Medtronic

Single Chamber Temporary External Pacemaker

53401

Technical Manual

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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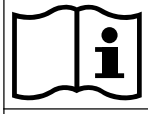
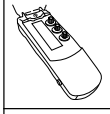
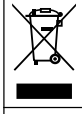
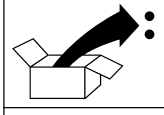
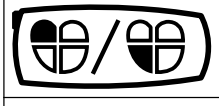
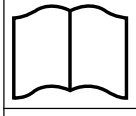
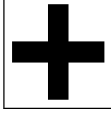
1 Overview

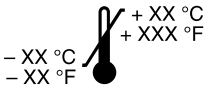
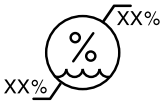
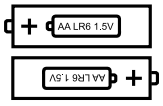
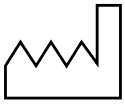
1.1 About this manual

This manual describes the features and functions of the Medtronic Model 53401 Single Chamber Temporary External Pacemaker (referred to as the “temporary pacemaker”).

1.2 Symbols

The following table describes symbols that may or may not be present on your product or package labels. The presence of a symbol in this table is not a statement of compliance.

Explanation of symbols	
	System meets the applicable Canadian and U.S. electrical safety standards.
	Consult instructions for use
	Follow instructions for use
	Caution
	Conformité Européenne (European Conformity) This symbol means that the device fully complies with applicable European Union Acts.
	Temporary external pacemaker
	Defibrillation-proof type CF applied part
	Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See http://recycling.Medtronic.com for instructions on proper disposal of this product.
	For US audiences only
	Package contents
	Single chamber temporary pacemaker
	Product documentation
	Accessories

Explanation of symbols	
	Storage temperature limitation
	Humidity limitation
	Battery
REF	Reorder number
EC REP	Authorized representative in the European Community
	Manufacturer/Date of manufacture
	Date of manufacture
SN	Serial number
	Non-ionizing electromagnetic radiation
	Notice of proper disposal
IP21	This product conforms to IP21. There are no openings that allow the user to insert a finger or similarly sized objects. The product is resistant to dripping water or vertically falling drops.
	MR Unsafe. An item that is known to pose hazards in all MR environments.

1.3 General description

The temporary pacemaker is a battery-powered, single chamber, external pulse generator designed primarily for temporary antibradycardia pacing therapy in asynchronous or demand (synchronous) modes. High-rate, burst pacing therapy up to 800 ppm for atrial tachyarrhythmias is available in the asynchronous mode.[1]

The temporary pacemaker is typically connected to temporary transvenous, epicardial, or myocardial pacing leads in a bipolar configuration, using either Medtronic patient cables, Medtronic surgical cables, or compatible patient cables (see Section 1.7).

The temporary pacemaker operates using 2 LR6-sized (AA-sized) alkaline batteries (see Section 7.1). The batteries are installed in the battery drawer at the bottom of the temporary pacemaker. The temporary pacemaker is classified as Internally Powered ME Equipment.

1.3.1 Safety features

The temporary pacemaker includes the following safety features:

[1] For atrial use only.

- Protective cover to prevent accidental manipulation of controls
- Self-test function
- Low battery indicator
- Lock feature to prevent accidental change of parameters
- Power button requires push-and-hold to turn off the temporary pacemaker to avoid unintended shutdown
- Runaway rate protection
- Protection from defibrillation shock
- Continuous operation during battery replacement
- Electrostatic protection
- Minimized susceptibility to electromagnetic and magnetic interference
- Protective cover over Rapid Atrial Pacing (RAP) controls to avoid unintentional use
- Cautionary label at the RAP controls

1.3.2 Operating features

The temporary pacemaker includes the following operating features:

- Three-dial operation – provides adjustable rate, output, and sensitivity settings
- Ability to pace in single chamber pacing modes – AAI, AOO, VVI, and VOO
- Easy-to-view rate, output, and sensitivity settings
- Pacing and sensing status indicators – shows temporary pacemaker interaction with the heart
- Low battery indicator – indicates when to replace the batteries
- Lock/Unlock button – safeguards against unintentional parameter changes
- Constant current device – the current output is maintained at a constant value when the temporary pacemaker emits a pulse. This value is set by the output control and does not vary.

1.4 Intended use

The Medtronic Model 53401 Single Chamber EPG pacemaker is intended to be used in conjunction with a cardiac pacing lead system for temporary atrial or ventricular pacing in a clinical environment. The 53401 Single Chamber EPG can be used where short-term demand (synchronous) or asynchronous pacing is indicated for therapeutic, prophylactic, or diagnostic purposes.

Specific indications for temporary cardiac pacing include, but are not limited to, the following indications:

- Complete heart block;
- Sinus bradycardia;
- Sick Sinus Syndrome;
- Bradycardia with congestive heart failure;
- Atrial and/or ventricular arrhythmias;
- Cardiac arrest;
- Temporary support, management, and evaluation of a patient prior to permanent pacemaker implantation;
- Support during permanent pacemaker replacement;
- Cardiac complications during invasive or surgical procedures;
- Temporary support of a patient following cardiac surgery;
- Acute myocardial infarction complicated by heart block; and
- High-rate burst pacing for the treatment of supraventricular tachyarrhythmias

The 53401 Single Chamber EPG can be used to determine sensing potentials of temporary and permanently implanted lead systems. When implanting a permanent pacemaker, however, Medtronic recommends the use of a Medtronic Pacing System Analyzer.

This device has not been specifically tested for pediatric use.

1.5 Contraindications

There are no known contraindications for the use of temporary pacing as a means to control heart rate. However, the patient's age and medical condition may dictate the type of temporary pacemaker and lead system that the physician uses.

1.5.1 Atrial pacing

Atrial pacing is ineffective in the presence of atrial fibrillation or flutter.

Single chamber atrial pacing is contraindicated in the presence of AV conduction disorders.

1.5.2 Asynchronous pacing

Asynchronous pacing is contraindicated in the presence of intrinsic cardiac rhythms.

1.5.3 Atrial high-rate burst pacing therapy

Atrial high-rate burst pacing therapy is intended for use in the atrium only. High-rate burst pacing is contraindicated in the ventricle; it may result in life-threatening arrhythmias.

1.5.4 Concomitant pacing

Temporary pacing is contraindicated in the presence of another pacing system.

Do not use the temporary pacemaker to pace a patient while another pacing system is also actively pacing the patient. Concomitant pacing can occur where both pacing systems compete to pace the patient.

If concomitant pacing occurs, the temporary pacemaker may not be able to pace the patient, or may pace the patient asynchronously. Concomitant pacing could cause the temporary pacemaker to potentially pace into a T-Wave or result in a pacemaker-mediated tachycardia.

1.6 Package contents

The temporary pacemaker is supplied with the following items:

- Two LR6-sized (AA-sized) alkaline batteries (see Section 7.1)
- Literature
- Carrying case

1.7 Compatible accessory components

The following compatible accessory components are available for the temporary pacemaker:

- Medtronic Model 5409 Disposable Pouch

The following reusable compatible cables are available for the temporary pacemaker:

- Medtronic Patient Cables (Model 5433 family)
- Medtronic Surgical Cables (Model 5832 family)

The following disposable compatible cables are available for the temporary pacemaker:

- Medtronic Surgical Cable (Model 5833 family)
- Medtronic Patient Cables (Model 5846 family)
- Medtronic Patient Cables (Model 5487 family)
- Compatible temporary transvenous, epicardial, or myocardial pacing leads

Contact your local Medtronic representative to order compatible accessory components and cables.

1.8 Special notice for the temporary pacemaker

Use of prior Medtronic temporary pacemakers has met with some success in the treatment of certain heart disorders, including heart block and heart arrhythmias. However Medtronic makes no warranty that the Model 53401 Single Chamber Temporary External Pacemaker will efficiently restore adequate cardiac function for all patients. For information regarding common causes of pacing difficulty, consult other portions of the manual.

2 Warnings, precautions, and adverse events

2.1 Warnings

Patient monitoring – Monitor the patient continuously while the temporary pacemaker is in use to ensure it is operating properly and delivering appropriate therapy to the patient.

Equipment modification – Do not modify the temporary pacemaker. Modifications could impact the temporary pacemaker effectiveness and adversely affect patient safety.

Temporary pacemaker compatibility – Only connect items that have been specified as part of the temporary pacemaker or that have been specified as being compatible with the temporary pacemaker.

Temporary pacemaker use – The temporary pacemaker is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Defibrillation/cardioversion – The temporary pacemaker is protected from damage caused by internal defibrillation discharges up to 50 J (watt-seconds) and external defibrillation discharges up to 360 J. However, it is recommended that paddles be placed as far away from the temporary pacemaker or the lead system as is practical.

Whenever possible, for the safety of the patient, disconnect the temporary pacemaker from the implanted lead system before defibrillating or cardioverting. Excessive defibrillation energy can damage the temporary pacemaker. This can result in a large current flowing through the implanted lead system and temporary pacemaker, which could reduce intended defibrillation energy delivered to the patient or cause myocardial damage.

If damage to the temporary pacemaker is suspected due to defibrillation, disconnect it from the patient and return it to Medtronic for service.

Line-powered equipment – An implanted lead or a lead with an extension cable constitutes a direct, low-resistance current pathway to the myocardium. Due to the danger of tachyarrhythmias resulting from alternating current leakage, extreme caution must be taken to properly ground all line-powered equipment used on or in the vicinity of the patient.

Electrosurgical units (cautery) – Electrosurgical units can cause loss of pacing from oversensing or tachyarrhythmias by inducing current on the leads, and thus should never be used within 15 cm (6 in) of the pacemaker/lead system.

Ablation (RF ablation or microwave ablation) – Ablation is a surgical technique in which radio frequency (RF) or microwave energy is used to destroy cells by creating heat. Ablation used in cardiac device patients may result in, but is not limited to, induced ventricular tachyarrhythmias, oversensing, unintended tissue damage, device damage, or device malfunction.

Pulse-modulated ablation systems may pose higher risk for induced ventricular tachyarrhythmias. Medtronic cardiac devices are designed to withstand exposure to ablation energy. To mitigate risks, observe the following precautions:

- Ensure that temporary pacing and defibrillation equipment is available.
- Avoid direct contact between the ablation catheter and the temporary leads.
- Position the return electrode patch so that the electrical current pathway does not pass through or near the device and leads.
- Continuously monitor the patient during ablation with at least two separate methods, such as arterial pressure display, ECG, manual monitoring of the patient's rhythm (taking pulse) or monitor by some other means such as ear or finger pulse oximetry, or Doppler pulse detection.

To avoid or mitigate the effects of oversensing, if appropriate for the patient, initiate asynchronous pacing.

Electromagnetic interference (EMI) – Pacemakers operating in the demand mode respond to intracardiac potentials with magnitudes of a few mV. This level of sensitivity makes the temporary pacemaker inherently sensitive to some external fields. In the presence of excessive levels of interference, the temporary pacemaker may inhibit completely or revert to asynchronous operation, pacing at the rate set by the RATE dial.

It is recommended that the temporary pacemaker be set to an asynchronous pacing mode at a rate higher than the patient's intrinsic rate when operated in the presence of strong electromagnetic interference (EMI).

The following list includes sources of excessively strong EMI that may temporarily affect the operation of the temporary pacemaker:

- Electrosurgical equipment
- Diathermy equipment
- Some medical telemetry equipment (when operated within 1 m [about 3 feet] of the pacemaker)
- Communication transmitters such as cellular phones, "walkie talkies", and transmitters in emergency transport vehicles
- Magnetic resonance imaging (MRI) equipment

Atrial High-Rate Burst Pacing Therapy (Rapid Atrial Pacing) – Use of high rates in the atrium could result in high-rate conduction to the ventricle. Defibrillation equipment should be on standby, immediately available during atrial high-rate burst pacing therapy.

There is no ventricular back-up pacing during delivery of atrial high-rate burst pacing therapy.

Connecting the lead system – The patient cables should be connected to the temporary pacemaker before the lead is connected to the patient cable.

Handling implanted leads – When handling implanted leads (temporary or permanent), the terminal pins or exposed metal must not be touched nor be allowed to contact electrically conductive or wet surfaces.

MR unsafe – The temporary pacemaker is MR unsafe. Do not bring the temporary pacemaker into Zone 4 (magnet room), as defined by the American College of Radiology.

2.2 Precautions

Random failures – The physician should be aware that operational failure of the temporary pacemaker can occur as the result of battery depletion, mishandling, or random component failure.

The following list includes possible operational failures of the temporary pacemaker:

- No output or erratic output
- No sensing or erratic sensing
- False indicator light signals
- Inappropriate variance of rate, output pulse width, or output amplitude

- Reversion to asynchronous pacing
- Loss of control of rate, output, sensitivity, or power

If loss of control of rate, output, sensitivity, or power occurs, and it is not due to a low battery, disconnect the temporary pacemaker from the patient and return it to Medtronic for service.

Temporary pacemaker repair – Do not attempt to repair the temporary pacemaker. Only a qualified Medtronic Technical Services representative can repair the temporary pacemaker. Contact Medtronic at the telephone number on the back cover of this manual if the temporary pacemaker requires service.

Service condition – Before each use, evaluate the temporary pacemaker for damage and observable defects. Do not use the temporary pacemaker if the case is cracked, the controls are not functioning, the display is not working, or if the controls, display, or connectors are broken. If the temporary pacemaker has any observable defects, contact Medtronic at the telephone number on the back cover of this manual for service.

Cleaning and disinfection – Clean and disinfect the temporary pacemaker as needed according to your organization's policies. Use only the recommended methods to clean and disinfect the temporary pacemaker.

Batteries – Only install the recommended batteries in the temporary pacemaker. Batteries with different physical dimensions, non-alkaline (e.g., lithium or rechargeable) or batteries with contamination on the battery terminals, may result in erratic operation of the temporary pacemaker, no pacing output, or damage to the temporary pacemaker, specifically to the battery compartment.

Replace the batteries when the low battery indicator flashes during temporary pacemaker operation.

Only use new batteries that have not passed their expiration date.

Inspect battery terminals for contamination. Using batteries with contaminated terminals can result in the temporary pacemaker turning off, decreased battery life, or corrosion to the battery compartment.

Check the battery status prior to use and routinely while in use. Replace the batteries when the low battery indicator flashes. Verify that the battery drawer is fully closed and latched in place.

Failure to ensure that the battery drawer is fully latched may result in loss of power. Continued temporary pacemaker operation is not an indication that the battery drawer is properly latched.

New battery installation – Ensure that the new batteries are installed with the correct battery polarity by verifying that the batteries align with the polarity markings on the inside of the battery drawer. The temporary pacemaker requires proper battery polarity for operation. After installing the batteries, ensure that the battery status indicator displays full battery power and that the low battery indicator is not flashing. The temporary pacemaker may temporarily continue to pace and sense with weak, dead, or incorrectly installed batteries.

Pacing leads and cables – Improper connection, displacement, or fracture of leads or cables may result in pacemaker system failure. Inspect leads and cables for damage before each use.

Pacing system adjustments – Monitor the patient's ECG and blood pressure. Keep defibrillation equipment on standby, immediately available for emergency use during evaluation of stimulation and sensing thresholds, pacemaker and pacing lead connections and adjustments, and atrial high-rate burst pacing therapy.

Default synchronous (demand) pacing mode – The default power-up settings for the synchronous (demand) pacing mode are not always appropriate for every patient or situation. Set the temporary pacemaker to the appropriate pacing mode to meet the pacing needs of the patient.

Patient monitoring after defibrillation – Monitor the patient after a defibrillation has occurred to verify that the temporary pacemaker and the cable/lead systems are still delivering the appropriate therapy.

Bipolar lead systems – Bipolar lead systems are recommended because they are less susceptible to electromagnetic interference. Separation between the positive (+) electrode and negative (–) electrode of the same lead system should not exceed 15 mm (0.6 in). Failure to follow this spacing recommendation could result in oversensing. Clinical risks for not following this spacing recommendation include, but are not limited to, loss of pacing output.

Unipolar lead systems – Unipolar lead systems are not recommended because they are more susceptible to electromagnetic interference, which may result in inappropriate pacing.

Atrial sensing – When use of the temporary pacemaker requires atrial sensing, the sensing threshold should be evaluated for sufficient safety margin.

Place the temporary pacing lead on the right atrial free wall, oriented along the direction of the myocardial fibers, approximately 1 cm (0.4 in) apart. It is important to achieve a sensing threshold of at least 1.0 mV. Set atrial sensitivity to a minimum of one-half the measured threshold. The setting ensures a minimum safety margin of two times the sensing threshold. Failure to follow this procedure can lead to delivery of asynchronous pulses.

Sensing thresholds – Do not use the temporary pacemaker to determine sensing thresholds for permanently implanted lead systems. When implanting a permanent pacemaker, Medtronic recommends the use of a pacing system analyzer (PSA).

Sensitivity settings – Since the sensitivity setting determines the smallest signal that can be sensed by the pacemaker, set the sensitivity dial to one-half the mV value of the patient's sensitivity threshold. This setting will provide a 2x safety margin to ensure proper sensing.

A more sensitive setting may be chosen to provide a greater safety margin. However, be aware that setting the sensitivity value too low (too sensitive) could result in inappropriate sensing of far field signals (for example, sensing of R-waves or T-waves on the atrial channel or P-waves on the ventricular channel), leading to inappropriate inhibition of pacing pulses.

