User/Operator Manual

English

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Tempus LS

Defibrillator

PHILIPS

Manufacturer's address

Tempus LS is distributed by Remote Diagnostic Technologies Limited.

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This manual is valid for software 1.3.4 or newer

If any serious incident has occurred in relation to the device it should be reported to Remote Diagnostic Technologies Limited and the competent authority of the Member State in which the user and/or patient is established.

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Chapter 6

Chapter 1
Introduction

The Tempus LS defibrillator (part number 00-3010) is used for the treatment of ventricular fibrillation (VF) and ventricular tachycardia (VT) in AED or manual defibrillation and a Cardioversion mode to convert abnormally fast heart rate (tachycardia) or other cardiac arrhythmias to a normal rhythm. The pacemaker module stimulates the heart with two operation modes, “Fix” or “Demand”. As an option, CPR assistance is available with the LifePoint sensor.

The Tempus LS is a battery-powered, small, lightweight device designed for use in pre-hospital and clinical environments.

Document library

Consult the instruction for use. These are provided in electronic format in the Philips Document library.

Important

Please check the Philips Document library regularly for new version of this document.

A paper copy of this document may be requested from Philips Document library or by sending a request to RDT_customerservice@philips.com.

1.1 General safety notes

1.1.1 Intended use/user profiles

▲ The **Tempus LS** is a defibrillator that can deliver a shock in automatic, manual or Pacemaker mode with the following feature:

- CPR Feedback sensor

▲ In addition, the ECG signal of the 3/4-wire ECG patient cable can be display (used normally for the Demand Pacemaker) and can be used for a continuously attended patient ECG signal display (without alarm handling)

▲ The device is for use by professional persons who are trained in basic life support (BLS) and defibrillation or advanced cardiac life support (ACLS). The device is intended for single patient use only.

▲ It is the user's responsibility to ensure they are properly prepared to use the product. The user must be trained in the use of this product and must read this manual thoroughly before use. RDT can provide direct training courses if preferred.

▲ The device is intended to be used in following environmental:

- Primarily in pre-hospital care and transport applications (including ambulances, fixed and rotary wing aircraft).
- The device is intended to be used by professional medics including doctors, nurses, paramedics and EMTs in civilian and military applications.

1.1.2 Contraindication for use

▲ The defibrillator of the Tempus LS must **not** be used in automated mode (AED) when the person:

- is responsive
- is breathing normally
- has a pulse

▲ Do not use the device in or near magnetic resonance imaging equipment (MRI) 

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▲ **Danger of explosion!** — The device must not be used in areas where there is any danger of explosion. There might be a danger of explosion in areas where flammable products (petrol), flammable anesthetic agents or products for skin cleaning/disinfection are in use, or where the ambient air oxygen concentration is higher than 25 %.

▲ The CPR feedback option is contraindicated for use on neonatal and pediatric patients under 8 years. CPR feedback option is contraindicated when manual CPR is contraindicated.

▲ Do not use the device for unattended ECG monitoring.

1.1.3 Responsibility of the User

- ▲ The numerical and graphical results and any interpretation given must be examined with respect to the overall clinical condition of the patient and the general recorded data quality.
- ▲ Do not use the Tempus LS when patient is unattended.
- ▲ The indications given by this equipment are not a substitute for regular checking of vital functions.
- ▲ The AED of the Tempus LS must only be used if the following symptoms are present:
  - not responsive
  - not breathing normally
  - no pulse
- ▲ The user must read and understand the user guide, and especially these safety notes.
- ▲ Operating a device with a defective casing, defective cables and sensors constitutes a danger to the patient or the user! Therefore:
  - – Immediately replace a damaged unit, damaged cables and damaged connections. Immediately replace damaged or missing components.
- ▲ Only use accessories and disposables recommended or supplied by RDT. The use of third-party accessories (including disposables) may result in injury, inaccurate information (electromagnetic disturbance) and/or damage to the device.
- ▲ The device including accessories must be serviced on a regular basis (see 6.1 Daily checks and Maintenance interval).
- ▲ The Tempus LS is an emergency device and must be ready for operation at any time and in all situations. Ensure that the device is always equipped with a sufficiently charged battery and keep a spare battery at hand.
- ▲ Properly dispose of the packing material and make sure it is out of children's reach.

1.1.4 Organizational Measures

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

1.1.5 Safety-Conscious Operation

- ▲ This user guide, and especially these safety notes, must be read and observed.
- ▲ **Danger of electric shock!**
  The energy applied to the patient can be conducted through the patient to other persons, who may suffer a lethal electric shock. Therefore:
  - Do not touch the patient, the electrodes or other conducting objects during defibrillation
  - Do not defibrillate the patient in a puddle of water or on other conductive surfaces
  - Switch the device off when it is not in use.
- ▲ To keep the patient safe, ensure that neither the electrodes, including the neutral electrode, nor the patient, or persons touching the patient, come into contact with conducting objects, even if these are earthed.
- ▲ Immediately report any changes that impair safety (including operating behavior) to the person responsible.
- ▲ Only connect original RDT accessories to the device.
- ▲ Before switching on, check if the unit's casing and electrode connection are undamaged.
- ▲ Only operate the device in accordance with the specified technical data (see Chapter 7 Specification and standards).
- ▲ Special caution must always be taken on intra cardiac application of medical equipment. Especially make sure that no conducting parts connected to the unit's isolated patient input (patient, plug, electrodes, sensor) come into contact with other, earthed conductive objects, as this might short-out the patient's isolation and remove the protection of the isolated input.
- ▲ Carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- ▲ Do not place the device where it can be controlled by the patient.
- ▲ Position the device so that there is no possibility of it falling on the patient or floor.
- ▲ To prevent cross-infection, do not reuse disposable accessories marked with the symbol  .
- ▲ If unexpected readings are obtained, the operator should check the connections and verify the readings according to section 6.2 Functional test.
- ▲ Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.
- ▲ Do not use the AC/DC power supply Type ASTEC Model DPS53-M above 4000 m/ 13123 ft sea level and outdoor (including ambulances, fixed and rotary wing aircraft)

1.1.6 Operation with other Devices

▲ The patient can be endangered by excessive leakage currents (summation of leakage currents) if:

- several devices are connected to the patient
- other equipment is connected to the Tempus LS.

→ For this reason, devices that are not required should be disconnected from the patient, and only equipment approved by RDT may be connected to the device.

▲ Accessory equipment connected to the analogue and digital interfaces must be certified according to the respective IEC standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC/EN 60601-1. Everyone who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC/EN 60601-1. If in doubt, consult the technical service department or your local representative.

▲ Magnetic and electrical fields of X-ray equipment, homographs, portable communication devices, HF radios and devices labeled with the  symbol can affect the operation of this device (see section 6.8.1 Measures to prevent electromagnetic interference). Avoid using such devices or keep a sufficient distance from them.

▲ The charging of energy and the release of the defibrillation impulse can disturb other devices. Check these devices before their further use.

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

▲ If the patient has a pacemaker implanted, do not position the electrode directly onto the pacemaker. Check the pacemaker after the defibrillation.

▲ The Tempus LS can be used together with high-frequency electro surgical devices. However, precautions must be observed when such HF equipment is used. To reduce the risk of burns in the case of a failure of the neutral HF electrode, a distance of at least 15 cm (5.9 in) must always be kept between the defibrillation electrodes and the HF surgical electrodes. If in doubt, disconnect the electrodes and sensors from the unit during use of a HF surgical device.

▲ If the ECG patient cable should become defective after defibrillation, if an electrode is displaced or an electrode resistance is too high, an audible and visual warning is issued.

1.1.7 Maintenance

▲ **Danger of electric shock!** Do not open the device. No serviceable parts inside. Refer servicing to qualified personnel only.

▲ Do not service, maintain or clean the device while in use with a patient.

▲ No modification of this equipment including sensor and accessories is allowed.

▲ Before cleaning, switch the unit off and remove the battery.

▲ Do not use high temperature sterilization processes (such as autoclaving). Do not use E-beam or gamma radiation sterilization.

▲ Do not use solvent or abrasive cleaners on either the unit or cable assemblies.

▲ Do not, under any circumstances, immerse the unit or cable assemblies in liquid.

1.1.8 Hygiene

- ▲ For cleaning and disinfection observe the instructions given in section 6.5 Cleaning.
- ▲ Only use cleaning agents and disinfectants recommended by RDT. Unsuitable agents can damage the device. Clean and disinfect the device in accordance with the instructions given in this manual.

1.2 Proprietary notice

The purpose of this document is to provide the user with adequately detailed information to efficiently install, operate, maintain and order spare parts for the Tempus LS defibrillator. Every effort has been made to keep the information contained in this document current and accurate as of the date of publication or revision. However, no guarantee is given or implied that the document is error free or that it is accurate with regard to any specification. RDT reserves the right to change specifications without notice.

A paper copy of this manual may be requested from RDT.

1.2.1 Implied authorization

NO IMPLIED LICENSE

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

The Bluetooth name and logo are owned by the Bluetooth SIG Inc. and any use of this name or mark is under license.

1.2.1.1 Limited warranty

Remote Diagnostic Technologies Limited ('RDT') warrants each new Tempus LS to be free from defects in workmanship and materials under normal conditions of use and service. For details please refer to the Terms and Conditions of Sale. Consumable items are expressly excluded from this Warranty. RDT's sole obligation under this warranty will be to repair or, at RDT's option, replace products that prove to be defective during the warranty period. The foregoing shall be the sole warranty remedy. Except as set forth herein, RDT makes no warranties, either expressed or implied, including the implied warranties of merchantability and fitness for a particular purpose. The warranty shall be void if the Tempus LS is in any way modified or if it is used with non-approved consumables, unless specifically authorized in writing by RDT, and RDT shall not be liable in any event for incidental or consequential damage. This warranty is not assignable. Full terms and conditions of sale are available from RDT and are provided with your order confirmation. All specifications quoted in this manual are nominal unless detailed otherwise.

1.2.1.2 Service support and returns

Repairs made under warranty to any Tempus LS must be made by the manufacturer. If the Tempus LS requires repair or return for any reason, please contact your local distributor or Remote Diagnostic Technologies in order to first obtain a returns reference (RMA) number. RDT reserves the right not to accept returns which have not first been provided with an RMA number. When calling, please be ready to quote the serial number of the Tempus LS.

The Tempus LS is designed to be as maintenance free as possible.

In the event that the device fails to operate correctly or in a way that is not described in this manual, stop using the device immediately and switch the device off immediately. Contact the manufacturer or distributor at once. Do not attempt any kind of corrective action and do not connect the device to a patient. If the device malfunctions and may have caused or contributed to a serious injury of a patient or user, RDT must be notified immediately by telephone, fax or written correspondence.

1.3 Display symbols and indicators

1.3.1 Symbols used in this user guide

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

DANGER

Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

WARNING

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury.

▲ For general safety notes as listed in this section.

Notes
For important and helpful information

The device is not intended to operate in an MR environment. The device is unsafe in a MR environment.

Consult the instructions for use. These are provided in electronic format.

1.3.2 Symbols used on the device

Symbol	Description	Symbol	Description
	Signal input type CF: Highly isolated port, defibrillation protected. However, it is only defibrillation protected when used with the original RDT patient cable.		Only for defibrillator input. Type BF classified, defibrillation protected.
CE 0123	Notified body of the CE certification (TÜV-Süd)		Used for electrical dangers during defibrillation (Tempus LS)
	Manufacturer symbol, manufacturing date		Note accompanying documents!
	Read the instruction for use	Rx Only	Prescription Only. Federal law restricts this device to sale by or on the order of a physician.
IP66	The device is protected against dust and powerful water jets against the enclosure from any direction shall have no harmful effects.		
	Symbol for the recognition of electrical and electronic equipment. The device must be disposed of in a municipally approved collection point or recycling center when it is no longer required. Improper disposal harms the environment and human health due to the presence of dangerous substances in electrical and electronic equipment.		

Symbol	Description	Symbol	Description
	**Devices with Bluetooth FCC ID: T7VPAN10** Attention: Non-ionic electromagnetic environment. The device contains an HF transmitter. The Tempus LS radiates high-frequency electromagnetic energy during telemetric ECG data transfer and can disturb other devices if not installed and operated in accordance with the user guide. However, even in the case of correct installation/operation, there is no guarantee that no interference can occur. If the Tempus LS causes interference, this can be prevented by switching off or not sending data. The user can take the following measures to solve this problem: • Increase the distance between the disturbed device and the Tempus LS. A minimum distance of 20 cm (7.9 in) must be kept between the device and a pacemaker. • Turn the device to change the antenna's angle of radiation. • Connect the device to a different mains connector. For more details, see section 6.8.1 Measures to prevent electromagnetic interference.		

1.3.3 Symbols used on the battery

Common symbols

Symbol	Description	Symbol	Description
	The unit/component can be recycled.		Battery must not be disposed of with domestic refuse.
	Manufacturer symbol, manufacturing date		Prescription Only. Federal law restricts this device to sale by or on the order of a physician.
	Read the instruction for use		

Safety notes on the Li-ion battery

WARNING

Risk of fire, explosion and burns.

▲ Never:

- short-circuit,
- puncture,
- deform,
- open,
- heat above 100 °C (212°F),
- immerse in water or incinerate
- charging below 0°C (32°F)

CAUTION

▲ Only for use with the charger supplied by RDT.

- Discharge temperature range -20 to +60 °C (-4 °F to + 140 °F)

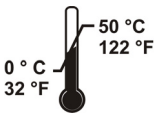
Storage temperature battery

3 to 12 months: -20 to +20 °C (-4 °F to + 68 °F)

1 to 3 months: -20 to +45 °C (-4 °F to + 113 °F)

< 1 month: -20°to +60 °C (-4 °F to + 140 °F)

1.3.4 Symbols used on the electrode package

Symbol	Description	Symbol	Description
	• Federal law restricts this device to sale by or on the order of a physician		Read the instruction before use
	• Low-density polyethylene (LDPE)		Disposable item; Single use only
	• Do not use if package is damaged		Storage temperature for the electrodes
	Keep out of direct sunlight		Keep dry
	Use within 1 day after opening		

1.4 Features list

Tempus LS comes with the following items:

- Lithium-ion battery with a battery life of 300 shocks with maximum energy or >12 hour ECG display
- Defibrillation/pacing electrodes (electrodes must be ordered separately see Section 6.9 Accessories and disposables for part numbers)
- Tempus LS user manual set
- Power supply

Tempus LS has the following features:

- > 100 hours memory (FIFO) data storage for multiple patients
- Water and dust resistant to IP66
- Multiple ways of reviewing patient data, including 3 waveform color display
- A daylight readable, NVG (night vision goggles) friendly display
- Wide operating & storage temperature range
- Data sharing with Tempus Pro via Bluetooth or USB.

The following functionality is available with the Tempus LS:

Items	Provided as Standard or Optional
Manual defibrillation	Standard
Synchronized defibrillation	Standard
AED	Standard
Pacer	Standard
ECG and heart rate	Standard
CPR Feedback with ARGUS LifePoint	Optional
ETCO2 (remote display from Tempus Pro)	Optional

1.5 Indications for use

The Tempus LS is for use for termination of ventricular fibrillation and ventricular tachycardia.

The device is for the use of qualified medical personnel who are trained in the use of the device and in basic and advanced life support.

The device is intended to be used by professional medics including doctors, nurses, paramedics and EMTs, in civilian and military applications.
The user group will be distinguished also by those paramedics who can stay at the site of injury and treat patients and those who can only transport and attempt to sustain the patient i.e. paramedics with less clinical capabilities who may need only AED mode of the product, such as fire departments (programmable by the system administrator).

The device is intended to be used in following environments:

- primarily in pre-hospital care and transport applications such as:
  - medical and military vehicles (including ambulances, fixed and rotary wing aircraft),
  - patient's homes or work places,
  - both indoors and outdoors, including austere environments
  - in Commercial Transport vehicles
- also in medical establishments (this is for technical information, the other areas where RDT markets the product are subject to a separate discussion) such as:
  - hospitals for ER wards and crash carts
  - military hospitals (which could be temporary "forward" bases, field hospitals, hospital ships and CONUS or OCONUS permanent hospitals)
  - doctors' clinics

The therapeutic indications are:

- Manual – manual defibrillation will be indicated for pulseless, unconscious, not breathing patients with VF or VT.
- AED will be indicated for VF and rapid/fine VT.
- Cardioversion will be indicated for atrial fibrillation, atrial flutter, paroxysmal supraventricular tachycardia and, in relatively stable patients, ventricular tachycardia. Pacing will be fixed, or on demand and for patients with symptomatic bradycardia. There is an 'overdrive' option within the fixed mode.

1.6 CE statement

Tempus LS bears the CE 0123 mark (Notified Body TÜV-SÜD Produkte Service GmbH, Ridlerstr. 65, 80339 Munich, Germany), indicating its compliance with the essential requirements of the Annex I of the Medical Device Directive 93/42/EEC regarding safety, functionality and labeling. The requirements apply to patients, users and third persons who come into contact with this device within the scope of its intended use.

Chapter 2
Getting started

This chapter explains the basic principles of operation i.e. connections, turning on, function buttons, LCD screen information, etc.

2.1 Unpacking the Tempus LS

The Tempus LS is supplied from the factory in protective outer packaging. No special precautions are required when unpacking the Tempus LS. RDT recommends that you keep the packaging.

RDT recommends that the equipment is inspected and tested on receipt to confirm that the unit has not been damaged and that all expected items and accessories have been received and are in working order. New batteries should be charged up for at least four hours on receipt.

Confirm that all items ordered have been received, as detailed in 1.4 Features list.

2.2 Before deployment

Carefully check all the relevant settings on each Tempus LS before it is deployed. When deploying multiple units, you may set up a single unit and export the configuration from one unit to the others (clone the settings). To export or import configuration files go to 2.2.1 Export/Import Settings user default to/from USB memory stick.

The following configuration settings are exported and imported:

Default settings include:

- AED
  - Energy pediatric shock 1..3
  - Energy adult shock 1..3
  - AED Key in MANUAL
  - Analysis Key
  - CPR Timer Counting
  - Start Metronome Default
  - Voice Prompts On
- Defi Manual
  - Energy Adult
  - Energy Pediatric
  - Auto Sync Enabled
  - Sync Soft -Key
  - SYNC ON After Shock
  - Start Metronome Default
  - Metronome Ratio Default
  - Secure MANUAL Start
  - Manual Mode Passkey
- Defi pacer
  - Pacer Enabled
  - Default Pacer Mode
  - Overdrive Enable
  - Default Pacer Rate
  - Pacer Key in AED
  - Pace Key in MANUAL
- Metronome Settings
  - Metronome Rate
- CPR Feedback Settings (LifePoint)
  - Rate Limit Upper (cpm)
  - Rate Limit Lower (cpm)
  - Depth Limit Upper (mm)

  - Depth Limit Lower (mm)
  - Feedback Delay (sec)
  - Voice Prompts On (AED)
  - Voice Prompts On (MANUAL)
  - Average Rate Max CPR
  - Enable Recoil
- Monitor (ECG display)
  - Mains Filter
- Printer
  - Print on SHOCK
  - Print on NO SHOCK Advised
  - Print on Start Pacing
- System settings
  - Ready-To-Use Settings (**On**/Off, Interval for test)
  - Default System Settings (Start up view, Brightness, Volume, ECG Amplitude and Speed, HR/PP source, Auto switch OFF, Units).
  - Tactical Mode Settings
  - Communication Settings
  - Language
  - Country
  - Date, Time, Timezone
  - Software Installation
  - Maintenance Passkey
  - Service settings

Important
Ensure that the Tempus LS is configured with the correct language before deployment. Language is configured in the System Settings menu, see "5.2.7 System Settings".

If the device outputs English voice messages (in AED mode) when the configured language is not English, please contact RDT to obtain the correct audio files.

Initial settings

Depending on the default settings **"Initial setting" On//Off** the device starts with the initial setting screen.

To switch the Initial settings screen On or Off go to Menu **System> Maintenance Settings > System settings > Service settings >** parameter **Initial setting** (see page 102). The following settings appears on the initial setting screen:

- Language
- Country
- Current time display
- Current Date display
- Timezone
- Setting Date, time, Timezone >>>

To go directly into the operational mode press button **"Cancel"**. The screen appears again after cycling power on/off.

To confirm the displayed setting or the changed setting press the button **"Confirm"**. Message "Default settings stored" appears. The screen does not appear again after cycling power on/off.

Important
With the confirmation of this dialog the ready to use display (RTU) is set to ON with an interval of 1 day (see "Ensuring operational readiness" on page 38). If Cancel the dialog the RTU display is set to off!

2.2.1 Export/Import Settings user default to/from USB memory stick

Configuration of the device can be made with the Export/Import function in Menu **System > Maintenance Settings >Default settings Storage** 5.2.8 Default settings storage.

1. Go to the Menu **System > Maintenance Settings >Default settings Storage.**
2. Plug the USB memory stick into the USB port of the Tempus LS.
3. Start the "Export Settings" function. The xml file is stored in the folder directory: "TempusLS\7021.000156**Settings**\default_settings.xml". The folder number 7021.000156 is the serial number of the device. Do not delete this directory with the serial number and the xml file. It will indicates from which device the Clone-USB is generated.
4. Remove the USB memory from the device, plug it to your computer and copy the "**Settings**" folder with the xml file into the directory: TempusLS\Settings. This is now your "Clone-USB".
5. Plug the Clone-USB to another Tempus LS. Go to the Menu **System > Maintenance Settings >Default settings Storage.**
6. Start the "Import Settings" function. If the xml file is successfully imported the notification "User Defaults Imported" appears.
7. To activated the new defaults cycle power off and on.
8. Verify the new default settings.

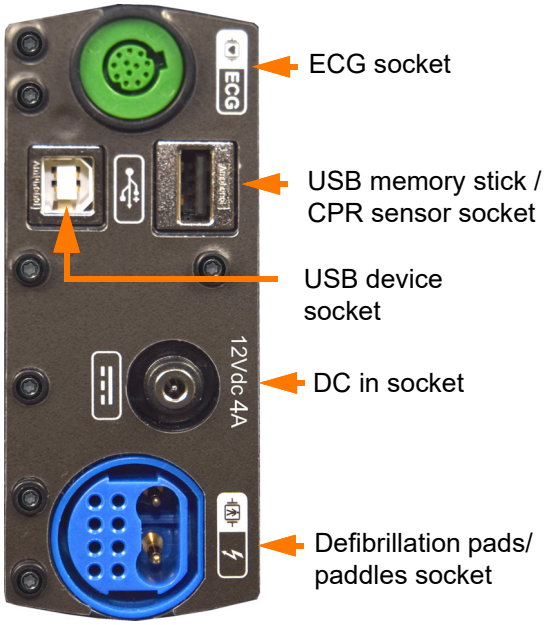
2.3 Overview of the Tempus LS

2.3.1 Key features of the unit front

The key features of the Tempus LS are annotated in the views below.

2.3.2 Back view with battery

2.3.3 Socket panel



ECG socket

USB memory stick / CPR sensor socket

USB device socket

DC in socket

Defibrillation pads/ paddles socket

Optional connectors with dust covers

2.3.4 LEDs

The LEDs give the following information:

Flashing red/green when a new battery is inserted. Stops flashing after power up. When RTU (ready to use) setting is on, refer to section "Ensuring operational readiness" on page 38.

