

corpuls **aed**

 GS Elektromedizinische Geräte

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For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation (EU) 2017/745 on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

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Service Address

For questions, please contact authorised sales and service partners:



Information on authorised sales and service partners can be found at:

www.corpuls.world

Versions of the User Manual

| Issue | Date | Versions of the User Manual | Version corpuls aed |
|-------|------------|-----------------------------|----------------------------|
| 1 | 2017-11-07 | 1.0 | CS50165-00A |
| 2 | 2018-05-11 | 2.0 | CS50165-00B CS50165-00C |
| 3 | 2018-12-13 | 3.0 | CS50165-00D |
| 4 | 2019-04-18 | 3.0 | CS50165-00D |
| 5 | 2019-05-29 | 4.0 | CS50165-00E |
| 6 | 2020-05-20 | 5.0 | CS50165-00F |
| 7 | 2020-08-03 | 5.1 | CS50165-00F |
| 8 | 2020-11-18 | 5.2 | CS50165-00F |
| 9 | 2020-12-17 | 5.3 | CS50165-00F |
| 10 | 2021-05-12 | 6.0 | CS50165-00G |
| 11 | 2022-12-06 | 7.0 | CS50165-00H |
| 12 | 2023-10 | 8.0 | CS50165-00I |

New in this Version

The following table gives an overview of all new features in this version:

| Description |
|---|
| New software version and editorial changes |
| New CPR feedback disposable sensor CPR Feedback and editorial changes |

Configuration Software and Evaluation Software

With every corpuls aed, a configuration software *corpuls.manager App* and an evaluation software for mission data corpuls.manager *REVIEW* is available free of charge. The configuration software *corpuls.manager App* is available for download in the App stores **App Store** (iOS) and **Google Play** (Android) (see the following QR code).



corpuls.manager App product compatibility

The evaluation software for mission data corpuls.manager *REVIEW* is available for download at my.corpuls.world.

The following table gives an overview of the compatibility of *corpuls.manager App* or corpuls aed *SETUP* to corpuls aed.

| Compatible corpuls aed version | Minimal needed <i>corpuls.manager App</i> version | | corpuls aed <i>SETUP</i> version |
|--------------------------------|---|---------|----------------------------------|
| | iOS | Android | |
| CS50165-00A | -- | -- | CS50227A |
| CS50165-00B | -- | -- | CS50227A |
| CS50165-00C | 1.0.0 | 1.0.0 | CS50227A CS50227B CS50227D |
| CS50165-00D | 1.0.0 | 1.0.0 | CS50227B CS50227D |
| CS50165-00E | 1.0.0 | 1.0.0 | CS50227D |
| CS50165-00F | 1.0.0 | 1.0.0 | -- |
| CS50165-00G | 2.0.0 | 2.0.0 | -- |
| CS50165-00H | 2.1.0 | 2.1.0 | -- |
| CS50165-00I | 2.2.0 | 2.2.0 | -- |

corpuls.manager (**ADMIN/ANALYSE/REVIEW**) product compatibility

The following table gives an overview of the compatibility corpuls.manager (**ADMIN/ANALYSE/REVIEW**) to corpuls aed.

| corpuls.manager (ADMIN/ANALYSE/REVIEW) version | Compatible corpuls aed version |
|---|--|
| Darwin 1906 (2.1) | CS50165-00C CS50165-00E |
| Everest 1908 Everest 1912 | CS50165-00C CS50165-00E CS50165-00F |
| Franklin 2005 Franklin 2009 | CS50165-00C CS50165-00E CS50165-00F |
| Galileo 2105 | CS50165-00C CS50165-00E CS50165-00F CS50165-00G |
| Hounsfield 2302 | CS50165-00C CS50165-00E CS50165-00F CS50165-00G CS50165-00H |
| Ives 2309 | CS50165-00C CS50165-00E CS50165-00F CS50165-00G CS50165-00H CS50165-00I |

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1 Performance Description

1.1 Intended Use

The corpuls aed is an automatic external defibrillator for use on patients without a life sign. The patient does not react, is e. g. unconscious, no normal breathing can be detected and neither a pulse nor other life signs can be detected. The AED is intended for use on adults and children.

The aed analyses the patient's ECG and based on the data obtained, gives the user a shock recommendation.

Depending on the configurations of the corpuls aed, monitoring of cardiopulmonary resuscitation with the corPatch CPR feedback function is possible. Via a metronome (smartMetronome), the user can be acoustically supported by an active clock pulse during CPR. In addition, the user can make an emergency call via the integrated GSM module. Via an integrated WLAN module, the AED can be accessed for service purposes and status queries.

1.2 Appropriate Use

If among others the following points are applicable, the user is in compliance with the appropriate use of the corpuls aed:

- The user optionally uses the corpuls aed with the CPR Feedback feedback function during cardiopulmonary resuscitation.
- The user complies with the operating requirements for operation of the corpuls aed (see 2.1 Requirements for the User on page 10)
- The user uses approved accessories, spare parts and consumables (see 4.2 Accessories on page 23)
- The user operates the corpuls aed on only one patient at a time.
- Defibrillation is performed only with eye contact to the patient.
- The user tries to avoid operating the corpuls aed under the influence of strong electromagnetic fields. Example: In the direct vicinity of radio masts, activated magnetic resonance tomography units, high voltage installations and overhead power lines.
- The user tries to avoid operating the corpuls aed in the vicinity of readily flammable anaesthetics or other flammable substances.
- The user tries to avoid operating the corpuls aed in an oxygen-rich (> 23 %) environment.

1.3 Indications and Contraindications in Use

Indications

In the following, indications of the corpuls aed are described. According to the age and weight of the patients, appropriate corPatch easy therapy electrodes (pre-connected/Pediatric) must be used.

AED

- The corpuls aed is used in semi-automatic or fully automatic mode in patients showing signs of circulatory arrest:
 - Unconsciousness
 - Abnormal breathing
 - No detectable pulse
- Specifications for the ECG rhythm analysis can be found in the user manual in the chapter „Defibrillation and Readiness for ECG Analysis“ of the technical specifications (see Tab. 5-18 Technical specifications - Decision-making reliability of the ECG analysis programme on page 67).
- If patients are younger than 8 years or weigh less than 25 kg, corPatch easy Pediatric electrodes should be used. The therapy should not be delayed in order to determine the age or weight.
- The use of the corpuls aed is not recommended in patients younger than 12 months.

ECG (1 lead ECG)

- The corpuls aed allows to display the ECG signals obtained by corPatch easy electrodes. The ECG curve and the heart rate are displayed.

CPR Feedback monitoring

- The CPR Feedback monitoring allows to guide the user in performing chest compressions according to currently valid guidelines by means of audiovisual feedback.

Contraindications

Contraindications of the corpuls aed are described in the following.

AED

- Patient breathes normally
- Patient is conscious and/or patient is reacting

ECG (1 lead ECG)

- No medical contraindications
The method of electrocardiography does not harbour special risks in the sense of a patient hazard, as the measuring process is harmless. Risks only consist of wrong measurement or wrong interpretation of readings. Pertaining warnings are described in the user manual (see 3 Safety on page 15).

CPR Feedback monitoring

- The CPR Feedback monitoring feature is not intended for use on patients under 8 years of age. The use of the CPR Feedback monitoring feature is contraindicated if cardiopulmonary resuscitation is contraindicated.

1.4 Patient group

The corpuls aed can be used with the corPatch easy therapy electrodes on patients at least 8 years old and having a body weight of at least 20 kg. With corPatch easy Pediatric therapy electrodes, patients from 1 year of age can be treated. The use of the corpuls aed is not recommended in children less than 12 months of age. According to the valid guidelines, the user should use pediatric electrodes, if the child's age is estimated younger than 8 years.

2 Directions for Users

2.1 Requirements for the User

The corpuls aed can be used by any first responder present who does not require training in immediate life-saving measures and the use of a defibrillator.

2.2 Use of the Manual

The user manual has been compiled to enable better understanding of the corpuls aed.

The user manual provides users with the following information:

- Safe and trouble-free operation of the corpuls aed.
- Using the corpuls aed on a patient.
- Maintenance of the corpuls aed.
- Troubleshooting help.

In addition to this user manual, the currently applicable laws, statutory- and hygiene regulations, generally accepted rules of technology as well as regulations for occupational health and safety and accident prevention must be complied with.

2.2.1 Typographic Conventions

The following table describes the typographic conventions.

| Typographic conventions | Description |
|---|--|
| Key | Indicates a key. |
| [Softkey] | Indicates a softkey (function key). |
| {Voice instruction} | Indicates a voice instruction. |
| <Text instruction>, <Info mode page> | Indicates a text instruction or an info mode page. |
| <<Info mode parameter>> | Indicates an info mode parameter. |
| ◆Error Messages◆ | Indicates an error code. |
| <i>Value</i> | Indicates the value of an info mode parameter value. |

Tab. 2-1 Typographic Conventions

2.2.2 Depiction of Warnings

Warnings alert the user of possible sources of danger. Warnings are categorised into four levels of danger. The levels of danger DANGER, WARNING and CAUTION denote bodily injuries. The danger level NOTICE indicates material- and environmental damage. Warnings for a chapter are listed at the beginning of the chapter. The user must heed warnings.



DANGER

A hazard with a high degree of risk which, if not avoided, will result in death or serious injury.



WARNING!

A hazard with a medium degree of risk which, if not avoided, may result in death or serious injury.

**CAUTION**

A hazard with a low degree of risk which, if not avoided, may result in minor or moderate injury.

NOTICE

A hazard with a low degree of risk which, if not avoided, may result in minor or moderate damage to property or the environment.

2.2.3 Depiction of Notices



Notes point out important information which the user must heed when carrying out an instruction. Notes provide the user with additional information on a particular issue.

2.2.4 Depiction of Instructions

An instruction describes the steps the user has to perform to complete the task.



















The symbol in the margin indicates an instruction and the pertaining steps. The instruction consists of the goal description, the pre-requisites, the individual steps and the results of a step.

2.3 Data Protection

















Some device options save or transfer personal data for provision of services and patient care in encrypted form. The General Data Protection Regulation (EU) 2016/679 as well as further applicable guidelines, ordinances and laws are respected.











2.4 Symbols

The following table describes the symbols used in this document.

| Symbol | Designation | Description |
|---|---|--|
|  | Status: ready for operation | Indicates in status display that the device is ready for operation. |
|  | Status: troubleshooting | Indicates a troubleshooting status in the status display. |
|  | Mission duration | Indicates the mission duration in the status line. Alternating every 5 s with „Remaining time until next analysis“. |
|  | Remaining time until next analysis | Indicates the remaining time until next analysis in the status line. Alternating every 5 s with „Mission duration“. |
|  | Delivered shocks | Indicates the number of delivered shocks in the status line. |
|  | Battery status | Indicates the battery status of the corpuls aed in the status line. |
|  | Patient class Adult | Indicates in the status line that the patient class Adult has been selected. |
|  | Patient class Child | Indicates in the status line that the patient class Child has been selected. |
|  | Emergency connection is being established | Indicates in the status line that the emergency connection is being established. |
|  | Emergency connection is established | Indicates in the status line that the emergency connection is established. |
|  | Emergency connection failed | Indicates in the status line that the emergency connection has failed. |
|  | Emergency connection ended | Indicates in the status line that the emergency connection has been terminated. |
|  | Manufacturer | Indicates the manufacturer of the corpuls aed on the rating plate. |
|  | Part number | Indicates the part number on the rating plate. |
|  | Serial number | Indicates the serial number on the rating plate. |
|  | Read the user manual | Indicates in the rating plate that the User Manual must be observed. |

Tab. 2-2 Symbols

| Symbol | Designation | Description |
|---|--|--|
|  | Trash can | Indicates in the rating plate that the materials should not be disposed of via the household waste. |
|  | Medical device | Indicates that the item is a medical device. |
|  | Repackaging | To identify that a modification to the original medical device packaging configuration has occurred. |
|  | Importer | Indicates the entity importing the medical device into the locale. |
|  | Distributor | Indicates the entity distributing the medical device into the locale. |
|  | Unique Device Identifier | Indicates a carrier that contains Unique Device Identifier information. |
|  | Protection | Indicates in the rating plate that the corpuls aed is dust- and splash-proof. |
|  | CE Mark | Indicates in the rating plate that the corpuls aed is approved by the Notified Body. |
|  | Regulatory compliance mark | Indicates in the rating plate that the corpuls aed is approved by the Australian Admission Board. |
|  | Caution | The battery rating plate indicates that the battery must be handled with care. |
|  | Do not throw the battery into fire | The battery rating plate indicates that the battery must not be thrown into fire. |
|  | Do not deform the battery | The battery rating plate indicates that the battery must not be deformed. |
|  | Socket for optional CPR Feedback disposable sensor | Indicates the socket of the CPR Feedback disposable sensor. |
|  | Socket for corPatch easy therapy electrodes | Indicates the socket of the corPatch easy therapy electrodes. |
|  | Defibrillation-proof, type BF patient socket | Indicates a defibrillation-proof application part, type BF (Body Floating) at the interface. Insulated application parts of this type are approved for external and internal application at the patient. |
|  | On/Off key | Indicates the On/Off key. |

| Symbol | Designation | Description |
|---|--|--|
|  | Emergency key | Indicates the Emergency key. |
|  | Shock key | Indicates the Shock key. |
|  | Softkey [Language selection] | Indicates the softkey [Language selection]. |
|  | Softkey [Language selection] | Indicates the softkey [Language selection] with a sticker besides the softkey. NOTE: With some semi-automatic models as an alternative to the symbol integrated into the softkey. |
|  | Read the user manual or the electronic user manual | Indicates that the user must observe the User Manual. |
|  | Keep dry | Indicates a medical device that has to be protected from wetness/moisture. |
|  | Fragile, handle with care | Indicates a medical device that can break or be damaged when handled carelessly. |
|  | Protect from (sun)light | Indicates a medical device that has to be protected from light sources. |
|  | Temperature limit | Indicates the temperature limit values to which the medical device can be exposed safely. |
|  | Here is the top | To indicate correct upright position of the transport package. |

Tab. 2-3 Symbols

3 Safety

3.1 Safety instructions for the user

3.1.1 General Terms



DANGER

Failure to perform resuscitation!

Delayed defibrillation may result in irreversible injury or the death of the patient.

- ▶ See the following instructions for fast therapy that is as successful as possible.



DANGER

Must not be used with conscious patients!

