

TIP CARD



Model 5392
Temporary External 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 ¹ (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 minimises access to the controls by unauthorised 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 minimise leakage, but fluid incursion may still occur.

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

¹Disposable Pouch available for the Model 5392 Temporary Pacemaker; Model # 5409.

Safety and technical checks should be carried out at least once every 12 months and after any malfunction or accident. Contact your local Medtronic representative to inquire further about the Medtronic Annual Test and Calibration Program.



MEDTRONIC MODEL 5392

BASIC OPERATION — LOWER SCREEN PACING PARAMETERS FOR DDD MODE.

1 Mode Selection

- DDD ←
- DDI
- DOO
- AAI
- AOO
- VVI
- VOO
- OOO

Back

2 A Sensitivity 0.5 mV

V Sensitivity 2.0 mV

A-V Interval 170 mS

Upper Rate 110 ppm

PVARP 300 mS

A. Tracking On

Settings Automatic

Rapid Atrial Pacing

Mode Selection

3 A Sensitivity 0.5 mV

V Sensitivity 2.0 mV

A-V Interval 170 mS

Upper Rate 110 ppm

PVARP 300 mS

A. Tracking On

Settings Automatic

Rapid Atrial Pacing

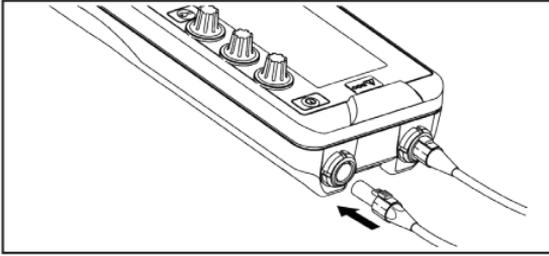
Mode Selection

4 RAP 250 ppm

Hold ← to DELIVER Rapid Atrial Pacing

Back

BASIC OPERATION

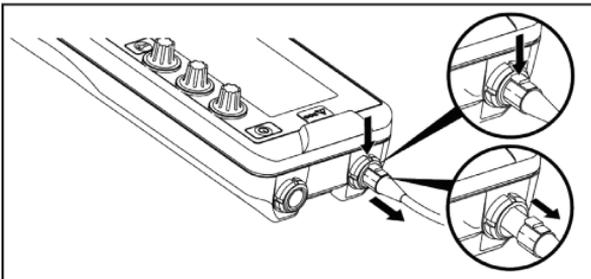


Connector Setup

1. Verify that the temporary pacemaker is turned off.
2. Plug the Model 5433A and Model 5433V patient cables or a pair of 5832S surgical cables into appropriate sockets on the connector block on top of the temporary pacemaker. One socket is marked A (atrium); the other is marked V (ventricle).
3. Verify that each patient cable clicks when it is inserted into the temporary pacemaker connector receptacle.

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

4. Pull gently on the patient cables after insertion to ensure a good connection.
5. Connect the leads to the appropriate cable. Match positive (+) and negative (-) leads to positive (+) and negative (-) sockets or clips for the atrium and ventricle (not shown). The sockets are also color-coded blue for atrium and white for ventricle.



Note: To disconnect the patient cables 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.

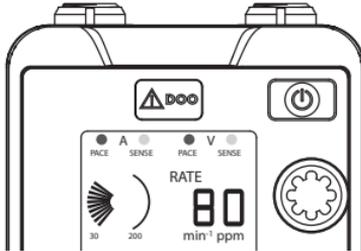
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BASIC OPERATION

To Turn On

- Press and hold the ON/OFF key momentarily to turn on the temporary pacemaker

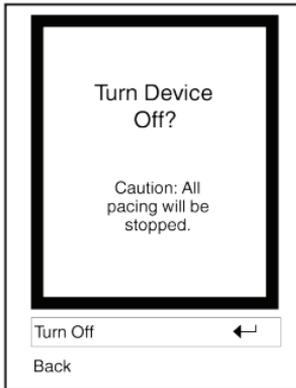
The upper screen and the backlight illuminate, a self-test is initiated, and the temporary pacemaker first paces, and then begins sensing and pacing in both chambers (DDD mode).



Note: Pressing a key while the self-test is in process can cause the device to fail the self-test, and display error code, "0004." The device may interpret the pressed key as being "stuck" and, therefore, malfunctioning. If a key is pressed during the self-test, remove and reinsert the battery to clear the error code.

To Turn Off

1. Unlock the temporary pacemaker, if it is locked (see following section).
2. Press the ON/OFF key once. A message is displayed in the lower screen to confirm temporary pacemaker shutdown (see Figure below).



3. Press the ENTER key once to confirm temporary pacemaker shutdown.



BASIC OPERATION

Lock/Unlock

The LOCK/UNLOCK key locks the temporary pacemaker to prevent inadvertent adjustment of the parameters, or unlocks the temporary pacemaker when it is locked.

