

Your life With care Anywhere

Tempus LS[®]

User/Operator Manual
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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.

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. CPR Feedback sensor is optionally available.
- ▲ The device is for use by professional persons who are trained in basic life support (BLS) and defibrillation or advanced life support (ALS). The device is intended for single patient use only.
- ▲ The device is intended to be used by professional medics including doctors, nurses, paramedics and EMTs in civilian and military applications.
- ▲ 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.

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).
- ▲ **Danger of explosion!** — The device must not be used in areas where there is any danger of explosion. There might be a danger of explosion in areas where flammable products (petrol), flammable anaesthetic agents or products for skin cleaning/disinfection are in use, or where the ambient air oxygen concentration is higher than 25 %.
- ▲ The CPR feedback option is contraindicated for use on neonatal and paediatric patients under 8 years. CPR feedback option is contraindicated when manual CPR is contraindicated.

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® and patient unattended, the Tempus LS® contains no alarm system.
- ▲ 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 [5.1 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 Organisational Measures



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

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 behaviour) 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 6 Specification and standards](#)).
- ▲ Special caution must always be taken on intracardiac application of medical equipment. Especially make sure that no conducting parts connected to the unit's isolated patient input (patient, plug, electrodes, sensor) come into contact with other, earthed conductive objects, as this might short-out the patient's isolation and remove the protection of the isolated input.
- ▲ Carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- ▲ 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 [5.2 Functional test](#).

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, tomographs, portable communication devices, HF radios and devices labelled with the  symbol can affect the operation of this device (see section [5.7.1 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 electrosurgical devices. However, precautions must be observed when such HF equipment is used. To reduce the risk of burns in the case of a failure of the neutral HF electrode, a distance of at least 15 cm must always be kept between the defibrillation electrodes and the HF surgical electrodes. If in doubt, disconnect the electrodes and sensors from the unit during use of a HF surgical device.

1.1.7 Maintenance



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

1.1.8 Hygiene



- ▲ For cleaning and disinfection observe the instructions given in section [5.4 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

Information contained in this document is copyright © 2017 by Remote Diagnostic Technologies Limited ('RDT') and may not be reproduced in full or in part by any means or in any form by any person without prior written permission from RDT.

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.

1.2.1 Implied authorisation

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 authorised 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 pictorals 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

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.
	Notified body of the CE certification (TÜV-Süd)		Used for electrical dangers during defibrillation (Tempus LS)
	Manufacturer symbol, manufacturing date		Note accompanying documents!
	Expiration date		Read the instruction for use
RX only	Prescription Only. Federal law restricts this device to sale by or on the order of a physician.	IP55	The device is protected against dust and powerful water jets against the enclosure from any direction shall have no harmful effects.
	<p>Symbol for the recognition of electrical and electronic equipment.</p> <p>The device must be disposed of in a municipally approved collection point or recycling centre when it is no longer required.</p> <p>Improper disposal harms the environment and human health due to the presence of dangerous substances in electrical and electronic equipment.</p>		
	<p>Devices with Bluetooth</p> <p>Attention: Non-ionic electromagnetic environment. The device contains an HF transmitter.</p> <p>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.</p> <p>However, even in the case of correct installation/operation, there is no guarantee that no interference can occur.</p> <p>If the Tempus LS causes interference, this can be prevented by switching off or not sending data.</p> <p>The user can take the following measures to solve this problem:</p> <ul style="list-style-type: none"> • Increase the distance between the disturbed device and the Tempus LS. A minimum distance of 20 cm must be kept between the device and a pacemaker. • Turn the device to change the antenna's angle of radiation. • Connect the device to a different mains connector. <p>For more details, see section 5.7.1 Measures to prevent electromagnetic interference.</p>		

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	RX only	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

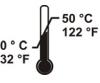
Storage temperature battery

3 to 12 months: -20 to +20 °C

1 to 3 months: -20 to +45 °C

< 1 month: -20° to +60 °C

1.3.4 Symbols used on the electrode package

Symbol	Description	Symbol	Description
	<ul style="list-style-type: none"> • Open clothes • Open the electrode package • Peel off the protective foil 		Disposable item; Single use only
	Do not bend packing		Expiration date
	Storage temperature for the electrodes		Read instruction before use
	Latex free		Use within 1 day after opening
	Keep dry		Keep out of direct sunlight

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 monitoring
- Defibrillation/pacing electrodes
- Tempus LS user manual set
- Power supply

Tempus LS has the following features:

- > 100 hours memory (FIFO) data storage for multiple patients
- Water and sand resistant to IP55
- Multiple ways of reviewing patient data
- A daylight readable, NVG friendly display
- Wide operating & storage temperature range

The following functionality is available with the Tempus LS:

Items	Provided as Standard or Optional
CPR Feedback with ARGUS Lifepoint	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 will also be an 'overdrive' mode (option).

1.6 CE statement

Tempus LS bears the  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/EE regarding safety, functionality and labelling. The requirements apply to patients, users and third persons who come into contact with this device within the scope of its intended use.

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). Exporting/importing configuration files go to: System/Maintenance Settings/Default setting storage (see [4.2 System and Maintenance settings](#))

The following configuration settings are exported and imported:

Default settings include:

- Defi pacer
 - Pacer enabled
 - Default Pacer mode
 - Default Pacer rate
- Defi Manual
 - Energy adult
 - Energy paediatric
 - Auto Sync Enabled
 - Sync soft -Key
 - SYNC ON after shock
 - Start Metronome default
 - Metronome ratio default
- AED
 - Analysis key
 - Start Metronome default
 - Pacer key
 - Voice prompts on
 - Energy paediatric shock 1..3
 - Energy adult shock 1..3
- AED Lifepoint
 - Rate limit upper (cpm)
 - Rate limit lower (cpm)
 - Depth limit upper (mm)
 - Depth limit lower (mm)
 - User feedback delay (sec)
 - Average rate max cpr
- Monitor
 - Mains filter
- Printer
 - Print on SHOCK
 - Print on NO SHOCK advised

- Print on START pacing
- System
 - Default ECG amplitude (mm/mV)
 - Default ECG speed (mm/s)
 - Default loudspeaker volume
 - Default display brightness
 - Ready-To-Use (including self test)
 - Interval for test
 - Time format
 - TimezoneSpec

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

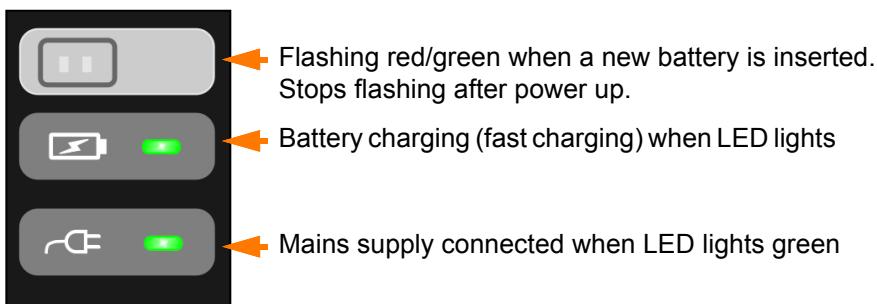


2.3.3 Socket panel



2.3.4 LEDs

The LEDs give the following information:



2.4 Switching the device on and off

2.4.1 Switching the device on

Switch the device on by pressing the green On/Off button .

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.

2.5 New patient

Select **New patient** from the Home screen menu to finish an intervention and start a new intervention, see [page 70](#).



An intervention is also finished when the device is switched off longer than 2 minutes.

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 anaesthetics. 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.

2.6.1 External DC supply

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 (3) and the battery status in the LCD according to [2.6.2 Battery operation](#).

2.6.2 Battery operation

Charging battery

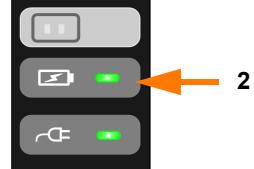
Important

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%.

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

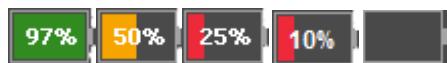
If the device gets to hot, charging stops. As soon as the temperature has decreased to an acceptable level, the charging resumes.



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 notification 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

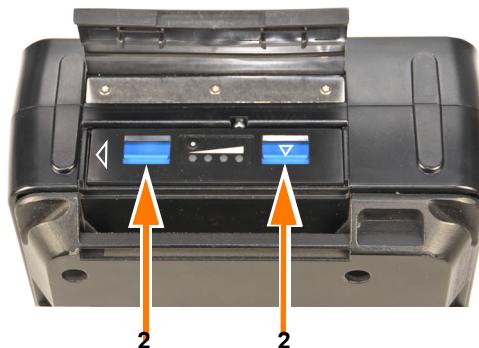
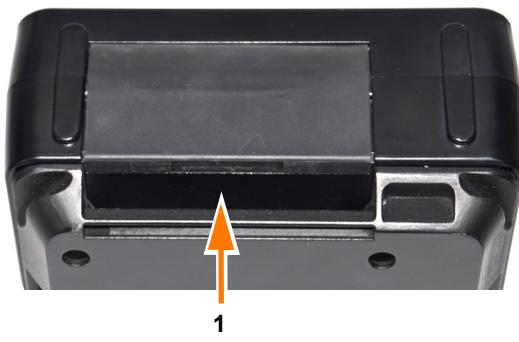

CAUTION

- ▲ Please note that no defibrillation shocks can be delivered when the battery is missing or defective even when an external power supply is connected.



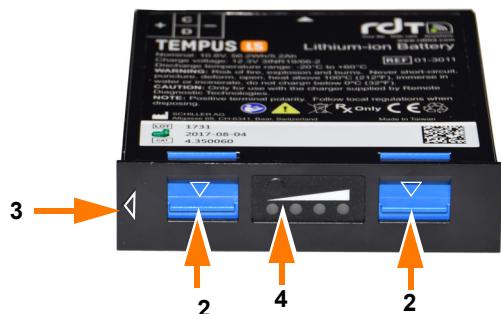
- The battery can only be inserted in one way.

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

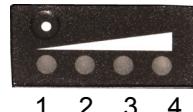


3. To replace, proceed as follows:

- 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.

2.7 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 -5°C to +50 °C. Lower or higher ambient temperatures will have a negative impact on battery life.

- Device failure status: flashing red LED
 - If the device detects an error during the self-test, an alarm sound is activated.