Electric shock while using the defibrillator may have the following side effects for patients, users and third parties: cardiac arrhythmia, ventricular fibrillation (VF) or asystole.

- ▶ Do not use the corpuls aed if the patient is conscious.
- ▶ Ventricular fibrillation (VT) or ventricular tachycardia (VT) may be detected even in patients who are conscious.



DANGER

Monitor patients at all times while using the device!

As the corpuls aed is designed exclusively for emergency treatment with resuscitation measures and defibrillation and extended patient monitoring is not possible, incorrect conclusions may be drawn.

- ▶ Use the corpuls aed exclusively for emergency treatment for resuscitation measures with defibrillation.
- ▶ Do not use the corpuls aed as a general patient monitor.



DANGER

Risk of swallowing or asphyxiation!

Because the corpuls aed and the accessories include small and very small parts, children may swallow them and be asphyxiated.

- ▶ Make sure that the corpuls aed and all its parts cannot be accessed by children.



WARNING!

Use of a high-frequency surgical device!

May lead to burn injuries to the user and patient due to current leakage from the high-frequency surgical device to the corPatch easy therapy electrodes.

- ▶ Do not operate the corpuls aed simultaneously with a high-frequency surgical device (e. g. electrocautery device) or MRI devices.

**WARNING!**

Device failure due to improper battery replacement!

The corpuls aed may be rendered inoperable due to improper battery replacement.

- ▶ Users are not permitted to replace batteries.
- ▶ To replace the battery see (see 8.2 Replacing the Battery on page 48).
- ▶ Do not remove the battery during defibrillation.

**WARNING!**

Non-approved device mission!

Repeated performance of the analysis or switching the device on and off repeatedly may cause the corpuls aed to overheat. This may cause burns or even functional failures in the corpuls aed.

- ▶ Do not restart the analysis multiple times.
- ▶ Do not switch the corpuls aed on and off several times in succession.

NOTICE

Device failure due to mechanical damage!

The corpuls aed may be rendered inoperable by mechanical damage (e.g. by dropping or throwing it).

- ▶ Do not drop or throw the corpuls aed.
- ▶ Make sure that the conductive parts of electrodes and attached plugs do not touch other conductive parts including the ground. Other conductive parts can be, e.g. metal parts of stretchers.

**WARNING!**

Reduction of the essential performance of the device!

Failure to observe the minimum distance between portable HF communications devices, including their accessories and corpuls aed, can lead to a reduction in the performance characteristics of this corpuls aed.

- ▶ Do not use portable/mobile HF communications equipment (including their accessories such as antenna cables and external antennae) at a distance less than 30 cm (12 In) to the corpuls aed.

**CAUTION**

Risk of infection

The primeCPR easy feedback sensor is an unsterile disposable article.

- ▶ To guarantee safe use and unlimited functionality and to prevent cross infections, the primeCPR easy feedback sensor must only be used once.

3.1.2 Defibrillation

**DANGER**

Burning or explosion of the defibrillator due to wrong environmental conditions during operation!

May lead to severe injuries or death of users, patients or third parties.

- ▶ Do not operate the corpuls aed in the following situations: in the vicinity of readily flammable anaesthetics or other flammable substances as well as in an oxygen-rich (>23 %) environment.

**DANGER**

Caution high voltage!

As the device uses a high electrical discharge voltage, there is an injury risk for the user.

- ▶ Do not touch patient or the device during shock release.

**DANGER**

Ineffective therapy or risk of injuries to the patient!

If the corPatch easy therapy electrodes are not attached as shown on the pictograms, the therapy may be ineffective or there is a risk of injuries to the patient.

- ▶ Attach the corPatch easy therapy electrodes as shown on the pictogram.

**DANGER**

Patients with implanted pacers!

In patients with an implanted pacer, it is possible that shockable ECG rhythms or arrhythmias will only be detected to a limited extent. The corpuls aed does not suppress the detection of the impulses of implanted pacers. With implanted pacers it may occur that the heart rate measurement or the ECG analysis erroneously measure the pacer frequency in case of cardiac arrest or other cardiac arrhythmia conditions.

- ▶ The patient's medical history and physical examination are important for determining whether a pacer is implanted.
- ▶ Patients with implanted pacers must be very closely monitored.
- ▶ Check the patient's pulse and do not rely exclusively on heart rate measurement.

**WARNING!**

Inadequate therapy with non-appropriate accessories!

The accessories have to be appropriate for the patient. Use only corPatch easy Pediatric therapy electrodes for children under 8 years or under 25 kg in weight.

- ▶ Use corPatch easy therapy electrodes for adults for all other patients.
- ▶ The type of the corPatch easy therapy electrode is shown on the label on the packaging.

**WARNING!**

Non-approved accessories!

Can cause malfunctions in the device and so delay or abort therapy.

- ▶ Use only accessories specified for the patient.
- ▶ The use of accessories and cables other than those specified for the corpuls aed may result in increased electromagnetic emissions or reduced electromagnetic immunity of the corpuls aed and result in faulty operation.
- ▶ Use only approved accessories (see 4.2 Accessories on page 23).
- ▶ Use only corPatch easy Pediatric therapy electrodes for children under 8 years or under 25 kg in weight.
- ▶ Use corPatch easy pre-connected therapy electrodes for adults for all other patients.



The type of the corPatch easy therapy electrode is shown on the label on the packaging.

**WARNING!**

Electric shock when using the defibrillator in a damp environment!

Using the corpuls aed and performing defibrillation on a wet or conductive surface or in a damp environment may cause injury (electric shock, burns, etc.) to patients, users and/or other persons in the immediate vicinity.

Can lead to the following side effects in patients, users and third parties: arrhythmias, ventricular fibrillation or asystole.

- ▶ Use the corpuls aed only in a dry and non-conductive environment.
- ▶ Place patients on a dry or non-conductive surface before defibrillation.
- ▶ Do not touch the patient during defibrillation.

**WARNING!**

Incorrect application of disposable products

If the disposable products (corPatch easy therapy electrodes and optional CPR Feedback disposable sensors) are applied for too long, the skin of the patient may be affected (red patches and skin irritation). Accessories labelled as disposable products or consumable materials must not be used more than once. The same disposable article must not be used for different patients.

- ▶ Replace corPatch easy therapy electrodes after use.
- ▶ Replace CPR Feedback disposable sensors after use.

**WARNING!**

Faulty ECG results due to shock, vibration or artificial respiration!

If the ECG analysis lasts too long, the results may be incorrect and may lead to misinterpretation of the ECG. This may cause diagnostic errors and as a result incorrect treatment.

- ▶ Do not touch patient during ECG analysis.
- ▶ Avoid external commotion and vibration during ECG analysis to avoid motion artefacts.
- ▶ Briefly discontinue artificial ventilation during ECG analysis.

**WARNING!**

Disturbance of the device functions when the electromagnetic interference is exceeded according to the guidelines and manufacturer's declaration!

Incorrect interpretation of the ECG analysis results and resulting misinterpretation of the ECG or device failure.

- ▶ Avoiding electromagnetic interference with values greater than specified in the Guidelines and Manufacturer's Declaration (see VI Guidelines and Manufacturer's Declaration on page 72).
- ▶ Do not store the corpuls aed in the immediate vicinity of other devices or stacked with other devices to avoid interference with electromagnetic fields.
- ▶ If operation is required close to or stacked with other equipment, observe the corpuls aed to verify its appropriate use in this arrangement.

 **WARNING!**


Insufficient effectiveness of the corPatch easy therapy electrodes during therapy!

If the corPatch easy therapy electrodes are not fully effective, a correct defibrillator therapy on the patient may not be guaranteed or the patient may suffer serious burns.

- ▶ Follow all safety instructions on the packaging of the corPatch easy therapy electrodes.
- ▶ Do not open pouch until ready for use.
- ▶ If the packaging is damaged or has previously been opened, do not use the corPatch easy therapy electrodes.
- ▶ Do not use corPatch easy therapy electrodes if the expiry date indicated on the packaging has passed.
- ▶ Do not use the corPatch easy therapy electrodes if they are damaged.
- ▶ Do not crush, bend, fold or store the corPatch easy therapy electrodes under heavy objects.
- ▶ If the gel has dried, do not use the corPatch easy therapy electrodes.
- ▶ Do not use additional gel on corPatch easy therapy electrodes.
- ▶ Do not overlap the corPatch easy therapy electrodes.
- ▶ Keep the corPatch easy therapy electrodes clear of other electrodes or metal parts in contact with the patient.
- ▶ Avoid contact between body parts of the patient, such as exposed skin on the head or limbs, with conductive fluids and metal objects.
- ▶ Disconnect the corpuls aed from the patient, if another defibrillator is used.

 **WARNING!**

Non-connected corPatch easy therapy electrodes with the setting "pre-connected electrodes"!

If the selftest option "Electrodes pre-connected" is configured in the corpuls aed, the corPatch easy therapy electrodes have to be connected before switching on. If they are not connected, the status display shows the red tool symbol .

- ▶ Connect the corPatch easy therapy electrodes and check positioning.

 **WARNING!**

Inadequate contact of the therapy electrodes during therapy!

Attaching the corPatch easy therapy electrodes or other product parts may cause allergic reactions or skin irritations.

- ▶ Apply therapy electrodes to the patient according to the instructions in the user manual.
- ▶ When placing the corPatch easy therapy electrodes on the patient's skin, make sure that no air pockets are included inside the adhesive surface.

 **WARNING!**

Device not operational in normal use due to incorrect operation of Shock key!

Pressing the Shock key for longer than 10 s switches the device to emergency mode (CPR-only mode) and indicates wrong handling.

- ▶ Only use the Shock key to release a shock.

**WARNING!**

User error during application of CPR!

If the user does not completely release the pressure during the phase between compressions when administering CPR, the feedback from the corpuls aed may be negative.

- ▶ Release the pressure on the patient's chest completely during the phase between compressions.

**CAUTION**

Ineffective rest position of the disposable corPatch CPR disposable sensor!

The detection of the rate and depth of chest compressions may be compromised by movement affecting the corPatch CPR disposable sensor.

- ▶ Protect the corPatch CPR disposable sensor from movement during complete application.

**CAUTION**

Insufficient contact of the corPatch easy therapy electrodes during therapy mission!

Can lead to the following side effects in patients with excessive hair or in case of incorrectly placed corPatch easy therapy electrodes: Irritated skin, burn injuries as well as reddening of the patient's skin.

- ▶ Remove excessive hair from the patient's skin as much as possible.
- ▶ Apply corPatch easy therapy electrodes to the patient according to the instructions in the user manual.
- ▶ When placing the corPatch easy therapy electrodes on the patient's skin, make sure that no air pockets are included inside the adhesive surface.

NOTICE






Effects of using the defibrillator on non-defibrillation-proof devices!

Can lead to malfunctions or failure of non-defibrillation-proof devices.

- ▶ Disconnect non-defibrillation-proof devices (e.g. separate ECG device) from the patient before defibrillation.
- ▶ Keep the corPatch easy therapy electrodes clear of other electrodes or metal parts in contact with the patient.

3.2 Warning- and Notice Labels on the Device

The following table describes the warning- and notice labels on the housing of the corpuls aed.

| Warning-/Notice labels | Description |
|--|---|
|  | Mind the user manual. |
|  | Defibrillation-proof application part, type BF (Body Floating). Insulated application parts of this type are approved for external and internal application at the patient. |
|  | Socket for corPatch easy therapy electrodes |
|  | Socket for optional CPR Feedback disposable sensor |
|  | Disposal notes battery |

Tab. 3-1 Warning- and Notice Labels on the Device

3.3 Cyber Security

The aim of cyber security is to protect companies and organisations from unauthorised data access by third parties and from resulting damage such as espionage, sabotage and hacker attacks.

An internal mechanism of corpuls aed prevents an unintended update. In order to protect the system integrity, updates or software changes have to be implemented with certain routines and codings. A selftest checks the system integrity and fails if the system integrity cannot be guaranteed. The corpuls aed is only partially ready for operation. Please contact authorised sales and service partners:

For safe operation of the corpuls aed, the following points have to be kept in mind:

- Description of device functions that protect important functions even if the cyber security of the corpuls aed has been compromised (see above).
- Device instructions and product specifications with regard to the recommended cyber security checks in the intended area of use (see 9.2 Error in standard mode (AED Mode) on page 52).
- Specific instructions for user with regard to the support of infrastructure requirements for the device to function properly (see Service Instruction, Modifying Device Settings).
- List of network ports and other interfaces which are expected to receive and/or send data as well as a description of the port functionality and if they are ingoing or outgoing ports (see Service Instruction, Interfaces and Ports for External Communication).

4 Scope of Delivery

4.1 Standard Scope of Delivery

The corpuls aed is supplied with:

- Electrode compartment/electrode compartment XL (mounted on the rear side of the corpuls aed) or accessory bag corpuls aed
- Battery
- corPatch easy pre-connected therapy electrodes (adult)
- User manual
- Sticker "corpuls aed fully automatic", which the operator can stick to the device if necessary.

4.2 Accessories

See below for an up-to-date list of accessories for the corpuls aed:

my.corpuls.world



Use of the corpuls aed with therapy master cable and "corPatch easy pre-connected therapy electrodes" is not permitted.

When using "corPatch easy defibrillation/pacing electrodes with cable (hard shell)", please note that these cannot be stored in the compartments "Electrode compartment (rear side) corpuls aed" and "Electrode compartment XL (rear side) corpuls aed". For this, use the accessory bag.

5 Device Description

5.1 Description of Functions

The user can use the corpuls aed for defibrillation of persons who are suffering from a sudden cardiac arrest. The corpuls aed analyses the cardiac rhythm of the patient, guides the user with voice instructions and pictograms and recognises whether a defibrillation is required or not. At the start of the analysis the corpuls aed automatically prepares for defibrillation. The method of shock administration depends on the model in use (semi-automatic or fully automatic).

The corpuls aed also supports the first responder with voice instructions and an acoustic metronome. The metronome sets a rhythm for the user administering immediate life-saving measures (chest compressions) for cardiopulmonary resuscitation.

(option)

The application of the optional CPR Feedback disposable sensor allows to display information of the completed chest compressions and issue voice instructions for adjustment of the chest compressions. If a corpuls aed device is delivered without the CPR feedback function, the connection interface is closed.



The corpuls aed is intended for infrequent use.

5.2 Available Models

The corpuls aed is available in different model variants.

