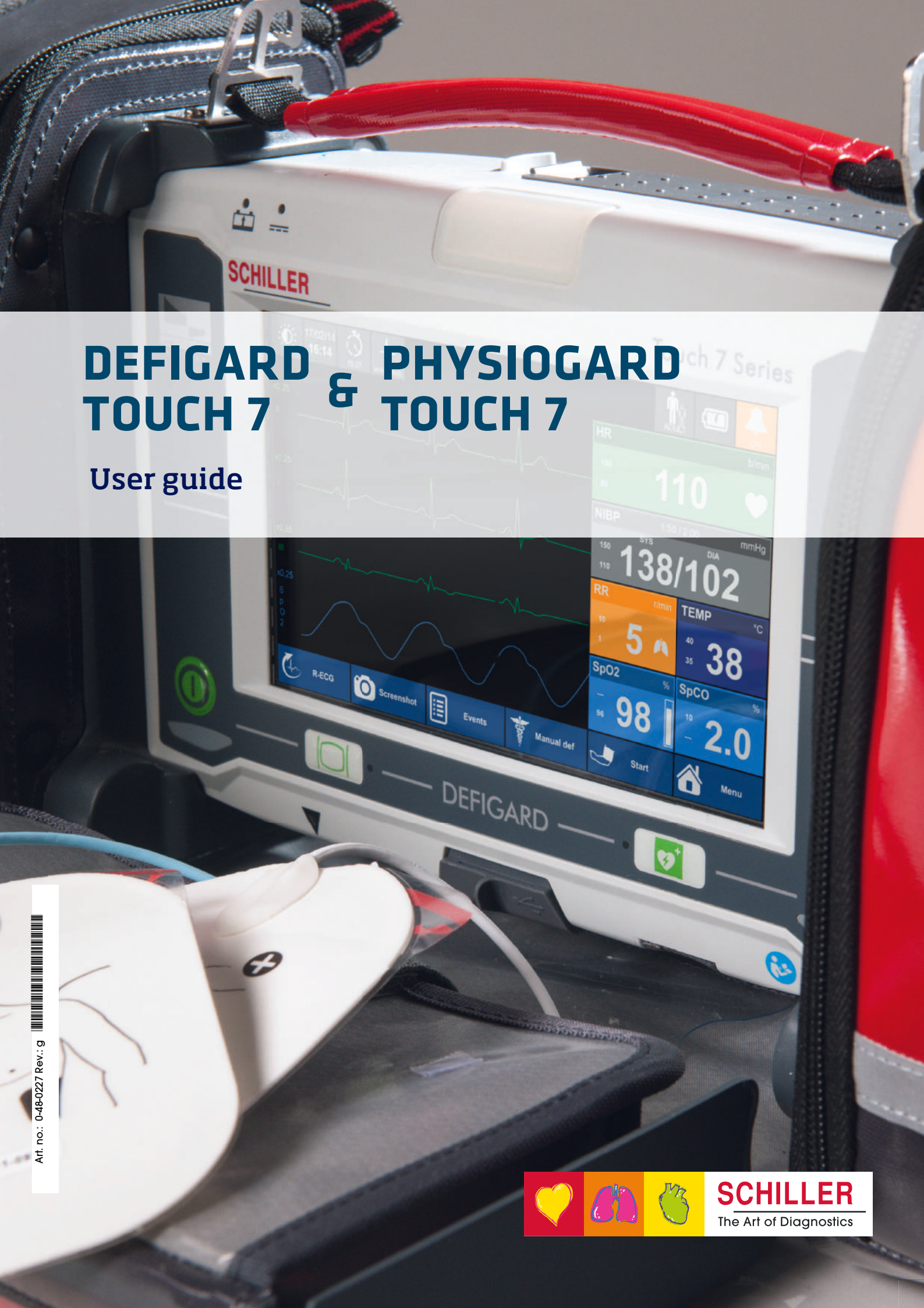
DEFIGARD TOUCH 7 & PHYSIOGARD TOUCH 7

User guide



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SCHILLER
The Art of Diagnostics

Sales and Service Information

The SCHILLER sales and service centre network is world-wide. For the address of your local distributor, contact your nearest SCHILLER subsidiary.
In case of difficulty, you can find a complete list of all distributors and subsidiaries on our Internet site:
http://www.schiller.ch
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CE 0459

Art. no./revision:	Date	Note
0-48-0227 a	16.12.2014	Version a for testing
0-48-0227 b	3.06.2015	Updated version for validation
0-48-0227 c	1.09.2015	Updated version with minor changes
0-48-0227 d	7.04.2016	Add new feature CO2 and PHYSIOGARD Touch 7 and other changes.
0-48-0227 e	25.01.2017	Adding correction according to Mantis. Add IBP and Pacemaker.
0-48-0227 f	3.11.2017	Update to Software revision 6
0-48-0227 g	8.02.2018	Adding correction according to Mantis .

CE 0459

The DEFIGARD Touch7 bears the CE-0459 mark (Notified Body LNE/G-MED), indicating its compliance with the essential requirements of the Annex I of the Medical Device Directive 93/42/EE regarding safety, functionality and labelling. The requirements apply to patients, users and third persons who come into contact with this device within the scope of its intended use. First declaration 26.04.2015
The PHYSIOGARD Touch 7 bears the CE-0459 mark (Notified Body LNE/G-MED), indicating its compliance with the essential requirements of the Annex I of the Medical Device Directive 93/42/EE regarding safety, functionality and labelling. The requirements apply to patients, users and third persons who come into contact with this device within the scope of its intended use. First declaration 7.04.2016

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1 Safety notes

The **PHYSIOGARD® Touch 7** is a monitor.

The **DEFIGARD® Touch 7** is an emergency monitor / defibrillator.

1.1 User profiles

Physician

The **DEFIGARD® Touch 7** must only be used by qualified medical or paramedic staff, if the manual defibrillation mode is activated.

The **PHYSIOGARD® Touch 7** must only be used by qualified medical or paramedic staff.

Other persons

The **DEFIGARD® Touch 7** can be used by other persons (AED mode only if trained in early defibrillation).

Training

An initial training of at least 30 minutes is necessary and sufficient to use the device.

1.2 Intended Use

Defibrillator

- The **DEFIGARD® Touch 7** defibrillation function is used for the treatment of ventricular fibrillation (VF) and ventricular tachycardia (VT).

Transcutaneous Pacemaker

- The pacemaker pulse is delivered using the same electrode pads (adult or child) as those used for defibrillation. The frequency and current of the pacemaker pulses are defined by the user. There are two pacemaker modes as follows:
  - Fix: The pacemaker pulse is delivered at a fixed frequency and current level defined by the user.
  - On demand: Current level and frequency are defined by the user. The unit monitors the ECG signal and generates pacemaker pulses if the pulse rate falls below the defined value.
- Depending on their configuration, the monitoring function of the **DEFIGARD® Touch 7** & **PHYSIOGARD® Touch 7** delivers the most important parameters – ECG, SpO2, SpCO, SpMet, CO2 – and allows continuous monitoring of the patient from the beginning to the end of an intervention.
- The devices are intended for single patient use only.
- The devices are designed to meet the specific needs of ground and air rescue services as well as in-house and inter-hospital transportation.
- The devices can be used for adults, children and neonates with the corresponding accessories.

ECG

- The ECG is used to diagnose cardiac abnormalities, acute myocardial ischaemia and infarctions in chest pain patients.

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NIBP

- ▲ The NIBP monitor is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure an adult, child and neonate patient's blood pressure. The NIBP can be used for patients of both sexes and all races.
- ▲ This NIBP can be used on pregnant patients or patients suffering from pre-eclampsia

IBP

- ▲ Invasive blood pressure: systolic, diastolic and mean pressure.

SpO2, SpCO, SpMet

- ▲ The Masimo Rainbow SET® Pulse CO sensor is indicated for use with adult and paediatric patients during both no-motion and motion conditions, and for patients who are well or poorly perfused.

etCO_2

- ▲ The IRMA mainstream sensor is intended to be connected to a patient breathing circuit for the continuous non invasive monitoring of breath rate and inspired/ expired gases during anaesthesia, recovery and respiratory care.
- ▲ The ISA gas analyser is intended to be connected to a patient breathing circuit for the continuous non invasive sidestream monitoring of breath rate and inspired/expired gases during anaesthesia, recovery and respiratory care.
- ▲ The CO_2 sensors are intended for use with adult, paediatric and infants populations.

1.3 Contraindication for use

Defibrillation (DEFIGARD® Touch 7)

- ▲ The defibrillator of the **DEFIGARD® Touch 7** must **not** be used in automated mode (AED) when the person:
  - – is responsiv
  - – is breathing normally
  - – has pulse
- ▲ Do not use the device in or near magnetic resonance imaging equipment (MRI).
- ▲ **Danger of explosion! —** The device must not be used in areas where there is any danger of explosion. There might be a danger of explosion in areas where flammable products (petrol), flammable anaesthetic agents or products for skin cleaning/disinfection are in use, or where the ambient air's oxygen concentration is higher than 25 %.

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1.4 Responsibility of the User

- ▲ The numerical and graphical results and any interpretation given must be examined with respect to the overall clinical condition of the patient and the general recorded data quality.
- ▲ The indications given by this equipment are not a substitute for regular checking of vital functions.
- ▲ Always ensure that the screen/alarm LED of the device can be seen in case the audible alarms cannot be heard or are turned off (see chapter 4.2.2 Operator's position page 38).
- ▲ The AED of the **DEFIGARD® Touch 7** must only be used if the following symptoms are present:
  - not responsive
  - not breathing normally
  - no pulse
- ▲ Make sure that the user has read and understood the user guide, and especially these safety notes.
- ▲ Operating a device with a defective casing, defective cables and sensors constitutes a danger to the patient or the user! Therefore:
  - Immediately replace a damaged unit, damaged cables, sensors and connections. Damaged or missing components must be replaced immediately.
- ▲ The device including sensor and accessories must be serviced on a regular basis. (see chapter 10.1.1 page 112)
- ▲ The **DEFIGARD® Touch 7** is an emergency device and must be ready for operation at any time and in all situations. Ensure that the device is always equipped with a sufficiently charged battery and keep a spare battery at hand.
- ▲ Properly dispose of the package material and make sure it is out of children's reach.

1.5 Organisational Measures

- ▲ Before using the unit, ensure that an introduction regarding the unit functions and the safety precautions has been provided and understood.
- ▲ Always store the user guide at hand near the device. Make sure that the instructions are always complete and legible.

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1.6 Safety-Conscious Operation

- This user guide, and especially these safety notes, must be read and observed.
- Danger of electric shock!
  The energy applied to the patient can be conducted through the patient to other persons, who may suffer a lethal electric shock. Therefore:
  - Do not touch the patient, the electrodes or other conducting objects during defibrillation
  - Do not defibrillate the patient in a puddle of water or on other conductive surfaces
  - Switch the device off when it is no longer used.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- To grant the patient's safety, it must be ensured that neither the electrodes, including the neutral electrode, nor the patient, or persons touching the patient, come into contact with conducting objects, even if these are earthed.
- Immediately report any changes that impair safety (including operating behaviour) to the person responsible.
- Only connect original SCHILLER accessories to the device.
- Before switching on, check if the unit's casing and electrode connection are undamaged.
- Only operate the device in accordance with the specified technical data.
- Do not expose the device to great temperature variations over a long period of time. Major temperature variations can cause condensation water on the unit. Should condensing water nevertheless occur, dry the unit, the defibrillation electrodes and all connections.
- In case of strong water/liquid spraying onto the device, check the absence of water/liquid in the battery compartment. If necessary, please remove the battery, dry water from compartment and replace battery.
- Special caution must always be taken on intracardiac application of medical equipment. Especially make sure that no conducting parts connected to the unit's isolated patient input (patient, plug, electrodes, sensor) come into contact with other, earthed conductive objects, as this might short-out the patient's isolation and remove the protection of the isolated input.
- Carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- The user shall always remain close to the patient during monitoring.
- Do not place the device where the device can be controlled by the patient.
- Position the device so that there is no possibility of it falling on the patient or floor.
- Do not reuse disposable accessories marked with the symbol  to prevent cross infection.
- If unexpected readings are obtained, the operator should check the connections and verify the readings according to section 10.2.5 page 115.

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1.7 Operation with other Devices

- ▲ Use only accessories and other parts recommended or supplied by SCHILLER. Use of other than recommended or supplied parts may result in injury, inaccurate information and/or damage to the unit.
- ▲ The patient can be endangered by too high leakage currents (summation of leakage currents) if:
  - – several devices are connected to the patient
  - – other equipment is connected to the **DEFIGARD® Touch 7** or **PHYSIOGARD® Touch 7**.

  For this reason, devices that are not required should be disconnected from the patient, and only equipment approved by SCHILLER may be connected to the device.
- ▲ Accessory equipment connected to the analogue and digital interfaces must be certified according to the respective IEC standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC/EN 60601-1. Everyone who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC/EN 60601-1. If in doubt, consult the technical service department or your local representative.
- ▲ Magnetic and electrical fields of X-ray equipment, tomographs, portable communication devices, HF radios and devices labelled with the  symbol can affect the operation of this device. (See section 10.9.3 Measures to prevent electromagnetic interferences page 126.) Avoid using such devices or keep a sufficient distance from them.
- ▲ The charging of energy and the release of the defibrillation impulse can disturb other devices. Check these devices before their further use.
- ▲ Sensors and devices that are not defibrillation proof must be disconnected from the patient before a shock is triggered.
- ▲ If the patient has a pacemaker implanted, do not position the electrode directly onto the pacemaker. Check the pacemaker after the defibrillation.
- ▲ The **DEFIGARD® Touch 7** & **PHYSIOGARD® Touch 7** can be used together with high-frequency electrosurgical devices. However, precautions must be observed when such HF equipment is used. To reduce the risk of burns in the case of a failure of the neutral HF electrode, a distance of at least 15 cm must always be kept between the defibrillation electrodes and the HF surgical electrodes. If in doubt, disconnect the electrodes and sensors from the unit during use of a HF surgical device. In addition, it may affect the accuracy or availability of the oximeter measurements.

1.8 Maintenance

- ▲ Danger of electric shock! Do not open the device. No serviceable parts inside. Refer servicing to qualified personnel only.
- ▲ No modification of this equipment including sensor and accessories is allowed.
- ▲ Before cleaning, switch the unit off and remove the battery.
- ▲ Do not use high temperature sterilisation processes (such as autoclaving). Do not use E-beam or gamma radiation sterilisation.
- ▲ Do not use solvent or abrasive cleaners on either the unit or cable assemblies.
- ▲ Do not, under any circumstances, immerse the unit or cable assemblies in liquid.

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1.9 Hygiene

- ▲ For cleaning and disinfection observe the legal requirements applicable.
- ▲ Only use cleaning agents and disinfectants recommended by SCHILLER. Unsuitable agents can damage the device. Clean and disinfect the device in accordance with the instructions given in this book.

1.10 Networks and Internet

- ▲ When the unit is part of a network, (LAN, WLAN, HIS, etc.), transmitting over a telephone network or any other transmission/reception medium, or if exposed to the Internet or other insecure networks, appropriate security measures must be taken to protect the stored patient data.
- ▲ SCHILLER takes no responsibility for the configuration of Windows.
- ▲ Patient data security and security of the network is the sole responsibility of the user.
- ▲ In order to guarantee the security of the network, Schiller recommends the following:
  - – isolating the **DEFIGARD® Touch 7** or **PHYSIOGARD® Touch 7** network from other networks
  - – defining access authorisation for the configuration of the host system, incl. **DEFIGARD® Touch 7** or **PHYSIOGARD® Touch 7**, so that no unauthorised alterations of the system are possible
  - – limiting the data transmission between the host and other systems/networks to a minimum

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1.11 Additional Terms

1.11.1 Implied Authorisation

Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would, alone or in combination with this device, fall within the scope of one or more of the patents relating to this device.

1.11.2 Terms of Warranty

Your SCHILLER **DEFIGARD® Touch 7** & **PHYSIOGARD® Touch 7** is warranted against defects in material and manufacture according the general term of conditions. Excluded from this guarantee is damage caused by an accident or as a result of improper handling. The warranty entitles free replacement of the defective part. Any liability for subsequent damage is excluded. The warranty is void if unauthorised or unqualified persons attempt to make repairs.

In case of a defect, send the apparatus to your dealer or directly to the manufacturer. The manufacturer can only be held responsible for the safety, reliability, and performance of the apparatus if:

- assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorised by him, and
- the **DEFIGARD® Touch 7**/**PHYSIOGARD® Touch 7** and approved attached equipment is used in accordance with the manufacturer's instructions.

There are no express or implied warranties which extend beyond the warranties hereinabove set forth. SCHILLER makes no warranty of merchantability or fitness for a particular purpose with respect to the product or parts thereof.

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1.12 Display Symbols/Indicators

1.12.1 Symbols Used in this User Guide

The safety level is classified according to ISO 3864-2. The following overview contains the safety symbols and pictorals used in this user guide.

⚠ DANGER

For a direct danger which could lead to severe personal injury or to death.

⚠WARNING

For a possibly dangerous situation, which could lead to heavy bodily injury or to death.

⚠ CAUTION

For a possibly dangerous situation which could lead to personal injury. This symbol is also used to indicate possible damage to property.

For general safety notes as listed in this section.

Used for electrical dangers, warnings and other notes in regarding operation with electricity.

NOTE for possibly dangerous situations which could lead to damages to property or system failure or **IMPORTANT** for helpful user information.

Reference to other guidelines

Touch-sensitive areas

This symbol is used to designate touch-sensitive areas that might not be self-evident.

Touch (to open/close menus and perform functions)

Move up or down.

Move to the right or left

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1.12.2 Symbols used on the device

BF symbol. The device's signal input is defibrillation protected.

Signal input type CF: Highly isolated port, defibrillation protected. However, it is only defibrillation protected when used with the original SCHILLER patient cable.

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Notified body of the CE certification (G-MED)

Note accompanying documents!

- Symbol for the recognition of electrical and electronic equipment.
- The device must be disposed of in a municipally approved collection point or recycling centre when it is no longer required.
- Improper disposal harms the environment and human health due to the presence of dangerous substances in electrical and electronic equipment.

Manufacturer symbol, manufacturing date

Read the instruction for use

Devices with WLAN or GSM

Attention: Non-ionic electromagnetic environment. The device contains an HF transmitter.

The DEFIGARD/PHYSIOGARD Touch 7 radiates high-frequency electromagnetic energy during telemetric ECG data transfer and can disturb other devices if not installed and operated in accordance with the user guide.

However, even in the case of correct installation/operation, there is no guarantee that no interferences can occur.

If the DEFIGARD/PHYSIOGARD Touch 7 causes interferences, these can be prevented by switching off or not sending ECGs.

The user can take the following measures to solve this problem:

- Increase the distance between the disturbed device and the DEFIGARD/ PHYSIOGARD Touch 7. A minimum distance of 20 cm must be kept between the device and a pacemaker.
- Turn the device to change the antenna's angle of radiation.
- Connect the device to a different mains connector.

For more details, see section 10.9.3 Measures to prevent electromagnetic interferences page 126.

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IP55	The device is protected against dust and spraying water from all directions.
	Used for electrical dangers during defibrillation (**DEFIGARD® Touch 7**)

1.12.3 Symbols Used on the Batteries

Common symbols

	The unit/component can be recycled.
	Battery may not be disposed of with domestic refuse.
	Do not burn, saw up or crash the battery
	Do not short-circuit the battery
	Expiration date

Power battery (Li-Ion)

	Rechargeable battery
	Storage temperature for the power battery: Unlimited: -10...+40 °C Limited: -20...+65 °C for 48 hours

Safety primary cell (Li/MnO2)

	Non rechargeable battery
	Storage temperature for the primary cell: Unlimited: 15...+25 °C Limited: 0...+60 °C for 48 hours
	Read the instruction for use

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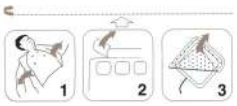
1.12.4 Symbols Used on the Electrode Package

This applies only to the **DEFIGARD® Touch 7**.



- Open clothes
- Open the electrode package
- Peel off the protective foil

Disposable item; Single use only

Do not bend packing

Storage temperature for the electrodes

Expiration date

Read instruction before use

Latex free

Use within 1 day after opening

Keep dry

Keep out of direct sunlight

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2 Components and Operation

The **DEFIGARD® Touch 7** is a lightweight mains and battery powered defibrillator featuring an ECG monitor, SpO2/SpCO/SpMet, etCO2,Temperature and NIBP measurements. It is designed for clinical use. Defibrillation is possible in non-synchronised or synchronised mode.

Moreover, the device can be switched to automated defibrillation (AED operation) by pressing a single key

The **PHYSIOGARD® Touch 7** includes the same features as the **DEFIGARD® Touch 7**, but without the defibrillation function.

Biocompatibility
The parts of the product described in this user guide, including all accessories, that come in contact with the patient during the intended use, fulfil the biocompatibility requirements of the applicable standards. If you have questions in this matter, please contact SCHILLER.

2.1 Design

Power supply

The **DEFIGARD® Touch 7** and **PHYSIOGARD® Touch 7** is powered by an integrated rechargeable battery. The capacity of one battery is sufficient for:

DEFIGARD® Touch 7
- 100 shocks with maximum energy or
- >6 hours of monitoring

PHYSIOGARD® Touch 7
- >6 hours of monitoring

The battery is recharged by an external DC supply.

Defibrillator

The **DEFIGARD® Touch 7** is a defibrillator featuring biphasic pulsed defibrillation impulse – ***Multipulse Biowave®***. The defibrillation is done using disposable adhesive electrodes (pads), which also measure the ECG signal for the analysis. Adhesive electrodes for children and adults are available. The device recognises the connected electrodes and selects the defibrillation energy levels accordingly. In the AED mode, the user will be given visual and audible instructions (display/ loudspeaker).

Monitoring

According to its configuration, the **DEFIGARD® Touch 7** and **PHYSIOGARD® Touch 7** monitoring function gives all important parameters – ECG, SpO2/SpCO/SpMet, etCO2, RR, NIBP, IBP and Temperature. The parameters are indicated in figures and as waveforms on the large 7” (800x480) LCD display.

Data storage

All intervention data – resting ECG data, lead II ECG, defibrillator ECG, SpO2 curves, trends, events, patient data.

Data transmission

- Easy transmission of a 12-lead ECG, trends and screenshots by WLAN or GSM during intervention
- GSM, WLAN, Ethernet (via USB adapter) Communication, for software and configuration updates and post-intervention data (PDF or Sema format) transmissions.

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- USB to Ethernet connector for software updates
- Import/export device configuration via USB

2.1.1 Standard unit and options

DEFIGARD® Touch 7

Standard
- Defibrillator (AED) with 4-lead ECG cable
- Temp (sensor not included)

Options:
- Manual defibrillation mode
- SpO_2
- Pacemaker
- SpCO
- SpMet
- NIBP
- IBP
- CO2 mainstream
- CO2 sidestream
- 12-lead ECG
- GSM/3G
- WLAN
- CPR feedback (FreeCPR)
- CPR feedback (ARGUS LifePoint)

PHYSIOGARD® Touch 7

Standard
- 4-lead ECG cable
- SpO_2
- NIBP
- Temp (sensor not included)

Options
- SpCO
- SpMet
- CO2 mainstream
- CO2 sidestream
- IBP
- 12-lead ECG
- GSM/3G
- WLAN

2.1.2 Additional accessories

- SCHILLER Charging Unit CS-1. External charging and calibrating unit for rechargeable batteries.
- DC/DC or AC/DC ambulance charging bracket. Holds the device securely while recharging the battery inside the device.
- AC/DC desktop charging bracket. Holds the device while recharging the battery inside the device.
- AC/DC Nomad charger
- DC/DC Nomad charger

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2.2 Operating Elements

2.2.1 Front panel DEFIGARD® Touch 7

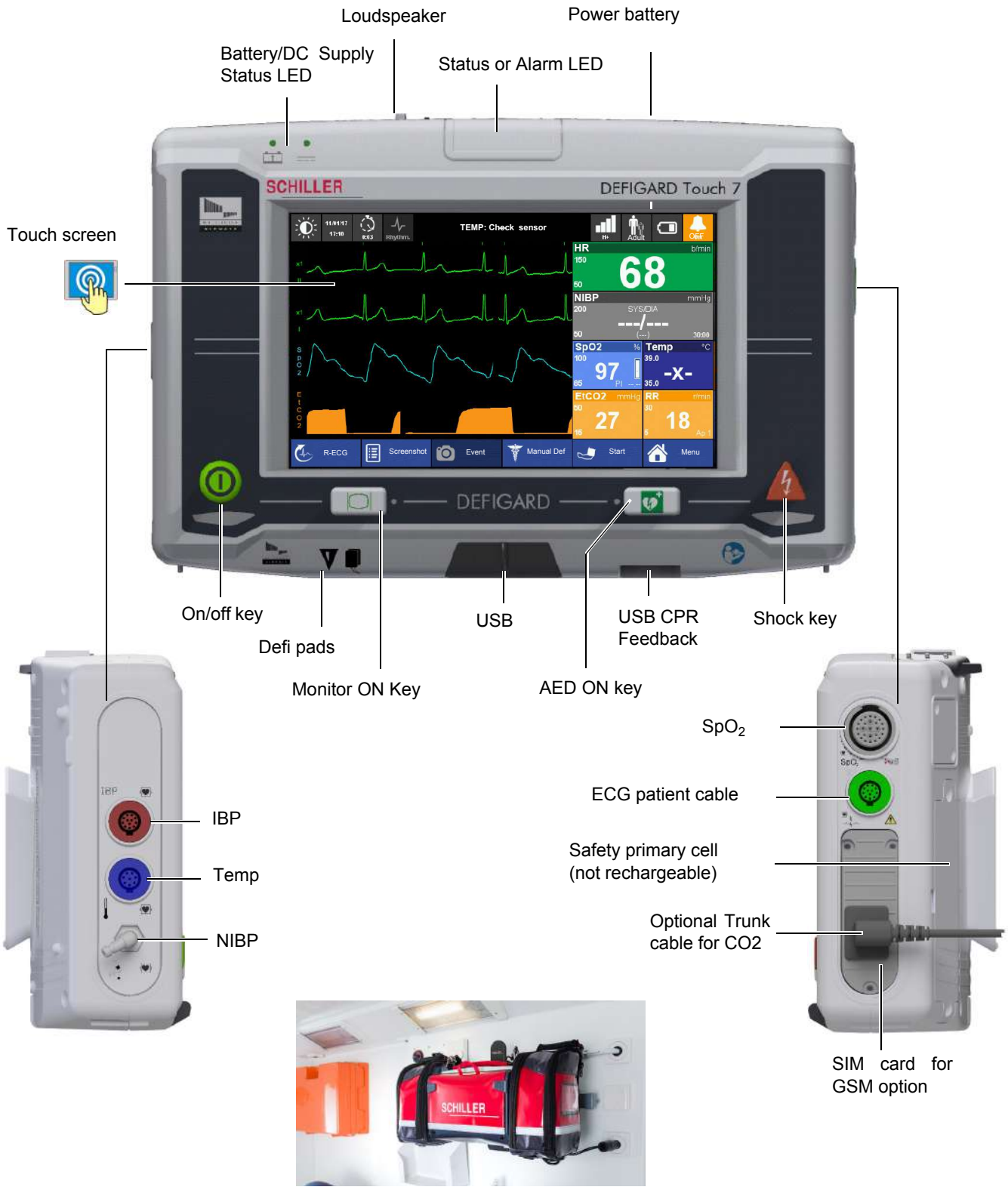

Fig. 2.1 Control elements at the device's front

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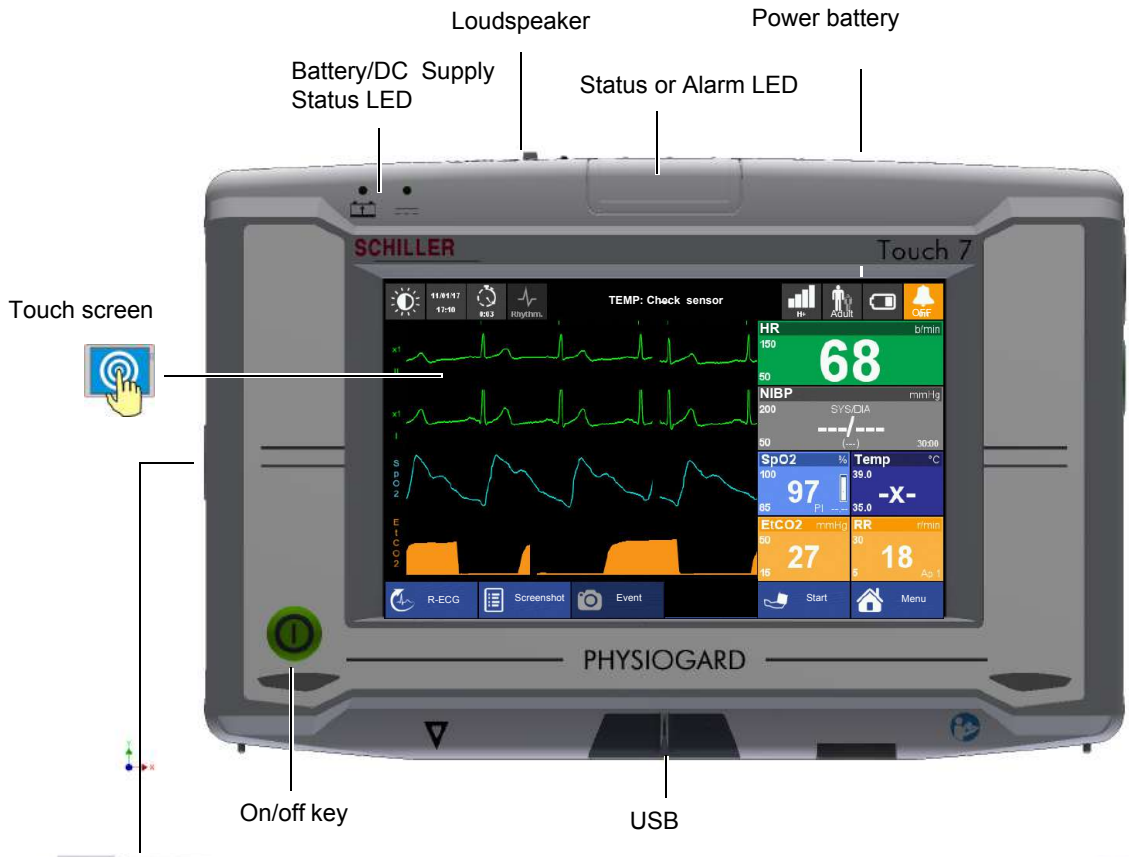
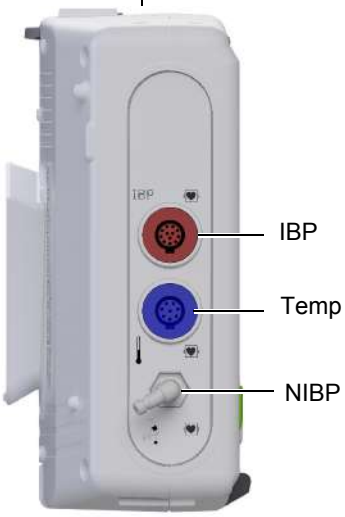
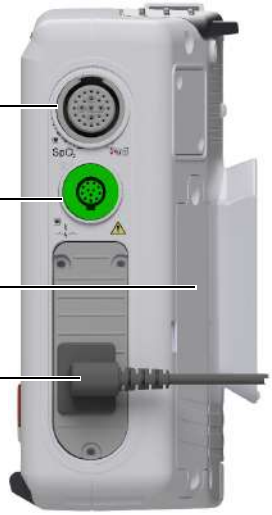
2.2.2 Front panel PHYSIOGARD® Touch 7







SIM card for GSM option

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2.2.3 Back Panel

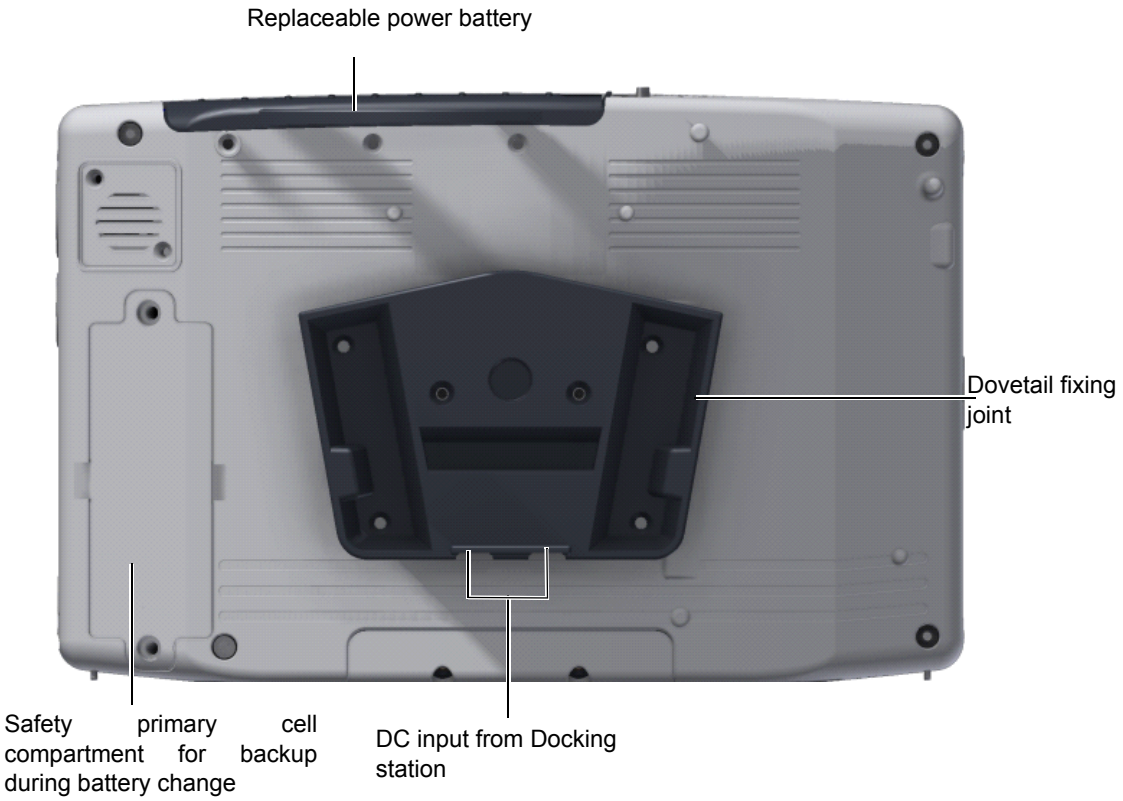

Fig. 2.2 Control elements at the device´s back

2.2.4 LEDs

The LEDs give the following information:

(1) Flashes while the battery is being recharged
(2) Unit connected to the external power supply.

