Instructions For Use

PACE 101H

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

Distributor
OSYPKA AG
Earl-H.-Wood-Strasse 1
D – 79618 Rheinfelden, Germany
Phone: +49 (7623) 7405 - 0
Fax: +49 (7623) 7405 - 160
e-mail: mail@osypka.de

CE 0123

5I-17-021X-B-04
Table of Contents

1 Preface ................................................................................................................................. 5
  1.1 General .......................................................................................................................... 5
  1.2 Checking the Delivery ................................................................................................. 5

2 Product Description .............................................................................................................. 7

3 Indications ................................................................................................................................ 9

4 Contraindications .............................................................................................................. 11

5 Possible Complications ..................................................................................................... 11

6 Precautionary Measures and Warnings ................................................................................ 13

7 Use and Application of the PACE 101 H ............................................................................. 15
  7.1 Construction of the PACE 101 H .................................................................................... 15
  7.2 Use .................................................................................................................................. 17
  7.2.1 Stimulation Leads ......................................................................................................... 17
  7.2.2 Connecting the Leads .................................................................................................. 17
  7.2.3 Functional description ................................................................................................. 18
  7.2.4 Determining the sensing threshold ............................................................................. 19
  7.2.5 Determining the cardiac capture threshold ................................................................. 20

8 Internal Surveillance ............................................................................................................. 21
  8.1 Battery surveillance ........................................................................................................ 21
  8.2 Operational surveillance ............................................................................................... 21

9 Storage .................................................................................................................................. 23

10 Care and Maintenance ....................................................................................................... 25
  10.1 Care and cleaning .......................................................................................................... 25
  10.2 Battery exchange .......................................................................................................... 25
  10.3 Safety check-ups of the pacemaker .............................................................................. 27
  10.3.1 Check-ups to be made by the manufacturer or authorized persons thereof: ........... 27
  10.3.2 Check-ups to be done by the user: ........................................................................... 27

11 Customer service ................................................................................................................ 29

12 Delivery Unit ...................................................................................................................... 29

13 Technical Data .................................................................................................................. 31

14 Conditions of Guarantee and Liability Restrictions .......................................................... 33

15 Declaration of Conformity ................................................................................................. 35
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 call our product manager before using.

Phone  +49 7623 7405 0

This product may only be placed in service when its proper use can be ensured.
This product has been distributed with the CE-mark since 1996
The PACE 101 H is a type CF device with internal power supply according to IEC 60601-1.

1.2 Checking the Delivery

Unpack the product and carefully check to see if any damage has occurred. Check to see if everything was delivered.
Please let us know immediately if something is missing or damaged. Claims that are filed at a later date can not be considered.
2 Product Description

The external pacemaker PACE 101H is used for temporary intensive care stimulation of the heart without spontaneous activity and with conduction system problems. The PACE 101H can be used for therapy of acute bradycardia heart rhythm problems and for pre-, intra- and post-operative stimulation of the heart as either a demand- (P-/R-wave inhibited) or as an asynchronous pacemaker. Stimulation frequency and amplitude can always be set in wide ranges to match the current therapeutic necessities.

The sensing of the heart’s own action as well as the emission of stimulation impulses is indicated optically by LED. Additionally, acoustic signals for sensing and stimulation can be switched on and off.

The PACE 101H has two modes of high rate stimulation for the treatment of tachycardia. At the touch of a button the pulse frequency can be doubled or quadrupled. The pacemaker then stimulates in asynchronous mode. An acoustic signal is automatically emitted during high rate stimulation.

Errors that occur during operation are indicated optically and acoustically.

A special circuit allows for automatic surveillance of the battery voltage. With the help of an LED as well as an acoustic signal, complete drainage of the battery can be prevented.

The PACE 101H has an additional safety feature (Run Away-Protection) in case too high a stimulation frequency is given due to a defect in the frequency generator. It limits the impulse emission to a maximum of 200 ppm.