Device Status

2.8 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

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

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 body weight is released. An increase of 2 joules/kg body weight is possible when the defibrillation is repeated.
- ▲ For the defibrillation of children weighing less than 25 kg, the paediatric 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.

3.1.3 General function

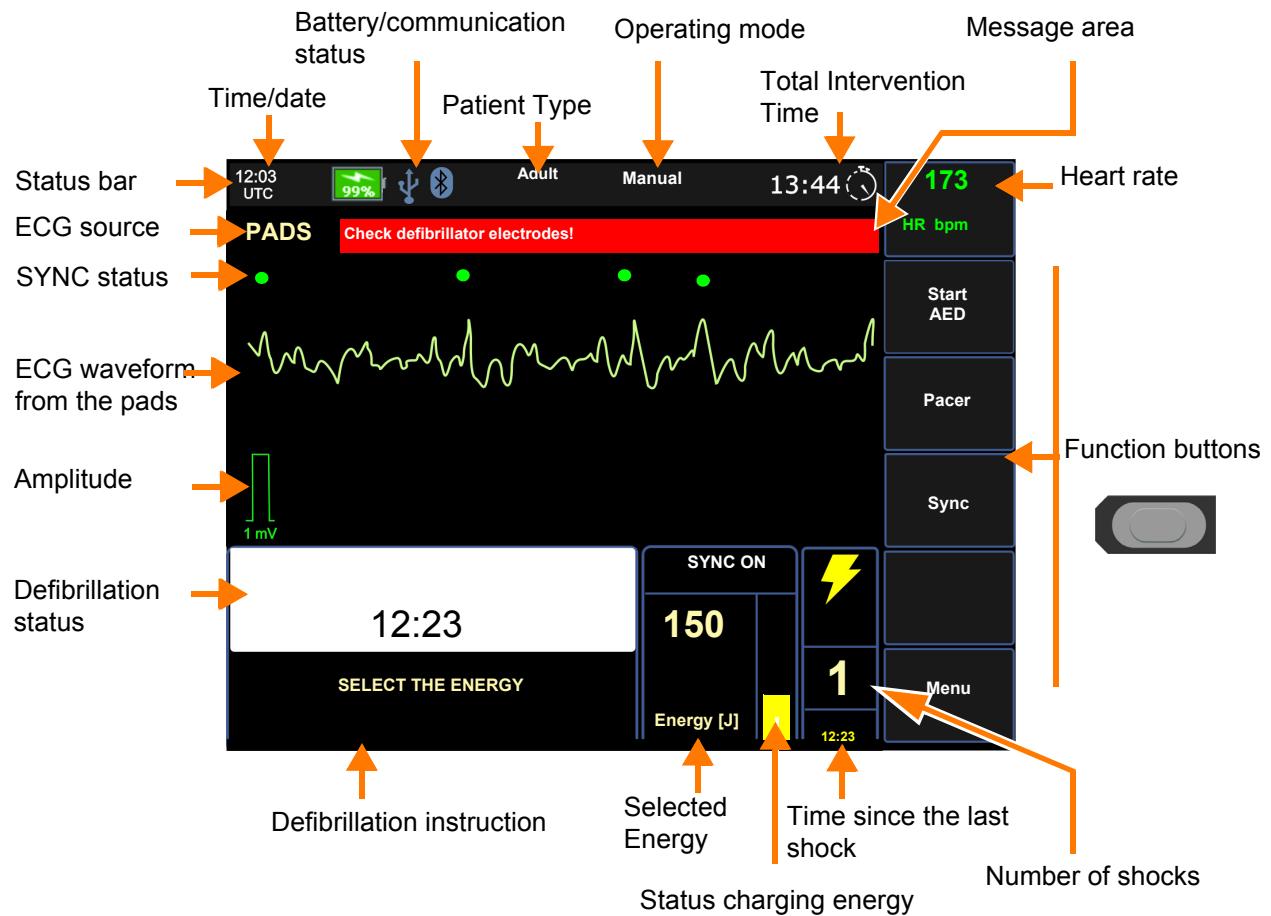


- The **Tempus LS** works with biphasic truncated exponential chopped defibrillation waveform impulses. Depending on the factory settings, the device either switches automatically from synchronised to non-synchronised defibrillation or the mode has to be changed manually using the **Sync** button.
- 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

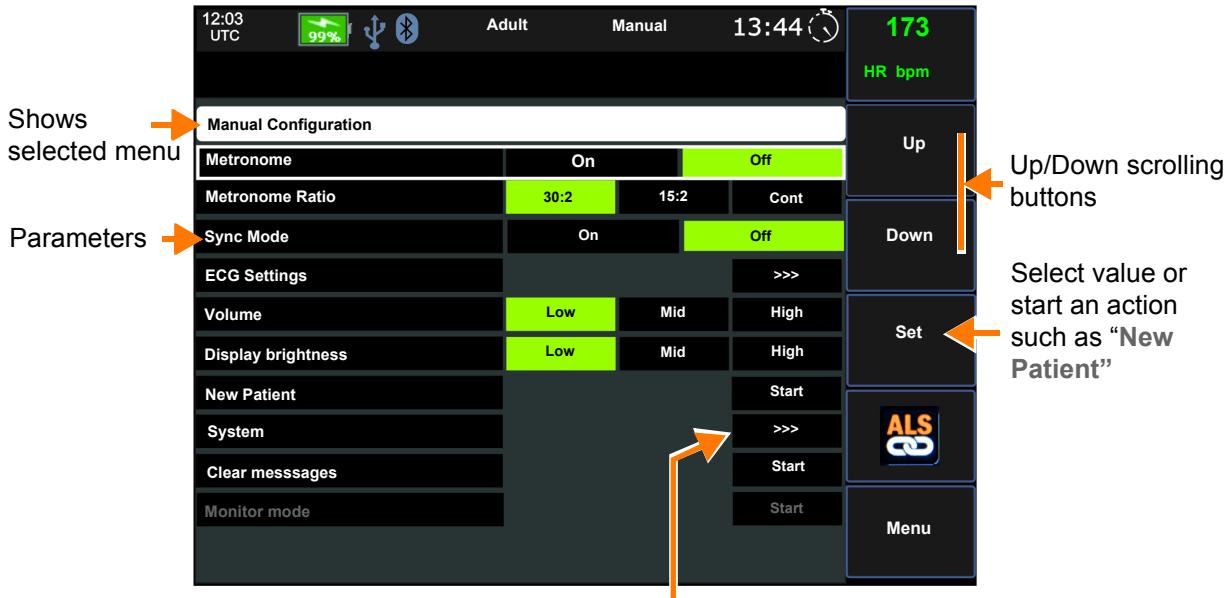
Adults	Paediatric
150 joules	90 joules

3.1.4 Home screen Manual defibrillation mode



Menu

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



The Symbol >>> opens a sub menu if selected and confirmed with SET function button

Menu Structure

Mode	Parameter	Sub-Menu >>>/Function
Manual	Metronome Metronome Ratio Sync mode Volume Display brightness	ECG Settings >>> New Patient System >>>

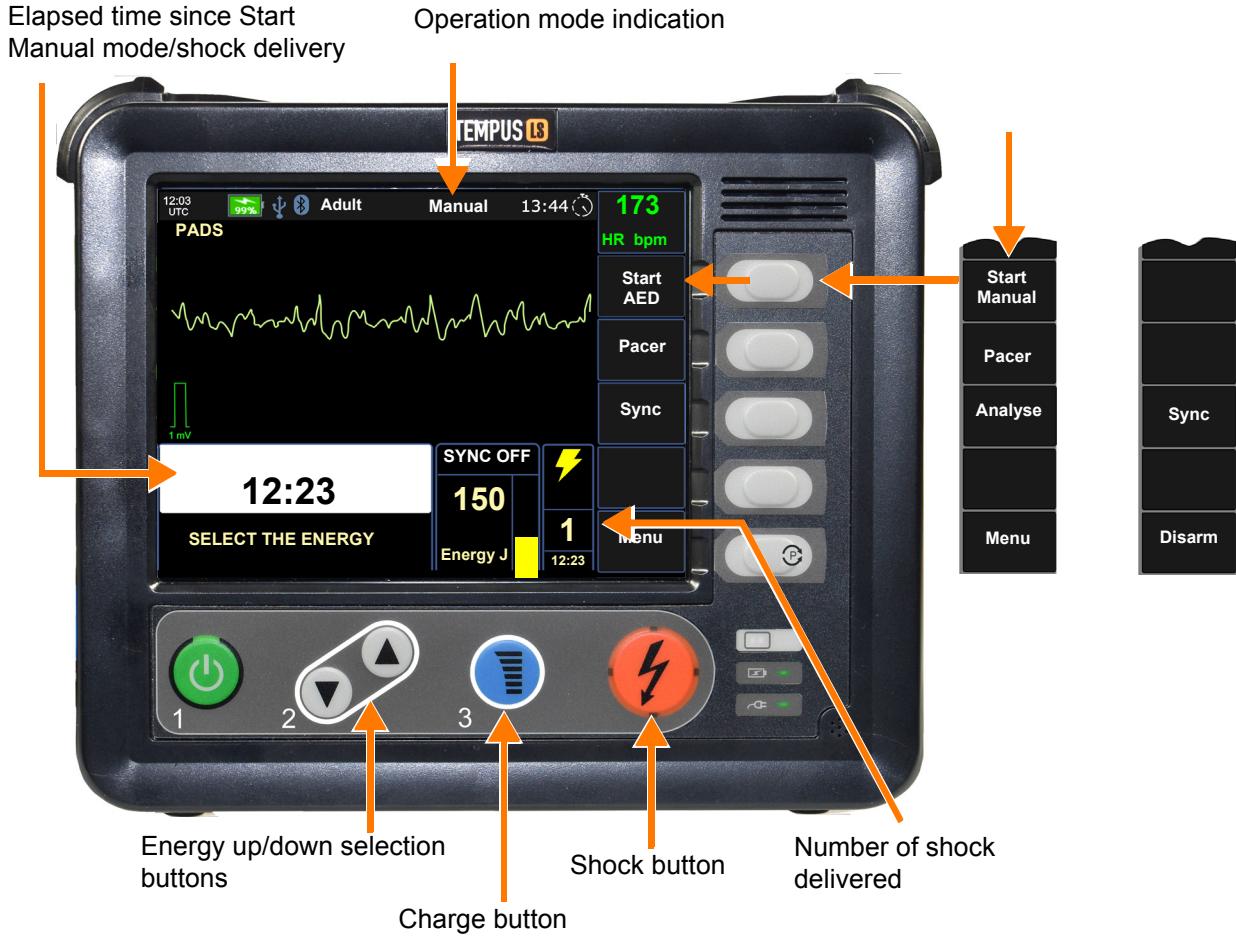
3.1.5 Initial operation **MANUAL (Defibrillation) Mode**

- Buttons Energy selection and Charge (see below) are activated (illuminated by white LED ring)
- Function button for synchronised defibrillation (SYNC ON/OFF) is available or selectable in the menu.
- Functions button 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. The Energy and Charge button lights up. The operating mode indication shows “Manual”.



