

**Model 53401**

Single Chamber Temporary Pacemaker

# Reference guide



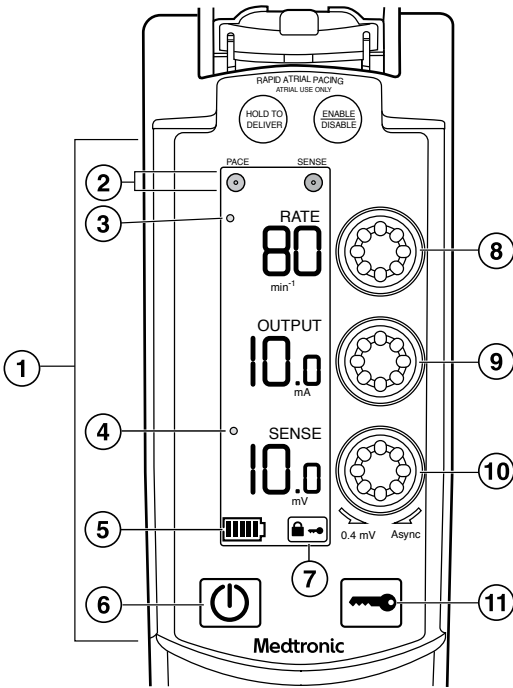
**Medtronic**

PRE-USE	What to do ...	What NOT to do ...
<b>Battery</b>	Replace the battery for each new patient.	Do NOT reuse battery.
<b>Physical condition*</b>	Check case for cracks/damage.* Check battery drawer for closure.* Check display for cracks/damage.*	Do NOT ignore visible physical damage; the device may appear to work properly immediately after being dropped or mishandled, but operational damage may have occurred.
<b>Cables</b>	Inspect cables and leads for possible defects, and secure connection before each use.	Do NOT use damaged leads or cables. Improper connection, displacement, or fracture may result in pacemaker failure. Do NOT reuse single-use cables.
<b>IN USE</b>		
<b>Placement</b>	Do not place the temporary pacemaker in any area outside of the direct observation by medical staff. If necessary, insert into a Disposable Pouch <sup>†</sup> (see-through plastic pocket) with an attachment panel (to hang from IV pole) that protects and holds the temporary pacemaker. Place the temporary pacemaker in an area that minimizes access to the controls by unauthorized personnel, such as patients and visitors.	Do NOT place the device in any area where the patient may interact with it.
<b>POST-USE</b>		
<b>Clean</b>	External surfaces of unit can be cleaned using a sponge or cloth moistened with water or 70% isopropyl alcohol. For internal surfaces, send to Medtronic for cleaning, safety, and technical check.	Do NOT attempt to clean any internal surfaces, including battery compartment. Do NOT immerse the device in water or cleaning agents; do NOT expose the unit to ethers, acetone, or chlorinated solvents.
<b>If dropped/ Visible exterior damage</b>	Send to Medtronic for safety and technical check.	Do NOT ignore; the device may appear to work appropriately immediately after being dropped or mishandled, but operational damage may have occurred.
<b>If spilled on</b>	Send to Medtronic for safety and technical check.	Do NOT ignore; the temporary pacemaker was designed to minimize leakage, but fluid incursion may still occur.

\*Should service or repair be necessary, contact your local Medtronic representative or call 1-800-638-1991. Technical Support information available at [MedtronicAcademy.com/technical-product-support](http://MedtronicAcademy.com/technical-product-support).

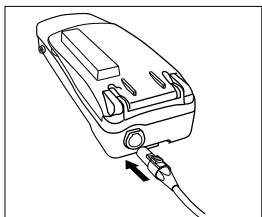
<sup>†</sup>Disposable Pouch available for the Model 53401 Temporary Pacemaker, Model #5409.