The use and application of the device is described in the following chapters. The technical data of the PACE 101H is found in chapter 13 on page 31.
3 Indications

The external cardiac pacemaker PACE 101H, combined with a stimulation lead system, can be used whenever temporary atrial or ventricular stimulation is indicated. The device can be employed for therapeutic as well as diagnostic purposes or be used as a prophylaxis.

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)
- 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 Contraindications

There are no existing contraindications for the usage of the PACE 101H in therapeutic, diagnostic, or prophylactic procedures. However, the physiological situation as well as the general condition of the patient can limit the selection of the pacing mode and the stimulation parameters.

5 Possible Complications

During the temporary use of external pacemakers such as the PACE 101H, the following problems may occur:

- Infection
- Embolism
- Thrombosis
- Muscle and nerve stimulation
- Lead perforation
  Lead dislocation
  Lead fracture
- Connection problems between the electrode system and the pacemaker
- Insufficient tightening of the connectors
  ⇒ intermittent or complete failure of effective stimulation and/or sensing
- Significant increase in the threshold
  ⇒ Loss of stimulation effectiveness (Exit-Block)
- Significant decrease in the ECG signal amplitude
  ⇒ Loss in sensing (Entrance-Block)
- Unusual pacemaker settings
  ⇒ abnormal rhythms
- Electromagnetic interference
  ⇒ erroneous reactions
- Reversed lead connection
  ⇒ erroneous operation, abnormal rhythms
- Battery failure or complete battery drainage
failure of impulse emission

- Sensitivity set unnecessarily high
  - Sensing of R- or T-waves in the atrium or P-waves in the ventricle, respectively; sensing of interference signals

- Technical defect in the PACE 101 H, failure of components
  - Failure or change of the impulse emission; altered or no sensing

In order to prevent unnecessary complications, the PACE 101H should only be connected used by medical personnel with sufficient experience in cardiac stimulation therapy.
6 Precautionary Measures and Warnings

Following are listed the important precautionary measures and warnings. Further important precautionary measures and warnings are found in the following chapters.

- The stimulation leads provide a direct, low-ohm current path to the heart. Therefore it is an absolute must that the connector plugs not be touched with the naked hand or come in contact with electrically conductive or wet surfaces. All possible static electricity sources must be kept away from the stimulation system.
- Devices that receive their current from a mains supply increase the chance of current being accidentally diverted to the heart.
- During defibrillation, such charges can cause current flows through the pacemaker-lead-circuit. To protect the patient, the stimulation circuit should therefore be interrupted, if possible, during defibrillation.
- If the PACE 101H is to be used with either a defibrillator or electro-surgical instruments at the same time, it is an absolute must that the patient be constantly monitored and prepared for a possible failure of the pacemaker.
- If the PACE 101H is to be used with electro-surgical instruments at the same time the PACE 101H should be set in a mode without sensing.
- Intercoms in hospitals, emergency cars, mobile phones, etc. may cause electro-magnetic interferences. Following risks may results:
  - misinterpretation of the interferences as signals of the heart itself together with a cessation of the stimulation in patients without own heart rhythm,
  - switching to malfunction mode together with not-desired asynchronous stimulation in patients with own heart rhythm.
- In case a patient cable is to be used, this must first be connected to the pacemaker before the stimulation lead is connected with the patient cable.
- While the lead is being introduced and the pacemaker is being connected, constant ECG-monitoring is required. For emergency situations, a defibrillator should always be nearby and in a ready-to-use state.
- After setting the stimulation parameters, the Plexiglas cover on the front of the PACE 101H is to be fully closed in order to prevent accidentally changing the parameters.
• Intracardiac measurements may only be recorded by type CF ECG recorders that are equipped with an insulated input (floating input) for measuring intracardiac signals.

• If the PACE 101H is to be used for a longer period of time, the threshold can rise. Therefore the threshold should be periodically checked (the first time after a few hours, then daily).

• Make sure that all devices found in the vicinity of the patient are properly grounded.

• Precautionary measures should be taken before handling the external impulse generator, the patient cable or implanted leads, in order to equalize the electrostatic potential between user and patient for example by touching the patient on a spot far away from the lead.