The semi-automatic model has extended analysis options and allows manual release of a shock.

The fully automatic model performs analysis and shock release automatically.

In addition to the model variant, options such as GSM emergency call, language selection and CPR Feedback function are available. Which options are integrated can be determined from the available keys on the front of the device and the available sockets at the top of the device.

5.3 Front Side of the Device

The available keys on the front of the device depend on the model: fully or semi-automatic, with or without emergency call function, with or without language selection. The front of the device is shown here using the example of the semi automatic device with emergency call function.

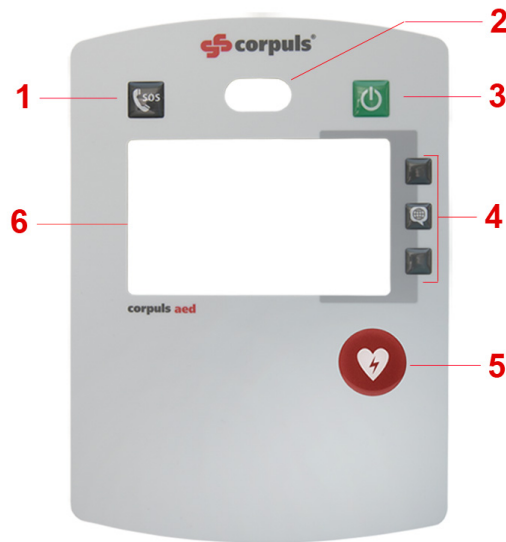


Fig. 5-1 Front panel layout (example: semi automatic device with emergency call function)

| Item | Element | Description |
|------|-----------------------|--|
| 1 | Emergency key | Key for emergency call function if available on that model. |
| 2 | Status display | Indicates the status of the corpuls aed. |
| 3 | On/Off key | On/Off power key. |
| 4 | Softkeys | Indicate possible function allocations e.g. softkey[Analyse] or language selection, if available on that model. |
| 5 | Shock key | Shock therapy key |
| 6 | Screen user interface | Displays a status line at the top, depending on the operator settings pictograms or curves and vital parameters, as well as text instructions below. |

Tab. 5-1 Display and operating elements



The language selection is accessed in all models with the softkey [Language selection]

As an alternative to the symbol integrated in the softkey, in some semi automatic models there may be a sticker with the following symbol besides the softkey:

The following table indicates which [Analyse] keys or softkeys are available with which model (x):

| | On/Off key | Emergency key | Shock key | Softkey [Analyse] | Softkey [Language selection] |
|--|------------|---------------|-----------|-------------------|------------------------------|
| Semi-automatic device - with emergency call function | X | X | X | X | X |
| Semi-automatic | X | | X | X | X |
| Fully automatic device (ext.) - with emergency call function | X | X | | | X |
| Fully automatic device (ext.) | X | | | | X |
| Fully automatic device - without language selection | X | | | | |

Tab. 5-2 Key/softkey availability by model

5.3.1 User Interface Screen

The user interface can be configured by the operator.

Depending on the configuration by the operator, the corpuls aed shows one of the two screen output types for the voice commands:

- Matching pictograms, including text instructions
- View with curves and vital parameters, including text instructions

Screen output type Pictograms

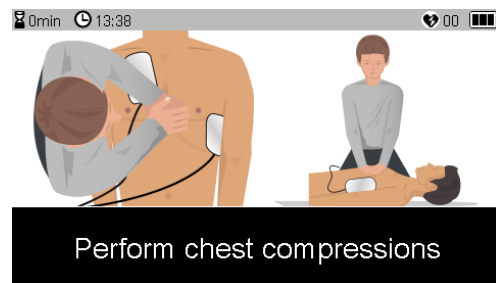


Fig. 5-2 User interface with pictogram with operating instructions, including text instructions (example)

Screen output type Curves and vital parameters

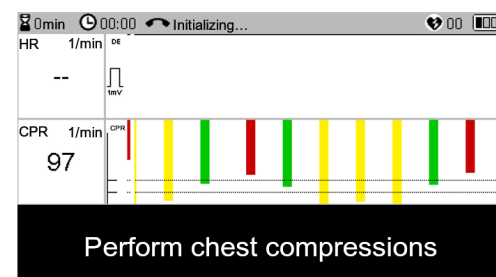


Fig. 5-3 User interface with curves, vital parameters and text instructions (example)

| Item | Element | Description |
|------|---------------------------------------|--|
| 1 | Status line | Indicates various status data of the corpuls aed. |
| 2 | ECG cardiac rhythm display | Indicates an ECG. The height of the calibration pulse before the curve indicates 1 mV. |
| 3 | CPR feedback display | Every bar of the CPR feedback display represents one chest compression detected by the optional CPR Feedback disposable sensor (see 6.2.1.7 Performing Cardio-pulmonary Resuscitation on page 40). |
| 4 | Text instructions | Indicates text instructions. |
| 5 | Parameter field for the CPR frequency | Indicates the frequency of the chest compressions detected by the optional CPR Feedback disposable sensor. The unit 1 /min stands for the number of compressions per minute. |
| 6 | Parameter field for the heart rate | Indicates the heart rate of the ECG obtained with the corPatch easy therapy electrodes. The unit 1 /min stands for the number of beats per minute. |

Tab. 5-3 Structure of the screen user interface

5.3.2 Status Line

The status line contains the following information:

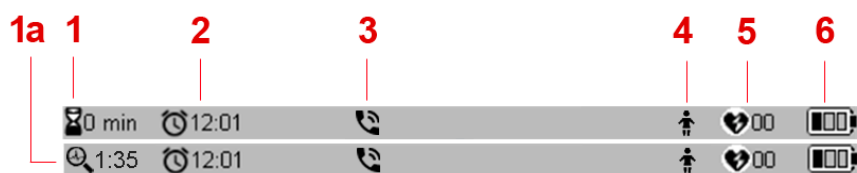


Fig. 5-4 Layout of the status line

- 1 Alternately: Mission duration / Remaining time until next analysis (1a)
- 2 Time
- 3 Status messages on the call
- 4 Patient class
- 5 Number of shocks in the current rescue operation
- 6 Battery status

Item 1 shows after the first assessment of heartrhythm either the „Mission duration“ in minutes or the „Remaining time until next analysis“ (Item 1a), alternating every 5 s. The timer always starts with 2 min/ 3 min, depending on the configuration of the AED parameter CPR time (see Service instruction).

5.4 Top of Device

The top of the device has the following sockets:

- corPatch CPR disposable sensor (1)
- corPatch easy therapy electrodes (2)



Fig. 5-5 Variant corPatch CPR

corPatch easy therapy electrodes (2)



Fig. 5-6 Variant without CPR Feedback

primeCPR easy disposable sensor (3) and
corPatch easy therapy electrodes (2)



Fig. 5-7 Variant primeCPR easy

5.5 Storage of Device and Accessories

For storing the accessories there is either an electrode compartment (also XL) or an accessory bag.



The corpuls aed can be wall-mounted with a wall mount (for electrode compartment) listed with the accessories.

If the corpuls aed is to be connected to a WLAN network on a wall-mount, ensure that WLAN network coverage is adequate at the installation location.

6 Bedienung

6.1 Switching on the Device



Use the corpuls aed in case of emergency, even if the status display shows the red screwdriver icon . In this case the corpuls aed tries emergency operation with as many functions as possible.



If configured by the operator, the corpuls aed records all conversations and noises in standard mode. The operator can download the audio records at any time.

Standard mode of the corpuls aed is required to perform a resuscitation.

In all models with language selection, the user can choose one of the three languages installed on the corpuls aed via the three softkeys. If only one or two languages are installed, only these can be selected. The language selection in these models can be changed anytime, also during use.

To switch on the corpuls aed in standard mode, proceed as follows:



1. Briefly press **On/Off** key.



Do not press the **On/Off** key any longer than 7 s, otherwise the info mode (visible in the screen user interface) will be started. If this is done accidentally, exit info mode and switch on the corpuls aed again. To exit info mode, press the **On/Off** key for 2 s.

If the user presses the **On/Off** key for longer than 12 s, the corpuls aed starts normally in standard mode.

See Info mode in the service instruction.

The corpuls aed issues a start tone and the following voice instruction once in a fully automatic model: {Call for help}



The corpuls aed is not ready for operation if the battery is discharged.

If the battery charge is low the corpuls aed will operate in emergency mode (CPR-only mode). This means that it supports the user in carrying out resuscitation measures, but does not perform ECG heart rhythm analysis and does not give any shock.

2. In models with language selection the language selection opens automatically.

The screen shows the three languages assigned to the softkeys.

3. In models with language selection: Press the softkey assigned to the selected language.

The language selection menu disappears and the corpuls aed switches to the selected language. The corpuls aed changes the text instructions immediately, the voice instructions at the start of the next voice instruction.



It is possible to change the voice instructions anytime during normal use.

Press softkey [Language selection] (or in some semi automatic models the softkey besides the symbol) to open.

6.2 Therapy

6.2.1 Performing Resuscitation

The corpuls aed guides the user through a standardised resuscitation protocol according to the recommendations of the currently valid guidelines. During this process the corpuls aed directs the user with voice instructions and pictograms or vital parameter curves, including text instructions on the screen.



The acoustic guidance by voice instructions and the visual guidance by pictograms, including text instructions, are simultaneous.



In the following chapters, the steps described are exemplary for the following device settings:

Screen output type Pictograms

-Voice instructions for the professional user



If the screen output type Pictograms is not set for a corpuls aed, these pictograms are omitted in the subsequent operating instructions in the chapter Operation - Therapy. In this case of a semi-automatic model, all necessary steps are still initiated by voice instructions and text instructions. With the use of a semi-automatic model, some of the steps described above are the responsibility of the user, even if no explicit voice instructions and text instructions have been issued. This is e.g. in a semi-automatic model with GSM emergency call the case.

6.2.1.1 Initiating Emergency Call

Fully automatic/semi automatic model without emergency call



To initiate an emergency call for a model without emergency call proceed as follows:

Prerequisite:

- ✓ The corpuls aed has issued the voice instruction {Call for help}.

1. When the following pictogram is displayed, dial the emergency number on a telephone or have another person in the immediate vicinity dial the number.

The following pictogram prompts the user to place an emergency call over a telephone:



Fig. 6-1 Pictogram Dial emergency number via telephone



If the pictogram-mode is not configured for a semi-automatic model, the initiation of an emergency telephone call is the responsibility of the user.

Fully automatic model with emergency call



To initiate an emergency call over a fully automatic model with emergency call proceed as follows:

1. After the pictogram appears, press the **Emergency call** key.
The following pictogram prompts the user to press the **Emergency call** key:



Fig. 6-2 Pictogram Press **Emergency call** button (fully automatic corpuls aed model with emergency call)

The corpuls aed automatically connects to the stored emergency number.

Semi automatic model with emergency call



To initiate an emergency call via a semi automatic model with emergency call, proceed as follows:

1. After the pictogram appears, press the **Emergency call** key.



If the pictogram-mode is not configured for a semi-automatic model, the initiation of an emergency telephone call with the **Emergency call** key is the responsibility of the user.

The following pictogram prompts the user to press the **Emergency call** key:



Fig. 6-3 Pictogram Press **Emergency call** button (Semi-automatic corpuls aed model with emergency call)

If more than one emergency call number is configured, the user interface of the corpuls aed shows a maximum of three preset numbers after pressing the **Emergency call** key. The telephone numbers are allocated to the softkeys.



If only one emergency number is configured, the corpuls aed will automatically connect to the pre-configured telephone number.

2. If more than one emergency numbers are configured, press the softkey allocated to the required number.

The corpuls aed connects to the number.

Both models with emergency call of the corpuls aed displays the connection status in the status line of the screen as follows:

| Symbol | Status |
|--------|------------------------------|
| | Connection being established |
| | Connection is established |
| | Connection failed |
| | Call finished |



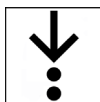
The telephone connection can be disconnected by the other end, by pressing the key **Emergency call** again or by switching off the corpuls aed.

If a connection to the GSM network has not yet been established, the corpuls aed memorizes the key being pressed and establishes the telephone connection if a GSM network is present.

6.2.1.2 Preparing the Patient

The patient must be prepared before using the corpuls aed.


To prepare the patient, proceed as follows:



1. Place the patient supine on a firm, non-electrically conductive and dry surface.
2. Remove clothing from the patient's chest region.
3. If possible, remove excessive hair from the patient's chest where the corPatch easy therapy electrodes will be attached.
4. If necessary, clean and dry the patient's skin where the corPatch easy therapy electrodes will be attached.

6.2.1.3 Use corPatch easy Therapy Electrodes



If the selftest option "Electrodes pre-connected" is configured in the corpuls aed, the corPatch easy therapy electrodes are connected and the status display still shows the red tool symbol , the user has to check positioning of the corPatch easy therapy electrodes.



To connect the corPatch easy therapy electrodes to the device and to attach them to the patient, proceed as follows:

1. If they are not yet connected, push in the plug of the corPatch easy pre-connected therapy electrodes into the black socket of the corPatch easy therapy electrodes to the stop.



Fig. 6-4 Socket for corPatch easy therapy electrodes

1 Socket for corPatch easy therapy electrodes



Connect cables in accordance with the colour codes.



Fig. 6-5 Connected corPatch easy therapy electrodes

1 corPatch easy therapy electrodes



Alternatively, as an extension, the therapy master cable (see 4.2 Accessories on page 23) - in combination with corPatch easy defibrillation/pacing electrodes with cable (hard shell) - can be used.

2. If the therapy master cable is used as an extension, connect the plug of the corPatch easy therapy electrodes (corPatch easy defibrillation/pacing electrodes with cable (hard shell)) to the socket of the therapy master cable and push the black plug of the therapy master cable all the way into the socket for corPatch easy therapy electrodes of the corpuls aed.



When using the extension with the therapy electrodes, it is not possible to store the feedback sensor in the XL electrode compartment.

3. Remove the corPatch easy therapy electrodes from the packaging.

4. Remove the protective foil and attach the corPatch easy therapy electrodes to the naked upper body of the patient, as shown on the front of the corPatch easy therapy electrodes.
Press the corPatch easy therapy electrodes firmly to the patient's skin (item 1, item 2) to ensure a good electrical contact.