3.1.5.2 Manual defibrillation procedure

1. Select manual defibrillation.
2. Select the required energy with the  button.
3. Charge the energy using the  button. The energy charging is indicated by the yellow progress bar, the lights around the shock key and audible beep. You can stop and discharge the energy anytime by pressing the displayed “Disarm” function key.
4. As soon the shock button is completely illuminated and charged tone sounds, release the shock with  button on the device.

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 paediatric electrodes



CAUTION

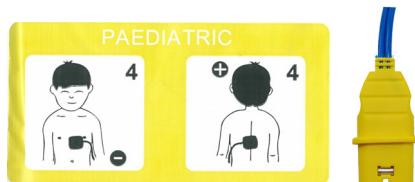
- ▲ Only use the pads up to their expiration date. Please note that the indicated expiration date only applies if the vacuum pack is intact.
- ② ▲ The pads are pre-gelled, so there is no need to use extra contact agent.
- ▲ Do **not** reuse the pads.

Adult electrodes



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

Paediatric electrodes



The paediatric electrodes with the yellow connector are used for children weighing less than 25 kg. When paediatric pads are connected the energy reverts to the default paediatric energy, which may be less than 90J.

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.

Adults and children more than 25 kg

Electrode placement is the same for adults and children weighing 25 kg or more (see [Fig. 3.3 Adult electrode application site](#) and [Fig. 3.4 Application sites for children more than 25 kg](#)).

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).
3. Apply the other electrode slantwise below the left breast as illustrated in [Fig. 3.3 Adult electrode application site](#)/[Fig. 3.4 Application sites for children more than 25 kg](#).
4. Make sure that the connections are positioned on the outside so that the cables do not hinder cardiopulmonary resuscitation (CPR).

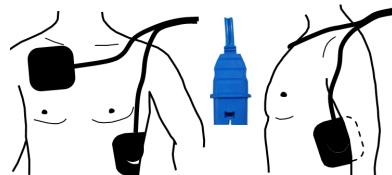


Fig. 3.3 Adult electrode application site

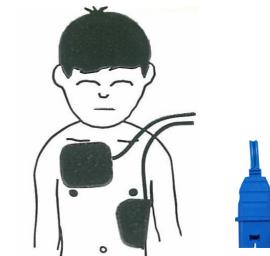


Fig. 3.4 Application sites for children more than 25 kg

Children weighing less than 25 kg

The energy setting is automatically reduced with the Paediatric electrodes.

1. Clean and dry the application points for the electrodes (see [Fig. 3.5 Application sites for children less than 25 kg](#)). 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. 3.5 Application sites for children less than 25 kg](#)
3. Apply the second electrode on the back on the same level as the chest electrode as illustrated in [Fig. 3.5 Application sites for children less than 25 kg](#).
4. Make sure that the connections are positioned on the outside so that the cables do not hinder cardiopulmonary resuscitation (CPR).

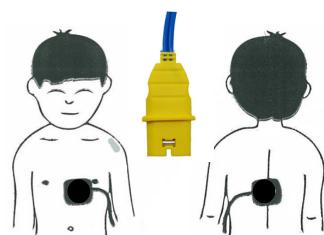


Fig. 3.5 Application sites for children less than 25 kg

3.1.6.3 Manual Defibrillation Using Pads - Procedure

1. Connect the electrode cable to the pads connector.
2. If the device is in **AED**, proceed according to the description in [3.1.5.1 Activating the manual defibrillation mode](#).



Fig. 3.4 Connecting Defibrillation Pads

3. Select the required energy with the button.
4. 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".



DANGER

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

5. As soon the shock button lights up, release the shock by pressing button on the device.
6. Finish the therapy (see [3.3.7 Finishing the therapy](#)).

3.2 Synchronised 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 synchronised with a QRS.

3.2.1 Warning erroneous triggering



WARNING

Erroneous triggering, interpretation hazard:

- ▲ Signal noise may disturb the ECG signal and cause artefacts. This must be considered chiefly in the synchronised 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 artefact
 - there are no major fluctuations in amplitude
 - the displayed trigger pulses are positioned exactly above the R-wave



3.2.2 Setup switching from unsynchronised to synchronised 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 4.2.2 Manual Settings, page 76](#))

Parameter	Value	Description
Auto Sync Enabled	• Yes/No	If set to "Yes" synchronized mode will be activated as soon a QRS trigger is detected.
Sync soft-key	• Yes/No	If set to "Yes" the user can switch between synchronised/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 synchronised defibrillation by pressing the **SYNC ON (1)** function button.

If "Auto Sync Enabled" = Yes

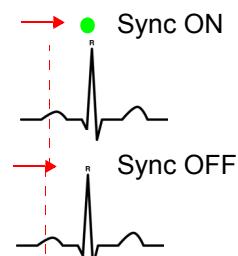
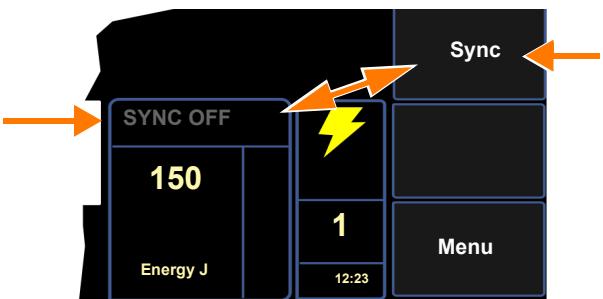
- the Synchronised defibrillation is activated as soon a QRS is detected.


WARNING

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

SYNC modes:

- SYNC OFF
- SYNC ON
- SYNC AUTO



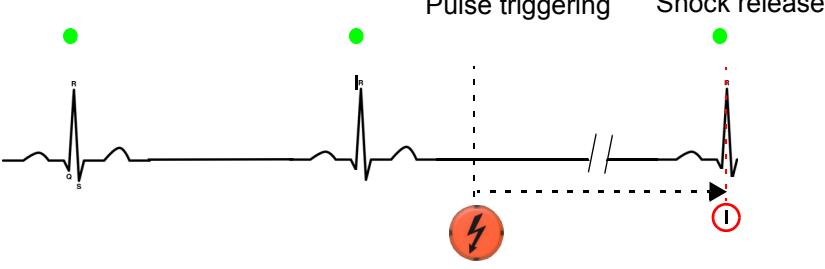
Sync On after shock

Depending on the setup, the synchronised mode stays activated after delivering the shock (SYNC ON after shock = Yes) or switches back to unsynchronised 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 synchronised 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 unsynchronised shock, it is important to deactivate it again.

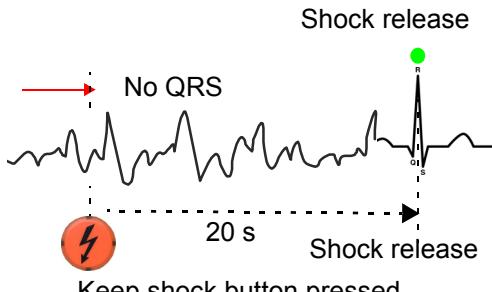
3.2.3 Function of the synchronised defibrillation procedure

 For synchronised defibrillation, the defibrillation shock is delivered in synchronisation 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 25 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.

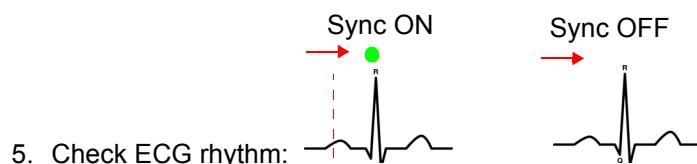


3.2.4 Synchronised defibrillation procedure

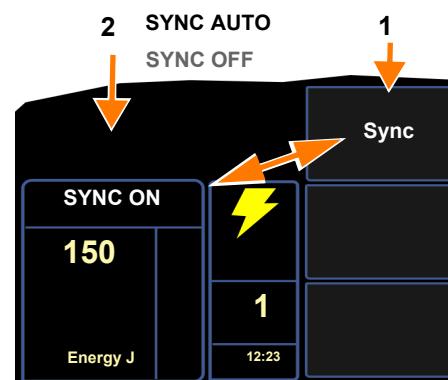


If an unsynchronised shock is required while in synchronised mode, it is possible at any time to switch (1) the synchronised mode to **SYNC OFF** and deliver the shock immediately (unsynchronised).

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 39](#).
3. Select synchronised 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.