Sensitivity threshold testing – Complete the sensitivity threshold testing to determine the appropriate settings for sensitivity. Clinical risks for failure to perform this step include, but are not limited to, asynchronous ventricular pacing.

Output threshold testing – Complete the output threshold testing to determine the appropriate settings for output. Clinical risks for failure to perform this step include, but are not limited to, loss of capture, induced tachycardia, and loss of hemodynamic support.

Electrostatic discharge (ESD) – The pacing lead(s) provides a low-impedance pathway to the heart. Therefore, it is recommended that attending health care professionals discharge any static electricity by touching a large metal or conductive, grounded surface before touching the patient, the cable, the leads, or the temporary pacemaker. Also, neutralize any static electricity from the patient by touching the patient away from (i.e., distal to) the leads.

Termination of pacing – Abrupt termination of pacing stimuli may result in intervals of asystole before an intrinsic rhythm is re-established. Before terminating pacing, set the temporary pacemaker to a demand mode (AAI/VVI); then gradually reduce the pacing rate below the patient's intrinsic rate.

2.3 Environmental precautions

The temporary pacemaker has been carefully designed and tested to ensure reliability during normal use. However, electronic devices are susceptible to many environmental stresses. To avoid damage to the temporary pacemaker, observe the following precautions:

- Do not drop the temporary pacemaker or handle it in a way that might physically damage it. The temporary pacemaker may appear to work appropriately immediately after being dropped or mishandled, but operational damage may have occurred. Perform safety and technical checks if the temporary pacemaker has been dropped.
- Secure the temporary pacemaker during use to prevent the temporary pacemaker from falling or being dropped. A fall or drop may cause dislodgement of the cables and/or leads from the temporary pacemaker or may cause damage to the temporary pacemaker.
- Do not place the temporary pacemaker in any area where a patient may interact with it. Tampering with programmed parameters may have direct and serious patient health effects. The temporary pacemaker should be placed in an area that minimizes tampering with the device by unauthorized personnel (for example, patients or visitors).
- Avoid spilling fluid on the temporary pacemaker. The temporary pacemaker was carefully designed to minimize leakage, but fluid incursion may still occur. Medtronic recommends the use of a protective cover, such as the Model 5409 Disposable Pouch, to minimize fluid incursion and exposure to contamination.
- Avoid contaminating the patient cable receptacles with blood or other body fluids.
- Always use safe electrostatic discharge (ESD) procedures; the temporary pacemaker could be adversely affected by ESD.
- Do not open the temporary pacemaker. The seam joining the unit is designed to minimize fluid incursion and may not be effective if improperly opened and resealed. Furthermore, removing the label on the back of the temporary pacemaker may compromise the ESD barrier. Opening the temporary pacemaker voids the warranty.
- Do not sterilize the temporary pacemaker by ethylene oxide, gamma irradiation, or steam (autoclave).The temporary pacemaker is not intended to be sterilized.
- Do not store the temporary pacemaker for long periods of time with the batteries in the battery drawer. Remove the batteries for long-term storage to prevent damage to the temporary pacemaker in the event of battery leakage.
- Rapid temperature changes may affect proper operation. Always allow the temperature of the temporary pacemaker to stabilize in the environment in which it will be used before attachment and operation.
- Prolonged storage or operation of the temporary pacemaker in high humidity may affect proper operation. Allow the temporary pacemaker to dry after exposure to humidity.
- Use only the recommended cleaners and disinfectants on the temporary pacemaker. Use of other cleaners and disinfectants may cause damage to the temporary pacemaker.

Other environmental factors may impact proper performance of the temporary pacemaker in the hospital setting. Use of appropriate environmental health and safety practices will help prevent environmental damage to the temporary pacemaker.

2.4 Adverse effects

Atrial high-rate burst pacing – Atrial high-rate burst pacing may result in the onset of tachycardia, acceleration of an existing tachycardia, or fibrillation. Application of temporary atrial high-rate burst pacing should be performed in a carefully monitored and controlled patient environment. Monitor the patient's ECG and blood pressure. Keep defibrillation equipment on standby and immediately available for emergency use.

Lead systems – Potential adverse effects related to the use of pacing lead systems used in conjunction with the temporary pacemaker include, but are not limited to, the following events:

- Inappropriate lead connections
- Inadvertent disconnection of the lead system
- Lead fracture or displacement causing intermittent or complete loss of capture and/or sensing
- Perforation and tamponade

Other potential adverse effects related to the use of any implanted lead system include, but are not limited to, the following events:

- Myocardial irritability resulting in fibrillation
- Infarction
- Pericarditis
- Body rejection phenomena (local tissue reaction)
- Muscle and nerve stimulation
- Infection

Nerve or muscle stimulation – Nerve or muscle stimulation can be caused by pacing lead contact with the nerve or muscle tissue and/or by high-output settings. The stimulation may be controlled by repositioning or replacing the electrode, or by reducing the output pulse amplitude.

Safety margins – Determine an adequate safety margin for sensing and pacing in both the ventricle and atrium. Failure to do so may result in inappropriate pacing.

Temporary pacemakers – Potential adverse effects related to the use of the temporary pacemaker include, but are not limited to, the following events:

- Asystole following abrupt cessation of pacing
- Inhibition or reversion in the presence of strong electromagnetic interference
- Initiation of a tachyarrhythmia or acceleration of an existing tachyarrhythmia

3 Controls, indicators, and other features

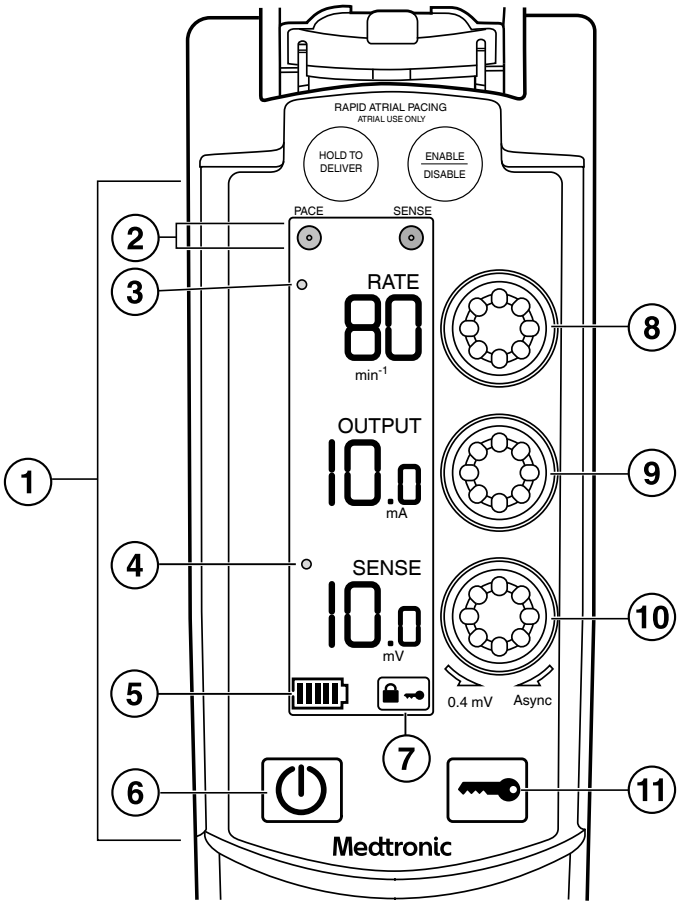
3.1 Temporary pacemaker controls and indicators

The screen indicators display the **RATE**, **OUTPUT**, and **SENSITIVITY** values, pacing and sensing status, Rapid Atrial Pacing (RAP) use, the battery status, and the lock status. See Figure 1.

The controls next to the screen are used to do the following actions:

- Adjust the **RATE**, **OUTPUT**, and **SENSITIVITY** values using the RATE, OUTPUT, and SENSITIVITY dials
- Turn on or turn off the temporary pacemaker by pressing the On/Off button
- Lock or unlock the temporary pacemaker by pressing the Lock button

Figure 1. Controls and indicators



1 Screen
2 Pacing and sensing status indicator LEDs
3 RAP indicator LED
4 ASYNC indicator LED
5 Battery status indicator
6 On/Off button
7 Lock indicator
8 RATE dial
9 OUTPUT dial
10 SENSITIVITY dial
11 Lock/Unlock button

Note: Screen values contained in this manual are presented for reference only. Actual values may vary, depending parameter value selections.

3.2 Controls

The dials and buttons used to control the functions and parameter settings of the temporary pacemaker are described in this section.

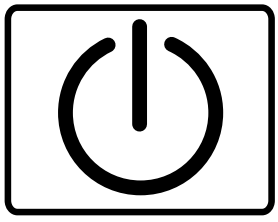
Notes:

- All adjustments to the RATE, OUTPUT, and SENSITIVITY dials take effect within the next two pacing cycles.
- The **RATE**, **OUTPUT**, and **SENSITIVITY** values are displayed numerically. The numerical value for each setting appears to the left of the dial.

3.2.1 On/Off button

Use the On/Off button to turn on or turn off the temporary pacemaker (see Figure 2).

Figure 2. On/Off button



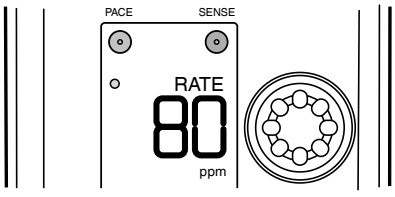
3.2.2 Rate dial

Use the RATE dial to set the base rate, in ppm, at which pacing pulses are delivered (see Section 5.1.4).

The **RATE** ranges from 30 to 200 ppm. Turn the **RATE** dial clockwise to increase **RATE** and counterclockwise to decrease **RATE**.

When the temporary pacemaker is turned on, the **RATE** is set to 80 ppm (nominal). See Section 7.1 for more information about the **RATE** range and increments.

Figure 3. RATE value and dial



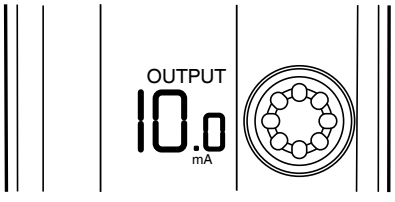
3.2.3 OUTPUT dial

The OUTPUT dial is used to set the current amplitude, in mA, of the pacing pulse (see Section 5.1.4).

The output ranges from 0.1 to 25 mA. Turn the **OUTPUT** dial clockwise to increase **OUTPUT**, or counterclockwise to decrease or turn off **OUTPUT**.

When the temporary pacemaker is turned on, **OUTPUT** is set to10 mA (nominal). See Section 7.1 for more information about the **OUTPUT** range and increments.

Figure 4. OUTPUT value and dial



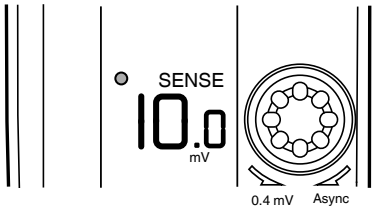
3.2.4 SENSITIVITY dial

The SENSITIVITY dial is used to enable and adjust the sensitivity, in mV, of the sensing circuitry (see Section 5.1.4).

The sensitivity ranges from 0.1 to 20 mV. When the sensitivity is set above 20 mV by turning the dial fully clockwise to the ASYNC position, the temporary pacemaker switches to asynchronous mode. To decrease **SENSITIVITY**, turn the dial clockwise (the mV value increases). To increase **SENSITIVITY**, turn the dial counterclockwise (the mV value decreases).

When the temporary pacemaker is turned on, **SENSITIVITY** is set to 2 mV (nominal). See Section 7.1 for more information about the **SENSITIVITY** range and increments.

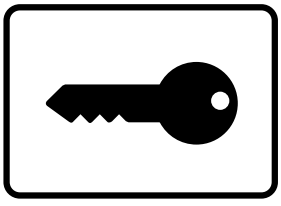
Figure 5. SENSITIVITY value and dial



3.2.5 Lock/Unlock button

The Lock/Unlock button locks the temporary pacemaker to prevent inadvertent adjustment of the pacing parameters, or unlocks the temporary pacemaker when it is locked. See Figure 6.

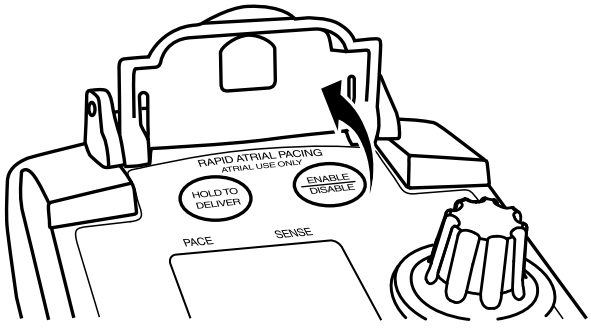
Figure 6. Lock/Unlock button



3.2.6 Rapid atrial pacing controls

The rapid atrial pacing controls activate and deliver rapid atrial pacing (RAP) therapy. The controls are located under the RAP cover. The ENABLE/DISABLE button activates or deactivates RAP, and the HOLD TO DELIVER button delivers RAP therapy. See Figure 7.

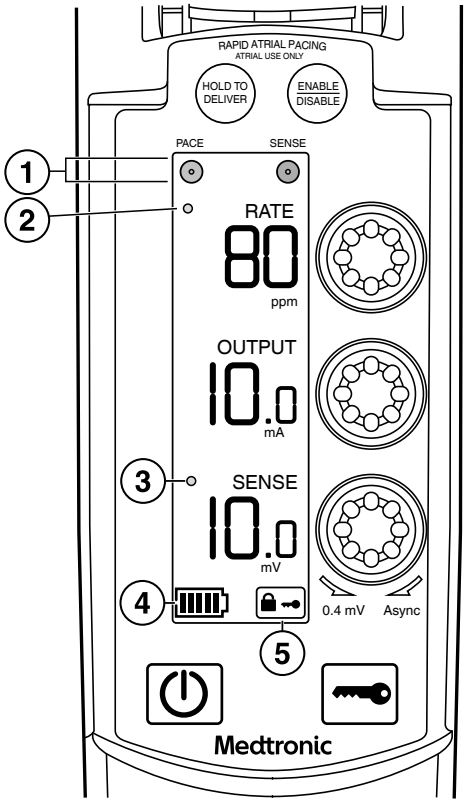
Figure 7. RAP controls



3.3 Indicators

The screen displays indicators for pacing and sensing status, Rapid Atrial Pacing (RAP) status, battery power, and lock status. See Figure 8.

Figure 8. Indicators



1 Pacing and sensing status indicator LEDs
2 RAP indicator LED
3 ASYNC indicator LED
4 Battery status indicator
5 Lock indicator

3.3.1 Pacing and sensing indicators

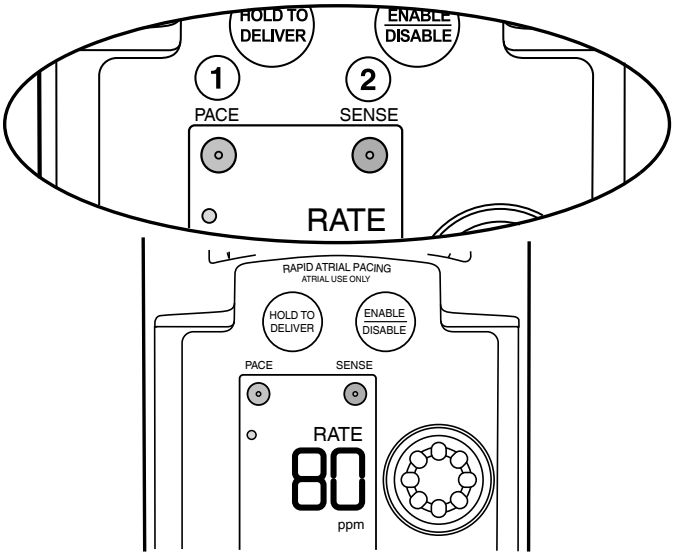
The **PACE** and **SENSE** LEDs indicate delivery of a pacing pulse or a sensed event. The following LED actions occur in response to pacing or sensing events:

- The green **PACE** LED in the upper left corner of the screen flashes each time the temporary pacemaker delivers a pacing pulse.

  Note: The green **PACE** LED flashes indicate delivery of a pacing pulse, but they are not confirmation that the pacing pulse has delivered cardiac stimulation.
- The blue **SENSE** LED in the upper right corner of the screen flashes when events are sensed.

  Note: The blue **SENSE** LEDs indicate a sensed event by the temporary pacemaker, but they are not confirmation of a cardiac contraction.

Figure 9. Pacing and sensing indicators

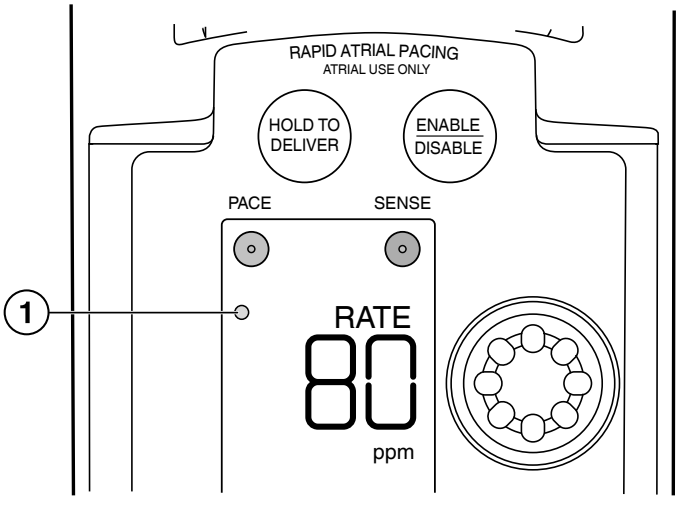


1 PACE indicator LED
2 SENSE indicator LED

3.3.2 Rapid Atrial Pacing (RAP) indicator

The **Rapid Atrial Pacing (RAP)** LED indicates delivery of rapid atrial pacing. The LED flashes when the temporary pacemaker is delivering RAP therapy.

