Instructions For Use

PACE 101H

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1 Preface

1.1 General

Read these instructions carefully before using the product described within. Should you have any questions about these instructions or the use of this product, please contact the customer service department before using the product:

In Germany:	Phone:	+49 (7623) 7405 0
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The product may only be placed in service when its proper use can be assured.

According to U.S. Standards, PACE 101H is a Class III device (21 CFR 862-892 [807.87(c)]).

According to European Standards, PACE 101H is a Class IIb medical product (Council Directive 93/42/EEC of 14 June 1993 (‘Medical Device Directive’), Annex IX).

1.2 Checking the Package

Unpack the product and carefully check to see if any damage has occurred during shipment. Check to see if everything was delivered as listed on the shipping list.

Please inform us immediately if something is missing or damaged. Claims that are filed afterwards will not be considered.

1.3 Writing Conventions of this Manual

The following conventions are used to identify special information in this manual:

Note Helpful hints and notes on the usage of the device and for understanding the modes of operation

Caution Conditions that may damage the pacemaker or that may prevent its safe and effective use

Warning Important facts and warnings to be observed

2 Product Description

PACE 101H is a battery-powered, external single-chamber pacemaker for clinical use. PACE 101H is connected to temporary stimulation leads (including myocardial heart wires).

The connection is made directly or via a separate extension cable and adapter, if necessary.

The following stimulation modes available: VVI (or AAI), V00 (or A00) as well as a high-rate function.

Adjustable are stimulation mode, basic rate, sensitivity threshold, pulse amplitude and high-rate (up to 720 ppm upon pressing a button).

Sensed events are indicated by a green LED (Sense), stimulated pulses by a yellow LED (Stim.). As an option these events are indicated acoustically, too (stimulation mode VVI Beep). A red LED informs about the remaining battery life (Low Batt./Error).

A defect of the device (failed self-test after the device was switched on) is indicated by continuously lit LEDs and an intermittent acoustic signal. If the self-test does identify any errors, the acoustic and visual signals will turn off after a few seconds.

The safety features of PACE 101H include:

- Visual display of sensed and stimulated events;
- Microprocessor-controlled pacing parameters;
- Timely visual and acoustic warning when the battery is almost depleted;
- Limitation of stimulation rate to 200 ppm in case of an device malfunction (runaway protection);
- A retractable, transparent cover of the controls to prevent accidental changes of the programmed parameters.

Temporary catheters, heart wires and leads with pins having a diameter within 0.9 mm - 2 mm can be connected directly to PACE 101H. Additional extension cables and adapters are available, too. This system offers a secure connection of transvenous catheters and myocardial leads, which are applied either unipolar or bipolar.

Refer to applicable sections of this manual for more detailed information on the use and maintenance of PACE 101H. The technical data is summarized at the end of this manual.

3 Indication

In conjunction with a stimulation lead system, PACE 101H can be used whenever temporary atrial or ventricular stimulation is indicated. PACE 101H can be employed for therapeutic as well as diagnostic purposes or be used prophylactically.

Some specific indications for temporary stimulation are:

- Complete (third-degree) or intermittent heart block
- Symptomatic sinus bradycardia
- Atrial or ventricular ectopic arrhythmia
- Sick sinus syndrome (SSS)
- Atrial tachyarrhythmia
- Acute myocardial infarction induced heart block
- Stimulation during a ventricular asystole
- Usage during the replacement of an implantable pacemaker
- Stimulation and monitoring before the implantation of a cardiac pacemaker
- Stimulation and monitoring following heart surgery

4 Contraindication

There are no contraindications with regards to the use of PACE 101H for temporary cardiac stimulation for therapy and prevention of arrhythmia. The state of health of the patient, however, can restrict the choice of operational mode and stimulation parameters.

For example, a mode of operation with atrial sensing is not suitable or appropriate when atrial fibrillation occurs. This is due to the excessive and chaotic frequency of detected fibrillation waves.

Overdrive-stimulation therapy must only be used in the atrium. Overdrive-stimulation in the ventricle could cause life threatening ventricular fibrillation.

5 Possible Complications

When using an external pacemaker such as PACE 101H, the following complications can arise and may lead to adverse events:

Complication	Result / Adverse Event
Infection	Sepsis
Thrombosis and pulmonary embolism	Death
Perforation of the heart	Hemopericardium, Hemothorax, Cardiac tamponade
Muscle and nerve stimulation	Patient discomfort
Dislocation of lead	System malfunction. Failure to stimulate.
Disconnection or breakage of lead contact problems at connection sites. Insufficient tightening of the collets.	Intermittent or complete failure of effective stimulation and/or sensing
Significant rise in the stimulation threshold	Loss of effectiveness of the stimulation (Exit Block)
Significant drop of the ECG-signal amplitude after lead dislocation or ingrown lead	Loss of sensing (Entrance Block)
Abnormal pacemaker settings	Erratic rhythm. Compromise in stroke volume / cardiac output

Complication	Result / Adverse Event
Inappropriately high sensitivity setting. Sensing of R or T waves in the atrium or P waves in the ventricle. Detection of interference (noise, electromagnetic interference).	Ventricular tachycardia, ventricular fibrillation, and death, if not recognized immediately.
Overdrive stimulation in the atrium = rapid atrial pacing	Accidental conduction into the ventricle can create ventricular arrhythmia
Battery failure or exhaustion	Failure of impulse emission. Failure to stimulate.
Technical defect in the PACE 101H (failure of components)	Failure or change in the impulse emission, changed (or no) sensing, incorrect displays. Failure to stimulate.
Undetected programming errors	Chaotic rhythm
Erroneous lead connection	Device does not function properly. Chaotic rhythm. Failure to stimulate as intended.
Influence of defibrillation and RF surgery	See 9.11 Environmental and Medical Therapy Hazards for the effects of using at the same time PACE 101H and defibrillators or electro-surgical instruments.