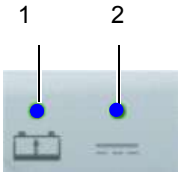

Fig. 2.3 LEDs

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2.2.5 Display

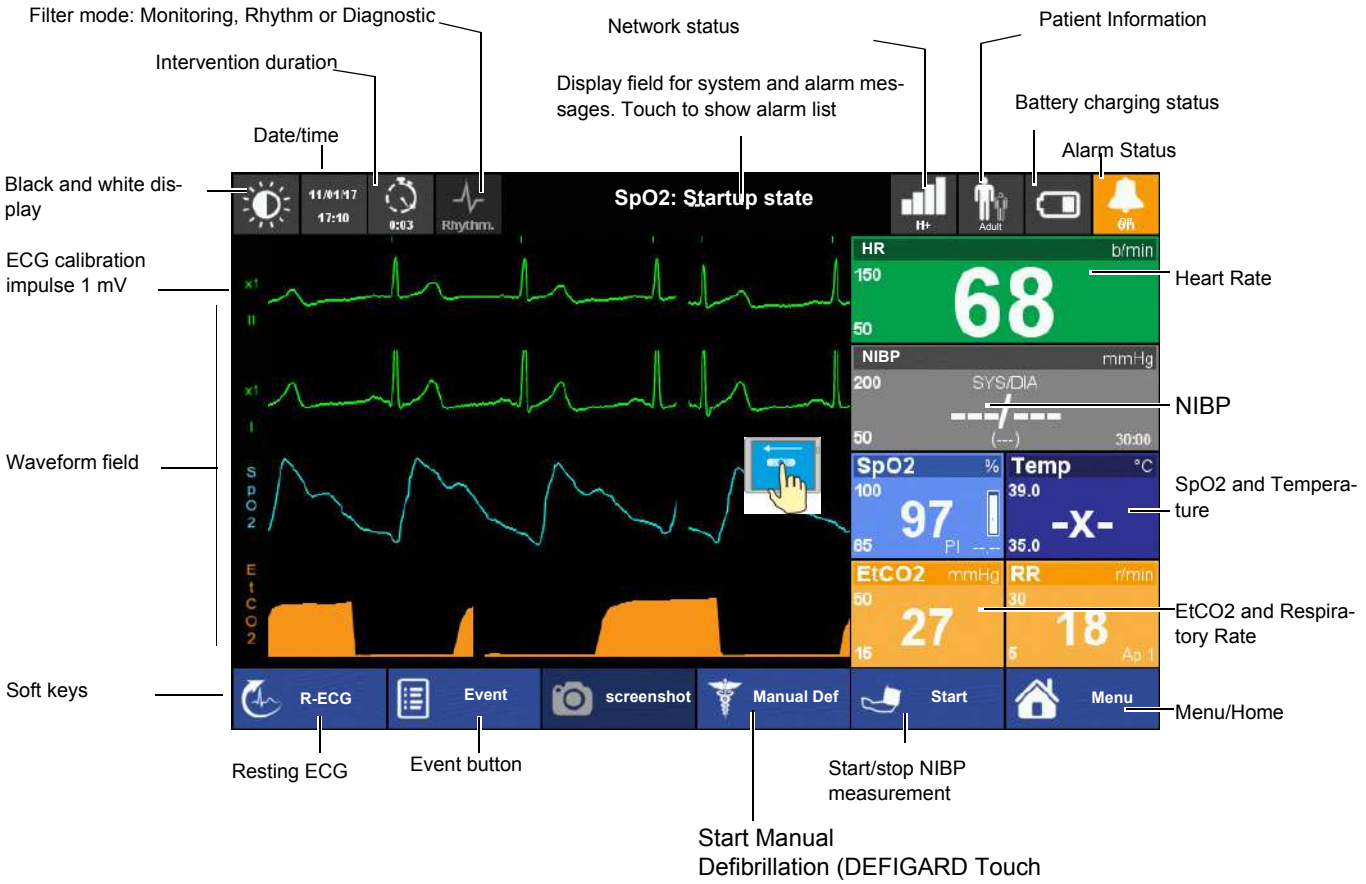

Fig. 2.4 Display elements of the device

The display can vary according to the settings and used options and selected views.

The following screen is displayed when swiping from right to left, see above.

Show ECG curve again:

➜ swipe from left to right

3 Initial Operation

DANGER

- Please read the safety notes in section 1 Safety notes page 9 before initial operation.
- Danger of explosion! The device is not designed for use in areas where an explosion hazard may occur. Also, it is not permitted to operate the defibrillator in an oxygen-enriched environment or in the presence of flammable substances (gas) or anaesthetics. Oxygenation in the vicinity of the defibrillation electrodes must be strictly avoided.
- Danger of electrical shock. The **DEFIGARD® Touch 7** is a high-voltage therapy device. Improper use of the device can endanger life. Always follow the instructions given in this user guide.
- The user must make sure that there are no conductive connections between the patient and other persons during ECG analysis and defibrillation.
- Avoid defibrillation in very moist or wet surroundings.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

3.1 External DC supply and Battery Operation

3.1.1 External DC Supply Operation

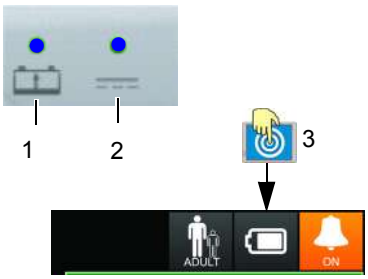

Fig. 3.1 Status LED supply

1. Put the device into the docking station. Insert a fully charged battery. Check the LED **2** is on if placed on the docking station.
2. Press the **on/off** button.
3. Touch the battery icon (3) to display further battery charging information.
4. Check battery charging LED **1** according to 3.1.2 Battery Operation page 27.

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3.1.2 Battery Operation

Charging the battery

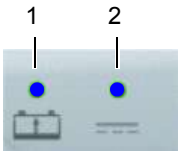

Fig. 3.2 LED battery operation

Important

The power battery is automatically recharged when the device is connected to the external DC supply via the docking station (LED 2). The power battery requires approx. 2 hour to be recharged at 90%.

The recharging of the battery is indicated by the LED above the battery symbol.

– LED (1) is continuously on = battery problem
– LED (1) is blinking = battery is charging
– LED (1) is continuously off = battery is fully charged

If the temperature in the device becomes too high, the charging is stopped. As soon as the temperature has decreased to an acceptable level, the charging resumes.


below 20%

below 10%

Fig. 3.3 Battery low indication

Low battery indication

When the battery is below 20 %, a red battery symbol with one bar is displayed in the top right corner of the screen.

When the battery is below 10%, a red empty battery symbol is displayed in the top right corner of the screen and a technical alarm is displayed and a voice prompt reminds to check the battery.

The device shuts-down automatically when the battery is below 5%.

Fig. 3.4 Battery defect indication

Battery status unknown

- When the battery is unknown, a red battery symbol with a question mark is displayed in the top right corner of the screen.
- This indicator is also displayed in case of a new battery. Any new battery has to be placed into the device and fully charged before use.

Battery status

Press on the battery icon. The following information will be displayed:

- Charge level in %
- Estimated autonomy in hours and minutes
- Estimated number of shock possible with the remaining capacity
- Safety Cell Voltage level

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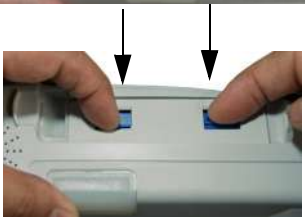
Changing the batteries

- The device does not need to be switched off. Monitoring is continued. The device is powered by the safety primary cell for another 30 seconds; after that, the device is switched off automatically.
- The battery can only be inserted in one way.

1. Open the battery cover.



2. To remove the battery, press the two blue catches to release and remove the battery.

➜ To replace, proceed as follows:
- Slide the battery into the battery compartment with the markings positioned as shown.
- Push home until the battery clicks in place with the blue catches.
- Close the battery cover and make sure that the cover is clicked in properly.

Click!

3.1.3 Operation with external constant voltage source

The device can be connected to an external direct-current source via the docking station.

Operation with an external power source is indicated by the LED  on the device.

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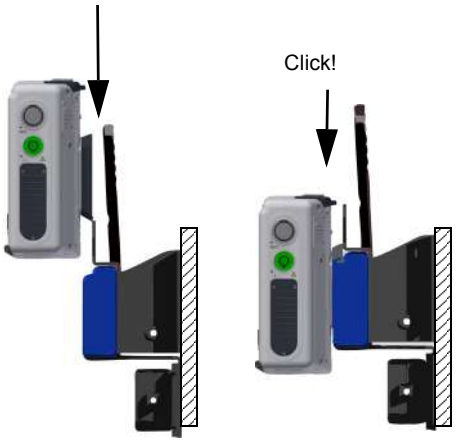
3.1.4 Operation ambulance charging bracket

⚠ CAUTION

▲ The charging bracket must be fixed to a stable wall.



Putting the device on the charging bracket

➜ Simply put the device back on the wall mounting. The device is locked automatically. You should clearly hear the **click** of the locking mechanism

Removing the device from the charging bracket

➜ Pull the release lever towards the device **(1)** and pull the device upwards **(2)**, while keeping the lever in the release position.

3.1.5 Operation of the desktop charging bracket

⚠ CAUTION

▲ The desktop charging bracket must be screwed on a table or VESA fixing system.

▲ The desktop charging bracket is only for indoor use. Do not use it in vehicles.

➜ The device can easily be slid onto the desktop charging bracket.

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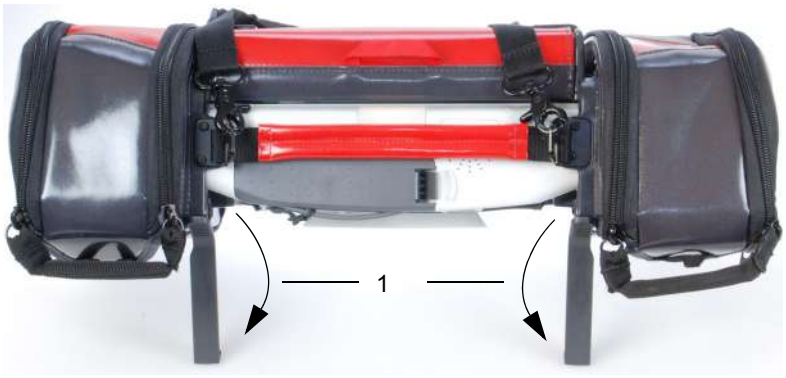
3.1.6 Operation and fixing during intervention

During intervention, the two positioning bars (1) can be folded out to keep the device in an ergonomic position.



During transportation, the device can be fixed on a rail (e.g. bed or stretcher rail)

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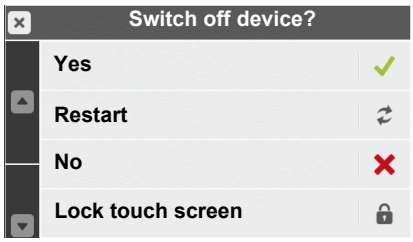
3.2 Switching off and disconnecting from the external DC supply



1. Press the **on/off** button.
2. The dialogue No/**Yes** is displayed.
3. Confirm switch-off or cancel with No.
4. Remove the device from the charging station if you do not want to recharge the battery.

The “Restart” function is used to exit the Post-Intervention or the control panel menu directly by restarting the device instead of switching it on and off.

Forced shutdown procedure

If the device cannot be switched off via the above procedures, press and hold the green **On/Off** button until the device is switched off.

3.2.1 Lock Touch screen

Lock the Touch screen In the ON/OFF dialogue, select “ Lock touch screen”.

Unlock Touch screen Press the button twice. The message appears “Touch screen unlocked”

Note: If you touch the locked touch screen, a message prompts you to press the ON/ OFF button twice to unlock the screen.

3.2.2 Internal safety discharge

The **DEFIGARD® Touch 7** has an internal safety discharge circuit for internal discharge of the defibrillator’s stored energy. The defibrillator displays the message "Internal discharge" during the safety discharge.The energy is internally discharged when

- the shock is not delivered within 20 s after charging
- a lower energy value is selected while the defibrillator is charging
- the battery voltage is insufficient
- the device is defective
- the device is turned off

Furthermore the residual energy stored in the defibrillator 100 ms after shock release is always discharged internally.

3.2.3 Interruption of external power supply

If the external DC supply is interrupted, the device automatically switches over to battery operation. The user settings are maintained.

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3.2.4 Ensuring Operational Readiness

- Do not expose the device to direct sunlight, or extremely high or low temperatures. The ambient temperature should be in the range of 0°C to 40 °C. Lower or higher ambient temperatures will have a negative impact on the battery's life.

To ensure its readiness for use, the device runs a self-test to check the unit and the battery. A self-test can be performed any time. An enhanced periodic test can be performed in a defined interval (standard setting every 5 weeks) and at a defined time (standard setting 12:00)

- Status OK: green blinking LED
- Device failure status: LED OFF.

If the device detects an error during the self-test, an alarm sound is activated.

➜ An auto test can be executed anytime see paragraph 10.2.4 Auto Test.

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3.3 Operation

The menus can be accessed as follows:

- Direct access by pressing on the curve or measurement field, or
- by clicking on the menu soft key or any other soft key or
- by clicking on a icon, or
- by moving finger up or down, left or right for scrolling or changing display

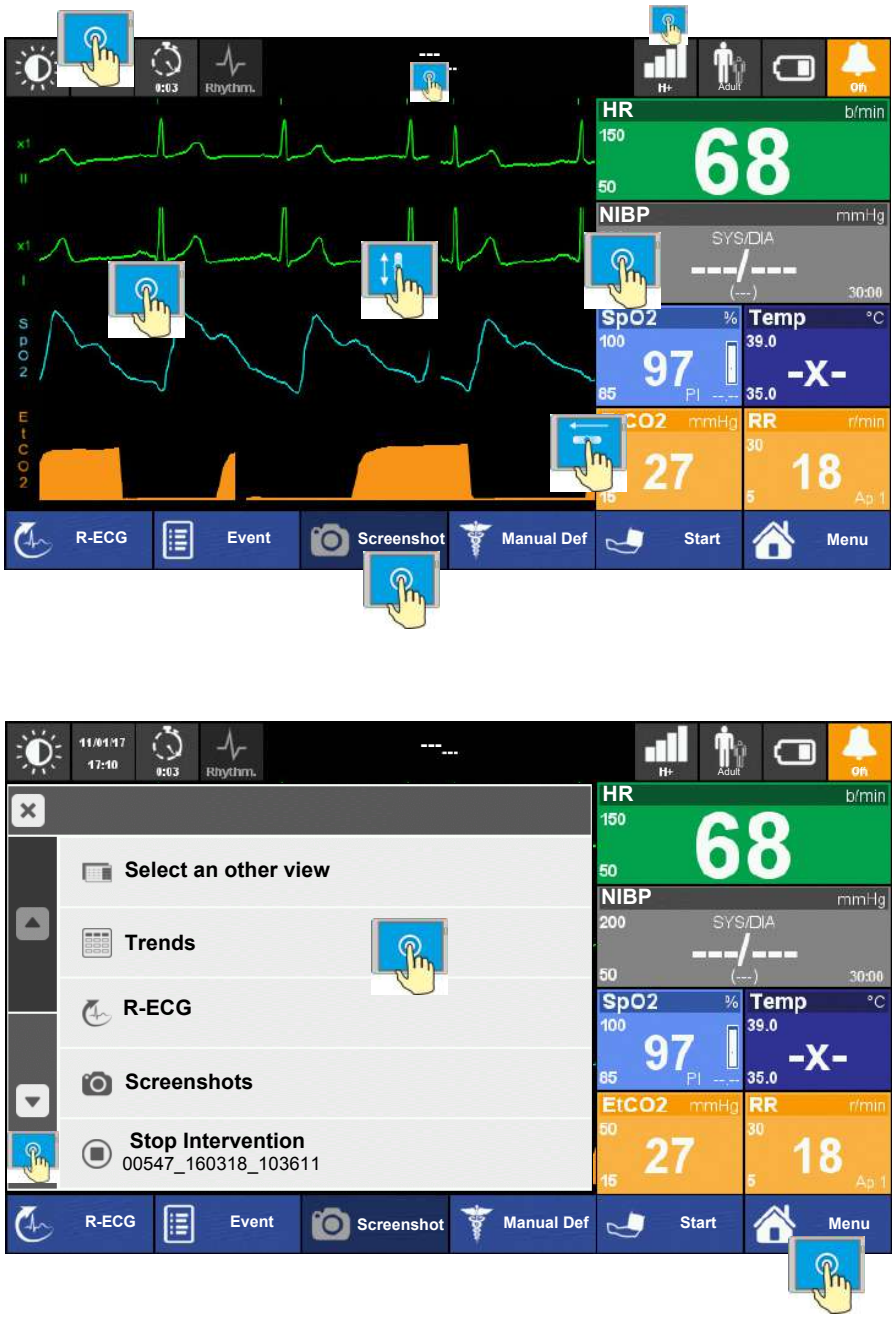

Fig. 3.5 Display with main menu and the touch-sensitive areas

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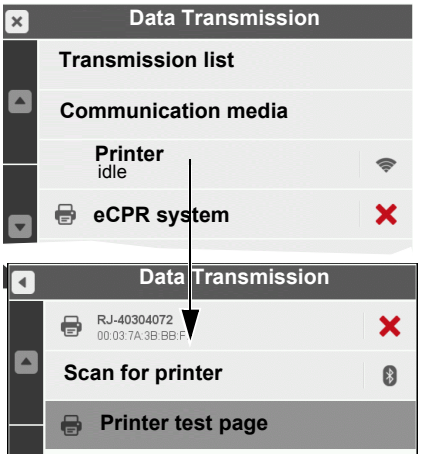
3.4 Printing

The following data can be printed on the Bluetooth printer:

- Recorded Resting ECG (incl. patient data, patient vitals, interpretation and ECG curves)
- Screenshots (+/- 5 sec from the moment of the screenshot that contains all displayed curves, patient data and vital data)
- Intervention report.

3.4.1 Pairing Bluetooth devices

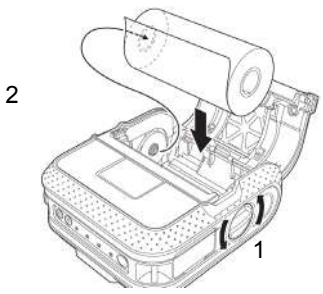


1. Select the transmission icon to display the **Data transmission** menu.
2. Select menu **Printer** to display the pairing menu.
3. Switch on the Bluetooth printer and make sure that Bluetooth is activated.
4. Select “Scan for Printer”. As soon as the printer is found, the printer’s identification number is displayed e.g. RJ-40304072.
5. As soon as the printer pairing is done, printer status in the Data transmission menu indicates .
6. Select “Printer test page” to check the printing function.

In case of communication problem with a Bluetooth device, switch it off and on again. Scan again for the Bluetooth device.

3.4.2 Brother Printer Overview

For detailed information, refer to the Brother P4030 printer user guide.



1. Press and hold the (Power) button to switch off the printer.
2. Open the cover (1).
3. Insert the RD Roll into the compartment (2).
4. Close the cover.
5. Press and hold the (Power) button to turn the printer on.
6. Press the (feed) button to set the paper in the right starting position.

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(1) Power On/OFF
(2) Paper feed
(3) Power On/Off status LED
(4) Status LED printer
(5) Battery status LED (blinks every 4 s = battery half, twice every 4 s =battery low, once every second =battery must be charged.
(6) Bluetooth Status LED
(7) Bluetooth On/Off button

3.5 Connection to a ePCR system

The following data can be transmitted via bluetooth to a ePCR (electronic patient care report) system:

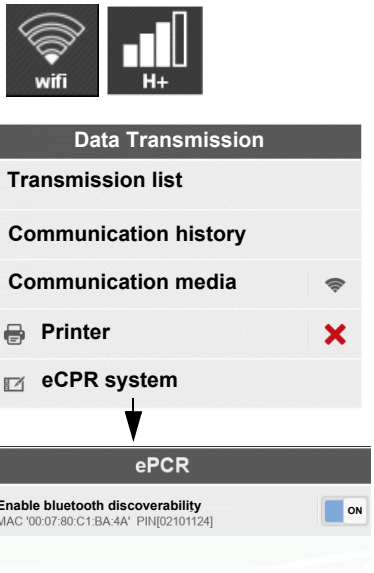
- Patient vital data
- Patient identification and information
- RECG in pdf format
- Trends

According to the ePCR settings this can be as spot measurement, regulary or for a defined period of time.

For details information refer to the ePCR manufacturer's user manual.

3.5.1 Pairing Bluetooth devices

- The DEFIGARD/PHYSIOGARD Touch 7 acts like a slave to the ePCR equipment, therefore, the pairing must be initiated on the ePCR equipment.
- The pairing is to be perfomed only the very first time that an ePCR equipement is connected.



1. Select the transmission icon to display the Data Transmission menu
2. Select ePCR
3. Activate the Bluetooth discoverability

- Please contact your local SCHILLER distributor for compatible ePCR systems list or interface request.
- In case of communication problem with a Bluetooth device, switch it off and on again. Scan again for the Bluetooth device.

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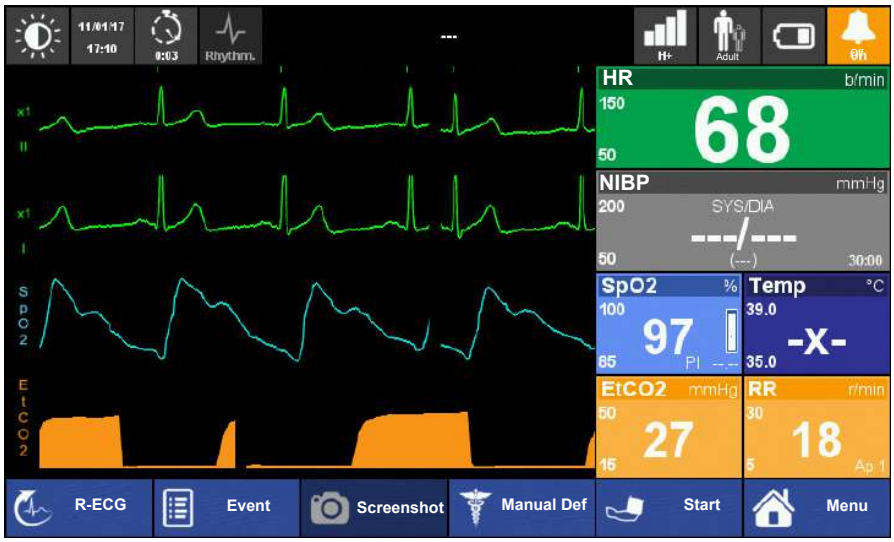
4 Monitoring

Operation and menu access is detailed on page 33.

4.1 Soft keys, Waveforms and Measurement Fields

The waveform and measurement fields are automatically displayed when the device is switched on (if options are installed). The device can basically be operated via the touch screen. The functions of the soft keys vary according to the selected screen.



Advanced monitoring view

Settings

The settings that are defined in the menus are set to default when the unit is switched off.

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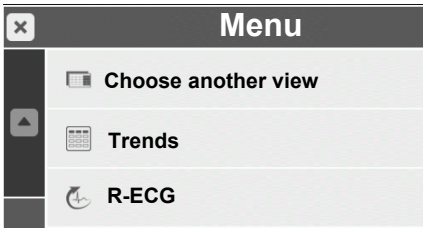
4.1.1 View selection

The default view after start up can be configured.



1. Go to menu “**Choose another view”.**
2. Choose one of the views:
   – Advanced monitoring
   – Basic monitoring
   – 12 leads ECG
   – Critical care

The display can vary according to the settings and used options. The default views are displayed as described below:

Basic monitoring
with 2 ECG leads and SpO2 curve, big measurements filed with heart rate, NIBP and SpO2 values.

Advanced monitoring
with 2 ECG leads, SpO2, **EtCo2** curve, measurements filed with heart rate, NIBP SpO2, **ETCO2, RR** and **Temp** values.

Critical care
with 2 ECG leads, SpO2, EtCo2, IBP curve, measurements filed with heart rate, SpO2, Temp, etCO2, RR, **IBP** and NIBP values.

12 lead ECG
with all 12 ECG leads.

As the displayed ECG is online and filtered with diagnostic filters the curves may be sensitive to motion artefacts. For better ECG quality it is advised to perform a "R-ECG" see paragraph 4.5.

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4.2 Alarm System

⚠ CAUTION

- ▲ In some countries, it is not permitted to disable audio alarms 

permanently. Therefore, this function is configurable.
- ▲ When pausing or switching off the audio alarm, even high-priority alarms such as VT/ VF and asystole are paused/switched off!
- ▲ Pausing or switching off of the audio alarm system is only allowed if the patient is permanently observed.

4.2.1 Alarm priority

Alarm type	Priority	Audible signal	Display
Technical alarm	Low	One beep once	• Text display in the alarm status field at the top • Displaying -?- in the parameter field • Orange LED is lit 
Physiological alarm	Medium	3 signals (beep beep beep)	• Text display in the alarm status field at the top • Orange flashing parameter field • Orange LED is flashing 
Physiological alarm	High	10 signals (beep beep beep - beep beep beep beep beep - beep beep)	• Text display in the alarm status field at the top • Red flashing parameter field • RED LED is flashing 

4.2.2 Operator's position

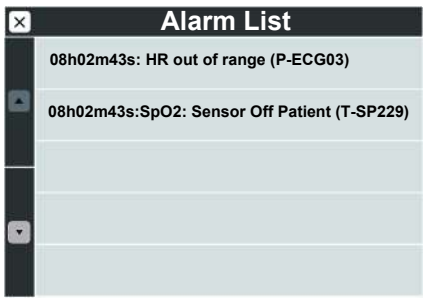
⚠ CAUTION

- ▲ Ensure that the environmental noise is below the alarm sound volume of 65 dB.

The visual alarm LED is visible to a distance of 4 meters and the flashing value is visible to a distance of 1 meter.

4.2.3 Alarm list

An alarm list can be displayed any time by touching the alarm status line.



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4.2.4 Physiological alarms

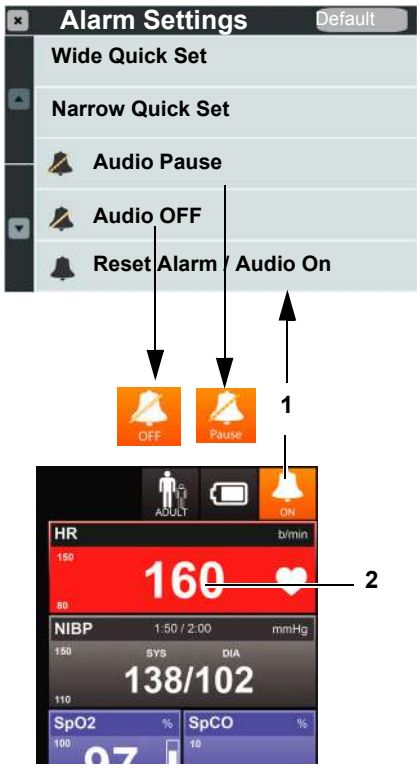


Fig. 4.1 Alarm indicators

When a measurement reading exceeds a threshold, an alarm is triggered after 3 seconds and:

- the device alarm LEDs are flashing orange (medium) or red (high)
- an interrupted alarm sounds
- the measurement value **(2)** flashes red
- a message is displayed in the alarm field

Pausing an audio alarm 

➜ Pause the audio alarm by pressing the button **(1)** and selecting **Audio Pause**
– the measurement reading is flashing red until it returns to the permissible range.
– if the measured value does not return to the permissible range within the 2 minutes, the audible alarm is reactivated automatically.

Switching off audio alarm system 

➜ Press the button **(1)** and select **Audio OFF.**
➜ The audible alarm system **is switched off permanently** until it is reactivated by selecting **Reset Alarm/Audio on** or **Audio Pause.**

A reminder signal (buub-buub) is issued every 2 minutes.

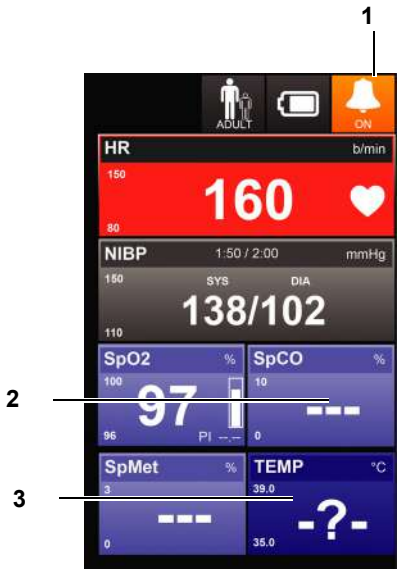
Reactivation of the paused or switched off audio alarm system

➜ Press the button **(1)** and select **Reset Alarm /Audio On.**

4.2.5 Technical alarms

When a technical error occurs:

- the orange device alarm LEDs are on
- a message is displayed in the alarm field
- one alarm beep once
- 3 dashes **(2)** are displayed if no sensor is connected before switching on (no LED or alarm)
- a question mark (-?-) is displayed instead of the measurement reading **(3)**



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4.3 Operator-Defined Alarm Thresholds

⚠ CAUTION

- ▲ Make sure that the patient's vital parameters are not critical before pressing the button **Wide Quick set or Narrow quick set.**
- ▲ Make sure that the right patient is selected (adult, child or neonate).
- ▲ The defined alarm thresholds are not a substitute for regular checking of vital functions.
- ▲ Setting the **Audio OFF** is only allowed if the patient is permanently observed.
- ▲ Standard or user-defined alarm limits as well as quick settings may vary for similar or the same devices. Therefore, always check the set alarm limits for the current patient.
- ▲ 30 seconds after main battery power interruption, the alarm threshold **Wide Quick set or Narrow quick set** is set to default.

Access the threshold menu by pressing the alarm icon and selecting **Wide Quick set or Narrow quick set.**

- With the **Default** key, the default threshold values are activated.
- With the **Quick Set** selection, all values are derived from the current measured values. See table on the following page.

➜ Make sure that the patient's vital parameters are not critical before pressing the button **Quick Set**.

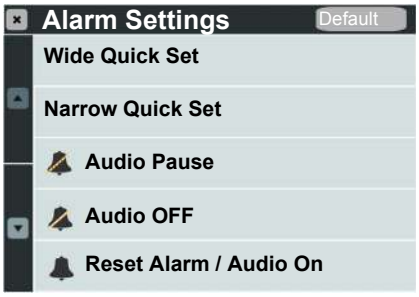

Fig. 4.2 Alarm Setting menu

- The operator-defined Quick set thresholds will be set to the default values after switching off the device.

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4.3.1 Table of wide/narrow threshold setting

The range values in brackets **()** are the default values activated when pressing "Default" in the alarm setting menu see Fig. 4.2, page 40. The values before the bracket "ECG 0-350 **(50-150) bpm"** are the low/high system limits.

HR [bpm]	**Pat. value**	**Wide limits**		**Narrow Limits**	
Range:		Low	High	Low	High
ECG 0-350 **(50-150) bpm**	<60	-20	+35	-10	+25
Pleth 25-240 **(50-150) bpm**	60-79	-25	+40	-20	+30
	80-104	-30	+40	-30	+30
	>=105	-35	+45	-25	+25
Allowed values		[30-150]	[100-240]	[30-150]	[100-240]

RR [rpm]	**Pat. value**	**Wide limits**		**Narrow Limits**	
Range: 0-60 **(5-30) resp/min**		Low	High	Low	High
	<15	-8	+8	-4	+4
	>=15	-15	+15	-8	+8
Allowed values		[5-15]	[10-60]	[5-15]	[10-60]

SpO2 [%]	**Pat. value**	**Wide limits**		**Narrow Limits**	
Range: 50-100 **(85-100) %**		Low	High	Low	High
	>=90	-5	+3	-5	+3
	<90	-5	+3	-5	+3
Allowed values		[85-100]	[90-100]	[85-100]	[90-100]

SpCO/SpMet [%]	**Pat. value**	**Wide limits**		**Narrow Limits**	
Range:		Low	High	Low	High
SpCO 0-40 **(0-10) %**	-	0%	10%	0%	10%
SpMet **0-15%**	-	0%	3%	0%	3%

Temperature [°C]	**Pat. value**	**Wide limits**		**Narrow Limits**	
Range: 0-46 **(35-39) °C**		Low	High	Low	High
	-	-3	+3	-1	+1
Allowed value	-	[31-41]	[31-41]	[31-41]	[31-41]

EtCo2 [mmHg]/ [%]	**Pat. value**	**Wide limits**		**Narrow Limits**	
Range: 5-70 mmHg/0.7-9.2 % **(15-50 mmHg/2-6.6 %)**		Low	High	Low	High
	<40/5.3	-10/1.3	+15/+2.0	-10/-1.3	+15/+2.0
	>=40/5.3	-10/1.3	+15/+2.0	+15/+2.0	+15/+2.0
Allowed values [mmHg]/ [%]		[5-60] / [0.7-7.9]	[20-70] / [2.7-9.2]	[5-60] / [0.7-7.9]	[20-70] / [2.7-9.2]

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NIBP SYS [mmHg]	Pat. value	Wide limits		Narrow Limits	
Range SYS: 30-255 **(50-200)** mmHg		Low	High	Low	High
	<90	-20	+35	-10	+25
	90-114	-20	+35	-10	+25
	115-140	-25	+35	-10	+20
	>140	-25	+35	-10	+20
Allowed values		[30-245]	[30-245]	[30-245]	[30-245]
NIBP DIA [mmHg]	**Pat. value**	**Wide limits**		**Narrow Limits**	
Range DIA: 15-220 **(20-150)** mmHg		Low	High	Low	High
	<65	-15	+25	-10	+25
	65-90	-15	+15	-15	+10
	>90	-15	+15	-15	+10
Allowed values		[12-210]	[12-210]	[12-210]	[12-210]
NIBP MAP [mmHg]	**Pat. value**	**Wide limits**		**Narrow Limits**	
Range MAP: 15-223 **(20-235)** mmHg	-	-	-	-	

IBP SYS [mmHg]	Pat. value	Wide limits		Narrow Limits	
Range SYS: 30-255 **(50-200)** mmHg		Low	High	Low	High
	<90	-20	+35	-10	+25
	90-114	-20	+35	-10	+25
	115-140	-25	+35	-10	+20
	>140	-25	+35	-10	+20
Allowed values		[30-245]	[30-245]	[30-245]	[30-245]
IBP DIA [mmHg]	**Pat. value**	**Wide limits**		**Narrow Limits**	
Range DIA: 15-220 **(20-150)** mmHg		Low	High	Low	High
	<65	-15	+25	-10	+25
	65-90	-15	+15	-15	+10
	>90	-15	+15	-15	+10
Allowed values		[12-210]	[12-210]	[12-210]	[12-210]
IBP MAP [mmHg]	**Pat. value**	**Wide limits**		**Narrow Limits**	
Range MAP: 15-223 **(20-235)** mmHg	-	-	-	-	

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4.4 ECG and heart rate monitoring

⚠WARNING

▲ False diagnosis! Only use silver/silver-chloride electrodes if the patient may have to be defibrillated while the ECG is being displayed. Other electrodes may create high polarisation voltages and the ECG trace on the monitor and on the recording may simulate cardiac arrest.

▲ Danger of destroying the device during defibrillation! The device is only type CF protected if the original SCHILLER patient cables are used.

Important

- The guidelines for patient electrode placement are provided as an overview only. They are not a substitute for medical expertise.
- If an electrode is faulty or has come off, a message indicates the faulty electrode.

4.4.1 Quick Diagnosis of the ECG Using Defibrillation Electrodes

This only applies for the **DEFIGARD® Touch 7**.

Isoelectric segments are excluded from the corresponding lead arc duration measurements (Q, R, S waves). Isoelectric parts (I-wave) are also excluded in the duration measurement of the respective adjacent waveform. (For more detailed information, see 2.530036c Statement_of_accurracy 3ed_ETM.

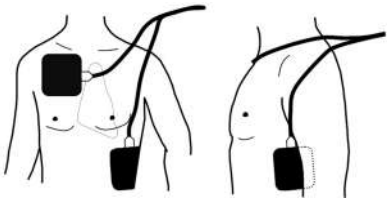
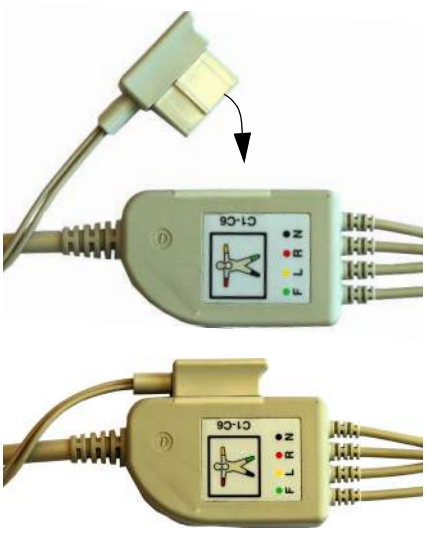


Fig. 4.3 Defibrillation electrodes

For a quick diagnosis, the ECG signal can be recorded from the patient's thorax using the defibrillation electrodes. In all other situations, we recommend acquiring the ECG via ECG electrodes and the patient cable.