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 synchronised 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

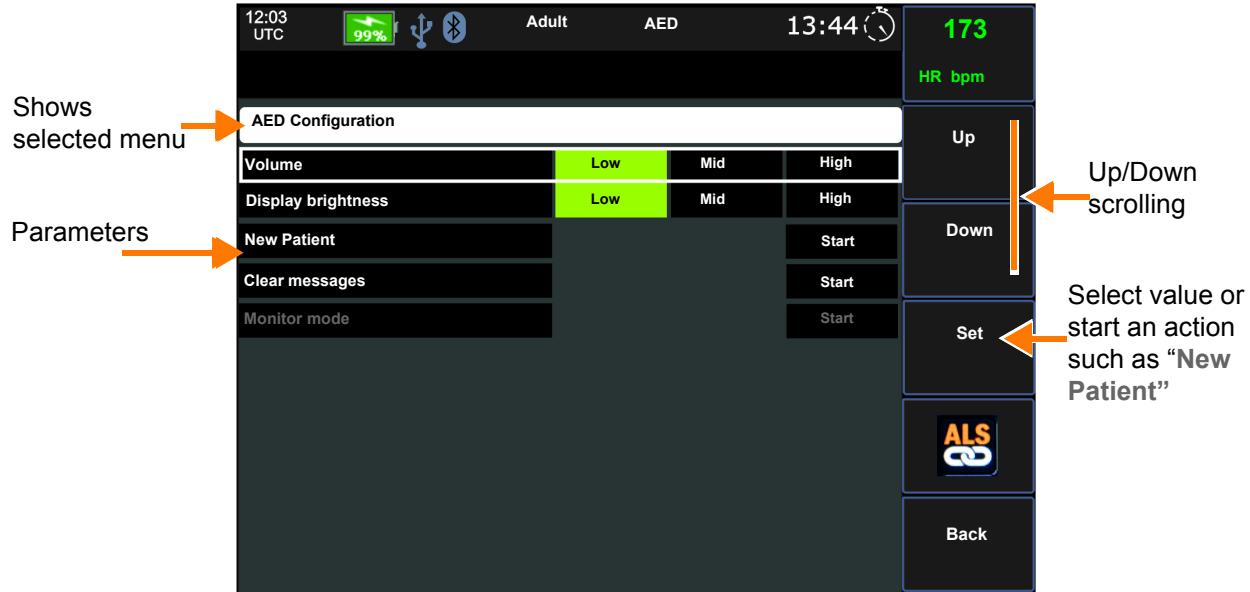
- ▲ The user must verify the prerequisites for the use of the AED by checking for lack of consciousness, lack of breathing and lack of circulatory signs using the ABCD system (BLS algorithm).
- ▲ The device must only be used if the following symptoms are found:
 - non-responsive
 - no respiration
 - 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 artefacts may otherwise lead to incorrect analysis results.
- ▲ If the ECG signal changes such that the shock is not recommended, the shock delivery is automatically blocked in the AED mode.

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	New Patient Clear messages

3.3.3 Initial operation AED Mode

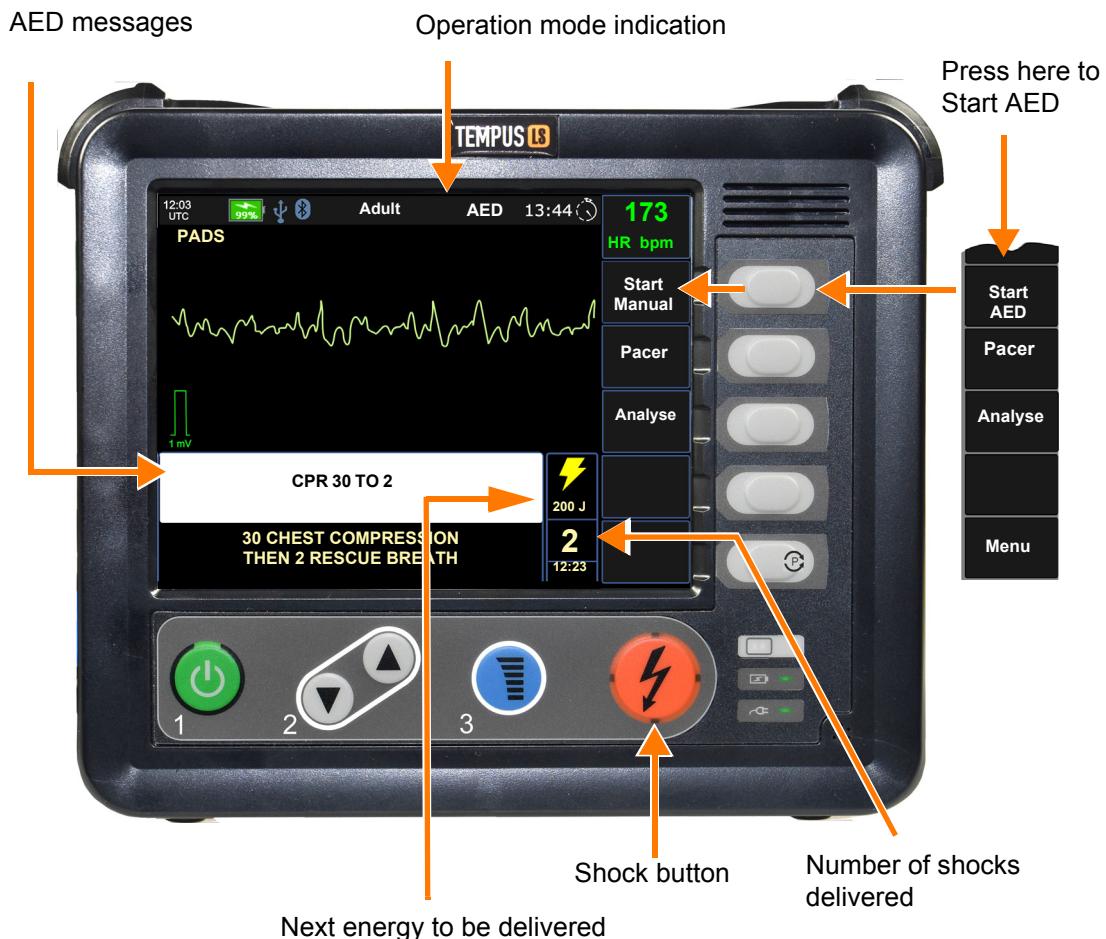
- Select energy button  and charge button  are deactivated
- Function button “Analyse” is available
- Functions button to select MANUAL or PACER mode. The accessibility of the pacer mode can be configured in the maintenance menu.

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 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.”

3.3.5 Voice messages in AED Mode

The following instructions will be spoken by the device:

Spoken instructions	Display	Note
Plug and Apply Electrodes	Plug and Apply Electrodes	Technical message: ELECTRODES/PATCH DEFAULT. 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; analysing will begin	
Do not touch the patient; analysis	Do not touch the patient; analysing	
Movement detected - Analysis cancelled, resume CPR	Movement detected - Analysis cancelled, resume CPR	Technical message: Patient was moved during analysis and device could not run analysis.
Device recommends a shock		
Shock advised		
Stand clear of patient; press orange button	Stand clear of patient, press orange button TO SHOCK	
Device does not recommend a shock		
No shock advised	No shock advised.	
Immediately resume CPR: 30 chest compressions, then 2 rescue breaths – continue until patient is breathing normally.	30 ¹ CHEST COMPRESSIONS THEN 2 RESCUE BREATHS	

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

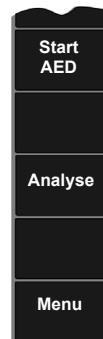
3.3.6 AED defibrillation procedure

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.
5. You are prompted to continue the resuscitation and to apply the electrodes.
6. Apply the defibrillation electrodes (see section [3.1.6.1 Applying the adult and paediatric 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 paediatric electrodes](#)



Step 2

Analysis

7. The analysis starts automatically when the electrodes are detected.
8. 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.

9. 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	Paediatric
1	150 joules	90 joules
2	150 joules	90 joules
from 3	150 joules	90 joules

Step 4

Cardiopulmonary resuscitation

10. Carry out cardiopulmonary resuscitation. Alternate between 30 chest compressions and 2 breaths¹ for 2 minutes². After 2 minutes, the device begins again with [Step 2, Analysis](#).

11. 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 cycle configuration" settings.

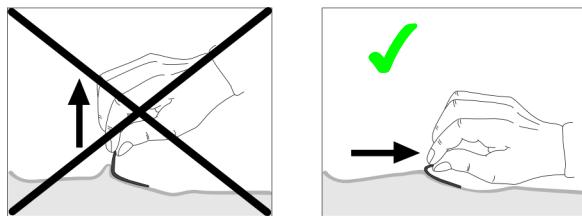
3.3.7 Finishing the therapy

1. Switch the device off as soon as the therapy is finished by pressing and holding for two seconds the 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 [5.4 Cleaning](#).

3.4 Pacemaker Function

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

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

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

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

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.

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.

3.4.1.3 Overdrive mode

 In the overdrive mode, the pacer will operate at three times the selected rate.

This operating mode 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.

3.4.2 Safety notes



WARNING

▲ Shock hazard

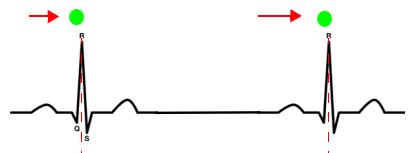
Never touch the pads or the patient's body near the pads while the pacemaker is in use.

▲ Disturbed ECG trigger signal! Signal noise may disturb the ECG signal and cause artefacts. 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 artefact
- there are no major fluctuations in amplitude
- the displayed trigger pulses are positioned exactly 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 authorised 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 authorised staff.
- ▲ Observe the user guide for the pacemaker's operation.
- ▲ The patient must not be left unattended during pacing.
- ▲ It is assumed that the patient's ECG 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.

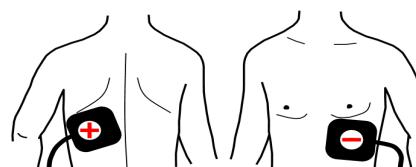
3.4.3.4 Attaching the pacer pads



- 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
 - 10 minutes of pacing using maximum energy and frequency output (150mA / 210 bpm)
 - A detailed application of electrodes is given in section [3.1.6.1 Applying the adult and paediatric electrodes](#).

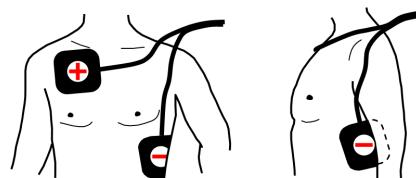
Anterior-posterior placement

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.



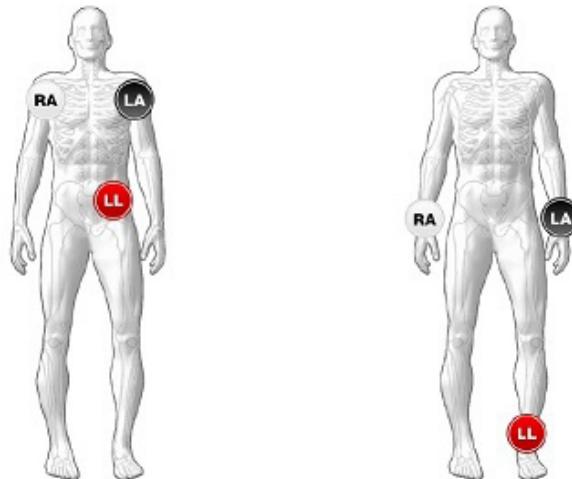
Anterior-anterior placement

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

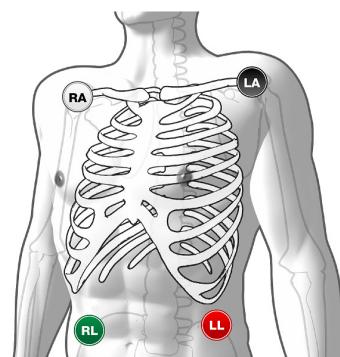
- Attach the electrodes to the patient using AAMI or IEC cables.