Battery charging (fast charging) when LED lights green.

Mains supply connected when LED lights green

2.4 Switching the device on and off

2.4.1 Switching the device on

Switch the device on by pressing and holding the green On/Off button until the green power LED illuminates.

2.4.2 Switching off and disconnecting from the external supply

1. Press and hold the **on/off** button until the Tempus LS beeps, the message “Shutdown in progress” appears.
2. Remove the external DC supply.

Forced shutdown procedure
If the device cannot be switched off via the above procedure, press and hold the green **on/off** button until the device switches itself off.

Switching off when connected to Tempus Pro

When Tempus LS uploads intervention data to Tempus Pro, a dialog box displays the remaining data in percent to upload before shutting down. This upload can be interrupted with the "SHUTDOWN" function key and the device switches off immediately.

2.4.3 The tactical mode

WARNING

- To ensure that the Tempus LS is safe to use when using NVGs (night vision goggles) go to the menu **System > Tactical mode >** and select “ON” or press the button “Tactical ON” if displayed: Brightness is set to Min and LED Indicators are set to off. Additional audio output and wireless transmission can be switched off.
- The Tactical mode button is intended for use by military and civilian pre-hospital care users for scenarios where low emitted light and low emitted sound is required or desired. Users are reminded that while these functions are enabled, the device will not emit audible alarms and voice prompts during AED mode from the speaker and may present a display that may be too dim to see in daylight conditions. Users should therefore ensure that they use these features only when required and recognize that greater levels of patient care and supervision will be required.

Activating tactical mode

Go to menu **System > Tactical mode >** and select “On”.

Setup tactical mode button

To display the tactical mode (ON/OFF) button on the main screen, go to menu **System > Maintenance Settings > System Settings > Tactical mode settings** (see page 101).

Tactical OFF

2.5 New patient

To finish an intervention and start a new intervention, go to **menu Patient > New Patient** and press **Start**

This finishes an intervention, stores the intervention file, resets the intervention timer and starts a new intervention. The following user settings will be restored to default settings:

- Sync mode
- ECG Amplitude (mm/mV)
- ECG Speed (mm/s)
- Pacemaker Mode

- An intervention is also finished when the device is switched off longer than 2 minutes.
- If the device is switched off for less than 2 minutes, the last settings remain stored and the intervention continues.
  - except when the data have been synchronized with a Tempus Pro at power off, the intervention is closed.

2.6 External DC supply and battery operation

DANGER

- Please read the safety notes in section 1.1 General safety notes before initial operation.
- **Danger of explosion!** The device is not designed for use in areas where an explosion hazard may occur. Also, it is not permitted to operate the defibrillator in an oxygen-enriched environment or in the presence of flammable substances (gas) or anesthetics. Oxygenation in the vicinity of the defibrillation electrodes must be strictly avoided.
- **Danger of electrical shock!** The **Tempus LS** is a high-voltage therapy device. Improper use of the device can endanger life. Always follow the instructions given in this user guide.
- The user must make sure that there are no conductive connections between the patient and other persons during ECG analysis and defibrillation.
- Avoid defibrillation in very moist or wet surroundings.
- Electrical shock hazard. Do not operate the unit if the earth connection is suspect or if the power supply unit/mains lead is damaged or suspected of being damaged.
- Do not use the external power supply above 4000 m or in outdoor environments including ambulances, fixed and rotary wing aircraft.

2.6.1 External DC supply

CAUTION

- Please note that **NO** defibrillation shocks can be delivered when the battery is depleted, missing or defective, even when an external power supply is connected.
- Position the external power supply so that the mains connection is easily accessible at all times.

1. Insert the battery.
2. Connect the external power supply **(1)**.

3. Connect the mains plug of the external power supply to the mains supply.
4. Check the LED **(3)** lights green when the power supply is connected to mains supply.
5. Check the LED **(2)** lights green (battery fast charging)
6. Press the **ON/OFF** button **(4)** to switch the **Tempus LS** on.
7. Check battery charging LED (2) and the battery status in the LCD according to 2.6.2 Battery operation.

2.6.2 Battery operation

WARNING

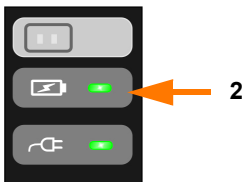
▲ Ensure that the Tempus LS battery charge is 100% every time you go on shift.

Charging battery

Important

The power battery is automatically recharged when the device is connected to the external DC supply via the external power supply. The power battery requires approx. 3 hours to be recharged to 90%.

To optimize battery life, fully recharge the battery whenever possible



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

- LED (2) is continuously on = battery is fast charging
- LED (2) is flashing = no battery inserted
- LED (2) is continuously off = battery is not in fast charge but may still be charging

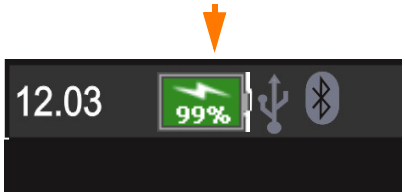
If the device gets to hot, charging stops. As soon as the temperature has decreased to an acceptable level, the charging resumes.

Battery status screen

When the device is switched on, the capacity status is displayed in the top left corner of the screen.

Tempus LS is **not** connected to mains power.

Tempus LS is connected to mains power and charging is in progress.



Tempus LS cannot communicate with the battery - check the following:

- Is the battery fitted?
- Are the battery clips fully engaged?
- Are the battery contacts clean and undamaged?
- Is the battery in deep discharge state?

Low battery indication

When the battery is nearly empty, the symbol 

is displayed in the top left corner of the screen, a technical notification is displayed **"CAUTION: Battery below 10%"** and an acoustic signal sounds.

The audio signal can be silenced by the user.

Empty battery indication

When the battery is nearly empty, the symbol  is displayed and in the top left corner of the screen and a technical alarm is displayed **"Battery empty: Shutdown in 2:00!"** and an acoustic signal sounds:

➜ Replace battery with a fully charged battery, or connect the power supply.

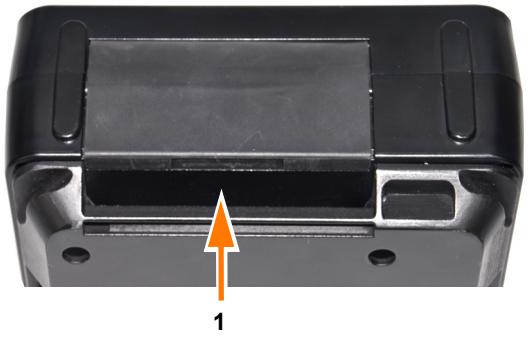
Changing battery

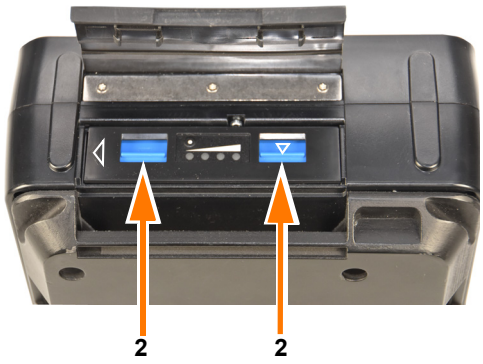
CAUTION

- ▲ Please note that **NO** defibrillation shocks can be delivered when the battery is depleted, missing or defective even when an external power supply is connected.
- ▲ Do not hot-swap the battery during analyzing or while charging or charged ready for shock.
- ▲ Replacement of lithium batteries by inadequately trained personnel could result in a hazard.

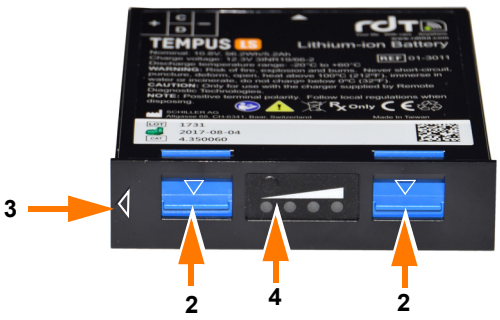
- The battery can only be inserted in one way.

1. Open the battery cover **(1)**.
2. Press the two blue catches **(2)** (direction indicated with two arrows) to release and remove the battery.

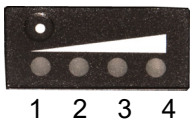




3. To replace, proceed as follows:
   - Press the battery test key **(4)**. The LEDs indicate the current charging level of the battery.
   - Slide the battery into the battery compartment with the markings positioned as shown **(3)**.
   - Push home until the battery clicks in place with the blue catches **(2)**.



- LED 1 flashing = < 10 %
- LED1 = 10...25%
- LED1/LED2 = 26...50%
- LED1 /LED2/LED3 = 51...75%
- LED1 /LED2/LED3/LED4 = 76...100%



If the battery voltage is too low or the battery is inoperable, there will be no LED indication

4. Close the battery cover and make sure that the cover is clicked in properly.
5. Turn the Tempus LS on and check battery charging LED and the battery status in the LCD according to 2.6.2 Battery operation.

2.6.3 Interruption of external power supply

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

2.6.4 Isolating from the mains

➜ To isolate the device from the mains supply, remove the mains plug from the external power

2.7 Ensuring operational readiness

Important
Do not expose the device to direct sunlight, or extremely high or low temperatures. The ambient temperature should be in the range 0°C to +50 °C. Lower or higher ambient temperatures will have a negative impact on battery life.

2.7.1 Ready to use LED

When “Ready to use” function is activated, the switched off device shows the operational readiness status based on the set test intervals (see "System Settings" on page 101). The operational readiness is indicated by the LED state:

- Green flashing = ready for use
- Red flashing = not ready for use, device failure
- Red/green flashing = switch the device on to confirm the battery status. This indication can also occur when the correct shutdown procedure failed.

→ If tests failed, switch the device on and read the notification in the message area and proceed according the "General errors & troubleshooting" on page 125 and "Technical alarms, notifications" on page 126

→ These tests can be executed also manual see "Self tests" on page 109.

Device Status ready to use

The following components are tested:

- Relay (High voltage)
- IGBT (Insulated Gate Bipolar Transistors)
- Battery
- Capacitor

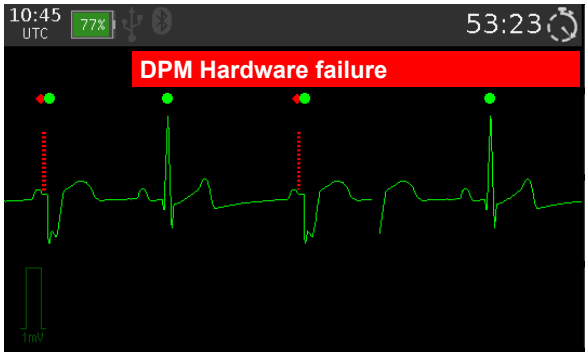
2.8 Display of technical alarms and notifications

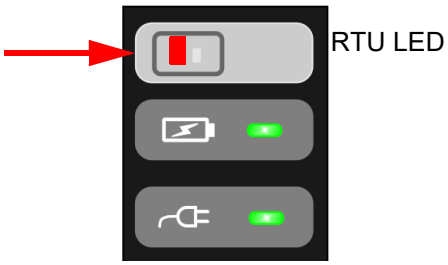
- Only technical alarms and notifications are issued, no physiological alarms.
- High priority technical alarms are issued according to 60601-1-8.
- Audible alarms can be suppressed by the “Tactical mode” see 2.4.3 The tactical mode.
- Notification and information are issued according the description below.

The technical alarms and notifications are displayed as follows:

- High Priority technical alarms
  - Text with red background
  - two beeps every 15 seconds
  - Red RTU LED blinks every 0.5s
- Notification (caution)
  - Text with orange background
  - one beep every 30 seconds
- Information
  - Text with blue background
  - one beep every 60 seconds

All alarms and notifications disappear automatically when the cause has been remedied.





Operator position

CAUTION

- ▲ Ensure that the environmental noise is below the set alarm sound volume (Volume Low/Mid/High 50/60/70dB).
- ▲ Do not set Volume below the environmental noise.
- ▲ Standard or user-defined alarm volume may vary for different environments. Therefore, always check the set volume for the corresponding environments.
- ▲ 2 minutes after switching off the device or main battery power interruption, the user-defined alarm volume alarm is set to default (standard setting = Low)
- ▲ If “Tactical mode” is programmed refer to section 2.4.3 The tactical mode and read the safety notes.

The visual alarm display (red background) and blinking red RTU LED is visible to a distance of 4 meters.

2.8.1 Technical high priority alarms

The following technical alarms alert the user to the need to correct the technical problem in order to ensure the operation of the unit. More alarms see 6.7.2 Technical alarms, notifications.

Alarm message	Description/Remedy
Battery not inserted. Shutdown in m:ss	• Displayed during battery replacement
Battery empty. Shutdown in m:ss	• Battery empty and automatic shutdown in progress ➜ Replace the battery
Battery cannot be used. Shutdown in m:ss	• Discharge Temperature outside the allowed limits below -20°C or above 60°C
Shock and pacing disabled due to low battery	• Low battery ➜ Replace the battery
Device not used. Shutdown in mm:ss	• Auto switch off activated (see Default System Settings>>> 15 or 30 min) ➜ Press any button
ECG VF/VT Detected	• VF/VT detected (only when defibrillation pads are connected)
Exit Monitor Because VF/VT Detected	• VF/VT detected during ECG monitoring (only when defibrillation pads are connected)
Key stuck detected	• Pressed or short circuit soft button detected ➜ Restart device again and make sure that no button on the device is pressed during startup.

2.8.2 Technical notification

The following technical notification provide the user with information on correct operation of the device. More technical notification see 6.7.2 Technical alarms, notifications

Notification message	Description/Remedy
Defibrillator	
Check Defibrillator Electrodes	No pads are connected ➜ Connect/apply defibrillator electrodes
SHOCK CANCELLED	If the capacitor is charging, no DC power and no energy is available from battery ➜ Replace the battery
Pacer	
Connect ECG cable	Not connected ECG cable ➜ Connect ECG cable
Check ECG Leads	ECG cable connected but Lead(s) off ➜ Check electrodes applied to the patient
Check Defibrillator Electrodes	Check defibrillator electrodes
Pacing stopped	• Device stops the pacing automatically when: ➜ ECG cable is disconnected ➜ ECG cable is off, check ECG Leads ➜ Defibrillator electrodes are off, check Defibrillator electrodes ➜ When battery is empty or removed, check battery ➜ Hardware failure
ECG	
ECG Leads Off	ECG cable connected but Lead(s) off. ➜ Check electrodes applied to the patient
ECG cable Off	Disconnecting ECG cable from the device while it was connected to the patient ➜ Reconnect ECG cable
Battery	
Battery Below 10%	Device is not plugged (no DC-IN) and the actual charge is below 10% but still able to deliver shocks ➜ Replace/recharge the battery

Notification message	Description/Remedy
Battery Cannot Be Charged (High/Low Temperature)	Battery stopped charging because of too high/Low temperature. ➜ Replace the battery with one within the temperature limits
Battery Charge Stopped	Device is plugged (DC-IN) but the main battery is not charging ➜ Check battery/replace battery
Defective / Unknown Battery	No communication with battery ➜ Check battery/replace battery
Memory	
FAILED To: – Restore Default Settings – Export User Defaults – Import User Defaults – Export interventions – Export Log Files	If any issue is encountered while loading/storing the default settings from/to the device or USB memory stick ➜ Check USB memory stick
Device	
Battery Test failed	Battery test failed during RTU or manual selftest Check battery/replace battery

2.9 Internal safety discharge

The **Tempus LS** has an internal safety discharge circuit for internal discharge of the defibrillator's stored energy. The energy is internally discharged when:

- the shock is not delivered within 20 seconds after charging
- function key "Disarm" is pressed (only in manual defibrillation)
- the battery voltage is insufficient
- the device is defective
- the device is turned off
- the Pads are detached (only in AED mode)

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

2.10 Using Tempus Pro with Tempus LS (optional)

Tempus LS can be connected to a Tempus Pro vital signs monitor via a TDL link. This allows Tempus LS to transmit event data to Tempus Pro and to display ETCO2 vitals received from Tempus Pro.

Instructions for setting up the TDL link are in the "*Tempus Pro User/Operator Manual"*, which can be downloaded from the RDT Support web page.

Device authentication is required for wireless TDL link operation between Tempus Pro and Tempus LS; authentication setup is described in the "*Tempus Pro Maintenance Manual".*

Important:
If the software versions of the Tempus LS and Tempus Pro are found to be incompatible on connection, the following dialog will be displayed by the Tempus Pro:

"Attention - Tempus LS Connection
Unable to connect to the Tempus LS
This could be because the software versions on the
Tempus Pro and Tempus LS are incompatible.
Ensure the Tempus Pro and Tempus LS are both updated
with the latest software."

If this message appears, contact RDT to obtain the latest software versions.

Chapter 3
Operation

This chapter explains the basic principles of operation during defibrillation in Manual, AED and Pacemaker modes.

3.1 Manual defibrillation

3.1.1 Application guidelines and safety notes

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

DANGER

▲ The patient must:

- **not** come into contact with the operator or other persons during defibrillation.
- **not** come into contact with metal parts, e.g. bed or be positioned on wet ground (rain, accident in swimming pool), to prevent unwanted pathways for the defibrillation current, which may endanger the operator or assistants.

▲ Do not allow the defibrillation electrodes to come into contact with other electrodes or metal parts which are in contact with the patient.

▲ The patient's chest must be dry, as moisture causes unwanted pathways for the defibrillation current. For safety, wipe off flammable skin cleansing agents.

▲ Owing to the high currents, there is a risk of skin burns at the site of the electrodes. This is why the electrodes must not be placed on or above the sternum, clavicle or mamillas.

▲ Immediately prior to the shock, the heart massage (CPR) and artificial respiration must be stopped and bystanders must be warned.

▲ Defibrillating a patient with an implanted pacemaker is likely to impair the pacemaker function or cause damage to the pacemaker. For this reason, do not apply the defibrillation electrodes in the vicinity of the pacemaker, have an external pacemaker at hand, and check the implanted pacemaker for proper functioning as soon as possible after the shock.

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

3.1.2 Defibrillating children/neonates

WARNING

▲ Please note that less energy is needed for children:
For the **first** defibrillation of infants and small children using biphasic shock, approx. 1 joule/kg (2.2 lbs) body weight is released. An increase of 2 joules/kg (2.2 lbs) body weight is possible when the defibrillation is repeated.

▲ For the defibrillation of children weighing less than 25 kg (55 lbs), the pediatric pads should be used.

CAUTION

Defibrillation on neonates

▲ When using the defibrillator on neonates, follow the local guidelines.

▲ Follow the energy setting for infants and small children as described above.

▲ The automatic energy setting for neonates is the same as for children.

- Menu **Patient > Patient Type** **Adult** or **Pediatric:**
  - When pediatric pads are used, the **Patient Type** setting **Adult** or **Pediatric does not** overrule the energy setting. When pediatric pads are connected to the device, the energy setting is always pediatric.
  - If no pediatric electrodes are available, adult electrodes can be used. When adult pads are used, the patient type setting “**Pediatric” does** overrule the energy setting Adult to Pediatric (default 50/50/50 joules in AED mode). In Manual mode the max. selectable energy is 100 joules.

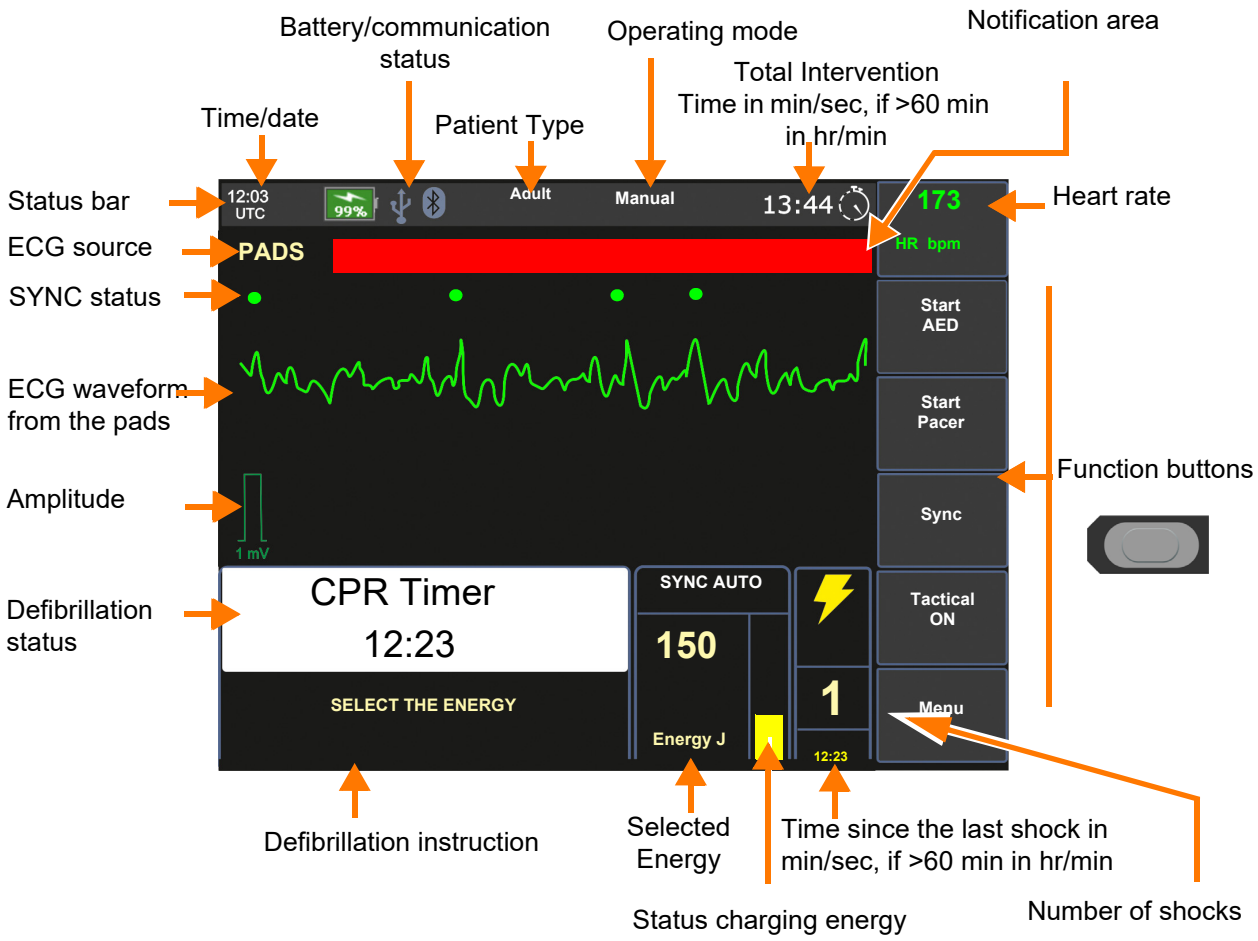
3.1.3 General function

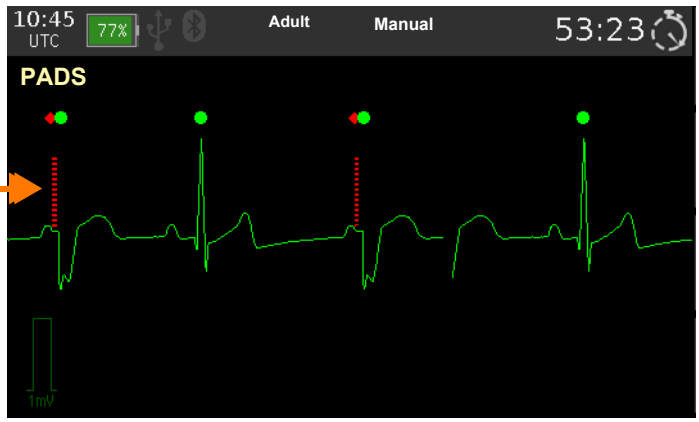
- The **Tempus LS** works with biphasic truncated exponential chopped defibrillation waveform impulses. Depending on the factory settings, the device either switches automatically from synchronized to non-synchronized defibrillation or the mode has to be changed manually using the **Sync** button.
- The required energy for a successful defibrillation depends on several parameters (body constitution, etc.). For emergency medical treatment, AHA/ERC recommend a biphasic impulse. Depending on configuration settings, the energy of the 3 first shocks can be increasing.