To apply the electrode pads, see section 5.3.1 Applying the adult and paediatric electrodes page 85.

4.4.2 Connecting a 4- or 10-wire ECG patient cable



4+6-wire ECG patient cable

The 4 + 6 wires cable is a two-part cable that provides the standard four monitoring (limb) electrode leads with the option of adding the 6 chest leads to provide a full 12-leads diagnostic ECG without the need to change the cable and remove the limb electrodes.

4-wire patient cable

Refer to the following pages for the electrode placement of the 4-wire cable. Connect the blanking connector to the cable junction.

10-wire patient cable

The electrode placement for the 10-wire cable is the same as for the 10-wire standard cable described on the following pages. The blanking connector must be removed and the connector for the additional 6 wires placed in the socket on the cable junction.

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4.4.3 Connecting a 4-wire ECG patient cable

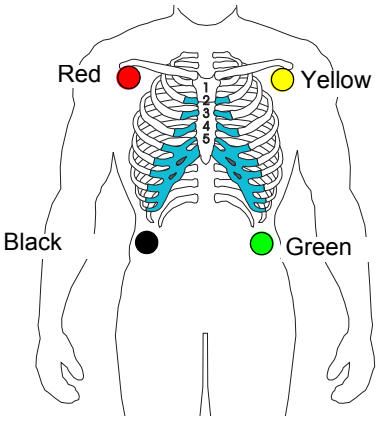

Fig. 4.4 4-wire cable

When a patient cable as well as the defibrillation electrodes are connected, you can select the heart rate signal source by touching the first curve (standard ECG:II) on the display and selecting ECG Defi. The first display curve is used to calculate the heart rate unless the HR source is set to Pleth.

4.4.4 Connecting a 10-wire ECG patient cable

*Note

The electrode positions shown here (O) are based on the diagnostic ECG. For patient monitoring, the limb electrodes can be attached on the upper body.

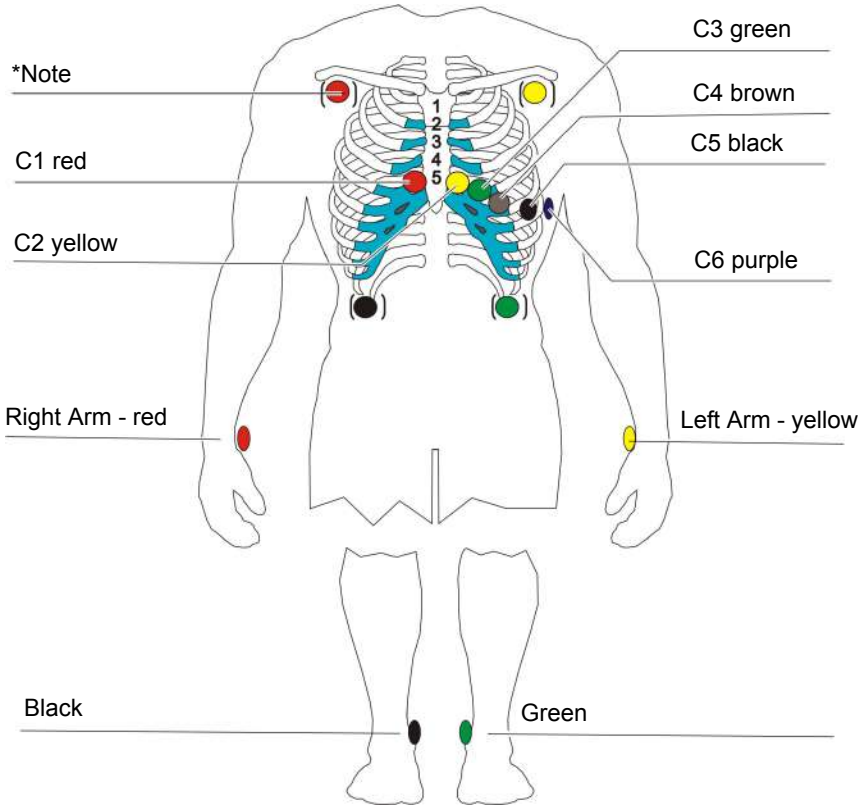

Fig. 4.5 10-wire cable

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4.4.5 Starting ECG monitoring

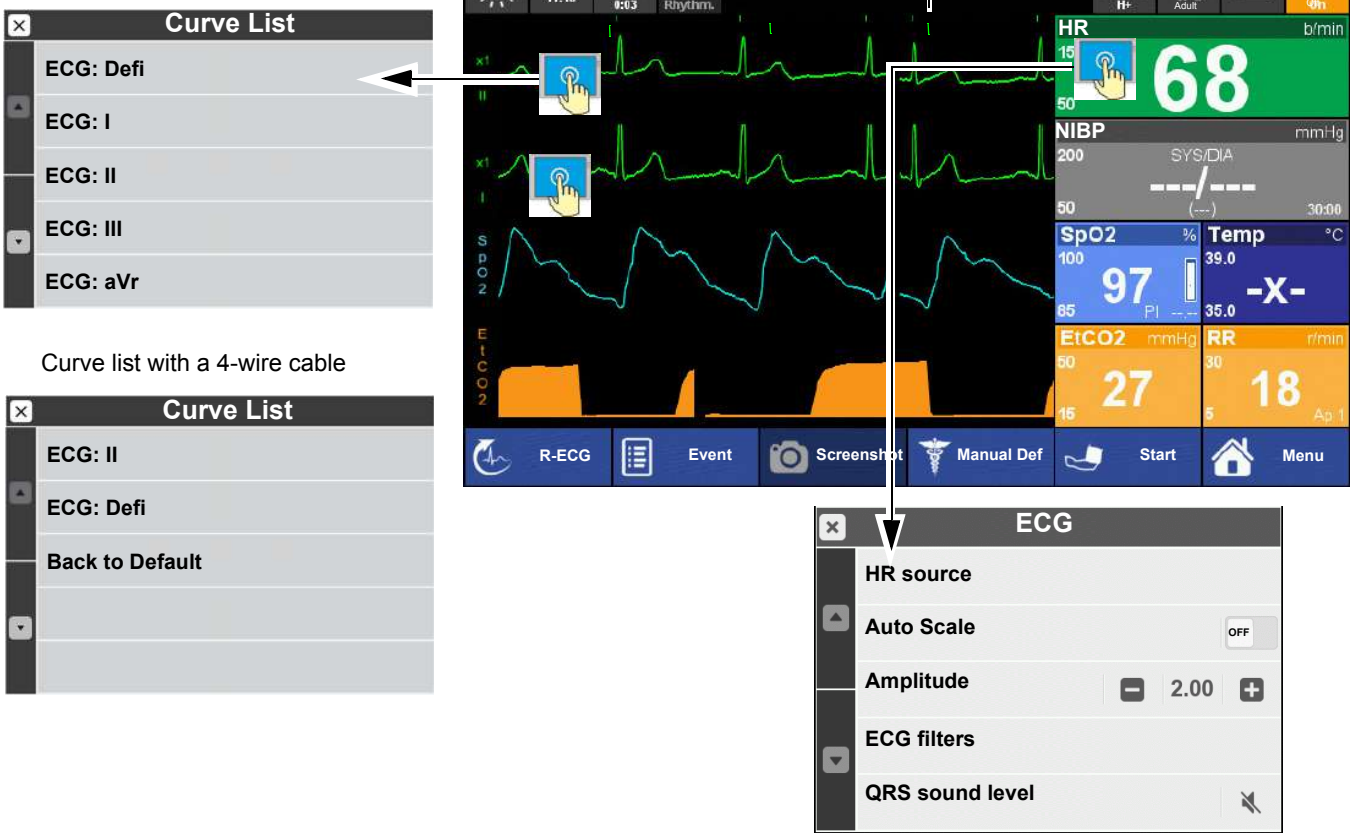
1. Apply the electrodes as shown in Fig. 4.4 or Fig. 4.5.
2. Connect the patient cable to the ECG signal input.
3. Define the ECG settings directly via the Touch screen curve or measurement field.
4. Open the HR module (ECG menu) and check the settings.

Fig. 4.6 ECG cable

The sweep speed on the screen is fixed to 25 mm/s.

QRS complexes are represented by green vertical dashes above the top ECG curve, pacemaker pulses by red vertical dashes.

Curve list with a 10-wire cable



Curve list with a 4-wire cable

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4.4.6 Monitoring a pacemaker patient

⚠ DANGER

- **Erroneous HR display**. In the monitoring of pacemaker patients, the possibility of pacer pulses being counted as QRS complexes cannot be excluded. Therefore, pacemaker patients should always be watched closely. It is recommend monitoring pacemaker patients by means of the plethysmogram HR source = Pleth in the ECG or SpO_2 menu).
- This device can reject double pacemaker pulses having amplitudes from ± 2 mV to ±700 mV (± 70mV) and pulse widths from 0.1 ms to 2.0 ms (± 0.3 ms) synchronized with an ECG or without ECG.
- Patients with a pacemaker must be observed continuously because the heart rate from the pacemaker might still be registered in case of a cardiac arrest or some arrhythmias.
- Pacemaker signals from different pacemakers vary. In the case of cardiac arrests or some arrhythmias, pacemaker signals might still be measured, especially signals from pacemakers generating high amplitudes (> 20 mV) or overshoot. Pacemaker patients need to be monitored very closely.

When monitoring the heart rate of pacemaker patients, it is important that the device will only count the QRS complexes and reject the pacer pulses.

Randomly, some pacemaker pulses could be missing on the display.

Pacemaker impulses are represented by red vertical dashes above the top ECG curve.

The device has an electronic pacer pulse suppression algorithm which rejects the pacer pulses so that they are not counted as QRS complexes. Depending on the pacemaker model used and on the position of the electrodes, the compensation pulse following every pacer pulse may be considered as a QRS complex. In this situation and when the pacer pulse is ineffective, the displayed heart rate may lead to a misinterpretation, and the device will not issue an alarm in the case of bradycardia or asystole. Whether or not the compensation pulse is counted as a QRS complex depends on the pacer pulse parameters.

For pacemaker patients, the ECG signal amplitude should be greater that 1 mV.

If the source of the heart rate is SpO_2, this is indicated by the blue HR (Pleth) measurement field instead of the green HR measurement field.

Fig. 4.7 Indication HR source SpO_2

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4.4.7 Curve list

MENU	Parameter	Description	Value
Curve list	Touch first curve	Selection of the displayed first curve. The first display curve is used to calculate the Heart rate unless the HR source is set to Pleth.	**II or** Defi Default:
	Touch the curves 2,3,4	Selection of the displayed curve	Defi/**I, II, III**, aVR, aVL, aVF, SpO2 plethysmograph, EtCO2:Respiration. IBP

4.4.8 HR Module (ECG)

The sweep speed on the screen is fixed set to 25 mm/s.

MENU	Parameter	Description	Value
ECG	HR Source	[a]Source based on which the heart rate should be determined.	**Auto**, Defi, ECG or Pleth If set to Auto, the device will automatically select the source with the following priorities: DEFI > ECG > Pleth.
	Auto Scale	Automatic scale of the ECG amplitude	**OFF**/ON
	ECG Curve amplitude	ECG amplitude setting	0.25 / 0.5 / 1 / 2 cm/mV
	ECG Filter	Filter settings	EMG ON/OFF (electromyogram) BLW ON/OFF (baseline wandering) Detailed information see ECG amplifier band pass page 140.
	QRS sound	Volume of the systolic sound	Off/Low/**Medium**/High

a. When the patient has a cardiac pacemaker, the HR source must be set to Pleth (see page 46).

4.4.9 ECG messages

Alarm	Cause	Remedy
Cable not detected	• Electrodes not attached to the patient; come off; bad contact • Electrodes defective; line break • The device is defective	➜ Check the contact between the electrodes and the patient. ➜ Check the ECG cable and electrodes ➜ Have the device repaired
No Patient	• Unable to calculate heart rate	➜ Check the ECG cable and electrodes
HR out of range	• Heart rate is out of set alarm limits.	➜ Check patient ➜ Check narrow/wide HR alarm limit and adjust it if necessary.
Asystole	• No heart rhythm	➜ Physiological alarm! Check Patient.
VF/VT	• Ventricular fibrillation or tachycardia	➜ Physiological alarm! Check Patient.

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4.4.10 Print and pdf formats

The device can generate the following formats according to its configurations:

PDF resting ECG format

- 12 averages + 6 leads, 12.5 mm/s (1 page)
- 1x12 leads, 50 mm/s (2 pages)
- 4x3 leads + 1 rhythm lead, 25 mm/s (1 page)
- 2x6 leads, 25 mm/s (1 page)
- 1x12 leads, 25 mm/s (1 page)

Print resting ECG format

- 12 averages + 4*3 leads, 25 mm/s (7 pages)
- 4x3 leads + 1 rhythm lead, 25 mm/s (2 pages)
- 4x3 leads + 1 rhythm lead, 50 mm/s (3 pages)
- 2x6 leads, 25 mm/s (2 pages)

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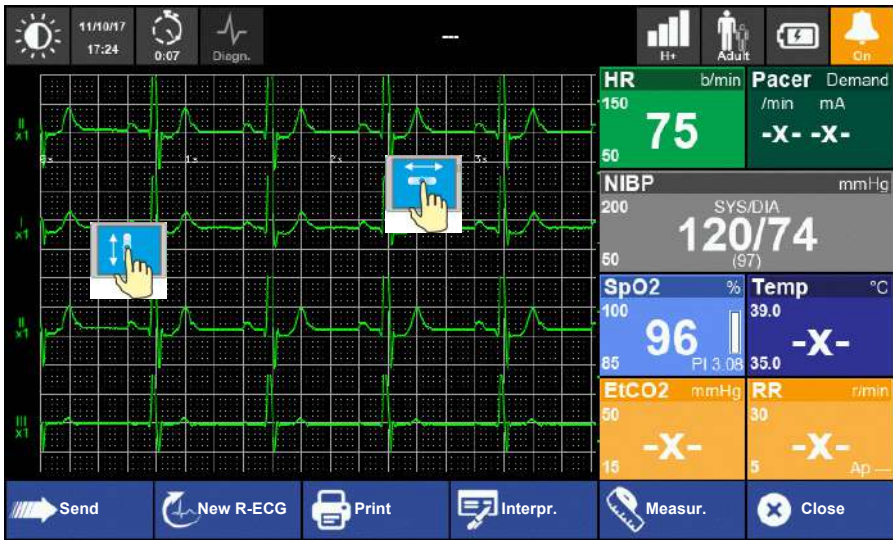
4.5 Diagnostic ECG (R-ECG)

1. Apply the electrodes of the 10-wire ECG cable as shown in Fig. 4.5.
2. Connect the patient cable to the ECG signal input.
3. Press the button R-ECG and:
   – the icon on the top changes from “Rhythm” to “Diagn.”
   – the lead placement screen appears, showing leads off with red circle.
4. Press Next:
   – the patient information dialogue is displayed for entering patient data if required
5. Press Next:
   – the “ECG acquisition in progress” screen appears.
6. It takes about 15 seconds to record the ECG. After acquisition, the “Send” and “Print” buttons are active. After about 8 seconds, the button “NEW R-ECG” is displayed so that another resting ECG can be recorded, if necessary.



7. It is now possible to scroll the R-ECG in the x-y axis for reviewing.
8. Transmit the ECG with following options:

➜ Press ”Send” to transmit the file via the defined transmission path e.g GSM/3G/ Wi-Fi, Bluetooth to:
   – SEMA
   – e-mail
   – USB storage

➜ Press “Print” to print the ECG to an external Bluetooth printer.

➜ Press “Interpr.” to open the interpretation information.

➜ Press ”Measur.” to open the measurement information

- If transmission of the data fails, the error icon appears in the top right status bar. The failed transmitted data can be re-sent in the main menu “R-ECG”.
- If you close the R-ECG Window without sending the data, the data can be re-sent via the main menu “R-ECG”.

For detailed information about the transmission, see chapter 4.6 page 50.45

- The resting ECG speed displayed on the recording depends on the configured printout- or pdf format (see chapter 4.4.10 Print and pdf formats, page 48).
- To display all 12 ECG leads see chapter 4.1.1 View selection, page 37.

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4.6 SpO_2-, SpCO, SpMet monitoring (Option)

- The pulse oximeter enables the continuous, non invasive monitoring of functional oxygen saturation of arterial haemoglobin as well as the pulse rate. The signal received from the patient sensor is used to calculate the patient's functional oxygen saturation and pulse rate.
- The Masimo Rainbow SET® technology for SpCO and SpMet measurements is based on the same principles as pulse oximetry. The Masimo Rainbow SET technology uses a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, blood with oxidized haemoglobin and blood plasma. Once the Masimo Rainbow SET technology receives the signal from the sensor, it calculates the patient's functional oxygen saturation (SpO2), fractional concentration of carboxyhaemoglobin (SpCO), fractional concentration of methaemoglobin (SpMet) and pulse rate.
- The display shows the continuous progress of the numeric SpO_2 value, pulse rate, plethysmographic waveform and signal quality.
- The displayed plethysmographic curve is not proportional to the pulse volume.
- The update period of the measurement readings on the display is 0.2 seconds.
- According to the relevant standards, the temporary alarm suppression must not exceed 2 minutes.
- Equipment used to perform functional tests cannot be used to give an indication as to the accuracy of the SpO_2 module.
- SpO2, SpCO and SpMet are empirically calibrated in healthy adult volunteers with normal levels of carboxyhaemoglobin (COHb).
- The peak wavelength and maximum optical power of the light emitted by the pulse oximeter probes has to be considered in certain cases, e.g. when performing photodynamic therapy. They are as follows:
  - Range of peak wavelengths: 600 nm to 900 nm
  - Maximum optical power output LNCS sensor: <15 mW
  - Maximum optical power output Rainbow sensor: <25 mW
- Masimo sensors use LEDs that are non-laser with the SpO2 module.
- High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow the pulse co-oximeter to obtain vital sign readings.

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⚠WARNING

- ▲ Only use SpO_2, SpCO and SpMet sensors listed in the order information for the DEFIGARD/PHYSIOGARD Touch 7. Other oxygen transducers (sensors) may lead to improper performance.
- ▲ The information in this user guide does not overrule any instructions given in the sensor's user guide, which must be consulted for full instructions.
- ▲ Never use the pulse oximeter as the sole means of monitoring a patient or as an apnoea monitor- always use the pulse oximeter in combination with an ECG trace.
- ▲ Never use a pulsoximeter during MR imaging. Induced current could potentially cause burns and the pulse oximetry may affect the image and accuracy of the measurements.
- ▲ Tissue damage can be caused by incorrect application or use of a sensor. Inspect the sensor application location as described in the sensor directions to ensure skin integrity and correct positioning and adhesion of the sensor.
- ▲ Do not use damaged patient cables, damaged sensors or sensors with exposed optical components.
- ▲ Change the position of the sensor at least every 4 hours, and every 2 hours if the perfusion is low.
- ▲ When patients are undergoing photodynamic therapy, they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.

4.6.1 Inaccurate or incorrect measurement result

⚠ CAUTION

- ▲ Inaccurate measurements can be caused in general by:
  - – Improper sensor application
  - – Low arterial perfusion
  - – Motion artefact
  - – Elevated levels of bilirubin
  - – Intravascular dyes such as indocyanine green or methylene blue
- ▲ Inaccurate measurements **SpCO and SpMet** can be caused by:
  - – Abnormal haemoglobin levels
  - – Low arterial oxygen saturation levels including altitude induced hypoxaemia
- ▲ Inaccurate **SpO2** measurements can be caused by:
  - – Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (co-Oximetry) of a blood sample should be performed.
  - – Externally applied colouring and texture, such as nail polish, acrylic nails, glitter, etc.
  - – Severe anaemia
- ▲ Interfering substances: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.
- ▲ If SpO2 values indicate hypoxaemia, a laboratory blood sample should be taken to confirm the patient's condition.

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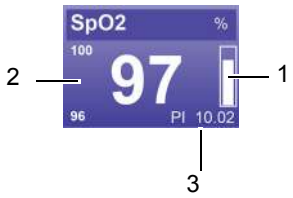
4.6.2 Starting SpO_2 monitoring and test



1. Apply the SpO_2 sensor to the patient. Insert the patient's forefinger into the probe as far as it will go, and make sure that the finger tip covers all of the probe window. This is to prevent that extraneous light reaches the photodetector.
2. Connect the SpO2 sensor to the device and secure the cable with the two velcro fasteners.
3. Check the bar graph for signal quality **(1)**.
4. Check Perfusion Index PI level **(3).**
5. Set the narrow SpO_2 alarm limit see page 40.
6. When the SpO2 value exceeds the alarm limit **(2)**, an alarm is issued.

Set the alarm limit to narrow or wide when the vital data are not critical.

Perfusion Index PI **(3)** with trending capability indicates arterial pulse signal strength and may be used as a diagnostic tool during low perfusion.

PI display ranges from 0.02% (very weak pulse strength) to 20% (very strong pulse strength).

Display "-?-" or "---" instead of the value:

➜ --- Sensor not connected to the device

➜ -?- Sensor not attached to finger

Fig. 4.8 SpO_2 measurement field

4.6.3 SpO_2 Module

MENU	Parameter	Description	Value
SpO2	HR Source	[a]Source based on which the heart rate should be determined.	**Auto**, Defi, ECG or Pleth If set to Auto, the device will automatically switch sources with following priority: DEFI > ECG > Pleth
	Average	Definition of the integration time for the calculation of the displayed average value.	4/6/**8**/10/12/14/16 seconds
	Sensitivity	Select the measurement sensitivity. Select High when the pulse is weak. APOD (Adaptive Probe off detection) is optimised for the detection of "Sensor has come off", regardless of the signal quality. The setting "High" must not be set as default setting.	**Normal,** Maximum, Adaptive Probe Off detection If set to "Maximum" and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental "noise" such as light, vibration, and excessive air movement.
	Line Frequency	Set to match regional power line frequency to allow for cancellation of noise introduced by fluorescent lights and other sources.	50 or 60 Hz
	SpO2 Sound level	Set the pulse tone. The pitch of the pulse tone also indicates if the saturation level is high (high pitch) or low (low pitch).	OFF, low, medium, high

a. When the patient has a cardiac pacemaker, the HR source must be set to Pleth (see page 46).

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4.6.4 SpO_2error and information messages

Alarm (measurement field)	Code	Cause	Remedy
SpO2: Low Perfusion Index The same accounts for: Low SpCO perfusion Low SpMet perfusion	I.SP214 I.SP206 I.SP209	• Weak pulse • Sensor not properly applied	➜ Check the patient ➜ Check the sensor and reapply. If this message is displayed repeatedly, the oxygen saturation needs to be verified by means of another method.
SpO2: Low SpO2 confidence The same accounts for: Low HR (pleth) Confidence Low SpCO confidence Low SpMet confidence	I.SP203 I.SP211 I.SP205 I.SP208	• Low pulse signal quality, measurements are based on a poor signal quality. The pulse tone, if activated, is low.	➜ Check the patient ➜ Check the sensor and reapply or replace sensor ➜ If this message is displayed repeatedly, the oxygen saturation needs to be verified by means of another method
Invalid functional SpO2 The same accounts for: Invalid HR (pleth) Invalid SpCO Invalid SpMet	I.SP204 I.SP212 I.SP207 I.SP210	• Value is not plausible • SpCO readings may not be provided if there are low arterial saturation levels or elevated methaemoglobin levels.	➜ Check the patient ➜ Check the sensor and reapply
Pulse Search	T.SP230	• Device is searching for the pulse	➜ Make sure that the sensor is well connected to the patient
Sensor Off patient	T.SP229	• Sensor not connected to the patient or off	➜ Check the contact between the sensor and the patient
Check sensor	I.SP231	• SpO_2 sensor failed or disconnected	➜ Check sensor, compatibility ➜ Replace the sensor
Board inoperative	T.SP201 T.SP202 T.SP203 T.SP204 T.SP205 T.SP206 T.SP207 T.SP208 T.SP209 T.SP210 & T.SP232	• No SpO2 module installed	➜ Module not installed or defective
Interference detected	T.SP226	• Interferences detected	➜ Check the sensor on the patient, check the cable connector, eliminate sources of interferences, e.g. high frequency devices or strong light sources. ➜ Check Line frequency setting 50 or 60 Hz
Check cable	T.SP211 T.SP212 T.SP213 T.SP214 T.SP215	• No cable connected • Cable life expired • Incompatible cable • Unrecognised cable • Defective cable	➜ Check/replace cable

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Alarm (measurement field)	Code	Cause	Remedy
Check sensor	T.SP216 T.SP217 T.SP218 T.SP219 T.SP220 T.SP221 T.SP222 T.SP223 T.SP224 T.SP225 T.SP227	• No sensor connected • Sensor life expired • Incompatible sensor • Unrecognised sensor • Cable and sensor fault • No adhesive sensor connected • Adhesive sensor life expired • Incompatible adhesive sensor • Unrecognised adhesive sensor • Defective adhesive sensor • Defective sensor	➜ Check/replace the sensor ➜ Check cable and sensor fault

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4.7 NIBP monitoring

The non-invasive blood pressure is measured by the oscillometric method.

The module performs single measurements and automatic measurements at selectable intervals.

The automatic measurements are suitable also for pregnant or pre-eclamptic patient.

Make sure that the cuff is on a level with the heart during blood pressure measurements. If this is not ensured, the hydrostatic pressure of the liquid column in the blood vessels will lead to incorrect results. When the patient is sitting, standing or supine during measurements, the cuff is automatically at the correct level.

Factory default cuff pressure adult = 180 mmHg, children = 150 mmHg,
neonates = 50 mmHg

The initial cuff pressure is configurable. The maximum cuff pressure configuration in neonatal mode is 150 mmHg.

WARNING

- To prevent extensive pressure on the extremity, it is very important to choose the correct cuff size and to check the setting patient type adult, children or neonates.
- On **neonatal** patient, it is imperative to selected first the neonatal MODE. A erroneous MODE selection will lead to higher pressure which can cause haematoma or an osseous deformation.
- When **neonatal** MODE is selected the maximal pressure is lowered and the time measure is shorter. An erroneous MODE selection on neonatal patients would engender inadequate pressure and time measure.
- In case of long-term monitoring or automatic operation, the connected body areas of the patient and the extremity to which the cuff is attached must be checked regularly for signs of ischaemia, purpura and/or neuropathy, especially in patients with decreased pain sensitivity (due to medication), or with older patients with decreased blood circulation of the extremities.
- The cuff must not be attached to a limb that is already used for interventions such as:
  - infusions or
  - SpO_2 measurement (loss of data can occur during cuff inflation) or
  - if an arterio-venous shunt is present.
- To prevent extensive pressure on the extremity and incorrect measurement results, make sure that the tube is not kinked or compressed.
- To achieve correct arterial pressure measurement, the cuff must always be installed on the level of the right atrium.
- In order to reduce interferences and the danger of burns for the patient, keep the cuff and hose as far away as possible from the operated area and the electrosurgical cables. Make sure that the electrosurgical return conductor (neutral) is well attached to the patient and that a good contact is guaranteed.
- In some patients petechiae, haemorrhages or subcutaneous haematomas may occur. All patients must be told when putting on the cuff that if they experience pain during the recording they should switch off the equipment and inform the doctor.
- When an automated measurement interval is defined, bruising or decreased blood circulation can occur in the arm. Only carry out recordings with automated measurement intervals under constant medical supervision.
- It must be certain that, according to the health of the patient, the use of the device will not damage blood circulation in the arm.

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⚠ CAUTION

- As with occasional blood pressure measurement, petechial bleeding can occur in patients with coagulation disorders or having anticoagulant treatment even with the correct cuff size.
- In patients who have had a single mastectomy, the cuff can be placed on the opposite arm.
- The cuff must not be placed over or near a wound that could cause further injury.
- To prevent incorrect measurement results, ensure that the tube is not pinched or compressed.
- A cuff that is applied to a patient in the recumbent or sitting position is normally located at the same level as the heart. However, if the cuff is located at a level higher than the heart (for instance if the arm of a patient in bed is lifted), this may result in lower-than-actual measurement readings (approx. 7.5 mmHg per 10 cm rise).

i

- The measurement may be inaccurate or impossible:
  - if a regular arterial pressure pulse is hard or impossible to detect, e.g. with cardiac arrhythmias, severe shock, hypothermia or with obesity or an edematous extremity
  - with excessive and continuous patient movement such as shivering or convulsion.

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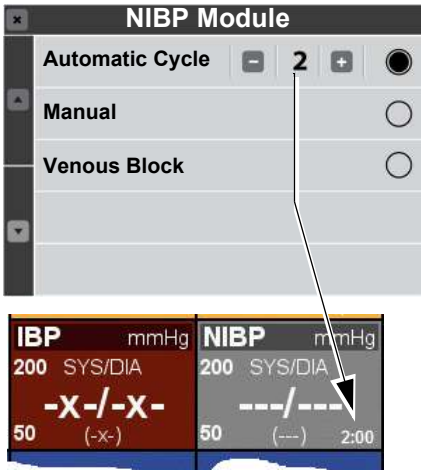
4.7.1 Starting NIBP monitoring



1. Note the cuff size for the respective patient type see chapter.13.2 Accessories DEFIGARD/PHYSIOGARD Touch 7 page 159.
2. The cuff is attached to the left or right upper arm, about 4 cm above the elbow (on children a little closer).
3. Connect the cuff tubing to the connection sleeve **(1)** and make sure it properly locks into place.
4. Define the NIBP settings directly via the Touch screen NIBP measurement field.
   – Patient type - adult, child or neonate (indicated at the top right)
5. Open the NIBP menu and check the settings.
   – Setting of the **Automatic cycle** time or **manual** measurement
6. Start the NIBP measurement by pressing the soft key “Start”.

➜ To disconnect the cuff tube, press the milled shell of the connecting sleeve backwards.

➜ Clean and disinfect the cuff after each use see chapter 10.5 Cleaning page 119 and 10.6 Disinfection page 120.

The following settings are available for the cycle time:

Automatic Cycles	2/3/5/10/30 minutes
Manual	The measurement is manually initiated by pressing the soft key.
Venous Block	The venous block is used to apply an intravenous access. The pressure is exactly 40 mmHg. The blockage time is limited to 80 second. You can stop anytime the blockage by the NIBP Stop key.

Fig. 4.9 NIBP soft key

- When the measurement is started, the increasing cuff pressure is displayed on the bar graph.
- The last four measurements are displayed in the window.

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4.7.2 NIBP Menu

MENU	Parameter	Description	Value
NIBP	Automatic cycles	Cycle time setting	Automatic cycle of 2/3/5/10/30 minutes
	Manual	The measurement is manually initiated by pressing the soft key.	soft key = Start

4.7.3 NIBP Information and Error Messages

NIBP Alarm	Code	Cause	Remedy
Module inoperative	T.NIBP01 T.NIBP02 T.NIBP03 T.NIBP04 T.NIBP05 T.NIBP06 T.NIBP07	• NIBP module failed	➜ Replace device
Unable to inflate cuff	T.NIBP08	• No pressure can be measured • The device is defective	➜ Check cuff and connection. ➜ Replace device
Invalid measurement	T.NIBP09 T.NIBP10 T.NIBP11	• Pressure/pulse below/above limits	➜ Check cuff and connection for leaks
Unable to measure	T.NIBP12	• No signal/pulse detected at 50 mmHg	➜ Check patient, cuff and hose
Cuff not present	T.NIBP13	• Pressure in the cuff remains too low < 10 mmHg during 10 s	➜ Check cuff and connection for leaks
Wrong cuff	T.NIBP14	• Pressure too high because - Too small cuff applied - Tube buckled	➜ Check cuff and connection.
Artefacts detected	T.NIBP15 T.NIBP16	• Measurement disturbed by external influences	➜ The patient must not move during measurement
Measurement timeout	T.NIBP17	• Measurement time exceeded with no results	➜ Check cuff and connection. ➜ Make sure that the cuff is well applied
Inflate timeout	T.NIBP18 T.NIBP19	• Pumping running time exceeded	➜ Check cuff and connection for leaks.
Pressure out of range	T.NIBP20	• Pressure below/above acceptable range	➜ Check patient, cuff and hose
No pulse	I.NIBP01	• No pulse detected	➜ Make sure that the cuff is well applied ➜ Check patient, cuff and hose

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4.8 IBP Monitoring

WARNING

- ▲ Carefully read the manufacturer's instructions before using the invasive blood pressure kit.
- ▲ When applying the kit to the patient, make sure that absolutely no air penetrates the system.
- ▲ To achieve correct arterial pressure measurement, the pressure sensor must be installed on the level of the right atrium.
- ▲ If the pressure sensor's position is changed after calibration, this might lead to wrong low or high values.
- ▲ If an invasive catheter for blood pressure measurement is introduced into an arterial vessel, the circulation in the terminal vessels must be checked in regular intervals.
- ▲ Single-use sensors and valves must not be reused.
- ▲ Do not use IBP kit if packaging is opened or damaged.
- ▲ To grant the patient's safety, it must be ensured that neither the electrodes nor the patient, or persons touching the patient, come into contact with conducting objects, even if these are earthed.
- ▲ Special care must be exercised when the unit is used with high-frequency equipment. To prevent incorrect IBP measurements, only use sensors that are protected against high-frequency radiation.

- The kit and operating procedure vary according to manufacturer. Please consult the manufacturer's documentation for connection.
- For warm-up time/ready for measurement and displacement for invasive transducers, refer to the documentation of the transducer manufacturer.

4.8.1 Preparing an IBP measurement

The rinse must be contained in a flexible container. This container must be surrounded by a pressure bag which should exert a pressure of 300 mmHg ± 30 mmHg on the container. This is in order to ensure a minimum flow of rinse of approximately 6 ml per hour to prevent occlusion of the catheter tip.

1. Unpack the disposable measuring kit and check all tube connections for tightness.
2. Secure the infusion bag and connect the infusion tube to the bag.
3. Fill up the system with liquid so it is completely void of air.
4. Hang the measuring kit in the holder and secure the holder.
5. Connect the cable of the transducer to the adaptor cable.
6. Connect the adapter cable to the DEFIGARD/PHYSIOGARD Touch 7 IBP input.