Table 1: Possible Complications

6 Precautionary Measures and Warnings

The following list presents important precautionary measures and warnings. Additional important precautionary measures and warnings will be found in the following chapters.

1. In order to prevent unnecessary complications, PACE 101H should only be applied and used by medical personnel with extensive experience in cardiac stimulation therapy. Additionally, the person using the device should be thoroughly familiar with the contents of this instruction manual.
2. All lead systems are to be connected to type CF devices only because of the danger of the current being diverted to the heart. Devices that are connected to a main power supply pose increased danger due to the current diversions to the heart.
3. Make sure that all devices in the vicinity of the patient are properly grounded.
4. Stimulation leads provide a direct, low-resistance current path to the heart. Therefore, it is absolutely necessary that the connector plug is not touched with bare hands or come in contact with electrically conductive or wet surfaces. All possible static electricity sources must be kept away from the stimulation system.
5. While the lead is being inserted and connected to the pacemaker, continuous ECG monitoring is mandatory. For emergency situations, a defibrillator should always be available in a ready-to-use state.
6. ECG monitoring should be continued during all times PACE 101H is in use to signal possible complications of different reasons immediately to the medical staff.
7. In either case it is necessary to monitor the patient and to be prepared for a failure of the pacemaker function. A back-up device for the pacemaker must be available.
8. Error messages and conflict warnings of PACE 101H do not replace an ECG monitoring.
9. During atrial overdrive-stimulation an accidental conduction into the ventricle is possible and may cause ventricular tachycardia. Therefore, continuous ECG-monitoring is mandatory. A defibrillator should always be available in a ready-to-use state.
10. If PACE 101H operates in an asynchronous mode, the pacing pulses may occur during the vulnerable phase of the patient's intrinsic activity (corresponds approximately in the ECG to the T-wave); and may cause ventricular fibrillation and ventricular flutter.

11. When PACE 101H is used in conjunction with electro-surgical instruments or defibrillators, it is mandatory to continuously monitor the patient and to be prepared for a possible failure or malfunctioning of the pacemaker
12. To protect the patient and the pacemaker from current passing through the pacemaker/lead-circuitry caused by defibrillation discharges, the stimulation circuit should always be opened during defibrillation if possible. Current flows caused by defibrillator discharges can endanger the patient and the high current amplitudes can also damage the pacemaker.
13. If PACE 101H is to be used for a long period of time on a patient, then the stimulation threshold should be checked from time to time. Initially, it should be checked after a few hours, then daily because an increase of the threshold may occur.
14. An unnecessarily high sensitivity (small sensitivity value) increases the probability that proper pacemaker functioning will be affected by external interference. If there are strong electromagnetic fields caused by telecommunication devices (like mobile phones) or other sources, an asynchronous mode should be set with a higher than the patient's intrinsic rate.
15. In case that PACE 101H is not used for long periods of time, the battery must be removed in order to prevent damage from possible battery acid leakage. (Such damage will not be compensated under the guarantee).
16. The pacemaker must not be submerged in either water or any other cleaning solution. Do not use any scrubbing powder/liquid on the device.
17. The device must not be sterilized in an autoclave. Sterilization with plasma, ultrasound or gamma radiation is also not allowed. PACE 101H can be damaged by such procedures.
18. Connector cables, which are intended for single use, cannot be re-sterilized and reused.
19. Only the manufacturer, or facilities authorized by the manufacturer, can perform repairs or calibration of PACE 101H.
20. All battery powered devices can lose their function due to normal discharge of the battery. It must also be considered that the pacemaker can stop operating as a result of an unpredictable component failure. The patient should not be left unattended by the medical staff and should always be supervised by a monitoring system.
21. Use only 9 V primary batteries for PACE 101H. Re-chargeable batteries (accumulators) should not be used (possibly low capacity and unstable charge condition may cause a malfunction of the pacemaker).

22. When used as intended, PACE 101H does not contain any parts which are subject to wear and tear.

7 Patient Safety

The external pulse generator PACE 101H meets all applicable international standards for patient safety:

IEC 60601-1	Medical electrical equipment. General requirements for safety
IEC 60601-1-2	Medical electrical equipment. Electromagnetic compatibility
IEC 60601-2-31	Medical electrical equipment. External cardiac pacemakers

In the event that the patient is connected to multiple electrical devices, the sum of leakage currents may exceed the allowable limits.

8 Electromagnetic Compatibility

The external pulse generator PACE 101H meets all applicable international standards with respect to electromagnetic compatibility (EMC).

IEC 60601-1-2	Medical electrical equipment. Electromagnetic compatibility
CISPR 11	Industrial, scientific and medical radio-frequency equipment. Electromagnetic disturbances
IEC 61000	Electromagnetic compatibility

Some sources of radiated emissions may impact the proper function of PACE 101H:

- Electrosurgical instruments operating with radio frequency
- Devices for diathermy therapy
- Magnetic resonance imaging (MRI)
- Medical telemetry systems

Special electromagnetic compatibility (EMC) precautions should be taken when using electrical medical equipment such as PACE 101H:

A	Portable and mobile RF communications equipment, such as mobile phones, can affect the function of PACE 101H. Mobile phones with a rated maximum output power of 2 Watt and a transmitter frequency up to 2.5 GHz should be used no closer to any part of PACE 101H (including patient cables and sensors) than a recommended separation distance of 10 m (30 ft).
B	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30 %.
C	Power frequency magnetic fields should be at levels characteristic of typical commercial or hospital environments.

For further information and guidance regarding EMC, refer to chapter 15 Conformity According to IEC 60601-1-2 on page 41.

9 Use and Application of PACE 101H

9.1 Design

PACE 101H with its controls and terminals is shown in Figure 1 and Figure 2.