• An inappropriately high sensitivity (small sensitivity value) increases the probability that the proper pacing function will be effected by external interference and the pacemaker will be switched to asynchronous stimulation.

• The device may not be sterilized with steam or ethylene oxide. Sterilization with ultrasound or gamma rays is equally forbidden. The pacemaker PACE 101H can be damaged by such procedures.

• Cables designated for one time use may not be resterilized and re-used.

• In case the PACE 101H is not to be used for longer periods of time, the battery must be removed in order to prevent damage from possible battery acid leakage. (Such damage can not be compensated for under the guarantee.)

• PACE 101H contains no parts that are subject to wear under conditions of proper use.

• PACE 101H contains no parts that are repairable or calibratable by anyone other than those authorized in writing by the manufacturer.
7 Use and Application of the PACE 101 H

7.1 Construction of the PACE 101 H

The front- and top side of the PACE 101H are shown in Figure 1 and Figure 2.

Figure 1: Front side of the PACE 101 H

Figure 2: Top side of the PACE 101 H
1) Lead connection sockets: Protected safety connectors for plug with a diameter of 0.9 mm to max. 2.0 mm.
   Different pole (−) black
   Indifferent pole (+) red
2) LED blinks synchronous to the detected P-/R-wave.
3) LED blinks synchronous to emission of the stimulation impulse.
4) Knob for setting the stimulation amplitude.
5) Mode switch:
   Off          Device off
   VVI          Inhibited pacemaker operation
   VVI Beep     Inhibited pacemaker operation with acoustic signal during sensing and stimulation (two different tones)
   ×2           stimulation frequency times two (High Rate-stimulation) activated
   ×4           stimulation frequency times four (High Rate-stimulation) activated
   During High Rate stimulation an acoustic signal is given automatically.
6) Button for starting High-Rate-stimulation with V00 mode.
7) Knob for setting the sensing threshold for the P-/R-wave.
   In position ‘f’ the pacemaker stimulates in the asynchronous (fixed frequency) mode.
8) Knob for setting the stimulation frequency.
9) LED for indicating errors and low battery voltage.
10) Plexiglas cover: protects against accidentally changing the chosen parameters.
11) Ridge for attaching an armband.
12) Battery compartment (see Chapter 10.2, Figure 3 on page 26)
7.2 Use

7.2.1 Stimulation Leads

For temporary stimulation of the heart with the PACE 101 H one can use myocardial leads, temporary transvenous leads or permanent leads. The leads are connected to the PACE 101 H either directly or with a patient cable with corresponding adapter.

Temporary transvenous leads: These leads are introduced transvenously into the heart and connected to the external pacemaker either directly or with the help of a patient cable. If the temporary stimulation is complete, the leads are then removed again.

Myocardial leads: Myocardial leads (heartwires) are used in open heart operations, if it is expected that the patient will need stimulation for a limited time after the operation. The heartwires are connected to the external pacemaker either directly or with the help of a patient cable. After completion of temporary stimulation the heartwires are then removed.

Permanent leads: Before the implantation of a pacemaker or during the exchange of one, stimulation can be maintained with the help of an external pacemaker. The permanent lead is connected to the external pacemaker with the help of an extension cable.

Attention: All lead systems are to be connected to type CF devices only, due to the danger of current being misdirected to the heart. This danger increases with mains supply devices.

The exact specifications of the leads and extension cables offered by Dr. Osypka GmbH are found in the OSYPKA product catalog.

7.2.2 Connecting the Leads

On the top of the external pacemaker are protected safety connectors with a diameter of 0.9 mm to 2.0 mm (Figure 1). The indifferent pole (+ pole) is red and the different pole (- pole) black.

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

1. When connecting the stimulation lead the pacemaker must be turned off. Turn the knob (5) to the ‘OFF’ position (Figure 1).
2. Open the safety connector (1)(Figure 1).
3. When using patient cables connect these to the pacemaker before connecting the stimulation leads to the patient cable.
Connect the patient cable or the optionally available Adapter Box (see 7.2.3) to the safety connectors of the pacemaker. Insure correct polarity.