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.

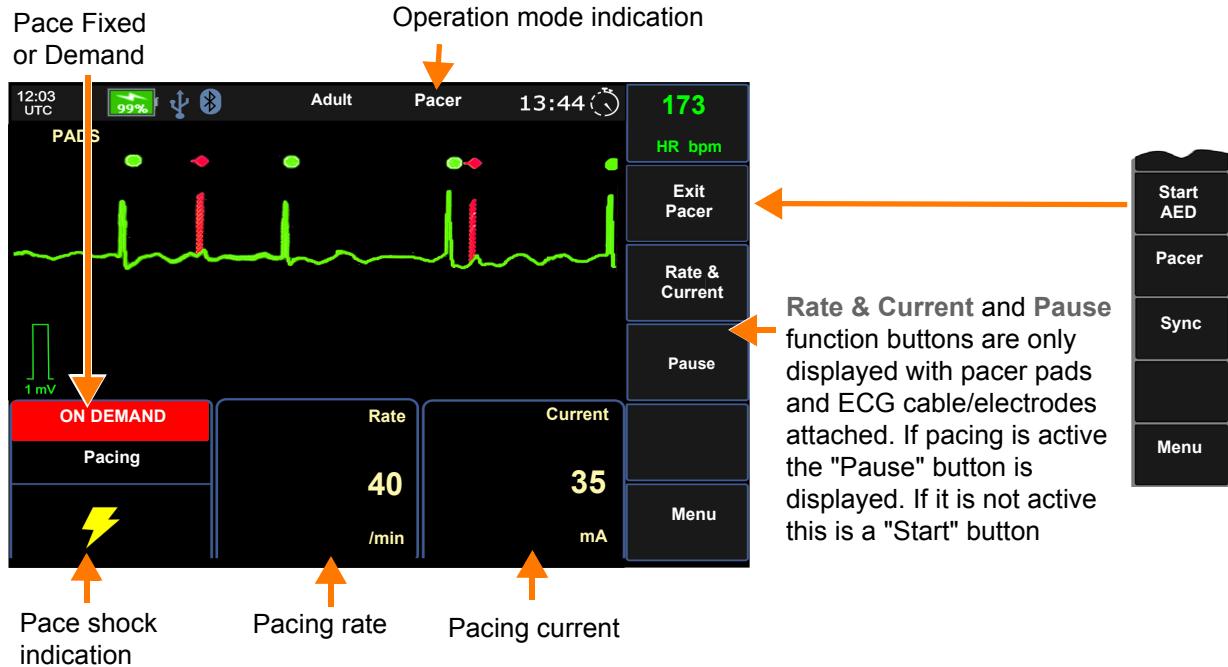


In order to be able to operate the pacemaker, the following conditions must be met:

- 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

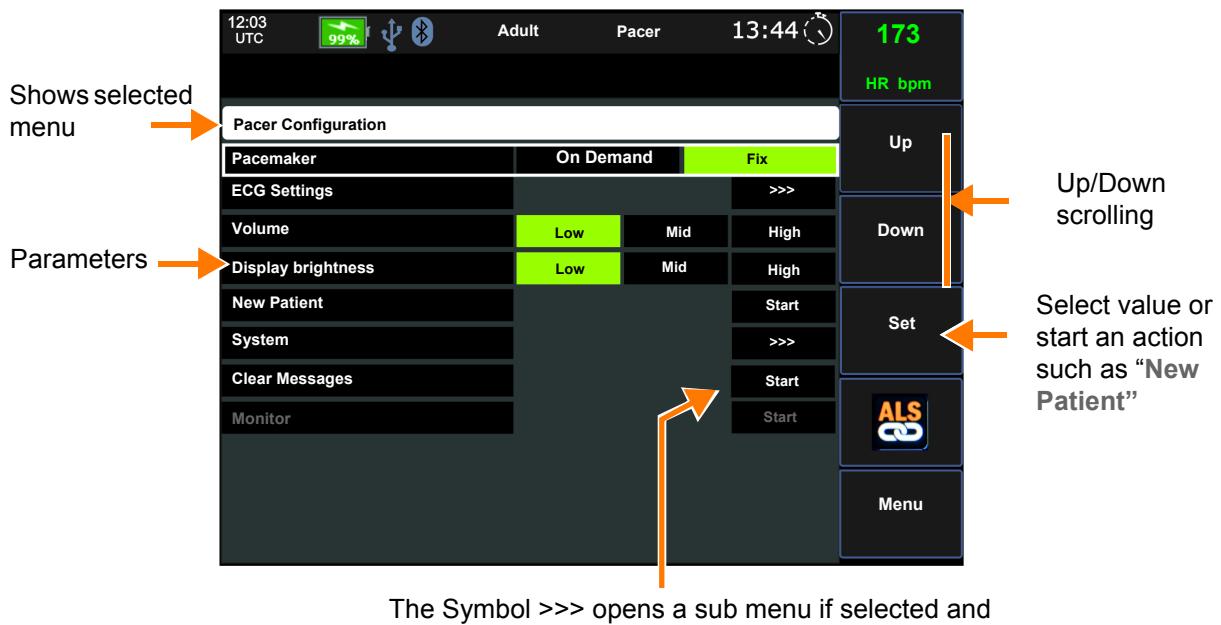
Select the function button **PACER** to display the pacemaker function.



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.

Menu

The screen below shows the parameters available for Pacemaker mode.



Menu Structure

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

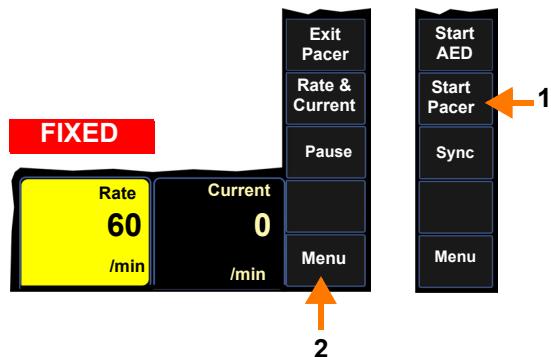
3.4.8 Initial operation pacemaker

PACER Mode

- 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.

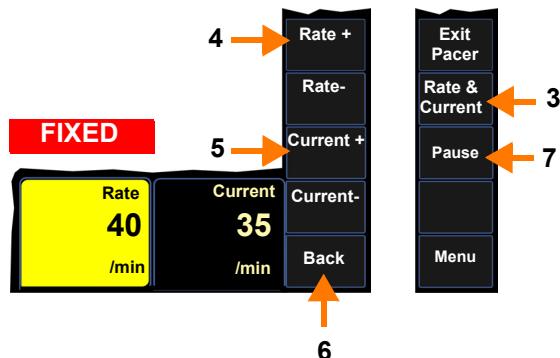
3.4.9 Selecting pacemaker mode Fix or Demand

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.



3.4.9.5 Pacemaker settings operational mode fix

1. Attach the pacer pads (see page 58).
2. Attach ECG patient cable (see page 59 or page 66).
3. Display pacemaker and select operational mode Fix.
4. Press the function button Rate & Current (3).
5. Select Rate +- (4) to set the impulse frequency.



WARNING

▲ Shock hazard

Pacing is started immediately when the pacemaker is switched ON and the current is set.

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

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).

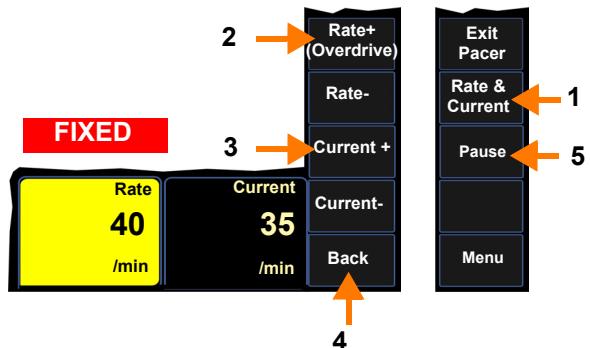
9. Finish the therapy as described in section 3.3.7 Finishing the therapy, page 55.

3.4.9.6 Overdrive Mode



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 58](#)).
2. Attach ECG patient cable (see [page 59](#) or [page 66](#)).
3. Display pacemaker and select operational mode Fix.
4. Press the function button Rate & Current (1) .
5. Select Rate + (Overdrive) (2) to set the impulse frequency.



WARNING

▲ Shock hazard

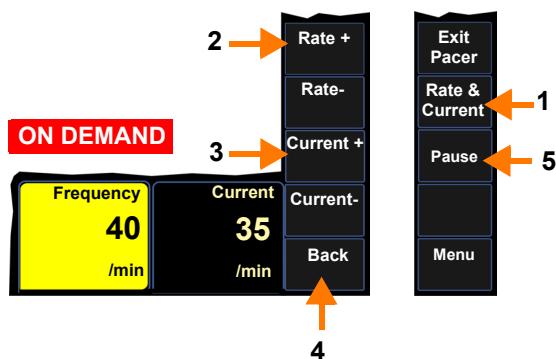
Pacing is started immediately when the pacemaker is switched ON and the current is set.

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

6. **Starting the pacemaker**
Press the Current + (3) to set the impulse current until the heart reacts to the stimulation.
7. **Press and hold the Rate + (Overdrive) (2) key** until the heart has reached the pacemaker's rate. With this function, the set frequency is multiplied by the factor 3.
8. Release the Rate + (Overdrive) (2) key. The heart should continue to beat with a normal heart rate
9. Exit the setting with the Back function button (4).
10. The pacemaker can be interrupted and restarted by selecting the Pause function button (5).
11. Finish the therapy as described in section [3.3.7 Finishing the therapy](#).

3.4.9.7 Pacemaker settings operational mode Demand

1. Attach the pacer pads (see [page 58](#)).
2. Attach ECG patient cable (see [page 59](#) or [page 66](#)).
3. Display pacemaker and select operational mode Demand
4. Press the function button Rate & Current (1).
5. Select Rate +- (2) to set the impulse frequency.



! WARNING

▲ **Shock hazard!**

Pacing is started immediately when the pacemaker is switched ON and the current is set.

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

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](#).