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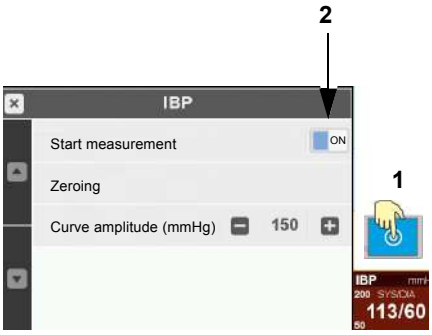
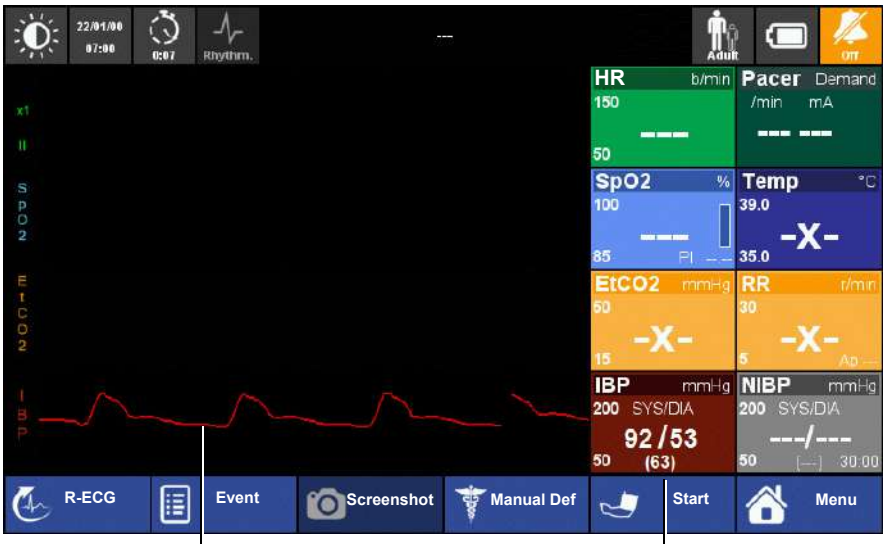
4.8.2 Start IPB measurements



1. Select the IBP measurement field **(1)** to open the IBP menu.
2. Select OFF/ON button **(2)** to start the measurement.
3. Zeroing the IBP (see Zeroing)
4. Check the IBP curve on the display to see if the connections have been made correctly and the IBP value is in the expected range.

IBP curve display



IBP curve

IBP measurement field with Systolic/Diastolic and mean arterial pressure

4.8.3 IBP menu settings

Access the IBP menu via the IBP measurement field as described on page 33.

The default settings are printed **bold**.

Menu item	Parameter	Description
IBP parameter	Start measurement	Starts the IBP measurement
	Zeroing	Zero adjustment of the IBP
	Limits	see Alarm limits
	Curve amplitude (mmHg)	Set the range for the IBP measurement: 0-30, 0-60, 0-150, 0-300 mmHg

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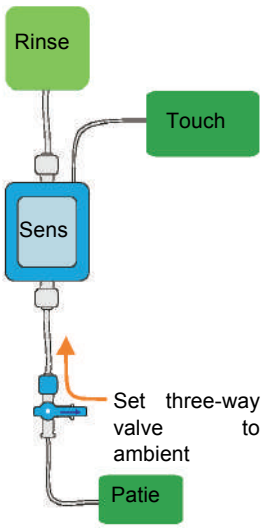
4.8.4 IBP zeroing

- Zeroing must be carried out before every application.
- To prevent incorrect measurement readings due to the sensor's physical null drift, calibrate the sensor every 24 hours.

Note

If the pressure sensor's position is changed after or during calibration, this might lead to wrong low or high values.



1. In accordance with the manufacturer's instructions, open the relevant valve(s) to equalise the system pressures as is shown in this example.
1. Select the IBP measurement field to display the IBP menu.
2. Select the parameter **Zeroing** to carry out the zeroing.

4.8.5 IBP alarms/messages

Alarm	Code	Cause	Remedy
No sensor	T_IBP01	• Cable not connected to the device	➜ Check cable connection to the device.
Catheter disconnected	T_IBP02	• Catheter disconnected • Catheter valve closed	➜ Check catheter ➜ Check catheter valve
Zero required	T_IBP03	• No zeroing has been done • Zero-point sensor too high/low by more than ±30 mmHg or unsteady pressure	➜ Check tube system, sensor and valves. ➜ Perform zeroing.
Zero not possible	I_IBP01	• Try to zeroing during valid patient measurement • Try to zeroing without sensor connected	➜ Check catheter valve is closed during zeroing ➜ Connect sensor
IBP SYS LOW/HIGH	P_IBP01	• Systolic pressure higher/lower than the alarm limits	➜ Check the patient and alarm limits.
IBP DIA LOW/HIGH	P_IBP01	• Diastolic pressure higher/lower than the alarm limits	➜ Check the patient and alarm limits.

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4.9 Temperature monitoring

- Depending on the sensor type, the sensor can be applied to the ear, the skin or per rectum.
- To achieve a reliable measured value, independent of the measuring site, the measurement duration must be at least 2 minutes.
- The temperature measurement method is “Direct mode”.

4.9.1 Start temperature monitoring

1. Connect the sensor to the temperature input.
2. Select the TEMP measurement field to open the Temp menu.
3. Select OFF/ON button to start the measurement.

4.9.2 Temperature menu settings

Access the temperature menu via the TEMP measurement field as described on 33.

The default settings are printed **bold**.

Menu item	Parameter	Description
	Start measurement	On or **OFF**
	Calibrate	Calibration of the sensor

4.9.3 Temperature alarms

Alarm	Cause	Remedy
Check sensor	• Temperature sensor not connected to the device	➜ Connect sensor.
TEMP: Out of range	• Temperature is out of set alarm limits.	➜ Check patient ➜ Check narrow/wide alarm limit and adjust it if necessary.

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4.10 CO2 mainstream

4.10.1 IRMA mainstream gas analyser

IRMA mainstream gas analyser is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care.

⚠WARNING

Paediatric airway adapter

Adult airway adapter

- ▲ The IRMA gas analyzer is intended for use by authorized healthcare professionals only.
- ▲ Risk of cross infection!
  - – Disposable airway adapters must not be re-used.
  - – Used disposable airway adapters must be disposed of in accordance with local regulations for contaminated and biologically hazardous fluids.
- ▲ Airway Adapters are non-sterile devices. Do not sterilise.
- ▲ Use only Masimo manufactured IRMA airway adapters.
- ▲ Use the correct adapter:
  - – Do not use the IRMA Paediatric/Adult airway adapter for infants because the adult adapter adds 6 ml dead space to the patient circuit.
  - – Do not use the IRMA Infant airway adapter for adults because this may cause excessive flow impedance.
  - – Do not use the airway adapter with metered dose inhalers or nebulized medications as this may affect the light transmission of the airway adapter windows.
- ▲ The IRMA sensor is not intended to be used as the only means of monitoring a patient.
- ▲ Never sterilise or immerse the sensor in liquid.
- ▲ Do not apply tension to the sensor cable.
- ▲ Do not place the IRMA airway adapter between the endotracheal tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.
- ▲ To keep secretions and moisture from pooling on the windows, always position the IRMA probe in a vertical position with the LED pointing upwards.
- ▲ Replace the airway adapter if rainout/condensation occurs inside the airway adapter.

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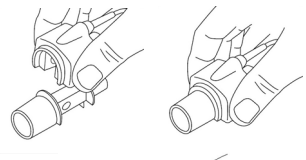
4.10.2 Preparing the IRMA sensor

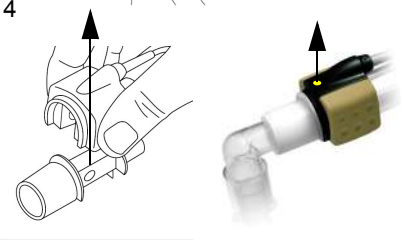
1



2

3

4

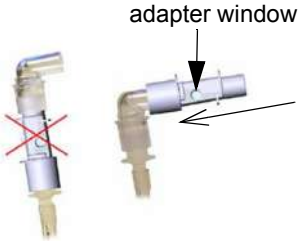


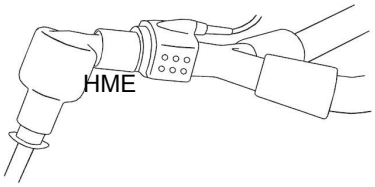
1. Insert the airway adapter.
2. Connect the 15 mm airway adapter end to the ventilator Y piece.
3. Connect the patient side of the airway adapter to the tube.

IMPORTANT

4. To keep moisture from pooling on the windows, position the airway adapter with its windows in a vertical position.(LED pointing upwards)

➜ To prevent the windows' soiling by secretions of the patient or condensing water, position the adapter in a slightly angled position between the endotracheal and the respiration tubes.





➜ Alternatively; connect a HME (Heat Moisture Exchanger) between the patient's endotracheal tube and the IRMA probe. Placing a HME in front of the IRMA probe protects the airway adapter from secretions and effects of water vapor and eliminates the need of changing the adapter. It allows free positioning of the IRMA probe as well. Unless the IRMA probe is protected with a HME always position the IRMA probe with the LED pointing upwards.

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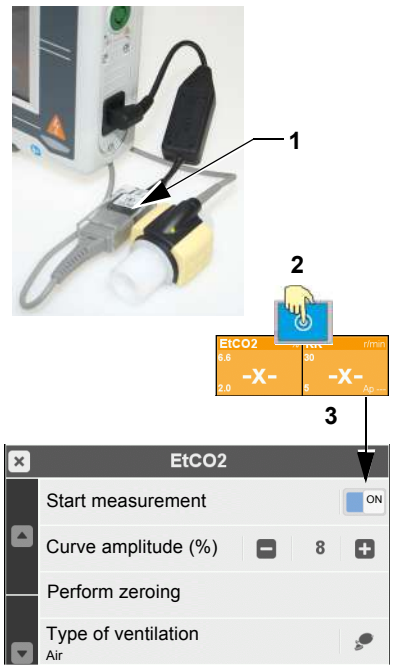
4.10.3 Initial operation of the IRMA sensor

- The sensor requires a warm-up time of around ten seconds to provide fully accurate measurements.
- A correction related to O2 usage is available in the menu setting **EtCO2>Type of ventilation**. If patient is ventilated with Air and O2, set **Type of ventilation** to = “Air + **O2**” if ventilated only with air set it to “**Air**”.



1. Connect the sensor cable to the main cable **(1)**. Snap the sensor head on top of the airway adapter. Make sure it clicks into place.
2. A green LED indicates that the sensor is ready for use.
3. Select the EtCO2 measurement field **(2)** to open the EtCO2 menu. “
4. Select OFF/ON button **(3)** to start the measurement.
5. Check if the $etCO_2$ value is zero.
6. If needed, carry out a zeroing (see page 66).
7. Connect the narrower end of the airway adapter to the breathing circuit Y-piece.
8. Connect the end of the airway adapter to the patient’s endotracheal tube.
9. Check the CO_2 curve on the display to see if the connections have been made correctly and the CO_2 value is in the expected range. The curve rises during expiration.

4.10.4 Placement of IRMA sensor

WARNING

▲ The IRMA probe is not intended to be in patient contact.

➜ When connecting the IRMA sensor to an infant patient circuit, it is important to avoid the direct contact between the IRMA sensor and the infant’s body. Use insulation material between the body and the IRMA sensor to avoid contact.

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4.10.5 Zeroing of the IRMA CO_2 sensor

⚠WARNING

- ▲ An incorrect zeroing leads to wrong measurement results.
- ▲ Therefore, make sure that the IRMA adapter is filled with ambient air (21% O2 and 0% CO2) during the zeroing.
- ▲ After start-up or changing of the adapter, wait for at least 10 seconds until the sensor has reached its operating temperature.
- ▲ During zeroing, no breathing air must enter the adapter.

Zeroing intervals for CO2 IRMA sensor

- When the message **"CO2 calibration is required"** is displayed
- When an offset in gas readings is discovered (0-offset)

Zeroing procedure

1. Snap a new airway adapter onto the sensor without connecting the airway adapter to the breathing circuit.
2. After start-up or changing of the adapter, wait for at least 10 seconds until the sensor has reached its operating temperature.
3. In the "etCO_2 settings" menu, select the menu item "**Perform zeroing".**
4. Carry out the **zeroing** by pressing the parameter "**Perform zeroing"** in the "et-CO_2 settings" menu. Make sure that no exhaled air enters the airway adapter. The green LED on the probe will be blinking for approximately 5 seconds while zeroing is in progress.
5. If the message **"CO2 calibration is required"** is again displayed, perform the zeroing again.
6. If the message **"CO2 calibration is required"** is no longer displayed, the zeroing has been performed.
7. Reconnect the airway adapter with the sensor to the breathing circuit.
8. Check the CO_2 curve on the display to see if the connections are correct and if the CO_2 value is in the expected range. The curve rises during expiration.

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4.10.6 Sensor LED indications

Apart from the indications on the screen, the LED on the sensor gives the following indications:

Steady green:	System OK
Steady red:	Sensor error
Flashing red:	Check the adapter
Flashing green:	Zeroing in process

4.10.7 Settings $etCO_2$ menu

Access the **$etCO_2$** menu via the **$etCO_2$** display field as shown on page 65.

The default settings are printed **bold**.

Menu item	Parameter	Description
	Start measurement	On or **OFF**
	Curve amplitude (%)	**8**, 12 or 15 %
	Perform zeroing	Zeroing the sensor to ambient air
	Type of ventilation	Air = patient ventilated only with air Air + O2 = patient ventilated with Air and O2

4.10.8 Curve list

MENU	Parameter	Description	Value
Curve list	Touch first curve	Selection of the displayed first curve. The first display curve is used to calculate the Heart rate unless the HR source is set to Pleth.	**II or** Defi Default:
	Touch the curves 2,3,4	Selection of the displayed curve	Defi/**I, II,** aVR, aVL, aVF, **SpO2 plethysmograph**, **EtCO2:Respiration**

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4.10.9 CO_2 error messages

Alarm	Code	Cause	Remedy
RR out of range	P.ETCO201	• Respiration rate out of set alarm limits.	→ Check patient → Check narrow/wide etCO2 alarm limit and adjust it if necessary. → Check ventilation settings
Apnoea	P.ETCO202	• Apnoea out of set alarm limits.	→ Check patient → Check narrow/wide alarm limit and adjust it if necessary. → Check ventilation settings
etCO2 out of range	P.ETCO203	• etCO2 is out of set alarm limits.	→ Check patient → Check narrow/wide etCO2 alarm limit and adjust it if necessary. → Check ventilation settings
CO2 calibration required	I.ETCO201	• an offset in gas readings is discovered	→ Perform zeroing
Check Sensor	T.ETCO201	• No Sensor connected, defective cable	→ Connect sensor, check cable
Zeroing in progress	T.ETCO202	• Zeroing process started	→ Wait till zeroing process ends
Replace adapter	T.ETCO204	• Adapter polluted with patient secretions	→ Replace CO2 adapter if polluted
No adapter	T.ETCO205	• No or incorrect CO2 adapter • Adapter not properly connected	→ Check if IRMA CO2 adapter is properly connected
Internal temp out of range	T.ETCO214	• Temperature sensor too high/low	→ Check standard operating condition if normal: → Replace sensor
Ambient pressure out of range	T.ETCO215	• Pressure to high/low	→ Check standard operating condition if normal: → Replace sensor
Inaccurate zero reference	T.ETCO216	• This alarm is due to Zeroing required message from the probe.	→ Check standard CO2 condition if normal: → Perform zeroing
Software error	T.ETCO218	• Sensor failure	→ Check sensor, replace sensor
Hardware error	T.ETCO219	• Sensor failure	→ Check sensor, replace sensor
Motor speed out of bounds	T.ETCO220	• Sensor failure	→ Check sensor, replace sensor
Factory calibration lost	T.ETCO221	• Sensor failure	→ Check sensor, replace sensor

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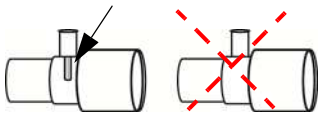
4.11 CO_2 Sidestream

4.11.1 ISA gas analyser (sidestream measurement)

- ISA sidestream gas analyser is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anaesthesia, recovery and respiratory care.
- A correction related to O2 usage is available in the menu setting **EtCO2>Type of ventilation**. If patient is ventilated with Air and O2, set **Type of ventilation** to = "**Air + O2**" if ventilated only with air set it to "**Air**".

⚠WARNING



- ▲ The ISA sidestream gas analyzer is intended for use by authorized healthcare professionals only.
- ▲ Disposable sampling lines must not be reused. Used sampling lines should be disposed of in accordance with local regulations for contaminated and biologically hazardous fluids.
- ▲ Only use Masimo´s Nomoline sampling lines.
- ▲ Do only use sample lines intended for anaesthetic agents if N2O and/or anaesthetic agents are being used.
- ▲ Make sure to select the correct configuration:
  - – Do not use T-adapter sampling line configurations for infants because these will add 7 ml dead space to the patient circuit.
  - – Do not use the Nomoline Airway Adapter Set Infant with adult/paediatric patients.
- ▲ Use only airway T-adapters with the sampling point in the centre of the adapter, see picture on the left.
- ▲ Do not use the sampling lines with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.
- ▲ The ISA sensor is not intended to be used as the only means of monitoring a patient.
- ▲ Excessive positive or negative pressure in the patient circuit (e.g. excessive scavenging suction pressure) might lead to incorrect readings.
- ▲ Exhaled gases should be returned to the patient circuit or scavenging system; do not apply negative pressure to the Nomoline (i.e. by means of a syringe) to remove condensed water.
- ▲ Always use a bacteria filter on the evacuation side if sampled gas is intended to be re-breathed.
- ▲ Use of high frequency electrosurgical equipment in the vicinity of the ISA sensor may produce interference and lead to incorrect measurements.
- ▲ Exhaust gases should be returned to the patient circuit or to a scavenging system.

⚠CAUTION

- ▲ The Nomoline sampling line and its interface are non-sterile devices. To avoid damage, do not autoclave any part of the sampling line.
- ▲ Do not apply tension to the sensor cable.
- ▲ Do not operate the device at temperatures outside the specified operating environment.
- ▲ Make sure that the ISA sensor is properly secured in order to prevent damages to the sensor.
- ▲ The use of a sampling line with an inner diameter of more than 1 mm can lead to a change in the response and rise time of the CO2 measurement. When the respiration rate is higher than 130/min, this might lead to a lower etCO2 value being displayed.

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▲ The Nomoline sampling line is designed for single use only; do not reuse.

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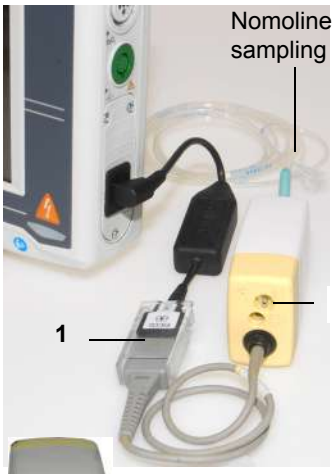
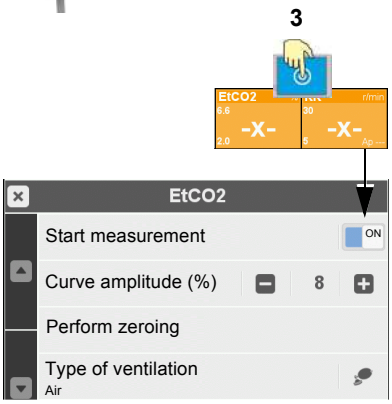
4.11.2 Initial operation of the ISA gas analyser

- The sensor requires a warm-up time of around ten seconds.





→ 1. Connect the sensor cable (**1**).
2. Connect the Nomoline sampling line **(2)** to the ISA gas analyser.
3. A green LED (2) indicates that the sensor is ready for use.
4. Select the EtCO2 measurement field **(3)** to open the EtCO2 menu. “
5. Select OFF/ON button to start the measurement.
6. Breathe briefly into the sampling line and check that the CO_2 curves and values are displayed correctly.
7. Occlude the sampling line with your fingertip and wait for 10 seconds.
8. Check that an occlusion alarm is displayed and that the gas analyser shows a flashing red light.

⚠ CAUTION

→ Replace the sampling line if the sampling line input connector (2) starts flashing red or the message “Sampling line clogged” is displayed on the device.

→ Connect the gas sample exhaust port ⇨ to the gas exhaust of the bag to prevent that CO2 enriched gas in the bag influences the zeroing of the ISA gas analyser

4.11.3 Sensor LED indications

In addition to the information given on the screen, the sensor LED indicates the following:

Steady green:	System OK
Flashing green:	Zero reference calibration in process
Steady red:	Sensor error
Flashing red:	Check/replace the sampling line

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4.11.4 Respiration rate alarms

Alarm	Code	Cause	Remedy
RR out of range	P.ETCO201	• Respiration rate out of set alarmlimits.	→ Check patient → Check narrow/wide etCO2 alarm limit and adjust it if necessary. → Check ventilation settings
Apnoea	P.ETCO202	• Apnoea out of set alarm limits.	→ Check patient → Check narrow/wide etCO2 alarm limit and adjust it if necessary. → Check ventilation settings
CO2 out of range	P.ETCO203	• ETCO2 is out of set alarm limits.	→ Check patient → Check narrow/wide etCO2 alarm limit and adjust it if necessary. → Check ventilation settings
CO2 calibration required	I.ETCO201	• An offset in gas readings is discovered	→ Perform zeroing
Check Sensor	T.ETCO201	• No Sensor connected, defective cable	→ Connect sensor, check cable
Zeroing in progress	T.ETCO202	• Zeroing process started	→ Wait till zeroing process ends
Sampling line clogged	T.ETCO207	• Indicates sampling line occlusion.	→ Replace sampling line
No sampling line	T.ETCO208	• Indicates that a sampling line needs to be fitted.	→ Check if IRMA CO2 adapter is properly connected
Internal O2 port failure	T.ETCO209	• Sensor failure	→ If persistent, replace sensor
Internal temp out of range	T.ETCO214	• Temperature Sensor to hight/low	→ Check standard operating condition if normal: → Replace sensor
Ambient pressure out of range	T.ETCO215	• Pressure to high/low	→ Check standard operating condition if normal: → Replace sensor
Inaccurate zero reference	T.ETCO216	• This alarm is due to Zeroing required message from the probe.	→ Check standard CO2 condition if normal: → Perform zeroing
Software error	T.ETCO218	• Sensor failure	→ Check sensor, replace sensor
Hardware error	T.ETCO219	• Sensor failure	→ Check sensor, replace sensor
Motor speed out of bounds	T.ETCO220	• Sensor failure	→ Check sensor, replace sensor
Factory calibration lost	T.ETCO221	• Sensor failure	→ Check sensor, replace sensor

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4.11.5 Settings $etCO_2$ menu

Access the **$etCO_2$** menu via the **$etCO_2$** display field as shown on page 71.

The default settings are printed **bold**.

Menu item	Parameter	Description
	Start measurement	On or **OFF**
	Curve amplitude (%)	**8**, 12 or 15 %
	Perform zeroing	Zeroing the sensor to ambient air
	Type of ventilation	Air = patient ventilated only with air Air + O2 = patient ventilated with Air and O2

4.11.6 Curve list

MENU	Parameter	Description	Value
Curve list	Touch first curve	Selection of the displayed first curve. The first displayed curve is used to calculate the Heart rate unless the HR source is set to Pleth.	**II or** Defi Default:
	Touch the curves 2,3,4	Selection of the displayed curve	Defi/**I, II,** aVR, aVL, aVF, **SpO2 plethysmograph**, **EtCO2, Respiration and IBP**

4.11.7 Zero adjustment of the CO_2 sidestream sensor

WARNING

- ▲ Incorrect zero adjustment leads to erroneous measurement results.
- ▲ Therefore, make sure that the calibration is performed in a well-ventilated room. Avoid breathing near the gas analyser before or during the calibration.
- ▲ If the ISA gas analyser is stowed in the transport bag, ensure good ventilation of the bag or check that the gas exhaust is connected before calibration.

- The ISA sidestream gas analyser performs zeroing automatically by switching the gas sampling from the respiratory circuit to ambient air. The automatic zeroing is performed after startup and 1 to 3 times per day and it takes less than 3 seconds.
- During zeroing, if ISA's exhaust gas is returned to the patient circuit, the returned gas level will be different from the gas level at the sampling site.

Calibration intervals for ISA CO_2 sensor

- When the message **"CO2 calibration is required"** is displayed
- When an offset in gas readings is discovered (0-offset)

Zeroing procedure

1. Select the menu **CO_2** > **$ETCO_2$** and then the menu item "**Perform zeroing".** The green LED on the ISA sensor is blinking and the **Zeroing process** is displayed on the DEFIGARD/PHYSIOGARD Touch 7.
2. When the green LED on the sensor stops blinking, the calibration is finished.
3. Check the $etCO_2$ curve in the display to see if the connections have been made correctly and if the $etCO_2$ value is in the expected range. The curve rises during expiration.

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4.12 Registering events

Fig. 4.10 Event button

When the event button is pressed, the pre-defined event texts are displayed. Select one of these texts; this text will be recorded in the data report together with the time.

➜ Select "Cancel last" to indicate that an incorrect event was selected. A "Cancel Last" event and time stamp are stored in the event list.

Data (ECG, automatic and manual events) can be displayed on a PC by use of the Schiller data reviewing Software.

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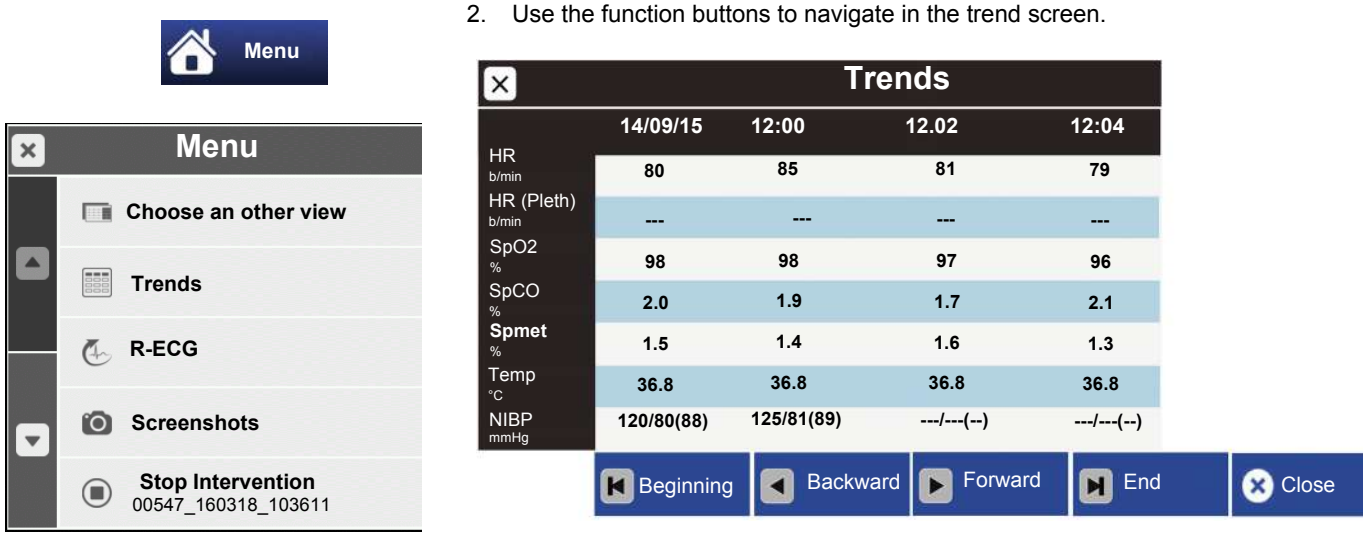
4.13 View Trend, R-ECG and Screenshots

All recorded trend data, resting ECGs and screenhots can be viewed during intervention. Additionally, the viewed resting ECG can be transmitted as described in chapter 4.6 page 50.

4.13.1 View Trends

1. Enter the main menu and select **Trends**.
2. Use the function buttons to navigate in the trend screen.

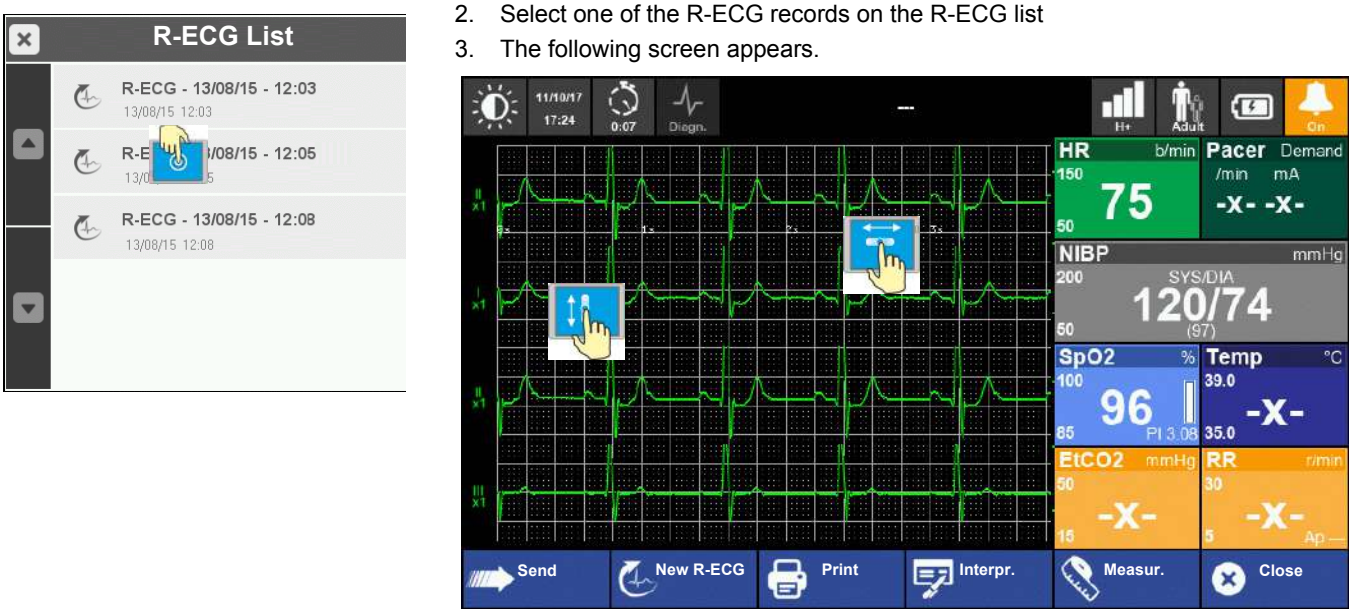


3. Close the Trends screen with the button ⊠ or “Close” button.

Fig. 4.11 Trends screen

4.13.2 View resting ECG

1. Enter the main menu and select **R-ECG.**
2. Select one of the R-ECG records on the R-ECG list
3. The following screen appears.



4. Exit the viewing mode by pressing the “Close” button.
5. To print the resting ECG, click on "Print"

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4.13.3 View /Print Screenshots

1. Enter the main menu and select **Screenshots.**
2. Select one of the screenshot on the list.
3. The screenshot appears with a watermark.
4. Exit the viewing mode by pressing the Red X button on the top left corner.

➜ To print a screenshot, tick the box on the right and click on "next".
Several screenshots can be selected and printed.

➜ The screenshot is available for printout only when the icon has switched from camera to camera + printer

▲ The printout files may take some time to be generated.

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4.14 Transmission

Various data are available for transmission via several communication channels e.g. GSM/3G, Wi-Fi, USB-Ethernet and USB storage.

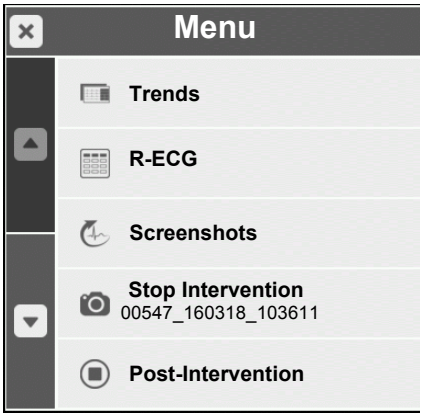
4.14.1 Selecting communication media Wifi or GPRS

To change the transmission media select the transmission icon Wifi or GPRS and select menu **Communication media**. Select Wifi or GPRS and the corresponding icon will be displayed on the top right status bar.

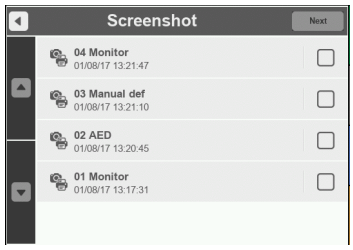
4.14.2 Transmission procedure

Ensure that a transmission line is connected to the device and that the required configurations in the **Control panel** menu have been made.

Transmitting R-ECG or Sreenshots



1. Enter the main menu and select **R-ECG or Sreenshots.**
2. Select one of the R-ECG records as example.



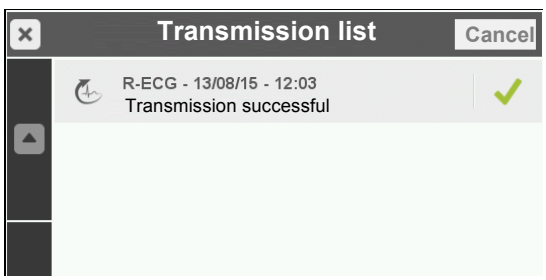
Transmission in progress

Transmission failed

Transmission successful

No connection to the WLAN or GPRS transmission channel. Transmission only to USB stick possible

3. Press the button next and select the desired transmission channel (GSM/3G, Wifi, USB/Ethernet or USB storage).
4. The transmission icon on the top right status bar shows the progress of the transmission.
5. Select the transmission icon to open the Transmission list.



If transmission of the data fails, the ECG/Screenshot file can be re-sent via the **Menu> ECG or Screenshots**

5 Defibrillation

This chapter applies only to the **DEFIGARD® Touch 7**.

5.1 Application guidelines and safety notes

Observe the following guidelines to ensure successful and safe defibrillation. Otherwise the lives of the patient, the user and bystanders are in danger.

⚠ DANGER

- The patient must:
  - **not** come into contact with the operator or other persons during defibrillation.
  - **not** come into contact with metal parts, e.g. bed or litter, or be positioned on wet ground (rain, accident in swimming pool), to prevent unwanted pathways for the defibrillation current, which may endanger the operator or assistants.
- Do not allow the defibrillation electrodes to come into contact with other electrodes or metal parts which are in contact with the patient.
- The patient's chest must be dry, as moisture causes unwanted pathways for the defibrillation current. For safety, wipe off flammable skin cleansing agents.
- Owing to the high currents, there is a risk of skin burns at the site of the electrodes. This is why the electrodes must not be placed on or above:
  - the sternum, clavicle or mamillas
- Immediately prior to the shock, the heart massage (CPR) and artificial respiration must be stopped and bystanders must be warned.
- Defibrillating a patient with an implanted pacemaker is likely to impair the pacemaker function or cause damage to the pacemaker. For this reason, do not apply the defibrillation electrodes in the vicinity of the pacemaker, have an external pacemaker at hand, and check the implanted pacemaker for proper functioning as soon as possible after the shock.

⚠ CAUTION

- Equipment damage! Sensors and devices that are not defibrillation proof must be disconnected from the patient before a shock is triggered.

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5.1.1 Additional safety information for AED Mode

In addition to the guidelines set forth in section 5.1, the following rules must be observed when using an AED, as failure to do so may compromise the success of the defibrillation or endanger the patient's life.

⚠WARNING

- ▲ The user is committed to verify the prerequisites for the use of the AED by checking for lack of consciousness, lack of breathing and lack of circulatory signs using the ABCD system (BLS algorithm).
- ▲ The device must only be used if the following symptoms are found:
  - non-responsive
  - no respiration
  - no pulse
- ▲ If, in the course of treatment, a patient spontaneously regains consciousness, a defibrillation shock that may have been advised just before must not be delivered.
- ▲ To ensure correct analysis of the heart rhythm, the patient must lie as still as possible and must not be touched, as artefacts may otherwise lead to incorrect analysis results.
- ▲ If the ECG signal changes such that the shock is not recommended, the shock delivery is automatically blocked in the AED mode.