4. Connect the stimulation lead to the safety connector or to the patient cable.

When using a bipolar transvenous stimulation electrode, connect the distal pole with the different output (- pole, black) and the proximal pole with the indifferent output (+ pole, red) of the PACE 101 H. This will produce a cathodic stimulation. If myocardial leads (heartwires) are used, the connection to the pacemaker is immaterial.

When using a unipolar stimulation lead connect this with the different pole (black). In order to close the circuit and permit stimulation, an indifferent lead must be connected to the positive pole (red) of the PACE 101 H. This lead must have a large surface area.

5. Secure the connections by turning the safety connectors tightly by hand.

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

7. Determine the sensing and cardiac capture thresholds (see chapter 7.2.4 and 7.2.5).

8. Monitor the proper functioning of the pacemaker with the help of an ECG-monitor or recorder.

Attention: When connecting the lead and turning on the pacemaker an ECG-surveillance of the patient is required. For emergencies a defibrillator should always be ready to use. All devices found in the vicinity of the patient must be properly grounded.

The stimulation leads provide a direct, low-ohm current path to the heart. Therefore it is an absolute must that the connector plug not be touched with the naked hand or come in contact with electrically conductive or wet surfaces. All possible static electricity sources must be kept away from the stimulation system.

7.2.3 Functional description

The PACE 101 H 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 the heart’s own activity. No impulse is given if the PP-/RR-interval is shorter than the beat-to-beat interval given by the frequency setting of the pacemaker. The pacemaker only stimulates if the beat-to-beat interval of the pacemaker is surpassed. The stimulation proceeds in these cases with constant frequency, until the pacemaker is inhibited by a spontaneous action or a faster rhythm of the heart’s own. To prevent erroneous controls the pacemaker PACE 101 H has a refractory time of 250 ms.
The mode of operation is selected with the mode switch (5). Normally the setting ‘VVI’ or ‘VVI Beep’ should be selected. The pacemaker then stimulates inhibited or with fixed frequency according to the set sensitivity value.

The PACE 101 H is set to the asynchronous mode of operation V00 by turning the Knob (7) (Figure 1) all the way to the left (to ‘f’). The value of the sensing threshold then approaches infinity and the PACE 101 H stimulates at a fixed frequency.

If the PACE 101 H is to be used as a demand pacemaker, one can turn the knob (7) to a lower sensitivity value, for example, the standard value of 2 mV.

It is also possible to stimulate in High Rate. Depending on the setting of the mode switch (5) to ‘×2’ or ‘×4’ the pulse frequency will be doubled or quadrupled, respectively, when the ‘High Rate’ button (6) is pushed. The PACE 101 H stimulates with a fixed rate during emission of High Rate-stimulation impulses, independent of the set sensitivity value. After releasing the High Rate-key the pacemaker switches to the previous mode of operation.

The stimulation frequency can be set with knob (8). In asynchronous mode it must be above the natural heart rate of the patient.

The PACE 101 H shows the sensing of P-/R-waves with the green LED (2). If the device detects no P-/R-waves in the demand-mode, the amplitudes lie under the set sensing threshold or the patient’s own frequency lies under the selected stimulation frequency. The device then stimulates at a fixed frequency.

The stimulation amplitude can be set with knob (3). The setting should take place after determining the cardiac capture threshold (see chapter 7.2.5).

After setting the stimulation parameters the Plexiglas cover on the front of the PACE 101 H is to be fully closed in order to prevent accidentally changing the parameters.

7.2.4 Determining the sensing threshold

The determining of the sensing threshold can only take place, if the patient has his own frequency that is haemodynamically tolerated over a period of several minutes. In this case the sensing threshold is determined as follows:

1. Set the stimulation amplitude (knob (4)) to the smallest value, so that the asynchronous stimulation that takes place during the procedure remains ineffective.

2. Select a basic frequency (knob (8)), that is 10 ppm under the patient’s own frequency.
3. If the pacemaker should sense the heart’s own signals, continue to reduce the sensitivity (i.e. raise the sensitivity value) until no more sensing takes place and the pacemaker stimulates asynchronous in the corresponding channel.