Default energy settings in manual mode

Adults	Pediatric
150 joules	50 joules

3.1.4 Home screen Manual defibrillation mode

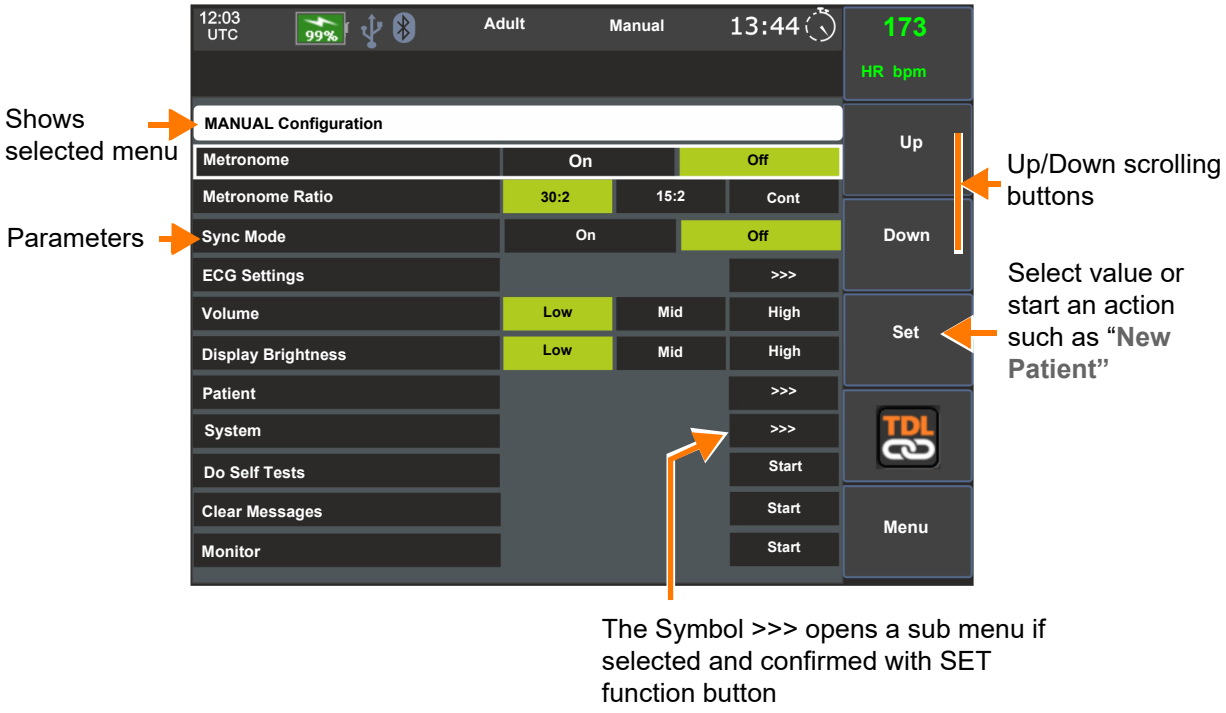




Detected pacemaker pulses (internal or external) are displayed as red, vertical dotted line

Menu

The menu screen below shows the parameters available for **Manual defibrillation** mode.



Menu Structure

Mode	Parameter	Sub-Menu >>>/Function
Manual	Metronome Metronome Ratio Sync mode Volume Display brightness	**ECG Settings >>>** **Patient >>>** **System >>>** Do self test Clear messages Monitor

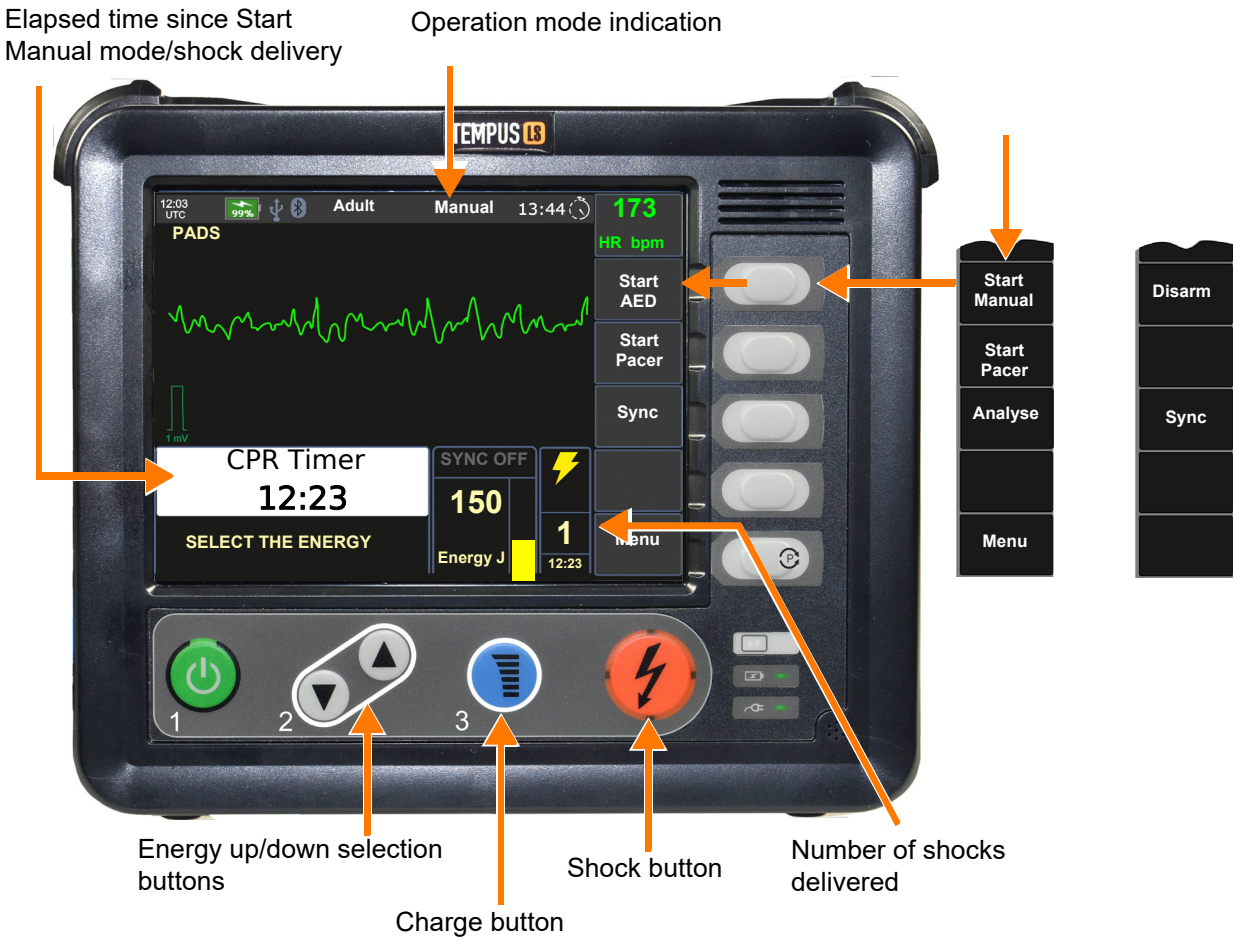
3.1.5 Initial operation *MANUAL (Defibrillation) Mode*

- The Energy selection and Charge buttons (see below) are activated (illuminated by white LED ring)
- Function button for synchronized defibrillation (SYNC ON/OFF) is available or selectable in the menu.
- Function buttons to select AED or PACER mode

3.1.5.1 Activating the manual defibrillation mode

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

➜ Press **Manual** function button. Confirm the manual defibrillation mode with function button **Yes.** If “Passkey” is activated enter first the key number (3211).The Energy and Charge button lights up. The operating mode indication shows “Manual”.



3.1.6 Manual defibrillation using pads

DANGER

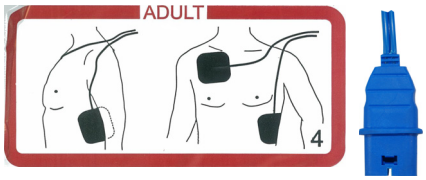
- ▲ Delivering a shock to a patient with normal heart rhythm may induce ventricular fibrillation. For this reason, first read the general rules and safety information in sections 3.1.1 Application guidelines and safety notes and 3.1.2 Defibrillating children/neonates.
- ▲ Electric shock hazard. Turn off the device before exchanging the defibrillation electrodes; exchanging the electrodes on a charged defibrillator initiates an internal safety discharge.

3.1.6.1 Applying the adult and pediatric electrodes

CAUTION

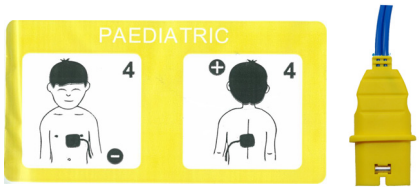
- ▲ Only use the pads up to their expiration date. Please note that the indicated expiration date only applies if the vacuum pack is intact.
- ▲ The pads are pre-gelled, so there is no need to use extra contact agent.
- ▲ Do **not** reuse the pads.

Adult electrodes



The adult electrodes with the blue connector are used for adults and children from 25 kg (55 lbs) and above.

Pediatric electrodes



The pediatric electrodes with the yellow connector are used for children weighing less than 25 kg (55 lbs). When pediatric pads are connected the energy reverts to the default pediatric energy, which may be less than 50 joules.

3.1.6.2 Applying the electrodes

WARNING

- ▲ Good contact between the skin and the adhesive electrodes must be ensured. Suntan oil, sand or salt reduce the adhesive quality.
- ▲ The applied pads must have good contact with the patient's skin, and air bubbles under the pads must be avoided. To do so, stick on one end of the pad then smooth it out to the other end.
- ▲ The minimum safe distance between the two electrodes should be approx. 3 cm (1.2 in).

Adults and children more than 25 kg (55 lbs)

Electrode placement is the same for adults and children weighing 25 kg (55 lbs) or more, see Fig.3.1 Adult electrode application site and Fig.3.2 Application sites for children more than 25 kg (55 lbs).

1. Clean and dry the application points for the electrodes. Only clean the skin by vigorously rubbing it with a dry cloth.
2. Apply one electrode above the right nipple. Do not apply it on the clavicle (uneven).

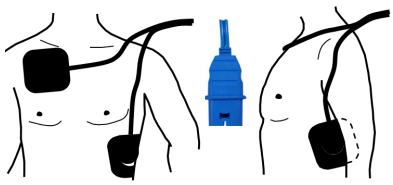


Fig.3.1 Adult electrode application site

3. Apply the other electrode slantwise below the left breast as illustrated in Fig.3.1 Adult electrode application site/ Fig.3.2 Application sites for children more than 25 kg (55 lbs).
4. Make sure that the connections are positioned on the outside so that the cables do not hinder cardiopulmonary resuscitation (CPR).

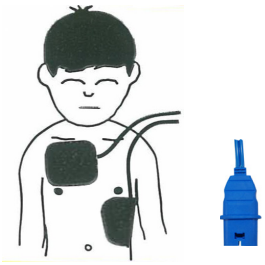


Fig.3.2 Application sites for children more than 25 kg (55 lbs)

Children weighing less than 25 kg (55 lbs)

The energy setting is automatically reduced with the Pediatric electrodes.

1. Clean and dry the application points for the electrodes, see Fig.3.3 Application sites for children less than 25 kg (55 lbs). Only clean the skin by vigorously rubbing it with a dry cloth.
2. Apply one electrode on the left of the right nipple as illustrated in Fig.3.3 Application sites for children less than 25 kg (55 lbs)
3. Apply the second electrode on the back on the same level as the chest electrode as illustrated in Fig.3.3 Application sites for children less than 25 kg (55 lbs).
4. Make sure that the connections are positioned on the outside so that the cables do not hinder cardiopulmonary resuscitation (CPR).

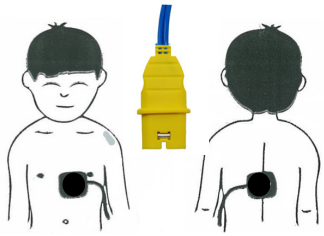


Fig.3.3 Application sites for children less than 25 kg (55 lbs)

3.1.6.3 Manual Defibrillation Using Pads - Procedure

1. Switch on the device by pressing the green button
2. Activate Manual mode with the **Start Manual** function button if not already in Manual mode. (see 3.1.5.1 Activating the manual defibrillation mode)
3. Check the state of the patient.
4. Connect the electrode cable to the pads connector and apply the electrodes.
   The message **Check Defibrillator Electrodes** is switched off as soon as the device measures an acceptable electrode resistance. If it is not switched off, see section 3.1.6.1 Applying the adult and pediatric electrodes

Fig.3.4 Connecting Defibrillation Pads

5. Select the required energy with the  button.
6. Initiate energy charging by pressing **"Charge"**  button.

As soon the charged button is pressed, the “Disarm” function key is displayed. You can activate a safety discharge of the energy at any time by pressing the function key “Disarm”.

An automatic disarm takes place after approx. 20 seconds. This is indicated by a change in the pitch of the alarm tone 5 seconds before disarming.

DANGER

▲ **Danger of electric shock!**

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

7. As soon the shock button lights up, release the shock by pressing  button on the device.
8. Finish the therapy (see 3.3.7 Finishing the therapy).

3.2 Synchronized defibrillation

To turn sync mode on/off use the sync mode button in the main menu (from manual mode); or use the on screen touch button (if enabled). When sync mode is on, shocks will be delivered when synchronized with a QRS.

3.2.1 Warning erroneous triggering

WARNING

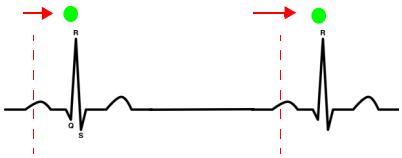
Erroneous triggering, interpretation hazard:

▲ Signal noise may disturb the ECG signal and cause artefact's. This must be considered chiefly in the synchronized mode. For this reason, the following should be observed:

- Do not touch the device during defibrillation to prevent electrostatic noise
- Keep the patient cable away from power cords, transformers etc.

▲ To achieve adequate ECG signal quality for reliable triggering, ensure that

- the ECG signal is free of artifact
- there are no major fluctuations in amplitude
- the displayed trigger pulses are positioned exactly above the R-wave



3.2.2 Setup switching from unsynchronized to synchronized mode

WARNING

▲ The current setting must be communicated to the user.

- You can find the settings below in the menu System/Maintenance Settings/Manual Settings (see section 5.2.2 Manual Settings, page 98).
- Default values are bold.
- The SYNC mode is always “SYNC OFF” when entering the MANUAL mode.

Parameter	Value	Description
Auto Sync Enabled	• Yes/**No**	If set to “Yes” synchronized mode will be activated as soon a QRS trigger is detected. (If set to “Yes” the Status is SYNC AUTO, if set “No” the status is set to SYNC ON)
Sync soft-key	• Yes/**No**	If set to “Yes” the user can switch between synchronized/ direct defibrillation If “No” is selected the Sync mode can be activated only via the manual configuration menu.
SYNC ON after shock	• Yes/**No**	If set to “No” the SYNC mode is set to Off (direct defibrillation) after a shock has been released in synchronized mode. Note, this function is only true if Auto Sync Enable is set to “No”.

Auto Sync Enable

Auto Sync Enable = **No**

- Activating the synchronized defibrillation by pressing the **SYNC ON (1)** function button.

If “Auto Sync Enabled“ = Yes

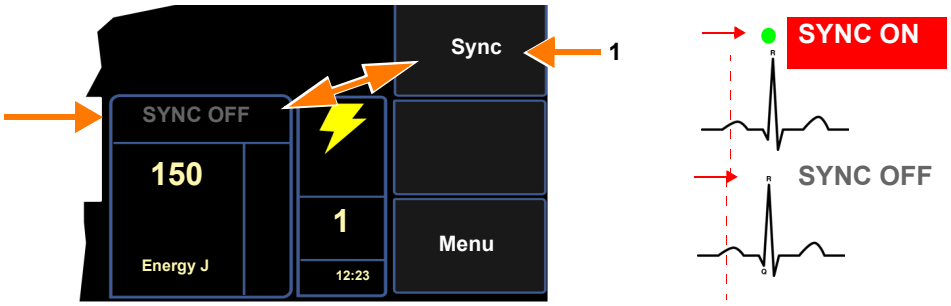
- the Synchronized defibrillation is activated as soon a QRS is detected.

WARNING

▲ The device switches to **SYNC OFF** if for 2 second no QRS is detected.

SYNC modes:

- SYNC OFF
- SYNC ON
- SYNC AUTO



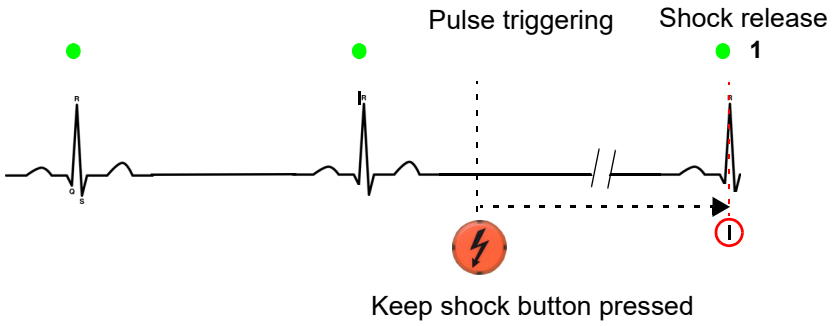
Sync On after shock

Depending on the setup, the synchronized mode stays activated after delivering the shock (SYNC ON after shock =Yes) or switches back to unsynchronized shock (SYNC ON after shock = **No**). The current setting must be communicated to the user.

- ▲ The default setting is “SYNC ON after shock” = **No”**:
  the manual activated **SYNC ON** mode as well the **SYNC AUTO** mode will be deactivated after delivering the shock. To deliver a second synchronized shock, it is important to activate it again.
- ▲ If the admin setting is “SYNC ON after shock” = YES**”:**
  the manual activated **SYNC ON** and as well the **SYNC AUTO** mode is maintained after delivering the shock. To deliver a unsynchronized shock, it is important to deactivate it again.

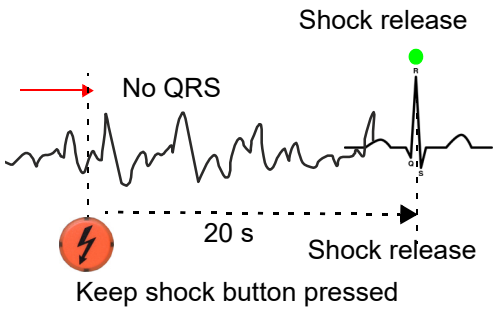
3.2.3 Function of the synchronized defibrillation procedure

For synchronized defibrillation, the defibrillation shock is delivered in synchronization with the heart action, as the heart is still working. After the physician has triggered the defibrillation shock, the trigger signal for the actual shock delivery will be derived from the subsequent QRS complex within < 60 ms after the trigger mark on the monitor screen **(1)**.



CAUTION

- ▲ Be aware: If **Auto Sync enabled is Yes**, after pressing the shock button and in the absence of a QRS, after 2 seconds the device switches automatically to unsynchronized shock and the shock will be delivered to the patient.

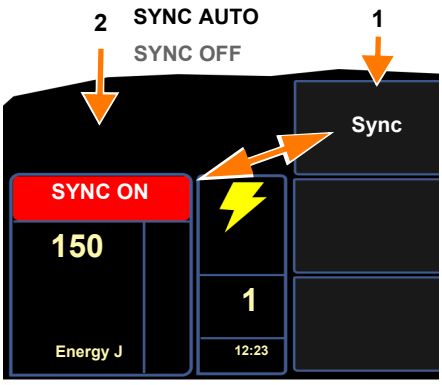


▲Be aware: If **SYNC ON is activated,** that after initiation of the shock, the actual shock will be delivered to the patient with the next trigger signal (QRS) derived from the ECG. This may lead in a shock delivery delay time of 20 seconds.

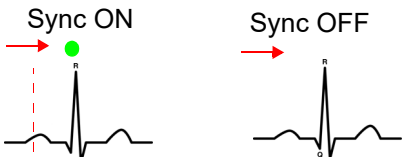
3.2.4 Synchronized defibrillation procedure

If an unsynchronized shock is required while in synchronized mode, it is possible at any time to switch **(1)** the synchronized mode to **SYNC OFF** and deliver the shock immediately (unsynchronized).

1. Connect the electrode cable to the pads connector.
2. If the device starts in **AED** mode, proceed according to the description in section 3.1.5.1 Activating the manual defibrillation mode, page 50.
3. Select synchronized defibrillation (**SYNC ON** or **SYNC AUTO**) with the function button **(1).**
4. The setting **SYNC ON/AUTO** (**2**) is displayed above the energy setting.



5. Check ECG rhythm:



   – the trigger pulses above the R-wave

6. Select the required energy with the button.
7. Initiate energy charging by pressing **"Charge"** button

➜ You have now 20 seconds to work through the steps 8 and 9, before the internal safety discharge is activated because of exceeding the time limit.

8. Check ECG rhythm (trigger pulses), **SYNC ON or AUTO (2)** and energy setting.

CAUTION

▲ Be aware: If Auto Sync is enabled (**SYNC AUTO**), after pressing the shock button and in the absence of a QRS, after 2 seconds the device switches automatically to **SYNC OFF** and the shock will be delivered immediately.

9. Deliver the shock by pressing the button and keep the button pressed until the shock is delivered at the next confirmed QRS.

DANGER

▲ **Danger, electric shock!**

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

➜ continuous next page

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

CAUTION

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

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

3.3 Semi Automated Defibrillation (AED)

DANGER

- ▲ Delivering a shock to a patient with normal heart rhythm may induce ventricular fibrillation. For this reason, first read the general rules and safety information in section 3.1.1 Application guidelines and safety notes.
- ▲ Electric shock hazard. Turn off the device before exchanging the defibrillation electrodes; exchanging the electrodes on a charged defibrillator initiates an internal safety discharge.
- ▲ According to AHA/ERC guidelines, even children under 8 year old may be defibrillated in semi-automated mode.
- ▲ In the semi-automated mode, the electrodes should be applied in the common anterior-anterior positions. With infants, anterior-posterior placement can be advised to prevent a short-circuit between the two defibrillation electrodes.
- ▲ If, in the course of treatment, a patient spontaneously regains consciousness, a defibrillation shock that may have been advised just before must not be delivered.
- ▲ During HF surgical interventions, ECG analysis is not permitted in the semi-automated mode.