When Locked:

- The **Rate, A Output** and **V Output** parameter values lock and cannot be adjusted
- Pacing therapy continues to be delivered at the currently selected values
- The Lock indicator appears in the status bar
- The lower screen does not appear. The Mode Selection options and pacing parameters cannot be adjusted.
- The PAUSE key is locked
- Press LOCK/UNLOCK key to unlock the 5392 before adjusting parameters
- Press LOCK/UNLOCK key to lock the 5392 after adjusting parameters

Notes

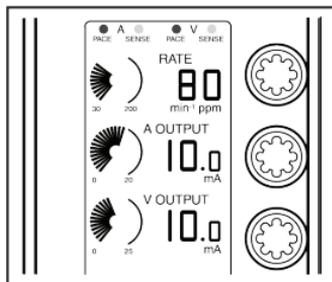
- The DOO/EMERGENCY key does not lock. If pressed while the temporary pacemaker is locked, the temporary pacemaker begins asynchronous pacing.
- The temporary pacemaker locks under one of the following conditions:
 - 60 s after the last parameter adjustment is made
 - When the LOCK/UNLOCK key is pressed

If any parameter dials are adjusted or any keys are pressed while the temporary pacemaker is locked (other than the DOO/EMERGENCY key), the Lock indicator flashes, and the lower screen displays the Locked message for approximately 30 s.

BASIC OPERATION

Rate and Output Adjustments

1. If the Lock indicator appears in the status bar, press LOCK/UNLOCK key.
2. To adjust RATE, A (Atrial) OUTPUT, or V (Ventricular) OUTPUT, turn the dials clockwise to increase their values; turn the dials counterclockwise to decrease their values, or to set the outputs to off.



Rate and output values appear on upper screen.

Viewing Patient's Intrinsic Rhythm

- Reduce the RATE gradually, while watching the ECG, until the patient's intrinsic rhythm takes over
- Press and hold PAUSE key to suspend pacing and sensing up to 10 seconds

Note: To pause again up to 10 seconds, release PAUSE key; then press and hold the PAUSE key again.

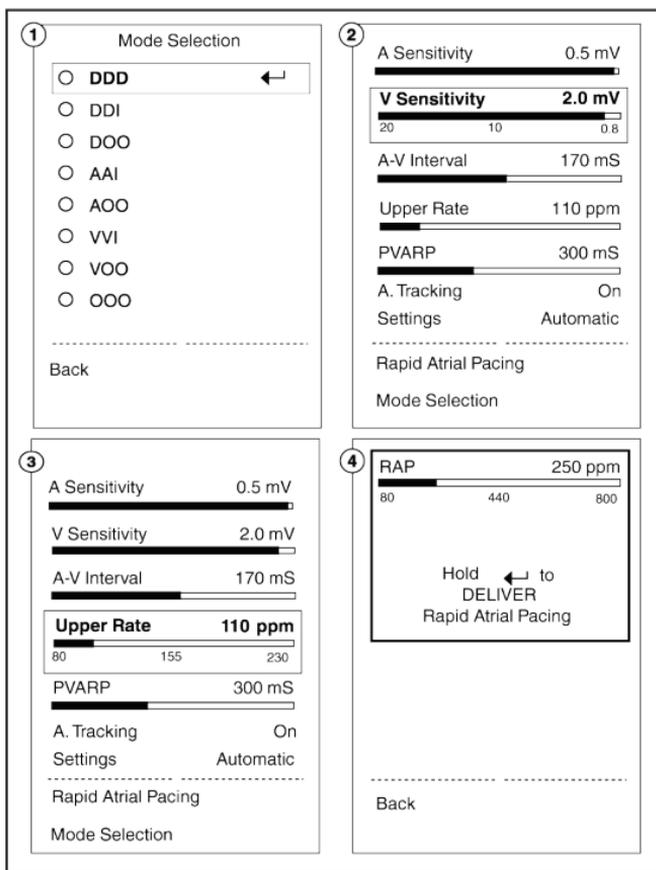
EMERGENCY Pacing

- Press DOO/EMERGENCY key to initiate high-output, dual chamber asynchronous pacing (DOO for emergency)

Note: Press the ENTER key to return to synchronous (demand) pacing, or select the modes with synchronised pacing from the Mode Selection menu and adjust A Sensitivity and/or V Sensitivity.

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LOWER SCREEN PACING PARAMETER ADJUSTMENTS



After a pacing mode has been selected, the Pacing Parameters menu for that pacing mode is displayed and the parameters can be adjusted.

