TIP
CARD

Model 53401
Single Chamber Temporary Pacemaker

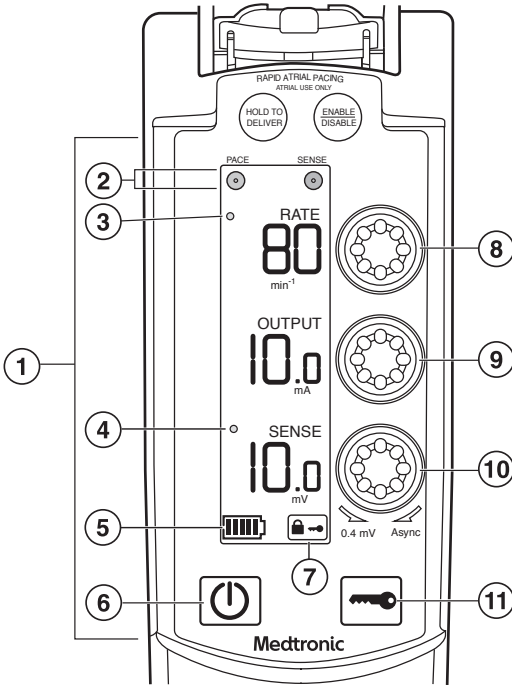**Medtronic**

PRE-USE	What to do …	What NOT to do …
Battery	Replace the battery for each new patient.	Do NOT reuse battery.
Physical Condition	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.
Cables	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.
IN USE		
Placement	Do not place the temporary pacemaker in any area outside of the direct observation by medical staff. If necessary, insert into a Disposable Pouch† (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.
POST-USE		
Clean	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.
If dropped/ Visible exterior damage	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.
If spilled on	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.

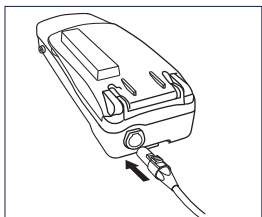†Disposable Pouch available for the Model 53401 Temporary Pacemaker: Model #5409.
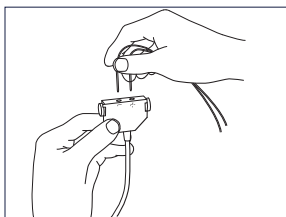
MEDTRONIC MODEL 53401
CONTROLS AND INDICATORS

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
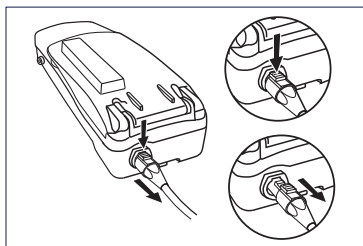
BASIC OPERATION

Connector Setup

1. Verify that the temporary pacemaker is turned off.

2. Plug the patient cable (5433, 5846, 5487) or surgical cable (5832S, 5833S) 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.

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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 elapses after the last parameter adjustment is made.
- When RAP is enabled, the temporary pacemaker will lock after 300 seconds/5 minutes have elapsed.
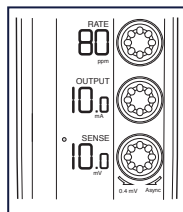- The Lock/Unlock button is pressed.

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.
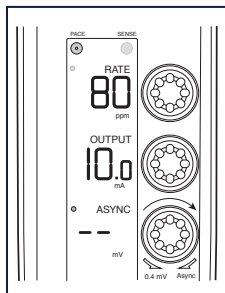
Determining the Pacing Mode

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.

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

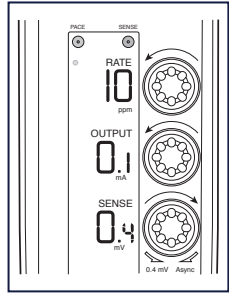1. Turn on the temporary pacemaker without connecting it to the patient lead system.
   Caution: Do not connect the temporary pacemaker to the patient lead system until step 4.
2. Set RATE to at least 10 ppm under the patient's intrinsic rate.
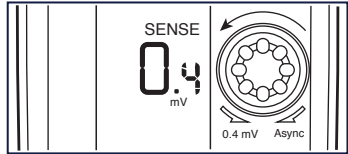3. Adjust the output to prevent the risk of competitive pacing by setting OUTPUT to 0.1 mA.
4. Connect the temporary pacemaker to the patient lead system.
5. Decrease Sensitivity: Slowly turn the dial clockwise (increase mV value) until the SENSE indicator stops flashing. The PACE indicator flashes continuously, 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.

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.
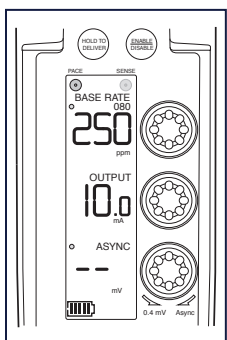

Caution: Pacemaker-dependent patients will have limited or no intrinsic rate/rhythm.

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 5 minutes have passed.

- ## MEDTRONIC MODEL 53401
  ### **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 s.
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.
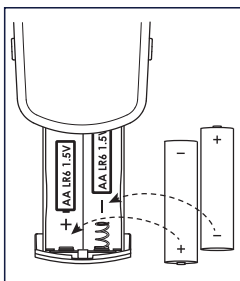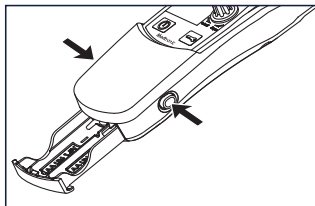
BATTERY REPLACEMENT

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 s under the following conditions: RATE of 80 ppm or less and OUTPUT of 10 mA or less with the backlight off.

Brief Statement

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.

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