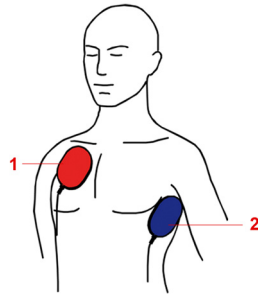


Fig. 6-6 Positioning the corPatch easy therapy electrodes



Place the corPatch easy therapy electrodes for adults or the corPatch easy Pediatric therapy electrodes for children on the apex (pos. 2) and sternum (pos. 1) positions or on the front and back of the thorax. Follow the information on the packaging of the corPatch easy therapy electrodes.

If the plug of the corPatch easy therapy electrodes is not yet connected to the corpuls aed, the corpuls aed will repeat the following voice instruction every 10 s
{Plug electrodes into device}
and shows the following pictogram:

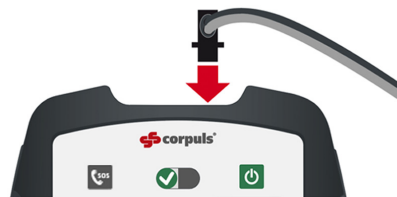


Fig. 6-7 Pictogram Plug in corPatch easy therapy electrodes

If both corPatch easy therapy electrodes have not yet been attached to the patient's upper body, the corpuls aed following voice instruction is repeated every 10 s:
{Undress patient's chest and stick the electrodes on it}
and shows the following pictogram:

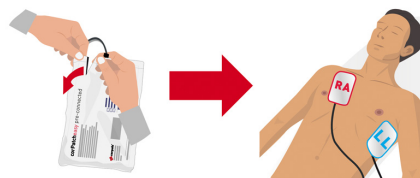


Fig. 6-8 Pictogram Attach corPatch easy therapy electrodes



If the above language instructions remain several times without an action of the user, a timeout terminates the voice instructions and the corpuls aed continues with the CPR phase.

If the corPatch easy therapy electrodes are correctly attached to the patient, the corpuls aed starts the analysis and recording of the ECG immediately.



If the device is a semi-automatic model or if an automatic analysis start is not set, the corpuls aed does not start until the [Analysis] softkey is pressed.

Based on the result of the analysis the corpuls aed determines whether defibrillation is required or not and informs the user.

6.2.1.4 Fully Automatic Model: Accompany Defibrillation

Accompany defibrillation

As a fully automatic device, the corpuls aed starts the analysis automatically after the remaining time until the next analysis has elapsed (see 5.3.2 Status Line on page 27). After starting the automatic analysis, the corpuls aed calculates the heart rate as the average of the last eight detected QRS complex intervals, and it is updated at every heart beat.



The operator (see Service instruction) has configured the fully automatic devices to start the analysis automatically. The [Analyse] softkey is not available.

At the start of heart rate measurement and at every restart the corpuls aed displays the value 0 /min until the third QRS complex interval. As soon as the corpuls aed detects three QRS complex intervals, it calculates the heart rate as the average of the three QRS complex intervals and updates it with every additional heart beat until eight QRS complex intervals have been reached.

If the corpuls aed does not detect a heart beat for a period exceeding 5 s, the corpuls aed displays the heart rate as 0/min.

If the corpuls aed detects a rhythm that requires defibrillation (ventricular fibrillation (VF) or ventricular tachycardia (VT)), the corpuls aed notifies the user that it is preparing for a shock.

To accompany the potential defibrillation with the fully automatic device proceed as follows:



Prerequisite:

✓ Analysis phase is complete

1. One of the following situations occurs:

a) Shock is recommended.

The corpuls aed issues the following voice instruction: {Do not touch patient. Shock recommended}

The corpuls aed warns the user with at least three signal tones and automatically triggers the shock.



If the corpuls aed is not ready to administer the shock after the third signal tone, the corpuls aed plays additional signal tones until the shock is administered.

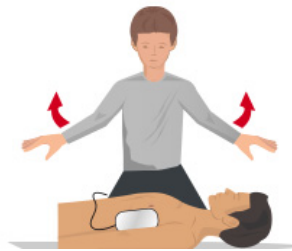


Fig. 6-9 Pictogram Do not touch patient (before and during shock administration)

b) There is a rhythm that does not require defibrillation.

The corpuls aed cancels the preparation for shock administration and internally discharges the defibrillator.

The corpuls aed issues the following voice instruction: {Shock not recommended}

The procedure is completed with a shock administration after a shock recommendation or is reset after a shock was not recommended.

6.2.1.5 Semi-automatic Model: Softkey Analyse and Defibrillation

Softkey [Analyse]

If the device is set to start the analysis manually with the [Analyse] softkey, the key flashes red before starting the analysis phase. The corpuls aed prompts the user with an voice instruction ({{Press the flashing Analyse key}}) and text instruction on the screen to press the [Analyse] softkey.

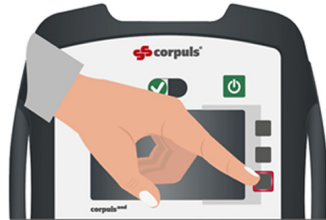


Fig. 6-10 Pictogram Press the softkey [Analyse]



The use of the [Analyse] softkey depends on the settings made by the operator (see Service instruction). The [Analyse] softkey is only available on the semi automatic corpuls aed model.

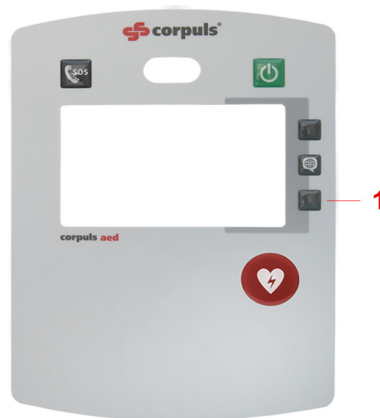


Fig. 6-11 Semi-automatic model with [Analyse] softkey

1 [Analyse] softkey



To start the ECG analysis with the semi automatic model proceed as follows:

Prerequisite:

✓ The {Press the flashing Analyse key} has issued the voice instruction

1. Press the [Analysis] softkey.

The ECG analysis phase starts.

The corpuls aed shows the following pictogram:



Fig. 6-12 Pictogram Do not touch patient (during ECG analysis)

After the ECG heart rhythm detection has been started, the corpuls aed carries out the following speech instruction as long as the ECG heart rhythm detector has not yet made a shock decision: {Do not touch patient. Analysing heart rhythm}

If the detector for the ECG heart rhythm measurement has not been able to make a clear decision after 15 s, the corpuls aed recommends no shock. The corpuls aed then asks the user to perform cardiopulmonary resuscitation (see chapter (see 6.2.1.7 Performing Cardiopulmonary Resuscitation on page 40)).

The status line shows either "Remaining time until next analysis or "Mission duration", alternating every 5 s (see 5.3.2 Status Line on page 27).

2. If a manual analysis start is configured, the user can cancel the cardiopulmonary resuscitation phase and restart the ECG analysis by pressing the [Analysis] softkey.

During the ECG analysis phase the user can restart the ECG analysis by pressing the [Analysis] softkey.



A safety device in the corpuls aed blocks restart of the analysis if the [Analysis] softkey is pressed more than five times within one minute. After that the [Analysis] softkey will not function until the corpuls aed has been restarted.

This prevents overheating of the corpuls aed by too frequent internal discharge of the HV capacitor.

Accompany defibrillation

If the corpuls aed detects a rhythm that requires defibrillation, the corpuls aed will prompt the user to perform the required steps.



To accompany the defibrillation and administer the shock with the semi automatic model proceed as follows:

Prerequisite:

✓ Analysis phase is complete

1. One of the following situations occurs:

a) Shock is recommended.

The **Shock** key flashes red and the corpuls aed emits a continuous tone.

The corpuls aed outputs the following voice instruction and repeats it every 5 s:

{Press the flashing Shock key} and shows the following pictogram:

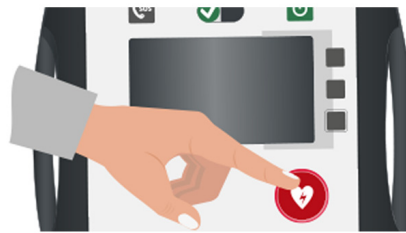


Fig. 6-13 Pictogram Press the flashing Shock key

b) There is a rhythm that does not require defibrillation.

The corpuls aed cancels the preparation for shock administration and internally discharges the defibrillator.



The shock cannot be triggered now.

The corpuls aed issues the following voice instruction: {Shock not recommended}

2. If a shock is recommended, press the **Shock** key.



After the defibrillator is charged, the selected energy is available for 15 s. If the user does not deliver a shock within this period of time, the corpuls aed discharges the energy internally.

The procedure is completed with a shock administration after a shock recommendation.

6.2.1.6 Using the disposable CPR feedback sensor (option)

There are 2 CPR Feedback disposable sensors available: Only plugs and sockets with matching colours can be used.

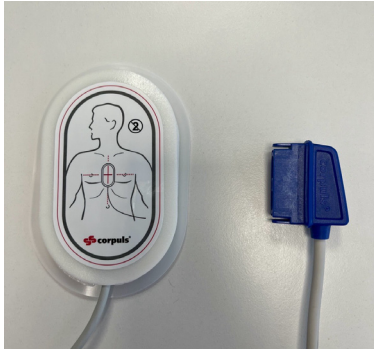
| | | |
|--|-----------------------------|--|
| <p>corPatch CPR disposable sensor (P/N 04235.2) with intermediate cable (P/N 06235.0)</p> <p>This variant is available until 2022-06-11.</p> | <p>Blue plug and socket</p> |  |
|--|-----------------------------|--|

Fig. 6-14 corPatch CPR disposable sensor


| | | |
|--|------------------------------|--|
| <p>primeCPR easy disposable sensor (P/N 04235.5) with intermediate cable (P/N 04235.50)</p> <p>This variant is available as of 2023-10-30.</p> | <p>Green plug and socket</p> |  |
|--|------------------------------|--|

Fig. 6-15 primeCPR easy disposable sensor

For the connection with the device, the CPR Feedback intermediate cable is needed.

To connect the CPR Feedback disposable sensor (option) to the device, proceed as follows:



✓ CPR Feedback disposable sensor is not connected with the device.

1. Insert the plug of the CPR Feedback intermediate cable into the socket with matching colour.



Fig. 6-16 Socket corPatch CPR intermediate cable to corpuls aed

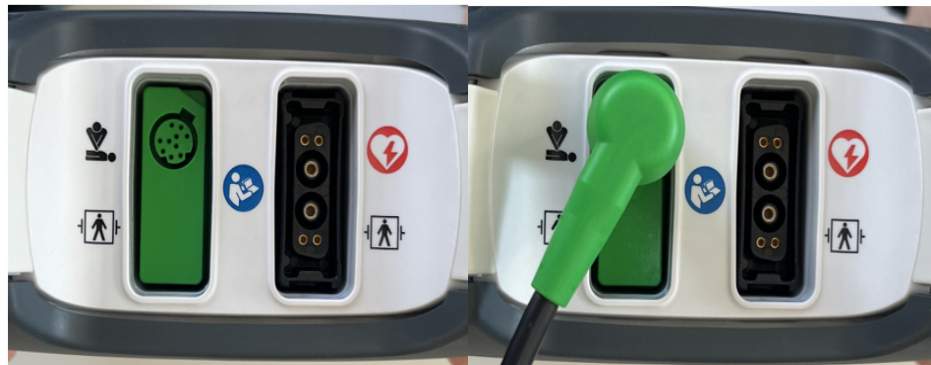


Fig. 6-17 Socket primeCPR easy intermediate cable to corpuls aed

2. Connect the CPR Feedback intermediate cable to the CPR Feedback disposable sensor.
3. Remove the CPR Feedback disposable sensor from the packaging.
4. Remove the protective foil.

5. Position the disposable CPR sensor on the upper body of the patient as shown in the picture.

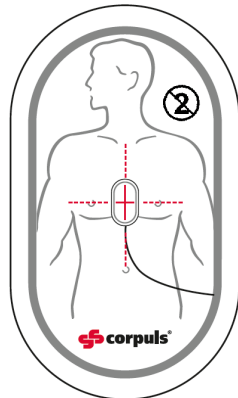


Fig. 6-18 Position of disposable sensor (option)

If in the corpuls aed the screen output type Pictograms is configured, the corpuls aed issues the following voice instruction

{Place CPR sensor}

and shows the following pictogram:

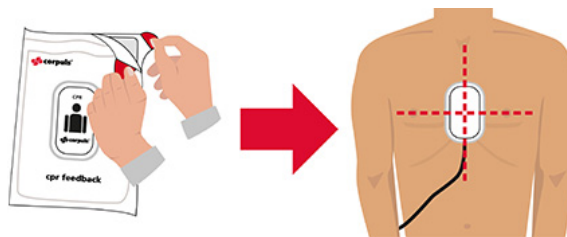


Fig. 6-19 Pictogram Attach CPR Feedback disposable sensor (option)



WARNING!

Incorrect application of disposable products

If the disposable products (corPatch easy therapy electrodes and optional CPR Feedback disposable sensors) are applied for too long, the skin of the patient may be affected (red patches and skin irritation). Accessories labelled as disposable products or consumable materials must not be used more than once. The same disposable article must not be used for different patients.

- ▶ Replace corPatch easy therapy electrodes after use.
- ▶ Replace CPR Feedback disposable sensors after use.

6.2.1.7 Performing Cardiopulmonary Resuscitation

The corpuls aed supports the user with the performance of cardiopulmonary resuscitation with voice instructions, text instructions and screen displays (type Pictogram or type Curve and vital parameters).

Depending on the settings of the operator, the following components are available for additional support for cardiopulmonary resuscitation:

- Acoustic metronome
- corPatch CPR disposable sensor (option)
- primeCPR easy disposable sensor (option)

The metronome specifies a rhythm for cardio-pulmonary resuscitation.

The disposable sensors convey information on chest compressions to the screen output type Curves and vital parameters, enabling the user to apply compressions at the correct compression rate and compression depth.



If a patient is under 8 years of age, the use of the optional CPR Feedback disposable sensor is not recommended.



The properties of the optional CPR Feedback disposable sensor function comply with the current scientific recommendations of international bodies for resuscitation, e.g. ERC.

During resuscitation the user must assess the status of the patient independently of the feedback information provided by the optional CPR Feedback sensor.



The optional corPatch CPR disposable sensor is covered under one or more of the following U.S.A. patents: 7,074,199; 7,108,665; 7,429,250; 8,147,433; 7,220,235

To perform cardiopulmonary resuscitation proceed as follows:



Prerequisite:

✓ Completed analysis and defibrillation phase

1. Follow the output of the following voice instructions, which the corpuls aed repeats at every switch between chest compressions and ventilation.