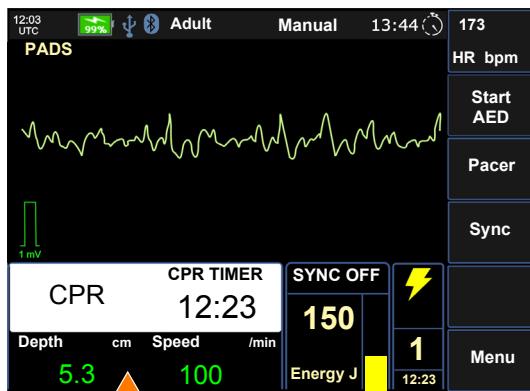
3.5 CPR feedback



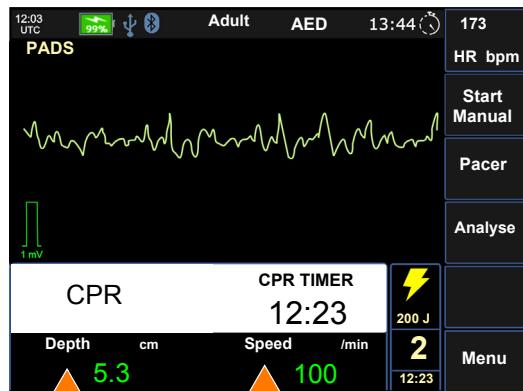
The manual and AED defibrillation mode offers a function for a guided CPR with the LifePoint sensor.

3.5.1 LifePoint

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

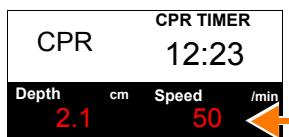


Advice to improve the CPR quality:



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

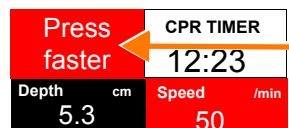
Display of CPR quality in Manual and AED mode:



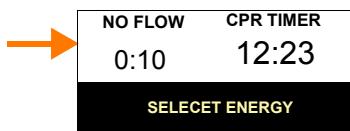
Values out of range are displayed red.



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.

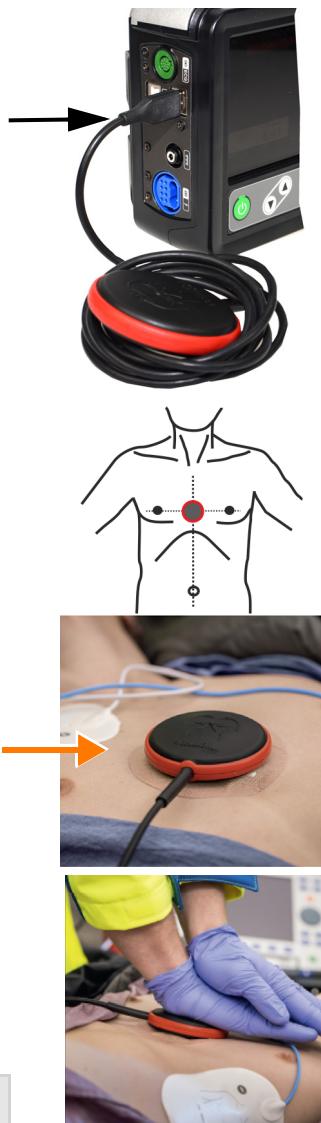


If CPR is stopped, "NO FLOW" and an up counting timer are displayed and advice is given:

- "Select Energy" in manual mode
- "Perform CPR: 30 Chest compressions then 2 rescue breaths" in AED mode.

3.5.2 Setup of the Lifepoint sensor

1. Switch on the device and select manual or AED defibrillation. The CPR values in AED mode are first displayed during CPR advice.
2. Connect the LifePoint USB cable to the Tempus LS USB connector.
3. Attach the adhesive pad to secure the sensor on the patient's chest.
4. Place the LifePoint on adhesive pad and start CPR.
5. The displayed measurements at the bottom of the screen inform you about your CPR quality (see page before)



The following limits are set by default for speed and depth. These settings can be adjusted by the administrator.

Compression rate per minute [/min]	Press faster	Press slower
100	≤ 90	≥ 120
Depth [cm]	Press harder	Press softer
1-12.7	≤ 4.5	≥ 6.2

Chapter 4

System settings

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

4.1 Overview settings

4.1.1 Overview settings in the operating modes

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

Mode	Menu >>/Parameter	Function/see details
Manual	• Metronome	see page 71
	• Metronome Ratio	
	• Sync mode	
	• ECG Settings >>	see page 72
	• Volume	see page 71
	• Display brightness	
	• New Patient	Start
	• System >>	see page 73
	• Clear messages	Start
AED	• Volume	see page 72
	• Display brightness	
	• New Patient	Start
	• Clear messages	Start
Pacer	• Pacer mode	see page 72
	• ECG Settings >>	see page 72
	• Volume	see page 72
	• Display brightness	
	• New Patient	Start
	• System >>	see page 73
	• Clear messages	Start

4.1.2 User settings manual mode



User setting 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 72
Volume	Low /Mid/High	Select the volume above the environmental noise
Display brightness	Low /Mid/High	--
New Patient	Start	
System >>	>>	see page 73
Clear messages	Start	Clears messages displayed in the status line

4.1.3 User settings AED mode

	User setting are automatic stored Default values are bold
---	---

Parameter	Value	Description
Volume	Low/Mid/High	Select the volume above the environmental noise
Display brightness	Low/Mid/High	---
New Patient	Start	
Clear message	Start	Clears messages displayed in the status line

4.1.4 User settings Pacer

	User setting are automatic stored Default values are bold
---	---

Menu>>/Parameter	Value	Description
Pacemaker mode	<ul style="list-style-type: none"> • On Demand • Fix 	
ECG Setting	>>	see below 4.1.5
Volume	Low/Mid/High	Select the volume above the environmental noise
Display brightness	Low/Mid/High	---
New Patient	Start	
Clear message	Start	Clears messages displayed in the status line

4.1.5 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	--

4.2 System and Maintenance settings



All System and maintenance 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/Default Settings Storage >>> Store Defaults”

System Menu	Sub-Menu >>>	Sub-Sub Menu >>>/ Parameter	Description
System >>>	<i>Intervention Management >>></i>	<ul style="list-style-type: none"> • 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. <ul style="list-style-type: none"> • Start • Start • Start • Start • Showing storage capacity in %
	<i>Device info >>></i>	<ul style="list-style-type: none"> • S/N • SW Version • HW Version • SW Version Defi • HW Version Defi • Address • UFN • Battery info (Sub-menu) • ECG cable info • ECG cable smalest dev. 	<ul style="list-style-type: none"> • Series number • Software version • Hardware version Defi • Software version Defi • Hardware version Defi • MAC Address • User Friendly name (Mac Address + Tempus LS) • Various information: <ul style="list-style-type: none"> – Full charge capacity – Battery version – Actual voltage – Actual charge – Current now – Temperature

continue next page

System Menu	Sub-Menu/Parameter	Sub-Sub Menu >>/Parameter	Description
System >>	Maintenance Settings >>	<i>This menu is only accessible with the passkey</i>	Enter the 4 digit passkey
		Organisation identification >>	Add here the information to assign the device to an organisation /user
		Main Filter	OFF/50 Hz/ 60 Hz
		AED Settings >>	See detail 4.2.1 AED Settings
		Manual Settings >>	See detail 4.2.2 Manual Settings
		Pacer Settings >>	See detail 4.2.3 Pacer Settings
		CPR Feedback Setting >>	See detail 4.2.4 CPR Feedback Settings
		Print/Event settings >>	See detail 4.2.5 Print/Event Settings
		System Settings >>	See detail 4.2.6 System Settings
		Default Settings Storage >>	See detail 4.2.7 Default setting storage
		Log file export (Start)	<ul style="list-style-type: none"> • Export log file to USB memory stick.

4.2.1 AED Settings

Default values are bold

Menu>>/Parameter	Parameter	Value	Description
AED Energies >>	<ul style="list-style-type: none"> Energy adult 1. shock Energy adult 2. shock Energy adult 3. shock Energy paediatric 1. shock Energy paediatric 2. shock Energy paediatric 3. shock 	<ul style="list-style-type: none"> 150 Joule 150 Joule 150 Joule 90 Joule 90 Joule 90 Joule 	These are configurable based on local guidelines.
Analyse Key		<ul style="list-style-type: none"> Yes/No 	--
Start Metronome by default		<ul style="list-style-type: none"> On/Off 	--
Voice prompts on		<ul style="list-style-type: none"> Yes/No 	--

4.2.2 Manual Settings


WARNING

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

Parameter	Value	Description
Default Energy Adult	<ul style="list-style-type: none"> • 150 Joule 	Preset of defibrillation energy when starting device with adult electrodes connected.
Default Energy Paediatric	<ul style="list-style-type: none"> • 90 Joule 	Preset of defibrillation energy when starting device with paediatric electrodes connected.
Auto Sync Enabled	<ul style="list-style-type: none"> • 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 unsynchronised to synchronised mode
Sync soft-key	<ul style="list-style-type: none"> • Yes/No 	If set to "Yes" the user can switch between synchronised/direct defibrillation If "No" is selected the Sync mode can be activated only via the manual configuration menu.
SYNC ON after shock	<ul style="list-style-type: none"> • 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"
Start metronome default	<ul style="list-style-type: none"> • On/off 	If set to "Yes" the metronome is started as soon Manual mode is ready.
Metronome ratio default	<ul style="list-style-type: none"> • 30:2/15:2/Cont 	<ul style="list-style-type: none"> • 30:2 for adult • 15:2 for children • Without rescue breath choose Continuous

4.2.3 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 labelled with the function "Overdrive".
Default Pacer Rate	60 p/m	Selecting of the default pacer rate at start. 40/50/ 60 /70/80...210 pulse/minute
Pacer Key in AED	Yes/No	Pacer key will be displayed in AEDF 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

4.2.4 CPR Feedback Settings



cpm = compressions per minute

Parameter	Value	Description
Rate limit upper (cpm)	120	see section 3.5
Rate limit lower (cpm)	90	see section 3.5
Depth limit upper (mm)	60	see section 3.5
Depth limit lower (mm)	45	see section 3.5
User feedback delay (sec)	15	Delay time till a new feedback is displayed
Average rate max cpr	5	Number of measurements to calculate the average cpr rate.