Figure 1: External Pulse Generator PACE 101H Front Face

Figure 2: External Pulse Generator PACE 101H Rear View

1 Lead connection sockets:

Protected safety connectors for plugs with a diameter of 0.9 mm to max. 2.0 mm.

Different pole (–) : black

Indifferent pole (+) : red

2 Green LED blinks synchronous to the sensed P-/R-wave.

3 Yellow LED blinks synchronously with the stimulation pulse.

4 Control for setting the stimulation pulse amplitude.

5 Mode Switch:

Off	Device is turned off
VVI	Inhibited pacemaker operation
VVI Beep	Inhibited pacemaker operation with acoustic signal during sensing and stimulation (two different tones)
x2	Stimulation rate times two (High-Rate stimulation) enabled
x4	Stimulation rate times four (High-Rate stimulation) enabled

During High-Rate stimulation an acoustic signal is given automatically.

6 Button to activate High-Rate stimulation (Basic Mode: V00 Beep)

7 Control for setting the sensing threshold for the P-/R-wave.

In position '**f**' the pacemaker stimulates in the asynchronous (fixed rate) mode.

8 Control for setting the basic stimulation rate ('basic rate', or just 'rate') .

9 Red LED indicates errors and low battery voltage.

10 Plexiglas cover. Protects against accidental change of the chosen parameters.

11 Ridge for attaching an arm strap.

12 Battery compartment (see Figure 2)

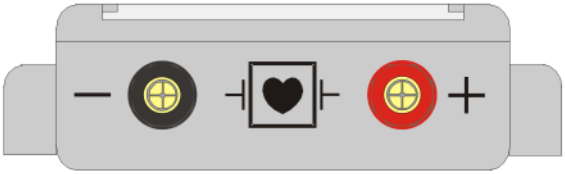

Figure 3: External Pulse Generator PACE 101H Top View

The internationally recognized pictograms have the following meaning:

Classification: CF (cardiac floating) applied part, defibrillation protected

Symbol: Follow instruction for use.

PACE 101H is marked with the symbol of a crossed-out garbage. The symbol indicates that the European WEEE[1] guideline applies to the disposal method of the device.

Symbol for Conformité Européenne (device and manufacturer meet all requirements of European guideline 93/42/EWG)

Symbol: Caution

PACE 101H can be used as either a demand- (P-/R-wave inhibited) or an asynchronous pacemaker. In the demand mode, the inhibition of the stimulation is caused by intrinsic activity. No impulse is given if the PP/RR interval is shorter than the interval of the chosen stimulation rate. The pacemaker only stimulates if the interval of the pacemaker is exceeded. In these cases, the stimulation proceeds at a constant rate until the pacemaker is inhibited by a spontaneous action (such as a premature atrial complex (PAC) or a premature ventricular complex (PVC)) or a faster intrinsic rhythm. To prevent inappropriate sensing after a paced or sensed event, PACE 101H has a refractory period of 250 ms.

[1] European Guideline 2002/96/EG on Waste Electrical and Electronic Equipment (WEEE)

The Mode switch allows the user to select between standard VVI stimulation with ('**VVI Beep**') or without ('**VVI**') audible signal upon sensed events and stimulation pulses, and High-Rate stimulation ('**x2**', '**x4**').

In the modes "VVI" or "VVI Beep" the pacemaker recognizes, depending on the set sensitivity value, intrinsic activity of the heart and stimulates or inhibits accordingly. In order to use the demand function of PACE 101H, the sensing threshold must be set to a value significantly lower than the R-wave peak amplitude (for instance, 2 mV).

Alternatively, PACE 101H is operated in asynchronous mode (V00) by turning the sensing threshold knob completely counter-clockwise to the left (position indicated by '**f**'), causing the pacemaker to stimulate at a fixed frequency without inhibition.

PACE 101H can be used for pacing therapy in the ventricle or in the atrium.

It is also possible to stimulate in High Rate mode. Depending on the setting of the Mode switch to '**X2**' or '**X4**', the stimulation rate will be doubled or quadrupled when the "High Rate" button is pushed. PACE 101H stimulates at a fixed rate, independent of the set sensitivity value. After the '**High Rate**' button is released, the pacemaker reverts to the previous mode of operation.

9.2 Connecting Temporary Stimulation Leads

PACE 101H provides two terminals located on top of the device. The receptacles (Figure 3) accommodate pin connectors with a diameter of 0.9 mm to 2.0 mm and, thus, most common connectors of pacing leads or electrodes or pacing (heart) wires.

The indifferent pole (+ pole) is colored red. The different pole (- pole) is black.

To connect the stimulation leads to PACE 101H, proceed as follows:

1. PACE 101H must be turned off before any lead is connected. Make sure the Mode Switch [5] is in the '**Off**' position (Figure 1).

2. Loosen the collets of the terminals by rotating the screws counter-clockwise.

3.

w/ Use of an Extension Cable	w/o Use of an Extension Cable
Connect the extension cable to the pacemaker **before** connecting the stimulation leads to the extension cable.	
Connect the stimulation lead to the extension cable.	Connect the stimulation lead to the pacemaker.

4. Ensure correct polarity:

Bipolar Leads		Unipolar Leads
Transvenous	Pacing (Heart) Wires	
Connect the lead's distal pole to the black terminal (-) and its proximal pole to the red terminal (+)	Polarity is not relevant	Connect lead to the black terminal (-) and a large-surface indifferent electrode to the red terminal (+)

5. Secure the connections by tightening the connector screws by hand.

6. Turn the pacemaker on and select the desired mode of operation.

7. Determine the cardiac capture and sensing thresholds.

8. Monitor safe and effective function of the pacemaker using an ECG monitor.

Warning	During lead connection, powering on, and setup of the pacemaker, the patient's ECG must be monitored. Make sure a defibrillator is on hand and ready-to-use for emergencies such as development of ventricular tachycardia.