Voice instructions: {Start CPR now} and {Perform two rescue breaths}

The corpuls aed repeats this sequence, depending on the settings by the operator, for 2 min or 3 min.



If the continuous metronome is set, the corpuls aed issues the voice instruction only once at the start of the chest compression phase.

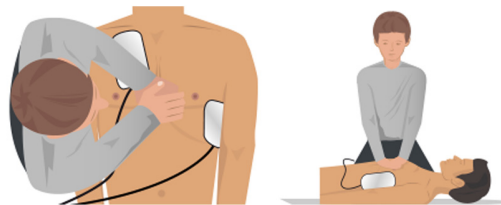


Fig. 6-20 Pictogram Perform chest compression



Fig. 6-21 Pictogram Perform two rescue breathes

Metronome

The metronome issues compression tones to set the rhythm for the chest compressions administered by the user. To signal the upcoming ventilation phase, the five last compression tones of the sequence are higher pitched than the preceding ones. The ventilation tones indicate when the user needs to ventilate the patient. The metronome switches automatically between compression tones and ventilation tones.

The metronome modes depend on the settings made by the operator (see "Service instructions"):

- *Off*: the metronome is off and does not issue audible compression- and ventilation tones.
- *30:2*: 30 compression tones are followed by 2 ventilation tones.
- *15:2*: 15 compression tones are followed by 2 ventilation tones.
- *Continuous*: the metronome issues compression tones continuously but no ventilation tones.

CPR Feedback disposable sensor (option)

The operator can set the frequency of the metronome from 100 /min to 120 /min.

The corpuls aed decides whether to use the settings for a child or an adult based on the connected corPatch easy therapy electrodes. The 15:2 setting is only available with the corPatch easy Pediatric therapy electrodes connected.

The corpuls aed measures the compression rate and -depth of the chest compressions when an optional CPR Feedback disposable sensor is used.

During cardiopulmonary resuscitation the user receives important information on the quality of the current chest compressions. The user can react directly and take appropriate action. Among the information are the display of the current compression rate as well as the curve progression of the compression depth, voice instructions and text instructions.

The CPR curve of the corPatch CPR disposable sensor signals the user, if the compression depth is sufficient (green bars) or can be improved (red bars). If the recommended compression depth is exceeded, the bars are also shown in green.

The CPR curve of the primeCPR easy disposable sensor signals the user, if the compression depth is sufficient (green bars), too shallow (red bars) or too deep (yellow bars).



A prerequisite for the display of this information about the compression depth is the configuration of the screen output type Curves and vital parameters by the operator.

The operator has the option of disabling the voice instructions for chest compressions.

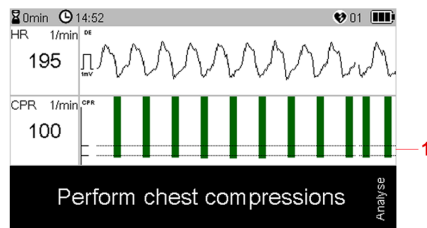


Fig. 6-22 User interface with corPatch easy therapy electrodes pre-connected and corPatch CPR disposable sensor

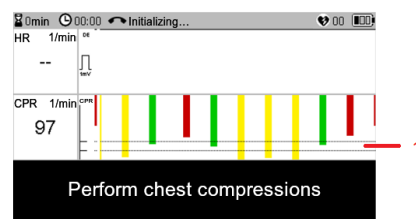


Fig. 6-23 User interface with corPatch easy therapy electrodes pre-connected and primeCPR easy disposable sensor

1 Scale with upper (6 cm) and lower (5 cm) target value

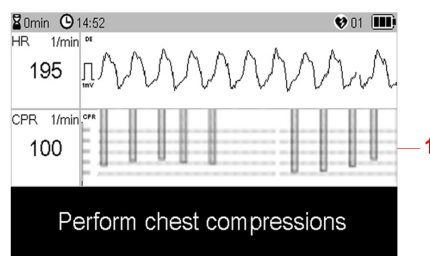


Fig. 6-24 User interface with corPatch easy therapy electrodes Pediatric and CPR Feedback disposable sensor

1 Scale with compression depth from 2 cm to 6 cm



The target range for the compression depth is between 5 cm and 6 cm.



To support the cardiopulmonary resuscitation with the optional CPR Feedback disposable sensor proceed as follows:

Prerequisite:

- ✓ The CPR Feedback disposable sensor is connected to corpuls aed and attached to the patient

1. Start chest compressions.

In the curve for compression depth of the user interface, the first coloured bars of the CPR curve are visible.

2. One of the following situations occurs:

- a) The voice instruction {Push harder. Fully release} is issued

Adjust the compression depth.

- b) The voice instruction {Good compressions} is issued

Compression depth is appropriate.



If at the same time corPatch easy Pediatric therapy electrodes are connected, only the voice instruction {Start CPR now} is issued.

3. Continue or finish standardised or locally valid resuscitation protocol with chest compressions to completion.

The corpuls aed can be used to defibrillate a patient in standard mode (AED mode). The corpuls aed obtains the ECG with corPatch easy (pre-connected/Pediatric) therapy electrodes.

6.2.2 Mission/Device Data

During the mission the corpuls aed automatically saves all generated mission data, such as vital parameters and graphs, in the device memory. If voice recording is enabled by the operator, the corpuls aed creates and saves an audio recording in standard mode (AED mode). The operator can read out all data (see "Service instruction").

6.3 End Therapy Mission

After the therapy has been completed, the user has to complete the application.

To finish the mission, proceed as follows:



1. Switch off the corpuls aed by pressing and holding the **On/Off** key for 2 s.
2. Pull the therapy electrode plug out of the socket and dispose of the therapy electrodes correctly.
3. If present, disconnect the CPR Feedback disposable sensor from the CPR Feedback intermediate cable and dispose of the sensor correctly.
4. Contact the operator immediately after use of the corpuls aed to have it prepared for the next mission.

7 Cleaning and Disinfection

Before commissioning the device and after every application or use, all used components must be cleaned and disinfected. The respective accepted standards of hygiene for handling and disinfecting equipment contaminated with bodily fluids must be observed. The locally valid regulations for disposal of infectious waste and material contaminated with bodily fluids must be observed.

7.1 Recommended Cleaning- and Disinfecting Agents

Regular cleaning and disinfection allows the user to hygienically prepare the corpuls aed and its accessories for the next use.

This applies for:

- Device housing
- Battery
- CPR Feedback intermediate cable
- Compartment for electrodes/Compartment for electrodes XL (backside) or accessory bag



Do not sterilise.

Checklist:

- Clean or disinfect the defibrillator and the accessories until all visible dirt has been removed.
- To remove all residue of cleaning- or disinfecting agents, wipe down the device after the contact time of the cleaning- or disinfecting agent has passed. Make sure the disinfection substance stays on the surface for the specified contact time according to the manufacturer's instructions.
- Check if all visible dirt has been removed.
- Exclusively clean and disinfect components that are intended to be re-used (device and accessories).
- After cleaning or disinfection, check the functionality of the defibrillator with the accessories.

The following disinfectants of PAUL HARTMANN AG (Bode Chemie) have been tested by the manufacturer and are recommended for effectiveness and material compatibility:

| Disinfectants | Active ingredients | CAS No. | Max. application concentration % (m/m) |
|---|-------------------------------|-------------|--|
| Mikrobac[®] Virucidal Tissues | Quaternary ammonium compounds | 7173-51-5 | 0.25 |
| | | 68391-01-5 | 0.25 |
| | Aminoalcohols | 141-43-5 | 1 |
| Bacillo[®] Sensitive 30 | Alcohols | 71-23-8 | 10 |
| | | 67-63-0 | 20 |
| | | 64-17-5 | 20 |
| | Surfactant | 139734-65-9 | 0.25 |
| Dismozon[®] plus | Peroxide | 84665-66-7 | 100 |
| | Fatty alcohol | 69011-36-5 | 2.5 |
| | Amine | 308062-28-4 | 2.5 |
| Kohrsolin[®] FF | Aldehyde | 111-30-8 | 10 |
| | Surfactants | 69011-36-5 | 10 |
| | | 68439-50-9 | 10 |
| | Quaternary ammonium compounds | 7173-51-5 | 5 |
| | | 68391-01-5 | 5 |
| | Alcohol | 67-63-0 | 3 |
| Mikrobac[®] Forte | Quaternary ammonium compound | 68391-01-5 | 20 |
| | Amine | 2372-82-9 | 5 |
| | Surfactants | 69011-36-5 | 3 |
| | | 68439-50-9 | 2.5 |

Tab. 7-1 Overview of recommended disinfectants



When using other disinfectants, make sure those belong to the same group of active substances.

7.2 Warnings

The following warnings inform the user of possible hazards when using the corpuls aed.

NOTICE

Wrong cleaning and disinfection!

Can damage the material of the corpuls aed and accessories, impair their functions or cancel out the cleaning/disinfecting effect of substances.

- ▶ To remove all residue of cleaning- or disinfecting agents, wipe down the device after the contact time of the cleaning- or disinfecting agent has passed. Make sure the disinfection substance stays on the surface for the specified contact time according to the manufacturer's instructions.
- ▶ To remove dirt or stains use clean cloths or soft brushes exclusively.
- ▶ Only use cleaning- and disinfecting agents recommended by the manufacturer or other cleaning and disinfecting agents with equivalent substance groups, to avoid damage and impaired function. Read the application instructions of the manufacturer of the cleaning and disinfecting agents.
- ▶ Do not mix different cleaning or disinfecting liquids, because there can be interactions between the substances that cancel out their effects. Rinse with clear water between the application of different cleaning or disinfecting liquids.
- ▶ Follow instructions from the manufacturer of the cleaning and disinfecting agents that vary from this instruction.
- ▶ corpuls aed and only surface-treat accessories. Do not immerse into cleaning or disinfection fluid.
- ▶ Do not let fluids penetrate into the plug connections.
- ▶ corpuls aed and do not clean, disinfect or sterilise accessories by machine.

7.3 Cleaning and Disinfecting the Device

To clean and disinfect the corpuls aed, proceed as follows:

Prerequisites:



- ✓ Cables are disconnected from the corpuls aed
1. Wipe surfaces with appropriate cleaning agent and allow to dry.
 2. Disinfect surfaces with a suitable disinfectant.
 3. Allow disinfected surfaces to dry.
 4. To remove any disinfectant residues, wipe the corpuls aed with a soft cloth soaked in clean water and then allow to dry.

8 Maintenance

8.1 Selftest, Visual inspection, Maintenance

8.1.1 Selftest

During a selftest the corpuls aed automatically switches on the screen and displays specific icons in the user interface, depending on the state.

At the end of a successful selftest the status display shows a green checkmark . If maintenance is required, the corpuls aed shows a red screwdriver icon  in the status display. Then the corpuls aed switches off.

If the user presses the On/Off key during the selftest, the corpuls aed stops the test and starts the standard operation (AED mode).

8.1.2 Regular Visual Inspections

8.1.2.1 Warnings

The following warnings inform the user of possible hazards when using the corpuls aed.



WARNING!


Device not ready for operation due to no visual inspection and no maintenance!



Can result in functions of the corpuls aed no longer working properly.

- ▶ Always follow the schedule for visual inspection (see 8.1.2.2 Visual check on page 47) and maintenance, regardless of whether the corpuls aed is only used rarely or is stored for long periods.
- ▶ Do not use the corpuls aed if a scheduled maintenance has not been performed.
- ▶ Make sure that visual inspections maintenance inspections are always performed according to schedule.
- ▶ The corpuls aed and the battery must be stored only under approved storage conditions. Temperature and humidity are very important. See the "Technical data" for the applicable values (see V Technical Specifications on page 62).
- ▶ The storage requirements for the corPatch easy therapy electrodes and the corPatch CPR disposable sensor are described on the packaging of these accessories.
- ▶ If necessary, stop using the corpuls aed.
- ▶ Regarding electromagnetic interference, no maintenance is required during the life of the device.

8.1.2.2 Visual check

In addition to the selftests, the user must ensure the function of the corpuls aed by a regular visual inspection. The intervals of the regular visual inspection depend on the operator configuration of the selftests in the chapter "Changeable settings" of the Service instruction.

The regular visual inspection consists of checking whether the status display shows a green checkmark .

If the status display shows a green checkmark icon , the corpuls aed is ready for operation. If the status display shows the red tool symbol , see the "Troubleshooting" chapter (see 9 Troubleshooting on page 51).

If the problem remains unsolved, contact your service and sales partner without delay.

The user should also check if the corpuls aed is still in place.


8.1.3 Maintenance

The maintenance schedule and the intervals for the extended visual inspection are regardless of whether the corpuls aed is used only rarely or is stored for extended periods. See the chapter "Extended visual inspection and maintenance" in the Service instruction. If a scheduled maintenance is not completed on schedule, the corpuls aed is not ready for operation. Make sure that maintenance and regular inspections are always fully performed.

8.2 Replacing the Battery

The corpuls aed is designed for easy use by end users. Separate storage of device and battery is not permitted. Commissioning or exchange must be performed by trained personnel.

The corpuls aed is not ready for operation if the battery is empty .

When standard operation is no longer possible due to low battery level, the corpuls aed operates in emergency mode (CPR-only mode)  and supports the user in carrying out the resuscitation measures. In this mode the corpuls aed does not perform an ECG analysis of the cardiac rhythm and does not release a shock. Below a critical voltage limit, the corpuls aed will switch off. In order to ensure operational status in an emergency, replace the battery in good time.



If the battery has been outside the device longer than an hour, the user must reset the date and time.



The corpuls aed does not have a buffer battery, but it has an energy buffer for the clock time. With this energy buffer the clock time is preserved for up to 1 h if the battery has been inserted in the device for at least 24 h previously. In rare cases, it is still possible that the clock time is lost.



The clock time has a significant effect on the calculation of the remaining battery capacity. If the clock time is not set, the corpuls aed assumes that the battery is maximally discharged. This can lead to a wrong display of battery capacity of up to 25%.



Semi-discharged batteries that are inserted for the first time can cause a selftest error (battery error) which is corrected after setting the correct time and repeating the selftest.