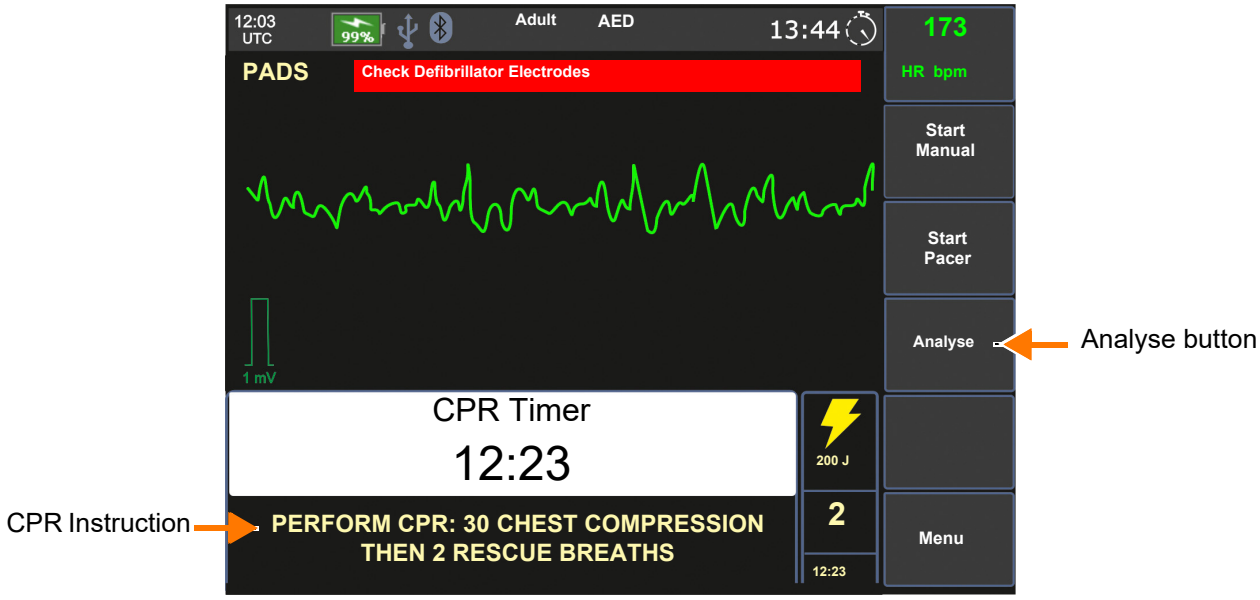
3.3.1 Additional safety information for AED Mode

In addition to the guidelines set forth in section 3.1.1 Application guidelines and safety notes, the following rules must be observed when using an AED, as failure to do so may compromise the success of the defibrillation or endanger the patient's life.

WARNING

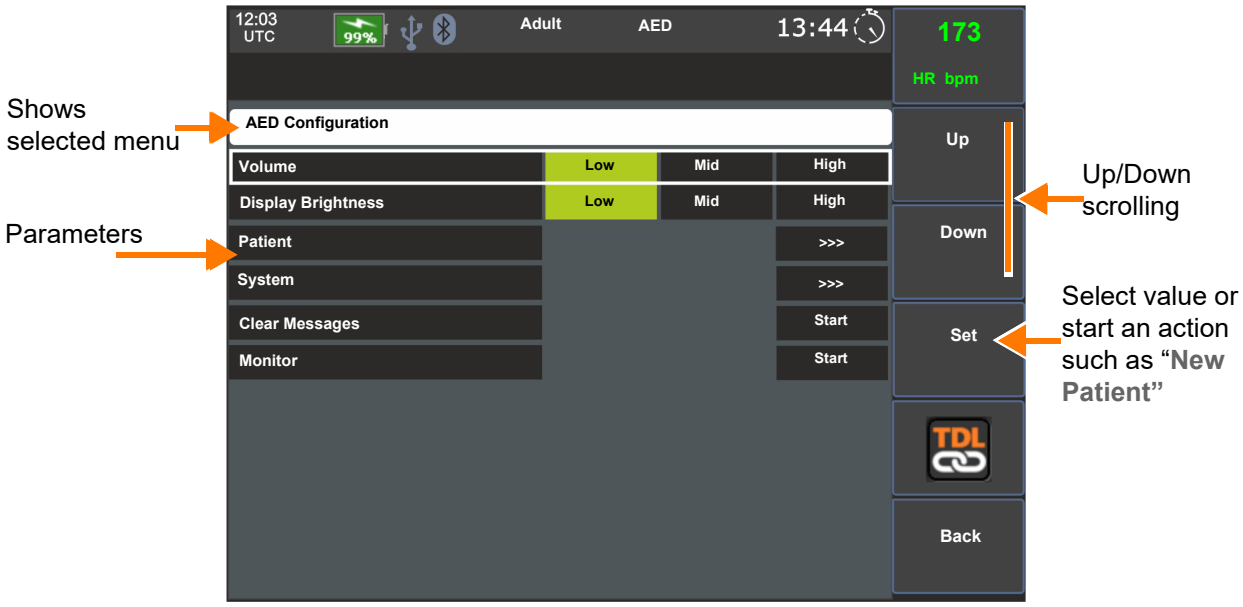
- ▲ The user must verify the prerequisites for the use of the AED by checking for lack of consciousness, lack of breathing and lack of circulatory signs using the ABCD system (BLS algorithm).
- ▲ The device must only be used if the following symptoms are found:
  - non-responsive
  - no respiration
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

3.3.2 AED home screen



Menu

The screen below shows the parameters available in AED Mode.



Menu Structure

Mode	Parameter	Sub-Menu >>>/Function
AED	Volume Display brightness	**Patient >>>** **System >>>** Clear messages Monitor

3.3.3 Initial operation AED Mode

- Select energy button  and charge button  are deactivated
- Function button “Analyse” is available (only displayed during CPR cycle)
- Functions button to select START MANUAL or START PACER mode. The accessibility of the pacer mode can be configured in the maintenance menu.

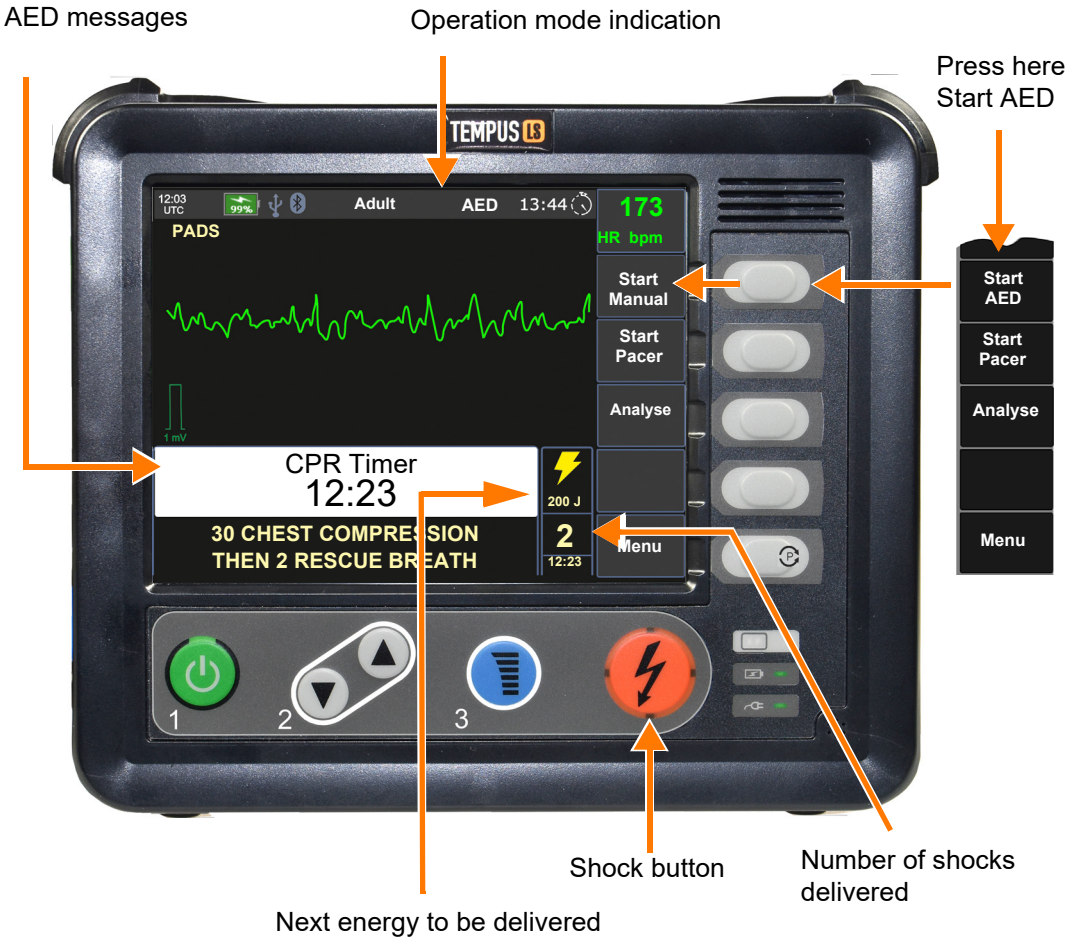
3.3.4 Activating semi-automated defibrillation (AED) procedure

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

➜ If not already in the AED mode press the “Start AED” function button.

➜ If pacer or monitoring mode is selected exit this mode and then press function button “Start AED”

The following screen shows AED mode:



- The “Analyse” button is only displayed when the setting in the menu “**System > Maintenance > AED > Analyse Key**” is set to Yes.
- The Metronome starts automatically when CPR is advised. The Metronome can be switched off in the menu **“System > Maintenance > AED >Start Metronome** by default.
- CPR cycle time can be set according to local regulation in the menu **System > Maintenance Settings > System Settings > Service Setting > AED service setting > CPR Time >** to 1, **2**, or 3 minutes. Default setting is 2 minutes.

3.3.5 Voice messages in AED Mode

- If the device outputs English voice messages when the configured language is not English, please contact RDT to obtain the correct audio files.
- Language is configured in the System Settings menu, see 5.2.7 System Settings.

The following instructions will be spoken by the device:

Spoken instructions	Display	Note
Plug and Apply Electrodes	Plug and Apply Electrodes	Technical message: CHECKING ELECTRODES/ ELECTODES FAILURE. The message disappears as soon as the electrodes are correctly applied and the resistance is between 25 to 250 Ohm.
Check electrodes connector is correctly fitted in machine and electrodes applied to shaved, dry patient's chest.	Check connector is fitted and electrodes applied on chest	After a number of seconds when electrodes are not applied or connected.
Do not touch the patient; analysis will begin	Do not touch the patient; analyzing will begin	
Do not touch the patient; analysis	Do not touch the patient; analyzing	
Movement detected - Analysis canceled, resume CPR	Movement detected - Analysis canceled, resume CPR	Technical message: Patient was moved during analysis and device could not run analysis.
Device recommends a shock		
Shock advised	Shock advised, do not touch the patient	
Stand clear of patient; press orange button	Press orange button to shock	
Device does not recommend a shock		
No shock advised	No shock advised.	
Immediately resume CPR: 30 chest compressions, then 2 rescue breaths – continue until patient is breathing normally.	PERFORM CPR: 30[1]CHEST COMPRESSIONS THEN 2 RESCUE BREATHS	

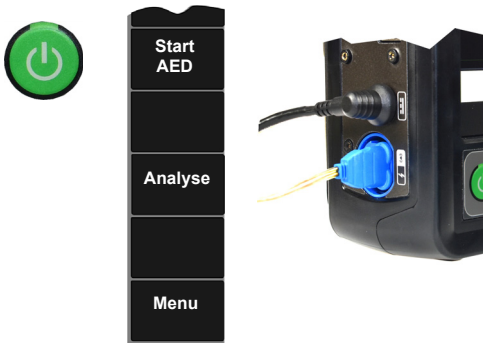
1.When pediatric electrodes are used, CPR is carried out in the ratio of 15:2 if 2 rescuers are on the spot, otherwise 30:2. A “continuous compressions" option is also available (i.e. no rescue breaths)

3.3.6 AED defibrillation procedure

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

Step 1

Switching on and preparing the device



1. Switch on the device by pressing the green button
2. Activate AED with the AED function button if not already in AED mode.
3. Check the state of the patient.
4. Connect the electrode cable to the pads connector and apply the electrodes.
   The message **Check Defibrillator Electrodes** is switched off as soon as the device measures an acceptable electrode resistance. If it is not switched off, see section 3.1.6.1 Applying the adult and pediatric electrodes.
5. If the electrodes are not placed within 30 seconds on the patient, you are prompted to continue the resuscitation.

Step 2

Analysis

6. The analysis starts automatically when the electrodes are detected.
7. You are prompted not to touch the patient any more.

The analysis key can be pressed any time during CPR to start a new analysis.

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

Step 3

Step 3 shock delivery

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

DANGER

▲ Danger, electric shock!

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

8. As soon the shock button lights up, release the shock with  button on the device.

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

The following default energy values are programmed. These values are all configurable in the maintenance settings.

Shock	Adults	Pediatric
1	150 joules	50 joules
2	150 joules	50 joules
3	150 joules	50 joules

Step 4

Cardiopulmonary resuscitation

9. Carry out cardiopulmonary resuscitation. Alternate between 30 chest compressions and 2 breaths[1] for 2 minutes[2]. After 2 minutes, the device begins again with Step 2, Analysis.
10. Finish the therapy (see 3.3.7 Finishing the therapy).

The CPR duration may vary according to country-specific standards.

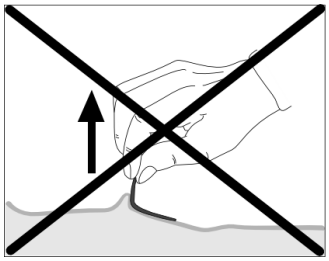
1. A "continuous compressions" option is also available (i.e. no rescue breaths)
2. CPR cycle duration can vary depending on the "CPR time" settings in the menu **System > Maintenance Settings > System Settings > Service Setting > AED service setting > CPR Time >** 1/**2**/3 minutes

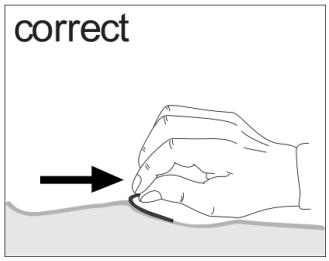
3.3.7 Finishing the therapy

1. Switch the device off as soon as the therapy is finished by pressing and holding for two seconds the On/Off button  .
2. Disconnect the electrode cable.

Adhesive electrodes

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





2. Discard the disposable pads immediately after use to prevent their reuse (hospital waste).
3. Clean the device and ECG cables as described in section 6.5 Cleaning.

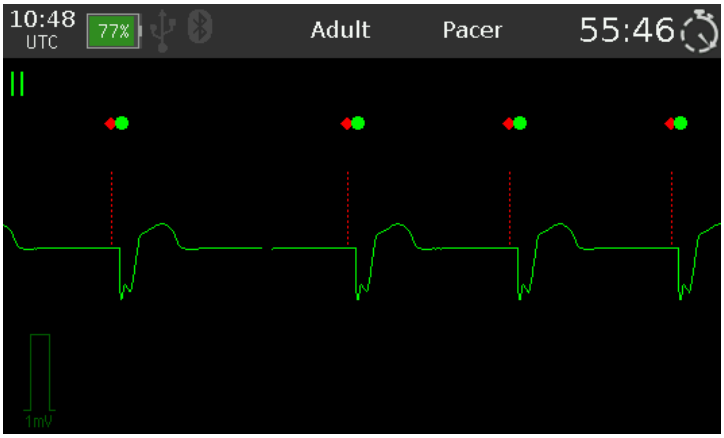
3.4 Pacemaker Function

- The Tempus LS pacemaker is the module for external transcutaneous stimulation of the heart.
- The pacemaker offers two modes of operation, demand and fixed-rate pacing. In demand and fix mode, the pacemaker requires an ECG signal for synchronization.
- The same, large adhesive electrodes used for defibrillation are also employed for pacing. They ensure good electrical contact with the skin. These electrodes and a 20 ms square-wave pulse reduce painful muscle contractions provoked by excessive current density.
- Pacer rate, pulse width and current are checked when the device is turned on and during operation; therefore, a functional test of the pacemaker module is not necessary.
- Filter setting during Pacer view:
  - HP filter: 0.3 Hz
  - LP filter: 40 Hz
- Detected pacemaker pulses (internal or external) are displayed as red, vertical dotted lines. (see screen 3.4.1.1 Fixed-rate mode (Fix) and 3.4.1.2 Demand mode)

3.4.1 Modes

3.4.1.1 Fixed-rate mode (Fix)

In this operating mode, the module delivers pacing impulses with the user-defined current at a user-defined rate. The selected rate remains constant and is not affected by intrinsic actions of the patient's heart. This mode is mainly used in the case of asystole. With the ECG signal from the ECG patient cable the result of the pacing can be monitored.Following an example of a paced ECG signal in fix mode:



Overdrive option

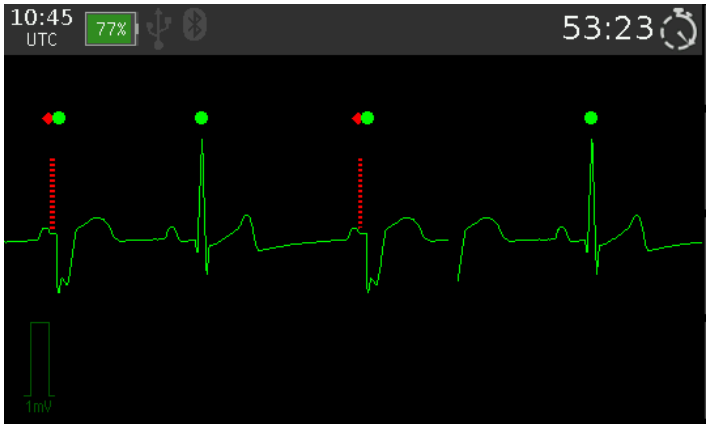
In the fixed-rate mode 'overdrive' option, the pacer will operate at three times the selected rate.

This option should be selected to correct conditions of tachycardia. The heart is stimulated with a rate that is above the intrinsic heart rate. At the end of the intervention, the heart rate should return to a normal rhythm.

3.4.1.2 Demand mode

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

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



3.4.2 Safety notes

WARNING

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

▲ Disturbed ECG trigger signal! Signal noise may disturb the ECG signal and cause artefact's. This must be considered chiefly in the demand pacing. For this reason, the following should be observed:

- Do not touch the device during pacing to prevent electrostatic noise
- Keep the patient cable away from power cords, transformers etc.

▲ To achieve adequate ECG signal quality for reliable triggering, ensure that

- the ECG signal is free of artifact
- there are no major fluctuations in amplitude
- the displayed trigger pulses are positioned above the QRS.

CAUTION

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

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

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

3.4.3 Guidelines for the Application of External Pacemakers

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

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

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

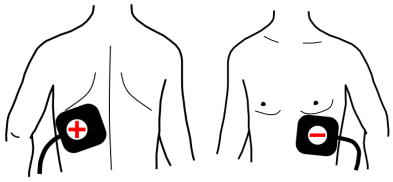
CAUTION

- ▲ Pacemakers must only be used under the supervision of trained, qualified and authorized staff.
- ▲ Observe the user guide for the pacemaker's operation.
- ▲ The patient must not be left unattended during pacing.
- ▲ It is assumed that the patient's ECG is being monitored to be able to assess the effect of pacing.
- ▲ When positioning the patient, take care that no electrically conductive connections exist between the patient and earthed metal parts (puddles of water, for instance, are capable of conducting the electrical current). Although the pacer current output is required to be floating, this is an additional safety precaution to ensure that the pacemaker current pulse flows only between the pacemaker electrodes.
- ▲ Set all values for the pacemaker to position 0, or the lowest value.
- ▲ Position stationary pacemakers close to the patient.
- ▲ After each defibrillation, check that the pacemaker is functioning properly.

3.4.3.1 Attaching the pacer pads

- The same adhesive electrodes used for defibrillation are also employed for pacing.
- The electrodes are designed for:
  - 1 hour of pacing using 140mA / 120 bpm, (pulse duration 20ms)
  - 8 hours of pacing using 70mA / 60 bpm, (pulse duration 20ms) with inspection of pads every 30 minutes
  - A detailed application of electrodes is given in section 3.1.6.1 Applying the adult and pediatric electrodes.

Anterior-posterior placement



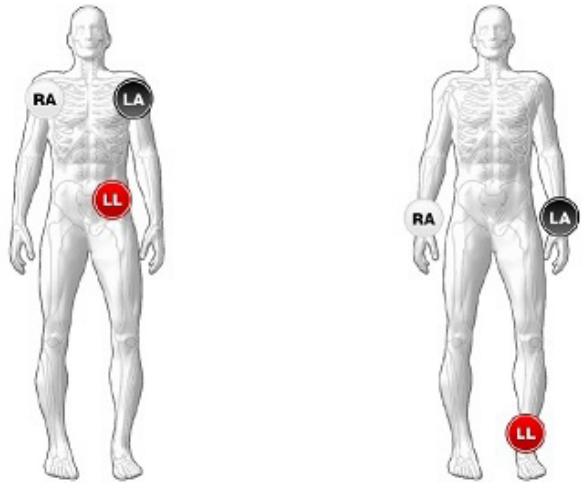
1. Apply the dorsal electrode **(+)** to the left scapular area and the precordial electrode **(-)** near the left lower sternal edge.
2. Connect the pads to the device.
3. If the dorsal electrode cannot be used, apply anterior-anterior placement.

Anterior-anterior placement

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

3.4.4 3 lead ECG setup for Pacemaker

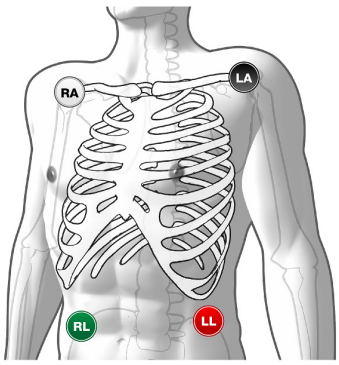
➜ Attach the electrodes to the patient using AAMI or IEC cables.



Position of electrode	AAMI	IEC
Right mid-clavicular line under clavicle or right wrist	RA White	R Red
Left mid-clavicular line under clavicle or left wrist	LA Black	L Yellow
Left hip or left ankle	LL Red	F Green

3.4.5 4- or more lead ECG setup for Pacemaker

➜ Attach the electrodes to the patient using AAMI or IEC compliant cables.



Position of electrode	AAMI	IEC
Right mid-clavicular line under clavicle or right wrist	RA White	R Red
Left mid-clavicular line under clavicle or left wrist	LA Black	L Yellow
Left hip or left ankle	LL Red	F Green
Right hip or right ankle	RL Green	N Black

3.4.6 Start-up of the Pacemaker

WARNING

▲ **Shock hazard!**
Pacing is started immediately when the pacemaker current is increased from 0 mA.