Warning	Stimulation leads provide a low-resistance electrical path directly to the heart. Make sure that any part of the electrically conductive part of the lead or lead extension is not touched with bare hands nor has contact with other electrically conductive or wet surfaces. Keep all possible sources of static electricity away from the stimulation system including the pacemaker, leads and extensions.

9.2.1 Lead Types

For temporary stimulation of the heart with PACE 101H, temporary transvenous leads or permanent leads, regardless of whether they are of bipolar or unipolar configuration, can be used. The use of myocardial leads is also permissible.

Temporary, transvenous pacing leads: These leads are advanced into the heart via a vein and are connected to PACE 101H either directly or by means of an extension cable.

Heart wires (myocardial pacing leads) Heart wires (myocardial leads) are affixed to the heart during open heart surgery, when it is expected that the patient may need stimulation for a limited period of time after surgery. Usually heart wires are connected to PACE 101H by means of an extension cable.

Permanent pacing leads: Prior to implantation of a permanent pacemaker, or during a pacemaker change, stimulation may be properly maintained with the assistance of PACE 101H. The permanent lead is connected to PACE 101H either directly or by means of an extension cable.

Warning	All lead systems are to be connected to type CF devices only because of the danger of the current being diverted to the heart. Devices that are connected to a main power supply pose increased danger due to the current diversions to the heart.

For exact specifications of leads and patient cables, please refer to our product catalog.

9.3 Powering On PACE 101H

Turn PACE 101H on by turning the Mode switch [5] clockwise from the "**Off**" position to any of the positions '**VVI**', '**VVI Beep**', '**x2**' or '**x4**'.

9.4 Powering Off PACE 101H

Turn PACE 101H off by turning the Mode switch [5] counter-clockwise to the "**Off**" position.

9.5 Determining the Sensing Threshold

Note	Sensing threshold is the minimum atrial or ventricular intracardial signal amplitude (measured in mV) required to inhibit or trigger a demand pacemaker.

For determination of the sensing threshold, the patient must have intrinsic heart activity with a rate that is hemodynamically tolerated over a longer period of time (a few minutes).

The determination of the sensing threshold (also referred to as sensitivity threshold) is performed as follows:

1.	Set the stimulation amplitude to the smallest value (0.3 V) so that asynchronous stimulation that occurs during the procedure remains ineffective.
2.	Set the basic rate 10 ppm below the patient's intrinsic rate.
3.	In the event the pacemaker already senses intrinsic heart rate activity, decrease the sensitivity (i.e., raise the sensitivity value!) such that the pacemaker will not sense intrinsic events. Eventually, the pacemaker operates in asynchronous stimulation mode.
4.	Slowly raise the sensitivity (i.e., lower the sensitivity value) until stimulation is inhibited. This sensitivity equals the sensitivity threshold.
5.	In order to create a "safety margin", the sensitivity must be raised further. The set value should be a 1/2 or 1/3 of the sensitivity threshold.

9.6 Determining the Capture Threshold

Warning	If the patient has a sufficient intrinsic heart rate, determine the sensitivity threshold before you determine the cardiac capture threshold. Reason: Avoid asynchronous stimulation super-imposed on intrinsic rhythm.

To determine the cardiac capture threshold, the following steps should be taken. Make sure that the patient's Electrocardiogram (ECG) is continuously monitored.

1.	Set the basic rate at least 10 ppm **above** the patient's own (intrinsic) rate. If the pacemaker is already effectively stimulating (i.e., capturing the heart), lower the stimulation amplitude until the stimulation pulse is no longer effective (i.e., does not capture the heart).
2.	Raise the stimulation amplitude slowly until the stimulation pulse captures the heart. This stimulation amplitude equals the cardiac capture threshold.
3.	In order to create a "safety margin", the stimulation amplitude must be raised further. The set value for the stimulation amplitude should be two to three times the cardiac capture threshold.

Warning	If the pacemaker is to be used for a longer period of time (for instance, more than 2 hours) on a patient, the cardiac capture threshold should be checked frequently because an increase in the cardiac capture threshold may occur.

9.7 Modes of Operation

The following terms are defined:

The **beat-to-beat interval** (a pacemaker parameter) is the programmed interval of a complete pacing cycle, measured in milliseconds (ms). It is determined as the inverse of the basic rate.

The **blanking period** is defined as the time during and after a sensed or paced event when the sensing channel of a pacemaker is insensitive. The purpose is to avoid sensing of late potentials. Thus, during the blanking period, no events are recognized.

Refractory period is a set time in the pacemaker, in which a signal in the respective channel will be recognized but not tracked or does not cause inhibition.

Sensing phase is the time period in which a signal that occurred in the respective channel will be recognized, interpreted as intrinsic, and tracked. Thus, this is the period outside blanking or refractory periods.

9.7.1 Demand Stimulation (VVI, AAI)

Upon sensing of intrinsic activity (the patient's own heart rhythm; P-waves in the atrial channel, R-waves in the ventricular channel), the pacemaker inhibits (i.e., does not stimulate).

After each sensed or paced event, the pacemaker is refractory for a period of 250 ms ± 5 % (the pacemaker ignores any intrinsic activity during this refractory period). Any sensed event occurring outside the refractory period resets the timing of the pacemaker to the beginning of a new beat-to-beat interval.

1.	Set the Mode switch [5] to '**VVI**' or '**VVI Beep**'.
2.	Determine the sensing threshold.
3.	"Safety margin": Set sensitivity value to 1/2 or 1/3 of the sensitivity threshold.
4.	Determine the cardiac capture threshold.
5.	"Safety margin": Set value for the stimulation amplitude two to three times the cardiac capture threshold.