4. Raise the sensitivity (again) (i.e. reduce the sensitivity value) until the stimulation emission is inhibited. This is the sensing threshold.

5. In order to create a buffer zone the sensitivity must be raised again. The setting should be around half of the value of the sensing threshold.

**Note:** With optimal lead position in the ventricle, the sensitivity value in demand mode should be at least 2 mV. If no inhibition occurs with continual heart activity at a setting of 2 mV, the lead has to be repositioned. If, in addition, no higher R-wave amplitude can be measured, the sensing threshold can be reduced below the standard value down to 1 mV.

**Attention:** A unnecessarily high sensitivity (i.e. smaller sensitivity value) increases the probability that proper pacing function will be effected by external interference and the pacemaker will be switched to asynchronous stimulation.

### 7.2.5 Determining the cardiac capture threshold

If the patient has a sufficient heart frequency of his own, the sensing threshold must be determined, before the capture threshold is determined. This insures that no asynchronous overlapping of stimulation and the heart’s own rhythm occurs.

To determine the cardiac capture threshold proceed as follows:

1. Select a basic frequency (knob (8)), that is 10 ppm over the patient’s own frequency. If the pacemaker is already effectively stimulating, slowly lower the stimulation amplitude (knob (4)) until the stimulus is no longer effective.

2. Slowly raise the stimulation amplitude until the stimulus is (again) effective. This is the cardiac capture threshold. In order to create a buffer zone the stimulation amplitude must be raised further. Select stimulation amplitude which is about double to triple the capture value.

**Attention:** If the PACE 101 H is to be used for a longer period of time, the capture threshold can rise. Therefore it should be checked periodically (the first time after a few hours, then daily).
8 Internal Surveillance

8.1 Battery surveillance

The external pacemaker PACE 101H is powered by a 9 V battery which is monitored internally by the PACE 101H. If the battery voltage falls under a certain value this will be indicated by a repeated short blinking of the red LED (9) (see chapter 8.1). With increasing discharging of the battery the interval of blinking decreases from 5 s at first to 1 s. At the same time an acoustic warning tone will be given. The interval between tones decreases from 5 min to 1 min.

Attention: When the blink interval jumps to 0.2 s and the warning tone-interval to 0.6 s, the battery must be changed immediately.

The lifespan of the battery is dependent upon the set stimulation parameters. At 100% stimulation with standard parameters (frequency 72 ppm, stimulation amplitude 8 V) the average lifespan of a recommended alkaline battery is about 38 days plus 2 days reserve after the first request to change the battery. With use of the recommended lithium battery the lifespan increases to 53 days plus 2 reserve days under the same operational conditions.

If the device is turned off after the request to change the battery, the battery must be changed before the pacemaker can be turned on again.

8.2 Operational surveillance

The PACE 101H has a surveillance controller that monitors the entire timing of the pacemaker processes. The sequence and the timing of the PACE 101 H output signals are monitored.

When a malfunction occurs, an error message is given by means of a constantly lit red LED (9). At the same time a repeating acoustic warning signal is given. The error is confirmed by turning the device off and on. If the error was not eliminated, the LED lights up again and additional warning tones will be given.

In addition to error messages, the PACE 101 H reacts differently according to the type of the errors or the affect on the function:
• Errors that require checking by the manufacturer are indicated as above. The pacemaker remains functioning, however.

• Errors that can effect unwanted High Rate stimulation lead to a temporary stoppage of stimulation in the sense of Run Away Protection. The pacemaker function is maintained below the frequency defined by the Run Away Protection.

• A failure of the pacemaker processes leads to a restart of the device.
9 Storage

Store the product cool and dry.

The storage temperature for the PACE 101H is -20°C to +60°C. Be sure, however, that the device is between +10°C and +45°C before use.

Avoid direct sunlight.