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

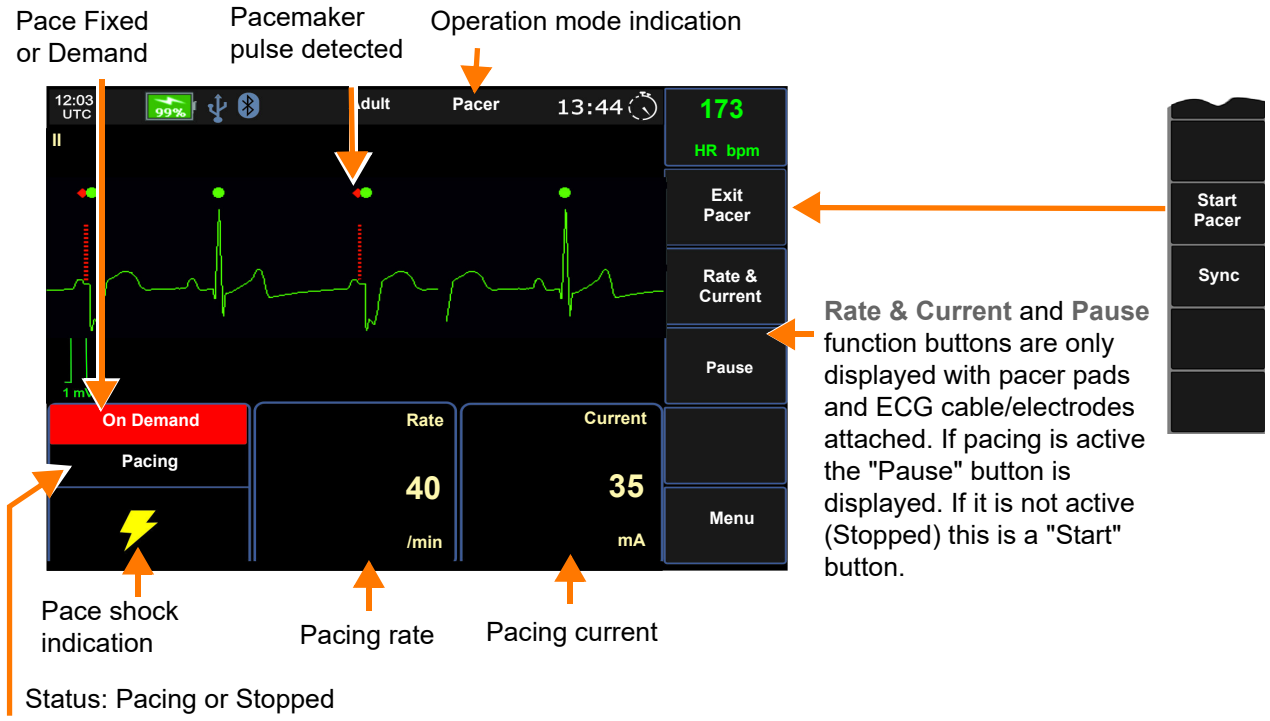
- Pads and ECG patient cable must be connected to the device.

➜ When the pacemaker is switched on, the current value is set to 0.

- The device can be switched from Defibrillation to pacing mode at any time.
- The device can be switched from pacing to Defibrillation mode at any time by **Exit Pacer** key. In this case, the pacemaker stops
- If the pacemaker operation is closed by pressing the **Exit Pacer** key, the frequency and current settings are saved.
- The function buttons **Rate & Current** and **Start/Pause** are only displayed with pacer pads and ECG cable / electrodes attached.

3.4.7 Home screen Pacemaker

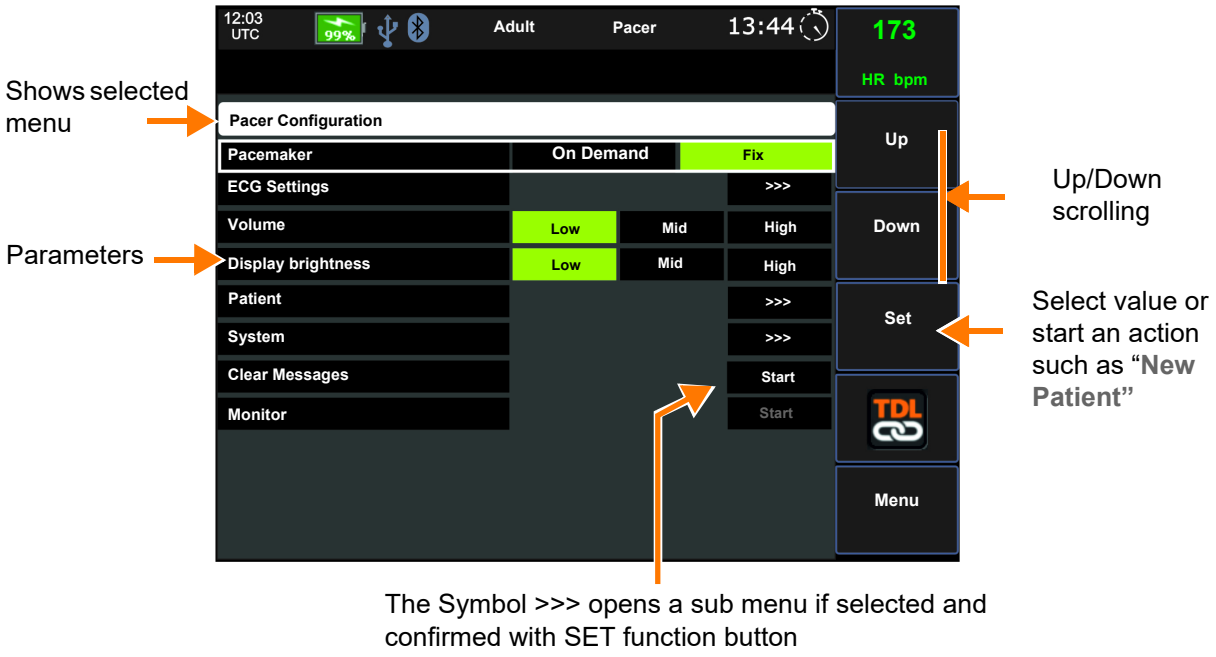
Select the function button **PACER** to display the pacemaker function.



The pacemaker default mode at switchover is “**FIXED**” mode; the “**ON DEMAND**” mode has to be selected manually in the Pacer Configuration menu. The default “**FIXED**” or “**ON DEMAND**” can be configured in the maintenance menu (see chapter 5.2.3).

Menu

The screen below shows the parameters available for **Pacemaker** mode.



Menu Structure

Mode	Parameter	Sub-Menu >>>Function
Pacer	Volume Display brightness	**ECG Settings>>>** **System>>>** **Patient >>>**

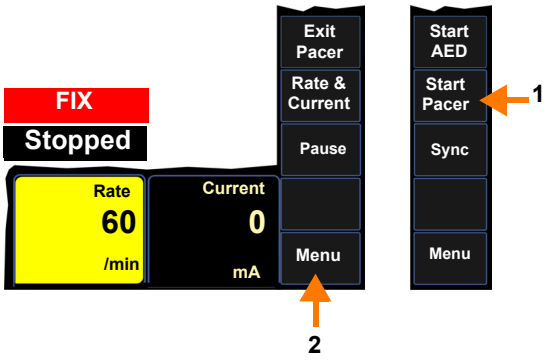
3.4.8 Initial operation pacemaker

PACER Mode

- The Select energy and Charge energy buttons are deactivated.
- Function button for **Rate & Current** setting are available with the pacer pads and ECG cable / electrodes attached.
- Function button **Exit Pacer** to return to MANUAL or AED mode, depending which mode Pacer was invoked from.

3.4.9 Selecting pacemaker mode Fix or Demand

1. Press the **Start Pacer** function button **(1)** to open the Pacemaker display.
2. Press the **Menu** function button **(2)** to open the Pacer configuration menu.
3. Select operational mode Fix or Demand.
4. Exit the menu with the **Back** function button.
5. The operational mode is displayed in the pacer red operating mode field.

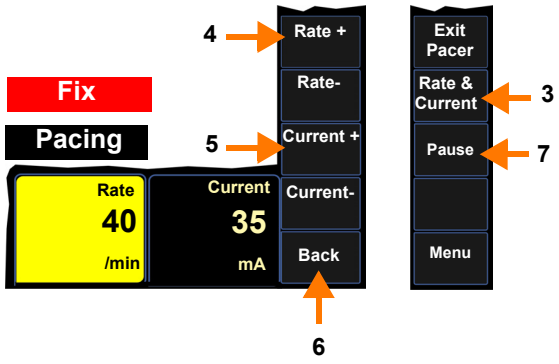


3.4.10 Pacemaker settings operational mode Fixed

3.4.10.1 Fixed mode without overdrive

The Rate + key is only displayed if the Pacer mode is FIXED and the function overdrive is NOT activated (see menu **System > Maintenance setting > Pacer setting > Overdrive enable > No**, page 99)

1. Attach the pacer pads (see page 70).
2. Attach ECG patient cable (see page 71).
3. Display pacemaker and select operational mode Fix.
4. Press the function button **Rate & Current (3).**
5. Select **Rate +- (4)** to set the impulse rate.



WARNING

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

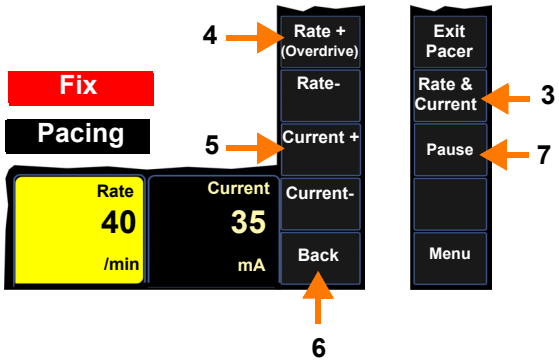
▲ Never touch the pads or the patient's body near the pads while the pacemaker is in use.

6. **Starting the pacemaker**
Press the **Current +** function button **(5)** to set the impulse current until the heart reacts to the stimulation.
7. Exit the setting with the **Back** function button **(6)**.
8. The pacemaker can be interrupted and restarted by selecting the **Pause** function button **(7).**
9. Finish the therapy as described in section 3.3.7 Finishing the therapy, page 66.

3.4.10.2 Fixed mode with overdrive

The **Rate + (Overdrive)** key is only displayed if the Pacer mode is FIX and the function overdrive is activated (see menu System>Maintenance setting>Pacer setting>Overdrive enable> Yes

1. Attach the pacer pads (see page 70).
2. Attach ECG patient cable (see page 71).
3. Display pacemaker and select operational mode Fix.
4. Press the function button **Rate & Current** **(3)** .
5. Select **Rate + (Overdrive)** **(4)** to set the impulse rate.



WARNING

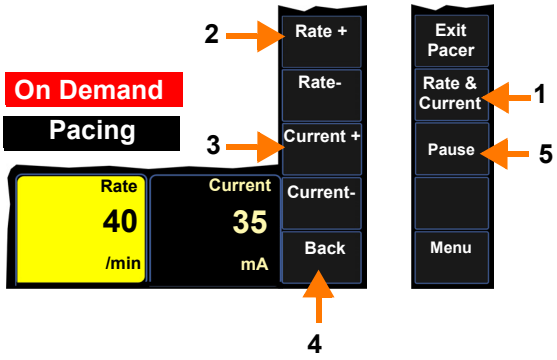
▲ **Shock hazard**
Pacing is started immediately when the pacemaker is switched ON and the current is set.

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

6. **Starting the pacemaker**
Press the **Current +** **(5)** to set the impulse current until the heart reacts to the stimulation.
7. **Press and hold** the **Rate + (Overdrive)** **(4)** key until the heart has reached the pacemaker's rate. With this function, the set rate is multiplied by the factor 3.
8. Release the **Rate + (Overdrive)** **(4)** key. The heart should continue to beat with a normal heart rate
9. Exit the setting with the **Back** function button **(6).**
10. The pacemaker can be interrupted and restarted by selecting the **Pause** function button **(7).**
11. Finish the therapy as described in section 3.3.7 Finishing the therapy.

3.4.11 Pacemaker settings operational mode Demand

1. Attach the pacer pads (see page 70).
2. Attach ECG patient cable (see page 71.
3. Display pacemaker and select operational mode Demand
4. Press the function button **Rate & Current** **(1).**
5. Select **Rate +-** **(2)** to set the impulse rate.



WARNING

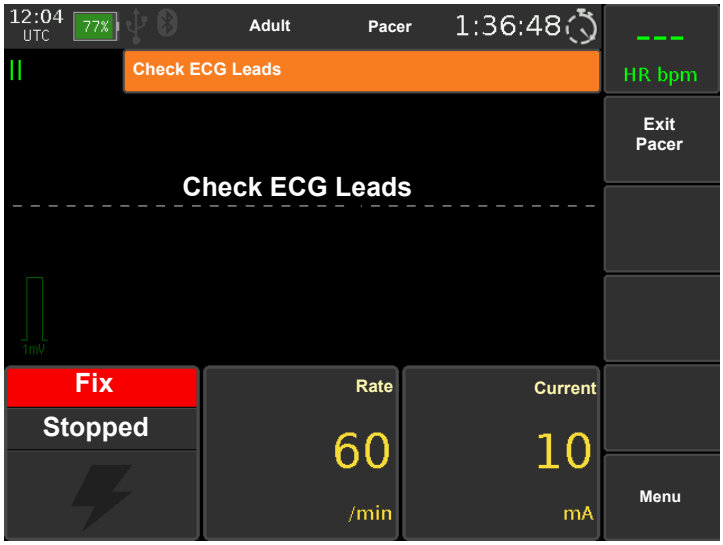
▲ **Shock hazard!**
Pacing is started immediately when the pacemaker is switched ON and the current is set.

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

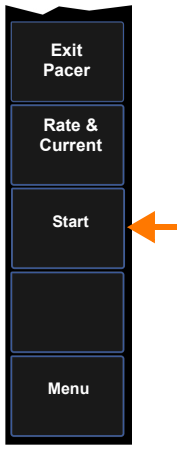
6. **Starting the pacemaker!**
Press the **(3)** **Current +** to set the impulse current until the heart reacts to the stimulation.
7. Exit the setting with the **Back** function button **(4).**
8. The pacemaker can be interrupted and restarted by selecting the **Pause** function button **(5).**
9. Finish the therapy as described in section 3.3.7 Finishing the therapy.

3.4.12 Pacing automatically stopped

In some cases the running pacer stops automatically. (see 2.8.2 Technical notification, Pacer). If this happens a technical notification is displayed and the Pacer function buttons disappears. To restart the pacer remedy the cause and press function button **Start.**



After remedy the cause for the automatic Pacer stop, the function buttons appears again.

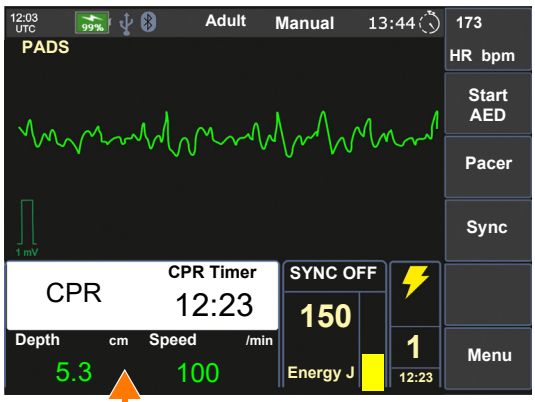


3.5 CPR feedback

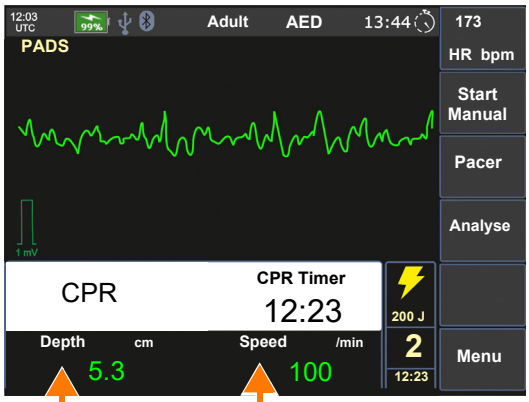
- The manual and AED defibrillation mode offers a function for a guided CPR with the ARGUS LifePoint sensor.
- Voice prompts can be activated or deactivated in the menu **System > Maintenance Settings >CPR feedback setting,** see 5.2.5 CPR Feedback Settings.
- **Important:** CPR feedback is only for adults and pediatric patients greater than 8 years old or 25 kg/55 lbs. If using pediatric electrodes or patient type is set to pediatric the CPR advices are not displayed.

3.5.1 LifePoint CPR feedback sensor

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

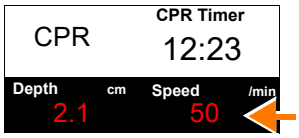


Advice to improve the CPR quality:

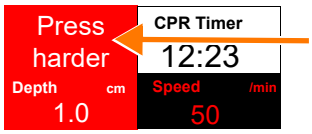


Measured values depth and speed of the compression. This is only displayed during CPR cycle.

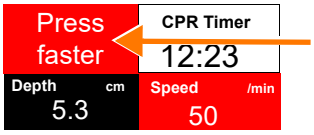
Display of CPR quality in Manual and AED mode:



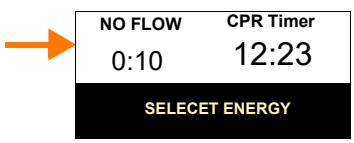
Values out of range are displayed red.



If value **“Depth”** stays out of range, advice to press harder/ softer is given.



If value **“Speed”** stays out of range, advice to press faster/ slower is given.



If CPR is stopped, **“NO FLOW”** and an up counting timer are displayed and advice is given:

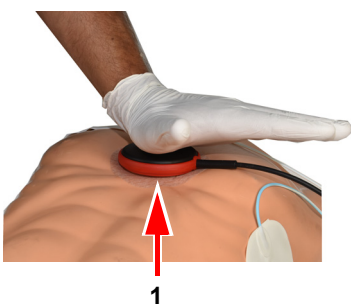
- “Select Energy” in manual mode
- “Perform CPR: 30 Chest compression then 2 rescue breaths” in AED mode.

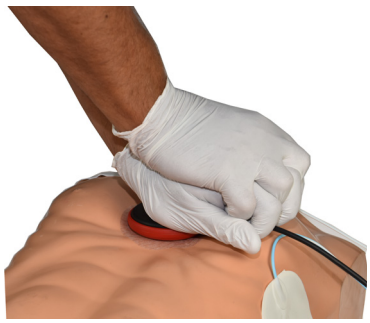
3.5.2 Setup of the ARGUS LifePoint sensor

- The range for the depth of compressions is 4.5 to 6.2 cm (1.77 to 2.36 inches) which is the range for adult patients. There is no recommended target depth for pediatric patients < 8 years or < 25 kg (55 lbs).
- The LifePoint is not suitable for use on children younger than 8 years or less than 25 kg (55 lbs) and is not available when patient type pediatric is selected.
- We recommend using an adhesive pad so that the sensor remains in position and does not lift off when relieved, which can lead to inaccurate measured values.
- The red side of the sensor must be attached to the adhesive pad.

1. Switch on the device.
2. Select manual or AED defibrillation. The CPR values in AED mode are first displayed during CPR advice.
3. Connect the LifePoint USB cable to the Tempus LS USB connector.
4. Place the adhesive pad on the lower third of the breastbone (= middle of the thorax) and remove the white foil.
5. Place the sensor with the red side on the adhesive pad.

6. Place your hand on the sensor so that the heel of your hand **(1)** is in the middle of the sensor.





7. Start with CPR and monitor the compression quality on the device and follow the instructions given by the device (see page before).

The following limits are set by default for speed and depth. These settings can be adjusted by the administrator (see 5.2.5 CPR Feedback Settings).

Compression rate per minute [/min]	Press faster	Press slower
100	≤ 90	≥120
Depth [cm]	**Press harder**	**Press softer**
0.1-12.7	≤ 4.5	≥ 6.0
Depth [inches]	**Press harder**	**Press softer**
0.04 to 5	≤ 1.77	≥ 2.36

Chapter 4
ECG Display

This chapter explains the basic principles of operation for continuously attended ECG signal display with the 3 or 4 wire patient cable. Also ETCO2 can be displayed from the Tempus Pro via Bluetooth connection.

4.1 ECG and heart rate display

WARNING

▲ No alarms are produced for heart rate or arrhythmias or asystole, but VF/VT warning messages are displayed when the defibrillator pads are connected. Therefore keep the patient under continuous observation.

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

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

Important

- The guidelines for patient electrode placement are provided as an overview only. They are not a substitute for medical expertise.
- If an electrode is faulty or has come off, the ECG waveform is displayed as a dotted line, an audible alarm is issued and message “Check ECG Electrodes” is displayed.

If VF/VT rhythms are detected during ECG monitoring, the message “ECG VF/VT” is displayed and an audio signal is given. In this case select immediately the **“Manual”** function button to exit ECG monitoring and starting the defibrillation.
Depending on the Monitor setting, the device automatically switches to defibrillation mode in case of detection of VT/VF rhythm or attached defib pads. See settings in the menu **System > Maintenance Settings > System Settings > Service Setting > Monitor Settings > Auto leave monitor when (** see page 102). Settings are:

- Pads attached (default setting)
- VF/VT detected
- Never

- Used filter setting during ECG display:
  - HP filter: CPS 0.5 Hz (ST diagnostic)
  - LP filter: MMF 40 Hz

4.1.1 ECG signal with a pacemaker patient

DANGER

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

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

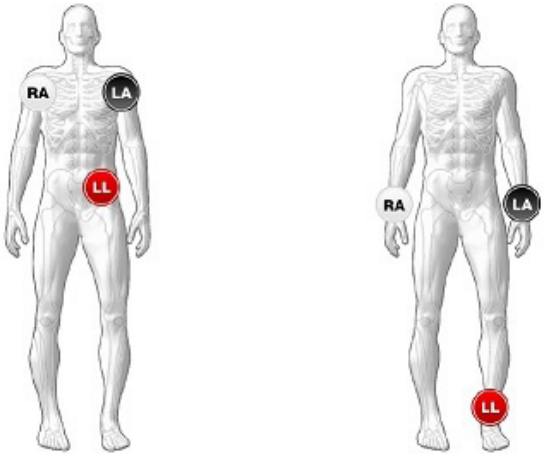
Pacer pulses are represented by a red rhombus above the top ECG curve, randomly, some pacer pulses could be missing on the display.

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

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

4.1.2 ECG signal display with 3 leads (3 wires)

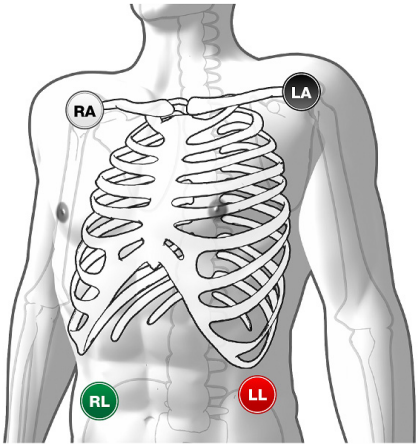
➜ Attach the electrodes to the patient using AAMI or IEC cables.



