- Incorrect application of the pulse oximetry sensor
- Placement of the pulse oximetry sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- Ambient light
- Failure to cover the pulse oximetry sensor site with opaque material in high ambient light conditions
- Excessive patient movement
- Dark skin pigment
- Intravascular dyes or externally applied coloring, such as nail polish or pigmented cream

Signal Loss

Loss-of-pulse signal can occur for several reasons:

- Pulse oximetry sensor applied too tightly
- Inflation of a blood pressure cuff on the same extremity as the attached pulse oximetry sensor
- Arterial occlusion proximal to the pulse oximetry sensor
- Poor peripheral perfusion

Recommended Usage

Select an appropriate Nellcor™ pulse oximetry sensor, apply it as directed, and observe all warnings and cautions presented in the Instructions for Use accompanying the sensor. Clean and remove any substances such as nail polish from the application site. Periodically check to ensure that the sensor remains properly positioned on the patient.

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of a Nellcor™ pulse oximetry sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material.

If patient movement presents a problem, try one or more of the following remedies to correct the problem:

- Verify the Nellcor™ pulse oximetry sensor is properly and securely applied.
- Move the sensor to a less active site.
- Use an adhesive sensor that improves patient skin contact.
- Use a new sensor with fresh adhesive backing.
- Keep the patient still, if possible.

If poor perfusion affects performance, consider using the Nellcor™ forehead SpO2sensor (MAXFAST).

12.2.3.2 Oximetry Considerations

Pulse Rate

The monitoring system only displays pulse rates between 20 and 250 bpm. Detected pulse rates above 250 bpm appear as 250. Detected pulse rates below 20 appear as a zero (0).

Saturation

The monitoring system displays saturation levels between 1% and 100%.

12.2.4 Nellcor™ Pulse Oximetry Sensors

When selecting a Nellcor™ sensor, you should take the patient's weight and activities, the appropriateness of the perfusion and the available sensor locations, the necessity of sterility and the likely duration of monitoring into account. Use the recommended sensor operating instructions in order to simplify the selection of the sensor or contact Covidien or a local Covidien representative. Reference Chap. 12.2.3. The Nellcor™ SPO2 interface cable DOC10 connects the monitoring system to the Nellcor™ sensor. Do not connect any cable to the sensor connection which is intended for computer use. Only use sensors and interface cables authorised by Covidien when connecting to the sensor connection.

Nellcor™ pulse oximetry sensor models and patient weight

Nellcor™ pulse oximetry sensor	Article description	Patient weight
Nellcor™ SpO2 sensor for premature babies, non-adhesive (for single-patient use only)	SC-PR	<1.5 kg
Nellcor™ SpO2 sensor for newborn babies, non-adhesive (for single-patient use only)	SC-NEO	1.5 to 5 kg
Nellcor™ SpO2 sensor for adults, non-adhesive (for single-patient use only)	SC-A	>40 kg
Nellcor™ SpO2 sensor with a poultice for adults and newborn infants (reusable with adhesives)	OXI-A/N	<3 or >40 kg
Nellcor™ SpO2 sensor with a poultice for adults and newborn infants (reusable with adhesives)	OXI-P/I	3 to 40 kg
Nellcor™ SpO2 sensor for children, two-part (sterile, not reusable)	P	10 to 50 kg
Nellcor™ SpO2 sensor for newborn infants and adults, two-part (sterile, not reusable)	N	<3 or >40 kg
Nellcor™ SpO2 sensor for adults, two-part (sterile, not reusable)	A	>30 kg