Figure 10. RAP indicator

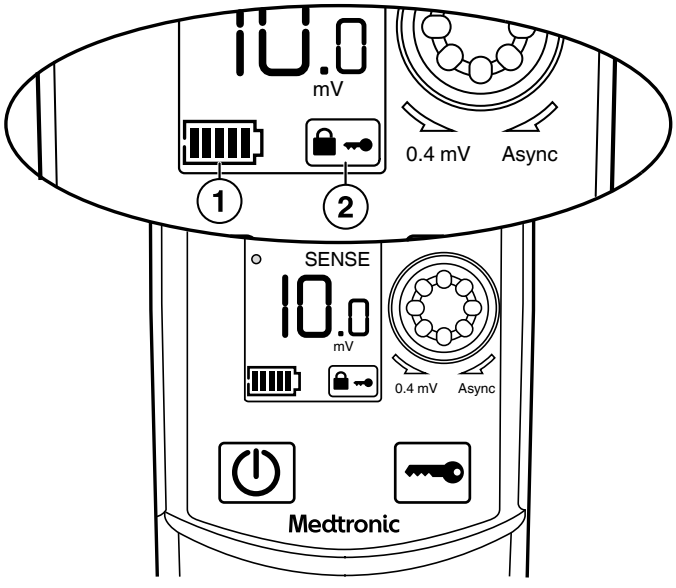


1 RAP indicator LED

3.3.3 Status indicators

The status indicators, at the bottom of the screen, display the battery status and lock indicators (see Figure 11).

Figure 11. Status indicators



1 Battery status indicator
2 Lock indicator

Battery status indicator – The battery status indicator displays the amount of available battery power remaining. When all of the indicator bars are visible, the batteries have full power or have been replaced with a new set of batteries.

The low battery indicator, a red light, flashes behind the battery status indicator when only one bar is visible. When the low battery indicator begins flashing, the temporary pacemaker has 24 hours of battery life remaining.

If the batteries are removed, no bars are visible in the battery status indicator and the battery indicator light flashes. The temporary pacemaker continues to pace and sense and the battery indicator light continues to flash until insufficient power is available (see Section 4.3). When new batteries are properly installed, bars will appear in the battery status indicator and the battery indicator light will no longer flash.

After the batteries are depleted, the temporary pacemaker shuts down.

Note: When the low battery indicator first appears, the temporary pacemaker maintains pacing for a minimum of 24 hours if the settings are at nominal values (see Section 7.1). The user should replace the batteries as soon as it is possible to do so safely.

Lock indicator – The Lock indicator appears when the temporary pacemaker is locked.

If any of the dials are turned or buttons are pressed while the temporary pacemaker is locked, the Lock indicator flashes in the lower right corner of the screen. When the temporary pacemaker is locked, the **RATE**, **OUTPUT**, and **SENSITIVITY** settings or pacing parameters cannot be adjusted until the temporary pacemaker is unlocked. See Section 5.1.2.

3.4 Physical features

3.4.1 Batteries

Battery drawer – The battery drawer, on the bottom of the temporary pacemaker, accepts two LR6-sized (AA-sized) alkaline batteries.

Battery life – The battery life is 7 days minimum with continuous operation for new alkaline batteries when the **RATE** is set at 80 ppm and all other parameters are at nominal values (see Section 7.1).

Note: The low battery status indicator flashes when the battery status displays 1 bar. When the low battery indicator begins flashing, the temporary pacemaker has 24 hours of battery life remaining when operated at nominal values (see Section 7.1).

Battery drawer latch release buttons – The battery drawer has two latch release buttons on either side of the temporary pacemaker. Both buttons must be simultaneously pressed to open the battery drawer.

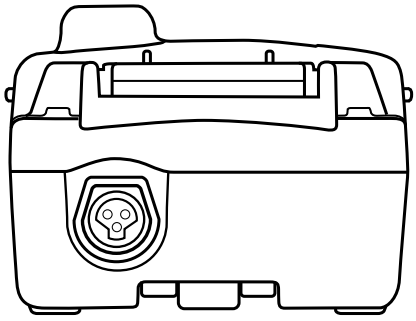
Continued operation after the batteries are removed – If the batteries are removed, the temporary pacemaker continues to operate for a minimum of 30 s (see Section 7.1) under the following conditions: **RATE** of 80 ppm or less and **OUTPUT** of 10 mA or less with the backlight off. If the batteries are removed, they should be replaced with new batteries within 30 s to ensure continued device operation.

Note: The temporary pacemaker may shut down immediately, depending upon the battery level, if the batteries are removed while it is turned on.

3.4.2 Connector block

The connector block, at the top end of the temporary pacemaker, has a single socket that accepts patient and/or surgical cables (see Figure 12).

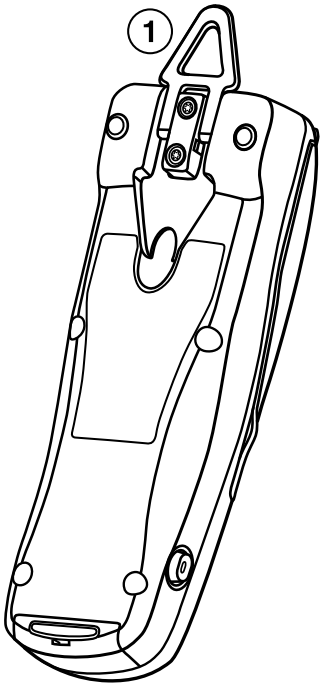
Figure 12. Temporary pacemaker connector block



3.4.3 IV pole hanger

The Medtronic Model 53407 IV pole hanger is attached to the back of the temporary pacemaker and is used to hang the temporary pacemaker on an IV pole (see Figure 13). Fold the IV pole hanger flat against the back of the temporary pacemaker when it is not in use.

Figure 13. IV pole hanger



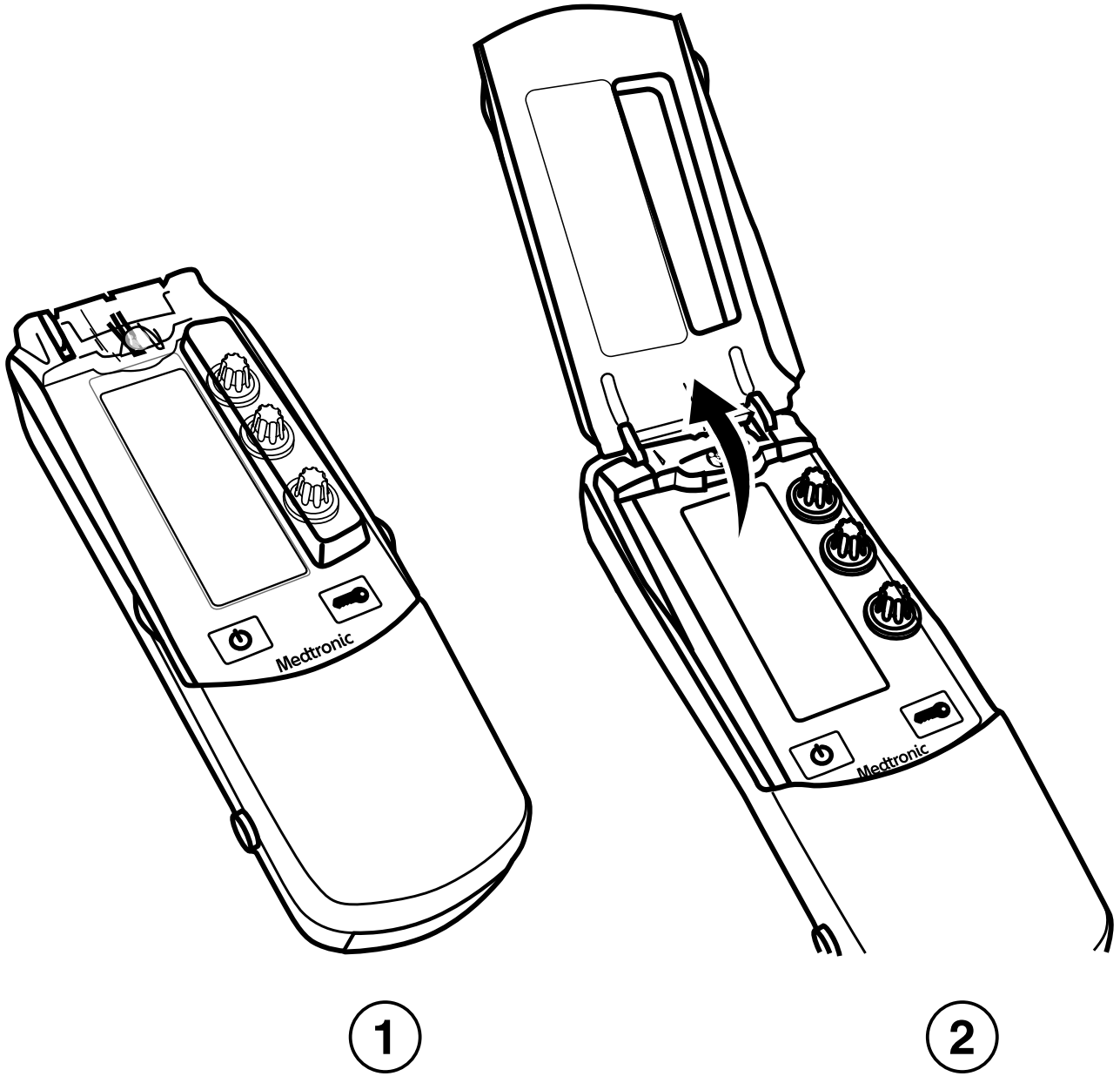
1 IV pole hanger

Note: If the Medtronic Model 53407 IV pole hanger requires replacement, contact your Medtronic sales or service representative.

3.4.4 Protective covers

Protective cover – The temporary pacemaker controls and screen are covered by the Medtronic Model 53408 clear protective cover (see Figure 14). The protective cover is removable and replaceable.

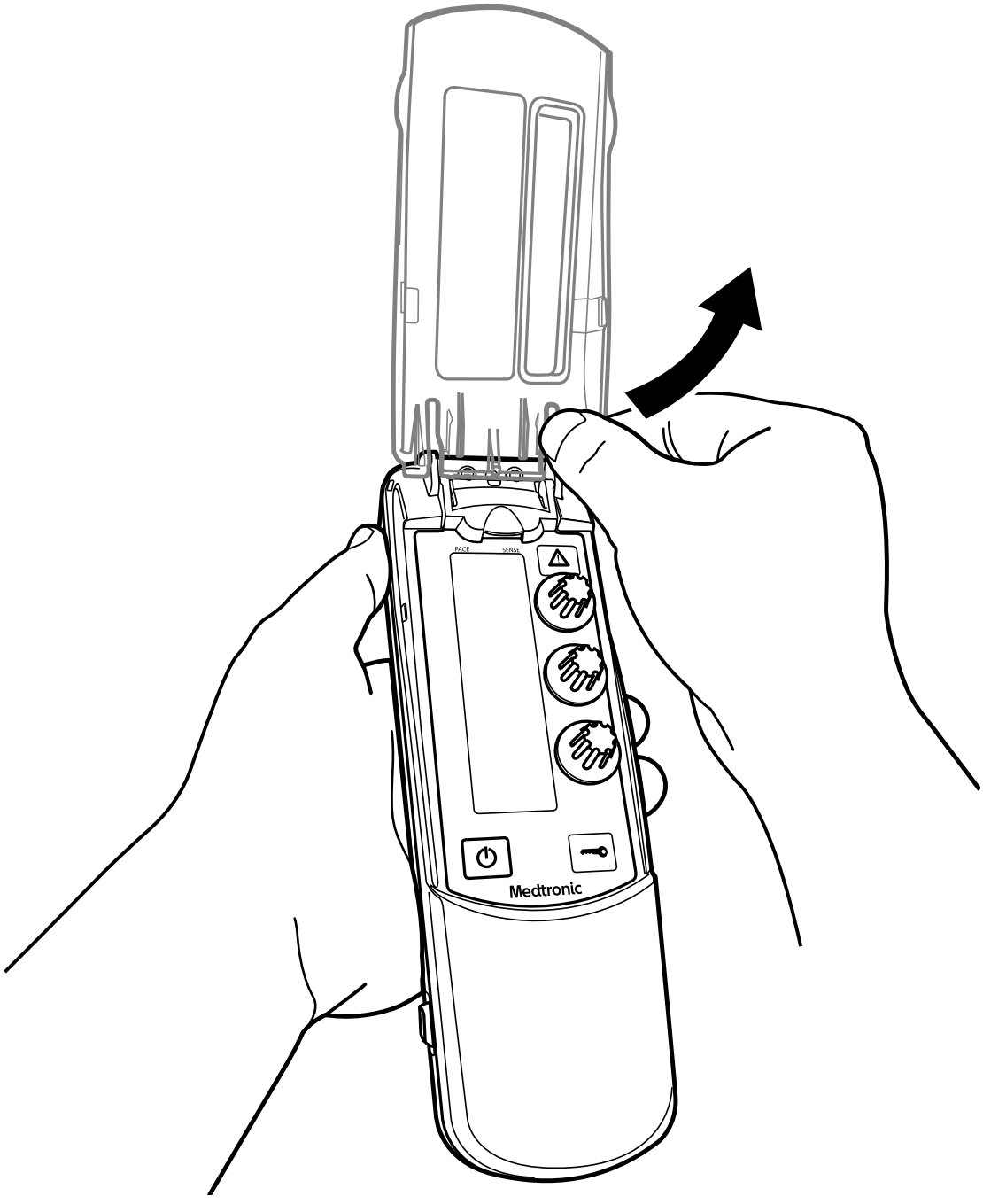
Figure 14. Protective cover



1 Temporary pacemaker with protective cover on and closed
2 Opening protective cover

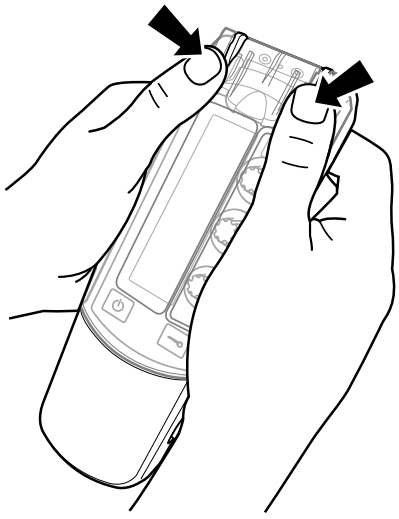
To remove the protective cover, open the cover and place the thumb and forefinger at the hinge (see Figure 15). Push the hinge up and away from the temporary pacemaker.

Figure 15. Removing protective cover



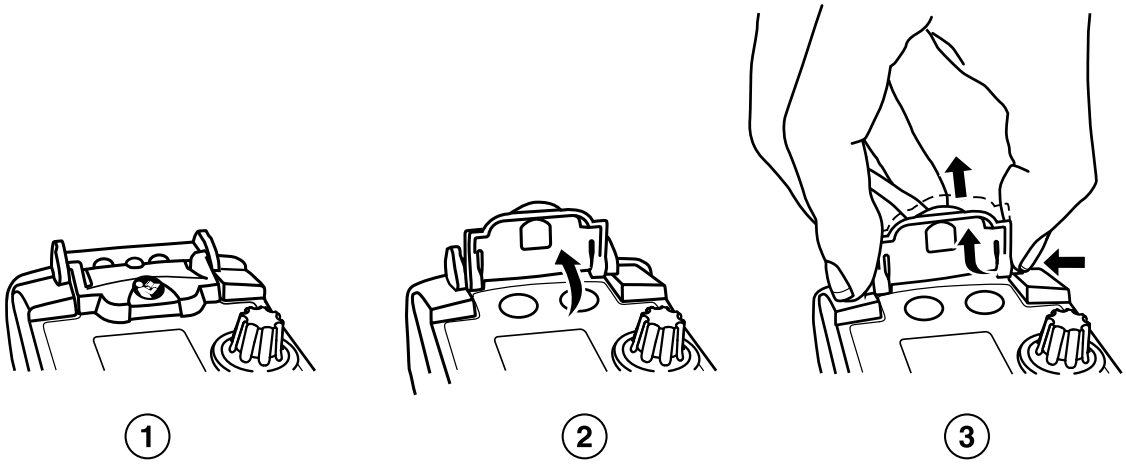
To replace the protective cover, align the hinges of the cover with the temporary pacemaker with the cover in the closed position. Press down on both hinges simultaneously as illustrated in Figure 16.