Position of electrode	AAMI	IEC
Right mid-clavicular line under clavicle or right wrist	RA White	R Red
Left mid-clavicular line under clavicle or left wrist	LA Black	L Yellow
Left hip or left ankle	LL Red	F Green

4.1.3 ECG display with 6 leads (4 wires)

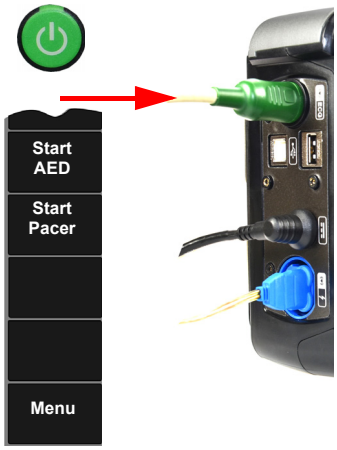
➜ Attach the electrodes to the patient using AAMI or IEC compliant cables.



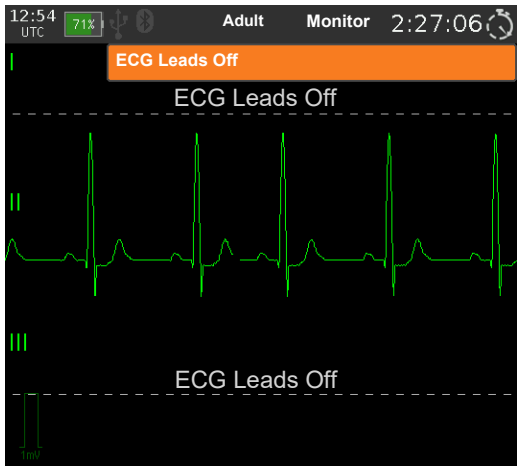
Position of electrode	AAMI	IEC
Right mid-clavicular line under clavicle or right wrist	RA White	R Red
Left mid-clavicular line under clavicle or left wrist	LA Black	L Yellow
Left hip or left ankle	LL Red	F Green
Right hip or right ankle	RL Green	N Black

4.1.4 Start ECG signal display

1. Apply the electrodes as shown in 4.1.2 ECG signal display with 3 leads (3 wires) or 4.1.3 ECG display with 6 leads (4 wires).
2. Connect the patient cable to the ECG signal input.
3. Press the Menu function button and select with button “Up” parameter “Monitor mode” and start the monitoring with the function button “Set”.
4. Press button “Lead Select” to display leads aVR, aVL and aVF.



ECG display



Electrode OFF detection

If an electrode is displaced or an electrode resistance is too high, an audible alarm is issued and message “ECG Leads Off” is displayed.

VF or VT detection

If VF or VT is detected, an audible alarm is issued and message "ECG VF/VT Detected” is displayed.

4.2 ETCO2 monitoring

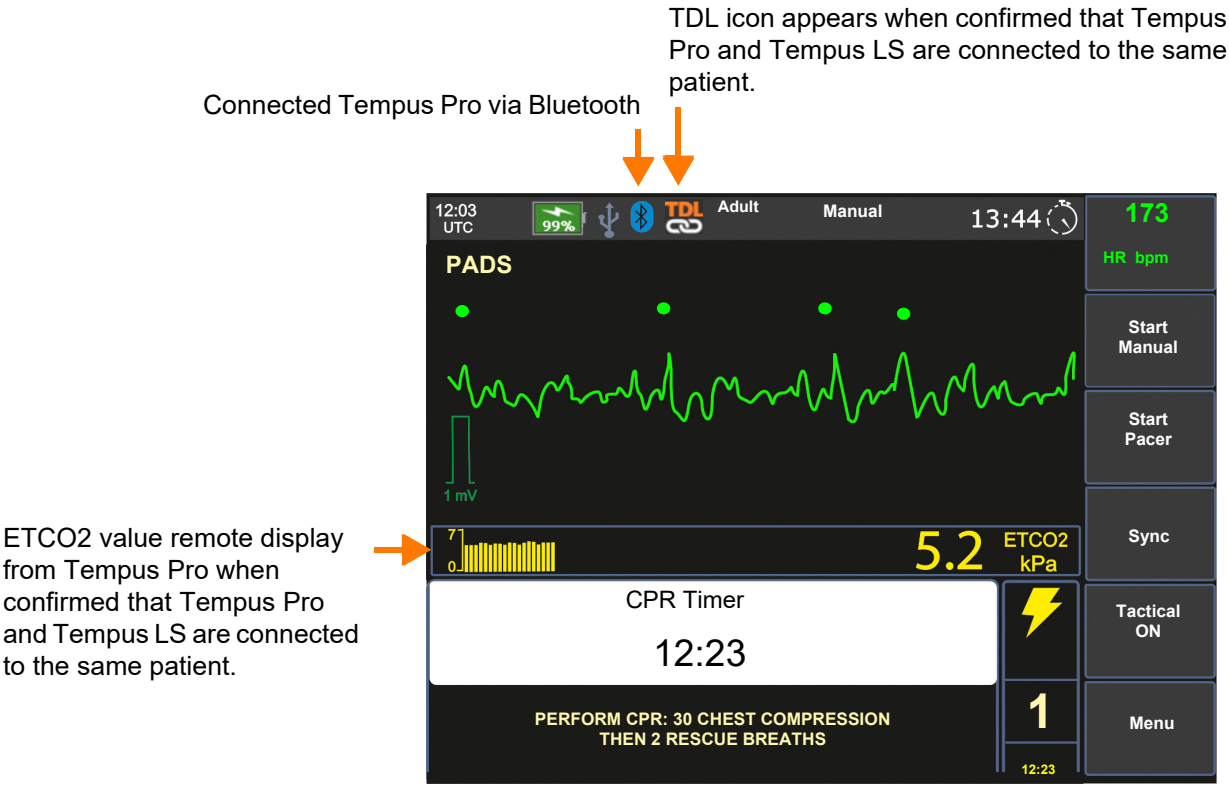
WARNING

▲ This ETCO2 monitoring feature does not comply with the IEC 60601-1-8. There is **no alarming** for critical ETCO2 values. Therefore keep the patient under continuous observation.

Note

- This feature allows the Tempus LS to monitor the ETCO2 value during intervention. This is only a remote display from the Tempus Pro connected ETCO2 sensor.
- The ETCO2 graph is updated every 10 seconds. The graph covers 15 minutes in total.
- The displayed units will be in kPa or mmHg depending on the received values from the Tempus Pro
- Consult the Tempus Pro user guide for safety notes and other information about the ETCO2 sensor.
- There are no settings for this sensor in the Tempus LS.
- To use this feature you will need to set up a TDL link with the Tempus Pro monitor - see 2.10 Using Tempus Pro with Tempus LS (optional).

4.2.1 ETCO2 display during defibrillation



Chapter 5
System settings

This chapter explains the system settings and gives an overview of all parameters.

5.1 Overview settings

5.1.1 Overview settings in the operating modes

The table below show the general settings for the user during operation. Each operating mode (Manual Defi, AED, Monitoring) has its own setup configuration

Mode	**Menu >>>**/Parameter	**Function**/see details
Manual	• Metronome	see page 92
	• Metronome Ratio	
	• Sync mode	
	• **ECG Settings >>>**	see page 93
	• Volume	see page 92
	• Display Brightness	
	• **Patient >>>**	see 5.2
	• **System >>>**	see page 95
	• **Do Self test**	**Start**
	• **Clear messages**	**Start**
	• **Monitor**	**Start (see next page)**
AED	• Volume	see page 93
	• Display Brightness	
	• **Patient >>>**	see 5.2
	• **System >>>**	see page 95
	• **Clear messages**	**Start**
	• **Monitor**	**Start (see next page)**
Pacer	• Pacer mode	see page 93
	• **ECG Settings >>>**	
	• Volume	
	• Display Brightness	
	• **Patient >>>**	see 5.2
	• **System >>>**	see page 95
	• **Clear messages**	**Start**
	• **Monitor**	**Start (see next page)**

Mode	Menu >>>/Parameter	Function/see details
Monitor	• **ECG Settings >>>**	see page 93
	• Volume	
	• Display brightness	
	• **Patient >>>**	see 5.1.6
	• **System >>>**	see page 95
	• **Clear messages**	**Start**

5.1.2 User settings manual mode

User settings are automatic stored.

Default values are **bold.**

Menu>>>/Parameter	**Value**	**Description**
Metronome	• On/**Off**	Switching the metronome On/Off
Metronome ratio	• **30:2** • 15:2 • Cont	• 30:2 for adult • 15:2 for children • Without rescue breath choose Continuous
Sync mode	• On/**Off** • Auto/**Off**	Switching Sync mode to On/Off or Auto. Auto/Off is displayed when parameter “Auto Sync Enable” in the menu System/Maintenance Setting/ Manual Setting is set to Yes.
ECG Settings >>>	>>>	see page 93
Volume	**Low**/Mid/High	Select the volume above the environmental noise (50, 60 or 70 dB)
Display Brightness	**Low**/Mid/High	--
Patient >>>	**>>>**	see page 94
System >>>	>>>	see page 95
Do self test	Start	Start all self test
Clear messages	Start	Clears messages displayed in the status line
Monitor	Start	Starts monitoring mode

5.1.3 User settings AED mode

User settings are automatically stored.

Default values are **bold.**

Parameter	Value	Description
Volume	**Low**/Mid/High	Select the volume above the environmental noise
Display brightness	**Low**/Mid/High	---
Patient	**>>>**	see 5.1.6
Clear message	Start	Clears messages displayed in the status line
Monitor	Start	Starts monitoring mode

5.1.4 User settings Pacer

User settings are automatically stored.

Default values are **bold.**

Menu>>>/Parameter	Value	Description
Pacemaker mode	• On Demand • Fix	Selecting Fix or demand mode see 3.4.7.
ECG Setting	**>>>**	see 5.1.5
Volume	**Low**/Mid/High	Select the volume above the environmental noise (50, 60 or 70 dB)
Display brightness	**Low**/Mid/High	---
Patient	**>>>**	see 5.1.6
System >>>	>>>	see page 95
Clear message	Start	Clears messages displayed in the status line
Monitor	Start	Starts monitoring mode

5.1.5 User ECG Settings

Parameter	Value	Description
ECG amplitude (mm/mV)	5/**10**/20 mm/mV	--
ECG wave speed (mm/s)	12.5/**25**/50 mm/s	--

5.1.6 User Patient Settings

Parameter	Value	Description
Patient Type	**Adult/** Pediatric	This is used to override the energy setting adult when using Adult defibrillation electrodes with children. The energy will be set to pediatric default energy in AED and Manual mode. In Manual mode the max. selectable energy is 100 joules.
New Patient	Start	see page 33

5.2 System, maintenance and service settings

All System, maintenance and service settings are in the Sub-menu System.

The maintenance setting menu is passkey protected. Changes in the maintenance menu must be stored, see **“System > Maintenance Settings> Default Settings Storage >>> Store Defaults”**

Menu System >>>	Parameter/**Sub-Menu >>>**	**Sub-Sub Menu >>>**/ Parameter	**Description**
System >>>	Tactical Mode	• ON/**OFF**	Switching the tactical mode ON/OFF when menu button “Tactical ON/OFF” is not displayed on the main menu. (This parameter ins only displayed when parameter “Tactical Mode Switch” is “Yes”, see page 101)
	Switch USB port	• Device/Auto	Device USB
	Intervention Management >>>	**Selective Export/Removal >>>** • Export all unexported • Export all • Remove all exported • Remove all • Free Storage	Select for export/Select for removal. Select “Start” to Export-/Removal selected files. • Showing storage capacity in %
	Device info >>>	• S/N • SW Version • HW Version • SW Version Defi • HW Version Defi ***Default setting info >>>*** • Address • UFN ***Battery Info >>>***	• Series number • Software version • Hardware version Defi • Software version Defi • Hardware version Defi • Display of the used default settings file with file name version and description • MAC Address • User Friendly name (TempusLS + Serial Number) • Various information: Battery version, Full and Actual capacity, voltage, current, safety state, cycle count, temperature, UPS battery state

continuous next page

Menu System >>>	**Sub-Menu**/ Parameter	**Sub-Sub Menu >>>**/Parameter	**Description**
SW Version Defi System >>>	***Device info >>>***	• Guidelines	-
	Maintenance Settings >>>	***This menu is only accessible with the passkey***	Enter the 4 digit passkey
		Organization identification >>>	Add here the information to assign the device to an organization /user
		Mains Filter	OFF/50 Hz/ 60 Hz
		AED Settings >>>	See detail 5.2.1 AED Settings
		MANUAL Settings >>>	See detail 5.2.2 Manual Settings
		Pacer Settings >>>	See detail 5.2.3 Pacer Settings
		Metronome Settings	See detail 5.2.4 Metronome Settings
		CPR Feedback Setting >>>	See detail 5.2.5 CPR Feedback Settings
		Print/Event settings >>>	See detail 5.2.6 Print/Event Settings
		System Settings >>>	See detail 5.2.7 System Settings
		Default Settings Storage >>>	See detail 5.2.8 Default settings storage
		Log file export >>>	See detail 5.2.9 Log file export

5.2.1 AED Settings

Menu **System > Maintenance Settings >AED setting.**

Default values are bold

Menu>>>/Parameter	**Parameter**	**Value**	**Description**
AED Energies >>>	• Energy adult 1. shock • Energy adult 2. shock • Energy adult 3. shock • Energy pediatric 1. shock • Energy pediatric 2. shock • Energy pediatric 3. shock	• **150 joules** • **150 joules** • **150 joules** • **50 joules** • **50 joules** • **50 joules**	These are configurable based on local guidelines.
AED Key in MANUAL		• **Yes**/No	If yes the AED appears in manual defibrillation mode
Analyse Key		• **Yes**/No	Display of the analyze key
CPR Timer Counting		• **Up**/down	Timer display during CPR phase starts counting up from zero to 2 minutes or from 2 minutes down to zero
Start Metronome Default		• **On**/Off	--
Voice Prompts on		• **Yes**/No	--

5.2.2 Manual Settings

Menu **System > Maintenance Settings >Manual setting**

WARNING

▲ The setting **Auto Sync Enabled** and **SYNC ON after shock** must be communicated to the user.

Parameter	Value	Description
Default Energy Adult	• **150** joules	Preset of defibrillation energy when starting device with adult electrodes connected.
Default Energy Pediatric	• **50** joules	Preset of defibrillation energy when starting device with pediatric electrodes connected.
Auto Sync Enabled	• Yes/**No**	If set to “Yes” Synchronized mode will be activated as soon a QRS trigger is detected. See 3.2.2 Setup switching from unsynchronized to synchronized mode
Sync soft-key	• Yes/**No**	If set to ”Yes” the user can switch between synchronized/direct defibrillation If “No” is selected the Sync mode can be activated only via the manual configuration menu.
SYNC ON After Shock	• Yes/**No**	If set to “No” the Sync mode is set to Off (direct defibrillation) after a shock has be released in synchronized mode. Note, this function is only true if Auto Sync Enable is set to “No”
Start Metronome Default	• On/**Off**/CPR	If set to “On” the metronome is started as soon Manual mode is ready. If set to “CPR” the metronome is started as soon CPR feedback sensor is connected.
Metronome Ratio Default	• **30:2**/15:2/Cont	• **30:2 for adult** • 15:2 for children • Without rescue breath choose Continuous
Secure MANUAL Start	• **None**/Dialog/Pass Key	Following dialogs appears when: Dialog = “Do you want to start MANUAL defibrillation” appears. Confirmation with Yes or No is needed. Pass Key = Enter the pass key to start the manual mode.
Manual mode Pass key	• 3211	Entering a pass key for the manual mode.

5.2.3 Pacer Settings

Menu **System > Maintenance Settings >Pacer settings**

Parameter	Value	Description
Pacer Enabled	**Yes**/No	Enabling pacer function
Default Pacer Mode	On Demand/**Fix**	Selecting preferred Pacer mode
Overdrive Enable	Yes/**No**	Activating overdrive function, function button “Rate+” will be labeled with the function “Overdrive”.
Default Pacer Rate	**60** p/m	Selecting of the default pacer rate at start. 40/50/**60/**70/80...180 pulse/minute
Pacer Key in AED	Yes/**No**	Pacer key will be displayed in AED when Yes is selected. Default = No.
Pacer Key in Manual	**Yes**/No	Pacer key will be displayed in Manual Defibrillation when Yes is selected. Default = Yes

5.2.4 Metronome Settings

Menu **System > Maintenance Settings >Metronome settings**

Parameter	Value	Description
Metronome Rate	**100**	Setting of the desired metronome rate

5.2.5 CPR Feedback Settings

Menu **System > Maintenance Settings >CPR feedback setting**

Parameter	Value	Description
Rate Limit Upper (cpm)	120	The CPR rate limits can be adjusted between 80 and 120 cpm, see section 3.5.
Rate Limit Lower (cpm)	90	
Depth Limit Upper (mm/inches)	60 (2.36 in)	see section 3.5
Depth Limit Lower (mm/inches)	45 (1.77 in)	
Feedback Delay (sec)	15	Delay time till a new feedback is displayed
Voice prompts on AED	**Yes**/No	Following voice prompts are given: Press harder Press softer Press faster Press slower Recoil (dependent on selected country, not for DE/FR/UK/USA)
Voice prompts on MANUAL	Yes/**No**	see above
Average Rate Max cpr	5	Number of measurements to calculate the average compression rate.
Enable Recoil	Yes/**No**	Displaying of the recoil value (dependent on selected country, not for DE/FR/UK/USA)

cpm = compressions per minute

5.2.6 Print/Event Settings

Menu **System > Maintenance Settings > Printer/Event settings**

Parameter	Value	Description
Print on SHOCK	Yes/**No**	-
Print on NO SHOCK Advised	Yes/**No**	-
Print on Start Pacing	Yes/**No**	-

5.2.7 System Settings

Menu **System > Maintenance Settings > System Settings**

Menu	Sub-menu >>>/Parameter	Value/Description
	QRS marker default	Yes/no
Ready to use Settings>>>	• Ready-To-Use • Interval For Test • Do Self Tests • Do Relay Test • Do IGBT Test • Do Battery Test • Capacitor Test	• **On**/OFF • **Daily**/Weekly/Monthly • Start of all tests • Start of individual test
Default System Settings>>>	Start up View	AED/**Manual**
	Default Display Brightness	**Low**/Mid/High
	Default Volume	**Low**/Mid/High (50, 60 or 70 dB)
	Default ECG Amplitude (mm/mV)	5/**10**/20 mm/mV
	Default ECG Speed (mm/s)	12.5/**25**/50 mm/s
	Auto Switch Off	15/**30** min. or never
	Units Settings	“metric” or “inches” **°C** or °F
Tactical Mode Settings>>>	• Tactical Mode Switch • NVG Brightness Control • Audio Control • Wireless Control	If “Yes” the Tactical ON/OFF switch appears in Defibrillation and monitoring mode. If “No” the Tact mode can be programmed with Menu System> Tact mode> ON/OFF (see page 32) The night vision google brightness dimming incl. LED OFF, Audio OFF and Wireless module off can be selected with Yes or No.
Communication Setting >>>	• Wireless Communication • Wired Communication • Switch USB port	Switching On/Off of the wireless and wired communication USB port auto: • selects automatic the docking or the device USB port USB port device: • the USB port on the connection panel is active.

Menu	Sub-menu >>>/Parameter	Value/Description
Language	Language selection table	Use button Next/Prev/Set to select and program the desired language.
Country	Country selection table	Use button Next/Prev/Set to select and program the desired country.
Date, Time, Timezone>>>	Time format	12h/ 24h
	Time hour/minutes	Set time
	Date day/ month, year	Set date
	Timezone >>>	Set time zones
Software Installation>>>	Install Firmware and bootloader data. Sub menu **SW version >>>** shows installed software versions	Start
Maintenance Passkey>>>	---	Definition of the maintenance pass key
Service Settings>>	Log File reset	Deleting the log file
	AED Service Setting >>>	Start With analysis Yes/No CPR Time 1, **2** or 3 minutes
	Monitor settings >>>	Auto leave monitor when: - **Pads attached** - VF/VT detected - Never
	Metronome Settings	Breath Time 1, **2** or 3 seconds
	Power report >>>	Information about the battery and power source
	Initial settings	On/**Off.** If on a initial setting screen appears during the first start up.
	License Settings >>>	Activating or deactivating modes and sensors: Mode pacer Mode AED Mode Monitoring Cardioversion EtCO2
	ECG Cable Info	Cable info of the attached ECG cable
	Impedance	Measured impedance of the defibrillation pads
	Last System Event	--

5.2.8 Default settings storage

Menu **System > Maintenance Settings >Default settings Storage**

To activate the changes and stored default setting, cycle power off and on.

CAUTION

In order to guarantee the Cyber security of the **Tempus LS**, RDT recommends the following:

- ▲ Installing the latest antivirus/firewall programs on the host in order to prevent malware on the USB stick from affecting the **Tempus LS**.
- ▲ Regularly installing security updates on the host.

Parameter	Value	Description
• Store defaults	Start	Any change in the maintenance menu must be stored with this function. A reminder message in the message bar appears “Defaults setting changed but not saved”. To activate the stored default setting cycle power off and on.
• Restore defaults	Start	Restores the default setting
• Restore factory defaults	Start	Restores the factory defaults and activates the initial setting screen appears during the first start up and the RTU display is set to off. (see "Initial settings" on page 29)
• Export settings	Start	Connect a USB memory stick to the device. Press start. The progress is displayed in the message bar.
• Import settings	Start	Copy the file into the following directory of the USB memory stick: TempusLS/Settings. Connect the USB memory stick to the device. Press start. The progress is displayed in the message bar. To activated the new defaults cycle power off and on.

5.2.9 Log file export

Menu **System > Maintenance Settings >Log file export**

Export of log files to a USB memory stick may take very long depending of the size of the log file. Therefore, a number of selections are available.

Parameter	Value	Description
• Short	Start	Export of a log file generated within the last 30 seconds. Depending of the number of log files the time frame of exported files can be various.
• Last 12 hours	Start	Export 12 hours log files
• Last 24 hours	Start	Export 24 hours log files
• Complete	Start	Export all available log files

Chapter 6
Daily checks and Maintenance

This chapter covers day-to-day maintenance and cleaning of the **Tempus LS**. There is little maintenance which the user is expected to perform, as most must be carried out by an RDT trained engineer.