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5.1.2 Defibrillating children/neonates

WARNING

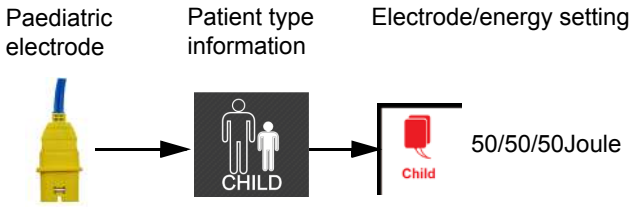
- Please note that less energy is needed for children:
  For the **first** defibrillation of infants and small children using biphasic shock, approx. 1 joule/kg body weight is released. An increase of 2 joules/kg body weight is possible when the defibrillation is repeated.
- For the defibrillation of children, the paediatric pads should be used.
- If no paediatric pads are available adult electrodes can be used when patient type "Child/Neonate" has been selected. Warning! Double check that the patient type setting and type of electrodes is "Child/Neonate". (see illustration **1** & **2** below).

CAUTION

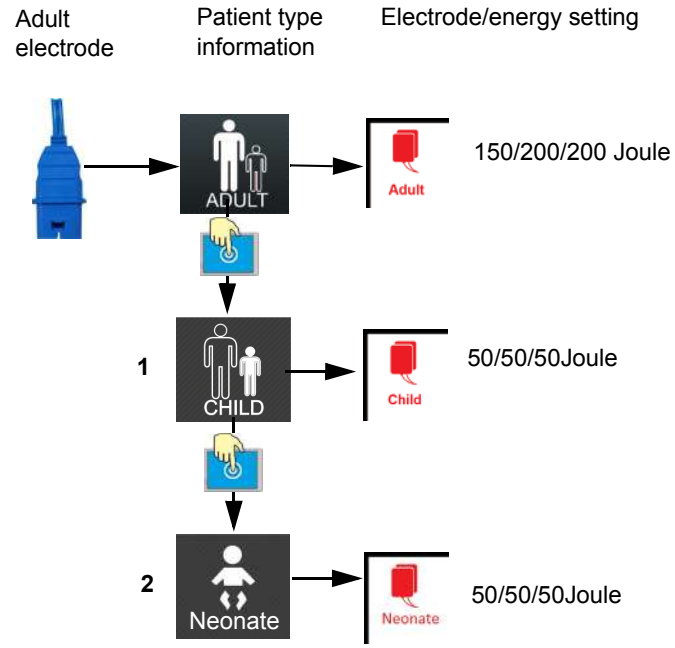
Defibrillation on neonates

- When using the defibrillator on neonates, follow the local guidelines.
- Follow the energy setting for infants and small children as described above.
- The automatic energy setting for neonates is the same as for children.

When paediatric pads are used, the patient type setting **Adult** or **Child/Neonate** on the screen **does not** overrule the energy setting: when paediatric pads are connected to the device, the energy setting is always paediatric.



If no children electrodes are available, adult electrodes can be used. When adult pads are used, the patient type setting "**Child/Neonate"** on the screen **does** overrule the energy setting Adult to "**Child/Neonate"**.



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5.2 General function

- The **DEFIGARD® Touch 7** works with biphasic truncated exponential chopped defibrillation waveform impulse. Depending on the factory settings, the device either switches automatically from synchronised to non-synchronized defibrillation or the mode has to be changed manually using the **Sync** button.
- When a patient cable is connected, you can select in the ECG menu if the ECG should be displayed via the separate ECG electrodes or the defibrillation electrodes.
- You can select a higher energy value while the defibrillator is charging. The device will charge to the new level. It is not possible, however, to reduce the charged energy. In this case, the stored energy will be discharged internally and you will have to recharge the defibrillator.
- The required energy for a successful defibrillation depends on several parameters (body constitution, etc.). For emergency medical treatment, AHA/ERC recommend a biphasic impulse. Depending on configuration settings, the energy of the 3 first shocks can be increasing.

Shock	Adults	Children
1	150 joules	50 joules
2	200 joules	50 joules
from 3	200 joules	50 joules

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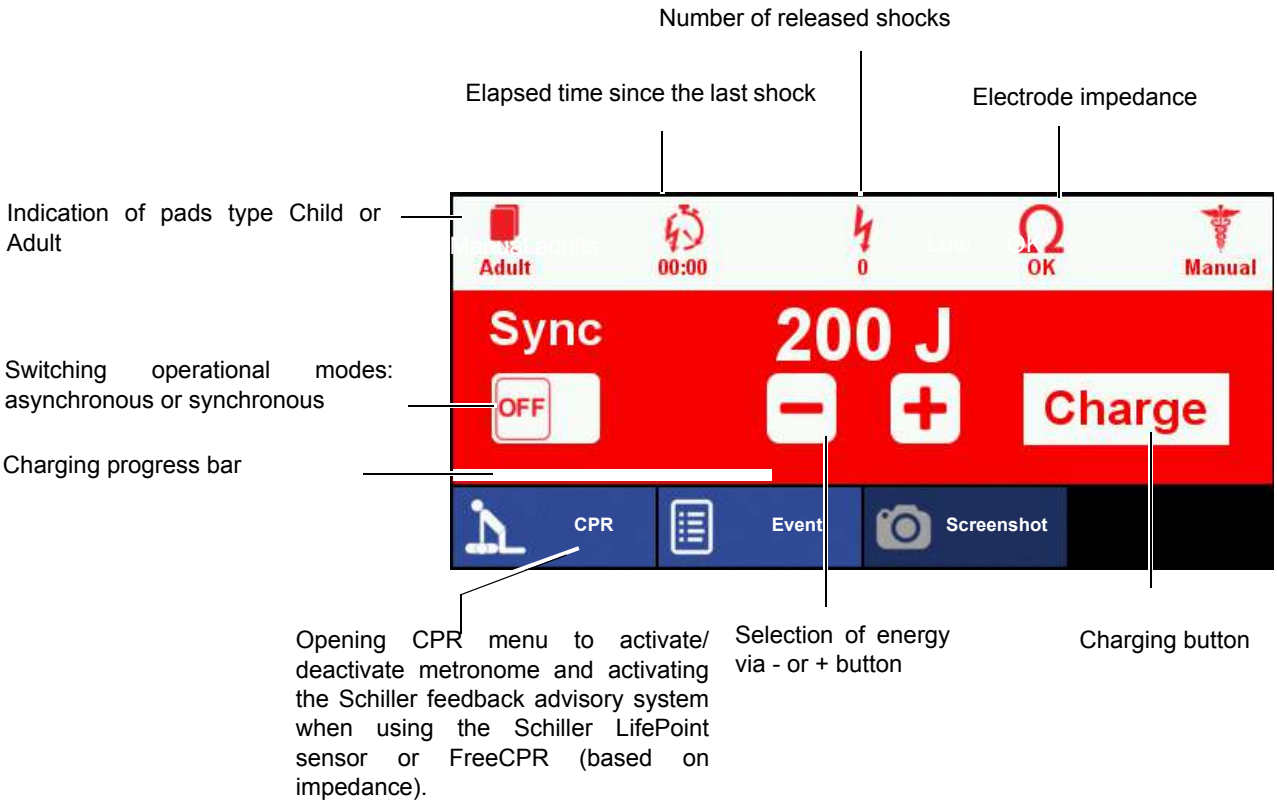
5.2.1 Activating the manual defibrillation mode

Depending on start-up configuration (performed by the administrator see 12.6.1 General configuration), the device can start in **Monitoring**, **AED** or **Manual Defibrillation** mode and confirmation is needed or not. Proceed as follows to activate the **Manual defibrillation** mode when the device does not directly start in manual defibrillation mode:

When the device starts in Monitoring  **or AED**  **mode:**

➜ Switch to manual mode by pressing the soft key **Manual Def** and confirm with **Yes**.



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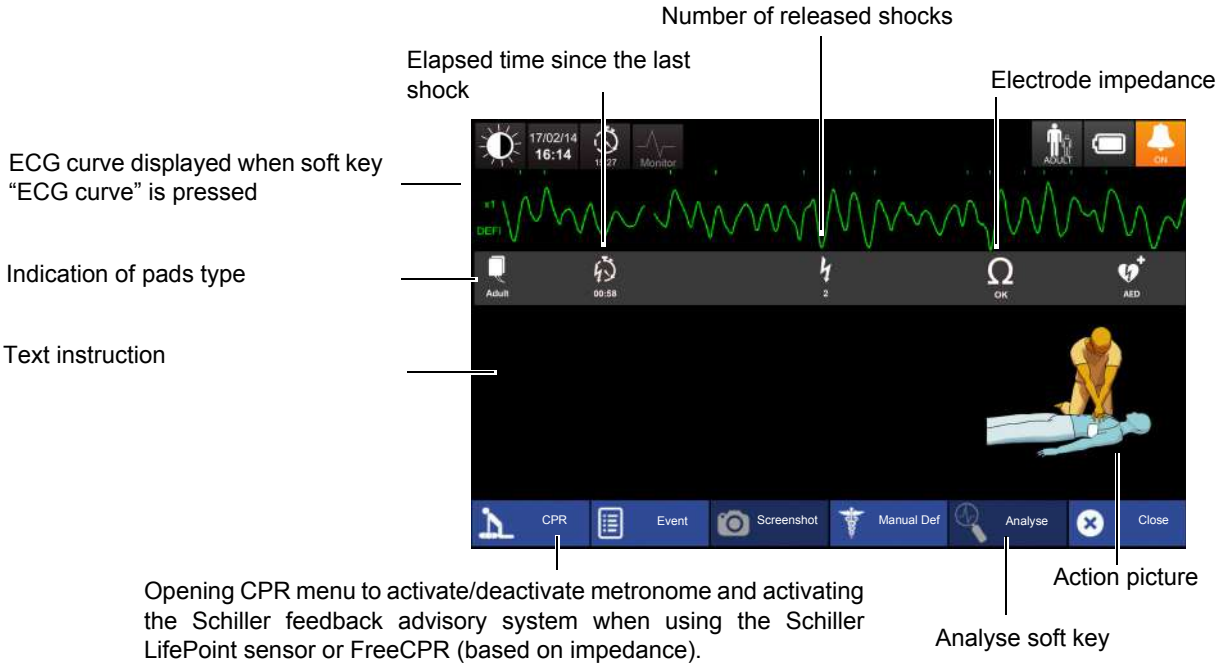
5.2.2 Activating the automated (AED) defibrillation mode

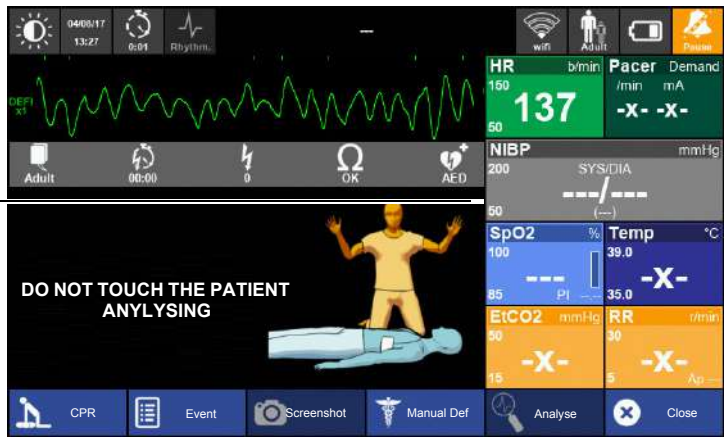
➜ Depending on start-up configuration (performed by the administrator see 12.6.1 General configuration) the device can start in **Monitoring**, **AED** or **Manual Defibrillation** mode. Proceed as following to activate the **AED** mode when device does not start direct in AED:

Monitoring  **and Manual Defibrillation** 

➜ Switch to AED mode by pressing the **AED key**.

In the AED operational mode, the alarm system remains active in the same state as in the monitoring operational mode.

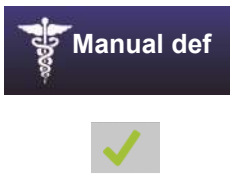




Same AED display as above but with parameter displayed at the right side. This view is defined by administrator configuration.

➜ Switching from the AED mode to Monitoring mode must be confirmed with Yes  . This depends on the device's configuration (see 12.6.1 General configuration)

5.2.3 Manual defibrillation procedure



1. Select manual defibrillation (see 5.2.1, page 82)

➜ Confirm switching to manual defibrillation (This depends on the device's configuration see 12.6.1 General configuration)

2. Select the required energy via the touch screen (button - or +).
3. Charge the energy using the "Charge" button.
4. Release the shock with shock button on the device.

Fig. 5.1 Defibrillator window

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5.3 Manual Defibrillation Using Pads

⚠ DANGER

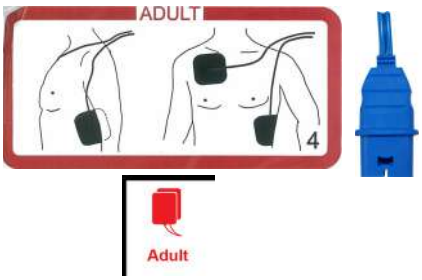
- ▲ Delivering a shock to a patient with normal heart rhythm may induce ventricular fibrillation. For this reason, first read the general rules and safety information in sections 5.1 and 5.2.
- ▲ Electric shock hazard. Turn off the device before exchanging the defibrillation electrodes; exchanging the electrodes on a charged defibrillator initiates an internal safety discharge.

5.3.1 Applying the adult and paediatric electrodes

⚠ CAUTION

- ▲ Only use the pads up to their expiration date. Please note that the indicated expiration date only applies if the vacuum pack is intact.
- ▲ The pads are pre-gelled, so there is no need to use extra contact agent.
- ▲ Do **not** reuse the pads.

Adult electrodes

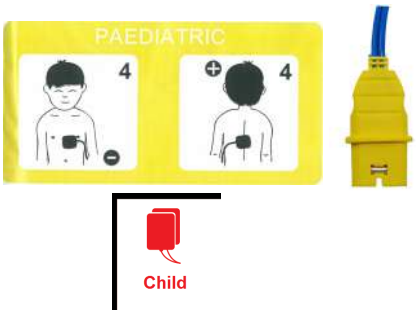


The adult electrodes with the blue connector are used for adults and children from 25 kg.

i

The adult electrode can be used for children when the patient type is set to “Child” (see 5.1.2 Defibrillating children/neonates page 80).

Paediatric electrodes



→ The paediatric electrodes with the yellow connector are used for children weighing less than 25 kg.The energy setting is automatically reduced (default 50 Joule) with the paediatric electrodes. The default can be set in the device’s configuration see 12.6.3 Defibrillator)

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5.3.2 Applying the electrodes

⚠WARNING

- ▲ Good contact between the skin and the adhesive electrodes must be ensured. Suntan oil, sand or salt reduce the adhesive quality.
- ▲ The applied pads must have good contact with the patient's skin, and air bubbles under the pads must be avoided. To do so, stick on one end of the pad then smooth it out to the other end.

Adults and children from 25 kg

Electrode placement is the same for adults and for and children weighing 25 kg or more (see Fig. 5.2 Adult electrode application sites and Fig. 5.3 Electrode application sites for children weighing 25 kg or more).

▲ The safety distance between the two electrodes should be approx. 3 cm.

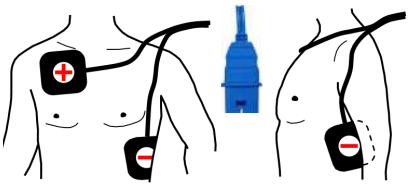

Fig. 5.2 Adult electrode application sites

1. Clean and dry the application points for the electrodes (see Fig. 5.2 Adult electrode application sites page 86/Fig. 5.3 Electrode application sites for children weighing 25 kg or more page 86). Only clean the skin by vigorously rubbing it with a dry cloth.
2. Apply one electrode above the right nipple. Do not apply it on the clavicle (uneven).
3. Apply the other electrode slantwise below the left breast as illustrated in Fig. 5.2 Adult electrode application sites page 86/Fig. 5.3 Electrode application sites for children weighing 25 kg or more page 86).
4. Make sure that the connections are positioned on the outside so that the cables do not hinder cardiopulmonary resuscitation (CPR).

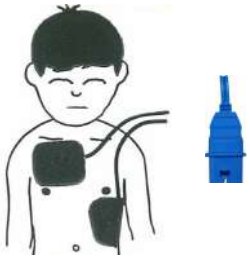

Fig. 5.3 Electrode application sites for children weighing 25 kg or more

Children weighing less than 25 kg

The energy setting is automatically reduced with the Paediatric electrodes.

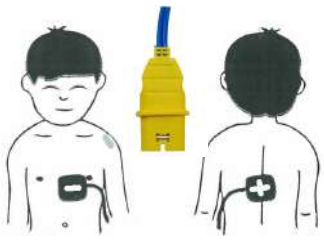

Fig. 5.4 Application sites for children less than 25 kg

1. Clean and dry the application points for the electrodes (see Fig. 5.4 Application sites for children less than 25 kg page 86). Only clean the skin by vigorously rubbing it with a dry cloth.
2. Apply one electrode on the left of the right nipple as illustrated in Fig. 5.4 Application sites for children less than 25 kg page 86
3. Apply the second electrode on the back on the same level as the chest electrode as illustrated in Fig. 5.4 Application sites for children less than 25 kg page 86.

Make sure that the connections are positioned on the outside so that the cables do not hinder cardiopulmonary resuscitation (CPR).

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5.3.3 Checking the electrodes

If the resistance between the skin and the electrodes is too high, the message "CONNECT THE ELECTRODES" (AED mode) or 

(Manual mode) is issued.
Proceed as follows:

1. Alternately press the electrodes/pads down firmly and check when the message disappears. Carefully press that pad onto the patient's skin once again.
   If the message does not disappear,
2. remove both defibrillation electrodes
3. wipe rests of contact agent off with a cloth
4. shave both application areas to remove the uppermost layer of skin
5. apply new defibrillation pads to these points.

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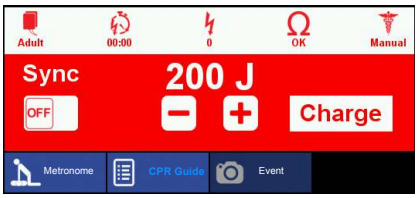
5.3.4 Manual Defibrillation Using Pads Procedure

1. Connect the electrode cable to the pads connector.
2. If the device starts in **Monitoring** or **AED** mode, proceed according to the description in chapter 5.2.1 Activating the manual defibrillation mode, page 82.



3. Select the energy via the touch screen +-.
4. Initiate the energy charging by pressing **"Charge"**.

⚠ DANGER

▲ Danger of electric shock!

- Do not, under any circumstances, touch the patient during shock delivery.
- Make sure that the patient does not touch any conducting objects.

5. Trigger the shock by pressing the button  .
6. Finish the therapy (see 7 Finishing the Therapy page 106).

Fig. 5.5 Manual defibrillation

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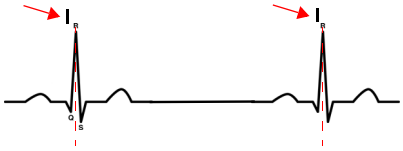
5.4 Synchronised defibrillation

5.4.1 Warning erroneous triggering

WARNING

▲ Erroneous triggering, interpretation hazard.
- For synchronised defibrillation, the ECG electrodes should be applied as far from the defibrillation electrodes as possible (e.g. on the limbs).
- Use only silver/silver-chloride electrodes, if you acquire the ECG via separate ECG electrodes. These electrodes prevent polarisation voltages which may be caused by the defibrillation shock, resulting in an ECG trace on the monitor screen or recording that simulates cardiac arrest.

▲ Disturbed ECG trigger signal! Signal noise may disturb the ECG signal and cause artefacts. This must be considered chiefly in the synchronised mode and in demand pacing. For this reason, the following should be observed:
- Do not touch the device during defibrillation to prevent electrostatic noise
- Keep the patient cable away from power cords, transformers etc.



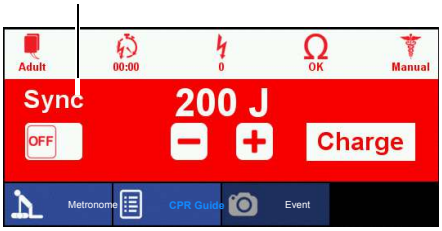
▲ To achieve adequate ECG signal quality for reliable triggering, ensure that
- the ECG signal is free of artefact
- there are no major fluctuations in amplitude
- the displayed trigger pulses are positioned exactly above the R-wave

5.4.2 Setup switching from synchronized to unsynchronized mode

WARNING

The synchronized mode **(1)** is manually activated (**Sync ON/OFF**). Depending on the factory setup, the synchronized mode stays activated after delivering the shock (Sync after sync shock =Yes) or switches back to unsynchronized shock (Sync after sync shock = **No**). The current setting must be communicated to the user.

1



▲ The default setting is “Sync after sync shock = **No**”:

➜ the manual activated synchronized mode will be **deactivated** after delivering a synchronized shock. To deliver a second synchronized shock, it is important to activate it again.

▲ If the admin setting is “Sync after sync shock = **YES**”:

➜ the manual activated synchronized mode is **maintained** after delivering a synchronized shock. To deliver a unsynchronized shock, it is important to deactivate it again.

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5.4.3 Function of the Synchronized Defibrillation Procedure

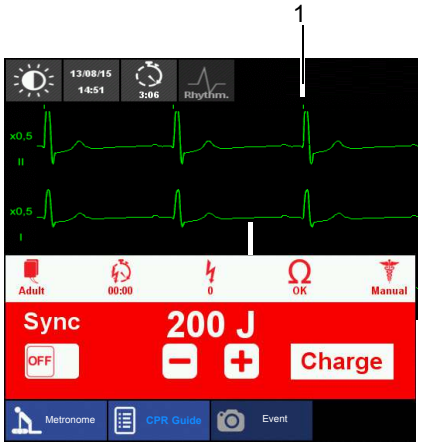
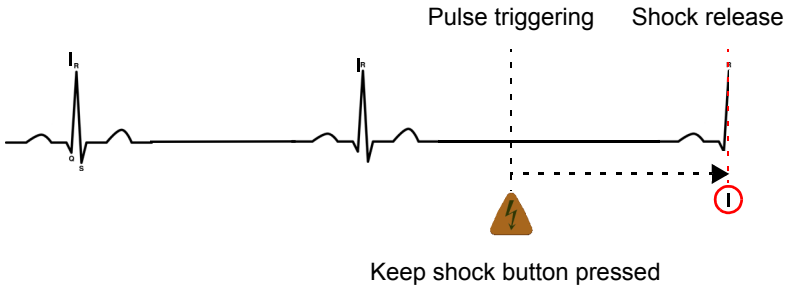


Fig. 5.6 Synchronised defibrillation

For synchronised defibrillation, the defibrillation shock is delivered in synchronisation with the heart action, as the heart is still working. As a prerequisite, the patient's ECG signal must be supplied to the defibrillator. After the physician has triggered the defibrillation shock, the trigger signal for the actual shock delivery will be derived from the subsequent QRS complex 25 ms after the trigger mark on the monitor screen **(1)**.



In case of absence of QRS, an internal discharge will occur in a delay of 20 – 30 seconds.

⚠ CAUTION

▲ Be aware that after initiation of the shock, the actual shock will be released with the next trigger signal (QRS) derived from the ECG. This may lead in a shock delivery delay time of 30 second.

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5.4.4 Synchronised defibrillation procedure

1. Connect the electrode cable to the pads connector.
2. If the device starts in **Monitoring** or **AED** mode, proceed according description chapter 5.2.1 Activating the manual defibrillation mode, page 82.

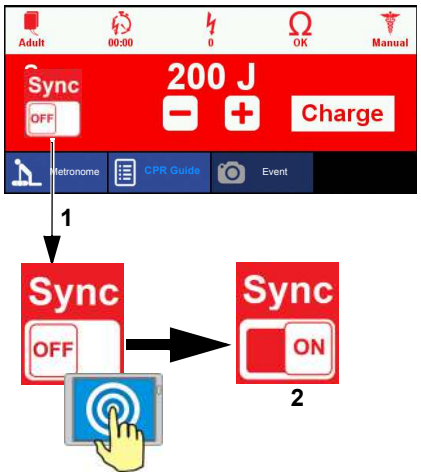

Fig. 5.7 Switching to synchronised defibrillation

3. Select synchronised defibrillation via the touch screen **(1).**
4. The setting **ON** (**2**) is displayed below the Sync label.
5. Check ECG rhythm:
   – the QRS beep sounds
   – the trigger pulses above the R-wave
6. Select the desired energy with the +/- button.
7. Charge the desired energy with the button **Charge.**
   As soon the defibrillator is ready for shock an audio signal sounds and the LED below the shock button is on.

➜ You have now 20 seconds to work through the points 8 to10, before the internal safety discharge is activated because of exceeding the time limit.

8. Check ECG curve, **SYNC (1) ON** and energy setting**.**

⚠ DANGER

9. Warning, electric shock!

- Do not, under any circumstances, touch the patient during shock delivery.
- Make sure that the patient does not touch any conducting objects.

10. Deliver the shock by pressing the button  ,

▲ Keep the button  pressed until the shock is delivered.

▲ Be aware that after initiation of the shock, the actual shock will be released with the next trigger signal (QRS) derived from the ECG. This may lead in a shock delivery delay time of 30 second.

11. After the shock is delivered, monitor the patient and the ECG signal.

▲ If the default setting is “Sync after sync shock = **No**” the synchronized defibrillation mode is switched back to OFF after delivering the shock.

12. If a second attempt is contemplated, return to step 4.

If an unsynchronized shock is required while in synchronized mode, it is possible at any time to switch the synchronized mode to OFF and deliver the shock immediately (unsynchronized).

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5.5 Semi-automated defibrillation

⚠ DANGER

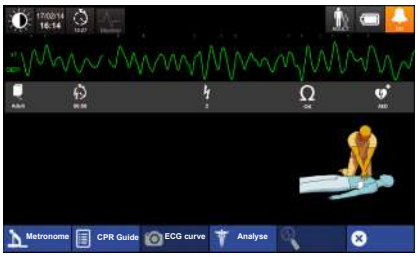
- ▲ Delivering a shock to a patient with normal heart rhythm may induce ventricular fibrillation. For this reason, first read the general rules and safety information in section 5.1, page 79.
- ▲ Electric shock hazard. Turn off the device before exchanging the defibrillation electrodes; exchanging the electrodes on a charged defibrillator initiates an internal safety discharge.
- ▲ According to AHA/ERC guidelines, even children under 8 year old may be defibrillated in semi-automated mode.
- ▲ In the semi-automated mode, the electrodes should be applied in the common anterior-anterior positions. With infants, anterior-posterior placement can be advised to prevent a short-circuit between the two defibrillation electrodes.
- ▲ If, in the course of treatment, a patient spontaneously regains consciousness, a defibrillation shock that may have been advised just before must not be delivered.
- ▲ During HF surgical interventions, ECG analysis is not permitted in the semi-automated mode.

5.5.1 Semi-automated defibrillation (AED) procedure

- In the AED operational mode, the patient is not under monitoring conditions.
- The switched off device can be started directly in AED mode by pressing the AED button  .

Depending on start-up configuration (performed by the administrator) the device can start in **Monitoring**, **AED** or **Manual Defibrillation** mode. Proceed as follows to activate the **AED** mode when the device does not directly start in AED mode:

→ Switch to AED mode by pressing the **AED key** and confirm with the **check box**.



When the AED mode starts, the spoken and visual instructions for the defibrillation are issued and the analyses will be running automatically as soon as the pads are applied. Closely follow the instructions.

→ Press the Monitor button  to leave the AED mode.

→ Switching from the AED mode to Monitoring mode must be confirmed with Yes  .

For qualified physicians only

The analysis can be repeated at any time during CPR by pressing the analysis button 

. CPR needs to be interrupted while the analysis is performed.

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5.5.2 Voice messages in AED Mode

WARNING

- ▲ The sequencing of AED instructions might be very fast and could cause confusion to the user because:
- ▲ The “Anteriority Analyse” feature pre-analyses the heart rhythm before the actual analysis. This feature can substantially reduce the duration of the analysis.

The following instructions will be spoken by the device:

Spoken instructions	Display	Note
Plug and apply electrodes	Illustration for electrode connection 	Technical alarm: Electrodes not yet applied. The message disappears as soon as the electrodes are correctly applied and the resistance is between 25 to 250 Ohm.
Do not touch the patient. Analysing	DO NOT TOUCH THE PATIENT ANALYSIS	
Movement detected - Analysis cancelled, resume CPR	Movement detected - Analysis cancelled, resume CPR	Technical alarm: Patient was moved during analysis and device could not run analysis.
Device recommends a shock		
Shock advised		
Stand clear of patient; press orange button	Stand clear of patient, press orange button TO SHOCK	
Device does not recommend a shock		
No shock advised	No shock advised.	
Immediately resume CPR: 30 chest compressions, then 2 rescue breaths – continue until patient is breathing normally.	30[a] CHEST COMPRESSIONS THEN 2 RESCUE BREATHS	

a. When paediatric electrodes are used, CPR is carried out in the ratio of 15:2 if 2 rescuers are on the spot, otherwise 30:2. A “continuous compressions" option is also available (i.e. no rescue breaths)

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5.5.3 Defibrillation procedure

When the device is switched on, spoken and displayed instructions are issued regarding the defibrillation. Closely follow the instructions.

Step 1

Switching on and preparing the device

Fig. 5.8 Switch unit on

1. Switch on the device by pressing the green button or the AED button directly.
2. Check the state of the patient.
3. Connect the electrode cable to the pads connector.
4. You are prompted to continue the resuscitation and to apply the electrodes.
5. Apply the defibrillation electrodes (see section 5.3.1 Applying the adult and paediatric electrodes page 85, page 85).
   The message **CONNECT THE ELECTRODES** is switched off as soon as the device measures an acceptable electrode resistance. If it is not switched off, see section 5.3.1 Applying the adult and paediatric electrodes page 85.

Step 2

Analysis

Fig. 5.9 Analysis

6. The analysis starts automatically when the electrodes are detected.
7. You are prompted not to touch the patient any more.
8. The analysis key can be pressed any time during CPR to start a new analysis.

If the device detects ventricular fibrillation or ventricular tachycardia with a heart rate exceeding 150 pulse/min, Step 3 shock delivery follows; otherwise continue with Step 4, Cardiopulmonary resuscitation, page 95.

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Step 3

Step 3 shock delivery

As soon as the energy for a shock is charged, the device prompts the user to deliver the shock by pressing button 3.

▲ Danger of electric shock!

- Do not, under any circumstances, touch the patient during shock delivery.
- Make sure that the patient does not touch any conducting objects.

9. Deliver the shock by pressing the button  .

   After the shock delivery, step **4** follows.

The following default energy values are programmed:

Shock	Adults	Children
1	150 joules	50 joules
2	200 joules	50 joules
3	200 joules	50 joules

Step 4

Cardiopulmonary resuscitation

10. Carry out cardiopulmonary resuscitation. Alternate between 30 chest compressions and 2 breaths[1] for 2 minutes[2]. After 2 minutes, the device begins again with Step 2, Analysis.
11. Finish the therapy (see page 106).

The CPR duration may vary according to country-specific standards (see page 110 Defibrillator ERC Protocol).

1. A "continuous compressions" option is also available (i.e. no rescue breaths)
2. CPR cycle duration can vary depending on the "CPR cycle configuration" settings.

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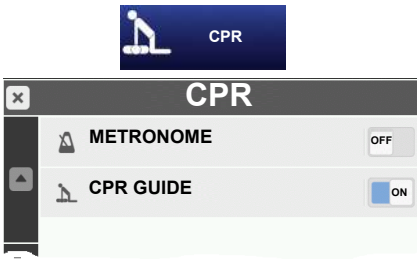
5.6 CPR Guide



The manual and AED defibrillation mode offers three functions for a guided CPR:

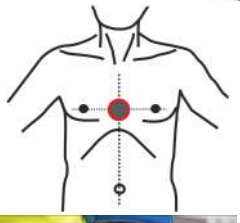
- CPR Guide with SCHILLER **LifePoint** sensor
- CPR Guide with **FreeCPR** based on the impedance measurement by the defibrillation electrodes
- Metronome

5.6.1 SCHILLER LifePoint

The LifePoint measures the compression depth and rate after each compression.

Measured value from LifePoint sensor

Advice to improve the CPR quality



1. Connect the LifePoint USB cable to the adapter cable.
2. Switch on the device and select manual or AED defibrillation.
3. Open the CPR menu and activate the CPR guide.
4. Place the LifePoint on the patient chest and start CPR.
5. The displayed measurements on the right side of the screen informs you about your CPR quality.
6. The following limits are set for speed and depth:

Metronome speed [/min]	Press Faster	Press Slower
100	≤ 90	≥120
110	≤ 100	≥130
120	≤ 110	≥140

Depth [mm]	Press Deeper	Press Shallower
1-127	≤ 45	≥ 62

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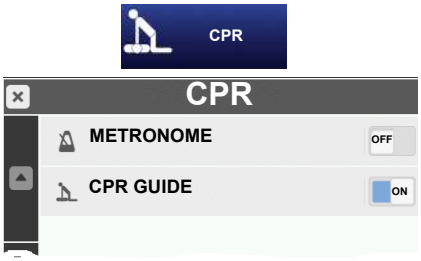
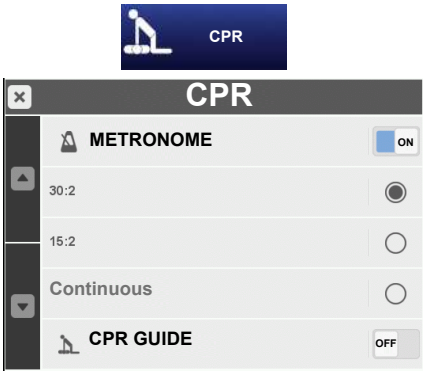
5.6.2 FreeCPR

- The FreeCPR measures the compression rate based on the impedance measurement by the defibrillation electrodes.



1. Switch on the device and select manual or AED defibrillation.
2. Apply the defibrillation electrodes.
3. Open the CPR menu and activate the CPR guide.
4. The displayed measurements on the right side of the screen inform you about the CPR quality and frequency.

5.6.3 Metronome settings



1. Open the CPR menu.
2. Activate the metronome.
3. The following settings are available:
   – 30:2
   – 15:2
   – Continuous

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5.7 Defibrillator Technical Messages

Alarm	Code	Cause	Remedy
Defibrillator inoperative	T.ECG11 T.DEFI01 T.DEFI02 T.DEFI03 T.DEFI04 T.DEFI05 T.DEFI06 T.DEFI07 T.DEFI10 T.DEFI13 T.DEFI14 T.DEFI15	• CPU peripheral board defective • Defi board defective	➜ Contact technical service
Incorrect electrodes	T.DEFI08 T.DEFI12	• Internal discharge while releasing shock “on impedance higher than 250 ohm” or if the current during the shock is 0 or above 105 A, because of poorly placed electrodes	➜ Check electrodes, if necessary re-apply electrodes
Internal discharge duration too long	T.DEFI09	• A shock that is not delivered within the specified duration causes an internal discharge.	➜ Do not exceed the time of 20 seconds till releasing the shock ➜ Contact technical service
Internal discharge smaller energy	T.DEFI11	• Internal discharge because of selecting lower energy after the device charged the selected higher energy	➜ Normal safety discharge

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6 Pacemaker

6.1 Pacemaker Function

The pacemaker is the module for external transcutaneous stimulation of the heart.

The pacemaker offers two modes of operation, demand and fixed-rate pacing. In demand mode, the pacemaker requires an ECG signal for synchronisation.

The same, large adhesive electrodes used for defibrillation are also employed for pacing. They ensure good electrical contact with the skin. These electrodes and a 20 ms square-wave pulse reduce painful muscle contractions provoked by excessive current density.

Pacer rate, pulse width and current are checked when the device is turned on and during operation; therefore, a functional test of the pacemaker module is not necessary.

6.1.1 Fixed-rate mode (Fix)

In this operating mode, the module delivers pacing impulses with the user-defined current at a user-defined rate. The selected rate remains constant and is not affected by intrinsic actions of the patient's heart. This mode is mainly used in the case of asystoles.