Figure 16. Replacing protective cover



RAP cover – The RAP controls are located underneath a flip-up RAP cover located at the top of the temporary pacemaker underneath the protective cover (see Figure 17). The RAP cover is removable and replaceable. To remove the RAP cover, open the cover and use the thumb to squeeze one hinge toward the other hinge. While squeezing, move the cover out and away from the temporary pacemaker. To replace the RAP cover, reverse this motion by engaging the hinge at one corner while squeezing the cover and aligning the other hinge before releasing.

Figure 17. RAP cover



1 Temporary pacemaker with RAP cover on and closed
2 Opening RAP cover
3 Removing RAP cover

Note: If the Medtronic Model 53408 protective cover or RAP cover require replacement, contact your Medtronic sales or service representative.

4 Preparation for use

4.1 Training

4.1.1 Training prior to use

Train clinical personnel on the functionality and use of the temporary pacemaker prior to initial use of the device, as needed, and per clinic procedures. Contact your Medtronic representative to schedule training.

4.2 Checks prior to use

4.2.1 Cleaning and disinfection

During normal use, the temporary pacemaker and cables can be contaminated. Verify that the temporary pacemaker is cleaned according to your organization's policies. See Section 6.2 for instructions on cleaning and disinfecting the temporary pacemaker.

Verify that the reusable cables are cleaned and sterilized according to your organization's policy.

Note: For information about cleaning and sterilizing the reusable cables, refer to the applicable technical manual.

Caution: Clean and disinfect the temporary pacemaker as needed according to your organization's policies. Clean and sterilize the reusable cables as needed according to your organization's policies.

4.2.2 Service condition

Check the temporary pacemaker and reusable cables before each use for a new patient to verify that there are no observable defects. Do not use the temporary pacemaker or the reusable cables if there are any observable defects. Verify that the temporary pacemaker controls function and that the battery drawer closes.

Visually inspect the reusable cables and connectors. Do not use the reusable cables if they are damaged. Damage includes, but is not limited to, deterioration of the cable insulation, brittleness, cracking, thinning, or bare spots. Do not use the reusable cables if the conductive wires are exposed.

Caution: Before each use, evaluate the temporary pacemaker for damage and observable defects. Do not use the temporary pacemaker if the case is cracked, the controls are not functioning, the displays are not working, or if the controls, displays, or connectors are broken. If the temporary pacemaker has any observable defects, contact Medtronic at the telephone number on the back cover of this manual for service.

4.2.3 Battery status

Check battery status prior to use. The battery status indicator displays the amount of available battery power remaining (see Section 3.3.3). Continue to check the battery status while in use according to your organization's policy. More frequent checks are recommended as less remaining power is displayed by the battery status indicator. Replace the batteries when the low battery indicator flashes.

Note: The specified battery life of 7 days minimum with continuous operation at nominal settings only applies when using new alkaline batteries. Continued use of partially depleted batteries that do not provide a full battery indication will result in early low battery indication. When the low battery indicator begins flashing, the temporary pacemaker maintains pacing for a minimum of 24 hours if the settings were at nominal values (see Section 7.1).

4.3 Batteries

The temporary pacemaker uses two LR6–sized (AA–sized) alkaline batteries for operation (for example, Duracell MN1500 or Eveready E91 batteries).

Warning: Properly ground all line-powered equipment used on the patient or in the vicinity of the patient (see Section 2.1).

Battery removal for long term storage – Remove the batteries when the temporary pacemaker is stored for long periods of time.

Cautions:

- Only install the recommended batteries in the temporary pacemaker. Batteries with different physical dimensions, non-alkaline (e.g., lithium or rechargeable) or batteries with contamination on the battery terminals, may result in erratic operation of the temporary pacemaker, no pacing output, or damage to the temporary pacemaker, specifically to the battery compartment.
- Inspect battery terminals for contamination. Using batteries with contaminated terminals can result in the temporary pacemaker turning off, decreased battery life, or corrosion to the battery compartment.
- Check the battery status regularly while the temporary pacemaker is in use. When new batteries are installed, the low battery indicator should turn off. If it persists, ensure that the battery door was fully closed and the inserted batteries were new.

4.3.1 Battery installation and replacement recommendations

Check the battery status prior to use. Replace the batteries when the low battery indicator flashes during temporary pacemaker operation (see Section 3.3.3).

Comply with the following instructions when installing batteries in the temporary pacemaker:

- Install only the recommended batteries. Using non-recommended batteries may result in less than 24 hours of battery life after the low battery indicator illuminates, degraded pacemaker performance, and/or overall reduced battery life.
- Install two new LR6-sized (AA-sized) alkaline batteries.
- Install the batteries with proper polarity. The temporary pacemaker does not turn on or provide pacing therapy with incorrect battery polarity.

Caution: Medtronic does not recommend replacing the batteries while the temporary pacemaker is turned on or actively pacing the patient. However, if during an emergency situation the batteries must be replaced while the temporary pacemaker is in use, ensure that the temporary pacemaker is locked before replacing the batteries with new batteries. When the battery drawer is opened, the temporary pacemaker will temporarily disable all knobs and buttons and the user will be unable to change the device's current settings. Pacing is maintained at the current settings for a minimum of 30 s if the settings are at nominal values (see Section 7.1).

4.3.2 Battery polarity

The temporary pacemaker requires proper battery polarity for operation. Ensure that the batteries align with the polarity markings on the inside of the battery drawer.

The temporary pacemaker does not turn on when batteries are installed with incorrect polarity. If the batteries are replaced while the temporary pacemaker is turned on and the battery polarity is incorrect, the temporary pacemaker continues to pace and sense until insufficient power is available. The low battery indicator continues to flash, and pacing is maintained at the current settings for a minimum of 30 s with the settings at nominal values. When internal reserve power is depleted, the temporary pacemaker shuts down.

The following events occur when the new batteries are installed with proper polarity in the temporary pacemaker:

- The low battery indicator stops flashing.
- The battery status indicator displays full battery power.

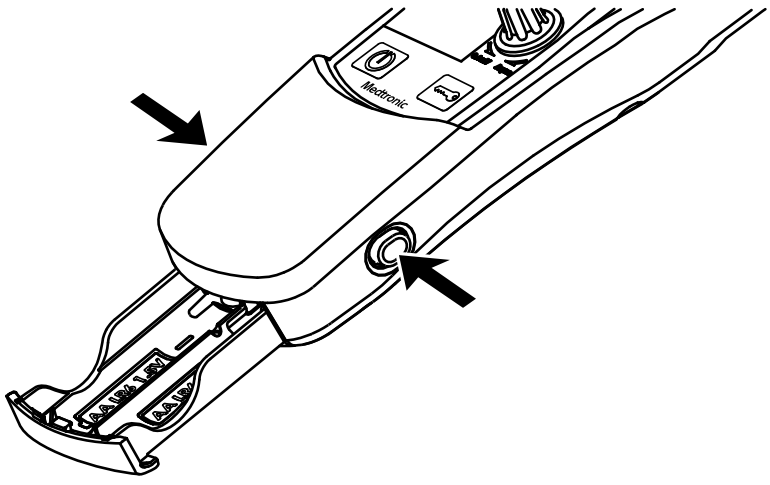
The following events occur when the batteries are installed with incorrect polarity:

- If the temporary pacemaker is turned off, it does not turn on.
- If the temporary pacemaker is turned on, the low battery indicator continues to flash. The temporary pacemaker continues to pace and sense until internal reserve power is depleted. When internal reserve power is depleted, the temporary pacemaker shuts down.

4.4 Battery installation and replacement

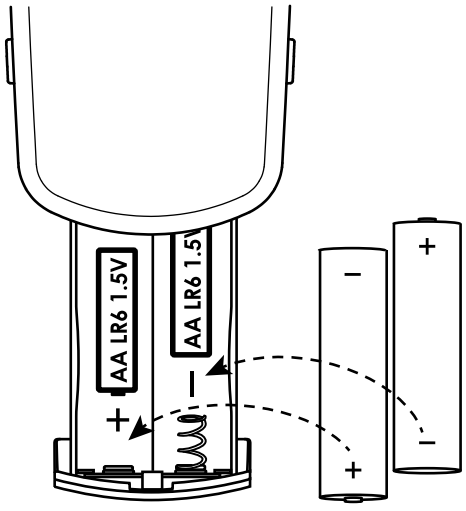
Perform the following actions to install (or replace) the batteries:

1. Press the battery drawer latch release buttons until the battery drawer opens (see Figure 18).
   Caution: Avoid contaminating areas that are difficult to clean on the temporary pacemaker. Keep hands and gloves free of blood and body fluids when opening and closing the battery drawer and installing or replacing the batteries.
   Figure 18. Battery drawer latch release buttons



2. Remove the old batteries.
3. Install two new LR6-sized (AA-sized) alkaline batteries. Verify that the batteries align with the polarity markings on the inside of the battery drawer (see Figure 19).

Figure 19. Installing the batteries with proper polarity



Caution: Ensure that the new batteries are installed with the correct battery polarity by verifying that the batteries align with the polarity markings on the inside of the battery drawer. The temporary pacemaker requires proper battery polarity for operation. After installing the batteries, ensure that the battery status indicator displays full battery power and that the low battery indicator is not flashing. The temporary pacemaker may temporarily continue to pace and sense with weak, dead, or incorrectly installed batteries.

4. Close the battery drawer firmly until the battery drawer is fully latched.

   Note: Failure to close the battery drawer completely can result in the battery drawer opening and the temporary pacemaker shutting down.
5. Discard the old batteries properly according to local regulations.

4.5 Connector Setup

4.5.1 Using cables with the temporary pacemaker

The temporary pacemaker is compatible with both reusable and disposable cables, which deliver the pacing therapy. Refer to Section 1.7 for a list of compatible cables. Comply with the following instructions before connecting the cable to the temporary pacemaker:

- Reusable cables are supplied non-sterile. Clean and sterilize reusable cables as needed according to your organization's policies. Refer to the applicable technical manual for cleaning, disinfecting, and sterilizing instructions.
- Carefully inspect the reusable cable for visible signs of wear or damage before connecting it to the temporary pacemaker. Do not use the reusable cable if it appears damaged. Damage includes, but is not limited to, deterioration of the cable insulation, brittleness, cracking, thinning, or bare spots. Do not use the reusable cable if the conductive wires are exposed.
- Do not connect the temporary pacemaker to the lead system if it is turned on and is operating at an output amplitude that could cause capture.

Warnings:

- Before connecting the cable to the temporary pacemaker, verify that it is turned off.
- Connect the cable to the temporary pacemaker before connecting the lead to the cable.
- To prevent pacing into the vulnerable period of the T-wave, turn on the temporary pacemaker and turn down OUTPUT to the minimum amplitude before connecting the temporary pacemaker to the patient's lead system. Determine sensing thresholds before turning up OUTPUT to threshold levels.

Cautions:

- When mechanical support is necessary, hang the temporary pacemaker by the IV pole hanger from an IV pole. Do not hang the temporary pacemaker to an IV pole by the cable.
- Avoid contaminating areas that are difficult to clean on the temporary pacemaker. Keep hands and gloves free of blood and body fluids when connecting or disconnecting the patient cable, surgical cable, and/or pacing lead to the temporary pacemaker.
- Monitor the patient's ECG and blood pressure and keep defibrillation equipment on standby, immediately available for emergency use during pacing lead insertion and pacemaker connection.

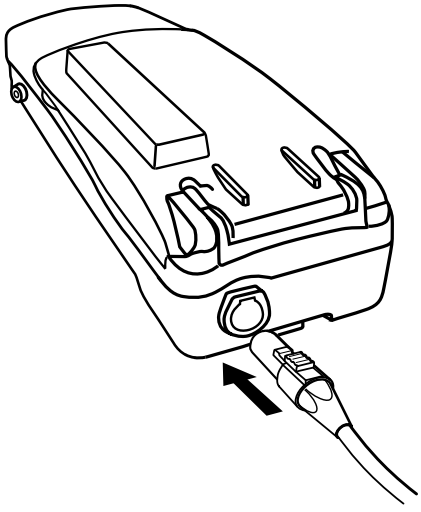
4.5.2 Connecting the cable to the temporary pacemaker

Perform the following actions to connect the cable to the temporary pacemaker:

1. Verify that the temporary pacemaker is turned off.
2. Plug the patient cable or surgical cable into the socket on the connector block on top of the temporary pacemaker. Connect the leads to the cable. Match positive (+) and negative (–) leads to positive (+) and negative (–) sockets or clips for the atrium and ventricle (not shown).
3. Verify that the cable clicks when it is inserted into the temporary pacemaker connector receptacle (see Figure 20).

   Note: The audible click verifies that the plug is completely inserted into the receptacle.

   Figure 20. Connecting the cable to the temporary pacemaker



4. To ensure a good connection, pull gently on the cable after insertion.

Refer to the applicable patient cable or surgical cable technical manual for more information.

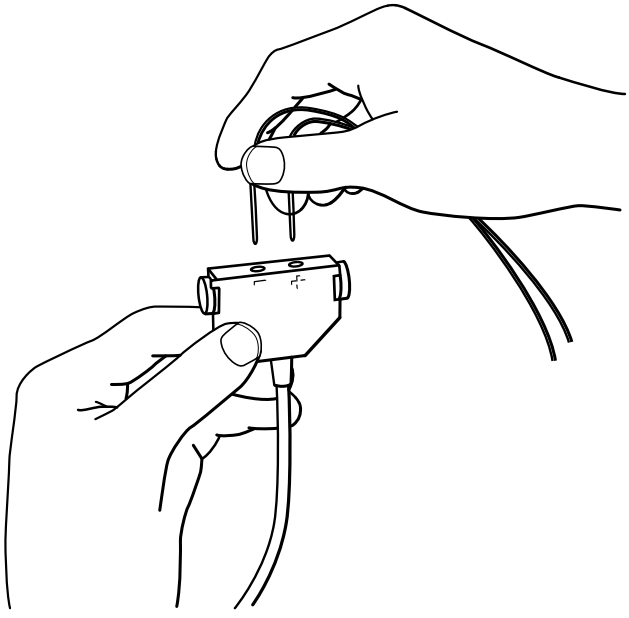
4.5.3 Connecting the pacing lead system to the patient cable

Caution: Unipolar lead systems are not recommended because they are more susceptible to electromagnetic interference, which may result in inappropriate pacing.

Perform the following actions to connect the pacing lead system to the patient cable:

1. Loosen the patient cable connector knob by twisting the knob counterclockwise until resistance is felt.
2. Insert the lead connector pins into the patient cable receptacle as shown (see Figure 21).
3. Rotate the patient cable connector knob clockwise until finger tight.
4. Gently pull on the lead conductor to verify secure connection.

Figure 21. Connecting the pacing lead system to the patient cable receptacle



Refer to the applicable patient cable technical manual for more information.

Bipolar systems – For bipolar systems, insert each connector pin into the appropriate receptacle (marked + and –). Bipolar lead systems may exhibit different threshold values depending on the polarity of the lead connections.

Refer to the applicable patient cable technical manual for more information.

Unipolar systems (1-lead systems) – Perform the following actions to connect single chamber unipolar lead systems to the temporary pacemaker:

1. Insert the cardiac lead connector pin into the negative (–) receptacle of the cable.
2. Insert the connector pin of the “indifferent” electrode (or “ground”) into the positive (+) receptacle of the cable.

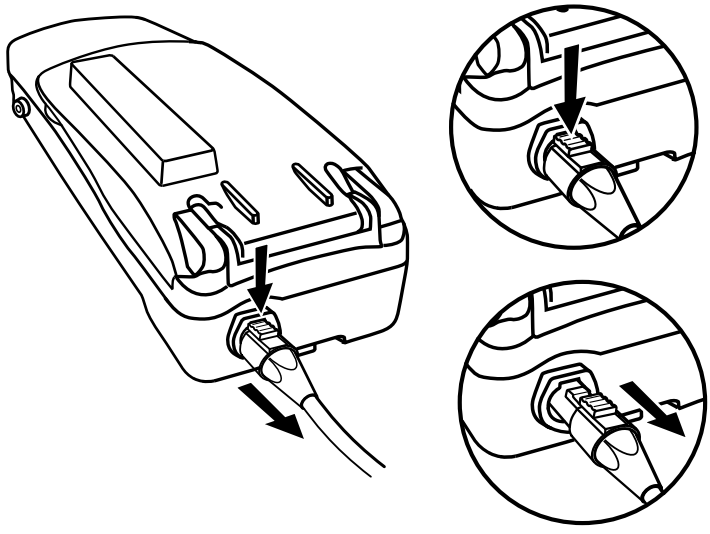
Refer to the applicable patient cable technical manual for more information.

4.5.4 Disconnecting the cable from the temporary pacemaker

Perform the following actions to disconnect the cable from the temporary pacemaker:

1. Set the controls of the temporary pacemaker to allow the patient’s intrinsic rhythm to take over pacing. See Section 5.1.3.
2. Press the connector release button on the cable plug (see Figure 22).
3. Gently pull the plug from the receptacle.

Figure 22. Disconnecting the cable from the temporary pacemaker



Refer to the applicable patient cable or surgical cable technical manual for more information.

4.6 Placement during use

When the temporary pacemaker is in use, place it in an area that reduces potential unauthorized access from patient interaction or tampering by non-medical personnel.

Do one or more of the following actions to reduce potential unauthorized access to the temporary pacemaker when it is in use:

- Verify that the temporary pacemaker is directly observable by medical staff.
- Hang the temporary pacemaker by either the IV pole hanger or the attachment panel of the disposable pouch to an IV pole.