Nellcor™ pulse oximetry sensor	Article description	Patient weight
Nellcor™ SpO2 sensor for newborn infants and adults (sterile, not reusable)	MAXN	<3 or >40 kg
Nellcor™ SpO2 sensor for babies (sterile, not reusable)	MAXI	3 to 20 kg
Nellcor™ SpO2 sensor for children (sterile, not reusable)	MAXP	10 to 50 kg
Nellcor™ SpO2 sensor for adults (sterile, not reusable)	MAXA	>30 kg
Nellcor™ SpO2 sensor for adults with a long cable (sterile, not reusable)	MAXAL	>30 kg
Nellcor™ SpO2 nasal sensor for adults (sterile, not reusable)	MAXR	>50 kg
Nellcor™ SpO2 forehead sensor (sterile, not reusable)	MAXFAST	>10 kg
Nellcor™ SpO2 sensor for adults, reusable (not sterile)	DS-100A	>40 kg
Nellcor™ SpO2 sensor for adults and children (except for babies and newborn infants), reusable (not sterile)	FLEXMAX Large	>20 kg
Nellcor™ SpO2 sensor for adults and children (except for babies and newborn infants), reusable (not sterile)	FLEXMAX-P Small	>20 kg
Nellcor™ SpO2 sensor for various locations, reusable (not sterile)	D-YS	>1 kg
Nellcor™ SpO2 ear sensor clip (not sterile)	D-YSE	>30 kg
Nellcor™ SpO2 sensor clip for children, reusable (not sterile)	D-YSPD	3 to 40 kg

Contact Covidien or a local Covidien representative for a Nellcor™ Oxygen Saturation Accuracy Specification Grid, which lists all the Nellcor™ sensors used with the monitoring system. Covidien retains a soft copy under www.covidien.com.

Note

Physiological conditions such as exaggerated patient movement, medical processes or external substances such as dysfunctional haemoglobin, arterial dyestuffs, low perfusion, dark pigment and externally applied dyestuffs such as nail polish, dyestuffs or pigmented cream may influence the capability of the monitoring system to recognise and show the capability of the monitoring system.

Nellcor™ sensor functions

The Nellcor™ sensor functions vary with sensors which have different revision statuses and by sensor type (adhesive, recycled and reusable). A sensor's revision status can be found on the sensor connector.

Biocompatibility test

The Nellcor™ pulse oximetry sensors were subjected to a biocompatibility examination in accordance with ISO 10993-1 (Biological evaluation of medical devices, part 1: Evaluation and testing). The pulse oximetry sensors successfully passed the recommended biocompatibility tests and thus meet the requirements of ISO10993-1.

12.2.5 Functional Testers and Patient Simulators

Some models of commercially available bench top functional testers and patient simulators can be used to verify the proper functionality of Covidien Nellcor™ monitoring systems, sensors, and cables. Reference the individual testing device's operator's manual for the procedures specific to the model of tester used. While such devices may be useful for verifying that the sensor, cabling, and monitoring system are functional, they are incapable of providing the data required to properly evaluate the accuracy of a system's SpO2 measurements.

Fully evaluating the accuracy of the SpO2 measurements requires, at a minimum, accommodating the wavelength characteristics of the sensor and reproducing the complex optical interaction of the sensor and the patient’s tissue. These capabilities are beyond the scope of known bench top testers. SpO2 measurement accuracy can only be evaluated in vivo by comparing monitoring system readings with values traceable to SaO2 measurements obtained from simultaneously sampled arterial blood using a laboratory CO-oximeter.

any functional testers and patient simulators have been designed to interface with the monitoring system's expected calibration curves and may be suitable for use with monitoring systems and/or sensors. Not all such devices, however, are adapted for use with the OxiMax™ digital calibration system. While this will not affect use of the simulator for verifying system functionality, displayed SpO2 measurement values may differ from the setting of the test device. For a properly functioning monitoring system, this difference will be reproducible over time and from monitoring system to monitoring system within the performance specifications of the test device.

12.3 Rhythm detection system in AED-Mode

The DefiMonitor XD rhythm detection system analyses the patient's ECG and supports it if the device detects a rhythm requiring defibrillation or not.

The device’s rhythm detection system comprises:

- Evaluating the electrode contact
- Automatic evaluation of the ECG
- Operator control of the defibrillation shock therapy

The transthoracic impedance of the patient is measured by the defibrillation electrodes. If the impedance measured is not within the valid range, the device establishes whether the electrodes have sufficient contact with the patient or are short-circuited. ECG analysis is hindered. The voice prompt "Check electrodes" follows if the electrode contact is inadequate.