9.7.2 Asynchronous Stimulation (V00, A00)

Ventricular asynchronous (V00) pacing is the simplest of all pacing modes because there is no sensing and no mode of response. The ventricular pacing stimuli occur at the programmed rate, regardless of any intrinsic cardiac event. Atrial asynchronous (A00) pacing behaves exactly like V00, but the pacing stimuli occur in the atrium.

1.	To select asynchronous operation, rotate the sensitivity control (Figure 1 on 15, [7]) completely counter-clockwise to position '**f**'.
2.	Set the Mode Select switch [5] to '**VVI**'. (Combined with the '**f**' position of the sensitivity control [7], the device will switch to A00/V00 mode.)
3.	Determine the cardiac capture threshold.
4.	For safety reasons, it is recommended that the stimulation amplitude be doubled; an increase in the stimulation threshold may take place.

9.7.3 High-Rate Stimulation (x2, x4)

High-rate stimulation, also known as rapid atrial pacing, is generally used to break atrial tachycardia by overdriving the patient's tachycardia and gradually decreasing the high-rate stimulation rate to reach the patient's intrinsic heart rate.

1.	Set the Mode Select switch [5] to either the '**x2**' or '**x4**' position. In these positions, PACE 101H will continue to operate as a pacemaker according to the set parameters for stimulation rate and pulse amplitude.
2.	While pressing the '**High Rate**' button, PACE 101H switches to twice ('**x2**') or four ("x4") times the preset stimulation rate. High-rate stimulation occurs only when the '**High Rate**' button is held pressed.
3.	The preset stimulation rate can be readjusted at any time during high-rate stimulation.

9.8 Basic Rate, Stimulation Amplitude and Sensitivity Threshold

One rotary dial is assigned to each of the parameters:

Parameter	Figure 1	Function
Basic Rate	[8]	Turn dial clockwise to increase Basic Rate and counter-clockwise for decrease thereof
Stimulation Amplitude	[4]	Turn dial clockwise to increase stimulation amplitude and counter-clockwise for decrease thereof
Sensitivity Threshold	[7]	Turn dial clockwise to increase *sensitivity* (and decrease *sensitivity threshold*). Turn dial counter-clockwise to decrease *sensitivity* (and increase *sensitivity threshold*).

9.9 Battery Surveillance

PACE 101H is powered by a standard 9 V battery.

PACE 101H continuously monitors the battery voltage. If the red LED (Figure 1 [9]) is blinking, the battery must be replaced.

As the battery continues to discharge, the interval of blinking decreases from 5 s to 1 s and an acoustic warning tone is given. The interval between tones decreases from 5 min to 1 min.

With the recommended battery, a safety margin of up to two additional days' reserve can be typically expected (72 ppm, 8 V). A battery change is also recommended after 38 or 53 days of operation for alkaline or lithium batteries, respectively.

Note	Once first warning indication occurs, i.e., the red LED (Low Batt./Error) is blinking, replace battery when possible.

Note	If the device is turned off after the battery warning signal begins, the battery must be exchanged before the pacemaker can be turned on again.

9.10 Device Surveillance

PACE 101H has surveillance circuitry that monitors the operation of the pacemaker, including the sequence and the timing of the output signals.

A continuously lit red LED (Figure 1 [9]), together with a repetitive audible signal, indicates a malfunction. The malfunction can be confirmed by turning the device off and on again.

9.11 Environmental and Medical Therapy Hazards

PACE 101H may be inhibited by strong external interferences that resemble the signal the pacemaker is designed to sense. Such interference may be produced by a variety of sources including electrocautery, diathermy, and other devices. PACE 101H will not be damaged by such interference and will resume its function as soon as the interference source is removed.

Special electromagnetic compatibility (EMC) precautions should be taken when using medical electrical equipment such as the PACE 101H:

- Portable and mobile RF communications equipment, such as mobile phones, can affect the function of PACE 101H. Mobile phones with a rated maximum output power of 2 watts and a transmitter frequency to 2.5 GHz should be used no closer to any part of PACE 101H (including cables and leads) than a recommended separation distance of 10 m (30 ft).
- Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30%.
- Power frequency magnetic fields should be at levels characteristic of typical commercial or hospital environments.
- All devices located in the vicinity of the patient must be properly grounded.
- Inappropriately high sensitivity (small sensitivity value) increases the probability that proper pacing function will be affected by external interference, and the device may switch to asynchronous stimulation as a result.
- Pacing leads provide a direct, low-resistance current path to the heart. Do not touch the connector plugs without gloves. Do not allow them to contact electrically conductive or wet surfaces. Keep all possible sources of static electricity away from the pacing system.
- Devices that receive their current from a wall outlet increase the chance of the current being accidentally diverted to the heart.
- Defibrillation current flow through the device-lead-circuit may damage the pacemaker or injure the patient. If possible, interrupt the circuit during defibrillation by unplugging the pacing lead or patient cable.

Warning	Using PACE 101H simultaneously with a defibrillator or electrosurgical instruments requires that the patient is continuously monitored, as the defibrillation energy could damage the pacemaker, resulting in a device failure.

10 Storage

Store PACE 101H dry and cool within the temperature range of –20 °C (–4 °F) to +60 °C (+140 °F).

For device operation temperature must be in the range of +10 °C (+50 °F) to +45 °C (+113 °F).

Warning	In case PACE 101H is not used for a longer period of time, remove the battery from the battery compartment in order to prevent damage from possible battery acid leakage. Damage caused by a leaking or defective battery is not covered by the manufacturer's limited guarantee.

11 Care and Maintenance

11.1 Care and Cleaning

As a precision electronic device, PACE 101H must be handled with corresponding care. Although the device is robustly constructed, it can be damaged by heavy mechanical stress, for example, by dropping on a hard surface.