4.2.5 Print/Event Settings

Parameter	Value	Description
Print on shock	Yes/No	-
Print on No shock advised	Yes/No	-
Print on start pacing	Yes/No	-

4.2.6 System Settings

Menu	Sub-menu >>/Parameter	Value/Description
	QRS marker default	Yes/no
Ready to use Settings	Do self tests	Starts all tests below.
	Do relay test Do IGBT test Do battery test Do capacitor test	Starts individual single test.
Default System Settings	Start up view	AED/Manual
	Default display brightness	Low/Mid/High
	Default loudspeaker volume	Low/Mid/High
	Default ECG amplitude (mm/mV)	5/ 10 /20 mm/mV
	Default ECG speed (mm/s)	12.5/ 25 /50 mm/s
Date, Time, Timezone	Time format	12h/ 24h
	Time hour/minutes	Set time
	Date day/ month, year	Set date
	Timezone >>	Set timezones
Licence Key		Showing licence key
Software Installation	---	--
Maintenance Passkey	---	user
Service Settings	Log File reset	Deleting the log file
	AED Service Setting >>	-----

4.2.7 Default setting 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
• 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.

Chapter 5 **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.

5.1 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.

5.1.1 Maintenance interval table

Interval	Maintenance	Responsible
Before or after each use, respectively	<p><i>Life-saving functions - check the following:</i></p> <ul style="list-style-type: none"> • Visual inspection of the device and accessories (see section 5.2.1) • Switch on the device and make sure that batteries are sufficiently charged (see section 5.2.3). <p><i>After every intervention</i></p> <ul style="list-style-type: none"> • Visual inspection of the device and accessories (see section 5.2.1). • Battery check (see section 5.2.3) • Button test (see sections 5.2.4) 	User
Every 12 months	<ul style="list-style-type: none"> – Measuring and safety checks and inspections according to the instructions in the maintenance manual – Defibrillator function check 	Service staff authorised by RDT
Limited life item replacement	<p><i>The following parts must be checked and replaced if necessary</i></p> <ul style="list-style-type: none"> • Replace the power battery, see section 5.3.1. • Replace the hot swap, see section 5.3.1. • 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

5.1.2 Service/Shelf life

Device

The device has a service life of 10 years.

Accessories shelf life

- Power battery (approx. 5 years)
- Button cell (approx. 10 years)
- Electrodes (approx. 2 years), see expiry date on the battery or electrodes pouch.

5.2 Functional test

A detailed description of the maintenance steps is listed in table 5.1.1. Enter the results in the check list in the section 5.5.

5.2.1 Visual inspection of the device and accessories

Check the device and accessories for the following:

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



WARNING

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

5.2.2 Self test

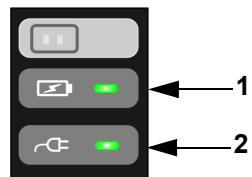


The device has an integrated self test. During this test the relay, battery and defibrillation capacitor are tested.

This test can be executed only in the menu **Manual configuration/System/Do Self Tests**. The results are displayed in the message area.

5.2.3 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 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. Spare battery check see [page 30](#).

5.2.4 Defibrillator key test

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 - a safety discharge is triggered.
6. Press the Start AED button - spoken instructions are issued.



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

5.2.5 Defibrillation 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. Select the required energy 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 and the defi 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.

5.3 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 according the expired date on the battery, regardless of whether or not the unit has been used.
- If a battery is not used, recharge it every 6 months.
- Recommendation: Store the battery with a state of charge between 50-70%.
- Check battery contacts for corrosion.

5.3.1 Replacing the batteries

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.

5.3.2 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.

5.4 Cleaning



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

5.4.1 Cleaning agents

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

Recommended cleaning agents

- 50 % isopropyl alcohol
- 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

5.4.2 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 sterilise them!
- ▲ Do not apply tension to the sensor cable.
- ▲ Do not use aggressive cleaners.
- ▲ Do not use any phenol-based agents or peroxide compounds for cleaning.
- ▲ Observe the manufacturer's notes when cleaning the sensors and cables.

1. Disconnect the device from the mains and remove the plug and sensors.
2. Wipe the equipment, with a dampened cloth and a mild cleaning solution see [section 5.4.1 Cleaning agents, page 87](#).
3. Dispose of single-use pads and protective coverings according to the relevant regulations.

5.4.3 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.

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



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

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

5.5 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 5.2.1).
- Battery charging status (see section 5.2.3).
- Button test (see sections 5.2.4)

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	20	30	31
	Jan.																																
	Feb																																
	Mar																																
	April																																
	May																																
	Jun																																
	July																																
	Aug																																
	Sep																																
	Oct.																																
	Nov																																
	Dec																																

5.5.1 Every 12 months

Inspection	Results	Inspection			
<i>Functional, safety checks and inspections</i>	Return the unit to your nearest authorised service point or your RDT agent for safety and functional checks.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Confirm the date of the last factory inspections and tests	Date of inspection:				
	Inspector:				

5.5.2 Limited life item replacement every 5 - 10 years

Inspection	Results	Replaced			
Battery	The battery needs to be replaced:				
Replace battery	when the “Full Charge Capacity” is less than 4000, see section 5.3.1 .	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Replace the internal button primary cell (every 10 years)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Date of inspection:				
	Inspector:				
Defibrillation capacitor	Send the unit to your nearest RDT service centre for capacitor replacement if the defibrillation capacitor deviates more than 15 % [joule] from the intended value.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Date of inspection:				
	Inspector:				

5.6 Error detection

	Forced shutdown procedure If it is not possible to get the device back into the normal operating condition, follow this procedure:
	<ul style="list-style-type: none"> 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.

5.6.1 General errors

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
No analysis	The device is defective	→ Perform cardiac massage again
	ECG signal interference through electromagnetic waves	→ Turn off source of signal interference. e.g. radio equipment or cell phone, or move patient outside field of interference
	ECG signal too weak	→ Do not move or touch patient during analysis
	Patient moved or touched during analysis	→ Replace device
Unable to deliver shock	Battery too low	→ Change batteries
	Electrode error caused by resuscitation measures	→ Reapply electrode
	Heart rhythm has changed	→ Run new analysis
	The device is defective	→ Replace device
Battery is not being charged	Temperature in the device or battery too high	→ Let device cool down, if possible; charging is continued once the temperature has reached an acceptable level.

5.7 Preventing electromagnetic interferences



The user can help avoid electromagnetic disturbances by keeping the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the **Tempus LS**. The distance depends on the output performance of the communication device as indicated below.

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	704-707	710/745/780	0.2	0.3
- GSM800/900 - LTE band 5 - Radio telephone (microcellular) 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 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.

5.7.1 Measures to prevent electromagnetic interference

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

- Increase distance to the source of interference.
- Turn the device to change the angle of radiation.
- Connect the device to a different mains connector.
- Only use original accessories (especially patient cables).
- 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 [5.1 Maintenance interval](#).

5.8 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.

5.8.1 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. <ul style="list-style-type: none"> • 100 - 240 VAC, max. 2.0 A, 50-60 Hz • 12 VDC, max. 5 A, 60 W 	01-2049
3P 2 m Power cable Schuko	Re-order code 01-2057
3P 2 m 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

Chapter 6

Specification and standards

6.1 Physical characteristics and environmental specifications

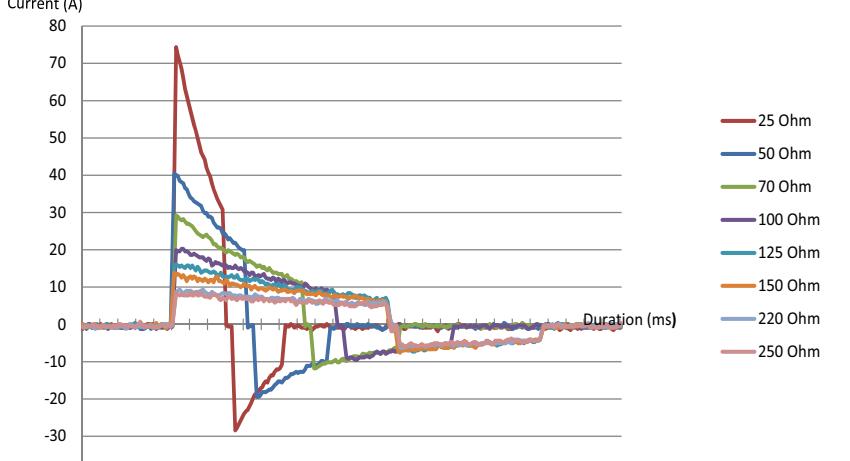
 Data refer to standard testing conditions.
Device name Tempus LS
Dimensions 200 x 164 x 72 mm (height x length x width)
Weight 1.95 kg with battery (without accessories)
Protection case IP 55 The device is protected against dust and water. Water projected from jets against the enclosure from any direction shall have no harmful effects.
Power supply AC/DC Input • 100 - 240 VAC, max. 2.0 A, 50-60 Hz output • 12 VDC, max. 5 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.
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
Environmental conditions For operation • -5 °C ... 50 °C relative humidity at 15 - 95 % (non-condensing) Atmospheric pressure 540...1060 hPa (5000 m/16404 ft) For transient operation • -20 °C ... 50 °C according to IEC 60601-1-12 For storage and transport • -40 °C ... 75 °C relative humidity at 0 - 95 % (non-condensing) Atmospheric pressure 500...1200hPa
Environmental conditions Defibrillation electrodes Storage • 0 °C...50 °C Storage max. 10 days • -40 °C...75 °C
Display Type • LCD colour with back-light, protected by tempered glass Dimensions • 116 x 87 mm
Signal sound level 85 dBA

Connections	<ul style="list-style-type: none">• Defibrillation -Pads, Paddle/Spoon• ECG - patient cable• DC power supply
Interfaces	<ul style="list-style-type: none">• USB• Bluetooth
Memory	> 100 hours memory (FIFO) Recording of Defi, ECG Lead I, II, III, Events, CPR feedback, patient data
EMC	<ul style="list-style-type: none">• IEC/EN 60601-1-2: 2014, 4th Edition• IEC/EN 60601-2-4: 2010 EMC part §202• CISPR 11: 2105; class B <p>The device can be exposed to the following source of interference without impairment of the essential performance:</p> <ul style="list-style-type: none">• Static discharges up to 15 kV• Field strength up to 20 V/m in the radio frequency range of (80...2500 MHz, 5 Hz modulated)• Magnetic fields of 100 A/m, 50 Hz