Automatic interpretation of the ECG

The rhythm detection system of the device is designed to recommend a defibrillation shock when the system is has been connected up to a patient and the system detects a rhythm which requires defibrillation. For all other ECG rhythms, including fine ventricular fibrillation, asystole and normal sinus rhythms, the rhythm detection system does not recommend defibrillation.

Operator control of the output of defibrillation shocks

The device's rhythm detection system triggers an automatic power charge if the device detects a cardiac rhythm which requires defibrillation. The defibrillator does not analyse the cardiac rhythm when charging energy and during readiness to shock. Optical and acoustic messages are generated to show the user that the device recommends giving a defibrillation shock. If a defibrillation shock is recommended, the user must decide whether and when the shock is to be given.

The algorithm

- Monitors the ECG rhythm during a continuous recording of up to 20 seconds
- Filters interference and measures artefacts
- Calculates several ECG signal parameters including frequency and morphological parameters - rejects implantable pacemaker artefacts
- Measures the QRS rate

Based on the parameters collected, the algorithm decides whether the rhythm required defibrillation. The first 4 seconds are used for initial diagnosis. If no rhythm has been established within the first 4

seconds which requires defibrillation, the analysis is continued up to 16 further seconds and a decision taken each second.

Adult mode

The following databases are used for validation purposes: AHA and MIT.

When calculating the characteristic section values in the ECG data sets for the above-named databases which are marked with the PhysioBank annotation code as requiring shocks, we view these as cardiac rhythms requiring defibrillation. These sections also contain ventricular tachycardias which, however, are not annotated extra and cannot therefore be part of the statistics.

Data sets with a length of 20 seconds without rhythm changes and artefacts were used for validation purposes. The database incorporates 1369 data sets not requiring defibrillation and 185 which require defibrillation. These sections also contain ventricular tachycardias. However, they are not separately annotated and cannot therefore be shown in the statistics.

The performance results meet the requirements of IEC 60601-2-4:2010:

Sensitivity	> 90 %
Specificity	> 95 %
Real predictive value	> 90 %
False positive rate	< 5 %

Paediatric Mode

The following database was used for validation purposes: Development and validation dataset of the Physical-Technical Federal Institute (PTB) Berlin. This data was collected by the PTB within the scope of the research project MNPQ 07/09 carried out by the German Federal Ministry of Economics and Technology.

The cardiac rhythms not requiring defibrillation cover bundle branch blocks and supraventricular tachycardia, as well as normal sinusoidal rhythms. These sections also contain ventricular tachycardias which, however, are not separately evaluated and cannot therefore be included in the statistics.

The performance results meet the requirements of IEC 60601-2-4:2010:

Sensitivity	> 90 %
Specificity	> 95 %
Real predictive value	> 90 %
False positive rate	< 5 %

12.4 Electromagnetic compatibility

Guidelines and manufacturer's declaration on electromagnetic emissions

<table>
<tr><td colspan="3">The DefiMonitor XD is designed for use in an environment like the one described below. The customer or user of the DefiMonitor XD should ensure that it is used in an environment of this kind.</td></tr>
<tr><td>Emitted interference measurements</td><td>Conformance</td><td>Electromagnetic environment – code of practice</td></tr>
<tr><td>HF emissions as per CISPR 11</td><td>Group 1
Class B</td><td>The DefiMonitor XD only uses HF energy for its internal function. This means that its HF emission is very low and it is unlikely that equipment in the vicinity will be disrupted.</td></tr>
<tr><td>Emission of harmonics as per IEC 61000-3-2</td><td>Class A</td><td rowspan="2">The DefiMonitor XD is suitable for use in all facilities (“professional healthcare”), including residential areas (“home healthcare”) and those directly connected to a public supply network which also supplies buildings used for residential purposes.</td></tr>
<tr><td>Emission of voltage fluctuations / flickers as per IEC 61000-3-3</td><td>Compliant</td></tr>
</table>

Guidelines and manufacturer's declaration on resistance to electromagnetic interference