6.1.2 Demand mode

In demand mode, the pacemaker does not deliver pacing pulses as long as the patient's intrinsic heart rate exceeds the set pacing rate. When the heart rate drops below the pacing rate, the pacemaker starts emitting stimulation pulses. This can only be ensured by continued monitoring of the ECG with a 4- or 10 -lead patient cable. The pacemaker reads the necessary ECG signal via the pads. If the module is not able to reliably identify QRS complexes, it will stimulate the heart permanently in demand mode.

The demand mode is the recommended pacing mode when the patient is at risk of developing bradycardia or even asystole as a result of a critical event. As the pacemaker function is controlled by the patient's ECG, the harmful competition between intrinsic and external stimulation, which could induce ventricular fibrillation, is excluded.

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6.2 Safety Notes

⚠WARNING

▲ **Shock hazard!**
Never touch the pads or the patient's body near the pads while the pacemaker is in use.

⚠ CAUTION

▲ **Patient hazard, equipment failure**!
Equipment delivering electrical energy to the patient at the same time as the pacemaker can disturb the pacemaker function. Particularly HF surgery equipment used on a pacemaker patient may cause interference, preventing the detection of QRS complexes. In this situation, the pacemaker must be set to fixed-rate pacing (FIX). Also please note that leakage currents could be transferred to other electric circuits, interfering with the functioning of devices connected to these circuits.

▲ For safety reasons, the external pacemaker should be disconnected from the patient in this situation and an internal pacemaker should be used.

▲ Accessories, wearing parts and disposables that affect the safe use of the pacemaker and that are to be used in conjunction with the pacemaker must be tested for safety and approved by an authorised test laboratory.

6.3 Guidelines for the Application of External Pacemakers

These guidelines apply to all pacemakers, irrespective of type and manufacturer.

All electrical devices that deliver energy to patients in any form or have an electrically conductive connection to the patient are a potential source of danger.

As the user is responsible for the safe application of the devices, observance of the instructions given in the user manual and of the guidelines below is of utmost importance.

▲ Pacemakers must only be used under the supervision of trained, qualified and authorised staff.

▲ Observe the user guide for the pacemaker's operation.

▲ The patient must not be left unattended during pacing.

▲ It is assumed that the patient's ECG and plethysmogram is being monitored to be able to assess the effect of pacing.

▲ When positioning the patient, take care that no electrically conductive connections exist between the patient and earthed metal parts (puddles of water, for instance, are capable of conducting the electrical current). Although the pacer current output is required to be floating, this is an additional safety precaution to ensure that the pacemaker current pulse flows only between the pacemaker electrodes.

▲ Set all values for the pacemaker to position 0, or the lowest value.

▲ Position stationary pacemakers close to the patient.

▲ After each defibrillation, check that the pacemaker is functioning properly.

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6.3.1 Attaching the pacer pads

- The same adhesive electrodes used for defibrillation are also employed for pacing.

The electrodes are designed for:

- 1 hour of pacing using 140mA / 120p/min (pulse duration 20ms)
- 8 hours of pacing using 70mA / 60p/min (pulse duration 20ms) with inspection of pads every 30 minutes
- 10 minutes of pacing using maximum energy and frequency output (150mA / 210p/min)

A detailed application of electrodes is given in section 5.3.1 Applying the adult and paediatric electrodes page 85.

Anterior-posterior placement

1. Apply the dorsal electrode **(+)** to the left scapular area and the precordial electrode **(-)** near the left lower sternal edge.
2. Connect the pads to the device.

If the dorsal electrode cannot be used, apply anterior-anterior placement.

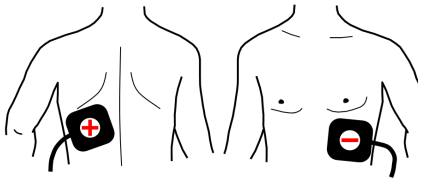

Fig. 6.1 Anterior-posterior placement

Anterior-anterior placement

1. Apply the "+" electrode on the right side below the clavicle and the "-" electrode to the left of the axillary line on a level with the 5th intercostal space so they do not hinder heart massage.
2. Connect the pads to the device.

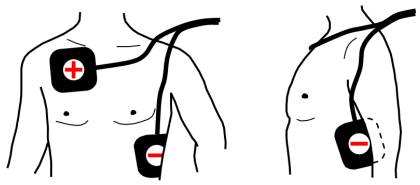

Fig. 6.2 Anterior-anterior placement

6.3.2 Checking the electrodes

If the resistance between the skin and the electrodes is too high, the message

“CONNECT THE ELECTRODES” Ω BAD is issued.

Proceed as follows:

1. Alternately press the electrodes/pads down firmly and check when the message disappears. Carefully press that pad onto the patient's skin once again.
   If the message does not disappear,
2. remove both defibrillation electrodes
3. wipe rests of contact agent off with a cloth
4. shave both application areas to remove the uppermost layer of skin
5. apply new defibrillation pads to these points.

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6.4 Start-up of the Pacemaker

WARNING

▲ **Shock hazard!**
Pacing is started immediately when the pacemaker is switched ON and the current is set.

In order to be able to operate the pacemaker, the following conditions must be met:

- the pacemaker (optional) needs to be activated.
- Pads must be connected to the device.
- When the pacemaker is switched on, the current value is set to 10 mA.
- The device can be switched from pacing to defibrillation mode at any time. The pacemaker is stopped by confirming the switchover.
- The device can be switched from pacing to monitoring mode at any time. In this case, the pacemaker screen is displayed as small measurement field at the top right.
- If the pacemaker function is **OFF** and closed by pressing the **Close key**, the frequency and current settings are reset.
- Pressing the monitoring  or **Close key** will minimize the pacemaker window (pacing is still running).
- When pacemaker is started only "Monitoring advanced" and "Critical care" views are available.

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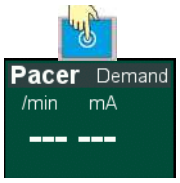
6.4.1 Pacemaker display



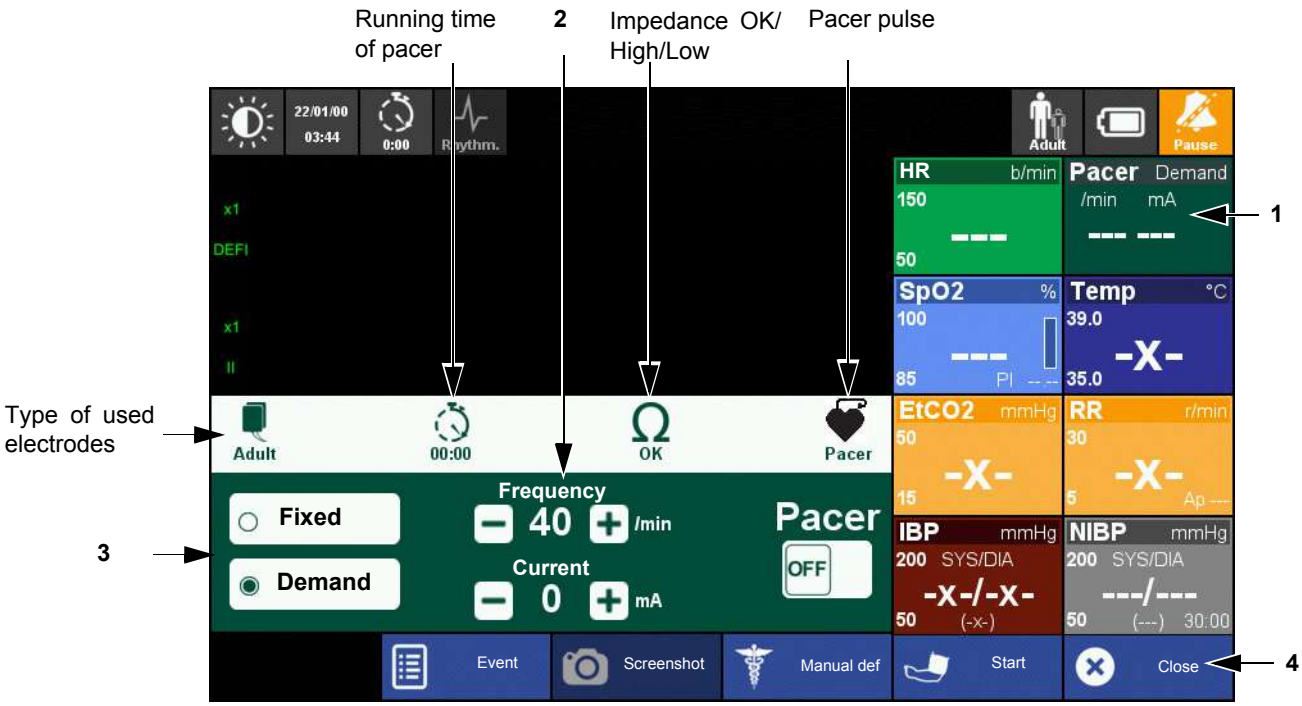
- Select the **Pacer** measurement field at the top right to display the pacemaker function.

The pacemaker menu with the pacemaker parameter is displayed.

The pacemaker default mode at switchover is “**Demand**” mode; the “**Fix**” mode has to be selected manually.

6.4.2 Selecting pacemaker mode

1. Press the Pacer measurement field **(1) to open the Pacer menu (2).**
2. Press operational mode **Fix** or **Demand (3)**
3. The operational mode is displayed in the pacer measurement field **(1)**



4. When the pacemaker is running, press **Close (4)** or switch to monitoring with the

monitoring key.

In this case, the pacemaker values are displayed as small measurement field **(1)** at the top right and the curve field shows again all curves.

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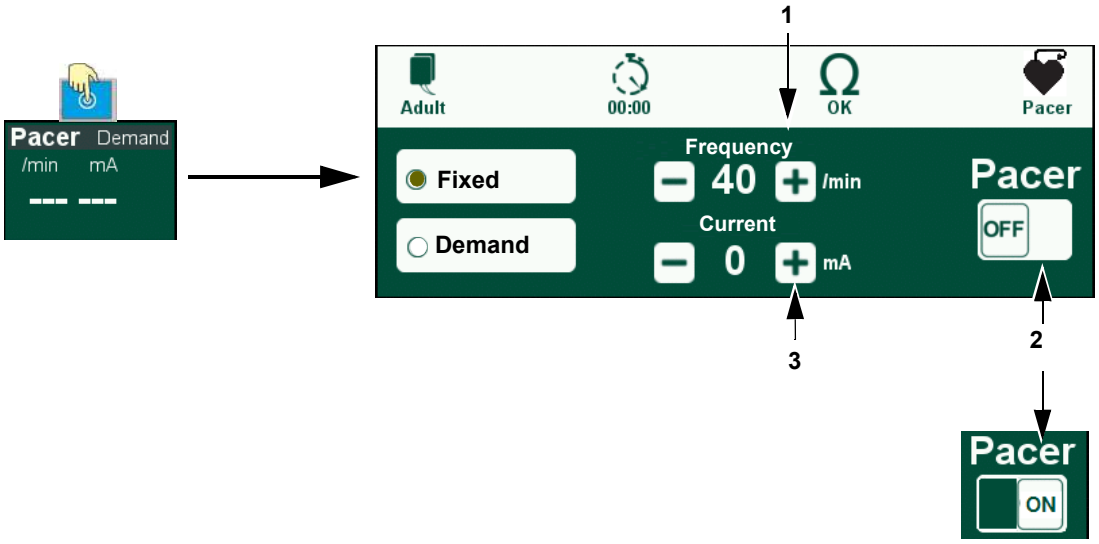
6.4.3 Pacemaker settings operational mode fix

1. Attach the pacer pads (see 101).
2. Display pacemaker and select operational mode Fix.
3. Select **(1) Frequency +-** to set the impulse frequency.



WARNING

▲ **Shock hazard!**
Pacing is started immediately when the pacemaker is switched ON and the current is set.

▲ Never touch the pads or the patient's body near the pads while the pacemaker is in use.

4. **Starting the pacemaker!**
Press the **Pacer OFF/ON (2)** to activate the pacemaker.
5. Press the **(3) Current +- mA** to set the impulse current until the heart reacts to the stimulation.
6. The pacemaker can be interrupted and restarted by selecting the **Pacer OFF/ON**.
7. Finish the therapy as described in section 7 Finishing the Therapy page 106.

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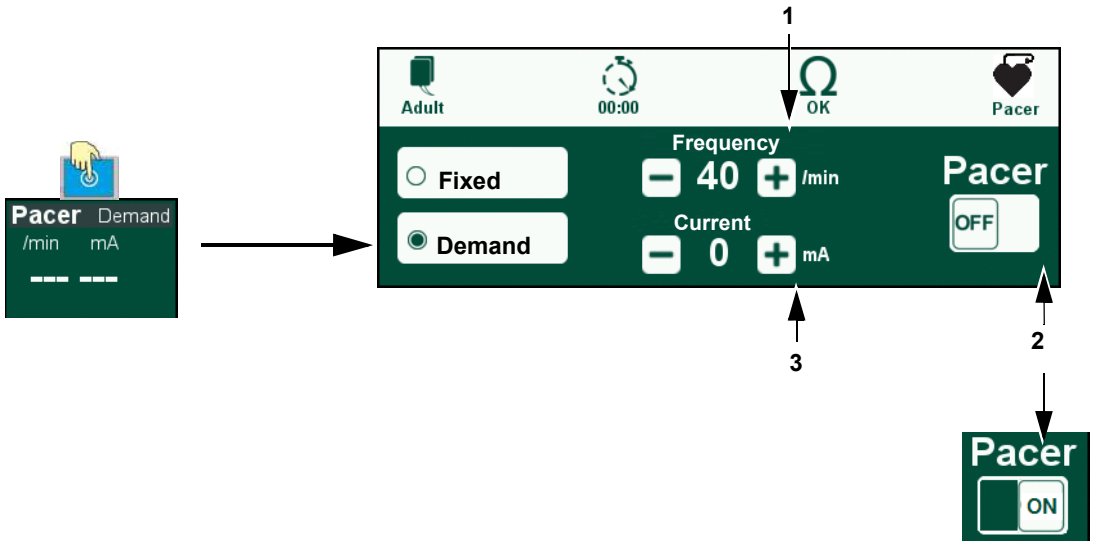
6.4.4 Demand Mode

To determine when a pacemaker pulse is required, the patient ECG must be monitored with a 4- or 10-lead ECG cable.

1. Attach the pacer pads (see 101).
2. Display pacemaker and select operational mode Demand.
3. Select **(1) Frequency +-** to set the impulse frequency.



WARNING

▲ **Shock hazard!**
Pacing is started immediately when the pacemaker is switched ON and the current is set.

▲ Never touch the pads or the patient's body near the pads while the pacemaker is in use.

4. **Starting the pacemaker!**
Press the **Pacer OFF/ON (2)** to activate the pacemaker.
5. Press the **(3) Current +- mA** to set the impulse current until the heart reacts to the stimulation.
6. The pacemaker can be interrupted and restarted by selecting the **Pacer OFF/ON**.
7. Finish the therapy as described in section 7 Finishing the Therapy page 106.

6.4.5 Switching from pacemaker to defibrillation

1. Press the AED key.
2. Use the same key to confirm stopping the pacemaker and switching to defibrillation mode.

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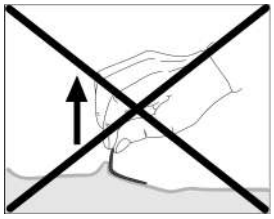
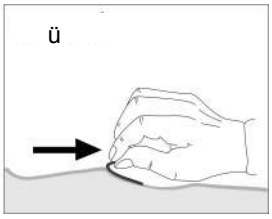
7 Finishing the Therapy

1. Switch the device off as soon as the therapy is finished by pressing the button  .The dialogue No/**Yes** is displayed.
2. Confirm switch-off.
3. Disconnect the electrode cable.

Adhesive electrodes

– Carefully remove the electrodes from the patient's skin.





– Discard the disposable pads immediately after use to prevent their reuse (hospital waste).

– Clean the device, ECG cables and sensors as described in section 10.6.2 page 119).

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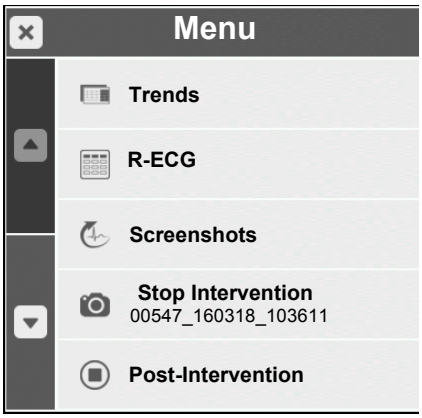
8 Intervention summary

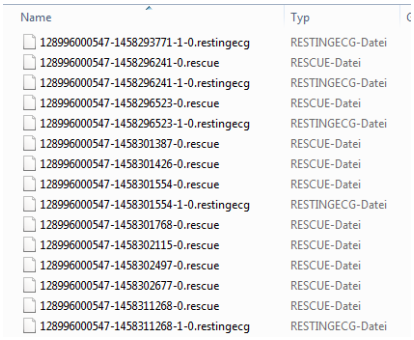
In order to document the intervention, the intervention data is saved.

The information can be read and displayed with the Schiller reviewing software or viewed directly on the device

- If the memory is full, the oldest data will be overwritten.
- The intervention data is stored as soon the device is switched off or the intervention has been stopped with the function “**Stop Intervention**” in the main menu.
- “**Stop Intervention**” is also used to start a new intervention.
- The data will be stored until the data has been transmitted via the menu “Post-Intervention”.
- All intervention data (R-ECG, Screenshots and Trends) can be reviewed and transmitted on the device via the menu <**Post-Intervention**> see next page.



Overview of events documented with date and time in the “rescue.file”:



- Power on
- Start of analysis
- Analysis result
- Defibrillator charging
- Defibrillation shock
- Internal discharge
- Switchover to manual operation
- Electrode alarm
- "Battery low" alarm
- Activation of a vital signs module
- Deactivation of a vital signs module
- Asystole alarm (manual mode)
- Fibrillation/flutter alarm (manual mode)
- Event button
- ECG curve

The “RestingECG.file” includes the resting ECG data.

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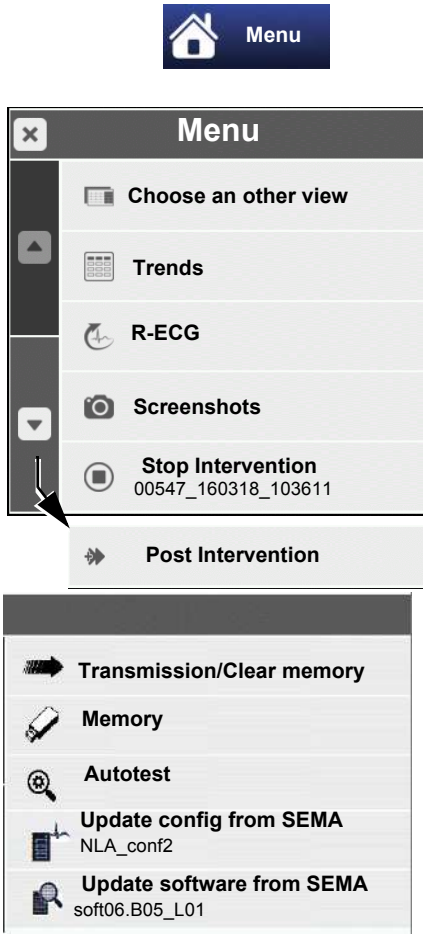
8.1 Post-intervention

Exiting this menu is only possible by switching off-on the device.

8.1.1 Reviewing intervention file on the device



1. To review the intervention data directly on the device, go to the main menu and select “Post-intervention.
2. Stop the patient monitoring. The Post-Intervention menu is displayed.
3. Select “Memory” to display the intervention list.
4. Select desired intervention.
5. For each intervention you can review, print or send the following data:

Data	Review	Print	Send
R-ECG	X	X	X
Screenshot	X	X	X
Trends	X	-	-
Intervention report	-	X	-

For each intervention it is also possible to printout a full intervention report composed of patient data, Trend table, first ECG, auto screenshots (Pacer ON/OFF, shock), last ECG.

Intervention report contains following elements:

- Intervention and patient details
- Trends table (15 columns max with adaptive intervals)
- ECG events (25 max)
  - 1st ECG
  - Issued shocks (1st, 2nd, 3rd and last shock)
  - Pacemaker On/Off
  - Last ECG

8.1.2 Transmitting the intervention file

1. To review/sending the post intervention data go to the main menu and select “Post-intervention.
2. Stop the patient monitoring. The Post-Intervention menu is displayed.
3. Select Transmit/Clear the memory to send all intervention data via Network or direct to USB memory stick.

8.1.3 Autotest

An autotest can be executed after a finalised intervention to check the performance of the device. Additionally, the autotest report can be viewed or sent via Network or directly to a USB memory stick.

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9 Main Menu

9.1 General setup

For the monitoring of vital parameters, physiological alarm thresholds are preset in the DEFIGARD/PHYSIOGARD Touch 7, which are activated when the device is turned on. The operator-defined thresholds (wide/narrow) can be set in the respective menus (see page 40, section 4.3);

1. Press the **Menu** soft key. The menu is displayed.

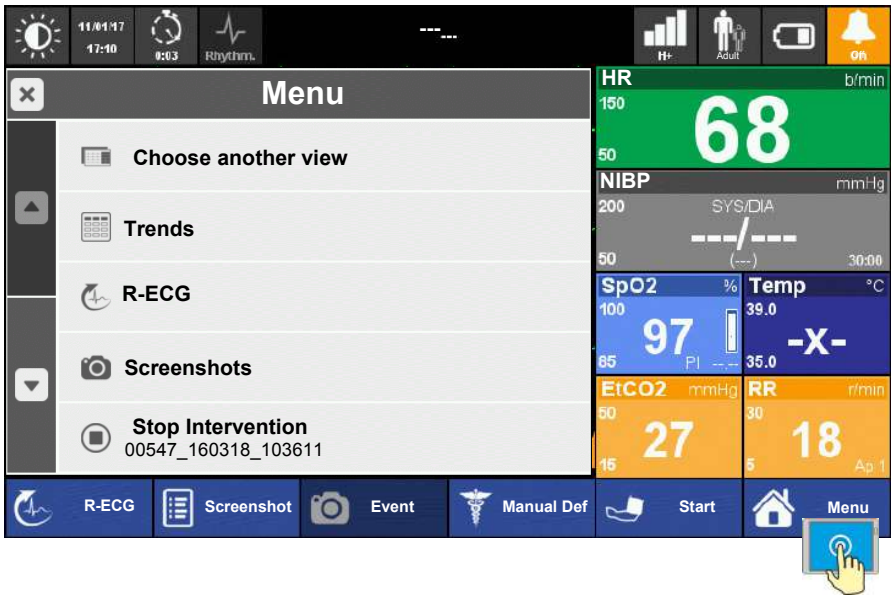

Fig. 9.1 Main menu

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9.1.1 Device Settings Menu 

Access the device settings menu via the menu button.

Menu	Sub-menu/Parameter	Description	Note
Choose another view	• Advanced monitoring • Basic monitoring • 12 leads ECG • Critical care	Selection of different view according users needs	The selection is depending on the configuration of the device
Trends	• ----	Shows the trend since the start of the intervention	see page 75, section 4.13.1
R-ECG	• Selecting R-ECG	List of the recorded R-ECG since the interventions starts	see page 75, section 4.13.2
Screenshots	• Selecting Screenshot	List of the screenshots done since the start of the intervention. The screenshot can be displayed, transmitted or printed.	see page 76, section 4.13.3
Stop Intervention	• Yes/No	Yes stops the recording of all data, saves data under the intervention file and resets the Stop-watch on the screen to zero. A new intervention is started.	The stopped intervention can be reviewed/transmitted in the Post-intervention menu. The number under the Stop Intervention parameter shows the Intervention ID with date and time.
Post- Intervention Exiting “Post-Intervention menu” only by switching off the device possible.	• Transmission/Clear memory	Transmission/Clears memory of all intervention files.	
	• Memory	Memory of all intervention files since the last clearing. The file can be reviewed via this menu.	see page 107, section 8.
	• Autotest	Running an autotest to confirm the functionality after finishing an intervention.	
	• Update config from SEMA	Download the configuration from the Schiller update server. The line below the parameter shows the current configuration file name.	
	• Update software from SEMA	Download the software from the Schiller update server. The line below the parameter shows the current software.	
	• Current version information	Shows actual installed software versions and configured options	
Control panel **(Password protected)** **Default password: schiller**	• Device Name	Entering of the a device name	Exiting “ Control panel menu” only by switching off the device possible.
	• Import/export Config – import from USB – Import config. from SEMA – Export to USB		Exiting “ Control panel menu” only by switching off the device possible.

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Menu	Sub-menu/Parameter	Description	Note
	• Software update – Update from USB – Search on server – Current version information		Exiting " Control panel menu" only by switching off the device possible.
	• Maintenance – Safety cell replaced – RFID Flasher – RFID Tag info – Export log to USB – Format log file – Format memory – Start auto test	Once the safety cell has been changed, press this button. Manual start of the Auto Test	Exiting " Control panel menu" only by switching off the device possible.
	• Ethernet config. – DHCP ON/OFF – Radius ON/OFF	If set to OFF: IP address Netmask Gateway DNS1-3 Server If DHCP is set to ON	
	• Check connectivities – Check SEMA connectivities – Check SUS connectivities	Select one of the desired communication channels GSM/ 3G or Wi-Fi for checking. ➜ Activates the connectivity check for SEMA ➜ Activates the connectivity check for SUS	
Language	• List of available languages	Select the desired language for the current use.	The language setting here is only for the current use. Once the device is switched off, it will use again the default configuration.

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10 Maintenance

10.1 Maintenance interval

Note

The unit must be serviced on a regular basis. The test results must be recorded and compared with the values in the accompanying documents.

Maintenance work described in this chapter may be performed by a qualified technician or by the user according to the Maintenance and Interval Table below.

The following table indicates the intervals and responsibilities of the maintenance work required. Local regulations in your country may stipulate additional or different inspection intervals and tests.

10.1.1 Maintenance Interval Table

Interval	Maintenance	Responsible
Before or after each use, respectively	**Life-saving functions - check the following:** • Visual inspection of the device and accessories (see section 10.2.1) • Switch on the device and make sure that both batteries are sufficiently charged (see section 10.2.2). **After every intervention** • Visual inspection of the device and accessories (see section 10.2.1). • Battery check (see section 10.2.2) • Button test (see sections 10.2.3) • Auto Test in the Post intervention menu (see section 10.2.4)	→ User
Monthly	• Functional test charging capacitor (see section 10.2.4)	→ User
Every 12 months	• Measuring and safety checks and inspections according to the instructions in the service handbook • NIBP check • ECG check • SpO_2 check • IBP check • EtCO2 Gas span check • Defibrillator function check (only **DEFIGARD® Touch 7**)	→ Service staff authorised by SCHILLER
Lifed item replacement	**The following parts must be checked and replaced if necessary** • Replace the power battery, see section 10.4.1. • Replace the safety cell (see expiring date or when device switches of immediately when replacing power battery) • Replace the internal button cell (every 10 years) • Replace the defibrillation capacitor (if the released energy [Joule] deviates more than 15 % from the intended value) only **DEFIGARD® Touch 7**	→ Service staff authorised by SCHILLER

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10.1.2 Service/Shelf life

Device The device has a lifetime of 10 years.

Accessories shelf life Power battery (approx. 5 years), safety cell (approx. 7 years), button cell (approx. 10 years) and electrodes (approx. 2 years), see expiring date on the battery or electrodes pouch. EtCO2 accessories see expiring date on the packaging.

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10.2 Functional test

A detailed description of the maintenance steps is listed in table 10.8. Enter the results in the check list on page 122.

10.2.1 Visual inspection of the device and accessories

Check the device and accessories for the following:

- ➜ Sufficient number of all required disposables available?
- ➜ Device housing undamaged?
- ➜ Electrode connection undamaged?
- ➜ Defibrillator / pacemaker pads available?
- ➜ Check the expiration date on the electrode package, battery and safety cell.
- ➜ Check the expiration date invasive blood pressure kit
- ▲ Defective units or damaged cables and damaged or expired accessories must be replaced immediately.

10.2.2 Battery check

- ➜ Connect the unit to the power supply (docking Station) and switch it on. The start screen is displayed.
- ➜ The external DC voltage indicator  is lit.
  - When the battery indicator is  **flashing,** the battery is being charged. Check the charging status once the indicator goes off.
  - The battery indicator  is **off** when the battery is fully charged - the full battery symbol  is displayed. The charging process can be reactivated and checked by disconnecting shortly from the external DC supply; indicator  is flashing.

Battery status

- ➜ Click on the Battery icon and check the following status:
  - Charge level
  - Estimated autonomy
  - Estimated numbers of shocks
  - Safety Cell Voltage Level

10.2.3 Defibrillator key test

1. Switch on the device. If the device starts in AED mode press the button Manual Def.
2. Use the button "**-**" to set the energy to 2 joule; then use the button "**+**" to set the energy to 4 joule.
3. Press the Charge button. Device is charging. Shock key is lit.
4. Press the Shock key - a safety discharge is triggered.
5. Press the AED key - spoken instructions are issued and the pads connector LED is flashing.

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10.2.4 Auto Test

The Auto Test can be executed any time and checks the most important function of the device.

1. Switch on the device
2. Select **Menu > Post-Intervention > Auto Test**
3. Start the auto test.
4. If message “Press shock button” appears, press the button to continue and finalizing the test.

Previous tests are listed in the sub-menu “Review/send previous tests”.

10.2.5 Functional test - measured values

Heart rate → Perform the functional test according to section 4.4.5 page 45 and verify the heart rate with the measured pulse rate of the SpO2.

SpO2 → This test is performed on a volunteer (finger measurement; section 4.6.3, page 52).

NIBP → This test is performed on a volunteer (arm measurement; section 4.7.1, page 57)

Manometer Test

See technical manual 0-48-0245_NT_DGTouch7_ANG

IBP This test only includes the connection between the sensor and the Touch 7, and the Zeroing function.

1. Connect the sensor to the Touch 7 according to section 4.8.1 page 59.
2. Perform a “zeroing according to section 4.8.4 page 61.
3. Zeroing is shown on the display.

CO2 Mainstream Perform the functional test according to section 4.10.3 page 65.

CO2 Sidestream Perform the functional test according to section 4.11.2 page 71.

10.2.6 Alarm tests

Alarm volume Check during the following tests that the alarm sound is higher than 65 dB.

Heart rate

1. Start the ECG monitoring (see section 4.4.5, page 45).
2. Set the alarms with the narrow quick set function (see section 4.3, page 40).
3. When the measured value exceeds the alarm thresholds, an alarm is issued.
4. Reset the alarm limits to their original values.

SpO2 See section 4.6, page 50.

NIBP

1. Start the NIBP monitoring (see section 4.7.1, page 57).
2. Set the NIBP alarm limits below/above the measured values and take a new measurement.
3. When the measured value exceeds the alarm thresholds, an alarm is issued.
4. Reset the alarm limits to their original values.

CO2

1. Start the CO2 monitoring according to section 4.10.3 page 65 or 4.11.2 page 71
2. Set the alarms with the narrow quick set function (see section 4.3, page 40).
3. When the measured value exceeds the alarm thresholds, an alarm is issued.

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4. Reset the alarm limits to their original values.

If the device does not behave as described in this user guide, there is an error that must be repaired by the after-sales service.

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10.3 Update Software

▲ Software updates must only be performed by authorized personnel.

Select **Menu > Control Panel > Software update.**

This function is only used for updating the software.The software can be updated via Wifi (update Server) or USB interface (memory stick).

10.3.1 Update via USB

The USB stick needs to have a memory of at least 32 MB.

1. Connect the USB stick.
2. Switch on the device and make sure that it is connected to the DC supply or that the battery is charged sufficiently. The device must not switch off during the update!
3. Select the parameter **Software update** and start the update by selecting the desired update source. During update, a progress bar is displayed.
4. As soon as the update is finished, the device switches off.
5. Switch the device on again and enter the **Menu > Control Panel > Software update > Current software version** to verify that the software has been installed.

10.3.2 Update via Server

The device initiates by itself regularly or on schedule a connection to the server to check for available updates.

Required accessories

- Wifi or GSM/3G connection to the update server.

Update

1. Switch on the device and make sure that it is connected to the DC supply or that the battery is charged sufficiently. The device must not switch off during the update!
2. Select the parameter **Software update** and start the update by selecting the desired update source. During update, a progress bar is displayed.
3. As soon as the update is finished, the device switches off.
4. Switch the device on again and enter the **Menu > Control Panel > Software update > Current software version** to verify that the software has been installed.

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10.4 Maintenance interval of the batteries

Important

- The battery's performance and life largely depend on how and under which ambient conditions the battery is used.

Power Battery

- The rechargeable power battery is maintenance-free during its normal life.
- The battery must be replaced according the expired date on the battery, regardless of whether or not the unit has been used.
- Only store fully charged batteries. If a battery is not used, recharge it every 6 months.

Safety primary cell

- The safety primary cell is maintenance-free during its normal life.
- The safety primary cell must be replaced according the expired date on the Cell, regardless of whether or not the unit has been used.

10.4.1 Replacing the batteries

Replacing the power battery:

The power battery needs to be replaced if the operating time in monitoring mode is less than 1 hour with a fully charged battery (see chapter 10.2.2 Battery check)

Replacing safety primary cell:

Check in the menu if safety cell is OK. (see chapter 10.2.2 Battery check)

10.4.2 Battery disposal

WARNING

- ▲ Danger of explosion! Battery may not be burned or disposed of with domestic refuse.
- ▲ Danger of acid burns! Do not open or heat up the battery.

The battery is to be disposed of in municipally approved areas or sent back to SCHILLER Médical.

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10.5 Cleaning

Cleaning removes dust, dirt and stains; however, this does not constitute a disinfection. Use commercially available detergents intended for clinics, hospitals and practices.

10.5.1 Detergents

Please refer to the manufacturer's information regarding the detergents.

Admissible detergents

- 70 % isopropyl alcohol
- Neutral detergents
- Soap water
- All products that are suitable for ABS plastic

Non-admissible detergents

Never use products containing the following:

- Ethyl alcohol
- Acetone
- Hexane
- Abrasive cleaning powder
- Plastic-dissolving products

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10.6 Disinfection

Use commercially available disinfectants intended for clinics, hospitals and practices to disinfect the device.
Wipe disinfection removes certain bacteria and viruses. Please refer to the manufacturer's information.

10.6.1 Disinfectant

Admissible disinfectants

- Isopropyl alcohol 70%
- Propanol (70-80 %)
- Ethyl hexanal
- Aldehyde (2-4 %)
- Ethanol (70-80 %)
- all products that are suitable for ABS plastic

Non-admissible disinfectants

Never use products containing the following:

- Organic solvents
- Ammonia-based detergent
- Abrasive cleaning agents
- 100% alcohol, Virex, Sani-Master
- Sani-Cloth®, Ascepti® or Clorox® wipes
- HB Quat®
- Conventional cleaner (e.g. Fantastic®, Tilex® etc.)
- Conductive solution
- Solutions or products containing the following ingredients:
  - Acetone
  - Ammonium chloride
  - Betadine
  - Chlorine, wax or wax compound
  - Ketone
  - Sodium salt

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10.6.2 Cleaning and disinfecting the device, cable and sensors

⚠WARNING

- ▲ Remove the battery and close the cover before cleaning. See section 3.2 Switching off and disconnecting from the external DC supply page 31.
- ▲ Do not immerse the unit nor the cable or sensors in liquid and do not sterilise them!
- ▲ Do not apply tension to the sensor cable.
- ▲ Do not use aggressive cleaners.
- ▲ Do not use any phenol-based agents or peroxide compounds for cleaning.
- ▲ Reusable sensors must be treated as biologically dangerous material after usage and sterilised according to the manufacturer's instructions.
- ▲ Observe the manufacturer's notes when cleaning the sensors and cables.