6.2 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: 2014, 3th Edition, Electrical safety <ul style="list-style-type: none"> • 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	IEC/EN 60601-2-25 The device is designed for intensive use
Requirements for medical electrical systems used in the home healthcare environment	IEC 60601-1-11
Ingress protection	IP 55 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 ISO 7137, June01, 1995, reference No. 3.7

6.3 Defibrillation Waveform

Form	<ul style="list-style-type: none"> Biphasic truncated exponential waveform Maintains the energy delivered to the patient at an approximately constant level with regard to patient resistance  <p>The graph plots Current (A) on the y-axis (ranging from -30 to 80) against Duration (ms) on the x-axis. Multiple curves are shown for different impedances: 25 Ohm (red), 50 Ohm (blue), 70 Ohm (green), 100 Ohm (purple), 125 Ohm (teal), 150 Ohm (orange), 220 Ohm (light blue), and 250 Ohm (pink). All curves show a biphasic truncated exponential decay, with higher impedances resulting in lower peak currents.</p>
Standard energy settings <ul style="list-style-type: none"> AED <ul style="list-style-type: none"> – Adult – Paediatric Manual mode <ul style="list-style-type: none"> – Adult – Paediatric 	<p>Deviation at 50Ω: ± 3 J or $\pm 15\%$ (the higher value is assumed)</p> <ul style="list-style-type: none"> • 150/150/150 joules (configurable) • 90/90/90 joules (configurable) <p>automatic selected when adult or paediatric electrodes are connected</p> <ul style="list-style-type: none"> • 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, joules
Charging time for shock in AED mode <ul style="list-style-type: none"> with 12 VDC mains voltage with fully charged battery after 15 discharges with max. energy from switch-on of the device with pads 	<p>(Time used to charge the storage capacitor to the max. energy of 200 J in AED mode)</p> <p>9 seconds</p> <p>9 seconds</p> <p>17 seconds</p>

Charging time for shock in manual model	(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	<ul style="list-style-type: none"> • Synchronised with heart action < 60 ms after R wave • Non synchronised • AED
Charge control and monitoring	<ul style="list-style-type: none"> • 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:	<ul style="list-style-type: none"> • pads removed • 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	<p>Electrode cable, 2 m long</p> <p>Deviating from the compliance statement according to 201.108.1.10 (IEC60601-2-4, 201.1.108.7. and 201.1.108.6), the following features have been measured for the universal electrode:</p>
Adult and Paediatric electrode	<ul style="list-style-type: none"> • 80 cm² active surface

6.3.1 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 recognised as standard in ECG tests. PhysioNet databases are ECG Holter recordings with full diagnostic bandwidth [0.05 - 125] Hz. The bandwidth of the devices that recorded the signals is larger than that of the **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 (\leq 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 artefacts-free MIT-VFDB signals:

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

6.4 Pacemaker

Operating Modes	<ul style="list-style-type: none"> • Demand • Fixed frequency (FIX or Overdrive (impulse frequency x 3))
Stimulation pulse	<p>Form</p> <ul style="list-style-type: none"> • Rectangle mono-phase with constant current source <p>Pulse duration</p> <ul style="list-style-type: none"> • 20 ms ± 5% <p>Pulse rate</p> <ul style="list-style-type: none"> • Configurable in steps of 40, 45, 50, 60, 70 ... 240 bpm ± 1.5% <p>Pulse current</p> <ul style="list-style-type: none"> • Configurable to 0 (pacemaker Off) and then from 10 ...200 mA, ± 10 % or 5 mA (the higher value is applied) <p>Refractory period</p> <ul style="list-style-type: none"> • 340 ms ≤ 80 bpm • 240 ms > 80 bpm <p>Signal connection</p> <ul style="list-style-type: none"> • Type CF, defibrillation-protected >5 kV <p>Readiness for operation</p> <ul style="list-style-type: none"> • Immediately
Pacer electrodes (same as defibrillation electrodes)	<p>Electrode cable, 2 m long</p> <p>Deviating from the compliance statement according to 201.108.1.10 (IEC60601-2-4, 201.1.108.7. and 201.1.108.6), the following features have been measured for the universal electrode:</p>
Adult and Paediatric electrode duration	<p>80 cm² active surface</p> <p>For up to 1 hour of pacing using 140mA / 120 bpm (pulse duration 20ms)</p> <p>For up to 8 hours of pacing using 70mA / 60 bpm (pulse duration 20ms) inspection of pads every 30 minutes</p>

6.5 ECG

Patient cable	3-lead and 4-lead (wire) cable, type CF
Heart rate	
Range	• 15 – 350 bpm
Accuracy	• $\pm 10\%$ or 5 bpm, whichever is greater
Lead display	Lead II display
Sensitivity	0.25, 0.5, 1, 2 cm/mV programmable
Blockage caused by defibrillation shock	Max. 5 seconds
Input impedance	$\geq 2.58 \text{ M}\Omega$
Current electrode test	< 0.5 μA
Suppression of large T-waves	max. amplitude of T-wave according to IEC 60601-2-27 section 201.12.1.101.17: 0.8 mV
HR averaging method	The heart rate calculation is done using a user-defined number of previous RR intervals (minimum 4, maximum 16). The RR intervals are reset and the heart rate is set to zero whenever an asystole condition has been detected
Response time HR measurement	<ul style="list-style-type: none"> Change from 80 to 120 beats per minute: 2.56 s Change from 80 to 40 beats per minute: 8 s
Reaction to an irregular rhythm	<ul style="list-style-type: none"> A1: 80 bpm A2: 60 bpm A3: 120 bpm A4: 90 bpm (except for triggers no. 6 and 7, HR < 90 bpm) (according to IEC specifications 60601-2-27, 6.8.2.bb)
Duration until alarm is triggered in the case of tachycardia	B1 and B2: 3 s (according to IEC specification 60601-2-27, 6.8.2.bb)
ECG amplifier	
Bandwidth	<ul style="list-style-type: none"> 0.05 to 150 Hz (-3 dB)
Sampling rate	<ul style="list-style-type: none"> 1000 Hz
Pacemaker detection	<ul style="list-style-type: none"> $\pm 2 \text{ mV}$ to $\pm 700 \text{ mV}/0.1$ till 2.0 ms
QRS detection range	<ul style="list-style-type: none"> Duration: 70 to 120 ms, amplitude: 0.5 to 5.0 mV
Protection	<ul style="list-style-type: none"> Fully isolated, defibrillation-protected >5kV
Mains filter	<ul style="list-style-type: none"> Distortion-free suppression of superimposed 50 / 60 Hz sinusoidal interferences by means of adaptive digital filtering.

6.6 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.

6.6.1 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	

6.6.2 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	IEC 60601-1 conformity	Floors should be made of wood, concrete or ceramic tiles. If floors are covered with synthetic material, relative humidity should be at least 30%. Note: In case of strong ESD discharges, artefacts 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	IEC 60601-1 conformity	Mains power quality should be that of a typical commercial and/or hospital environment. Note: In the case of a strong fast transient / burst, artefacts 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. If the user of the Tempus LS is reliant on permanent operation even in the case of a power failure, it is suggested connecting the Tempus LS to an uninterruptible power supply or use it with a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	100 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
			<p>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.</p>
Conducted HF IEC 61000-4-6	<p>3 V_{eff} between 150 kHz and 80 MHz outside of the ISM frequency bands^a</p> <p>10 V_{eff} between 150 kHz and 80 MHz within the ISM frequency bands^a</p>	<p>3 V</p> <p>10 V</p>	$d = \frac{3,5}{3} \times \sqrt{P}$ $d = \frac{12}{10} \times \sqrt{P}$
Radiated HF IEC 61000-4-3	20V/m 80 MHz to 2.5 GHz	10 V/m	<p>ECG, and defibrillator:</p> <p>$d = \frac{12}{20} \times \sqrt{P}$ between 80 MHz and 800 MHz</p> <p>$d = \frac{23}{20} \times \sqrt{P}$ between 800 MHz and 2.5 GHz</p> <p>where P is the maximum transmitting power of the transmitter in Watt (W) according to manufacturer data, and d the recommended minimum distance in metres (m)^b.</p> <p>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.</p> <p>When operating the device near devices bearing the symbol "ionising radiation", interferences can occur.</p> 
Proximity fields from RF wireless communications equipment IEC 61000-4-3	see section 6.6.3	see section 6.6.3	see section 6.6.3
<p>Note 1 For 80 MHz to 800 MHz, the higher frequency range applies.</p> <p>Note 2 These guidelines might not always be applicable. Electromagnetic radiation is influenced by absorption and reflection on structures, objects and people.</p>			

Interference testing	IEC 60601 test level	Conformity level	Electromagnetic environment - explanations
a. The ISM frequency bands (ISM = industrial, scientific, medical) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. b. The conformity levels within the ISM frequency bands between 150 kHz and 80 MHz and between 80 MHz and 2.5 GHz serve to minimise the probability of interferences caused by mobile/portable communication equipment that accidentally happens to be in the patient environment. The formula for the calculation of the recommended distance has been adapted by the factor 10/3 for transmitters in this frequency range. c. The field strength of stationary transmitters, e.g. base stations for radio telephones (mobile or cordless) and portable radio equipment, amateur radios, AM and FM radios and TV signals cannot be predicted accurately in a theoretical way. In order to analyse electromagnetic environments caused by stationary HF transmitters, an electromagnetic analysis on site should be considered. If the measured field strength exceeds the HF conformity level, it needs to be checked whether the Tempus LS can be used in this environment. If an abnormal behaviour is detected, additional measures need to be taken, e.g. reorientation or change of location of the Tempus LS . d. For the frequency range between 150 kHz and 80 MHz, the field strength must be lower than 3 V/m.			

6.6.3 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	704-707	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

6.6.4 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 metres (m) can be calculated using a formula based on the transmitter's frequency, where P is the max. transmitting power of the transmitter in Watts (W) (according to manufacturer data).

Note 1 These guidelines might not always be applicable. Electromagnetic radiation is influenced by absorption and reflection on structures, objects and people.

Note 2 To calculate the recommended minimum distance of transmitters in the ISM frequency bands between 150 kHz and 80MHz and in the frequency band between 80 MHz and 2.5 GHz, the additional factor 10/3 is used to minimise the probability of interferences caused by mobile/portable communication equipment that accidentally happens to be in the patient environment.