## Controls and indicators



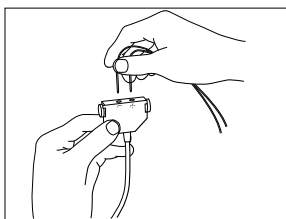
1. Screen
2. Pacing and sensing status indicator LEDs
3. RAP indicator LED
4. ASYNC indicator LED
5. Battery indicator
6. On/Off button
7. Lock indicator
8. RATE dial
9. OUTPUT dial
10. SENSITIVITY dial
11. Lock/Unlock button

## Basic operation



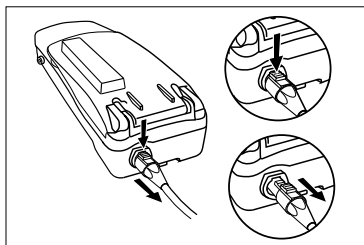
### Connector Setup

1. Verify that the temporary pacemaker is turned off.
2. Plug the patient cable (5492AL/VL, 5846AL/VL, 5487L), surgical cable (5832S, 5833SL), or Medtronic compatible cable into the socket on the connector block on top of the temporary pacemaker.
3. Verify that the cable clicks when it is inserted into the temporary pacemaker connector receptacle. The audible click verifies that the plug is completely inserted into the receptacle.
4. Pull gently on the cable after insertion to ensure a good connection.
5. Connect the lead to the cable. Match positive (+) and negative (-) leads to positive (+) and negative (-) sockets or clips for the atrium or ventricle.



**Note:** To disconnect the cable from the temporary pacemaker, do the following:

1. Press the connector release button on the patient cable plug.
2. Gently pull the plug from the receptacle.



## Basic operation

### To Turn On

- Press and hold the On/Off button momentarily to turn on the temporary pacemaker.

The screen and the backlight illuminate, a self-test is initiated, and the temporary pacemaker first searches for cardiac activity and then begins sensing and pacing (AAI/VVI mode).

- When the temporary pacemaker is turned on, the values are:

**RATE:** 80 ppm (range 30-200 ppm)

**OUTPUT:** 10 mA (range 0.1-25 mA)

**SENSITIVITY:** 2 mV (range 0.1-20mV)

**Note:** If the batteries are nearing depletion, a red backlight begins flashing behind the battery status indicator.

**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 the threshold values.

### To Turn Off

1. Unlock the temporary pacemaker, if it is locked (see following section).
2. Press 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.

## Basic operation

### 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.

### When Locked:

- 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:

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

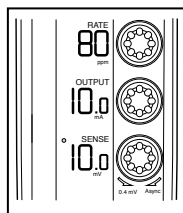
- 60 seconds elapse after the last parameter adjustment is made.
- When RAP is enabled, the temporary pacemaker will lock after 300 seconds/2 minutes have elapsed.
- The Lock/Unlock button is pressed.

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

## Basic operation

### Rate, Output, and Sensitivity Adjustments

1. If the Lock indicator appears in the lower right, press LOCK/UNLOCK button.
2. 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.



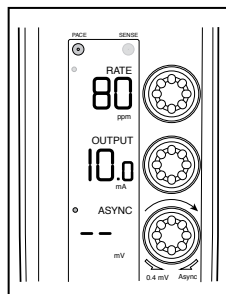
*The screen displays a numerical value that reflects the current setting for each dial.*

### Viewing 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.

### 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).
- To turn off **SENSITIVITY** and allow the temporary pacemaker to pace asynchronously, turn the **SENSITIVITY** dial clockwise until the screen displays the term **ASYNC**.

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## Sensing thresholds

**Note:** The sensing threshold is the least sensitive setting at which the pacemaker can detect a heartbeat. To find the atrial and ventricular thresholds, monitor the patient's ECG as you follow the procedure below.

**Caution:** Pacemaker-dependent patients will have limited or no intrinsic rate/rhythm.

### To Find Atrial or Ventricular Sensing Thresholds

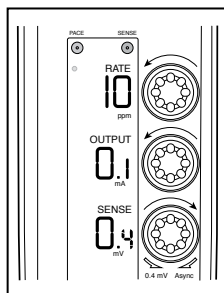
1. Turn on the temporary pacemaker without connecting it to the patient lead system.  
**Caution:** Do not connect the temporary pacemaker to the patient lead system until step 4.