1. Disconnect the device from the mains and remove the plug and sensors.
2. Wipe the equipment, cable and sensors with a dampened cloth and a mild cleaning solution. The manufacturer recommends using 70% alcohol.
3. Dispose of single-use sensors and protective coverings according to the relevant regulations.

Notes on the cleaning and disinfection

NIBP cuff The manufacturer recommends using 70% alcohol to clean and disinfect the NIBP cuff and tube.

SpO_2 sensor The manufacturer recommends using 70 % alcohol to clean the cable and sensor. Dry the sensor before reuse.

ECG cable The cable can be wiped with a mild cleaning agent or with 70 % alcohol.

CO2 sensors The IRMA probe can be cleaned using a cloth moistened with ethanol or isopropyl alcohol (< 70 %).

The ISA sidestream gas analyzers and the Nomoline Adapter may be cleaned using a cloth moistened (not wet) with max 70% ethanol or isopropyl alcohol.

To prevent cleaning liquids and dust from entering the ISA gas analyzer through its sampling gas inlet connector, keep the Nomoline Family sampling line fitted while cleaning the analyzer.

10.7 Disposal at the end of the device's useful life

This unit must be disposed of in a municipally approved collection point or recycling centre when no longer used.

If no such collection point or recycling centre is available, you can return the unit to your distributor or the manufacturer for proper disposal. In this way, you contribute to the recycling and other forms of utilisation of old electrical and electronic equipment.

Improper disposal harms the environment and human health due to the presence of dangerous substances in electrical and electronic equipment.

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10.8 Inspection and Checklist Tables

In accordance with the maintenance interval detailed previously, the following check list should be copied and followed.

Checking life-saving functions

The following tests (sections 10.8.1 to 10.8.3) need to be performed before or after each intervention, respectively. Enter the results in the check list.

- Visual inspection of the device and accessories (see section 10.2.1).
- Battery charging status (see section 10.2.2).
- Button test (see sections 10.2.3)
- Auto Test in the Post intervention menu (see section 10.2.4)

Year	Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
	Jan.																															
	Feb.																															
	Mar.																															
	Aprl.																															
	May																															
	June																															
	July																															
	Aug.																															
	Sept.																															
	Oct.																															
	Nov.																															
	Dec.																															

10.8.1 Monthly

- Functional test charging capacitor with maximum energy. This is done with the **Auto test** function (see section 10.2.4)

Month	Date	Periodic test results OK	Periodic test results NOT OK
1		o	o
2		o	o
3		o	o
4		o	o
5		o	o
6		o	o
7		o	o
8		o	o
9		o	o
10		o	o
11		o	o
12		o	o

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10.8.2 Every 12 months

Inspection	Results	Inspection				
Functional, safety checks and inspections						
➜ Confirm the date of the last factory inspections and tests	• Return the unit to your nearest authorised service point or your SCHILLER agent for safety and functional checks.	o	o	o	o	o
	Date of inspection:					
	Inspector:					

10.8.3 Lifed-item replacement every 5 - 10 years

Inspection	Results	Replacement				
Battery						
➜ Replace battery	• The battery needs to be replaced:					
	– when the operating time is less than 1 hour, see section 10.4.1.	o	o	o	o	o
	– Replace the safety primary cell (see expiring date or when device switches of immediately when replacing power battery)	o	o	o	o	o
	– Replace the internal button primary cell (every 10 years)	o	o	o	o	o
	Date of replacement:					
	Inspector:					
Defibrillation capacitor						
➜ Replace defibrillation capacitor	• Send the unit to your nearest SCHILLER service centre for capacitor replacement if the defibrillation capacitor deviates more than 15 % [joule] from the intended value.	o	o	o	o	o
	Date of replacement:					
	Inspector:					

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10.9 Error Detection

⚠ CAUTION

▲ If a technical alarm is still present at shut down a reminder is displayed.

▲ If it is not possible to get the device back into operating condition within a reasonable period of time, continue cardiopulmonary resuscitation.

Forced shutdown procedure

▲ If it is not possible to get the device back into operating condition, follow this procedure:

➜ Press and hold the green button until the device has switched off. Then switch on again.

10.9.1 General errors

Error	Cause	Remedy
The screen is not lit when the device is switched on	• Battery not inserted correctly or defective • Battery empty • The device is defective	➜ Insert battery correctly or replace it ➜ Connect to the power supply (docking Station) and charge battery ➜ Replace device
Device cannot be switched off	• Software hangs • The device is defective	➜ Keep the green button pressed for at least 10 seconds. ➜ Replace device
No analysis	• ECG signal too weak • ECG signal interference through electromagnetic waves • Patient moved or touched during analysis • The device is defective	➜ Perform cardiac massage again ➜ Turn off source of signal interference. e.g. radio equipment or cell phone, or move patient outside field of interference ➜ Do not move or touch patient during analysis ➜ Replace device
Unable to deliver shock (**DEFIGARD® Touch 7**)	• Battery too low • Electrode error caused by resuscitation measures • Heart rhythm has changed • The device is defective	➜ Change batteries ➜ Reapply electrodes ➜ Run new analysis ➜ Replace device
Battery is not being charged	• Temperature in the device or battery too high	➜ Let device cool down, if possible; charging is continued once the temperature has reached an acceptable level.

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10.9.2 Technical Information and Error Messages

Alarm	Cause	Remedy
CPU BOARD INOPERATIVE	• T.CPU01 • T.CPU02 • T.CPU03 • T.CPU04 • T.CPU05 • T.CPU06 • T.CPU07	➜ Replace device
BACKUP BATTERY EMPTY	• T.CPU08 • T.CPU09	➜ Replace device
SAFE BATTERY EMPTY	• T.CPU10 • T.CPU11	➜ Replace device
LOW POWER BATTERY	• T.CPU12	➜ Replace device
POWER BATTERY EMPTY	• T.CPU13	➜ Replace device
POWER BATTERY CHARGE FAILURE	• T.CPU14	➜ Replace device
ECG INOPERATIVE	• T.ECG01 • T.ECG02 • T.ECG03 • T.ECG04 • T.ECG05 • T.ECG06 • T.ECG07 • T.ECG08 • T.ECG09 • T.ECG10	➜ Replace device
DEFI INOPERATIVE(**DEFIGARD® Touch 7**)	• T.ECG11	➜ Replace device

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10.9.3 Measures to prevent electromagnetic interferences

"Non-ionic electromagnetic radiation"

The user can help avoid electromagnetic disturbances by keeping the minimum distance between portable and mobile RF telecommunication devices (transmitters) and the DEFIGARD/PHYSIOGARD Touch 7. The distance depends on the output performance of the communication device as indicated below.

HF source	Transmitter frequency [MHz]	Power P [W]	Distance d [m]
Radio telephone (microcellular) CT1+, CT2, CT3	885-887	0.010	0.23
Cordless DECT telephone, WLAN, UMTS phone	1880-2500	0.25	1.17
Mobile phone USA	850/1900	0.6	1.8
Mobile phone - GSM900, - GSM850, NMT900, DCS 1800	 900 850,900,1800	 2 1	 3.3 2.3
Walkie-talkie (rescue service, police, fire brigade, service)	81-470	5	2.6
Mobile telephone system (rescue service, police, fire brigade)	81-470	100	11.7
RFID (active and passive transponders and reading devices)	433 865-868	0.5	0.85 1.62

It can be deducted from the table that **portable** RF telecommunication devices must not be used within a radius of 3 m from the device and its cables.

⚠ CAUTION

▲ However, there is no guarantee that no interference can occur in certain installations. If the DEFIGARD/PHYSIOGARD Touch 7 causes interferences, these can be prevented by switching off the device.

Further measures to prevent electromagnetic interferences:

The user can take the following measures to prevent electromagnetic interferences:

- Increase distance to the source of interference.
- Turn the device to change the angle of radiation.
- Connect the device to a different mains connector.
- Only use original accessories (especially patient cables)
- The device should not be used adjacent to or stacked with other equipment.

For more detailed information, please refer to page 156.

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11 SCHILLER Charging Unit CS-1

⚠ CAUTION

- ▲ The batteries supplied are rechargeable Lithium-Ion 4.65 Ah batteries. Only use rechargeable batteries supplied by SCHILLER.
- ▲ We recommend that the batteries are replaced every 1000 charge / discharge cycles.

i In battery slot 1, the battery can also be calibrated.

The charging unit is optional.

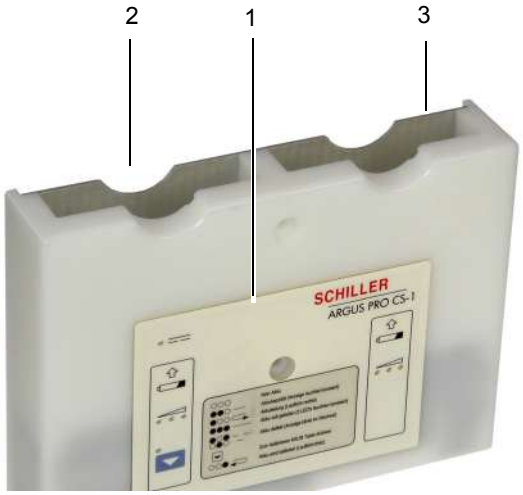
11.1 Battery Charging Options

The following options are available to charge the batteries:

- Batteries can be removed and charged using the optional charging unit SCHILLER CS-1 (see following).
- The DEFIGARD/PHYSIOGARD Touch 7 batteries are also charged when the DEFIGARD/PHYSIOGARD Touch 7 is connected to the external power supply.

11.2 Inserting a battery

- Insert the battery in the charger unit and push home until the battery clicks in place with the blue catches.
- To remove a battery, press the two blue catches to release it.



i The charger has double contacts and a battery can be inserted in either way.

(1) Control/indicator panel
(2) Battery slot 1 - only this slot can be used for battery calibration.
(3) Battery slot 2.

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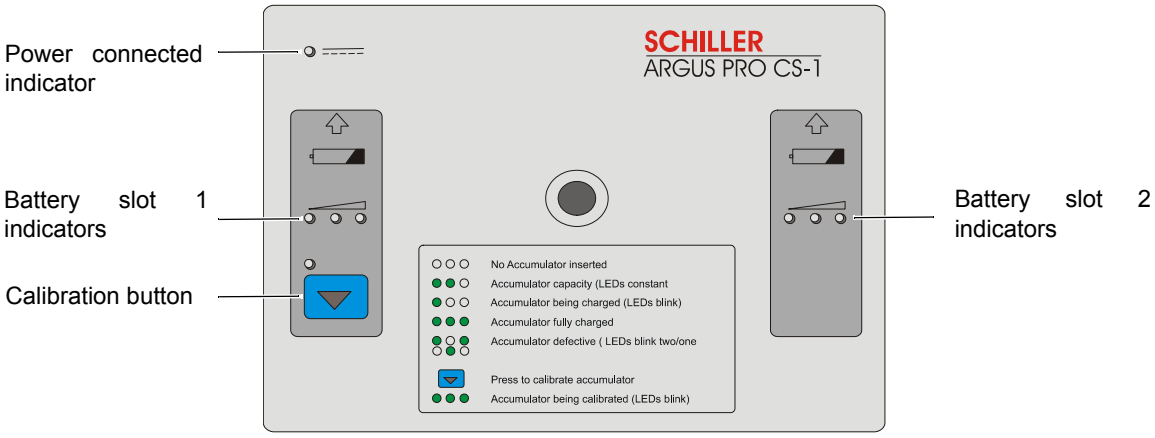
11.3 Control Panel



The LED indicators give the following information:

LED	Function
○ ○ ○	**No LEDs lit** - No battery inserted.
● ● ○ ——	**Constant display for 5 seconds** - When a battery is first inserted, one, two or three LEDs are lit for 5 seconds. This indicates the battery charge state (1 LED = 1/3 capacity, 2 LEDs = 2/3 capacity and 3 LEDs = 100% capacity).
● ○ ○ →	**LEDs are flashing in sequence (left to right)-** After 5 seconds of a battery being inserted, the charge sequence starts.
● ● ● ——	**All LEDs lit** - battery fully charged.
○ ○ ● ←	**LEDs are flashing in sequence (right to left) -** battery being calibrated (see page129).
● ○ ● ○ ● ○	**LEDs blink two/one in sequence** - faulty battery.

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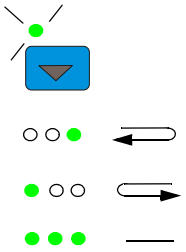
11.4 Battery Calibration

Every battery has an individual calibration and capacity circuit. The DEFIGARD/ PHYSIOGARD Touch 7 uses this information to display the battery capacity. New batteries are factory calibrated before use and should not need recalibrating during their normal life cycle. If a battery seems to have a low capacity or is near the end of its life, it may need recalibrating.

Calibrate a battery as follows:

1. Place the battery in the left battery slot of the charger.
2. Press the **Cal** key to start the calibration procedure. The stages to calibrate a battery are as follows:
   - The battery is completely discharged.[1]
   - The battery is charged and calibrated.



The calibration cycle takes approximately 2.5 - 5 hours to complete - the full charge cycle (after full discharge) takes approximately 2.5 hours. During the calibration process:

- The LED above the calibration key is lit.
- To indicate the discharge cycle the three indicators LEDs blink in sequence - right to left.
- When the discharge cycle is finished, the three indicators LEDs blink in sequence left to right to indicate the charge cycle.
- When the calibration is successfully completed, all LEDs are lit and the LED above the calibration key is extinguished.

If for any reason the battery cannot be calibrated, the LED above the **CAL** key is flashing. This indicates that the battery cannot be calibrated and the battery should not be used any longer.

The calibration process can be stopped at any time, by again pressing the **Cal** key.

1. The power stored in the battery to be calibrated is transferred by ‘dynamic power distribution’ to the battery in the other slot, or used for any connected device, so that no energy is wasted.

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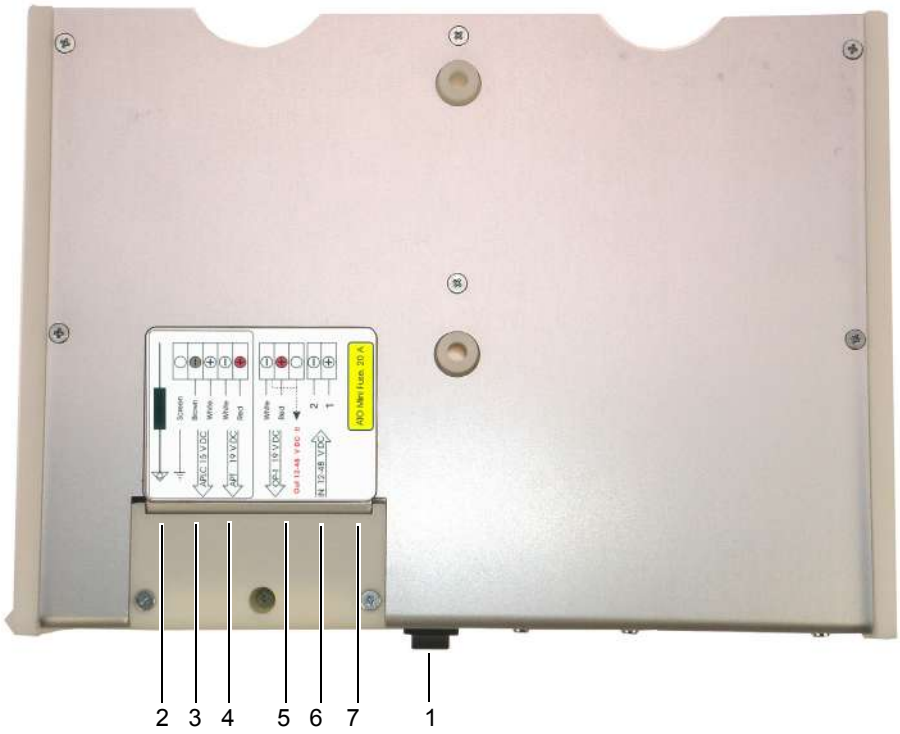
11.5 Input and Output Supplies

The SCHILLER CS-1 Charging Unit has the following input and output power supplies:



(1)	On / Off switch	
(2)	Potential equalisation (to vehicle common earth). Yellow/Green Cable.	
(3)	Power output **(do not use)**	15 V
(4)	Spare power output to docking station 8...48 VDC **(do not use)**	19 V
(5)	Spare power output to docking station 8...48 VDC **(do not use)**	19 V fix or 12 V to 48 V
(6)	DC IN from vehicle power supply	12 V to 48 V DC
(7)	Fuse	5 x 20 mm, 20 A

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12 Technical Data

Data refer to standard testing conditions.

Technical data about the defibrillation (chapter 12.2) applies only to the **DEFIGARD® Touch 7**.

12.1 System data

Manufacturer	SCHILLER MEDICAL
Device type	**DEFIGARD® Touch 7 & PHYSIOGARD® Touch 7**
Dimensions	160 x 250 x 70 mm (h x l x w) without bag
Weight	3.3 kg with battery and bag for **DEFIGARD® Touch 7** 2.9 kg with battery and bag for **PHYSIOGARD® Touch 7**
Protection case	IP 55
Power supply DC/DC	**Ambulance bracket**
Input	10.8 till 17.6 VDC
Output	15 VDC/4.0 A
Power supply AC/DC (desktop charger and ambulance bracket)	Type XP Power Model: AHM85PS15 Medical grade switching power supply, protection class I.
Input	100 - 240 VAC, max. 1.0 A, 50-60 Hz
Output	15 VDC, max. 5.67 A
Power battery	
Battery type	Lithium/ion 11.1 V, 4.65 Ah, 51.6 Wh
Autonomy	100 shocks with maximum energy or >6 hour monitoring
Charging time	90 %: 2 hours after full discharge and device switched off
Safety primary cell	Ensures continued monitoring for approx. 30 seconds when replacing the power battery
Battery type	Lithium/MnO2, 6 V, 1.4 Ah
Environmental conditions	
For operation	• 0 ºC ... 40 ºC relative humidity at 15 - 95 % (non condensing) Atmospheric pressure 700...1060 hPa • If higher or lower temperatures prevail during use, a limited operation time of up to **1 hour** is possible, if device has been stored previously at room temperature. See next page “environmental conditions for transient operation”

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Environmental conditions	
For transient operation	Operation in NORMAL USE for a period not **more than 20 min** under the following environmental operating conditions: • a temperature range of - 20 °C to + 50 °C; • a relative humidity range of 15 % to 90 %, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa. Operation in NORMAL USE for a period of **1 hour** under a temperature range of - 10°C to + 50°C;
Environmental conditions	
For Transport and storage between uses	• - 40 °C to + 5 °C without relative humidity control; • + 5 °C to + 35 °C at a relative humidity up to 90 %, non-condensing; • > 35 °C to 70 °C at a water vapour pressure up to 50 hPa; after having been removed from its protective packaging and subsequently between uses.
Time for warming up/cooling down	• 30 minutes; Time required for the DEFIGARD/PHYSIOGARD Touch7 to warm or cool from the minimum/maximum storage temperature between uses until the DEFIGARD/ PHYSIOGARD Touch7 is ready for its intended use when the ambient temperature is 20 °C.
MIL STD 810G	Device was tested in accordance with: • MIL STD 810G Method 501.5 Procedure III • Tactical-standby to Operational (+60°C) • MIL STD 810G Method 502.5 Procedure II Operation (-26°C).
Environmental conditions Defibrillation electrodes	
Storage	• 0 ºC...50 ºC
Storage max. 10 days	• -40 ºC...75 ºC
Display	
Type	• High-resolution colour LCD capacitive touch screen, protected by tempered glass
Dimensions	• 7 “ (154 x 85.92 mm)
Alarm sound level	65 dBA for medium and high priority alarms
Connections	ECG patient cable, SpO_2, NIBP, Temperature, CO2, IBP
Interfaces	USB

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Memory	24 hours memory (FIFO) Recording of Defi, ECG Lead II, Impedance curves, Events, CPR feedback, patient data, patient vitals, screenshots
Safety standard	IEC/EN 60601-2-4 The device is designed for intensive use
EMC	• IEC/EN 60601-1-2 • IEC/EN 60601-2-4 • CISPR 11 class B The device can be exposed to the following interferences without any impairment: • Static discharges up to 15 kV • Field strength up to 20 V/m in the radio frequency range of (80...2500 MHz, 5 Hz modulated) • Magnetic fields of 100 A/m, 50 Hz
Conformity	CE according to directive 93/42/EEC class IIb
Protection class	Class I according to IEC/EN 60601-1

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12.2 Defibrillation Waveform

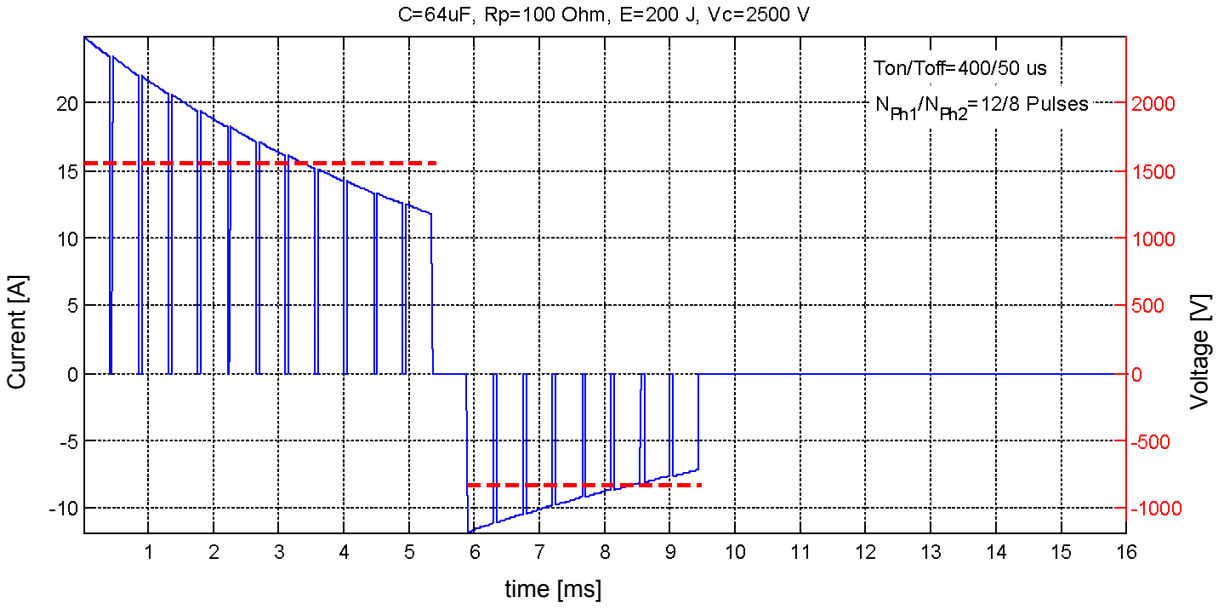
The chapter 12.2 applies only to the **DEFIGARD® Touch 7**.

Form

- Biphasic pulsed defibrillation waveform with fixed physiological optimum phase durations
- Near stabilisation of the emitted energy in function with the patient resistance using pulse-pause modulation depending on the measured patient resistance (duty cycle 80%).

Curve at an impedance of 100 Ω

Printout: Current – left y-axis, (--- mean current calculated for each cycle)
Condenser voltage – right y-axis.



Overview on the measured values with regard to the impedance

200 joule released in:	25 Ω	40 Ω	50 Ω	60 Ω	75 Ω	80 Ω	100 Ω	125 Ω	150 Ω	175 Ω
First phase										
Max. current [A]	99.5	62.2	49.8	41.5	33.26	31.1	24.9	19.9	16.6	14.2
Mean current [A]	55.9	38.4	31.1	26.2	21.5	19.2	15.6	12.7	9.7	8.8
Duration [ms]	1.8	2.25	2.7	3.15	3.6	4.5	5.4	6.3	9.45	9.86
Second phase										
Max. current [A]	36.6	28.5	23.5	20	17.1	14.3	11.8	9.9	6.6	6.5
Mean current [A]	18.6	16.4	14.7	12.6	11.5	9.4	8.2	7.1	4.9	4.9
Duration [ms]	2.25	2.700	2.700	3.150	3.150	3.600	3.600	4.050	4.050	4.050
Total shock duration [ms**]** incl. 0.5 ms of pause between first and second phase.	4.55	5.45	5.9	6.8	7.25	8.6	9.5	10.85	13.55	14.4
Energy delivered [J]	196	192	189	188	182	187	182	179	184	177

Note: In the case of high patient impedance or some other specific usage cases, the energy delivered to the patient might be lower than expected(e.g If patient impedance >= 150 Ohms, the rated energy level is set to 190J when 200J is selected)

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Standard energy settings	Deviation at 50Ω: ± 3 J or ± 15 % (the higher value is assumed)
AED	
Adult	150/200/200 joules (configurable see page 149)
Paediatric	50/50/50 joules (configurable see page 149) (automatic selected when the paediatric or adult electrodes are connected)
Manual mode	
Adult	**150** joules (configurable see page 149)
Paediatric	**50** joules (configurable see page 149) (default energy settings when starting in manual mode, adjustable anytime during intervention)
Charging time for shock	(Time used to charge the storage capacitor to the max. energy of 200 J in manual mode)
• with fully charged battery	8 seconds
• with 15 VDC mains voltage after 15 discharges with max. energy	9 seconds
• from switch-on of the device with pads	19 seconds
Cycle Time Rhythm Analysis – Shock Standby in AED Mode	
• with fully charged battery	1st shock = 11 s max.
• with 15 VDC mains voltage after 15 discharges with max. energy	1st shock = 11 s max.
• from switch-on of the device to charge at max. energy	1st shock = 23 s
Cycle time shock – shock	<15 s
Operating Modes	• Synchronised with heart action < 60 ms after R wave • Non synchronised • AED
Charge control and monitoring	• Automatic shock recommendation of analysis in AED mode • Direct via touch screen • Display of selected energy
Patient resistance	25 ...250 Ω
Indication when ready to shock	LED below  is lit
Shock delivery	Using key 

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Safety discharge when:	• the battery voltage is insufficient • the shock is not released within 20 seconds • a lower energy value is selected while the defibrillator is charging • the device is defective • the device is turned off • a non shockable rhythm is detected
Shock delivery	• Via applied disposable adhesive defibrillation electrodes
Defibrillation electrode connection	Type BF, defibrillation-protected >5 kV
Defibrillation electrodes	Electrode cable, 2 m long
	Deviating from the compliance statement according to 201.108.1.10 (IEC60601-2-4, 201.1.108.7. and 201.1.108.6), the following features have been measured for the universal electrode:
Adult and Paediatric electrode	• 80 cm2 active surface Measurements after 60 minutes of pacemaker at maximum setting, followed by a shock at 200 Joule: • Defibrillation recovery 720 mV after 4 s and 710 mV after 60s • DC offset voltage 785 mV after 1 minute of stabilisation

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12.2.1 Shock Advisory System

The Shock Advisory System (SAS) validation test set consists of 17,803 ECG waveforms coming from the PhysioNet databases [1]. These files (MIT-VFDB) are subsets of the general PhysioNet databases recognised as standard in ECG tests. PhysioNet databases are ECG Holter recordings with full diagnostic bandwidth [0.05 - 125] Hz. The bandwidth of the devices that recorded the signals is larger than that of the **DEFIGARD® Touch 7**. However, when the analogue signals of the database are run the the electrode connector, the rhythm detector signal-processing characteristics are applied. Moreover, these signals are of appropriate length to allow decisions to be made by the detector system.

The validation test set database used to establish compliance with the AHA requirements [2] and the IEC Standards [3] is independent from the one used to develop the rhythm recognition detector.
The SAS validation test set contains the following ECG samples (see test sample size in Table 1):

- coarse ventricular fibrillation (VF) (>200 µV peak-to-peak amplitude)
- shockable ventricular tachycardia (VT hi) (HR >150 bpm, rushes that last more than 8s)
- asystole (≤100 µV peak-to-peak amplitude)
- normal sinus rhythm (NSR) (PQRS-T waves visible, HR 40-100 bpm)
- other organized rhythm (N) (includes all rhythms except those in other listed categories)

For each test sample, in function of the expert rhythm annotation and the SAS decision (shock/no shock), an interpretation table is built and shows the true positive (correct classification of a shockable rhythm), true negative (correct classification of a non-shockable rhythm), false positive (non-shockable rhythm incorrectly classified as a shockable rhythm), false negative (shockable rhythm incorrectly classified as non-shockable). Finally, the results of the detector performance are reported in terms of: specificity-Sp (TN/(TN+FP)), true predictive value (TP/(TP + FP)), sensitivity-Se (TP/(FN + TP)), false positive rate (FP/(FP + TN)).

Table 1: **DEFIGARD® Touch 7** SAS performance by rhythm category meets AHA recommendations [2] and IEC Standards [3] for adult defibrillation on artefacts-free MIT-VFDB signals:

Rhythms		Test sample size	Performance goal	Observed performance
Shockable	Coarse VF	308	Sensitivity > 90%	Meets [2-3]
	VT hi	202	Specificity > 75%	Meets [2-3]
Non Shockable	NSR	1023	Sensitivity > 99%	Meets [2-3]
	Asystole	4798	Sensitivity > 95%	Meets [2-3]
	Other rhythms	1425	Sensitivity > 95%	Meets [2-3]
	Total NS	7246	Sensitivity > 95%	Meets [3]

The **DEFIGARD® Touch 7** SAS when configured as “Analysis with anteriority to ON” uses a combination of algorithms which are launched in two-stages [4-6] to deliver a shock advisory decision at minimal delay after actual CC stoppage. The SAS configured as “Analysis with anteriority to OFF” starts a chest compression-free VF detection at an analysis request, without trying to optimize hands-off time. In both configurations, the SAS does not continue analyzing after a shock advised decision is reached.

[1]: The MIT-BIH Malignant Ventricular Arrhythmia Database http://physionet.org/physiobank/database/vfdb/

[2]: Automatic External Defibrillators for Public Access Defibrillation : Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms and Enhancing Safety ; Circulation, 1997 ; 95 :1677-1682.

[3]: Standard IEC 2010 60601-2-4, ed 3.

[4]: Shock advisory system with minimal delay triggering after end of chest compressions: Accuracy and gained hands-off time. Jean-Philippe Didon, Vessela Krasteva, Sarah Ménétré, Todor Stoyanov, Irena Jekova, Resuscitation 82S (2011) S8-S15

[5]: Circulation. 2011; 124: A219, Resuscitation Science Symposium Abstracts, Best Original Resuscitation Science Poster Session, Abstract 219: Combination of Algorithms to Decrease Preshock Pause for Automated External Defibrillators. Jean-Philippe Didon, Irena Jekova, Sarah Ménétré, Todor Stoyanov, Vessela Krasteva.

[6]: Circulation. 2010; 122: A253, Resuscitation Science Symposium Abstracts, Best Original Resuscitation Science Poster Session, Abstract 253: Method for Minimal Delay Triggering of VF Detection During Cardio Pulmonary Resuscitation. Jean-Philippe Didon; Sarah Ménétré, Irena Jekova, Vessela Krasteva. »

The **DEFIGARD® Touch 7** SAS test has been completed with a validation database consisting of 2,475 couples of ECG and transthoracic Impedance Cardiogram (ICG) from out-of-hospital cardiac arrest (OHCA) interventions, recorded with Automated External Defibrillators (FredEasy, Schiller Medical SAS, France) used by the fire brigade of Paris.

This supplementary test completes the validation of both SAS configurations and provides performance fully in accordance with these summarized in Table 1. A report of the global validation test results is available on request.

12.3 Pacemaker

Operating Modes	• Demand • Fixed frequency (FIX)
Stimulation pulse	
Form	Rectangle mono-phase with constant current source
Pulse duration	20 ms ± 5%
Pulse rate	Configurable in steps of 40, 45, 50, 60, 70 ... 240 beats/min, ± 1.5%
Pulse current	Configurable to 0 (pacemaker Off) and then from 10 ...200 mA, ± 10 % or 5 mA (the higher value is applied)
Refractory period	• 340 ms ≤80 b/min • 240 ms >80 b/min
Signal connection	Type BF, defibrillation-protected >5 kV
Readiness for operation	Immediately
Pacer electrodes (same as defibrillation electrodes)	Electrode cable, 2 m long
	Deviating from the compliance statement according to 201.108.1.10 (IEC60601-2-4, 201.1.108.7. and 201.1.108.6), the following features have been measured for the universal electrode:
Adult and Paediatric electrode	
Duration	80 cm2 active surface • For up to 1 hour of pacing using 140mA / 120ppM (pulse duration 20ms) • For up to 8 hours of pacing using 70mA / 60ppM (pulse duration 20ms) inspection of pads every 30 minutes

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12.4 Technical data - monitoring

12.4.1 ECG

Leads	Simultaneous, synchronous recording of all 9 active electrodes giving 12 leads
Patient cable	4-, 10-wire cable (4+6), type CF
Heart rate	
Range	• 15 – 350 beats/min
Accuracy	• ±10 % or 5 beats/min, whichever is greater
Lead display	Selection of 1 or 12 leads
Sensitivity	0.25, 0.5, 1, 2 cm/mV programmable
Blockage caused by defibrillation shock	Max. 5 seconds
Input impedance	≥ 2.58 MΩ
Current electrode test	< 0.5 µA
Suppression of large T-waves	max. amplitude of T-wave according to IEC 60601-2-27 section 201.12.1.101.17: 0.8 mV
HR averaging method	The heart rate calculation is done using a user-defined number of previous RR intervals (minimum 4, maximum 16). The RR intervals are reset and the heart rate is set to zero whenever an asystole condition has been detected
Response time HR measurement	Change from 80 to 120 beats per minute: 2.56 s Change from 80 to 40 beats per minute: 8 s
Reaction to an irregular rhythm	• A1: 80/min • A2: 60/min • A3: 120/min • A4: 90/min (except for triggers no. 6 and 7, HR < 90/min) (according to IEC specifications 60601-2-27, 6.8.2.bb)
Duration until alarm is triggered in the case of tachycardia	B1 and B2: 3 s (according to IEC specification 60601-2-27, 6.8.2.bb)
ECG amplifier	
Sampling rate	500 Hz
Pacemaker detection	± 2 mV to ± 700 mV/0.1 till 2.0 ms
QRS detection range	Duration: 70 to 120 ms, amplitude: 0.5 to 5.0 mV
Protection	Fully isolated, defibrillation-protected >5kV
Mains filter	Distortion-free suppression of superimposed 50 / 60 Hz sinusoidal interferences by means of adaptive digital filtering.
Frequency range	The ECG frequency range depends on the ECG cable, the ECG view and the selected settings (see table next page).

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ECG amplifier band pass

The band pass depends on the ECG source.

Patient cable	BLW Filter	EMG Filter	Display Monitoring	Display Rhythm	"R-ECG" display Diagnostic
4 & 10 leads	OFF	OFF	0.05 – 42 Hz	-	0.05 – 150 Hz
4 & 10 lead	ON	ON	--	0.6 – 25 Hz	-
4 & 10 lead	ON	OFF	-	0.6 – 42 Hz	-
4 & 10 lead	OFF	ON		0.05 – 25 Hz	-
Defibrillator	-	-	1 – 25 Hz	1– 25 Hz	-

To pass distortion test according IEC 60601-2.25, Clause 201.12.4.107.1, use the 4 or 10 lead patient cable to set the ECG amplifier band pass to 0.05-150 Hz (see table above).