Caution: Tampering with programmed parameters may have direct and serious patient health effects.

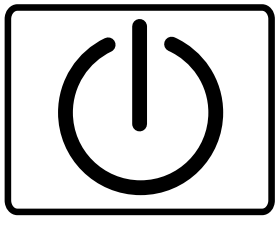
5 Instructions for use

5.1 Basic operation

5.1.1 Turning on or turning off the temporary pacemaker

Turning on the temporary pacemaker – To turn on the temporary pacemaker, press and hold the On/Off button (Figure 23) momentarily.

Figure 23. On/off button



The following actions occur when the temporary pacemaker is turned on:

- The screen and the backlight illuminate.

  Note: If the batteries are nearing depletion, a red backlight begins flashing behind the battery status indicator, indicating that the batteries have approximately 24 hours of battery life. If the batteries are depleted, the LEDs may flash momentarily when the On/Off button is pressed, but the temporary pacemaker does not operate.
- A self-test is initiated (see Section 6.5.1).
- When the self-test completes successfully, the temporary pacemaker first searches for cardiac activity (during the first pacing cycle), and then begins sensing and pacing (AAI/VVI pacing mode).

Notes:

- If the temporary pacemaker fails the self-test, it remains on but does not pace, and the LEDs will remain illuminated until the user re-starts the device.
- See Section 7.1 for nominal values when the temporary pacemaker is turned on.

Warning: To prevent pacing into the vulnerable period of the T-wave, turn on the temporary pacemaker and turn down OUTPUT to the minimum amplitude. Determine sensing thresholds before turning up OUTPUT to threshold levels.

Turning off the temporary pacemaker – Perform the following actions to turn off the temporary pacemaker:

1. Unlock the temporary pacemaker if it is locked (see Section 5.1.2).
2. Press and hold the On/Off button for two seconds.

   Note: If the On/Off button is not held for two seconds, the temporary pacemaker remains on and continues to pace at the currently selected values.

5.1.2 Lock/Unlock

The Lock/Unlock button locks the temporary pacemaker to prevent inadvertent adjustment of the parameters, or unlocks the temporary pacemaker when it is locked (see Section 3.2.5).

The temporary pacemaker locks when one of the following events occurs:

- 60 s elapses after the last parameter adjustment is made

  Note: When RAP is enabled, the temporary pacemaker will lock after 300 s have elapsed
- The Lock/Unlock button is pressed

When the temporary pacemaker locks, the following changes occur:

- The **RATE**, **OUTPUT**, and **SENSITIVITY** parameter values lock and cannot be adjusted.
- Pacing therapy continues to be delivered at the currently selected values.
- The Lock indicator appears in the lower right corner of the screen.
- The On/Off button and RAP buttons lock and will not function

Notes:

- If any parameter dials are adjusted or any buttons are pressed while the temporary pacemaker is locked, the Lock indicator flashes.

Press the Lock/Unlock button to unlock the temporary pacemaker if it is locked.

When the temporary pacemaker unlocks, the following changes occur:

- The Lock indicator disappears.
- Pacing therapy continues to be delivered at the currently selected values.
- The **RATE**, **OUTPUT**, and **SENSITIVITY** pacing parameters unlock and can be adjusted.
- The On/Off button and RAP buttons unlock and will function

5.1.3 Viewing the patient's intrinsic rhythm

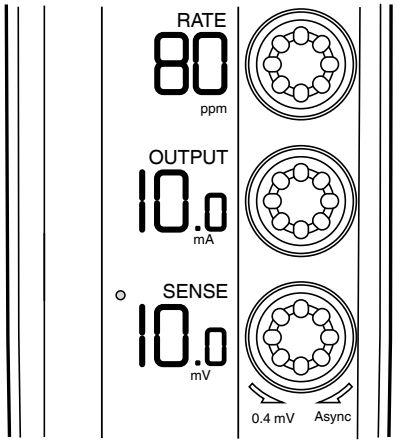
To view the patient's intrinsic rhythm, Reduce the **RATE** gradually, while watching the ECG, until the patient's intrinsic rhythm takes over and the temporary pacemaker is no longer pacing.

5.1.4 RATE, OUTPUT, and SENSITIVITY adjustments

Use the dials next to the screen to adjust the pacing rate, output, and sensitivity. The screen displays a numerical value that reflects the current setting for each dial. See Figure 24.

Caution: Avoid contaminating areas that are difficult to clean on the temporary pacemaker. Keep hands and gloves free of blood and body fluids when touching and/or turning the RATE, OUTPUT, and SENSITIVITY dials.

Figure 24. RATE, OUTPUT, and SENSITIVITY



To adjust **RATE**, **OUTPUT**, and **SENSITIVITY**, turn the RATE, OUTPUT, and SENSITIVITY dials clockwise to increase their values; turn the dials counterclockwise to decrease their values.

See Section 7.1 for **RATE**, **OUTPUT**, and **SENSITIVITY** ranges.

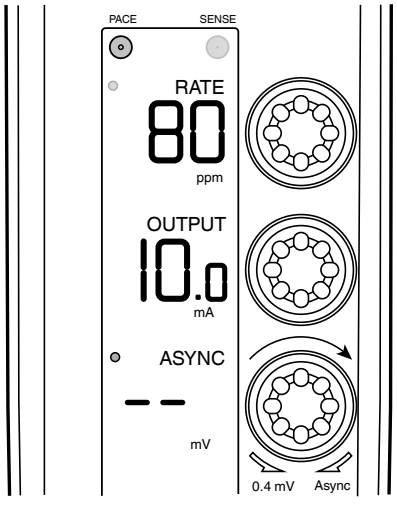
5.1.5 Determining the pacing mode

The pacing mode is determined by the chamber in which the lead is placed and by the **SENSITIVITY** setting. The temporary pacemaker can be set to several single chamber pacing modes (AOO, VOO, AAI, VVI).

The sensitivity setting determines whether the pacemaker is in a synchronous (demand) or asynchronous mode. The pacing mode can be set by adjusting the **SENSITIVITY**. To increase **SENSITIVITY**, turn the dial counterclockwise (the mV value decreases). To decrease **SENSITIVITY**, turn the dial clockwise (the mV value increases). Changes to **SENSITIVITY** take effect within the next two pacing cycles.

To turn off **SENSITIVITY** and allow the temporary pacemaker to pace asynchronously, turn the **SENSITIVITY** dial clockwise until the screen displays the term **ASYNC** (see Figure 25).

Figure 25. Adjusting SENSITIVITY to ASYNC mode



The pacing information tables (see Section 7.2) provide a quick reference for selecting a pacing mode.

5.1.6 Synchronous (demand) pacing

During synchronous (demand) pacing, output is inhibited when the pacemaker senses intrinsic activity to minimize competition between the paced rhythm and the intrinsic activity of the heart.

Note: Determine sensitivity and stimulation thresholds (see Section 5.2); otherwise asynchronous pacing and/or loss of heart capture may occur.

Synchronous pacing occurs as the default pacing mode when the device is powered on and provides pacing in either the AAI or the VVI pacing mode.

The AAI pacing mode provides synchronous pacing in the atrium. Pacing and sensing occur only in the atrium during the AAI pacing mode. No pacing or sensing occurs in the ventricle.

The VVI pacing mode provides synchronous pacing in the ventricle. Pacing and sensing occur only in the ventricle during the VVI pacing mode. No pacing or sensing occurs in the atrium.

To pace using a synchronous mode, adjust the SENSITIVITY dial to a setting (between 0.4 and 20 mV) that is one-half the mV value of the patient's sensitivity threshold (see Section 5.2.2).

5.1.7 Asynchronous pacing

Patients best suited for asynchronous (non-sensing) modes have one of the following issues:

- An intrinsic rate consistently below the pacing rate.
- No intrinsic activity.

Caution: Because it may compete with the intrinsic activity of the heart, asynchronous pacing may result in tachyarrhythmia. Use caution when setting the device to asynchronous modes.

Asynchronous pacing occurs when **SENSITIVITY** is decreased (the mV value is increased) to the point where the temporary pacemaker is no longer sensing and provides pacing in either the AOO or VOO pacing mode. During asynchronous pacing modes, adjust **OUTPUT** to provide an adequate safety margin (see Section 5.2.1).

The AOO pacing mode provides asynchronous pacing in the atrium. Pacing occurs only in the atrium and no sensing occurs during the AOO pacing mode. No pacing occurs in the ventricle.

The VOO pacing mode provides asynchronous pacing in the ventricle. Pacing occurs only in the ventricle and no sensing occurs during the VOO pacing mode. No pacing occurs in the atrium.

To pace using an asynchronous mode, turn the **SENSITIVITY** dial fully clockwise to the ASYNC position and adjust **OUTPUT** to provide an adequate safety margin (see Section 5.2.1).

Note: Determine the patient's stimulation threshold; otherwise loss of heart capture may occur (see Section 6.5.4).

Terminating asynchronous pacing – To terminate asynchronous pacing and to return to synchronous (demand) pacing, adjust **SENSITIVITY** by turning the dial counterclockwise and selecting an appropriate SENSITIVITY value. The **ASYNC** LED will no longer be illuminated when the device has exited asynchronous pacing mode.

5.2 Thresholds

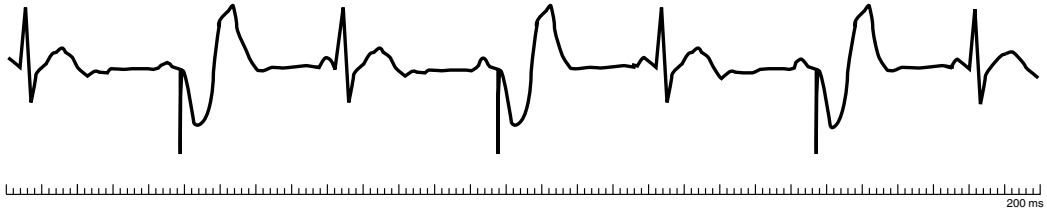
Threshold values are needed to determine the appropriate settings for output and sensitivity. Procedures for finding atrial and ventricular sensing and stimulation thresholds are described in this section.

Note: To reduce the risk of competitive pacing, determine the sensing thresholds first, if the patient's intrinsic rhythm is adequate.

5.2.1 Sensing definitions

The ECG in Figure 26 shows the intrinsic beats mixed with paced beats. The temporary pacemaker detects the heart's own beat and does not deliver a pacing stimulus. When undersensing occurs, the temporary pacemaker does not detect intrinsic activity and thus paces on or between beats.

Figure 26. Sensing



Sensing threshold – The sensing threshold is the least sensitive mV setting at which the temporary pacemaker can detect a heartbeat. Monitor the patient's ECG and blood pressure as you follow the procedure below to determine the sensing thresholds.

Sensing threshold safety margin – Lead maturation and drug therapy can affect the sensing threshold. To ensure sensing and accommodate a changing threshold, it is important to provide at least a 2:1 safety margin. Set **SENSITIVITY** to values that are at least one-half to one-third of the sensing threshold values. For example, an appropriate setting for a patient with a 5.0 mV sensing threshold is 2.5 mV or less.

Caution: Avoid selecting a pacing mode that requires sensing if adequate sensing margins cannot be established. A 2:1 safety margin cannot always be achieved due to a low sensing amplitude and/or a high pacing amplitude. If a 2:1 safety margin cannot be achieved, increase monitoring of the patient to verify that the expected therapy is being delivered.

5.2.2 Determining atrial or ventricular sensing thresholds

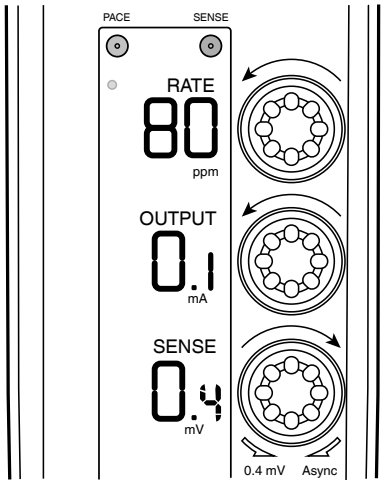
Caution: Pacing-dependent patients have limited or no intrinsic rate or rhythm. Only use this procedure on patients with adequate intrinsic rhythm.

To determine atrial or ventricular sensing threshold, perform the following steps:

1. Turn on the temporary pacemaker without connecting it to the patient lead system.

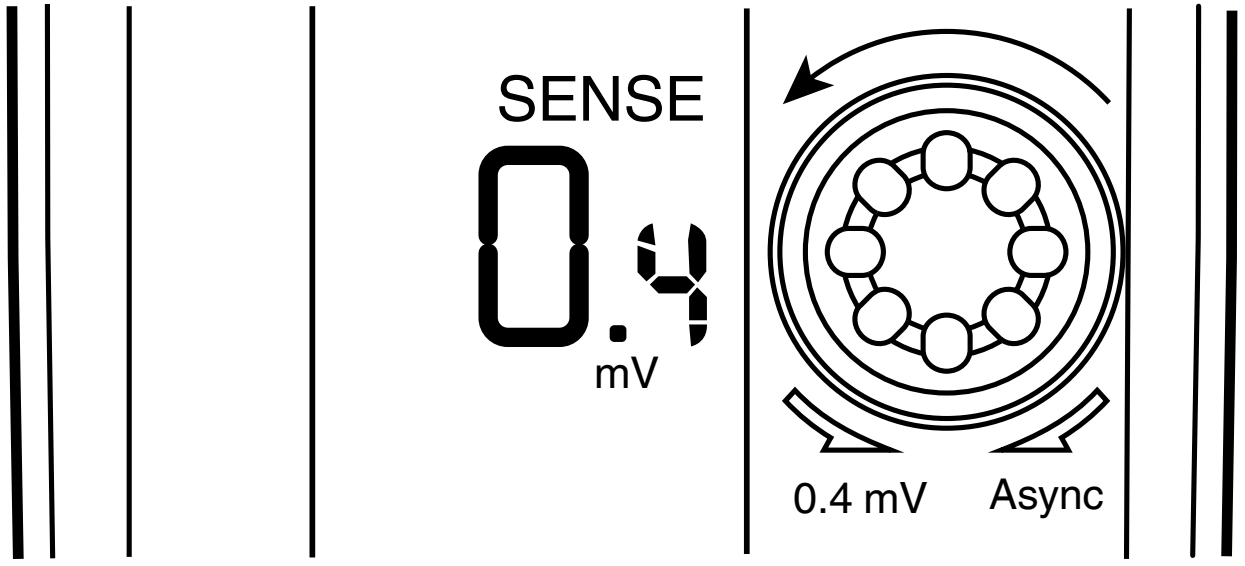
   Caution: Do not connect the temporary pacemaker to the patient lead system until step 4.
2. Set **RATE** to at least 10 ppm under the patient's intrinsic rate (see Figure 27).
3. Adjust the output to prevent the risk of competitive pacing (see Figure 27), by setting **OUTPUT** to 0.1 mA.
4. Connect the temporary pacemaker to the patient lead system. If necessary, reduce **RATE** until the temporary pacemaker is not pacing the patient.
5. Decrease **SENSITIVITY**: Slowly turn the dial clockwise (increase mV value) until the **SENSE** indicator stops flashing (see Figure 27).

   Figure 27. Decrease RATE , OUTPUT, and SENSITIVITY



   The **PACE** indicator flashes continuously, but capture is not likely because the **OUTPUT** value is set to minimum.
6. Increase **SENSITIVITY**: Slowly turn the dial counterclockwise (decrease mV value) until the **SENSE** indicator starts flashing (see Figure 28). The following events occur:
   - The **PACE** indicator stops flashing.
   - This value is the sensing threshold.

Figure 28. Increase sensitivity



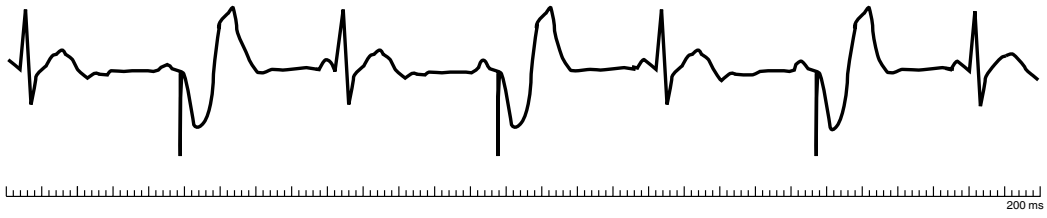
7. Set **SENSITIVITY** to half (or less) the threshold value. This setting provides at least a 2:1 safety margin.
8. Restore **RATE** and **OUTPUT** to previous values.

Note: Determine the atrial or ventricular stimulation thresholds after determining sensing thresholds.

5.2.3 Capture definitions

When a pacing pulse captures the heart, it causes the heart to beat — that is, contract and pump blood. The ECG shows a P-wave or QRS complex after the pulse. The example in Figure 29 shows a QRS complex after the pulse. When capture is lost, the ECG shows no heart response after the pulse.

Figure 29. Capture



Stimulation threshold – The stimulation threshold is the minimum output (mA) needed to consistently capture the heart. Monitor the patient's ECG and blood pressure as you follow the procedure to find the atrial or ventricular stimulation thresholds.