The effects of defective, semi-discharged and empty batteries can be as follows:

- If the corpuls aed cannot release a shock and cannot perform ECG analysis because the battery is too weak, the device switches to emergency mode (CPR-only mode) which only supports resuscitation measures.
- The corpuls aed marks the battery as defective or empty, if either an error during shock release or during operation has been detected.
- The corpuls aed marks the battery as defective or empty, if the calculated battery capacity falls below a threshold value. Marked batteries are recognised as defective or empty, if the clock time is set (value 1 in the corresponding block in the error code).

To replace the battery, proceed as follows:



Prerequisites:

- ✓ The corpuls aed is switched off
- ✓ The corpuls aed is not connected to the patient, e.g. via the corPatch easy therapy electrodes

1. Push the bar on the back of the device in the direction of the arrow to unlock the battery.

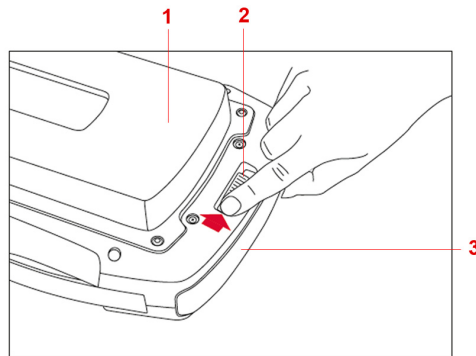


Fig. 8-1 Unlocking for battery replacement

- 1 Rear side corpuls aed
- 2 Lock
- 3 Battery

The battery is unlocked.

2. Remove the battery as indicated.

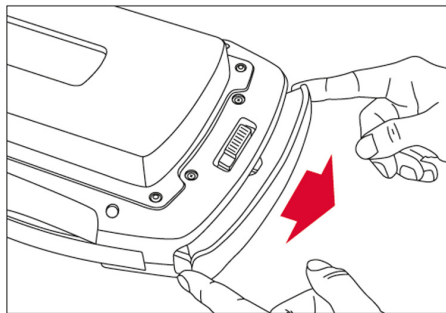


Fig. 8-2 Remove the battery

Battery is removed.

3. Insert a new battery into the battery compartment of the corpuls aed until it locks with a click.

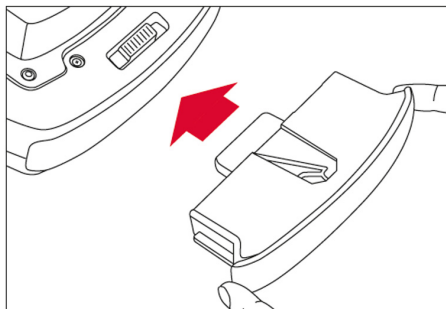


Fig. 8-3 Insertion of battery

The battery is inserted.

4. Make sure that the bar is closed.

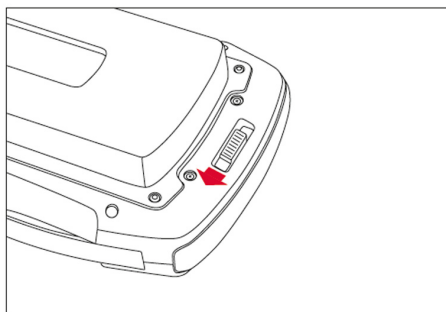



Fig. 8-4 Closed bar

The bar is closed.

5. The corpuls aed automatically performs a large selftest and then switches off.
6. Start corpuls aed in info mode (see corpuls aed "User manual").
7. Use the configuration software **corpuls.manager App**, which must be connected to the corpuls aed via WLAN, to set the time.
8. Check battery capacity of the corpuls aed in info mode.
9. Check if the status display shows the green tick symbol  (operational readiness).
The battery is replaced and integrated into the system.

9 Troubleshooting

9.1 Info Messages in Info Mode

Info mode


If an error appears during a user test or when checking the status display, more information on the cause of the error (information messages) can be found in the info mode.



The info mode on the corpuls aed is intended for experienced users only.

Open info mode by pressing and holding the **On/Off** key between 7 s and 12 s. Info mode is disabled by the user restarting the corpuls aed.



If the status display on the corpuls aed shows the red screwdriver icon , the user can continue to use the corpuls aed in an emergency.

For "Start info mode" and "Scroll between screens" see Service instruction.

First, check that the date is correctly set. If the date is incorrect, the check of the expiry date of the cor-Patch easy therapy electrodes and the information on the battery charge may not be correct.

In the info mode the following items can be observed on the information pages under the corresponding parameters:

| Information page | Parameters | Cause | Measure/Error |
|---------------------------------|---|-------------------------------|---|
| 〈Device serial number and WLAN〉 | The WLAN parameter settings are not correct. | No WLAN network connection | a) Have the WLAN parameter settings corrected by the operator. |
| | The WLAN parameter settings on the page are correct, but the corpuls aed cannot establish a connection. | No WLAN network connection | a) Check whether WLAN network reception is available at the location of the corpuls aed. |
| 〈Device information〉 | The value of the parameter 〈〈Latest Selftest results〉〉 is not 0x0. | Device defect | a) Contact service and sales partner and report the error code from the following parameters: 〈〈Latest Selftest results〉〉 and 〈〈Error code〉〉. |
| | The value of the parameter 〈〈Total number of HV charges〉〉 is greater than 2000. | Number of HV changes exceeded | a) The corpuls aed has exceeded its service life. b) Contact authorised sales and service partners. |
| 〈Battery information〉 | Check the values of the parameters 〈〈Production Date〉〉 and 〈〈Remaining Capacity %〉〉. | Battery empty | a) Have the operator install a new battery. |

Tab. 9-1 Information on the cause of the error in info mode

| Information page | Parameters | Cause | Measure/Error |
|--------------------------|---|---|---|
| ⟨Electrodes information⟩ | The ⟨⟨Electrodes Expiry Date⟩⟩ parameter shows that the date is passed. | corPatch easy therapy electrodes expired | a) Connect new corPatch easy therapy electrodes. NOTE: Date and time of the defibrillator must be correctly set. Have the operator make the settings. |
| | The value of the ⟨⟨Electrodes Preconnected Setting⟩⟩ parameter shows the value Yes, but corPatch easy therapy electrodes are not connected. | corPatch easy therapy electrodes not connected (in spite of default setting indicating otherwise) | a) Connect corPatch easy therapy electrodes or have the operator change the settings so the value of the parameter ⟨⟨Electrodes Preconnected Setting⟩⟩ is "No". |
| | The value of the ⟨⟨Electrodes Authorized⟩⟩ parameter indicates that non-approved electrodes are connected. | Non-approved therapy electrodes are connected | a) Use original accessories. |
| ⟨Miscellaneous⟩ | The value of the ⟨⟨Date & Time⟩⟩ parameter does not show the correct date or does not show the date and time. | Date and time not set | a) Have the operator set the date and time. b) Make sure that the corpuls aed is never left more than 30 min without a battery. Otherwise the time will be lost and the operator will have to reset the time. |
| ⟨GSM information⟩ | The ⟨⟨Signal Strength⟩⟩ parameter shows the value 0. | No GSM network connection | a) Check whether GSM network reception is available at the position of the corpuls aed. |
| | The parameter ⟨⟨Signal Strength⟩⟩ indicates a value above zero but the corpuls aed cannot establish a GSM network connection. | No GSM network connection | a) Check that the SIM card is valid and has credit. b) Make sure that a PIN is not required or that the PIN is set correctly. If necessary, have the operator modify the PIN settings. If necessary, activate, load or replace the SIM card. |

Tab. 9-2 Information on the cause of the error in info mode

9.2 Error in standard mode (AED Mode)




Standard mode

If the corpuls aed has an unexpected reaction or defective operation in standard mode, this may have various causes.



In case the corpuls aed behaves in an unspecified manner and data are shown, report the defective device to your authorised sales- and service partner.

The following observations may be made in standard mode (AED mode):

| Observation | Description/ Cause | Measure/correction |
|--|---|--|
| The corpuls aed does not issue voice instructions. | Hardware fault | a) Send corpuls aed to the sales and service partner. |
| The corpuls aed shows nothing on the screen or the display is faulty. | Hardware fault | a) Send corpuls aed to the sales and service partner. |
| The corpuls aed shows the battery icon without bars  . | Battery empty | a) Check the date and time, if necessary have them set by the operator. b) Have the operator install a new battery. NOTE in case of emergency: use corpuls aed until it switches itself off. |
| Although the corPatch easy therapy electrodes are attached to the patient, the corpuls aed does not perform the analysis but only the CPR phase. The corpuls aed shows the battery icon without bars  . | Battery empty | a) Have the operator install a new battery. NOTE in case of emergency: use corpuls aed until it switches itself off. |
| Although the corPatch easy therapy electrodes are attached to the patient, the corpuls aed does not perform the analysis but only the CPR phase. The battery icon shows one or more bars  . | Hardware fault | a) Send corpuls aed to the sales and service partner. |
| The corpuls aed does not perform analyses. Instead, it alternates performing a CPR phase and prompting the user to attach the corPatch easy therapy electrodes. | corPatch easy therapy electrode cable is not correctly connected to the patient | a) Check if the corPatch easy therapy electrodes are correctly attached to the patient: Press the corPatch easy therapy electrodes down firmly. Make sure that the chest is dry and does not have excessive hair. If necessary, remove excess hair. b) Check if original therapy electrodes (corPatch easy therapy electrodes) are being used. c) Check that the corPatch easy therapy electrodes have not passed their expiry date and if necessary replace the corPatch easy therapy electrodes. |

Tab. 9-3 Error in standard mode (AED Mode)

9.3 Voice Instructions in Standard Mode (AED Mode)

Voice instructions are used for audible instruction of the user. Text instructions provide additional support for the user in the user dialogue or provide an alternative means of instruction for the user in addition to the voice instructions.

The following table shows an overview of the voice instructions and text instructions that may be output during operation:

| Voice instruction by lay users | Voice instruction by professional users | Text instruction | Description |
|--|---|--|--|
| {Press the flashing Analyse key} | {Press the flashing Analyse key} | <Press Analyse key> | Voice instruction/text instruction, to press the flashing Analyse key. |
| {Press the flashing Shock key} | {Press the flashing Shock key} | <Press Shock key> | Voice instruction/text instruction, to press the flashing Shock key. |
| {Plug electrodes into device} | {Plug electrodes into device} | <Connect therapy electrodes with device> | Voice instruction/text instruction to insert the plug of the corPatch easy therapy electrodes. |
| {Push harder and allow full recoil between compressions} | {Push harder. Fully release} | -- | Voice instruction, to push harder and fully release. |
| {Perform two rescue breaths} | {Perform two rescue breaths} | <Perform 2 rescue breaths> | Voice instruction/text instruction, to ventilate two times. |
| {Place the heel of the hand on the centre of the chest. Push down according to the beat} | {Start CPR now} | <Perform chest compressions> | Voice instruction/text instruction for chest compression. |
| {Good compressions} | {Good compressions} | -- | Voice instruction, that the chest compression is good. |
| {Breathe now} | {Breathe now} | <Breathe now> | Voice instruction/text instruction, to ventilate now. |
| {Shock not recommended} | {Shock not recommended} | <Shock not recommended> | Voice instruction/text instruction, that no shock is recommended. |
| {Shock not possible} | {Shock not possible} | <Shock not possible> | Text instruction, that a shock is possible. |

Tab. 9-4 Voice instructions and text instructions

| Voice instruction by lay users | Voice instruction by professional users | Text instruction | Description |
|--|--|--|--|
| {Place CPR sensor as shown on the package} | {Place CPR sensor} | <Place CPR sensor as shown> | Voice instruction/text instruction, to attach the CPR Feedback disposable sensor. |
| {Call for help} | -- | Lay user: <Call for help> Professional user: -- | Voice instruction/text instruction, to make an emergency call. |
| {Undress patient's chest. Unpack the electrodes and stick them on patient's chest} | {Undress patient's chest and stick the electrodes on it} | <Stick electrodes firmly on patients bare chest> | Voice instruction/text instruction, to attach the corPatch easy therapy electrodes to the patient's unclothed chest. |
| {Do not touch patient. Analysing heart rhythm} | {Do not touch patient. Analysing heart rhythm} | <Do not touch patient> | Voice instruction/text instruction, not to touch patient as the heart rhythm is analysed. |
| {Do not touch patient. Shock recommended} | {Do not touch patient. Shock recommended} | <Shock recommended> | Voice instruction/text instruction, not to touch patient as a shock is recommended. |

Tab. 9-5 Voice instructions and text instructions

Appendix

I List of Abbreviations

| | |
|----------------|---|
| a | Year |
| AAM | Acoustic Advisory Mode |
| Para. | Paragraph |
| AC | Alternating Current |
| AED | Automatic external defibrillator |
| AP | Access Point |
| P/N | Product number |
| B | Width |
| BF | Body Floating |
| CF | Cardiac Floating |
| CPR | Cardiopulmonary Resuscitation |
| DC | Direct Current |
| DEFI | Defibrillator |
| DHCP | Dynamic Host Configuration Protocol |
| DSSS | Direct Sequence Spread Spectrum |
| EKG/ECG | Electrocardiogram/Electrocardiography |
| etc. | Et cetera |
| FLASH | Non-volatile data storage |
| GMSK | Gaussian Minimum Shift Keying |
| GSM | Global System for Mobile Communications |
| GUI | Graphical User Interface |
| H | Height |
| HR | Heart rate |
| HLW | Cardio-pulmonary resuscitation |
| HV | High voltage |
| IP | Internet Protocol |
| kgKG | Kilogramme body weight |
| LCD | Liquid Crystal Display |
| LED | Light emitting diode |
| Li | Lithium |
| MIT-BHI | Massachusetts Institute of Technology - Boston's Beth Israel Hospital |
| Mn | Manganese |
| MPBetreibV | Medical Devices Operator Ordinance |
| MRI | Magnetic Resonance Imaging |
| n/a | Not available |
| O ₂ | Oxygen |
| OFDM | Orthogonal Frequency-Division Multiplexing |

| | |
|--------------|--|
| PC | Personal Computer |
| PCI | Percutaneous Coronary Intervention |
| PCB | Printed Circuit Board |
| PIN | Personal Identification Number |
| Item | Position |
| QRS | Indicates a QRS complex in the ECG |
| SMS | Short Message Service |
| SSID | Service Set Identifier |
| STK | Technical safety check |
| T | Depth |
| TFT | Thin-film transistor |
| inter alia | Among others |
| and the like | And the like |
| UDP | User Datagram Protocol |
| UMDNS | Universal Medical Device Nomenclature System |
| USB | Universal Serial Bus |
| etc. | And so on |
| VF | Ventricular fibrillation |
| VP | Vital parameter |
| VT | Ventricular tachycardia |
| WiFi | Company consortium of a wireless interface = Wireless Local Area Network (WLAN). |
| WLAN | Wireless Local Area Network |
| e. g. | For example |