6.1 Daily checks and Maintenance interval

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

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

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

6.1.1 Maintenance interval table

Interval	Maintenance	Responsible
Before or after each use, respectively	***Life-saving functions - check the following:*** • Visual inspection of the device and accessories (see section 6.2.1) • Switch on the device and make sure that batteries are sufficiently charged (see section 6.2.3). ***After every intervention*** • Visual inspection of the device and accessories (see section 6.2.1) • Battery check (see section 6.2.3) • Button test (see sections 6.2.4)	User
Daily	• Visual inspection of the device and accessories (see section 6.2.1) • Each day, before turning on the device, check the Ready-to-Use indicator light (see section 2.7.1). If necessary (no indicator light), manually run the self-test (see section 6.2.2) • ECG signal test (see section 6.2.6) • Alarm test (see section 6.2.7)	User or User's organization
Every 12 months	– Measuring and safety checks and inspections according to the instructions in the maintenance manual – Defibrillator function check	Service staff authorized by RDT

Interval	Maintenance	Responsible
Limited life item replacement	***The following parts must be checked and replaced if necessary*** • Replace the power battery, see section 6.3.1 • Replace the hot swap battery • Replace the internal button cell (every 10 years) • Replace the defibrillation capacitor (if the released energy deviates more than 15 % from the intended value)	Service staff authorised by RDT
Wear parts	• Handle replacement 6.4.1 • Battery cover and handle see section 6.4.2 • Dust covers see section 6.4.3 • Rear clip see section 6.4.4	User

6.1.2 Service/Shelf life

Device

- The device has a service life of 10 years.
- Power battery (approx. 5 years)
- Hot swap battery (approx. 4 years)
- Button cell (approx. 10 years)

Accessories shelf life

- Electrodes pads (approx. 3 years), see expiry date on the pouch.
- CPR feedback sensor securing pads (approx. 2 years), see expiry date on the product labeling.

6.2 Functional test

A detailed description of the maintenance steps is listed in table 6.1.1. Enter the results in the check list in the section 6.6.

6.2.1 Visual inspection of the device and accessories

Check the device and accessories for the following:

- Sufficient number of all required disposables available?
- Check handles, battery cover, dust cover, connectors and keypad for wear.
- Device housing undamaged?
- Electrode connection undamaged?
- Defibrillator / pacemaker pads available?
- Check the expiration date on the electrode package.

WARNING

▲ Defective units or damaged cables and damaged or expired accessories must be replaced immediately.

6.2.2 Self tests

The device has an integrated self-test. During this test the relay, battery and defibrillation capacitor are tested.
These tests can be executed in the menu **Manual configuration/Do Self -Tests.**

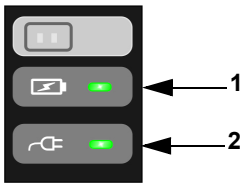
The results are displayed in the message area. Following tests are executed:

- Relay test
- IGBT test
- Battery test
- Capacitor test
- Remedy of failed test see "General errors & troubleshooting" on page 125

These tests correspond to the same tests that are performed during the RTU test. When the unit is switched off after a failed test, the RTU LED status is reactivated see "Ready to use LED" on page 38.

6.2.3 Battery check

1. Connect the unit to the power supply and switch it on. The start screen is displayed.
2. The external DC voltage indicator **(2)** is lit.



   – When the battery indicator LED **(1)** lights green, the battery is being fast charged. Check the charging status once the indicator goes off.

   – The battery indicator LED **(1)** is **off** when the battery is not being fast charged.

3. Check the top left corner of the display for the battery charge status.

4. If the charge is 10% or lower, change the battery, see page 36.
5. Spare battery check see page 36.

6.2.4 Defibrillator key test

Shock release via the electrode connector is done by means of the simulator.

1. Switch on the device. If the device starts in AED mode press the **Start Manual** button.
2. Connect the simulator to the electrode connector.
3. Use the  button to set the energy to 2 joule; then use the  button to set the energy to 4 joule.
4. Press the  button. Device is charging. Shock key is lit.
5. Press the  button - to release into the simulator.
6. Press the **Start AED** button - spoken instructions are issued.
7. Switch the device off.

If the device does not behave as described in this user guide, contact RDT.

6.2.5 Defibrillation test

- Use a simulator that displays the received energy level.
- Shock release via the electrode connector is done by means of the simulator.
- The value in Joule stated next to the LED indicator corresponds roughly to the energy emitted by the device; however, the DSD simulator must not be used to perform measurement checks.

1. Switch on the device. If the device starts in AED mode press the **Start Manual** button.
2. Connect the simulator to the electrode connector.
3. Select the required energy (150 J) with the  button.
4. Initiate the energy charging by pressing **"Charge"**  button.

DANGER

▲ **Danger of electric shock!**

- Make sure that the connection cable between the DSD simulator and the defib pads connector of the Tempus LS is fitted correctly

5. As soon the shock button lights up, release the shock with  button on the device.
6. Check that the 150 J LED on the simulator is lit.
7. Switch the device off.

If the device does not behave as described in this user guide, contact RDT.

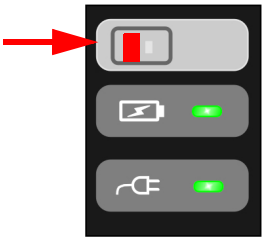
6.2.6 ECG display test

This test is performed on a volunteer or with a ECG simulator

1. Apply the electrodes as shown in 4.1.2 ECG signal display with 3 leads (3 wires) or 4.1.3 ECG display with 6 leads (4 wires) or use a ECG simulator.
2. Connect the patient cable to the ECG signal input.
3. Press the Menu function button and select with button “Up” parameter “Monitor mode” and start the monitoring with the function button “Set”.
4. Check the ECG signal by pressing button “Lead Select” to display all leads aVR, aVL and aVF.
5. Remove one lead and check that the audible notification is issued and message “ECG Leads Off” is displayed.

6.2.7 Alarm test

1. Switch the device on.
2. Unlock the battery.
3. High priority alarm “Battery not inserted” appears.
4. Audible alarm is issued with the set volume low, mid or high.
5. Visual alarm LED blinks.



6.3 Maintenance interval of the batteries

Important

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

Power Battery

- The rechargeable power battery is maintenance-free during its normal life.
- The battery must be replaced approx. every 5 years (see manufacturing date on the battery), regardless of whether or not the unit has been used.
- If device is not used, recharge battery (incl. spare battery) every 6 months.
- Recommendation: Store the battery with a state of charge between 50-70%.
- Check battery contacts for corrosion.
- Make sure that not used batteries are stored in a protective case, to prevent short circuit with conductive parts and the battery contacts.

Hot swap batteries

- The hot swap battery is maintenance-free during its normal life.
- The hot swap battery must be replaced when the device runs less than 2 minutes when the power battery is removed.

6.3.1 Replacing the batteries

WARNING

▲ Replacement of lithium batteries by inadequately trained personnel could result in a hazard.

Replacing the power battery:

The power battery needs to be replaced when the battery capacity indication in the menu **System > Device Info > Battery info**, parameter **“Full Charge Capacity”** is below 4000.

Replacing hot swap battery:

We recommend to replace the hot swap battery every 4 years or when the running time of the device is below 2 minutes when the power battery is removed.

6.3.2 Battery disposal

DANGER

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

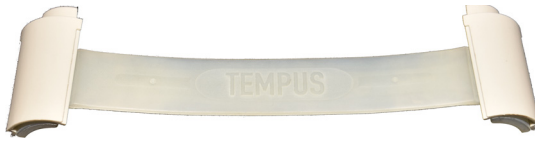
▲ The battery is to be disposed of in municipally approved areas.

6.4 External servicing

The following parts can be replaced by the user. Important is to use always a Torque driver to tighten the screws.

6.4.1 Handle replacement

Parts and tools required

Parts and tools	Part number SAG / RDT / Philips	Picture
Service KIT 8 Handle	3.940598 / 26-5007 / 989706012300	Note: This Kit number includes all part numbers listed below:
Handle	4.435388	
Handle fitting right Handle fitting left	4.310670 4.310671	
2 screws M3x35, T10	4.910269	--
Torque driver set to 0.8 Nm	N/A	
T10 TORX	N/A	

Procedure

1. Remove the 2 screws.
2. Remove the handle fittings and replace the handle
3. Use a drop of silicon oil to slide the cover back again.
4. Tighten the screws with a torque of 0.8 Nm.

6.4.2 Battery cover replacement

Parts and tools required

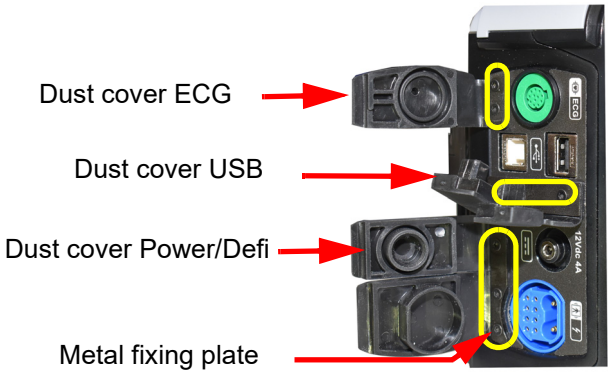
Parts and tools	Part number SAG / RDT / Philips	Picture
Service KIT 9 Dust cover battery	3.940599 / 26-5008 / 989706012310	Note: This Kit number includes all part numbers listed below:
1x Cover 1x Metal fixing plate 10 Screws M 2.5x5 T8	4.435386 4.415871 4.914079	
Torque driver set to 0.6 Nm	N/A	
T8 TORX	N/A	

Procedure

1. Remove the 3 screws.
2. Replace the cover
3. Tighten the screws with a torque of 0.6 Nm.

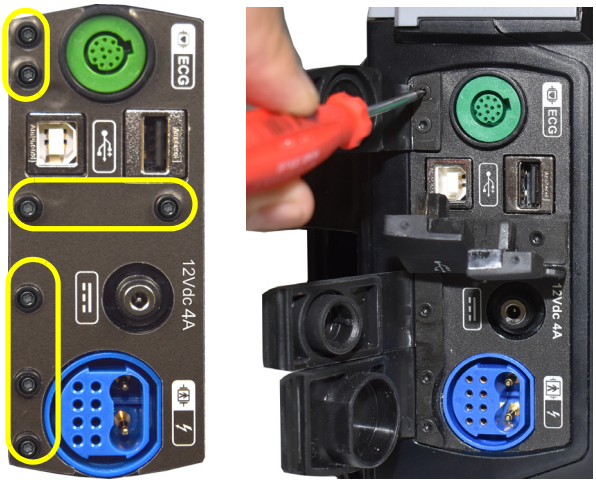
6.4.3 Dust cover fitting/replacement

Parts and tools required

Parts and tools	Part number SAG / RDT / Philips	Picture
Service KIT 12 Dust covers	3.940585 / 26-5011/ 989706012340	Note: This Kit number includes all part numbers listed below:
1x Dust cover ECG 1x Metal fixing plate ECG 1x Dust cover USB 1x Metal fixing plate USB 1x Dust Cover DC/Defi 1x Metal fixing plate DC/Defi 7x Screws M 2.5x3 T8	4.435382 4.415868 4.435385 4.435869 4.435384 4.415870 4.910275	
Torque driver set to 0.6 Nm	N/A	
T8 TORX	N/A	

Procedure

1. Remove all 7 screws (yellow).
2. Fit dust covers and metal plates.
3. Tighten the screws with a torque of 0.6 Nm.



6.4.4 Rear clip replacement

Parts and tools required

Parts and tools	Part number SAG / RDT / Philips	Picture
Service KIT 10 Rear clip	3.940587 / 26-5009 / 989706012320	Note: This Kit number includes all part numbers listed below:
1x Rear clip	3.940575	
Torque driver set to 0.6 Nm	N/A	
T10 TORX	N/A	

Procedure

1. Remove all 4 screws (yellow).
2. Remove the rear clip.
3. Fit the new rear clip.
4. Tighten the 4 screws with a torque of 0.6 Nm

6.5 Cleaning

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

6.5.1 Cleaning agents

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

Recommended cleaning agents

- Isopropyl alcohol 50%
- Propanol (50 %)
- Aldehyde (2-4 %)
- Ethanol (50 %)
- Neutral detergents
- Soap water
- All other products that are suitable for PC plastic

Cleaning agents not allowed

Never use products containing the following:

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

6.5.2 Cleaning the device and ECG patient cable

WARNING

- ▲ Remove the battery and close the cover before cleaning. See section 2.6.3 Interruption of external power supply and close the connector with the protective cap.
- ▲ Do not immerse the unit nor the cable in liquid and do not sterilize them!
- ▲ Do not apply tension to the sensor cable.
- ▲ Do not use aggressive cleaners.
- ▲ Do not use any phenol-based agents or peroxide compounds for cleaning.
- ▲ Observe the manufacturer's notes when cleaning the sensors and cables.

Device

1. Disconnect the device from the mains and remove the plug and sensors.
2. Wipe the equipment, with a dampened cloth and a mild cleaning solution see section 6.5.1 Cleaning agents, page 119.
3. Dispose of single-use pads and protective coverings according to the relevant regulations.

ECG cable

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

LifePoint sensor

➜ The Sensor and cable can be wiped with the detergent and disinfectants listed below:

With time, the casing may become less resistant if an alkaline cleaner or a cleaner with a high alcohol concentration is left for a long time on the surface, or if a warm disinfectant or detergent is used. For this reason, Schiller AG recommends using only cleaning agents with alcohol content that are adequate for sensitive materials such as TPU or PU, at room temperature (approx. 20 °C).

Approved detergents

- Isopropyl alcohol (50 %); neutral, mild detergent (wipe and rub dry)

Recommended disinfectants:

- Bacillol® 30 foam/ Bacillol® 30 Tissues
- Mikrozid® AF
- Meliseptol® Foam pure/ wipes
- RTU Wex-Cide®
- 10% bleach/water solution

6.5.3 Check and cleaning the battery contacts

1. Remove the battery and check the battery contacts for dust or sand.
2. Wipe the contacts with a cloth. Do not use corrosive cleaning agents.

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

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

If no such collection point or recycling center is available, you can return the unit to your distributor or the manufacturer for proper disposal. In this way, you contribute to the recycling and other forms of utilization of old electrical and electronic equipment. Improper disposal harms the environment and human health due to the presence of dangerous substances in electrical and electronic equipment.

6.6 Inspection and checklist tables

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

Checking life-saving functions

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

- Visual inspection of the device and accessories (see section 6.2.1).
- Battery charging status (see section 6.2.3).
- Button test (see sections 6.2.4)

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

6.6.1 Every 12 months

Inspection	Results	Inspection			
Functional, safety checks and inspections Confirm the date of the last factory inspections and tests	Return the unit to your nearest authorized service point or your RDT agent for safety and functional checks.	☐	☐	☐	☐
	Date of inspection:				
	Inspector:				

6.6.2 Limited life item replacement every 5 - 10 years

Inspection	Results	Replaced			
Battery Replace battery	The battery needs to be replaced:				
	when the “Full Charge Capacity” is less than 4000, see section 6.3.1.	☐	☐	☐	☐
	Replace the hot swap battery every 4 years or when the running time of the device is below 2 minutes when the power battery is removed.	☐	☐	☐	☐
	Replace the internal button primary cell (every 10 years)	☐	☐	☐	☐
	Date of inspection:				
	Inspector:				
Defibrillation capacitor Replace defibrillation capacitor	Send the unit to your nearest RDT service center for capacitor replacement if the defibrillation capacitor deviates more than 15 % [joule] from the intended value.	☐	☐	☐	☐
	Date of inspection:				
	Inspector:				

6.6.3 Wear parts

Inspection	Results	Replaced			
Battery cover	Replace it when cover does not close	◻	◻	◻	◻
Handle	Replace it when it is worn out, dirty or has cracks	◻	◻	◻	◻
Dust covers connectors	Replaced it when cover does not close	◻	◻	◻	◻
Rear clip	Replace it when it has cracks or when the rear bracket is broken	◻	◻	◻	◻
	Date of inspection:				
	Inspector:				

6.7 Error detection

Forced shutdown procedure

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

- Press and hold the green button  until the device has switched off. Then switch on again.
- If the device does not return to normal operating condition within a reasonable period of time, continue cardiopulmonary resuscitation.

6.7.1 General errors & troubleshooting

Error	Cause	Remedy
The screen is not lit when the device is switched on	• Battery not inserted correctly or defective	➜ Insert battery correctly or replace it
	• Battery empty	➜ Connect to the power supply (docking station) and charge battery
	• The device is defective	➜ Replace device
Device cannot be switched off	• Software hangs	➜ Keep the green button pressed till the device switches off
	• The device is defective	➜ Replace device
ECG signal disturbed	• ECG signal interference through electromagnetic waves or discharges see picture page 129	➜ Turn off source of signal interference. e.g. radio equipment or cell phone, electrical bed drive or move patient outside field of interference.
Unable to deliver shock	• Electrode error caused by resuscitation measures	➜ Reapply electrode
	• Heart rhythm has changed	➜ Run new analysis
	• Battery empty or defective	➜ Replace battery with a fully charged.
	• The device is defective	➜ Replace device
Battery cannot Be charged (High/Low Temperature)	• Temperature in the device or battery too high/low	➜ Let device cool down, if possible; charging is continued once the temperature has reached an acceptable level.
Test Not Executed Due to Connected Electrodes	• Electrodes are connected during automatic RTU self-test	➜ Disconnect electrodes and execute a manual RTU self-test.
Relay test failed	• Relay defective	➜ Replace device
IGBT test failed	• IGBT defective	➜ Replace device

Error	Cause	Remedy
Capacitor test failed	• Capacitor defective	➜ Replace device
Battery test failed	• Battery not sufficient capacity or defective	➜ Recharge battery, check battery ➜ Replace battery

6.7.2 Technical alarms, notifications

- The following technical alarms and notifications indicates that the device is defective and must be repaired.
- All other alarms that can be resolved by the user are described in the section 2.8 Display of technical alarms and notifications.

High priority technical alarms

Alarm message	Description
The device must be repaired if the following messages appears:	
Battery defect. Shutdown in m:ss	• Battery defect, replace battery
DPM Hardware failure	• Hardware failure of the DPM, device defect
Internal Discharge. Defibrillator Failure	• DPM error INT. DISCH 6 (current 0 or >105A) • DPM error INT. DISCH 8 (voltage capacitor not valid) • DPM error INT. DISCH 9 (voltage capacitor to high)
Internal Discharge. Charging Not possible	• DPM error INT. DISCH 4 (charging time too long)
Key stuck detected	• Pressed or short circuit of a soft button detected ➜ Restart device again and make sure that no button on the device is pressed during startup.

Technical notification

Notification message	Description/Remedy
Defibrillator	
SHOCK CANCELLED	• If the capacitor is charging, no DC power and no energy is available from the battery, check battery and DC power ➜ Replace the battery and check if battery is charging with DC power if not: ➜ Get device repaired
ECG	
ECG amplifier failure	• Device is not able to configure the ECG amplifier ➜ Get device repaired
Pacemaker	
Pacing Stopped	• Device stops the pacing automatically when: ➜ ECG cable is off, check electrodes ➜ Defibrillator electrodes are off, check Defi electrodes) ➜ When battery is empty or removed, check battery ➜ Hardware failure DPM
Battery	
UPS Battery Defective	• Whenever the UPS-Charger fails to charge the UPS Battery ➜ Device still operational except battery replacement without shutdown. Get device repaired as soon as possible.
Device	
• IGBT Test failed • Capacitor Test failed • Relay Test failed • Test Not Executed Due to Connected Electrodes	• Test failed during RTU or manual selftest (see trouble shooting) ➜ Get device repaired

6.8 Preventing electromagnetic interferences

The user can help avoid electromagnetic disturbances by keeping the minimum distance between portable and mobile **radio frequency** (RF) telecommunication devices (transmitters) and the **Tempus LS**. The minimum distance of 0.3 m has been tested according to IEC 60601-1-2 for a wide range of telecommunication equipment, as shown in the following table.

HF source wireless communications devices	Transmitter frequency [MHz]	Testing frequency [MHz]	Max. power P [W]	Distance d [m]
Various radio services (TETRA 400)	380-390	385	1.8	0.3
- Walkie-talkies (FRS) - Rescue service, police, fire brigade, servicing (GMRS)	430-470	450	2	0.3
LTE band 13/17	704-787	710/745/780	0.2	0.3
- GSM800/900 - LTE band 5 - Radio telephone (micro-cellular) CT1+, CT2, CT3	800-960	810/870/930	2	0.3
- GSM1800/1900 - DECT (radio telephone) - LTE Band 1/3/4/25 - UMTS	1700-1990	1720/1845/1970	2	0.3
- Bluetooth, WLAN 802.11b/g/n - LTE Band 7 - RFID 2450 (active and passive transponders and reading devices)	2400-2570	2450	2	0.3
WLAN 802.11a/n	5100-5800	5240/5500/5785	0.2	0.3

CAUTION

- **Portable** HF telecommunication devices must not be used within a radius of 0.3 m (1 ft) from the **Tempus LS** and its cables.
- Do not place the **Tempus LS** on top of other electric/electronic devices - i.e. maintain a sufficient distance to other devices (this includes the patient cables).

For permanent HF telecommunication devices (e.g. radio and TV), the recommended distance can be calculated using the following formula: $d = 0.6 \times \sqrt{P}$. (The formula is based on the max. immunity level of 10 V/m in the frequency domain of 80 MHz to 3000 MHz).

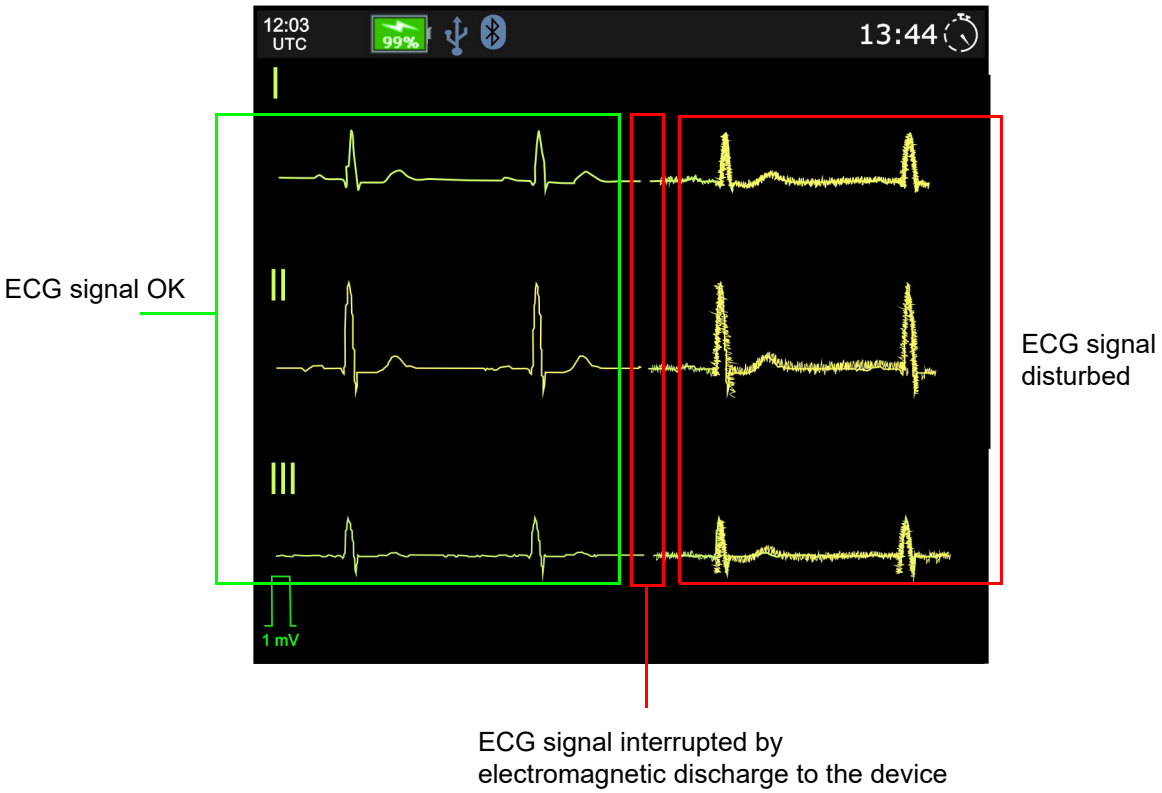
- d = recommended minimum distance in meters
- P = transmitting power in Watts

For more information on operation in an electromagnetic environment according to IEC/EN 60601-1-2, please consult RDT.