12.4.2 Features of pacemaker pulse rejection

According to IEC 60601-2-27 Clause 201.12.1.101.13

Single pacemaker pulse	• Duration 2.0 ms, amplitude > 2 mV and a overshoot of <0.25 mV • Duration 0.1 ms, amplitude > 2 mV and a overshoot of <0.8 mV
followed by a QRS complex	• Duration 2 ms, amplitude > 4 mV • Duration 0.1 ms, amplitude > 25 mV
Pacemaker pulse followed by an identical pulse within 150 ms	• Duration 2.0 ms, amplitude between 4 mV and 300 mV • Duration 0.1 ms, amplitude between 25 mV and 300 mV
followed by a QRS complex	• Duration 2.0 ms, amplitude between 4 mV and 300 mV • Duration 0.1 ms, amplitude between 25 mV and 700 mV without overshoot • Duration 0.1 ms, amplitude between 25 mV and 300 mV with overshoot
Pacemaker pulse followed by an identical pulse within 250 ms	• Duration 2.0 ms, amplitude between 4 mV and 400 mV • Duration 0.1 ms, amplitude between 25 mV and 400 mV
followed by a QRS complex	• Duration 2.0 ms, amplitude between 4 mV and 300 mV • Duration 0.1 ms, amplitude between 25 mV and 700 mV without overshoot • Duration 0.1 ms, amplitude between 25 mV and 300 mV with overshoot

Note: pacemaker signals from different pacemakers vary. In the case of cardiac arrests or some arrhythmias, pacemaker signals might still be measured, especially signals from pacemakers generating high amplitudes (> 20 mV) or overshoot. Pacemaker patients need to be monitored very closely.

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12.4.3 NIBP - non-invasive blood pressure

Measurement	Automatic or manual
Measuring method	Oscillometric
Connection	Type CF
Measurement range	
Adults(Child	• Sys 30...255 mmHg, dia 15...220 mmHg
Neonate	• Sys 30...135 mmHg, dia 15...110 mmHg
Accuracy	± 3mmHg and ± 2 beats/min

12.4.4 IBP - invasive blood pressure

Measuring range	-150...400 mmHg
Accuracy	1 mmHg or ± 1% (whichever is greater)
Sampling rate	500 Hz
Amplifier	Type CF, defibrillation-protected >5 kV
Zeroing	Manual

12.4.5 Temperature

Measuring method	Direct
Sensor	YSI 401, rectal, oesophageal, skin
Amplifier	Type CF, defibrillation-protected >5 kV
Sampling rate	2 Hz
Measurement interval	1x per second
Measuring range	15 °C to 45 °C
Resolution	0.1 °C
Accuracy	± 0.1 °C from 25 to 45 °C

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12.4.6 SpO_2 - pulsoximetry

Amplifier	Masimo™
Patent	see web site www.masimo.com/patents.htm for detailed patent information
Operation	Normal and sensitive
Measuring range	
SpO_2	0 % to 100 %
PP	25 to 240 /min
SpCO	0 to 99 %
SpMet	0 to 99.9 %
PI	0.02 to 20 %
Accuracy[a]	
SpO_2 (no movement)	• 60 to 80 % ± 3 % adults/children (10 -50 kg)/infants (3-20 kg) • 70 to 100 % ± 2 adults/children/infants; ± 3 neonates
SpO_2 (movement)	70 to 100 % ± 3 adults/children/infants/neonates
SpO_2 (low perfusion)	70 to 100 % ± 2 adults/children/infants/neonates
PP (no movement)	25 to 240/min ± 3 digits adults/children/infants/neonates
PP (movement)	25 to 240/min ± 5 digits adults/children/infants/neonates
PP (low perfusion)	25 to 240/min ± 3 digits adults/children/infants/neonates
SpCO	1 to 40 % ± 3 adults/children/infants
SpMet	1 to 15 % ± 1 adults/children/infants/neonates
Resolution	
SpO_2	1 %
PP	1 /min
SpCO	1 %
SpMet	0.1 %
Calibration range	70 ... 100 %
Connection	Type CF
Displayed range	1 ... 100 %
Blockage caused by defibrillation shock	Max. 10 seconds
Skin surface temperature	less than 41°C in a minimum 35°C environment

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a.

SpO_2, SpCO and SpMet accuracy was determined by testing on healthy adult volunteers in the range of 60-100% SpO_2, 0-40% SpCO, and 0-15% SpMet against a laboratory CO-Oximeter. SpO_2 and SpMet accuracy was determined on 16 neonatal NICU patients ranging in age from 7-135 days old and weighing between 0.5-4.25 kg. Seventy-nine (79) data samples were collected over a range of 70-100% SpO_2 and 0.5-2.5% MetHb with a resultant accuracy of 2.9% SpO_2 and 0.9% SpMet.

The Masimo sensors have been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

The Masimo SET Technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

The Masimo sensors have been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Biotek Index 2 simulator. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

The following substances may interfere with pulse CO-Oximetry measurements:

- Elevated levels of Methaemoglobin (MetHb) may lead to inaccurate SpO_2 and SpCO measurements
- Elevated levels of Carboxyhaemoglobin (COHb) may lead to inaccurate SpO_2 measurements.
- Very low arterial Oxygen Saturation (SpO_2) levels may cause inaccurate SpCO and SpMet measurements
- Severe anaemia may cause erroneous SpO_2 readings.
- Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.
- Elevated levels of total bilirubin may lead to inaccurate SpO_2, SpMet, and SpCO readings.

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12.4.7 $etCO_2$ - Capnography

The IRMA and ISA sensors are equipped with an automatic barometric pressure compensation.

Extremely compact infrared mainstream and sidestream gas analyser.

Trademarks	Masimo IRMA™Masimo ISA™, Nomoline™
Masimo AB patents	SE519766; SE519779; SE523461; SE524086
Standards	MDD 93/42/EEC, EN ISO 80601-2-55:2011, IEC 60601-1:2005, IEC 60601-1-2:2007, EN ISO 5356-1:2004, EN 1789:2007
Modules	Masimo IRMA mainstream and Masimo ISA sidestream
Cable length	2.5 m (IRMA) 0.5 m (ISA)
Surface temperature IRMA (at environment temp. of 23° C)	Max. 39 °C
Accuracy	The following specifications are valid for a dry gas at 22 ± 5°C and 1013 ± 40 hPa (standard conditions).
in standard conditions	• 0...15 % (± 0.2 vol % + 2 % of reading) • 15... 25 % (no information on accuracy)
in all conditions	• ± (0.3 kPa + 4 % of reading) Specification of accuracy in all conditions is valid for all specified ambient conditions (see page 131). Deviating from these, influences are specified in the table “Interfering gas and vapour effects” and in section “Effects from water vapor partial pressure on gas readings”. These technical specification can be found in the IRMA/ISA user guide chapter 2.
Breath detection	Adaptive threshold value, min. 1 vol% change in CO2 concentration
Respiration rate	0-150 /min. The respiration rate is displayed after three breaths and the average value is updated after every breath.
Rise time	IRMA: CO_2 < 90 ms ISA: CO_2 < 500 ms

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Total system response time	IRMA: < 2 second ISA: < 4 seconds (using 2 m long sampling line)
Protection class	IP44 (IRMA) IP4X (ISA)
Airway adapter IRMA	
Adults/children adapter	Increases dead space by less than 6 ml Pressure drop less than 0.3 cm H2O @ 30 LPM
Infant adapter	Increases dead space by less than 1 ml Pressure drop less than 1.3 cm H2O @ 10 LPM
Sampling rate	1 second
Sampling flow rate ISA	50 (±10) ml/min

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12.5 Telecommunication GSM (option)

Frequency range	Quad band GSM/GPRS/EDGE 850/900/1800/1900 MHz UMTS/HSPA+ 850/900/AWS1700/1900/2100 MHz
Supported SIM cards	3 and 1.8 V
Data transmission	GPRS class B
Max. transmitting power	• UMTS/HSPA – Class 3 (0.25 watt) • GSM 850/900 MHz – Class 4 (2 watt) • GSM 1800/1900 MHz – Class 1 (1 watt) • EDGE 850/900 MHz – Class E2 (0.5 watt) • EDGE 1800/1900 MHz – Class E2 (0.4 watt)
FCC identification **IC**	R17HE910 5131A-HE910
Standards	• FCC, IC • PTCRB • R&TTE • GCF • RoHS/WEEE • CE • ANATEL • KCC • CCC • JATE

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12.6 Device Configuration

12.6.1 General configuration

Parameter	Values	Description
Notch filter	• **None*** • 50Hz • 60Hz	This option shall be activated if artefacts are detected on ECG signals when the device is plugged to the mains. The notch filter must be chosen according the location. • 50Hz: Europe, Africa, Middle- East (except Saudi Arabia), Asia-Pacific (except Japan, Taiwan and Philippines), Australia • 60Hz: The American continent (except Chile, Argentina, Uruguay, Paraguay, Bolivia, French Guyana)
Boot mode by default	• AED • **Monitoring*** • Manual def	Sets the mode your device shall start in when pressing the On/Off button
Monitoring display mode	• Monitoring no curve • **Advanced monitoring** • Basic monitoring • 12 leads ECG • Critical care	Sets the desired default view in monitoring. • Monitoring without curve: No curves are displayed by default, only big monitoring values
Default heart rate source	• **Auto*** • Defi ECG • Pleth	Sets the behaviour of the HR parameter box between following possibilities: • Auto: The device automatically detects the HR source with predefined priorities level. DEFI higher than ECG higher than SpO2 (pulse) • Defi: Always force the HR calculation on DEFI • ECG: Always force the HR calculation on ECG lead II SpO2: Always force the HR calculation on SpO2 (pulse)
Audio pause at start	• **2min*** • Off	When this option is activated, the device will always remain silent for 2 minutes at start, even if an alarm occurs
Periodic test frequency	• **Daily*** • Weekly	The device wakes up by default weekly to perform a self test. Is is possible to set a daily test. Hereafter, the details of content of the automatic and manual self test
Time of test	• 12	This parameter specifies when the device will automatically wake up to perform its self test. This field must be specified in hours in 24 hours format. Always specify time in HH and not in HH:mm Example: 13 refers to 1PM Example: 13:30 is not allowed
Technician password	• schiller	Sets the password that will be asked to enter the Control Panel
Confirmation required on mode change	• **True*** • False	If this option is activated, the device will ask a confirmation in following situations - Switch from AED to monitor - Switch from AED to manual def - Switch from monitor to manual def
Enable printer	• **True*** • False	Activating this option will allow to pair a Bluetooth printer and will make the printer button available
Curve thickness	• **0.5mm*** • 0.7mm • 0.9mm	Sets the thickness of the curves printed on the Bluetooth printer.

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Parameter	Values	Description
Default language	• **English*** German French Spanish Italian etc…	Sets of the language in which the device will always start by default. Even if the language is modified during the use on the device, it will start again with the language specified here
Alarm sound level	• Low • Medium • **High***	Selection of the overall sound level applied to technical and physiological alarms
Audio off allowed	• False • **True***	If this option is activated, the user will have the possibility to shut down totally sound alarming

12.6.2 ECG

Parameter	Values	Description
PDF Format	• 1p avg 1x6 10sec 12.5mms • 2p 1x12 5sec 50mms • **1p 2x6 5sec 25mms*** • 1p 4x3+1 2sec 25mms • 1p 1x12 10 sec 25mms	Sets the PDF layout for the resting ECG report. This layout will be used for the PDF sent by Email
Encrypt PDF	• True • **False***	PDF encryption If this option is activated, every Resting ECG sent by the device will be password protected with the password specified in the setting PDF password
PDF password	• schiller	Sets the wished password to protect the PDF of Resting ECG
R-ECG Low pass filter	• 40Hz • **150Hz***	Sets the low pass filter frequency for the resting ECGTrue False*
Printout format	• 4x3 10sec 25mms + avg 7p • **4x3 +1 2.5sec 25mms 2p*** • 4x3 +1 2.5sec 50mms 3p • 2x6 5sec 25mms 2p	Sets the layout for the resting ECG printed out on the external thermal printer

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12.6.3 Defibrillator

Parameter	Values	Description
Default energy for adults in manual def.	• 2, 4, 8, 15, 30, 50, 70, 90, 120, **150***, 200 Joule	Sets the energy which will be displayed by default when entering manual defibrillation mode in adult mode
Default energy for children in manual def.	• 2, 4, 8, 15, 30, **50***, 70, 90, Joule	Sets the energy which will be displayed by default when entering manual defibrillation mode in child mode
Sync. after sync shock	• True • **False***	If this option is activated, the device remains in sync. mode after a synchronized shock in manual defibrillation
First shock for adults	• 2, 4, 8, 15, 30, 50, 70, 90, 120, **150**, 200 Joule	Sets the energy which will be delivered for the first shock in AED in adult mode
Second shock for adults	• 2, 4, 8, 15, 30, 50, 70, 90, 120, **150**, 200 Joule	Sets the energy which will be delivered for the second shock in AED in adult mode
Third shock for adults	• 2, 4, 8, 15, 30, 50, 70, 90, 120, **150**, 200 Joule	Sets the energy which will be delivered for the third shock in AED in adult mode
First shock for children	• 2, 4, 8, 15, 30, **50***, 70, 90, Joule	Sets the energy which will be delivered for the first shock in AED in child mode
Second shock for children	• 2, 4, 8, 15, 30, **50***, 70, 90, Joule	Sets the energy which will be delivered for the second shock in AED in child mode
Third shock for children	• 2, 4, 8, 15, 30, **50***, 70, 90, Joule	Sets the energy which will be delivered for the third shock in AED in child mode

12.6.4 Display

Parameter	Values	Description
Anteriority Analysis	• **False*** • True	Enables the analysis with anteriotity (part of the signal analysis is done on the signal before the device mentions the start of the analysis).
Analysis key	• False • **True***	If this option is activated, the analysis key will be displayed to allow additional manual analysis in AED mode.
Alarm on Vfib or Vtach detection	• False* • **True***	High priority alarm will be issued if Vfib or Vtach is detected during monitoring on both ECG cable and Defi pads.
Precognitive Analysis	• **False*** • True	Not used at the moment, has no impact on the unit.

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12.6.5 AED

Parameter	Values	Description
Display curve in AED	• False • **True***	If enabled, ECG lead Defi is displayed in AED mode
AED voice level	• High • **Medium*** • Low	Metronome default behaviour in adult mode This behaviour can be changed during intervention on the device
Metronome behaviour adult	• **30:2*** • 15:2 • Continuous Off	Metronome default behaviour in adult mode This behaviour can be changed during intervention on the device
Metronome behaviour child	• 30:2 • **15:2*** • Continuous Off	Metronome default behaviour in child mode This behaviour can be changed during intervention on the device
Metronome rate	• **100cpm*** • 110cpm • 120cpm	Sets the frequency of the metronome
Metronome audio level	• High • **Medium*** • Low	Sets the audio level of the metronome
CPR depth unit	• **cm*** • inch	Sets the unit in which the chest compression depth value will be displayed
CPR cycle duration	• 1min • **2min*** • 3min	Sets the duration of the CPR cycle

12.6.6 ECG

Parameter	Values	Description
ECG curve amplitude	• 0.25mv • 0.5mv • **1mv*** • 2mv • auto	Sets the default ECG curve amplitude, If Auto is selected, the displayed amplitude will be automatically adapted depending on the signal amplitude
ECG 16,7 Hz filter	• **False*** • True	Not used at the moment, has no impact on the unit
QRS sound level	• Off • **Low*** • Medium • High	Sets the audio level of the QRS sound issued by the ECG

12.6.7 IBP

Parameter	Values	Description
IBP curve amplitude	• **30**, 60, 100, 300mmHg	Sets the default IBP curve amplitude

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12.6.8 NIBP

Parameter	Values	Description
Deflation rate	• 3, 4, 5, 6, **7**, 8, 9 mmHg/s	Sets the cuff deflation rate
NIBP unit	• **mmHg*** • kpa	Sets the unit in which the NIBP values will be displayed and stored
Automatic cycles at start	• **False*** • True	Automatic NIBP measurement cycle starts once a first measurement is initiated manually
Initial pressure for adults	• 90, 120, 150, **180*,** 210, 240, 270mmHg	Sets the initial cuff pressure for measurement in adult mode
Initial pressure for children	• 90, 120, **150***, 180, 210, 240, 270mmHg	Sets the initial cuff pressure for measurement in child mode
Initial pressure for neonate	• **50***, 70, 90 110,130, 150mmHg	Sets the initial cuff pressure for measurement in neonate mode

12.6.9 SpO2

Parameter	Values	Description
SpO2 average	• 4, 6, 8, 10,**12*,**14, 16sec	Sets the integration time for the calculation of the displayed average value.
SpO2 sensitivity	• **Normal*** • Automatic Probe Off Detection	Sets the measurement sensitivity. Adaptive Probe Off Detection is optimised for the detection of Sensor has come off, regardless of the signal quality.
SpO2 sound level	• Off • Low • **Medium*** • High	Sets the audio level of the pulse sound

12.6.10 Temp

Parameter	Values	Description
Temperature unit	• **Celcius*** • Fahrenheit	Sets the unit in which the temperature value will be displayed and stored

12.6.11 EtCO2

Parameter	Values	Description
Respiration curve amplitude	• **50*,** 75, 100mmHg	Sets the respiration curve amplitude to be displayed by default
EtCO2 unit	• vol% • **mmHg***	Sets the unit in which the EtCO2 value will be displayed and stored

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12.6.12 Time and date

Parameter	Values	Description
Date format	• **DD/MM/YY*,** MM/DD/YY YY/MM/DD	Sets the format in which the date will be displayed
Time format	• AM/PM • **24H***	Sets the time format
Time zone	• Europe/Berlin • **Europe/Paris*** • Europe/London • GMT-12...-1 • GTM 0 • GTM 2....+12	Sets the time zone to calculate appropriate date & time

12.6.13 Event

Parameter	Values	Description
Event (from 1 to 20)	• Event(1 to 20)	Enter an event name (for example a medication). This event can be selected on the device in the events list during intervention. Once selected it is stored in the memory and flagged in the intervention report (20 customisable fields)

12.6.14 Email configuration

Parameter	Values	Description
Email server	-	Any hostname of SMTP provider (example: smtp.myinternetprovider.com)
Email address source	-	The email from which the Emails are going to be sent (example: mymail@myinternetprovider.com)
Server port	-	The port that is used to communicate with the SMTP server (example: 25, 465, 587)
TLS	• **False*** • True	Enables TLS/SSL encryption for communication with the SMTP Server. This setting must be done according to SMTP Server requirements.
Authentication required	• **False*** • True	Enables authentication for communication with the SMTP Server. This setting must be done according to SMTP Server requirements
Login	-	The login used for SMTP server authentication
Password	-	The password used for SMTP server authentication

12.6.15 Email adresses

Parameter	Values	Description
Email address (from 1 to 30)	-	The Email address must be correctly entered Example: user@myinternetprovider.com
Alias (from 1 to 30)	-	This text will be displayed on the device for a better recognition of the recipient.Example: Dr USER

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12.6.16 Transmission

Parameter	Values	Description
Automatic R-ECG transmission	• **False*** • True	If this option is activated, the device will automatically send over the media selected in configuration Transmission media during intervention to the address specified for SEMA Server There will be no preview of the resting ECG on the device, after acquisition, it will be automatically sent
Automatic intervention data transmission	• When device plugged on docking station • At device power off • **Off***	The device is capable of transmitting automatically its memory after an intervention using the media selected in Transmission media by automatic wake up, with the following scenario: - Never (Off) - 10 minutes after the device has been shutted down (After device power off) - When a external power supply is detected (When device plugged on docking station)
Transmission media during intervention	• **Wi-Fi*** • GSM/3G • USB/Ethernet	The selected media will always be selected by default at manual start of the device. This media can always be changed by the user during the intervention
Transmission media by automatic wake up	• **Wi-Fi*** • GSM/3G • USB/Ethernet	The selected media will always be selected by default during automatic wake up of the device (automatic intervention data transmission, automatic self test results transmission...)

12.6.17 Ethernet

Parameter	Values	Description
Ethernet ping serve	• 8.8.8.8	Sets the IP that will be used to test the connectivity of the device over Ethernet. Usually, it's recommended to use either common DNS server(e.g. 8.8.8.8), or the public SEMA Server IP address

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12.6.18 WIFI

Parameter	Values	Description
SSID	-	SSID of the Wi-Fi Network that shall be used for data transmission
Encryption type	• WEP • WPA • **WPA2*** • WPA-EAP • WPA2-EAP • None	Type of encryption from the Wi- Fi Network that shall be used for data transmission
Security key	-	Security key of the Wi-Fi Network that shall be used for data transmission
Wi-Fi Login	-	Login used for EAP authentication
Wi-Fi Password	-	Password used for EAP authentication
Wi-Fi ping server	-	Sets the IP that will be used to test the connectivity of the device over WIFI. Usually, it's recommended to use either common DNS server(e.g. 8.8.8.8), or the public SEMA Server IP address

12.6.19 GSM

Parameter	Values	Description
PIN	-	Sets the PIN code to unlock SIM card It's recommended to either use the same PIN for all devices, or to disable PIN on all SIM cards. Both are accepted by the device
APN name	-	Sets the APN of the M2M Internet provider Example: orange.m2m.spec or MATOOMA, or A1.net
APN port	-	Sets the APN port (if required by the APN)
APN user	-	Sets the APN user (if required by the APN)
APN password	-	Sets the APN password (if required by the APN)
APN extra commands	-	If required by the APN, extra commands can be specified here
GSM ping server	8.8.8.8	Sets the IP that will be used to test the connectivity of the device over GSM. Usually, it's recommended to use either common DNS server(e.g. 8.8.8.8), or the public SEMA Server IP address

12.6.20 SEMA

Parameter	Values	Description
SEMA server	-	Sets the IP address or the hostname of the SEMA Server Should the device be able to send data to SEMA over Internet (typically through GSM), the public IP address or hostname must be specified and not the private Example: 188.165.287.137 (public IP) and not 192.168.200.32 (private IP)
SEMA server port	8181	Sets the port with which SEMA Server is reachable. This port might be different whether the device tries to connect with or without SSL encryption Example: By default, 8080 is used for HTTP and 8181 is used for HTTPS
SEMA SSL encryption	• False • **True***	Sets SSL encryption. It's recommended to activate this option to secure the communication, especially if transmission are done over the Internet

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Parameter	Values	Description
SEMA login	-	Sets device login to SEMA. To be able to transmit data to SEMA, a login and password must be specified for each device (it can be the same login/password for all device though)
SEMA password	-	Sets device password to SEMA. To be able to transmit data to SEMA, a login and password must be specified for each device (it can be the same login/password for all device though)
SEMA Attending name	-	Sets Technician ID. This field is only necessary if Multi-tenancy is used in SEMA in order to split recordings belonging. Typically the Attending name is a specific login in SEMA Server

12.6.21 SUS (Schiller Update server)

Parameter	Values	Description
SUS server	-	Sets either the IP address or the hostname of the SUS Server Should the device be able to update itself over Internet (typically through GSM), the public IP address or hostname must be specified and not the private Example: 188.165.287.137 (public IP) and not 192.168.200.32 (private IP)
SUS server port	8181	Sets the port with which SUS Server is accessible. This port might be different whether the device tries to connect with or without SSL encryption Example: By default, 8080 is used for HTTP and 8181 is used for HTTPS
SUS SSL encryption	• False • **True***	Sets SSL encryption. It's recommended to activate this option to secure the communication, especially if transmission are done over the Internet
SUS login	-	Sets device login to SUS. To be able to retrieve data from SUS, a login and password must be specified for each device (it can be the same login/password for all device though)
SUS password	-	Sets device password to SUS. To be able to retrieve data from SUS, a login and password must be specified for each device (it can be the same login/password for all device though)

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12.7 Electromagnetic interferences

The DEFIGARD/PHYSIOGARD Touch 7 is intended to be used in the electromagnetic environments listed in the following tables. The user of the DEFIGARD/PHYSIOGARD Touch 7 has to ensure that the device is operated in an adequate environment.

12.7.1 Electromagnetic emissions

Emission measurement	Compliance with the regulations	Electromagnetic environment - explanations
HF emissions CISPR 11	Group 1	DEFIGARD/PHYSIOGARD Touch 7 only uses HF energy for internal functions. Therefore, HF emissions are very low and interferences with electronic devices nearby are unlikely.
HF emissions CISPR 11	Class B	DEFIGARD/PHYSIOGARD Touch 7 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Class B	
Voltage fluctuations IEC 61000-3-3	Compliant	

12.7.2 Electromagnetic immunity

Interference testing	IEC 60601 test level	Conformity level	Electromagnetic environment - explanations
Electrostatic discharge IEC 61000-4-2	± 8 kV contact ± 8 kV air	IEC 60601-1 conformity	Floors should be made of wood, concrete or ceramic tiles. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	IEC 60601-1 conformity	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	± 1 kV between conductors ± 2 kV conductor-earth	IEC 60601-1 conformity	Mains power quality should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % nominal voltage during 0.5 period 40 % nominal voltage during 100 ms at 50/60 Hz 70 % nominal voltage during 500 ms at 50/60 Hz 0% nominal voltage during 5 s at 50/60 Hz	IEC 60601-1 conformity	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the DEFIGARD/PHYSIOGARD Touch 7 is reliant on permanent operation even in the case of a power failure, it is suggested connecting the DEFIGARD/ PHYSIOGARD Touch 7 to an uninterruptible power supply or use it with a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be that of a typical commercial and/or hospital environment.

Note: U_T indicates the AC voltage of the mains before the test level.

Interference testing	IEC 60601 test level	Conformity level	Electromagnetic environment - explanations
			Recommended minimum distances Portable and mobile HF telecommunication devices must keep the recommended minimum distance from the DEFIGARD/PHYSIOGARD Touch 7 and all its components, incl. cables; the recommended minimum distance is calculated based on the transmitter's frequency.

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Interference testing	IEC 60601 test level	Conformity level	Electromagnetic environment - explanations
Conducted HF IEC 61000-4-6	3 Veff between 150 kHz and 80 MHz outside of the ISM frequency bands[a] 10 Veff between 150 kHz and 80 MHz within the ISM frequency bands[a]	3 V 10 V	$d = \frac{3,5}{3} \times \sqrt{P}$ $d = \frac{12}{10} \times \sqrt{P}$
Radiated HF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m 20 V/m 	SpO2 monitor: $d = \frac{12}{10} \times \sqrt{P}$ between 80 MHz and 800 MHz $d = \frac{23}{10} \times \sqrt{P}$ between 800 MHz and 2.5 GHz ECG, Temp, NIBP monitoring and defibrillator: $d = \frac{12}{20} \times \sqrt{P}$ between 80 MHz and 800 MHz $d = \frac{23}{20} \times \sqrt{P}$ between 800 MHz and 2.5 GHz where P is the maximum transmitting power of the transmitter in Watt (W) according to manufacturer data, and d the recommended minimum distance in metres (m)[b]. The field strength of stationary HF transmitters (according to an on-location measurement [c]) must not exceed the conformity level for each frequency range [d]. When operating the device near devices bearing the symbol “ionising radiation”, interferences can occur.

Note 1 For 80 MHz to 800 MHz, the higher frequency range applies.
Note 2 These guidelines might not always be applicable. Electromagnetic radiation is influenced by absorption and reflection on structures, objects and people.

a. The ISM frequency bands (ISM = industrial, scientific, medical) 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.

b. The conformity levels within the ISM frequency bands between 150 kHz and 80 MHz and between 80 MHz and 2.5 GHz serve to minimise the probability of interferences caused by mobile/portable communication equipment that accidentally happens to be in the patient environment. The formula for the calculation of the recommended distance has been adapted by the factor 10/3 for transmitters in this frequency range.

c. The field strength of stationary transmitters, e.g. base stations for radio telephones (mobile or cordless) and portable radio equipment, amateur radios, AM and FM radios and TV signals cannot be predicted accurately in a theoretical way. In order to analyse electromagnetic environments caused by stationary HF transmitters, an electromagnetic analysis on site should be considered. If the measured field strength exceeds the HF conformity level, it needs to be checked whether the DEFIGARD/PHYSIOGARD Touch 7 can be used in this environment. If an abnormal behaviour is detected, additional measures need to be taken, e.g. reorientation or change of location of the DEFIGARD/PHYSIOGARD Touch 7.

d. For the frequency range between 150 kHz and 80 MHz, the field strength must be lower than 3 V/m.

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12.7.3 Recommended minimum distances

The DEFIGARD/PHYSIOGARD Touch 7 is intended to be used in electromagnetic environments in which it is possible to control radiated HF interferences. The user of the DEFIGARD/PHYSIOGARD Touch 7 can prevent electromagnetic interferences by always keeping a minimum distance between portable/mobile HF communication devices (transmitters) and the DEFIGARD/PHYSIOGARD Touch 7. The recommended minimum distances are listed in the following table according to the transmitters' max. transmitting power.

Max. transmitting power of the transmitter (W)	Distances according to the transmitter's frequency (m)			
	$d = \frac{3,5}{3} \times \sqrt{P}$ between 150 kHz and 80 MHz **outside of** the ISM frequency band	$d = \frac{12}{10} \times \sqrt{P}$ between 150 kHz and 80 MHz **within** the ISM frequency band	$d = \frac{12}{10} \times \sqrt{P}$ between 80 MHz and 800 MHz	$d = \frac{23}{10} \times \sqrt{P}$ between 800 MHz and 2.5 GHz
0.01	0.12	0.12	0.12	0.23
0.1	0.37	0.38	0.38	0.73
1	1.17	1.2	1.2	2.3
10	3.69	3.79	3.79	7.27
100	11.67	12	12	23

For transmitters with a max. transmitting power that is not listed in the above table, the recommended minimum distance d in metres (m) can be calculated using a formula based on the transmitter's frequency, where P is the max. transmitting power of the transmitter in Watts (W) (according to manufacturer data).

Note 1 These guidelines might not always be applicable. Electromagnetic radiation is influenced by absorption and reflection on structures, objects and people.
Note 2 To calculate the recommended minimum distance of transmitters in the ISM frequency bands between 150 kHz and 80M Hz and in the frequency band between 80 MHz and 2.5 GHz, the additional factor 10/3 is used to minimise the probability of interferences caused by mobile/portable communication equipment that accidentally happens to be in the patient environment.

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13 Appendix

13.1 Accessories and disposables

⚠WARNING

▲ Always use SCHILLER replacement parts and disposables, or products approved by SCHILLER. Failure to do so may endanger essential performance, life and/or invalidate the warranty.

Your local representative stocks all the disposables and accessories for the **DEFIGARD® Touch 7**. A full list of all SCHILLER representatives can be found on the SCHILLER website (www.schiller.ch).

13.2 Accessories DEFIGARD/PHYSIOGARD Touch 7

Article no.	Article description
Device	
3.940100	Battery Li/ion 11.1V, 4.65 Ah, 51.6 Wh(rechargeable)
4-07-0022	Battery Li/MnO2, 6 V, 1,4 Ah
ECG	
0-05-0051	4- or 10-lead set, press stud, IEC (4+6-lead press stud patient cable)
0-21-0033	ECG electrodes pouch of 4 (box of 10 pouches)
0-21-0034	ECG electrodes pouch of 6 (box of 10 pouches)
0-05-0052	6-pol. leadset, press stud, IEC 4-lead patient cable "6in4" P/N 0-05-0051 is necessary
NIBP	
0-04-0012	Cuff for neonatal soft, 4 cm (Arm circumference 6-12 cm)
0-04-0016	Cuff for Child, 8 cm (Arm circumference 11-22 cm)
0-04-0014	Cuff for Child, 11 cm (Arm circumference 16-28 cm)
0-04-0013	Cuff for Adult, 13 cm (Arm circumference 26-33 cm)
0-04-0017	Cuff for Adult, 15 cm (Arm circumference 33-41 cm)
0-04-0015	Cuff for Adult, 19 cm (Arm circumference 39-55 cm)
0-87-0006	Hose assembly NIBP, 2 m
SpO2	
2.310301	Connection cable SpO2 Masimo 1.2 m
2.100598	Adult (> 30 kg) reusable finger clip sensor, 1m, M-LNCS DCI
2.100565	Adult (> 30 kg) soft reusable finger clip sensor, 1m, M-LNCS DBI
0-13-0031	Paediatric/slender (10-50 kg) reusable finger clip sensor, 1 m, M-LNCS DCIP
2.100627	Disp. adult (> 30 kg) adhesive finger sensor, 1m, 20/box, M-LNCS ADTX-3
2.100628	Disp. paediatric (10-50 kg) adhesive finger sensor, 1m, 20/box, M-LNCS PDTX-3
2.100629	Disp. infant (3-20 kg) adhesive sensor, 1m, 20/box, M-LNCS INF-3
2.100630	Disp. neonatal/adult (< 3 kg or > 40 kg) SpO2 adhesive sensor, 1m, 20/box, M-LNCS NEO-3
SpCO, SpMet, SpO2	
2.310301	Connection cable SpO2 1.2 m
2.100599	Adult (>3 0 kg) reusable finger clip sensor, 1m, Rainbow DCI

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Article no.	Article description
0-13-0033	Paediatric (10-50 kg) reusable finger sensor, 1m, Rainbow DCIP
Temp	
2.101108	Reusable temperature probe rectal / oesophageal, adult, 2m
2.101109	Reusable temperature probe rectal / oesophageal, child, 2m
2.101104	Temperature probe skin adult
2.310298	Reuseable connecting cable for disposable temperature probe
CO2 IRMA/ISA	
2.100571	IRMA CO2 sensor
6-17-0015	Trunk cable IRMA/ISA etCO2 with adapter plate
2.100567	ISA sidestream etCO2 sensor
IBP	
2.310285	IBP cable assembly Braun
2.310297	IBP cable assembly Baxter
2.310299	IBP cable assembly Transpac IV
2.310164	IBP cable assembly Utah, Mallinckrodt
2.310308	IBP cable assembly PCB Combitrans
2.310296	IBP cable assembly Ohmeda
2.310246	IBP cable assembly Medex
DEFI	**DEFIGARD® Touch 7**
0-21-0040	Disposable adhesive defibrillation electrode pads for adults (preconnectable) with detection of shelf life by RFID
2.155067	Disposable adhesive defibrillation electrode pads for children
2.100860	ARGUS LifePoint (CPR feedback sensor)
6-17-0012	Adapter cable for LifePoint CPR feedback sensor
2.100519	Adhesive pad set of 5 pcs
General accessories	
0-80-0023	Carrying bag
3.940100	Li/Ion 11.1 V, 4.65 Ah, 51.6 Wh (rechargeable)
1-128-5080	Ambulance bracket with **AC/DC** charging module. The battery is charged in the device via ambulance bracket.
1-108-5181	Ambulance bracket with **DC/DC** charging module. The battery is charged in the device via ambulance bracket.
1-128-5180	**Desktop** bracket with **AC/DC** charging module. The battery is charged in the device via Desktop bracket.
1-128-5181	Nomad AC/DC charging module
1-128-5182	Nomad DC/DC charging module
2.100018	Charging unit CS-1, external battery charger

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13.3 Literature

European Resuscitation Council (2015) Guidelines 2015 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (

American Heart Association (2015) Guidelines 2015 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care

Cansell A. (2000) Wirksamkeit und Sicherheit neuer Impulskurvenformen bei transthorakaler Defibrillation – Biphasische Impulskurvenformen – Notfall- & Rettungsmedizin, Springer-Verlag 3: 458 – 474.

Clinical experience with a low-energy pulsed biphasic waveform in out-of-hospital cardiac arrest Jean-Philippe Didon, Guy Fontaine, Roger D. White, Irena Jekova, Johann-Jakob Schmid, Albert Cansell; Clinical experience with a low-energy pulsed biphasic waveform in out-of-hospital cardiac arrest, Resuscitation (2008) 76, pp 350—353.

13.4 Glossary

AED Automated external defibrillator

BLS Basic Life Support (artificial respiration and cardiac massage)
CPR is frequently used synonymously

CPR Cardiopulmonary resuscitation

VT Ventricular tachycardia

VF Ventricular fibrillation

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