II Measuring Units and Operators

Measuring units:

| | |
|-----------------|--------------------|
| % | Percent |
| ° | Degree (angle) |
| °C | Degree Celsius |
| °F | Degree Fahrenheit |
| μA | Microampere |
| μs | Microsecond |
| μV/bit | Microvolt/Bit |
| 1/min | Rate |
| a | Year |
| A | Ampere |
| A/m | Ampere/Metre |
| Ah | Ampere hour |
| cm | Centimetre |
| cm ² | Square centimetre |
| dB | Decibel |
| g | Gramme |
| g/dl | Gramme/Decilitre |
| GB | Gigabyte |
| GHz | Gigahertz |
| h | Hour |
| Hz | Hertz |
| in | Inch |
| J | Joule |
| J/kg | Joule/Kilogramme |
| kB | Kilobyte |
| kg | Kilogramme |
| Body weight | Body weight |
| kHz | Kilohertz |
| kV | Kilovolt |
| kΩ | Kilo ohms |
| lb | Pound |
| m | Metre |
| mA | Milliampere |
| MB | Megabyte |
| MHz | Megahertz |
| min | Minute |
| mm | Millimetre |
| mm/s | Millimetres/second |
| ms | Millisecond |

| | |
|-------|-------------|
| mV | Millivolt |
| MΩ | Megaohm |
| nA | Nanoampere |
| nm | Nanometer |
| s | Second |
| sq in | Square Inch |
| V | Volt |
| V/m | Volt/metre |
| W | Watt |
| Ω | Ohm |

Operators:

| | |
|---|--------------------------|
| < | Smaller than |
| ≤ | Smaller than or equal to |
| > | Greater than |
| ≥ | Greater than or equal to |
| ± | Plusminus |

III Warranty

In addition to the statutory warranty conditions, the manufacturer offers a limited warranty on material defects and manufacturing faults. The scope of the warranty can be viewed in the respective guarantee conditions.

This warranty conclusively regulates the legal relationship between the purchaser and the manufacturer. Further damage claims are excluded, unless liability is prescribed by law.

Excepted from the warranty are:

- Wear parts.
- Errors and damages that are the result of
 - Improper handling
 - Faulty storage or installation
 - Extraneous causes, such as transport damage, damage caused by impact
 - Repair work and changes carried out by a non-authorised third party.

The claim under the warranty shall be void as well if accessories or spare parts are used that were not purchased from the manufacturer or from an authorised sales and service partner. Furthermore, the claim under the warranty shall be void as well if non-authorised accessories are used (see 4.2 Accessories on page 23). Software support (except updates) is not covered under the warranty.

In case the corpuls aed is defective or in case of a warranty and guarantee handling please contact an authorised sales and service partner or the manufacturer. The manufacturer shall only accept liability for user- and operating safety of the corpuls aed if maintenance, technical safety checks, repairs, additions and new settings were performed by the manufacturer or persons specifically authorised by the manufacturer. Additionally, the general terms and conditions of the manufacturer shall apply in the current version until further amendment.

IV Protection Rights and Patents



The software used in this product contains copyrighted GPL licence software. A copy of this licence can be found at www.gnu.org. The pertaining software can be requested from the manufacturer within 3 years of new purchase of the product.

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It is therefore not permitted to, e.g.:

- dismantle parts of the corpuls aed and use them for other purposes.
- replicate components or accessories.

Goods are mentioned in the instruction documents without mention of any existing patents, samples or trademarks.

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V Technical Specifications

General technical specifications

| General | |
|---|---|
| Protection class of the application part corPatch easy therapy electrodes | Type BF insulated >5 kV, defibrillation-proof |
| Protection class of the application part CPR Feedback disposable sensor | Type BF insulated >5 kV, defibrillation-proof |
| Protection against malfunction caused by electro-surgery devices | No |
| Resuscitation protocol | Recommendations of the general therapeutic guidelines |
| Comportment at interruption of power supply < 30s | If the power supply is interrupted in standard mode (AED mode), the corpuls aed carries out a selftest and then returns to standard mode. |
| Adjustable volume levels | 60 dB to 85 dB in 5 steps |

Tab. 5-6 Technical specifications - General

| Dimensions corpuls aed – without accessory bag or electrode compartment/electrode compartment XL | | |
|--|---------|---------|
| Height | 25.5 cm | 10.4 in |
| Width | 21.0 cm | 8.27 in |
| Depth | 5.8 cm | 2.28 in |

Tab. 5-7 Technical specifications - Dimensions

| Dimensions corpuls aed - with accessory bag | | |
|---|---------|----------|
| Height | 28.5 cm | 11.22 in |
| Width | 22.0 cm | 8.66 in |
| Depth | 10.5 cm | 4.13 in |

Tab. 5-8 Technical specifications - Dimensions with accessory bag

| Weight corpuls aed – without accessory bag or electrode compartment/electrode compartment XL | | |
|--|--------|---------|
| Weight without battery | 1550 g | 3.42 lb |
| Weight with battery | 1880 g | 4.14 lb |

Tab. 5-9 Technical Specifications - Weight

| General to battery | | | |
|--|--|--|----------------------|
| Type | Lithium manganese dioxide (Li-MnO ₂) | | |
| Dimensions | 3 cm x 9 cm x 18 cm | 1.18 in x 3.54 in x 7.09 in | |
| Weight | 330 g | | |
| Nominal capacity | 4.8 Ah at 10.0 mA and 8 V discharge voltage (+23 °C) | | |
| Nominal voltage | 12 V | | |
| Remaining time | From when message "Battery empty" is displayed, the remaining running time is at least 30 min Number of possible shocks: At least 15 shocks with full energy | | |
| Rechargeable | No | | |
| Operating temperature range | -40 °C to +85 °C | -40 °F to +185 °F | |
| Storage temperature range | permanently or briefly (max. 10 % of the storage period): -40 °C to +85 °C | permanently or briefly (max. 10% of the storage period): -40 °F to +185 °F | |
| | With acceptable self-discharge: 0 °C to +45 °C | With acceptable self-discharge: +32 °F to 113 °F | |
| Atmospheric pressure (operation and storage) | Atmospheric pressure | Altitude of earth's atmosphere | |
| | 600 hPa to 1060 hPa | 4750 m to -382 m | 15583 ft to -1253.28 |
| Air humidity (operation and storage) | 95 % (without condensation) | | |

Tab. 5-10 Technical specifications - Battery, general

| Operation time in standard mode (AED mode) | |
|---|------------|
| Factory settings, without accessories connected (monitoring mode) | 15 h |
| Factory settings with connected accessories and connected patient (normal use (AED mode) with 12 s CPR) | 4 h 50 min |

Tab. 5-11 Technical specifications - Operational periods

| Screen | | |
|---------------------|----------------------------------|-------------------|
| Type | 4.3 in TFT LCD screen 24 bit RGB | |
| Size | 9.5 cm x 5.4 cm | 3.74 in x 2.13 in |
| Vertical resolution | 840 pixels x 272 pixels | |

Tab. 5-12 Technical Specifications - Screen

| Environmental requirements of the corpuls aed | | | |
|---|-----------------------------|--------------------------------|-------------------------|
| Environmental Temperature | -10 °C to +55 °C | +14 °F to +131 °F | |
| Environmental temperature in CPR-only mode, i.e. without defibrillation and only to support the CPR | -20 °C to -10 °C | -4 °F to +14 °F | |
| Atmospheric pressure | Atmospheric pressure | Altitude of earth's atmosphere | |
| | 600 hPa to 1060 hPa | 4750 m to -382 m | 15583 ft to -1253.28 ft |
| Relative humidity | 95 % (without condensation) | | |
| Protection class against dust and water penetration | IP66 | | |
| Necessary storage time for heating from minimum storage temperature to operating condition | 50 s | | |
| Necessary storage time for cooling from maximum storage temperature to operating condition | 1 h | | |
| Maximum lifetime | 12 a | | |

Tab. 5-13 Technical Specifications - Environmental requirements

| Storage and transport conditions corpuls aed | | | |
|--|-----------------------------|--------------------------------|-------------------------|
| Environmental Temperature (without battery, corPatch easy therapy electrodes and CPR Feedback disposable sensor) | -30 °C to + 70 °C | -22 °F to +158 °F | |
| Atmospheric pressure | Atmospheric pressure | Altitude of earth's atmosphere | |
| | 600 hPa to 1060 hPa | 4750 m to -382 m | 15583 ft to -1253.28 ft |
| Relative humidity | 95 % (without condensation) | | |

Tab. 5-14 Technical specifications - Storage and transport conditions

| Defibrillation and Readiness for ECG Analysis | |
|---|---|
| Wave form of shock | Biphasic, current limited, impedance compensated - see Topic "Biphasic shock impulse" |
| Defibrillation voltage | 2 kV |
| Adjustable energy levels for adults and children > 20kg | 150 J, 170 J, 200 J |
| Adjustable energy levels for children < 25 kg | 50 J, 70 J, 100 J |
| Shock sequence | Consistent energy level |
| Precision of the energy released | See topic "Biphasic shock impulse" |
| Number of possible shocks with full battery | At least 219 shocks with 200 J |
| Impedance compensation | Yes |
| Patient impedance range within which a shock can be delivered | 0 Ω to 400 Ω |
| Dynamic range | ±5 mV |
| ECG curve sweep speed | 12.5 mm/s |
| Maximum electrode offset voltage | ±300 mV |
| Scanning frequency | 300 Hz |
| Maximum patient auxiliary current | Measurement of patient impedance by means of alternating current with rectangular wave form 15 μA _{pp} , I = 0.3 μA _{eff} , 50 kHz |
| Duration from power-on to energy output | < 15 s |
| Duration of analysis and energy output | < 15 s |
| Time until "ready for shock" status is cancelled | 15 s |
| Recovery time of the ECG after shock output | 3 s |
| Noise reduction | Yes |
| Breathing detection | No |
| Heart rate range | 30 /min to 300 /min |
| Heart rate averaging | Calculation of the heart rate mean value by averaging up to 8 heartbeat intervals. Update with every heart beat. |
| Accuracy of heart rate measurement | All complexes are recognized. The heart rate display is calculated from the shortest and the longest detected interval between two QRS complexes. |
| Response time of the heart rate display | <3 s at 120 /min |
| Maximal T-wave rejection capability | 0.9 mV |
| Accuracy of the heart rate display and comportment in case of arrhythmias according to IEC 60601-2-27 | Ventricular bigeminy: 80 /min |
| | Slow changing ventricular bigeminy: mostly 30 /min |
| | Fast changing ventricular bigeminy: 120 /min |
| | Bidirectional systoles: 88 /min to 96 /min |
| Pacer recognition | No |

| Defibrillation and Readiness for ECG Analysis | |
|--|---|
| Response to implanted pacer | Pulses from implanted pacers affect the arrhythmia detection so that the corpuls aed cannot detect all of the shockable rhythms. In these cases, the corpuls aed does not recommend a shock. |
| Analysis time (VF/VT) | 7.2 s under typical conditions |
| Asystole threshold | 0.2 mV |
| Sensitivity | 99.26 % for VF with > 0.35 mV based on 944 shockable test data sets 95.24 % for VT with f > 180 /min based on 252 shockable test data sets |
| Specificity | 98.05 % based on 3070 non-shockable test data sets |
| Used databases for testing the ECG rhythm recognition detector | <ul style="list-style-type: none"> • Creighton University Ventricular Tachyarrhythmia Database • American Heart Association (AHA) ECG Database • MIT-BIH Malignant Ventricular Arrhythmia Database |
| Adjustable lengths of the CPR phase | 2 min, 3 min |

Tab. 5-15 Technical Specifications - Defibrillation and Readiness for ECG Analysis

| Mission Data Storage | |
|-----------------------------|------------------|
| ECG data (incl. heart rate) | Approx. 5 MB/h |
| CPR feedback data | Approx. 2 MB/h |
| Technical events | Approx. 300 kB/h |
| Audio data | Approx. 80 MB/h |

Tab. 5-16 Technical specifications - Mission data storage

| Radio Interfaces | |
|-------------------------------|--|
| GSM frequency range | 850/900/1800/1900 MHz |
| GSM Effective radiated power | 33 dBm (for 850/900 MHz) 30 dBm (for 1800/1900 MHz) |
| GSM modulation type | GMSK |
| WLAN frequency range | 2.4 GHz |
| WLAN effective radiated power | 20 dBm |
| WLAN modulation type | OFDM/DSSS |
| WLAN Security options | WPA, WPA2 |

Tab. 5-17 Technical specifications - Mission data storage

The following table refers to the ECG analysis program in AED mode, which issues a therapy recommendation.

| Decision-making reliability of the ECG analysis programme | |
|---|--|
| Sensitivity and specificity | The quality of an ECG analysis programme is determined by the values sensitivity and specificity |
| Performance indicators | Based on shockable signals (see "Indications/contraindications"). For the evaluation of the performance of the algorithm the following performance indicators were defined: a = number of correct positive decisions b = number of false positive decisions c = number of false negative decisions d = number of correct negative decisions |
| Total number of measurements | 4266 |
| Result | Value |
| a | 1177 |
| b | 60 |
| c | 19 |
| d | 3010 |
| This therefore yields: Sensitivity = $a / (a+c) = 0.9841$; required >90 % according to recommendations of the general guidelines for therapy) Positive predictive value = $a / (a+b) = 0.9515$ False positive ratio = $b / (b+d) = 0.0195$ Specificity = $d / (b+d) = 0.9805$; required >95 %, according to general guidelines for therapy) | |

Tab. 5-18 Technical specifications - Decision-making reliability of the ECG analysis programme

Biphasic shock impulse

The shock impulse of the corpuls aed is characterised by the limitation of the maximum current. As a result, the risk of myocardial damage can be reduced, in particular in the case of low patient impedances. The output current is regulated to a nominal value, so that a sawtooth-like pulse is produced. The ratio of the electrical charge delivered between the second (negative) and first (positive) phases is on average 0.38. For safety reasons, voltages of not more than 2000 V are used. The pulse delivered to the patient depends, based on the set energy level, on the transthoracic impedance of the patient.