The enclosure and the keypad of PACE 101H are protected against accidental liquid spills. To clean the device, use a towel or sponge moistened with water or alcohol.

For disinfection, the enclosure of PACE 101H can be cleaned with Alhydex, Cydex, or with Detergizide.

Warning	Do not submerge PACE 101H in either water or any other cleaning solution. Do not use any scrubbing powder/liquid on the device.

Do not sterilized PACE 101H in an autoclave. Sterilization using ultrasound or gamma rays is also not permitted. PACE 101H can be damaged by such procedures.

PACE 101H and accessories can be sterilized with gas if the following conditions are met:

- Remove battery from battery compartment.
- During sterilization do not exceed a temperature of 55°C (131°F) and a relative humidity of 90 % during the sterilization.
- During sterilization do not exceed atmospheric pressure.
- Follow the instructions for use of the sterilization equipment.
- Validate the sterilization by using approved methods.
- After each use, clean, disinfect and sterilize reusable cables.
- Do not reuse disposable extension cables.

11.2 Changing the Battery

PACE 101H continuously monitors the battery voltage. If during operation the red LED (Figure 1 [9]) is blinking along with an acoustic signal, the battery must be replaced. Replace the battery after 38 (Alkaline) or 53 (Lithium) days of operation.

For battery replacement, adhere to the following instructions:

1. Have a new 9 V-battery (6LR61) on hand.
2. Open the battery compartment by sliding the compartment cover [12] to the right side.
3. Take the battery out and carefully disconnect it from the battery connection cable.
4. Attach a new 9 V battery to the battery connection cable. The orientation of the battery polarity is important. Place battery into battery compartment.
5. Close the battery compartment.
6. It is mandatory to dispose of the battery in an environmentally friendly, legal manner.

Figure 4: Access to battery compartment

Warning	Avoid handling with spillage while the battery compartment is open!

Warning	Use 9 V-battery (6LR61) produced only by a reliable battery manufacturers. Do not use rechargeable batteries!

11.3 Safety Check-Ups of the Pacemaker

In order to assure safe operation of PACE 101H, the following check-ups must be carried out on a regular basis.

Before each use

Visual inspection:

- Inspect the device and accessories for visible damage.
- Inspect the connections for visible damage.

Function test

- Inspect all connections to see if they affix and function properly.
- Inspect all operating elements and displays for perfect function.

After each use

- Clean the device and its accessories according to the instructions provided earlier in this chapter.

Annual Functional and Safety Check

- Measuring the auxiliary currents
- Measuring the stimulation parameters (amplitude, pulse width)
- Measuring the stimulation rate
- Measuring the sensitivity
- Check the battery surveillance

Warning	A repair or calibration must be executed by the manufacturer or a manufacturer-authorized designee; otherwise the warranty is void.

11.4 Product Return Policy

For service and repair, contact the distributor or manufacturer to obtain a return-to-manufacturer authorization (RMA).

Regarding disposal of PACE 101H, the European guideline 2002/96/EC on waste electrical and electronic equipment (WEEE directive) applies to the return to the manufacturer and disposal method of the PACE 101H (Figure 5).

Devices which cannot be repaired can be returned to the manufacturer, who disposes the devices in accordance with the WEEE guidelines.

Figure 5: Pictogram WEEE Guidelines

12 Customer Service

If you have any questions, the customer service can be reached at:

Distributor:

OSYPKA AG
Earl-H.-Wood-Strasse 1
79618 Rheinfelden, Germany
Phone: +49 (7623) 7405 0
FAX: +49 (7623) 7405 213
E-mail: mail@osypka.de

Manufacturer:

Osypka Medical GmbH
Albert-Einstein-Strasse 3
12489 Berlin, Germany
Phone: +49 (30) 6392 8300
Fax: +49 (30) 6392 8301
E-Mail: mail@osypkamed.com

13 Technical Data

Classification		
Safety Class:	Device with internal power supply (primary battery)	
Applied part classification:	Type CF	
Protection degree	IP 41	
Sterilization classification:	PACE 101H: non-sterile Extension cables connecting to pacing electrodes / wires: sterile	
No protection against inflammable anesthesia supplies:	PACE 101H must not be used in the presence of inflammable mixtures of anesthesia supplies and air, oxygen or nitrous oxide (N_2O).	
According to European Directives 93/42/EWG and 2007/47/EC:	Class IIb Continuous operation Active therapeutical medical device	
According to U.S. Regulations for medical devices:		
Cardiac Pacemaker	Number:	21 CFR 870.3600
	Name:	External Pacemaker Pulse Generator
	Regulatory Class:	3
	Product Code:	74DTE
Extension cable	Number:	21 CFR 870.2900
	Name:	Cables, Transducer and Electrode, Patient
	Regulatory Class:	2
	Product Code:	74DSA

Classification	
Conformity to Standards	The cardiac pacemaker is designed according to and meets IEC 60601-1 IEC 60601-1-2 IEC 60601-2-31

Parameter	
Measurement conditions:	Environment temperature: 20 ± 2°C Voltage supply: 9 ± 0.5 V Load resistance: 500 Ω ± 1% Test impulse: as specified in ISO 14702-8 (Triangle 2 ms / 13 ms)
Pacing modes:	VVI, V00, AAI, A00
Basic Rate:	30 … 180 ppm ± 10 %
Atrial overdrive stimulation:	Asynchronous; Basic Rate x2 or x4
Output pulse:	Cathodic, biphasic, asymmetric, capacitive coupled, passive discharge
Nominal pulse amplitude (500 Ω):	0.3…12 V ± 10 % ± 0.1 V
Pulse duration:	0.75 ms ± 0.05 ms
P/R wave sensitivity:	1 … 20 mV ± 20 %, ∞
Input impedance:	24 kΩ ± 10 %
Output impedance:	< 20 Ω for load resistance > 150 Ω
Load impedance range:	200 Ω…2000 Ω
Refractory period:	250 ms ± 5 %

Parameter	
Acoustic signaling:	Different for stimulation, sensing and warnings; acoustic signaling for stimulation and sensing can be turned on (Mode '**VVI Beep**') or off (Mode '**VVI**").