2. Set **RATE** to at least 10 ppm under the patient's intrinsic rate.

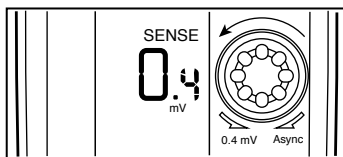
3. Adjust the output to prevent the risk of competitive pacing by setting **OUTPUT** to 0.1 mA.

4. Connect the temporary pacemaker to the patient lead system.

5. Decrease **SENSITIVITY**: Slowly turn the dial clockwise (increase mV value) until the SENSE indicator stops flashing. 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.



- The PACE indicator stops flashing.
- This value is the sensing threshold.

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.



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## Stimulation thresholds

**Note:** The stimulation threshold is the minimum output pulse needed to consistently capture the heart. To find this threshold, monitor the ECG as you follow the procedure below. To reduce the risk of competitive pacing, find the sensing threshold first (if the patient's intrinsic rate is adequate).

### To Find Atrial or Ventricular Stimulation Thresholds

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.

This adjustment ensures pacing. The PACE indicator will be flashing.

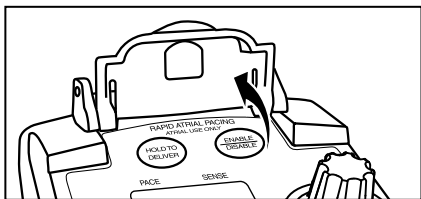
3. Decrease **OUTPUT**: Slowly turn the **OUTPUT** dial counterclockwise until the ECG shows loss of capture.
  - The PACE and SENSE indicators flash intermittently.
4. Increase **OUTPUT**: Slowly turn the **OUTPUT** dial clockwise until ECG shows consistent capture.
  - The PACE indicator flashes continuously; the SENSE indicator stops flashing.
  - This value is the stimulation threshold.
5. Set **OUTPUT** to a value at least 2 to 3 times greater than the stimulation threshold value. This setting provides at least 2:1 safety margin.
6. Restore **RATE** to previous value.

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

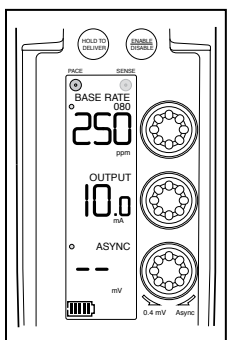


**Caution:** Pacemaker-dependent patients will have limited or no intrinsic rate/rhythm.

### 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 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 (range 80 ppm-800 ppm).
4. Press and hold the **HOLD TO DELIVER** button to deliver RAP burst. During RAP delivery:
  - 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 minutes have passed.

## Rapid atrial pacing (RAP)



### Adjusting Rate or Atrial Output during RAP Delivery:

The RAP rate and OUTPUT can be adjusted during RAP delivery.

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

1. Release the **HOLD TO DELIVER** button.  
The temporary pacemaker stops delivering RAP and resumes operation at the non-RAP settings within 3 seconds.
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.

If the **OUTPUT** is adjusted during RAP, the new setting is retained when RAP is terminated.

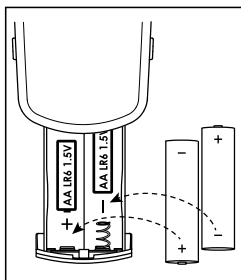
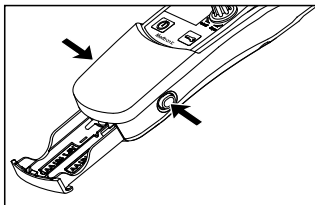
**Caution:** If the temporary pacemaker continues to deliver RAP after the **HOLD TO DELIVER** button is released, press and hold the On/Off button to stop RAP. If RAP continues to be delivered, remove the batteries from the temporary pacemaker and return the temporary pacemaker for service.