**Note:** In case the PACE 101 H is not to be used for longer periods of time, the battery must be removed in order to prevent damage from possible battery acid leakage. (Such damage can not be compensated by the guarantee.)
10 Care and Maintenance

10.1 Care and cleaning

As a precision electronic device the external pacemaker PACE 101H is to be handled with corresponding care. Although the device is robustly constructed, it can be damaged by heavy mechanical stress, for example falling on a hard floor.

Due to the device’s construction, dirt and dust can be easily removed with a sponge or towel dampened with water or alcohol.

To disinfect the pacemaker, the casing can be rubbed down with alhydex or cydex or with detergicide.

**Attention:** The pacemaker may not be submerged in water or in any other cleaning solution. Do not use any scrubbing powder/liquid on the device.

The pacemaker may not be sterilized with steam or ethylene oxide. Equally forbidden is sterilization with ultrasound or gamma-radiation. The external pacemaker PACE 101 H can be damaged by these procedures.

10.2 Battery exchange

Battery exchange during operation should take place when the request to change occurs for the first time (red LED lights up as well as the emission of an acoustic warning signal). The remaining time from this moment until complete drainage of the battery depends heavily on the type of battery used and therefore can not be definitely given. With the recommended battery a 2 day reserve can typically be expected if the PACE 101 H is set to 72 ppm frequency and 8 V stimulations amplitude.

A battery change is additionally recommended after 38 or 53 days of operation for alkaline or lithium batteries respectively.

To change the battery slide the compartment lid (12) (Figure 3) to the side. After pulling out the battery and the battery clip the old battery can be removed. The new battery (9 V transistor battery) must be connected with correct polarity to the battery clip. Close the battery compartment lid when finished.

Please dispose of the old battery properly!
Figure 3: Back side of the PACE 101H
10.3 Safety check-ups of the pacemaker

In order to guarantee the safe operation of the PACE 101 H, the following check-ups must be carried out on a regular basis.
They consist of check-ups that have to be carried out by two groups of persons who, because of their training, knowledge and experience gained through practical work, can carry out such safety check-ups properly and do not require any special instructions or directives. The one group being users/service persons and the other, the manufacturer or authorized persons thereof.

10.3.1 Check-ups to be made by the manufacturer or authorized persons thereof:

Yearly checks:
✓ Measuring the differential or auxiliary currents
✓ Measuring the stimulation parameters (amplitude, pulse width)
✓ Measuring the stimulation rate
✓ Measuring the sensing sensitivity
✓ Measuring the refractory period
✓ Inspecting the interference behavior
✓ Inspecting the battery surveillance

We recommend having the manufacturer carry out the yearly safety check-ups and the function inspection.

10.3.2 Check-ups to be done by the user:

Before each use Visual inspection and function test:
✓ Inspect the device and accessories for visible damage
✓ Inspect the connections for visible damage
✓ Inspect all connections to see if they hold tight and function perfectly
✓ Inspect all operating elements and displays for perfect function

After each use:
✓ Care and cleaning of the device and of the accessories is to be done according to the instructions
Warning: The PACE 101H contains no parts that are subject to wear during normal use. The PACE 101H contains no parts that are repairable or calibratable by anyone other than those authorized in writing by the manufacturer.
11 Customer service

If you have any questions, our product management is available under the following number:

Phone: +49 7623 7405 0

12 Delivery Unit

- PACE 101H incl. Battery
- Arm cuff with Velcro fastener\(^1\)
- One lead-connector cables D 2P-SP

\(^1\) For wear over clothing only
## 13 Technical Data

### PACE 101 H external demand pacemaker with high-rate stimulation and acoustic signals

<table>
<thead>
<tr>
<th>Measurement conditions:</th>
<th>Environment temperature 23 ± 4°C</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Relative humidity 30 - 75 %</td>
</tr>
<tr>
<td></td>
<td>Load resistance 500 Ω ± 1%</td>
</tr>
<tr>
<td></td>
<td>Voltage supply 9 V ± 5 %</td>
</tr>
<tr>
<td></td>
<td>Test impulse: triangle 2 ms / 13 ms</td>
</tr>
</tbody>
</table>

| Modes: | A00, AAI, V00, VVI, acoustic signals can be turned on or off; (different tones for sensing and stimulation). |