Safety	
Interference recognition:	Interference frequencies >283 ppm ± 5 % cause a switch to asynchronous safety stimulation
Defibrillation protection:	Built-in suppression diode
Runaway protection:	200 ppm ± 10 ppm

Battery	
Battery:	9 Volt (identification per IEC 86: 6LR61) Recommended types: Duracell® Procell® MN1604 Ultralife® Lithium® Power Cell®
Life span of recommended battery (Alkaline):	38 days (72 ppm, 8 V)
Life span of recommended battery (Lithium):	53 days (72 ppm, 8 V)
Battery Power Reserve:	Plus 2 days reserve after first appearance of low battery indication
Battery surveillance:	Continuous. Replacement indication: acoustic and by blinking of the red LED

Operating Environment	
Operating temperature:	+10 °C (+50 °F) … +45 °C (+113 °F)
Storage temperature (w/o battery):	–20 °C (-4 °F) … +60 °C (+140 °F)
Relative humidity:	30 % … 75 %, non-condensing
Atmospheric pressure:	700 hPa … 1060 hPa
Operation in explosion hazard areas:	The device may not be used in areas where flammable agents are present.

Dimensions	
Housing dimensions (L×W×D):	Approx. 115 mm × 60 mm × 22 mm (4.5” × 2.4” × 0.9”)
Weight without battery:	Approx. 125 g (0.275 lb)
Weight with battery:	Approx. 170 g (0.374 lb)
Lead connections:	Protected terminals (collets) for plugs with 0.9 mm – 2.0 mm diameter

We reserve the right to make changes without notice.

14 Delivery Unit

PACE 101H is delivered in a carrying case with the following content:

- PACE 101H SSI External pulse generator
- 9V Battery
- Arm Strap (L = 45 cm / 17.7”)
- PACE 101H User’s Manual

Contact your local OSYPKA AG representative for temporary stimulation electrodes / pacing wires and accessories such as extension cables and adaptors.

15 Conformity According to IEC 60601-1-2

Manufacturer guidelines and declarations:

Electromagnetic Radiation

Standard: IEC 60601-1-2: Table 1

PACE 101H is intended for use in an electromagnetic environment as described below. The user should make sure that PACE 101H is used in such an environment.

Emissions Test	Compliance Level	Guidelines for the Electromagnetic Environment
RF emissions CISPR 11	Group 1	PACE 101H uses radio-frequency (RF) energy exclusively for its own function. Therefore, the high-frequency interference is very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	PACE 101H is suitable for use in all areas, excluding residential areas and buildings that are connected directly to the public power supply lines.
Harmonic emissions according to IEC 61000-3-2	Not applicable	
Voltage fluctuations according to IEC 61000-3-3	Not applicable	

Electromagnetic Immunity

Standard: IEC 60601-1-2: Table 2

PACE 101H is intended for use in an electromagnetic environment as described below. The user should make sure that PACE 101H is used in such an environment.

Testing the Immunity to Interference	Test Level according to IEC 60601	Compliance Level	Guidelines for the Electro-magnetic Environment
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact discharge	± 6 kV contact discharge	Floors should be made of wood, concrete or ceramic tiles. If floors consist of a synthetic material, the relative humidity should be at least 30 %.
	± 8 kV air discharge	± 8kV air discharge	
Fast transient electrical interference / bursts according to IEC 61000-4-4	Not applicable		
Surge voltages (surges) according to IEC 61000-4-5	Not applicable		
Voltage drops, brief interruptions and fluctuations on power supply lines according to IEC 61000-4-11	Not applicable		
Magnetic field at the supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	The magnetic field strength should correspond to levels typical to commercial or hospital environments.

Electromagnetic Immunity for External Cardiac Pacemakers

Standard: IEC 60601-1-2: Table 3

PACE 101H is intended for use in an electromagnetic environment as described below. The user should make sure that PACE 101H is used in such an environment.

Testing the Immunity to Interference	Test Level according to IEC 60601	Compliance Level	Guidelines for the Electromagnetic Environment
			Portable and mobile radio-frequency (RF) communication equipment are not used closer to any part of PACE 101H, including cables and leads, than the recommended safety distance. **Recommended safety distance:**
Conducted RF interferences according to IEC 61000-4-6	10 V_{rms} 150 kHz to 80 MHz outside of ISM bands[a]	10 V_{rms} 150 kHz to 80 MHz outside of ISM bands[a]	$d = [0.35]\sqrt{P}$
	10 V_{rms} 150 kHz to 80 MHz inside of ISM bands[a]	10 V_{rms} 150 kHz to 80 MHz inside of ISM bands[a]	$d = [1.2]\sqrt{P}$
Radiated RF interference according to IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 2.5 GHz	$d = [1.2]\sqrt{P}$ for 80 MHz to 800 MHz
			$d = [2.3]\sqrt{P}$ 800 MHz to 2.5 GHz

Testing the Immunity to Interference	Test Level according to IEC 60601	Compliance Level	Guidelines for the Electromagnetic Environment
			P is the maximum rated power of the transmitter in watts (W) according to the information of the transmitter manufacturer and *d* is the recommended safety distance in meters (m).[b] Field strength of stationary RF transmitters must be determined site [c] and must be less than the compliance level at all frequencies[d]. Interference may occur in the vicinity of devices marked with the following symbol: 
Note 1:	At 80 MHz and 800 MHz, the higher frequency range applies.		
Note 2:	These guidelines do not necessarily apply in all situations. The propagation of electromagnetic waves is influenced by absorption and reflection from structures, objects and humans.		