The DefiMonitor XD is designed for operation in an electromagnetic environment like the one described below. The customer or user of the DefiMonitor XD should ensure that it is used in an environment of this kind.			
Test for interference resistance	IEC 60601-1-2: 2014 test level	Compliance level	Guidance for the electromagnetic environment
Electrostatic discharge (ESD) as per IEC 61000-4-2	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharge	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharge	Corridor floors should be made of wood or concrete or be covered with ceramic tiles. If the floor is covered with a synthetic material, the relative air humidity should be at least 30%.
Rapid transient electrical disturbance variables / bursts as per IEC61000-4-4	± 2 kV (wire to wire) @ 100 kHz refresh rate for power cables	± 2 kV (wire to wire) @ 100 kHz refresh rate for power cables; power supply is protection class II The device has no signal from input and output sections. Cannot be used when run off battery	The quality of the voltage supply should correspond to that of a typical residential, business or hospital environment.
Surge voltages (surges) as per IEC 61000-4-5	± 0,5 kV, ± 1 kV (wire to wire) for power cables	± 0,5 kV, ± 1 kV (wire to wire) for power cables power supply is protection class II The device has no signal from input and output sections. Cannot be used when run off battery	The quality of the voltage supply should correspond to that of a typical residential, business or hospital environment.
Voltage dips, short breaks and fluctuations in the supply voltage as per IEC 61000-4-11	0 % U_T (100 % dip in U_T) for ½ period @ 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; (see above) for 1 period and 70 % U_T for (25 periods at 50 Hz / 30 periods at 60 Hz) @ 0° 0 % U_T (see above) for 250 periods at 50 Hz / 300 periods at 60 Hz	0 % U_T (100 % dip in U_T) for ½ period @ 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; (see above) for 1 period and 70 % U_T for (25 periods at 50 Hz / 30 periods at 60 Hz) @ 0° 0 % U_T (see above) for 250 periods at 50 Hz / 300 periods at 60 Hz Cannot be used when run off battery	The quality of the voltage supply should correspond to that of a typical residential, business or hospital environment. The DefiMonitor XD can continue to function within the limits of its battery capacity without any interruptions thanks to its rechargeable battery. If the permissible duration of use is exceeded, it is recommended that a spare battery or an uninterrupted power supply is used.

Magnetic field at the supply frequency (50/60 Hz) as per IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields for the mains frequency should correspond to the typical values found in a residential, commercial or hospital environment.
NOTE: U_t is the a.c. supply voltage before applying the test level.			

The DefiMonitor XD is designed for operation in an electromagnetic environment like the one described below. The customer or user of the DefiMonitor XD should ensure that it is used in an environment of this kind.		
Test for interference resistance	IEC 60601-1-2: 2014 test level	Compliance level
Conducted HF interference as per IEC 61000-4-6 - on the power cable - on the ECG input - on the SpO2 input	3 V_{eff} 150 kHz to 80 MHz with 80% AM at 1 kHz; outside the ISM and amateur radio bands [a] 6 V_{eff} 150 kHz to 80 MHz with 80% AM at 1 kHz; within the ISM and amateur radio bands [a]	3 V_{eff} 150 kHz to 80 MHz with 80% AM at 1 kHz; outside the ISM and amateur radio bands [a] 6 V_{eff} 150 kHz to 80 MHz with 80% AM at 1 kHz; within the ISM and amateur radio bands [a]
Conducted HF interference as per IEC 60601-2-4: 2010 - on the power cable	3 V_{eff} 150 kHz to 80 MHz with 80 % AM at 5 Hz	3 V_{eff} 150 kHz to 80 MHz with 80 % AM at 5 Hz
Radiated HF interference as per IEC 61000-4-3 and IEC 60601-2-4	10 V/m, 80 MHz–2,7 GHz, 80 % AM with 5 Hz - no unwanted discharge - no unintentional change of status - no unwanted activation of the rhythm detection system 20 V/m, 80 MHz–2,7 GHz, 80 % AM with 5 Hz - no unwanted energy output	20 V/m
Radiated HF interference as per IEC 80601-2-61:2011	20 V/m, 80 MHz–2,7 GHz, 80 % AM with 1000 Hz	20 V/m
Interference resistance for HF surgical equipment as per IEC 60601-2-49:2011 / IEC 60601-2-27:2011 Chapter 202.6.2.101 with images 202.103 and 104	@ 400 kHz +/-10 %: a) PureCut 300W 10s b) Uro Pure Cut 300W 10s c) Clamp Coag 100W 10s d) Forced Prep 100W 10s	Short-term disruption is possible without permanent interference [b]
Frequency ranges close to wireless communication equipment	380 – 390 MHz: 27V/m 430 – 470 MHz: 28V/m 704 – 787 MHz: 9V/m 800 – 960 MHz: 28V/m 1700 – 1900 MHz: 28V/m 2400 – 2570 MHz: 28V/m 5100 – 5800 MHz: 9V/m	380 – 390 MHz: 27V/m 430 – 470 MHz: 28V/m 704 – 787 MHz: 9V/m 800 – 960 MHz: 28V/m 1700 – 1900 MHz: 28V/m 2400 – 2570 MHz: 28V/m 5100 – 5800 MHz: 9V/m