Stimulation threshold safety margin – Lead maturation and drug therapy can affect the stimulation threshold. To achieve consistent capture and accommodate a changing threshold, it is important to provide at least a 2:1 safety margin. Set **OUTPUT** to a value at least 2 to 3 times greater than the stimulation threshold value. For example, the appropriate output setting for a patient with a 1.0 mA threshold is 2.0 mA or greater.

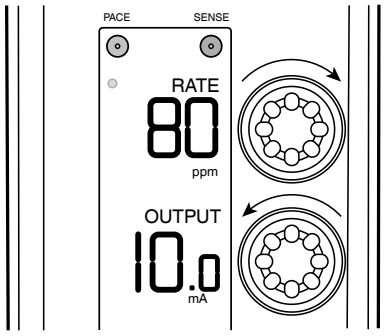
Caution: A 2:1 safety margin cannot always be achieved due to a very high pacing amplitude. If a 2:1 safety margin cannot be achieved, increase monitoring of the patient to verify that the expected therapy is being delivered.

5.2.4 Determining atrial or ventricular stimulation thresholds

To determine atrial or ventricular stimulation thresholds, perform these steps:

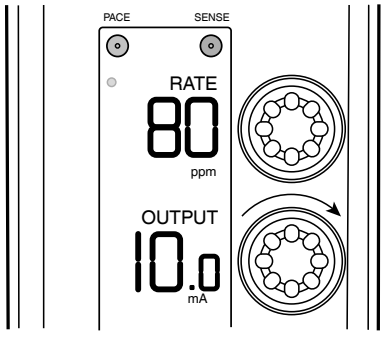
1. Verify that the patient is connected to the temporary pacemaker and is being monitored on the ECG.
2. Set **RATE** at least 10 ppm above the patient's intrinsic rate (see Figure 30).
   If necessary, continue to increase the **RATE** until the temporary pacemaker is pacing the patient. The **PACE** indicator flashes.
3. Decrease **OUTPUT**: Slowly turn the **OUTPUT** dial counterclockwise until the ECG shows loss of capture (see Figure 30).
   The **PACE** and **SENSE** indicators flash intermittently.

Figure 30. Increase RATE, decrease OUTPUT



4. Increase **OUTPUT**: Slowly turn the output dial clockwise until ECG shows consistent capture (see Figure 31). The following events occur:
   - The **PACE** indicator flashes continuously; the **SENSE** indicator stops flashing.
   - This value is the stimulation threshold.

Figure 31. Increase OUTPUT



5. Set **OUTPUT** to a value at least 2 to 3 times greater than the stimulation threshold value. This setting provides at least a 2:1 safety margin.
6. Restore **RATE** to the previous value.

5.3 Rapid Atrial Pacing (RAP)

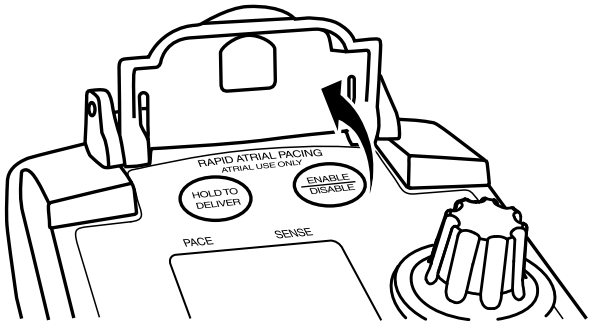
RAP can be used to interrupt some types of atrial tachycardias or to induce an atrial tachycardia.

Caution: RAP is for atrial use only. Before enabling RAP, be sure that the atrial leads are connected to the atrium, not the ventricle.

5.3.1 Rapid Atrial Pacing (RAP) overview

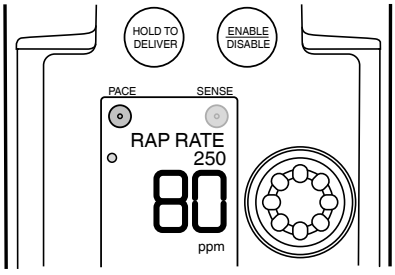
To access the RAP controls, flip open the small plastic RAP cover at the top of the temporary pacemaker and expose the controls. See Figure 32.

Figure 32. Rapid Atrial Pacing controls



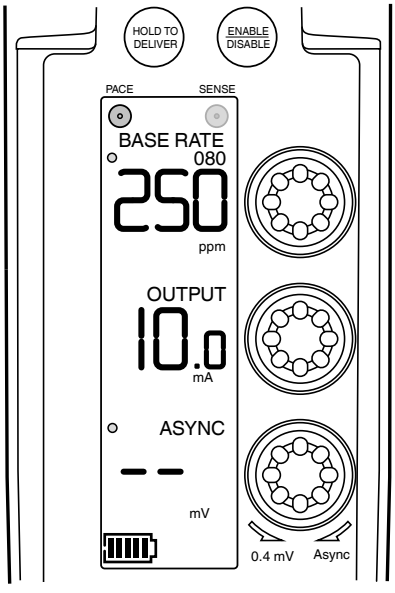
Press the **ENABLE/DISABLE** button to enter and exit RAP Standby mode. Once the device is in RAP Standby, the user can change the RAP pacing values by turning the **RATE** dial. The value of the RAP rate will appear in small text above the RATE value. See Figure 33.

Figure 33. RAP rate display



When the **HOLD TO DELIVER** button is pressed and held, the temporary pacemaker waits a maximum of two pacing cycles, and then begins pacing asynchronously in the atrium (AOO pacing mode) at the selected RAP rate. See Figure 34.

Figure 34. Delivering rapid atrial pacing



Note: The temporary pacemaker does not deliver RAP until the **HOLD TO DELIVER** button is pressed and held. **RATE** and **OUTPUT** remain at their selected values for the current pacing mode until the **HOLD TO DELIVER** button is pressed and held.

5.3.2 Using RAP

Caution: RAP may result in tachycardia, acceleration of existing tachycardia, or fibrillation. Apply high rates under careful patient monitoring and control. Monitor the patient's ECG and blood pressure, and ensure that defibrillation equipment is immediately available.

Delivering RAP – Perform the following steps to deliver RAP:

1. Open the RAP cover to expose the RAP controls.
2. Press the **ENABLE/DISABLE** button once to enable RAP and enter RAP Standby. The RAP LED illuminates next to the RAP rate. The RAP rate (initially the rate of 320 ppm) displays in small text above the current pacing rate. Pacing continues at the currently displayed settings.
3. Adjust the RAP rate as needed. Turn the **RATE** dial clockwise to increase the RAP rate, or counterclockwise to decrease the RAP rate. The range for RAP is 80 ppm to 800 ppm.
4. Press and hold the **HOLD TO DELIVER** button to deliver RAP burst. During RAP delivery, the following events occur:
   - The previously set pacing rate and the RAP rate will switch places between the small and large text fields during RAP delivery.
   - AOO pacing begins at displayed RAP rate and current atrial OUTPUT. The **PACE** LED flashes during delivery of RAP pulses.
   - RAP delivery stops when either the **HOLD TO DELIVER** button is released, or after 2 min have passed.

Value settings during RAP – During the delivery of RAP, the following value settings occur:

- **OUTPUT** does not lock and may be adjusted during RAP delivery.
- The **SENSITIVITY** is automatically adjusted to ASYNC during RAP delivery and the **ASYNC** LED illuminates.

Adjusting rate or atrial output during RAP delivery – The RAP rate and **OUTPUT** can be adjusted during RAP delivery. Follow these steps to adjust the RAP rate and OUTPUT:

1. Continue to press and hold the **HOLD TO DELIVER** button.
2. Turn the **RATE** dial clockwise or counterclockwise to adjust RAP rate.
3. Turn the **OUTPUT** dial clockwise or counterclockwise to adjust atrial output.

Resuming pacing at previous settings – Perform the following steps to resume pacing at previous settings:

1. Release the **HOLD TO DELIVER** button to resume pacing at the previous settings. The temporary pacemaker stops delivering RAP and resumes operation at the non-RAP settings within 3 s. The RAP rate and pacing rate will switch places between the small and large text fields.

   Note: If the **OUTPUT** is adjusted during RAP, the new setting is retained when RAP is terminated.
2. Press the **ENABLE/DISABLE** button once to exit RAP Standby and disable RAP controls. The RAP LED will no longer be illuminated when the device has exited RAP Standby mode, and the RAP rate will no longer be displayed above the pacing rate.

Note: When resuming operation in a synchronous mode, the temporary pacemaker first searches for cardiac activity (during the first pacing cycle), and then begins sensing and pacing (AAI/VVI pacing mode).

Caution: If the temporary pacemaker continues to deliver RAP after the **HOLD TO DELIVER** button is released, press and hold the On/Off button to stop RAP. If RAP continues to be delivered, remove the batteries from the temporary pacemaker and return the temporary pacemaker for service.

6 Cleaning, disinfecting, and maintenance

6.1 Cautions and notes for cleaning and disinfection

Cautions:

- Clean and disinfect the temporary pacemaker as needed according to your organization's procedures. Depending on the level of contamination, such as exposure to blood or body fluid, it is recommended to clean and disinfect the temporary pacemaker promptly after use to minimize drying and cross contamination.
- Do not immerse the temporary pacemaker in water or cleaning agents. Severe damage to the temporary pacemaker may occur. Do not use automated machine washers. Do not sterilize the temporary pacemaker by ethylene oxide, gamma radiation or steam-sterilization (autoclave). Damage to the temporary pacemaker may occur using these methods.
- Use only the recommended methods to clean and disinfect the temporary pacemaker. If the temporary pacemaker cannot be sufficiently cleaned using these methods, return the temporary pacemaker to Medtronic for service.
- Use only recommended cleaners and disinfectants on the temporary pacemaker. Using other cleaners and disinfectants may cause damage to the temporary pacemaker plastic, circuitry, or metal components.
- If cleaning the battery drawer, ensure the batteries are removed prior to cleaning.
- Excess amounts of cleaners or disinfectants in the battery drawer may damage the temporary pacemaker. If the temporary pacemaker cannot be easily or completely cleaned using the recommended procedure below, return the temporary pacemaker to Medtronic for service.

Notes:

- The temporary pacemaker should be cleaned and disinfected at normal operating temperature and normal environmental pressure and humidity.
- The provided disinfection method has been tested and shown to achieve a 4.8 log or greater reduction.
- The temporary pacemaker is designed to withstand normal cleaning and disinfection over its normal product life.
- During use, the temporary pacemaker can become too contaminated for effective cleaning by the clinic. If the temporary pacemaker has blood or soil ingress in its battery compartment, cable ports, or under the knobs, return it to Medtronic for service. When blood or soil enters into these areas, the clinic cannot effectively clean the temporary pacemaker.
- Do not expose the temporary pacemaker to ethers, acetone, chlorinated solvents, or disinfectants that are not included in the instructions below. These solvents may damage the case, labels, or metal components.
- For more information on cleaning and disinfecting medical devices, visit the CDC and HICPAC website (http://www.cdc.gov/hicpac/Disinfection_Sterilization/14_00ReuseMedicalDevices.html).

6.2 Cleaning and disinfecting the temporary pacemaker

6.2.1 Disassembly

Figure 35. Disassembly, Step 1. Remove the clear plastic cover.

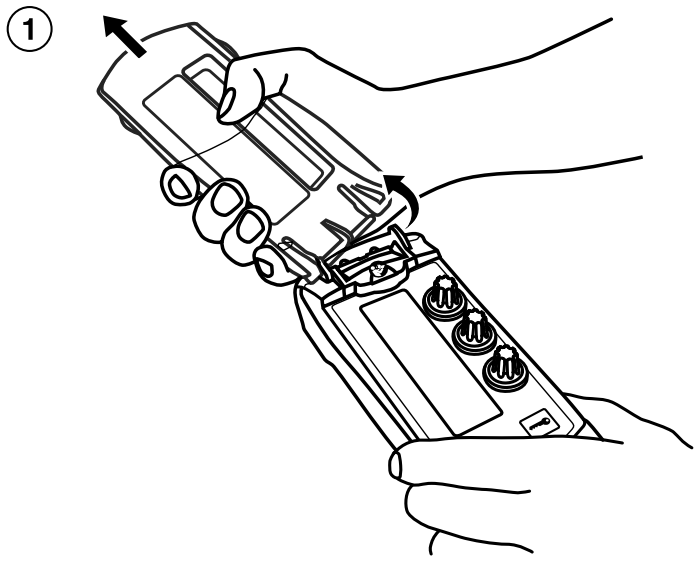
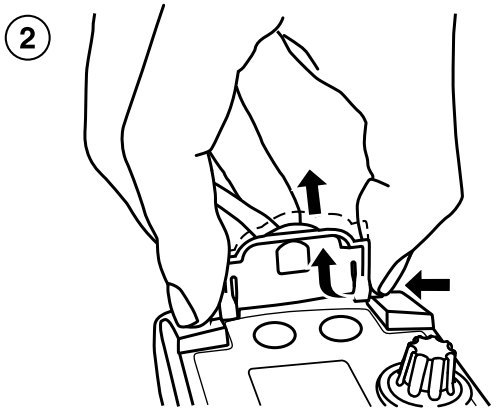


Figure 36. Disassembly, Step 2. Remove the Rapid Atrial Pacing (RAP) cover.



6.2.2 Cleaning

Figure 37. Cleaning, Step 3. Clean all surfaces of the temporary pacemaker thoroughly using a 70% isopropyl alcohol prep pad.

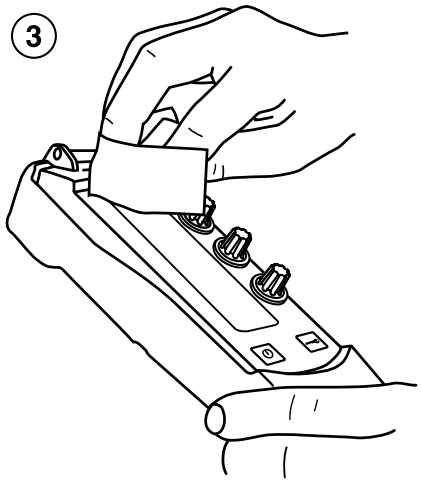


Figure 38. Cleaning, Step 4. Clean all surfaces of the clear plastic cover using a 70% isopropyl alcohol prep pad.

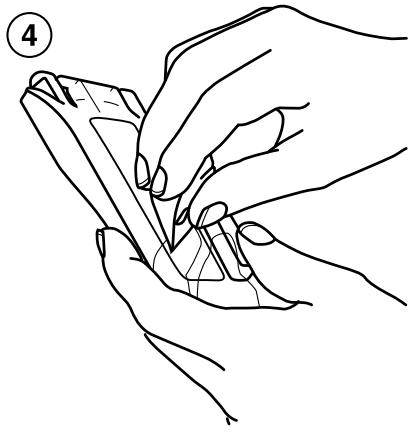
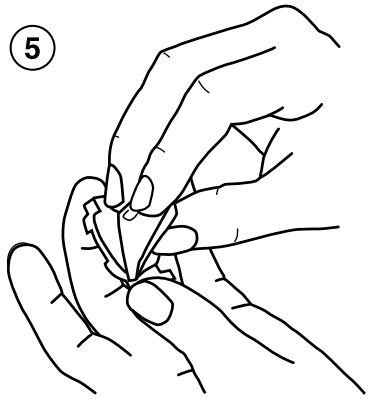


Figure 39. Cleaning, Step 5. Clean all surfaces of the Rapid Atrial Pacing (RAP) cover using a 70% isopropyl alcohol prep pad.



Cleaning, Step 6. Allow the temporary pacemaker, clear plastic cover, and RAP cover to air dry approximately 5 min or until dry.

6.2.3 Disinfecting

15 min of wet/damp exposure to 70% isopropyl alcohol is needed for disinfection. To achieve 15 min of moistened exposure, wrap the temporary pacemaker and covers in cloths dampened with 70% isopropyl alcohol and place them in a sealed bag or container.

Figure 40. Disinfection, Step 7. After cleaning, wrap the temporary pacemaker in damp cloth.

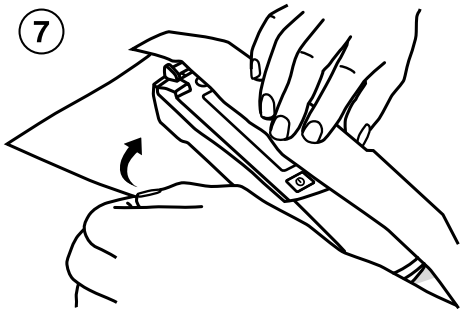


Figure 41. Disinfection, Step 8. Wrap the clear plastic cover in damp cloth.

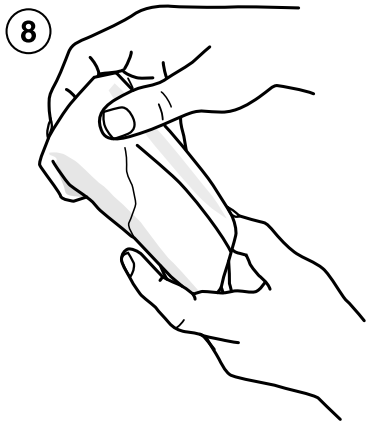


Figure 42. Disinfection, Step 9. Wrap Rapid Atrial Pacing (RAP) cover in damp cloth.