## Battery replacement

### Battery Installation and Replacement

**Note:** Medtronic recommends disconnecting device from patient before replacing battery.

1. Press the battery drawer latch release buttons until the battery drawer opens.
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.



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.

#### Notes:

- Replace the temporary pacemaker batteries in the following situations:
  - Replace the batteries for each new patient.
  - Replace the batteries when the low battery indicator flashes during temporary pacemaker operation.
- Install the batteries with proper polarity. The temporary pacemaker does not turn on or provide pacing therapy with incorrect battery polarity.
- If the batteries are removed while the temporary pacemaker is in use, the temporary pacemaker continues to operate for a minimum of 30 seconds under the following conditions: RATE of 80 ppm or less and OUTPUT of 10 mA or less with the backlight off.

*This information is intended only for users in markets where Medtronic products and therapies are approved or available for use as indicated within the respective product manuals. Content on specific Medtronic products and therapies is not intended for users in markets that do not have authorization for use.*

#### **Brief Statement**

See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events.

Consult instructions for use at this website. Manuals can be viewed using a current version of any major Internet browser. For best results, use Adobe Acrobat Reader® with the browser.



[www.medtronic.com/manuals](http://www.medtronic.com/manuals)

For further information, please contact your local Medtronic representative and/or consult the Medtronic website at [medtronic.com](http://medtronic.com).

## Brief Statement: Model 53401 Temporary External Pacemaker

### Intended Use

The Medtronic Model 53401 Temporary External Pacemaker is intended to be used in conjunction with a cardiac pacing lead system for temporary atrial or ventricular pacing in a clinical environment by trained personnel. The temporary pacemaker can be used where short-term demand (synchronous) or asynchronous pacing is indicated for therapeutic, prophylactic or diagnostic purposes. The temporary pacemaker must be used in an environment where the patient is monitored continuously to ensure that it is operating properly and delivering appropriate therapy to the patient.

### Contraindications

There are no known contraindications to the use of temporary pacing as a means to control the heart rate. The patient's age and medical condition, however, may dictate the type of temporary pacemaker and lead system used by the physician. Single chamber atrial pacing is contraindicated in the presence of AV conduction disorders. Asynchronous pacing is contraindicated in the presence of intrinsic cardiac rhythms. Atrial high-rate burst pacing therapy is intended for use in the atrium only. High-rate burst pacing in the ventricle may result in life-threatening arrhythmias. The temporary pacemaker is MR Unsafe.

### Warnings/Precautions

Monitor the patient continuously while the temporary pacemaker is in use to ensure it is operating properly and delivering appropriate therapy to the patient. ECG monitoring should be in use and defibrillating equipment should be placed on standby and be kept immediately available during pacing lead insertion, pulse generator connection and adjustment, measurements of stimulation thresholds or sensed potentials, and application of antitachycardia burst therapy. Use of high rates in the atrium may result in accidental conduction to the ventricle. Defibrillation equipment should be kept immediately available during high-rate pacing.

Operational failure of the temporary pacemaker can occur as the result of battery depletion, mishandling, or random component failure. Complications related to the use of temporary external pacemakers include, but are not limited to, asystole following abrupt cessation of pacing, inhibition, and reversion. Potential complications related to the use of pacing lead systems with the temporary pacemaker include, but are not limited to, myocardial irritability resulting in fibrillation, infarction, pericarditis, rejection, muscle and nerve stimulation, and infection. Complications may result due to inhibition or reversion of the pacemaker in the presence of strong electromagnetic interference.

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.

A lead with extension cable constitutes a direct, low-resistance current path to the myocardium. During connection and testing procedures, only battery-powered instrumentation should be used. Extreme caution must be taken to properly ground all line-powered equipment used in the vicinity of the patient. Electrosurgical units can cause tachyarrhythmias by inducing current on the leads.

Improper connection, displacement or fracture of leads or cables may result in pacemaker system failure. Inspect leads and cables for damage before each use. The pacing lead system may cease to function at any time due to improper connections or lead-related problems such as displacement or fracture.

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

*See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at medtronic.com.*

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

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