[a] The ISM frequency bands (for industrial, scientific and medical applications) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz. The amateur radio frequency bands between 0.15MHz and 80 MHz are 1.8 MHz – 2.0 MHz; 3.5 MHz – 4.0 MHz; 5.3 MHz – 5.4 MHz; 7.0 MHz – 7.3 MHz; 10.1 MHz – 10.15 MHz; 14.0 MHz – 14.2 MHz; 18.07 MHz – 18.17 MHz; 21.0 MHz – 21.4 MHz; 24.89 MHz – 24.99 MHz; 28.0 MHz – 29.7 MHz and 50.0 MHz – 54.0 MHz.

[b] Simultaneous use of HF surgical equipment and the DefiMonitor XD is to be avoided if possible, or made to last for as short a time as possible. If these devices are used for a longer period, the DefiMonitor XD should be temporarily separated from the patient.

Recommended protective distances between portable and mobile HF telecommunication devices and the DefiMonitor XD.
The DefiMonitor XD is designed for use in an electromagnetic environment in which the HF interference is controlled. The customer or user of the DefiMonitor XD can help avoid electromagnetic interference by maintaining

the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the Defi-Monitor XD – independently of the output power of the communication device, as shown below				
Power rating of transmitter in W	Protective distance depends on the transmission frequency m			
	150 kHz to 80 MHz outside the ISM bands d=1.2√P	150 kHz to 80 MHz inside the ISM and amateur radio bands d=2√P	80 MHz to 800 MHz d=0.6√P	800 MHz to 2.7 GHz d=1.15√P
0.01	0.12	0.2	0.06	0.12
0.1	0.38	0.64	0.19	0.36
1	1.2	2	0.6	1.15
10	3.8	6.4	1.9	3.64
100	12	20	6	11.5
For transmitters with a maximum power rating that is not given in the table above, the distance can be determined by using the equation that belongs to the respective column, whereby P is the maximum power rating of the transmitter in Watts (W) according to the manufacturer of the transmitter. NOTE 1: The higher frequency range applies at 80 MHz and 800 MHz NOTE 2: The ISM frequency bands (for industrial, scientific and medical applications) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz. NOTE 3: The conformity levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency band from 80 MHz and 2.7 GHz are defined to reduce the probability that mobile/portable communication devices can cause interference, if they are unintentionally brought into the vicinity of the patient. For this reason, an additional factor of 10/3 is applied when calculating the recommended safety distances in these frequency ranges. NOTE 4: These guidelines may not be applicable in all cases. The spread of electromagnetic factors is affected by absorption and reflections from buildings, objects and people.				

12.5 Optional accessories

Article	Article no.	Remarks
SavePads Connect (5 pair)	96710	
SavePads PreConnect	97789	
SavePads Mini	97534	
SavePads Mini Connect	97690	
ECG electrodes (10 packs = 300 pcs.)	96592	
Printer paper (10 pieces)	96365	58 mm, 25 m, smudge-proof, with grid lines
Conductive gel for defibrillation (15 pieces)	96364	Tube 100 g

Subject to change without notice. Additional accessories available on request.

Index of figures

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