<table>
<thead>
<tr>
<th>Stimulation frequency:</th>
<th>Variable from 30 ppm to 180 ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exactness of setting: ±10%</td>
</tr>
</tbody>
</table>

| High Rate stimulation: | async., freq. ×2, ×4, with acoustic signals |

<table>
<thead>
<tr>
<th>P-/R-waves sensitivity:</th>
<th>Variable from 1 mV to 20 mV, ∝</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exactness of settings: ±20 %</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Input resistance:</th>
<th>24 kΩ ± 10 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Output resistance:</td>
<td>&lt; 25Ω; for load resistance &gt; 150Ω</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Defibrillation protection:</th>
<th>Suppression diode built in</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensing visualization:</td>
<td>Green LED blinks synchronous to detected P-/R-wave</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Output impulse:</th>
<th>Polarity: cathodic, capacitively coupled</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Form: biphasic, asymmetric</td>
</tr>
<tr>
<td></td>
<td>Duration: 0.75 ms ± 0.05 ms</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Output impulse amplitude:</th>
<th>Variable from 0.3 V - 12 V</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exactness of setting: ± 10 % ±0.1V</td>
</tr>
</tbody>
</table>

| Output impulse visualization: | Yellow LED blinks synchronous to the emission of the stimulation impulse |

<table>
<thead>
<tr>
<th>Run Away-Protection:</th>
<th>200 ppm ± 10 ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refractory period:</td>
<td>250 ms ± 5%</td>
</tr>
<tr>
<td>Interference recognition:</td>
<td>Interference frequencies &gt;283 ppm ± 5% cause a switch to asynchronous safety stimulation</td>
</tr>
<tr>
<td>Feature</td>
<td>Specification</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Battery surveillance:</td>
<td>Continuous</td>
</tr>
<tr>
<td></td>
<td>Replacement indication: acoustic and by blinking of the red LED.</td>
</tr>
<tr>
<td></td>
<td>Battery threshold voltage (7.2 ± 0.2 V)</td>
</tr>
<tr>
<td>Battery:</td>
<td>IEC 6LR61, 9 Volt</td>
</tr>
<tr>
<td></td>
<td>Recommended types:</td>
</tr>
<tr>
<td></td>
<td>Duracell alkaline MN 1604</td>
</tr>
<tr>
<td></td>
<td>Lithium SLM</td>
</tr>
<tr>
<td>Lifespan of the recommended</td>
<td>Alkaline: typically 38 days (72 ppm, 8 V)</td>
</tr>
<tr>
<td>batteries:</td>
<td>Lithium: typically 53 days (72 ppm, 8 V)</td>
</tr>
<tr>
<td></td>
<td>with an additional 2 day reserve after Low Batt.</td>
</tr>
<tr>
<td>Casing dimensions (L×W×H):</td>
<td>60 mm × 115 mm × 20 mm, plastic housing</td>
</tr>
<tr>
<td>Weight without/with battery:</td>
<td>125 g / 170 g</td>
</tr>
<tr>
<td>Lead connection:</td>
<td>Protected safety connectors for plugs with 0.9 to 2.0 mm diameter</td>
</tr>
</tbody>
</table>

We reserve the right to make technical improvements without notice.
14 Conditions of Guarantee and Liability Restrictions

The medical technology products of the company Osypka Medical GmbH 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.
15 Declaration of Conformity

We,

Osypka Medical GmbH
Albert-Einstein-Strasse 3
12489 Berlin

declare under our sole responsibility, that the medical device

External Single Chamber Pacemaker PACE 101H
including accessories


This Declaration of Conformity covers all in our company manufactured loads of the above mentioned device, which are labelled with the CE mark. This Declaration of Conformity is based on the Full Quality Assurance System certification with the registration number G1 10 04 39212 013 issued by the Notified Body Nr. 0123, the TÜV Product Service GmbH in Munich.

Berlin, 2010/06/21

Dr.-Ing. Bernd Tröger
Plant Manager

Dipl.-Ing. (FH) Thilo Thümecke
Quality Manager