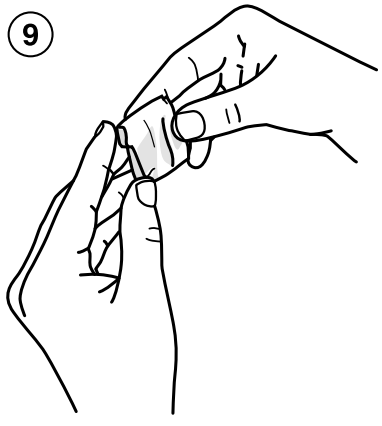


Figure 43. Disinfection, Step 10. Place the wrapped temporary pacemaker, clear plastic cover, and RAP cover in a sealed bag for 15 min.

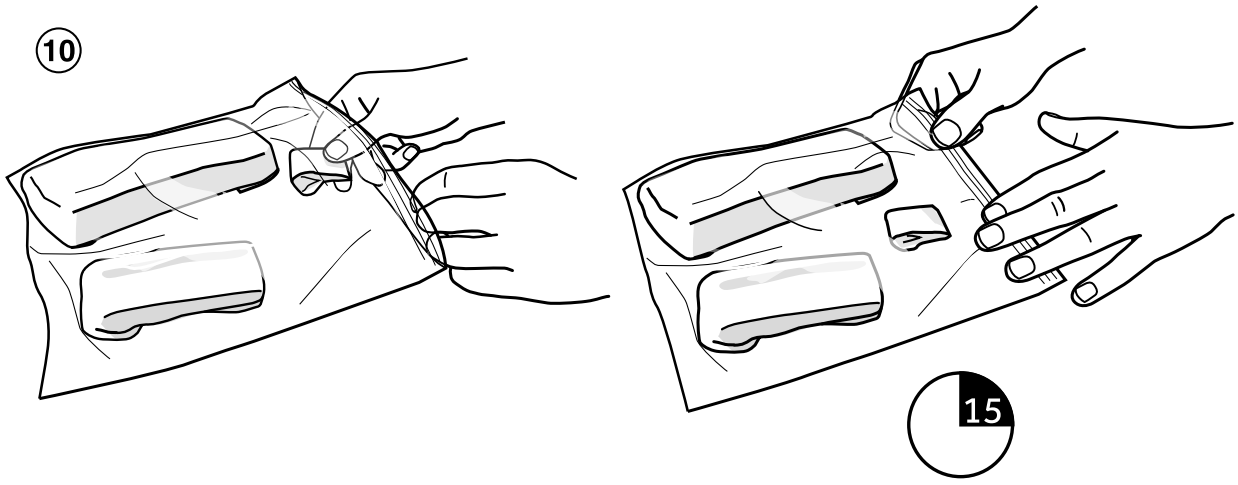
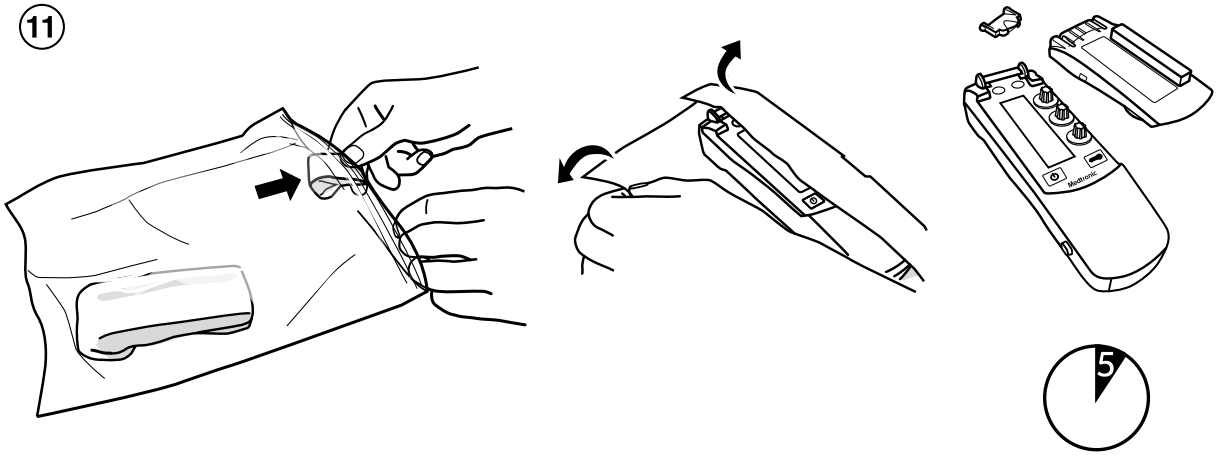


Figure 44. Disinfection, Step 11. Remove the items from the bag. Unwrap them and allow them to air dry for 5 min or until dry.



6.2.4 Reassembly

Figure 45. Reassembly, Step 12. After cleaning or disinfection, reattach the Rapid Atrial Pacing (RAP) cover.

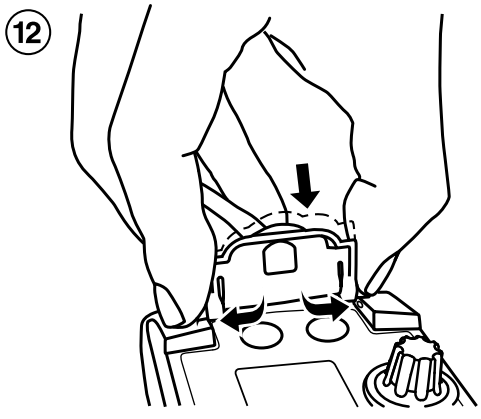


Figure 46. Reassembly, Step 13. Reattach the clear plastic cover.

6.2.5 Additional resources

For additional information about cleaning and disinfecting the temporary external pacemaker, contact Medtronic Instruments Technical Services:

- Phone: +1 800 638 1991
- Email: tshelp@Medtronic.com

For more information and resources on cleaning and disinfecting medical devices, visit the CDC and HICPAC websites.

6.3 Safety and technical checks

Perform safety and technical checks on the temporary pacemaker periodically and after any malfunction or accident (such as dropping the temporary pacemaker or a defibrillation event). Medtronic recommends that qualified engineers and technicians trained in the service of Medtronic products perform the checks. Contact your Medtronic sales or service representative for additional service or training. If a checkout or test of a pacemaker indicates improper operation, the unit should be returned to Medtronic for evaluation and repair. Understanding the warnings listed in this manual is necessary to perform safety and technical checks successfully.

Note: There is no method to adjust an out-of-tolerance parameter at an off-site location. The temporary pacemaker must be returned for recalibration.

Note: Do not open the external case of the temporary pacemaker. Opening the external case of the temporary pacemaker voids the warranty.

6.3.1 Visual inspection

Perform the following visual inspections each time the temporary pacemaker is used:

- Check that there is no mechanical or physical damage to the temporary pacemaker.
- Inspect the battery compartment and battery connection for corrosion and other contamination.

6.3.2 Functional inspection

Perform the following functional inspections each time the temporary pacemaker is used:

- Verify that the temporary pacemaker passes the self-test at power-up.
- Verify that the front panel dials, buttons, and displays function and work properly.
- Inspect all connections and cables. Verify that the patient cables are properly connected and are not damaged.

6.3.3 Conducting a system test

Test Equipment – When conducting tests on temporary pacemaker, Medtronic recommends the use of a Transvenous External Temporary Pacemaker Analyzer (Transvenous Analyzer) such as Sigma Pace 1000, Netech EXPMT, or Bio-Tek PMA testers.

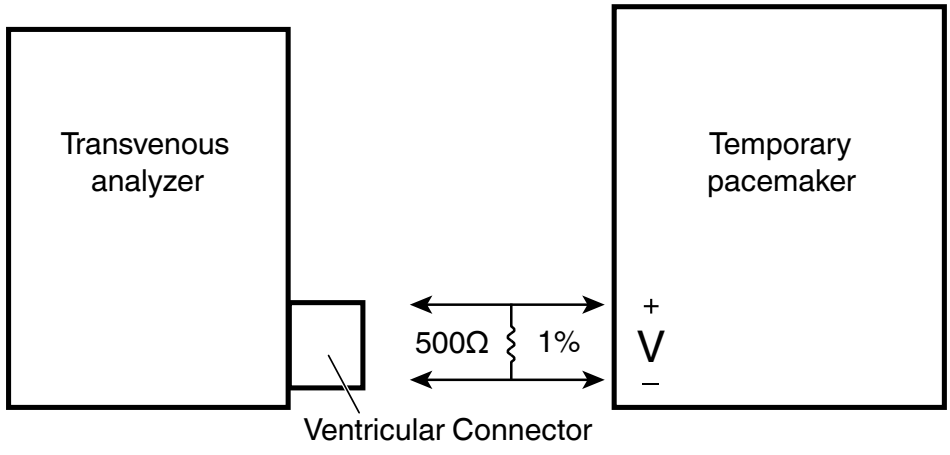
Note: The temporary pacemaker should be tested through the ventricular channel of the transvenous analyzer. Atrial testing is not required. Use of a test analyzer designed for defibrillators is not recommended test equipment for the temporary pacemaker. If you use the defibrillator test analyzer, the device MUST have the following capabilities:

- The defibrillator test analyzer MUST have the capability to test a transvenous temporary pacemaker.
- The defibrillator test analyzer MUST have the capability to inject a simulated R-wave for sensitivity testing.
- The defibrillator test analyzer MUST have the capability of applying an impedance load of 500 Ω

Notes:

- When using the Sigma Pace 1000, make sure you have selected “invasive” test and 500 Ω load.
- When using the Netech EXPMT, make sure the selection switch is in the A-V position.
- When using the Bio-Tek PMA, you must use the ventricular channel of the tester to measure Ventricular Sensitivity.

Figure 47. Setup for Testing Rate, Pulse Width, Pulse Amplitude



6.3.4 Practical measurements

The following paragraphs define each of the test parameters covered by the checkout procedures in this manual:

Rate – Rate is the number of output pulses per minute (ppm). It is the inverse of the time interval measured between successive output pulses. A control knob sets the base rate.

Rapid Atrial Pacing Rate – The rapid rate delivered only to the atrium is measured in the same manner as the base rate.

Pulse Width – Pulse width is the time duration of any given output pulse. Pulse width is fixed at 1.5 ms in the temporary pacemaker.

Output – Output current is determined by measuring the voltage amplitude of a pulse delivered to a known resistive load. The output current is then calculated by dividing the measured voltage by the value of the resistive load in Ω.

Sensitivity – Sensitivity is tested by determining the amplitude of a test wave (simulated R wave) that will inhibit pacing. This test first injects a sub-threshold signal, resulting in the temporary pacemaker pacing. The test increases amplitude until it is above the threshold, resulting in the temporary pacemaker sensing.

6.3.5 Test conditions

For an accurate measurement of temporary pacemaker parameters the test instrument inaccuracy should not exceed 10% of the tolerance for that particular parameter.

Note: A defibrillator analyzer with pacemaker test function is for transcutaneous pacemakers and is not recommended for testing the temporary pacemaker. Medtronic recommends that a transvenous analyzer be used for testing the temporary pacemaker.

Measurements are to be made under the following conditions and at the specified parameter settings:

- All unspecified tolerances ± 5%
- Temperature 21.11 ± 11°C (70 ± 20°F)
- Relative humidity 80% or less
- Analyzer test load 500 Ω ± 1%
- New batteries
- Analyzer simulated R wave 40 ms (25 Hz) sine2 pulses at 400 ms intervals
- Temporary pacemaker settings shall be the nominal settings in the AAI/VVI mode (see Section 7.1), unless otherwise specified.

6.3.6 Rate test procedure

- Use a transvenous analyzer as in Figure 47.

Note: If available on the transvenous analyzer, select the ventricular test.

- Set the output to 10 mA and the sensitivity to 2.0 mV. Set the rate to the values listed below and verify that the pulse to pulse intervals are within specified tolerances.

Table 1. Rate test procedure tolerances

Setting	Acceptable range
30 ppm	27-33 ppm
80 ppm	72-88 ppm
200 ppm	180-220 ppm

6.3.7 Rapid atrial pacing (RAP) test

- Use a transvenous analyzer as in Figure 47.

Note: The RAP test can be completed using the ventricular channel of the transvenous analyzer.

- Press the **ENABLE/DISABLE** button. **RAP RATE** will illuminate on the display above RATE display. The base rate will remain at 80 ppm. Above the base rate the default RAP of 320 ppm will be displayed. Once the **ENABLE/DISABLE** button is pressed, the output will continue at the programmed level and the displayed rate will be replaced by the RAP rate.
- To increase the RAP rate, rotate the **RATE** dial. An amber LED to the left and beneath RAP indicates that the RAP function is active.
- Press the **HOLD TO DELIVER** button and measure the output rate. It should be 320 ppm ±10% (304-336 ppm). RAP is available over the range of 80-800 ppm ±10%, using the rate control knob to adjust the rate. Increase the RAP rate to 800 ppm ±10% (760-840 ppm) and measure the output rate.

6.3.8 Pulse width test

- Use a transvenous analyzer as in Figure 47.
- Set the temporary pacemaker rate to 80 ppm, output to 10 mA, and sensitivity to 2 mV.
- Verify that the pulse width is 1.5 ms ± 10% (1.35-1.65 ms).

6.3.9 Output test

- Use a transvenous analyzer as in Figure 47.
- Set the temporary pacemaker rate to 80 ppm and sensitivity to 2 mV.
- Set the temporary pacemaker's output to the values listed in the table below. Verify the measured outputs are within specified tolerances.

Table 2. Output test tolerances

Output Setting	Acceptable range
1 mA	.9-1.1 mA
10 mA	9-11 mA
20 mA	18-22 mA

6.3.10 Sensitivity test

- Use a transvenous analyzer as in Figure 47.

Note: If available on the analyzer, use the invasive test and the 500 Ω setting.

- Select the Ventricular channel to test sensitivity. The SENSITIVITY range is 0.4-20 mV ± 55%.
- Use a simulated R-wave input and 40 ms SSQ (Sine Square Wave).

Note: If the analyzer has a selection for adjusting the amplitude, start at the lowest mV or output level available on the analyzer. An example would be starting sensitivity testing with the analyzer output set to .05 mV with the temporary pacemaker SENSITIVITY set to 2 mV.

- Turn on the temporary pacemaker and set the rate to 80 ppm and the output to 10 mA.
- Set SENSITIVITY to the values in the table below. For each setting of the temporary pacemaker, the test analyzer output will automatically increase (simulated R-wave) from below threshold, resulting in pacing by the temporary pacemaker. Output will increase to above threshold (the device senses at least five consecutive input signals). The test result must fall within the range specified for each setting.

Table 3. Sensitivity test tolerances

SENSITIVITY setting	Specified tolerance
2 mV	1-3 mV
10 mV	5-15 mV

6.3.11 Battery removal test

Note: The temporary pacemaker settings shall be the nominal settings in the AAI/VVI mode (see Section 7.1), unless otherwise specified.

- Using a new set of batteries, turn on the temporary pacemaker and let it operate for a minimum of 3 min.
- After the temporary pacemaker has been operating for 3 min, open the battery drawer.
- With the battery door open, the temporary pacemaker will continue to operate and the battery indicator will flash red.
- The temporary pacemaker should operate with the battery door open for a minimum of 30 s.

6.4 Service

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products. Medtronic also maintains a professional staff to provide technical consultation to product users. For medical consultation, Medtronic can often refer product users to outside medical consultants with appropriate expertise. For more information, contact your local Medtronic representative.

Should service or repair be necessary, contact your local Medtronic sales or service representative.

A serial number identifying each individual temporary pacemaker is printed on the back surface of the device. Reference this serial number in any correspondence regarding this device.

6.5 Troubleshooting

6.5.1 Self-test

The self-test includes a check of all buttons and critical internal circuits. The **PACE**, **SENSE**, **ASYNC**, and **RAP** LEDs illuminate during the self-test. These LEDs remain illuminated until the self-test successfully completes.

Note: Pressing any button while the self-test is in process can cause the temporary pacemaker to fail the self-test. The temporary pacemaker interprets the pressed button as being “stuck” and, therefore, malfunctioning. If a button is pressed during the self-test, causing a self-test failure, the screen displays an error message until the button is released.

The screen initializes when the temporary pacemaker turns on. All indicators display, including the low battery indicator, for 2 s. The low battery indicator displaying during the screen initialization does not indicate that the batteries are low. If the batteries are low, the low battery indicator remains visible during temporary pacemaker operation.

After successful completion of the self-test, the temporary pacemaker first searches for cardiac activity (during the first pacing cycle), and then begins sensing and pacing (AAI/VVI pacing mode).

If the temporary pacemaker fails the self-test, the **PACE**, **SENSE**, **ASYNC**, and **RAP** LEDs remain on, indicating the failed test, and no output pulses are issued. Failure codes may be displayed on the screen. Follow the instructions that appear on the screen to restart the temporary pacemaker, or to return the temporary pacemaker for service (contact your Medtronic representative). When returning the temporary pacemaker, remove the batteries, and return both the temporary pacemaker and the batteries.