The following table shows the accuracy of the energy output via corPatch easy therapy electrodes (adult):

| Load impedance (Ohm) | Energy selected (J) ¹ | Rated delivered energy (J) ² | Measured delivered energy (J) ³ | Accuracy reference range (J) ⁴ | |
|---|----------------------------------|---|--|---|-------------|
| | | | | Lower limit | Upper limit |
| 25 | 150 | 84 | 83.9 | 71.4 | 96.6 |
| 50 | | 161 | 160.5 | 136.9 | 185.2 |
| 75 | | 185 | 184.5 | 157.3 | 212.8 |
| 100 | | 174 | 174.2 | 147.9 | 200.1 |
| 125 | | 161 | 160.8 | 136.9 | 185.2 |
| 150 | | 147 | 147.3 | 125.0 | 169.1 |
| 175 | | 138 | 138.2 | 117.3 | 158.7 |
| | | | | | |
| 25 | 170 | 95 | 94.4 | 80.8 | 109.3 |
| 50 | | 180 | 180.3 | 153.0 | 207.0 |
| 75 | | 196 | 195.8 | 166.6 | 225.4 |
| 100 | | 190 | 189.5 | 161.5 | 218.5 |
| 125 | | 179 | 178.8 | 152.2 | 205.9 |
| 150 | | 167 | 167.4 | 142.0 | 192.1 |
| 175 | | 156 | 156.1 | 132.6 | 179.4 |
| | | | | | |
| 25 | 200 | 133 | 132.6 | 113.1 | 153.0 |
| 50 | | 202 | 202.0 | 171.7 | 232.3 |
| 75 | | 211 | 211.1 | 179.4 | 242.7 |
| 100 | | 213 | 212.5 | 181.1 | 245.0 |
| 125 | | 208 | 207.6 | 176.8 | 239.2 |
| 150 | | 201 | 200.5 | 170.9 | 231.2 |
| 175 | | 188 | 188.3 | 159.8 | 216.2 |
| | | | | | |
| 1) Energy which the corpuls aed is intended to deliver, as determined by the settings done by the operator. | | | | | |
| 2) The energy that details the approximate output energy at a particular selected energy and patient impedance. | | | | | |
| 3) The energy output measured by an measuring device. | | | | | |
| 4) Accuracy reference range : Rated delivered energy ± 15 %. | | | | | |

Tab. 5-19 Technical specifications - Precision of the energy released for corPatch easy electrodes (Adult - fully automatic/semi automatic model)

The following table shows the accuracy of the energy output via corPatch easy therapy electrodes (child):

| Load impedance (Ohm) | Energy selected (J) ¹ | Rated delivered energy (J) ² | Measured delivered energy (J) ³ | Reference range of accuracy (J) ⁴ | |
|---|----------------------------------|---|--|--|-------------|
| | | | | Lower limit | Upper limit |
| 25 | 50 | 27 | 27.2 | 23.0 | 31.1 |
| 50 | | 52 | 51.8 | 44.2 | 59.8 |
| 75 | | 73 | 73.1 | 62.1 | 84.0 |
| 100 | | 71 | 70.7 | 60.4 | 81.7 |
| 125 | | 65 | 65.4 | 55.3 | 74.8 |
| 150 | | 60 | 59.8 | 51.0 | 69.0 |
| 175 | | 55 | 55.4 | 46.8 | 63.3 |
| | | | | | |
| 25 | 70 | 38 | 38.1 | 32.3 | 43.7 |
| 50 | | 72 | 72.1 | 61.2 | 82.8 |
| 75 | | 108 | 108.0 | 91.8 | 124.2 |
| 100 | | 109 | 109.4 | 92.7 | 125.4 |
| 125 | | 100 | 100.4 | 85.0 | 115.0 |
| 150 | | 95 | 92.3 | 80.8 | 109.3 |
| 175 | | 86 | 85.6 | 73.1 | 98.9 |
| | | | | | |
| 25 | 100 | 54 | 54.3 | 45.9 | 62.1 |
| 50 | | 103 | 103.1 | 87.6 | 118.5 |
| 75 | | 140 | 139.9 | 119.0 | 161.0 |
| 100 | | 135 | 135.0 | 114.8 | 155.3 |
| 125 | | 125 | 124.7 | 106.3 | 143.8 |
| 150 | | 112 | 112.4 | 95.2 | 128.8 |
| 175 | | 105 | 104.5 | 89.3 | 120.8 |
| | | | | | |
| 1) Energy which the corpuls aed is intended to deliver, as determined by the settings done by the operator. | | | | | |
| 2) The energy that details the approximate output energy at a particular selected energy and patient impedance. | | | | | |
| 3) The energy output measured by an measuring device. | | | | | |
| 4) Accuracy reference range : Rated delivered energy ± 15 %. | | | | | |

Tab. 5-20 Technical specifications - Precision of the energy released for corPatch easy electrodes (Child - fully automatic/semi automatic model)

The following illustration shows the biphasic shock impulse with 200 J at different patient impedances.

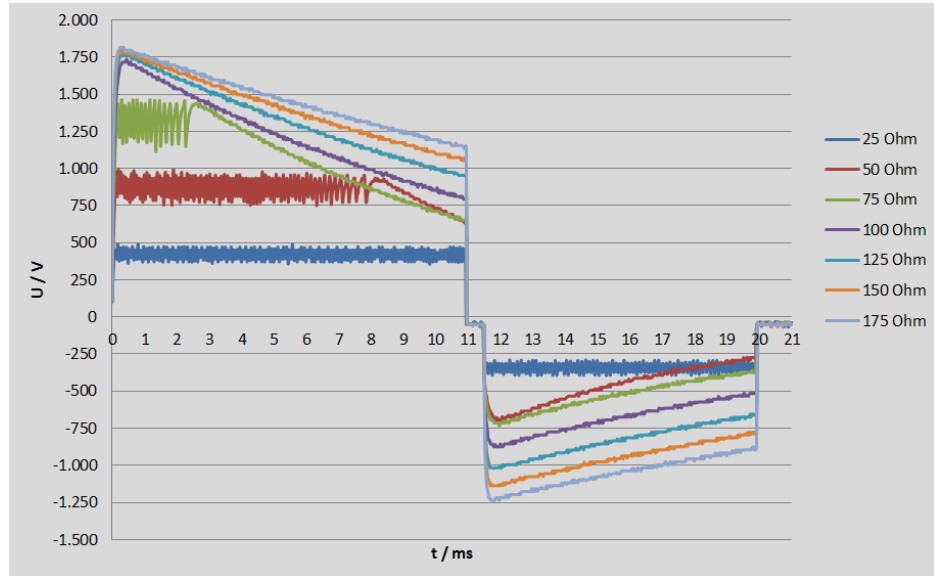


Fig. 5-1 Biphasic shock impulse - Impedances of 25 Ohm to 175 Ohm

corPatch easy therapy electrodes - General specifications

| Conductive surface of therapy electrodes | | |
|--|----------------------------|---------------------|
| corPatch easy pre-connected | Approx. 87 cm ² | Approx. 13.38 sq in |
| corPatch easy Pediatric | Approx. 42 cm ² | Approx. 6.46 sq in |
| Operating temperature range (electrodes) | 0 °C to +50 °C | -17.8 °F to +122 °F |

Tab. 5-21 Technical specifications - Conductive surface of therapy electrodes

primeCPR easy disposable sensor (option) - General specifications

| primeCPR easy - General Specifications | | |
|--|---|-----------------------------|
| Measurement range | 70 to 150 compressions/min | |
| | 1.0 cm to 10.0 cm | 0.39 in to 3.94 in |
| Measurement interval | 500 Hz | |
| Operating temperature (sensor) | -20 °C to +55 °C | -28.9 °F to +131 °F |
| Storage temperature (sensor) | -40 °C to +70 °C | -40 °F to +158 °F |
| Relative humidity (sensor) | ≤93 % (without condensation) | |
| Air humidity during storage (Sensor) | ≤95 % (without condensation) | |
| Sensor size (Length x Width x Depth) | 85 mm x 60 mm x 16.7 mm | 3.35 in x 2.36 in x 0.66 in |
| | Sensor weight: approx. 50.0 g | |
| Cable length Sensor | 0.6 m | 23.62 in |
| Cable length Intermediate cable | 1.4 m | 55.12 in |
| Accuracy - Rate *) | ±4 compressions/min | |
| Accuracy - depth *) | ±0.5 cm | ±1.97 in |
| | Protection against water and dust: IP66 | |
| Power supply | 5 V supply voltage via USB | |

Tab. 5-22 Technical Specifications - General primeCPR easy (option)

corPatch CPR disposable sensor (option) - General specifications

| corPatch CPR - General Specifications | | |
|--|---|---------------------|
| Amplifier input | Type BF insulated >5 kV, defibrillation-proof | |
| Function principle (sensor) | Acceleration sensor | |
| Displayed parameters | Combined curve for display of compression depth and compression frequency | |
| | CPR rate (compression rate) | |
| Measurement range | 70 to 150 compressions/min | |
| | 1.9 cm to 16.6 cm | 0.75 in to 4 in |
| Measurement interval | Continuous | |
| Operating temperature (sensor) | -20 °C to +60 °C | -28.9 °F to +131 °F |
| Storage temperature (sensor) | -30 °C to +65 °C | -22 °F to +149 °F |
| Relative humidity (sensor) | ≤93 % (without condensation) | |
| Air humidity during storage (Sensor) | ≤93 % (without condensation) | |
| Sensor dimensions (length x width with foam padding) | 101 mm x 64 mm | 4 in x 2.5 in |
| Sensor weight (with cable) | 50.2 g | |
| Sensor weight (without cable) | 28.8 g | |
| Accuracy - Rate | ±3 compressions/min | |
| Accuracy - depth | ±0.635 cm | ±1.97 in |
| Recovery time of CPR feedback measurement after shock delivery | 5 s | |

Tab. 5-23 Technical Specifications - General corPatch CPR (option)

VI Guidelines and Manufacturer's Declaration

| Electromagnetic emission | | |
|---|------------|---|
| The corpuls aed is intended for operation in the electromagnetic environment indicated below. The operator or the user must ensure that the corpuls aed is used in such an environment. | | |
| Emission measurements | Compliance | Electromagnetic environmental guidelines |
| HF emissions in accordance with CISPR 11 | Group 1 | The corpuls aed uses HF energy only for its internal function. The HF emission is very low. Therefore the risk of the corpuls aed impairing the function of adjacent electronic devices is unlikely. |
| HF emissions in accordance with CISPR 11 | Class B | The corpuls aed is suitable for use in the following areas: all facilities, including those in residential areas that are directly connected to the public mains supply. Furthermore, the corpuls aed is suitable for use in vehicles, aeroplanes and on ships. |

Tab. 6-24 Electromagnetic emission

| Electromagnetic interference immunity | | | |
|---|--|--|---|
| The corpuls aed is intended for operation in the electromagnetic environment indicated below. The operator or the user must ensure that the corpuls aed is used in such an environment. | | | |
| Interference immunity tests | IEC 60601-test level | Compliance level | Electromagnetic environment - guidelines |
| Electrostatic discharge (ESD) in accordance with IEC 61000-4-2 | ±8 kV contact discharge ±15 kV aerial discharge | ±8 kV contact discharge ±15 kV aerial discharge | Floors should be made of wood, concrete or metal or be covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity should be at least 30%. |
| Magnetic field of the supply frequency (50/60 Hz) in accordance with IEC 61000-4-8 | 30 A/m | 30 A/m 50/60 Hz | Do not operate the corpuls aed near an activated MRI unit (magnetic resonance imaging). |


Tab. 6-25 Electromagnetic interference immunity part 1

| Electromagnetic interference immunity | | | |
|---|-----------------------------|------------------|---|
| The corpuls aed is intended for operation in the electromagnetic environment indicated below. The operator or the user must ensure that the corpuls aed is used in such an environment. | | | |
| Interference immunity tests | IEC 60601-test level | Compliance level | Electromagnetic environment - guidelines |
| -- | -- | -- | Portable/mobile radio devices should not be used at a distance less than the recommended protection distance to the corpuls aed including the leads. This distance is calculated according to the equation applicable to the transmission frequency. A protection distance of at least 30 m is recommended. |
| Radiated HF interference according to IEC 61000-4-3 | 20 V/m 80 MHz to 2.7 GHz | 20 V/m | No unintentional change in condition, no unintentional energy output. |
| These guidelines may not be applicable in all cases. Propagation of electromagnetic variables is influenced by absorption and reflection via buildings, objects and people. | | | |

Tab. 6-26 Electromagnetic interference immunity part 2

| Interference immunity of the corpuls aed against portable/mobile HF communication devices | | | | | | |
|---|------------------------------------|--|--------------------------------------|-----------------------|------------------|-------------------------------|
| The housing of the corpuls aed is tested according to the specifications in this table using the procedures defined in IEC 61000-4-3. | | | | | | |
| Test frequency in MHz | Frequency band ^a in MHz | Radio service ^a | Modulation ^b | Maximum power in W | Distance in m | Test level immunity in V/m |
| 810 870 930 | 800 to 960 | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | Pulse modulation ^b 18 Hz | 2 | 0.3 | 28 |
| 1720 | | | | | | |
| 1845 1970 | | | | | | |
| 2450 | 2400 to 2570 | Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation ^b 217 Hz | 2 | 0.3 | 28 |
| 5240 5500 5785 | 5100 to 5800 | WLAN 802.11 a/n | Pulse modulation ^b 217 Hz | 0.2 | 0.3 | 9 |
| | | | | | | |
| | | | | | | |
| NOTE: If necessary to achieve the immunity test level, the distance between the transmitting antenna and the corpuls aed may be reduced to 1m. The 1 m test distance is permitted by IEC 61000-4-3. | | | | | | |
| ^a For some services, only the uplink frequencies are included. | | | | | | |
| ^b The carrier shall be modulated using a 50 % duty cycle square wave signal. | | | | | | |
| ^c As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. | | | | | | |

Tab. 6-27 Interference immunity against portable/mobile HF communication devices

 **WARNING!**

Limited availability of the device!

A too small distance between portable and mobile RF communication devices and corpuls aed can lead to a reduction in the performance characteristics of this corpuls aed.

- ▶ Portable HF communication devices should not be used at a closer distance than 30 cm (or 12 in) to the corpuls aed.

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