6.8.1 Measures to prevent electromagnetic interference

In the case of certain electromagnetic interference, artefact's can occur, which are distinguishable from the ECG signal. The essential performance characteristics of the device are not affected by these artefact's, but the user can take the following measures to prevent electromagnetic interference:

Typical disturbed ECG signal



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

- Increase distance to the source of interference.
- Turn off the source of interference.
- Turn the device to change the angle of radiation.
- Connect the device to a different mains connector.
- Only use original accessories (especially patient cables).
- Immediately replace defective cables, especially patient cables with defective sheathing.
- Make sure the patient cable is securely screwed on.
- Observe the maintenance intervals as stated in 6.1 Daily checks and Maintenance interval.

6.9 Accessories and disposables

WARNING

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

6.9.1 Accessories Tempus LS

The following Tempus LS accessories and consumables are available from RDT:

Product name & description	RDT Part number
Tempus LS	00-3010
Tempus LS Battery	01-3011
Tempus LS SMART mount (Vehicle/Aircraft mountable) (PSU and Power Cable ordered separately)	01-3012
Medical grade switching power supply, protection class I. • 100 - 240 VAC, max. 2.0 A, 50-60 Hz • 12 VDC, max. 5 A, 60 W	01-2049
3P 2 m (6.6 ft) Power cable Schuko	Re-order code 01-2057
3P 2 m (6.6 ft) Power cable UK	Re-order Code 01-2056
CPR Reusable Puck	01-3010
Tempus LS CPR Puck Reusable adhesive chest pads (5pk)	01-3014
Tempus LS Defibrillation/Pacing electrodes - Adult (1pk)	01-3001
Tempus LS Defibrillation/Pacing electrodes - Paediatric (1pk)	01-3013
Tempus Pro 3- lead ECG Cable (IEC) 6 ft (1.8 m)	01-2038
Tempus Pro 4- lead ECG Cable (IEC) 8 ft (2.4 m)	01-2181

Chapter 7
Specification and standards

7.1 Physical characteristics and environmental specifications

Data refer to standard testing conditions.

Device name	**Tempus LS**
Dimensions	200 x 164 x 72 mm (width x height x depth) 7.9 x 6.5 x 2.8 inches (width x height x depth) With rear clip depth is 96 mm (3.8 inches)
Weight	1.95 kg (4.3 lbs) with battery (without accessories)
Protection case	IP66 The device is protected against dust and water. Water projected from jets against the enclosure from any direction shall have no harmful effects.
Power supply AC/DC	Type ASTEC Model: DPS53-M Medical grade switching power supply, protection class I.
Input	• 100 - 240 VAC, max. 2.0 A, 50-60 Hz
output	• 12 VDC, max. 4 A, 60 W The power supply's altitude rating of 4000m must be adhered to. Do not use the power supply outside of its specification. Do not use it outdoor or in ambulances, fixed and rotary wing aircraft)
Power battery	
Battery	• Lithium/ion 10.8 V, 5.2 Ah, 56.2 Wh
Autonomy	• 300 shocks with maximum energy or >12 hour monitoring
Charging time	• 90 %: 3 hours after full discharge and device switched off • 100 %: approx. 4 hours after full discharge and device switched off
Hot swap battery	Ensures continued monitoring for approx. 2 minutes when replacing the power battery
Battery type	• 2 x Li/ion polymer 3.7 V 0.33 A
Environmental conditions	
For operation	• -5 ºC ... 50 ºC (32 °F to 122 °F) relative humidity at 15 - 95 % (non-condensing) Atmospheric pressure 540...1060 hPa (5000 m/16404 ft) between 610 and 540 hPa (4000 to 5000 m/ 13123 to 16404 ft) only without external AC/DC power supply
For transient operation	• -20 ºC ... 50 ºC (-4 °F to122 °F) according to IEC 60601-1-12

Environmental conditions	
For storage and transport between uses	• -20 ºC ... 70 ºC (-40 °F to 176 °F) relative humidity at 0 - 95 % (non-condensing) Atmospheric pressure 500...1200hPa
Time for warming up/ cooling down	• > 60 minutes; Time required for the Tempus LS manual to warm or cool from the minimum/maximum storage temperature between uses until the Tempus LS manual is ready for its intended use when the ambient temperature is 20 °C
Environmental conditions Defibrillation electrodes	
Storage	• 0 ºC...50 ºC (32 °F to 122 °F)
Storage max. 10 days	• -40 ºC...75 ºC (-40 °F to 176 °F)
Display	
Type	• LCD color with back-light, protected by tempered glass
Dimensions	• 116 x 87 mm (4.6 x 3.4 in)
Signal sound level	>50/ >60/ >70 dBA (Low/Mid/High)
Connections	• Defibrillation -Pads • ECG - patient cable • DC power supply
Interfaces	• USB • Bluetooth
Memory	> 100 hours memory (FIFO) Recording of Defib, ECG Lead I, II, III, Events, CPR feedback, patient data
EMC	• IEC/EN 60601-1-2: 2014, 4th Edition • IEC/EN 60601-2-4: 2010 EMC part §202 • CISPR 11: 2015; class B The device can be exposed to the following source of interference without impairment of the essential performance: • Static discharges up to 15 kV • Field strength up to: – 3 V/m for ECG signal mode (80% AM at 1kHz) – 20 V/m in Defibrillation mode (5Hz AM) – 10 V/m for Pacemaker mode (5Hz AM) for all in the radio frequency range of 80...2700 MHz • Magnetic fields of 100 A/m, 50/60 Hz

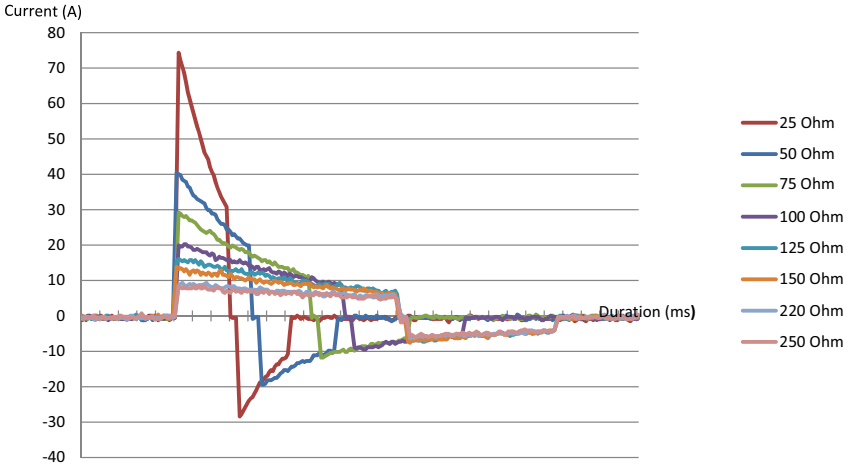
7.2 Standards

Conformity	CE according to directive 93/42/EEC class IIb
Defibrillator	IEC/EN 60601-2-4 The device is designed for intensive use
Electrical protection class	According IEC 60601-1: 2012, Electrical safety • The **Tempus LS** is internally (battery) powered. • Power supply is class I • Applied part type CF • Applied part type BF for defibrillator input
Requirements for the basic safety and essential performance of electrocardiograph monitoring	IEC/EN 60601-2-27 (without alarm system)
Requirements for medical electrical systems used in the home healthcare environment	IEC 60601-1-11
Ingress protection	IP66 according IEC 60529
Environmental condition for emergency medical devices	IEC 60601-1-12
Environmental Conditions and Test Procedures for Airborne Equipment	RTCA DO-160G, 2010 section 21 cat. M and section 20 cat. R ISO 7137, June01, 1995, reference No. 3.7 MIL-STD 810G 514.5 cat. 9
EMC	• IEC/EN 60601-1-2: 2014, 4th Edition • IEC/EN 60601-2-4: 2010 EMC part §202 • IEC/EN 60601-2-27: 2011 EMC part §202 • CISPR 11: 2015; class B
AED Protocol	According ERC/AHA 2015 guidelines

7.3 Defibrillation

Waveform

- Biphasic truncated exponential waveform
- Maintains the energy delivered to the patient at an approximately constant level with regard to patient resistance



Accuracy of delivered shock

Deviation from the selected energy (1 till 200 J) at 25 till 175 Rpat [Ω]: ± 3 J or ± 15 % (the higher value is assumed) see below:

At any energy level, the measured DELIVERED ENERGY into the load resistances of 25, 50 , 75, 100, 125, 150, and 175 Ω, did not deviate from the DELIVERED ENERGY for that impedance by more than +/- 3 joules or +/- 15 %, the higher of the two

Energy Level	DELIVERED ENERGY in a load resistance of							Deviation from indicated Energy, (Joules)							Deviation from indicated Energy, (%)						
	25Ω	50 Ω	75Ω	100 Ω	125 Ω	150 Ω	175 Ω	25Ω	50 Ω	75Ω	100 Ω	125 Ω	150 Ω	175 Ω	25Ω	50 Ω	75Ω	100 Ω	125 Ω	150 Ω	175Ω
Minimum 1J	1,16	1,11	1,12	1,15	1,11	1,1	1,03	0,16	0,11	0,12	0,15	0,11	0,1	0,03	-	-	-	-	-	-	-
Intermediate 1 30J	30,4	30	29,6	29,2	29,4	28,5	27,2	-	-	-	-	-	-	-	1,3	0	1,3	2,7	2	5	9,3
Intermediate 2 90J	92,1	89,3	88,2	87	87,6	84,4	81,2	-	-	-	-	-	-	-	2,3	0,8	2	3,3	2,7	6,2	9,8
Maximum 200J	204,8	198,7	197	193	195	188	180	-	-	-	-	-	-	-	2,4	0,7	1,5	3,5	2,5	6	10

Standard energy settings

AED

– Adult

– Pediatric

- 150/150/150 joules (configurable)
- 50/50/50 joules (configurable)

automatic selected when adult or pediatric electrodes are connected

Manual mode

– Adult

– Pediatric

- 1, 2, 3...to 10, 15, 20, 30, 50, 70, 90, 100, 120, **150,** 170, 200 joules
- 1, 2, 3, 4, 5, 6, 7, 8, 9,10, 15, 20, 30, **50**, 70, 90, 100 joules

Charging time for shock in AED mode	(Time used to charge the storage capacitor to the max. energy of 200 J in AED mode)
with 12 VDC mains voltage with fully charged battery	9 seconds
after 15 discharges with max. energy	9 seconds
from switch-on of the device with pads	17 seconds
Charging time for shock in manual mode	(Time used to charge the storage capacitor to the max. energy of 200 J in manual mode)
with 12 VDC mains voltage with fully charged battery	9 seconds
after 15 discharges with max. energy	9 seconds
from switch-on of the device with pads	14 seconds
Operating Modes	• Synchronized with heart action < 60 ms after R wave • Non-synchronized • AED
Charge control and monitoring	• Automatic shock recommendation of analysis in AED mode • Display of selected energy
Patient resistance	25 ...250 Ω (Impedance is compensated up to 200 Ω)
Indication when ready to shock	LED  is lit
Shock delivery	Using key 
Safety discharge occurs when:	• pads removed (only in AED mode) • the battery voltage is insufficient • the shock is not released within 20 seconds • the device is defective • the device is turned off • the disarm function key is pressed in manual mode • a non shockable rhythm in AED mode is detected
Shock delivery	Via applied disposable adhesive defibrillation electrodes
Defibrillation electrode connection	Type CF, defibrillation-protected >5 kV

Defibrillation electrodes Adult and Pediatric electrode	Electrode cable, 2 m (6.6 ft) long • 80 cm² active surface
Frequency range defibrillation ECG amplifier	1 - 25 Hz

7.3.1 Shock Advisory System

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

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

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

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

Table 1: **Tempus LS** SAS performance by rhythm category meets AHA recommendations [2] and IEC Standards [3] for adult defibrillation on artefact's-free MIT-VFDB signals:

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

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

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

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

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

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

7.4 Pacemaker

Operating Modes	• Demand • Fixed frequency (FIX or Overdrive (impulse frequency x 3))
Stimulation pulse	
Form	• Rectangle mono-phase with constant current source
Pulse duration	• 20 ms ± 5%
Pulse rate	• Configurable in steps of 40, 45, 50, 60, 70 ... 240 bpm ± 1.5%
Pulse current	• Configurable to 0 (pacemaker Off) and then from 10 ...200 mA, ± 10 % or 5 mA (the higher value is applied)
Refractory period	• 340 ms ≤80 bpm • 240 ms >80 bpm
Signal connection	• Type CF, defibrillation-protected >5 kV
Readiness for operation	• Immediately
Pacer electrodes (same as defibrillation electrodes)	Electrode cable, 2 m (6.6 ft) long
Adult and Pediatric electrode duration	80 cm² active surface For up to 1 hour of pacing using 140mA/ 120 bpm (pulse duration 20ms) For up to 8 hours of pacing using 70mA / 60 bpm (pulse duration 20ms) inspection of pads every 30 minutes

7.5 ECG monitoring

Patient cable	3-lead and 4-lead (wire) cable, type CF
Heart rate Range Accuracy	 • 15 – 300 bpm • ±10 % or 5 bpm, whichever is greater
Lead display	Lead I, II, III and aVR, aVL, aVF selectable, additional leads selectable
Sensitivity	5, 10, 20 mm/mV programmable
Blockage caused by defibrillation shock	Max. 5 seconds according to IEC specifications 60601-2-27 Cl. 201.7.9.2.9.101 a) 4).
Input impedance	≥ 2.58 MΩ
Applied patient DC lead off current	< 0.5 μA applied to the patient according to IEC specifications 60601-2-27, 201.7.9.2.9.101 b)1)
Suppression of large T-waves	max. amplitude of T-wave according to IEC 60601-2-27 section 201.12.1.101.17: 0.8 mV
HR averaging method	The heart rate calculation is done using a user-defined number of previous RR intervals (minimum 4, maximum 16). The RR intervals are reset and the heart rate is set to zero whenever an asystole condition has been detected
Response time HR measurement	• Change from 80 to 120 beats per minute: 5 s • Change from 80 to 40 beats per minute: 8 s (according to IEC specifications 60601-2-27, 201.7.9.2.9.101 b5)
Reaction to an irregular rhythm	• A1: 80 bpm • A2: 60 bpm • A3: 124 bpm • A4: 94 till 121 bpm (except for triggers no. 6 and 7, HR < 90 bpm) (according to IEC specifications 60601-2-27, 201.7.9.2.9.101 b4
ECG amplifier Bandwidth Sampling rate Pacemaker rejection QRS detection range Protection Mains filter Frequency range ECG display	 • 0.05 to 150 Hz (-3 dB) • 1000 Hz • ± 2 mV to ± 700 mV/0.1 till 2.0 ms without overshoot • ± 2 mV to ± 700 mV/0.1 till 2.0 ms with overshoot < 20 ms • Duration: 70 to 120 ms, amplitude: 0.5 to 5.0 mV • Fully isolated, defibrillation-protected >5kV • Distortion-free suppression of superimposed 50 / 60 Hz sinusoidal interferences by means of adaptive digital filtering. • 0.5 - 40 Hz ECG signal view (measurements has ST segment quality (CBS filter)

7.6 Electromagnetic interference

The **Tempus LS** is intended to be used in the electromagnetic environments listed in the following tables. The user of the **Tempus LS** must ensure that the device is used in a suitable environment.

7.6.1 Electromagnetic emissions

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

7.6.2 Electromagnetic immunity

Interference testing	IEC 60601 test level	Conformity level	Electromagnetic environment - explanations
Electrostatic discharge IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be made of wood, concrete or ceramic tiles. If floors are covered with synthetic material, relative humidity should be at least 30%. Note: In case of strong ESD discharges, artefact's can occur, which are clearly distinguishable from the ECG signal. The essential performance characteristics of the device are not affected by this.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2.2 KV	Mains power quality should be that of a typical commercial and/or hospital environment. Note: In the case of a strong fast transient / burst, artefact's can occur, which are clearly distinguishable from the ECG signal. The essential performance characteristics of the device are not affected by this.
Surge IEC 61000-4-5	± 1 kV between conductors ± 2 kV conductor-earth	IEC 60601-1 conformity	Mains power quality should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % nominal voltage during 0.5 period 40 % nominal voltage during 100 ms at 50/60 Hz 70 % nominal voltage during 500 ms at 50/60 Hz 0% nominal voltage during 5 s at 50/60 Hz	IEC 60601-1 conformity	Mains power quality should be that of a typical commercial and/or hospital environment. The Tempus LS switches during interruption to the internal battery mode. the intended use and basic safety are not affected.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	100 A/m	Power frequency magnetic fields should be that of a typical commercial and/or hospital environment.
Note: U_T indicates the AC voltage of the mains before the test level.			

Interference testing	IEC 60601 test level	Conformity level	Electromagnetic environment - explanations
			Recommended minimum distances Portable and mobile HF telecommunication devices must keep the recommended minimum distance from the **Tempus LS** and all its components, incl. cables; the recommended minimum distance is calculated based on the transmitter's frequency.
Conducted HF IEC 61000-4-6	3 Veff between 150 kHz and 80 MHz outside of the ISM frequency bands[a] 6 Veff between 150 kHz and 80 MHz within the ISM frequency bands[a]	3 V 6 V	$d = \frac{3,5}{3} \times \sqrt{P}$ $d = \frac{12}{6} \times \sqrt{P}$
Radiated HF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	20 V/m 	ECG and defibrillator: $d = \frac{12}{20} \times \sqrt{P}$ between 80 MHz and 800 MHz $d = \frac{23}{20} \times \sqrt{P}$ between 800 MHz and 2.7 GHz where P is the maximum transmitting power of the transmitter in Watt (W) according to manufacturer data, and d the recommended minimum distance in meters (m)[b]. The field strength of stationary HF transmitters (according to an on-location measurement [c]) must not exceed the conformity level for each frequency range [d]. When operating the device near devices bearing the symbol “ionizing radiation”, interferences can occur.
Proximity fields from RF wireless communications equipment IEC 61000-4-3	see section 7.6.3	see section 7.6.3	see section 7.6.3
Note 1 For 80 MHz to 800 MHz, the higher frequency range applies. Note 2 These guidelines might not always be applicable. Electromagnetic radiation is influenced by absorption and reflection on structures, objects and people.			

a. The ISM frequency bands (ISM = industrial, scientific, medical) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
b. The conformity levels within the ISM frequency bands between 150 kHz and 80 MHz and between 80 MHz and 2.5 GHz serve to minimize the probability of interferences caused by mobile/portable communication equipment that accidentally happens to be in the patient environment. The formula for the calculation of the recommended distance has been adapted by the factor 10/3 for transmitters in this frequency range.
c. The field strength of stationary transmitters, e.g. base stations for radio telephones (mobile or cordless) and portable radio equipment, amateur radios, AM and FM radios and TV signals cannot be predicted accurately in a theoretical way. In order to analyze electromagnetic environments caused by stationary HF transmitters, an electromagnetic analysis

on site should be considered. If the measured field strength exceeds the HF conformity level, it needs to be checked whether the **Tempus LS** can be used in this environment. If an abnormal behavior is detected, additional measures need to be taken, e.g. reorientation or change of location of the **Tempus LS**.

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

7.6.3 Immunity to proximity fields from RF wireless communications equipment

Test frequency [MHz]	Band[1] [MHz]	Service	Modulation	max. power P [W]	Distance [m]	Immunity level [V/m]
385	380-390	Various transmitting services (TETRA 400)	Pulse modulation[2] 18 Hz	1.8	0.3	27
450	430-470	- Walkie-talkie (FRS) - Rescue, Police Fire brigade, Maintenance (GMRS)	FM [3] ±5 KHz ±1 KHz sine	2	0.3	28
710 745 780	704-787	L TE Band 13/17	Pulse modulation 217 Hz	0.2	0.3	9
810 870 930	800-960	- GSM800/900 - LTE band 5 - Mobile phone CT1+, CT2,CT3	Pulse modulation 18 Hz	2	0.3	28
1720 1845 1970	1700-1990	- GSM1800/1900 - DECT (mobile phone) - LTE Band 1/3/4/25 - UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400-2570	- Bluetooth, WLAN 802.11b/g/n - LTE Band 7 - RFID 2450 (active and passive Transponder and reader)	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11a/n	Pulse modulation 217 Hz	0.2	0.3	9

1.For some services, only the uplink frequencies are included.
2.The carrier shall be modulated using a 50 % duty cycle square wave signal.
3.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

7.6.4 Recommended separation distances

For fixed installed HF-Transmitters (z.B Radio und TV transmitters) the following minimum distance to the transmitter can be calculated as follows:

Max. transmitting power of the transmitter (W)	**Distances according to the transmitter's frequency (m)**			
	$d = \frac{3,5}{3} \times \sqrt{P}$ between 150 kHz and 80 MHz **outside of** the ISM frequency band	$d = \frac{12}{20} \times \sqrt{P}$ between 150 kHz and 80 MHz **within** the ISM frequency band	$d = \frac{12}{20} \times \sqrt{P}$ between 80 MHz and 800 MHz	$d = \frac{23}{20} \times \sqrt{P}$ between 800 MHz and 2.5 GHz
0.01	0.12	0.06	0.06	0.12
0.1	0.37	0.19	0.19	0.38
1	1.17	0.6	0.6	1.8
10	3.69	1.895	1.895	3.64
100	11.67	6	6	11.5

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

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

7.7 Bluetooth standard

Module	PAN1026
FCC ID **IC ID**	T7VPAN10 216Q-PAN10
Transmission standards	Bluetooth version 4.0 LE
Frequency range	2.402 ...2480 MHz
Max. power output	+4 dBm
Singapore IMDA license information	**Complies with IMDA Standards DA102408** DA102408 for wifi/WLAN/Bluetooth/NFC capability

7.8 ARGUS LifePoint

Sensor name	ARGUS LifePoint
Dimensions	80 x 25 mm (diameter/ depth)
Weight	152 g
Cable length	2 m
Power supply	5 VDC via USB from the medical device
Environmental conditions Operation Transport Storage For Transport and storage between uses	• -5 ºC ... 50 ºC relative humidity at 15 - 95 % (non condensing) • -10...50°C / +5...50°C, humidity 10...95% (non condensing), pressure 500...1060 hPa. • -40... 75 ºC, relative humidity of 10...95 % (non-condensing) Atmospheric pressure 500...1060 hPa (5000m to -400m) for above
Measured values Frequency Compression depth	 1 to 160 compression/min (cpm) 1 to 127 mm
Accuracy	± 3 compressions/min ± 5% at 50 mm (laboratory condition)
Life cycle	500’000 compressions
Dust and water protection	IP66
Protection class	Type BF defibrillation proof

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