a The ISM bands (for industrial, scientific and medical applications) between 150 kHz and 80 MHz are 6.765 MHz to 6,795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

b The compliance level in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz is intended to reduce the likelihood that mobile/portable communications devices cause interference if they are unintentionally brought into patient areas. For this reason greater safety distance is recommended separation distance in these frequency ranges (factor 1.2 instead of 0.35).

c The field strengths of stationary transmitters, such as base stations for mobile phones and land mobile radios, amateur radio stations and radio broadcast and TV broadcast cannot be predicted with accuracy. To assess the electromagnetic environment by fixed RF transmitters, a study of the location should be considered. If the measured field strength exceeds the HF compliance level at the location where PACE 101H is used, PACE 101H must be observed to ensure correct functioning. Additional measures may be necessary, such as reorienting or relocating PACE 101H.

d In the frequency range 150 kHz to 80 MHz the field strengths should be less than 10 V/m.

Recommended Safety Distances to Portable and Mobile RF Equipment

Standard: IEC 60601-1-2: Table 5

PACE 101H is intended for use in an electromagnetic environment, in which the RF interference is under control. There user of the PACE 101H can help to prevent electromagnetic interference by maintaining a safety distance to mobile RF communication equipment (transmitters) – depending on the output power of the communication equipment as described below. The user should make sure that PACE 101H is used in such an environment.

Rated output power of transmitter P [W]	**Safety Distance *d* [m] corresponding to Frequency of Transmitter**			
	150 kHz to 80 MHz outside of ISM bands	150 kHz to 80 MHz inside of ISM bands	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = [0.35]\sqrt{P}$	$d = [1.2]\sqrt{P}$	$d = [1.2]\sqrt{P}$	$d = [2.3]\sqrt{P}$
0.01	0.04	0.12	0.12	0.23
0.10	0.11	0.38	0.38	0.73
1.00	0.35	1.20	1.20	2.30
10.00	1.11	3.79	3.79	7.27
100.00	3.50	12.00	12.00	23.00

For transmitters whose rated power output is not specified in the table above, the safety can be calculated using the specified formula for the corresponding frequency. Here *P* is the rated output power of the transmitter in watts [W] and d the safety distance in meters [m].

Note 1: At 80 MHz and 800 MHz, the safety distance for the higher frequency range applies.

Note 2: The ISM bands (for industrial, scientific and medical applications) between 150 kHz and 80 MHz are 6.765 MHz to 6,795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

Note 3: The compliance level in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz is intended to reduce the likelihood that mobile/portable communications devices cause interference if they are unintentionally brought into patient areas. For this reason greater safety distance is recommended separation distance in these frequency ranges (factor 1.2 instead of 0.35).

Note 4: These guidelines do not necessarily apply in all situations. The propagation of electromagnetic waves is influenced by absorption and reflection from structures, objects and humans.

16 Declaration of Conformity

OSYPKA MEDICAL
Berlin, Germany • San Diego, California, USA

in accordance with Medical Device Directive 93/42/EEC Annex II excluding (4)

We,

Osypka Medical GmbH
Albert-Einstein-Strasse 3
12489 Berlin
Germany

declare under our sole responsibility, that the medical device

PACE 101H
External Single Chamber Pacemaker
including accessories

complies with the essential requirements according the Medical Device Directive 93/42/EEC Annex I.

Classification: device class IIb, non-sterile, Annex IX, rule 9

This Declaration of Conformity covers all in our company manufactured loads of the above mentioned device, which are labelled with the CE mark. Start of CE marking was April 30, 1996.

This Declaration of Conformity is based on the Full Quality Assurance System certification with the registration number G1 10 12 39212 014 issued by, the TÜV SÜD Product Service GmbH in Munich, Ridlerstraße 65, 80339 München. The certification is valid until June 20th, 2015

Berlin, March 26th, 2014

Thilo Thümecke
Regulatory Affairs Manager

Anke Barkowsky
Quality Assurance Manager

17 Conditions of Guarantee and Liability Restrictions

The medical technology products of the company OSYPKA AG are produced from high quality materials and under strict adherence to controlled and proven manufacturing processes. The quality is continuously verified during production and assured before delivery.

Nevertheless, should you recognize that a product under warranty performs inefficiently, or improperly, you must return it to us within 30 days of occurrence of the malfunction. Please enclose a description of the defect or fault. The product in question will then be thoroughly examined in our factory. We will repair or replace, free of charge, all components that are found to be defective.

The guarantee expires 24 months after delivery of the product to the user (customer). This guarantee does not include any batteries.

Product damage that occurs through improper storage or use, arbitrary alterations to the product, use other than that which the product is intended for, or by unauthorized re-use and re-sterilization, are explicitly excluded from the guarantee. The right to this guarantee is voided, if the stipulated safety check-ups are not regularly carried out.

If inspections, interventions, alterations or changes are made by parties other than those authorized in writing by the manufacturer, the guarantee becomes void.

This guarantee only applies to the repair or replacement of the device itself. All further claims for replacement by the purchaser and from third parties are excluded. All risks that exist in connection with the medical application of our products are solely and explicitly the responsibility of the purchaser, user or patient, if applicable.

THIS WARRANTY IS GIVEN IN LIEU OF ANY OTHER WARRANTY; EXPRESSED OR IMPLIED; INCLUDING, BUT NOT LIMITED TO, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE.

The remarks set forth herein contain the sole remedy available to any person. The manufacturer will not be liable to any person for any medical expenses, or any direct or consequential damages, resulting from the failure or malfunction of the product or accessories, whether such claim is based on warranty, contract, tort, or otherwise. No person has the authority to bind the manufacturer to any representation or warranty contrary to, or in addition to this warranty. There are no other warranties, which extend beyond the face hereof.

Manufacturer :

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