6.5.2 Loss of sensing

Figure 48. Loss of atrial sensing (AAI/VVI pacing mode)

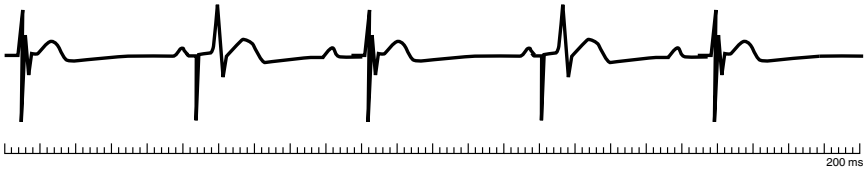
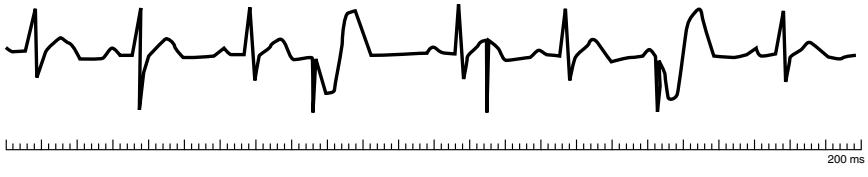


Figure 49. Loss of ventricular sensing (AAI/VVI pacing mode)



Keys to identifying loss of sensing – If a P-wave or R-wave is present, the temporary pacemaker does not detect intrinsic activity and delivers a pacing pulse. The following events occur during loss of sensing:

- Pacing artifacts are seen asynchronously on the ECG.
- The sense indicator does not flash, though the ECG shows depolarization.

Potential causes for loss of sensing – Loss of sensing may occur due to several causes:

Heart/patient related

- inadequate cardiac signal

Patient cable/lead related

- Loose connection at the connector block
- Inappropriate lead placement
- Insulation break or wire fracture

Temporary pacemaker related

- Inappropriate sensitivity setting
- Inappropriate pacing mode selection
- Small sensing window
- Electrical noise

Potential solutions for loss of sensing – Perform one or more of the following actions to troubleshoot the cause of loss of sensing:

- Check the cable connections for loose wires.
- Verify that the apparent loss of sensing is not due to blanking periods.
- Perform a sensing threshold test for the affected chamber. Provide at least a 2:1 safety margin.
  Note: If the patient does not have adequate intrinsic rhythm, consult a physician before the test.
- Increase SENSITIVITY for the appropriate chamber. Slowly turn the **SENSITIVITY** dial counterclockwise (decrease mV until the ECG shows intrinsic activity).
  Note: Use caution when adjusting SENSITIVITY for patients with a history of sustained ventricular tachycardia.

6.5.3 Oversensing

Figure 50. Atrial oversensing

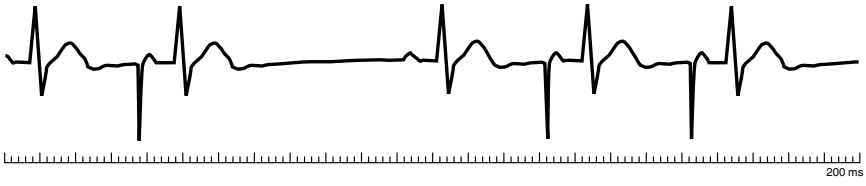
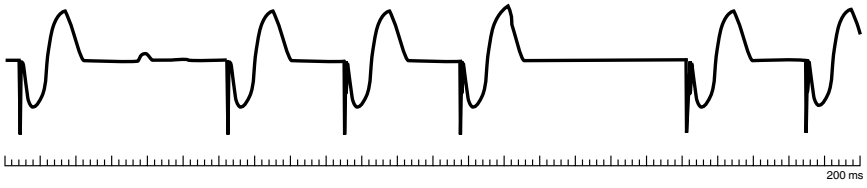


Figure 51. Ventricular oversensing



Keys to identify oversensing – During oversensing, the following events may occur:

- The ECG shows erratic prolonging or shortening of the pacing interval.
- Persistent oversensing may result in asynchronous pacing or no pacing output.

Potential causes of oversensing – Oversensing may occur due to one (or more) of several causes:

Heart of patient related

- T-wave sensing
- Far-field sensing (sensing, P- waves, or R-waves)
- Muscle sensing
- EMI

Patient cable or lead related

- Insulation break
- Conductor wire fracture

Temporary pacemaker related

- Inappropriate sensitivity setting(s)

Potential solutions for oversensing – Perform one or more of the following actions to troubleshoot the cause of oversensing:

- Check the cable connections for loose wires.
- Replace the cable if there is an insulation break or wire fracture.
- Perform the sensing threshold test for the affected chamber. Provide at least a 2:1 safety margin.
  Note: If the patient does not have adequate intrinsic rhythm, consult a physician before the test.
- If the source is muscle activity, EMI, T-wave, or far-field sensing, decrease SENSITIVITY for the affected chamber. Slowly turn the **SENSITIVITY** dial clockwise (increase the mV value).
  Note: When adjusting SENSITIVITY or OUTPUT, verify the appropriate safety margin.

6.5.4 Loss of capture

Figure 52. Loss of atrial capture

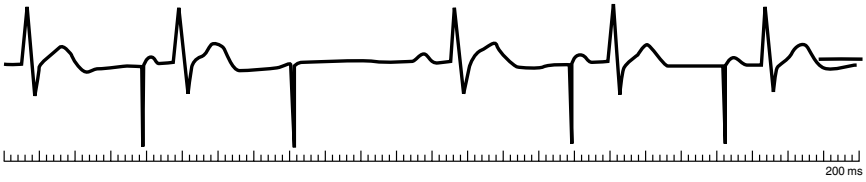
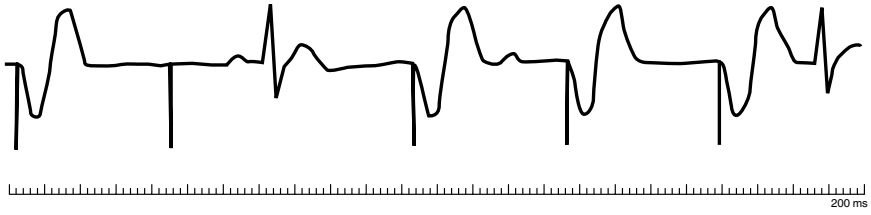


Figure 53. Loss of ventricular capture



Keys to identifying loss of capture – If the ECG shows no depolarization after delivery of a pacing stimulus, loss of capture has occurred.

Note: If the intrinsic event occurs just before pacing, see Section 6.5.2.

Potential causes of loss of capture – Loss of capture may occur due to one of the following causes:

Heart or patient related

- Increased stimulation threshold
- Exit block
- Tissue changes
- General metabolic imbalances
- Drug effects

Patient cable or lead related

- Loose connection at the connector block
- Heartwire dislodgement
- Inappropriate lead placement
- Insulation break or wire fracture

Temporary pacemaker related

- Inadequate output setting – mA

Possible misdiagnosis of loss of capture – Loss of capture may be misdiagnosed due to one or more of the following causes:

- The bipolar artifacts are too small to be seen.
- The digital ECG monitor or recorder is not sensitive to pacing spikes.

Possible solutions for loss of capture – Perform one or more of the following actions to troubleshoot the cause of loss of capture:

- Check the cable connections for loose wires.
- Replace the cable if there is an insulation break or wire fracture.
- Verify that the correct chamber is being paced.
- Verify the pacing mode.

- Perform the stimulation threshold test for the affected chamber. Provide at least a 2:1 safety margin.
- If necessary, increase the output for the appropriate chamber. Slowly turn the **OUTPUT** dial clockwise until the ECG shows capture.

  Note: Use caution when adjusting OUTPUT for patients with a history of sustained ventricular tachycardia.

6.5.5 Stimulation of chest wall or diaphragm

Potential causes of stimulation of the chest wall or diaphragm – Stimulation of the chest wall or diaphragm may occur due to one of the following causes:

Patient cable or lead related

- Improper lead placement
- Loose connection at the connector block
- Conductor wire fracture

Temporary pacemaker related

- Excessive output settings – mA

Possible solutions for stimulation of chest wall or diaphragm – Perform one or more of the following actions to troubleshoot the cause of chest wall or diaphragm stimulation:

- Determine if the lead is the cause of the problem by reducing OUTPUT to the lead.
- Perform the stimulation threshold test. Set the output to a value more than 2 times the threshold value, but below the point of stimulating the chest or diaphragm.
- If the outcome does not improve, correct the placement of the lead.

6.5.6 No output pulse

Key to identifying output pulse – The ECG does not show the pacing spikes when there is no output.

Possible misdiagnosis of no output pulse – No output pulse may be misdiagnosed due to one or more of the following causes:

- Pacing is inhibited because of sensed noise or intrinsic activity.
- The digital ECG monitor or recorder is not sensitive to pacing spikes.

Possible solutions for no output pulse – Perform one or more of the following actions to troubleshoot the cause of no output pulse:

- Observe the pace indicators.
- Re-insert the patient cable.
- Replace the batteries.
- Change the ECG monitor or recorder.
- Set OUTPUT to the appropriate safety margin.

6.5.7 Hemodynamic changes

Keys to identifying hemodynamic changes – Check the following items when identifying possible causes of hemodynamic changes:

- Decreased blood pressure
- Altered brachial pulse rate

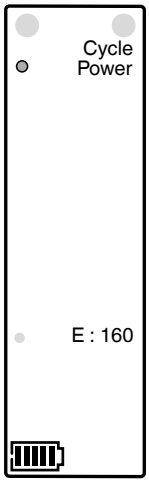
Possible solutions to hemodynamic changes – Perform one or more of the following actions to troubleshoot the cause of hemodynamic changes:

- Consult a physician.
- Check the pacing mode. If necessary, change to the AAI/VVI pacing mode.
- Verify that sensing or capture has not been lost. Correct if necessary.
- Adjust the pacing rate (increase it in most cases).

6.5.8 Recoverable error message

If the temporary pacemaker displays the recoverable error message (see Figure 54), press and hold the **ON/OFF** button until the temporary pacemaker powers off. Then, press the **ON/OFF** button to restart the temporary pacemaker. Upon restarting, the temporary pacemaker will perform the self-test.

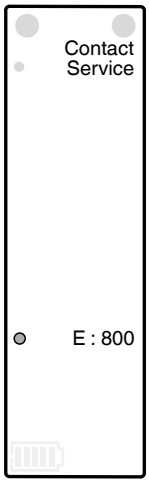
Figure 54. Recoverable error message



6.5.9 Non-recoverable error message

If the temporary pacemaker displays the non-recoverable error message (see Figure 55), contact Medtronic for service.

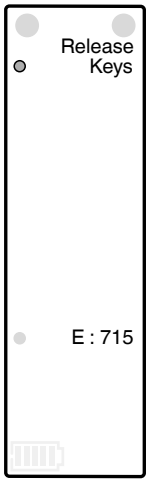
Figure 55. Non-recoverable error message



6.5.10 Button press detected error message

If the temporary pacemaker displays the Button Press Detected error message, a button has been pressed while the temporary pacemaker is turning on. Release any pressed button and the temporary pacemaker continues to power on normally.

Figure 56. Error – Button Press Detected



6.6 Product life

Long-term reliability of the temporary pacemaker is subject to the actual use conditions of the device. The routine testing and preventative maintenance recommended in this manual will help provide reliable operation of the temporary pacemaker.

The service life of the temporary pacemaker is seven years. Medtronic will not service or repair the temporary pacemaker after seven years. Contact your Medtronic representative to replace your temporary pacemaker after it has been in service for seven years.

7 Specifications

7.1 Device specifications

Table 4. Temporary pacemaker specifications

Pacing modes	AAI, AOO, VVI, VOO		
RATE	Range (in ppm)	Increments (in ppm)	Tolerance
	30 – 50 50 – 100 100 – 170 170 – 200	5 2 5 6	30 – 200 ±2%
RAP rate	Range (in ppm)	Increments (in ppm)	Tolerance
	80 – 250 250 – 320 320 – 430 430 – 800	20 5 10 20	80 – 360 ±2% 370 – 800 ±4%
Output amplitude	Range (in mA)	Increments (in mA)	Tolerance
	0.1 – 0.4 0.4 – 1.0 1.0 – 5.0 5.0 – 25	0.1 0.2 0.5 1.0	0.1 – 20 Greater of ±0.1 mA or ±10% (200-1000 Ω) 20 – 25 ±10% (200–500 Ω)
Pulse width (fixed)	1.5 ms ±10%		
Input impedance	40,000 Ω		
Sensitivity[a]	Range (in mV)	Increments (in mV)	Tolerance
	0.4 – 1.0 1.0 – 3.0 3.0 – 10 10 – 20	0.2 0.5 1.0 2.0	±55%
Blanking[b]			
200 ms +5/-30 ms – after pace			
120 ms +2/-30 ms – after sense			

Table 4. Temporary pacemaker specifications (continued)

RATE limit (non-RAP)	230 ppm	If a non-RAP rate exceeds 230 ppm, pacing is terminated, a recoverable error message will be displayed.
Nominal values		
Pacing mode	AAI/VVI	
RATE	80 ppm	
Output amplitude	10 mA	
Pulse width (fixed)	1.5 ms	
Sensitivity	2.0 mV	
RAP rate	320 ppm	
Dimensions		
Height	20.27 cm (7.98 in) ±10%	
Width	6.68 cm (2.63 in) ±3%	
Depth	4.14 cm (1.63 in) ±4%	
Weight (with battery)	499 g (17.6 ounces) maximum	
Temperature		
Operating	10°C to 40°C (50°F to 104°F)	
Storage (without battery)	-25°C to 70°C (-13°F to 158°F)	
Humidity (storage)	> 80% and ≤ 95% at 40°C (104°F), use after 48 hours dry time ≥ 10% and ≤ 80% at 40°C (104°F), for immediate use	
Battery type	Two IEC type LR6-sized (AA-sized) 1.5 V alkaline batteries (Duracell MN1500, Eveready E91 or equivalent)	
Battery life	7 days minimum, when the RATE is 80 ppm, and all other parameters are at the nominal values. Higher amplitudes and rates decrease battery life.	
Operation after battery removal	30 s (typical) under the following conditions: RATE of 80 ppm or less and OUTPUT of 10 mA or less, backlight off.	
Standards	The temporary pacemaker complies with requirements from IEC 60601-1.	

[a]When sensing 40 ms-wide Haversine waveform.

[b]When tested with a 1 ms square pulse with sufficient amplitude.

7.2 Pacing information tables

Table 5. Temporary pacemaker single chamber pacing setup table

Pacing mode	**AOO/VOO**	**AAI/VVI**
PACE and SENSE Indicators	PACE	PACE + SENSE
Instructions		
1. Set **OUTPUT**	On	On
2. Set **SENSITIVITY**	ASYNC	On

Table 6. Rate and interval conversion chart for RATE and RAP

Rate		**RAP**	
Rate	Interval	Rate	Interval
30 ppm	2000 ms	80 ppm	750 ms
35 ppm	1714 ms	100 ppm	600 ms
40 ppm	1500 ms	120 ppm	500 ms
45 ppm	1333 ms	140 ppm	429 ms
50 ppm	1200 ms	160 ppm	375 ms
52 ppm	1154 ms	180 ppm	333 ms
54 ppm	1111 ms	185 ppm	324 ms
56 ppm	1071 ms	190 ppm	316 ms
58 ppm	1034 ms	195 ppm	308 ms
60 ppm	1000 ms	200 ppm	300 ms
62 ppm	968 ms	205 ppm	293 ms
64 ppm	938 ms	210 ppm	286 ms

Table 6. Rate and interval conversion chart for RATE and RAP (continued)

Rate		**RAP**	
66 ppm	909 ms	215 ppm	279 ms
68 ppm	882 ms	220 ppm	273 ms
70 ppm	857 ms	225 ppm	267 ms
72 ppm	833 ms	230 ppm	261 ms
74 ppm	811 ms	235 ppm	255 ms
76 ppm	789 ms	240 ppm	250 ms
78 ppm	769 ms	245 ppm	245 ms
80 ppm	750 ms	250 ppm	240 ms
82 ppm	732 ms	260 ppm	231 ms
84 ppm	714 ms	270 ppm	222 ms
86 ppm	698 ms	280 ppm	214 ms
88 ppm	682 ms	290 ppm	207 ms
90 ppm	667 ms	300 ppm	200 ms
92 ppm	652 ms	310 ppm	194 ms
94 ppm	638 ms	320 ppm	188 ms
96 ppm	625 ms	330 ppm	182 ms
98 ppm	612 ms	340 ppm	176 ms
100 ppm	600 ms	350 ppm	171 ms
105 ppm	571 ms	360 ppm	167 ms
110 ppm	545 ms	380 ppm	158 ms
115 ppm	522 ms	400 ppm	150 ms
120 ppm	500 ms	420 ppm	143 ms
125 ppm	480 ms	440 ppm	136 ms
130 ppm	462 ms	460 ppm	130 ms
135 ppm	444 ms	480 ppm	125 ms
140 ppm	429 ms	500 ppm	120 ms
145 ppm	414 ms	520 ppm	115 ms
150 ppm	400 ms	540 ppm	111 ms
155 ppm	387 ms	560 ppm	107 ms
160 ppm	375 ms	580 ppm	103 ms
165 ppm	364 ms	600 ppm	100 ms
170 ppm	353 ms	620 ppm	97 ms
176 ppm	341 ms	640 ppm	94 ms
182 ppm	330 ms	660 ppm	91 ms
188 ppm	319 ms	680 ppm	88 ms
194 ppm	309 ms	700 ppm	86 ms
200 ppm	300 ms	720 ppm	83 ms
		740 ppm	81 ms
		760 ppm	79 ms
		780 ppm	77 ms
		800 ppm	75 ms

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M962462A001 E
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