Screen 1: Mode Selection screen

Screen 2: V Sensitivity selected on the DDD pacing parameters screen

Screen 3: Upper Rate selected on the DDD pacing parameters screen

Screen 4: RAP screen

Note: Parameters displayed on menus are based on currently programmed pacing mode and rate. *Parameters that do not apply to the current chambers being paced and sensed are not displayed. Parameters that did not apply in the previous mode are set to nominal values in the new mode.*

LOWER SCREEN PACING PARAMETER ADJUSTMENTS

To Adjust Atrial/Ventricular Sensitivity

1. Press **MENU** key until Menu 1 is displayed.
2. Press **SELECT** key until **A Sensitivity** or **V Sensitivity** is highlighted.
3. Turn **MENU PARAMETER** dial clockwise to increase sensitivity; counterclockwise to decrease sensitivity or set to **ASYNC**.
 - *A Sensitivity range: 0.4 mV - 10 mV and ASYNC*
 - *V Sensitivity range: 0.8 mV - 20 mV and ASYNC*

Notes

- Setting A Sensitivity or V Sensitivity to ASYNC turns sensing off and starts asynchronous pacing
- The highest number (in mV) for Sensitivity is the least sensitive setting; the lowest number (in mV) is the most sensitive setting

To Turn Atrial Tracking Off or On

(Set to DDI or DDD mode)

1. Press **MENU** key until Menu 1 is displayed.
2. Press **SELECT** key until **A Tracking** is highlighted.
3. Turn **MENU PARAMETER** dial counterclockwise to display OFF (DDI mode); clockwise to display ON (DDD mode)

Note: Atrial tracking can be set to OFF only from DDD mode and set to ON only from DDI mode.

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LOWER SCREEN PACING PARAMETER ADJUSTMENTS



Rate-Dependent Parameters

Upper Rate, PVARP, and A-V Interval are *automatically* set whenever rate is adjusted, but can be *manually* adjusted from lower screens.

Note: An asterisk (*) is shown next to the value of each setting that is manually adjusted.

A Sensitivity	0.5 mV
V Sensitivity	2.0 mV
A-V Interval	*170 mS
Upper Rate	*110 ppm
PVARP	*300 mS
A. Tracking	On
Settings	Manual (*)
Rapid Atrial Pacing	
Mode Selection	

To Adjust A-V Interval

1. Navigate to the Pacing Parameters menu.
2. Press the UP or DOWN ARROW key to highlight **A-V Interval**.
3. Turn the MENU PARAMETER dial clockwise to lengthen the A-V Interval, or counterclockwise to shorten the A-V Interval.

Range: 20 ms - 300 ms

To Adjust Upper Rate

1. Navigate to the Pacing Parameters menu.
2. Press the UP or DOWN ARROW key to highlight **Upper Rate**.
3. Turn the MENU PARAMETER dial clockwise to increase the upper rate, or counterclockwise to decrease the upper rate. The Upper Rate parameter is only adjustable in DDD mode.

Range: 80 min⁻¹ - 230 min⁻¹

LOWER SCREEN PACING PARAMETER ADJUSTMENTS

To Adjust PVARP

1. Navigate to the PACING PARAMETERS menu.
2. Press the UP or DOWN ARROW key to select **PVARP**.
3. Turn the MENU PARAMETER dial clockwise to increase the **PVARP**, or counterclockwise to decrease the **PVARP**.
Range: 150 ms - 500 ms

To Reset Rate-Dependent Values to Automatic Settings

1. Navigate to the PACING PARAMETERS menu.
2. Select **Settings**.
3. Turn the MENU PARAMETER dial either clockwise or counterclockwise until **Automatic** replaces **Manual**.
4. Use the MENU PARAMETER dial to alternate between Automatic and Manual parameter settings, as long as Settings remains selected.

*Previous **Manual** settings are lost when **Automatic** is selected for Upper Rate, PVARP and A-V Interval.*

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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 Threshold

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 min^{-1} (ppm) under the patient's intrinsic rate. This adjustment ensures non-pacing.
3. Adjust the atrial or ventricular output to prevent the risk of competitive pacing.

- **Atrial:** Set **A Output** to 0.1 mA
- **Ventricular:** Set **V Output** to 0.1 mA

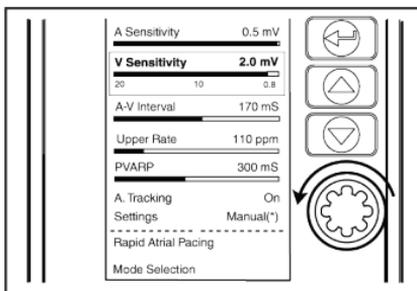
4. Connect the temporary pacemaker to the patient lead system.
5. Navigate to the **MODE SELECTION** menu and select the appropriate pacing mode for the patient leads that are connected to the patient.
 - Select **DDD** mode if both channels are connected
 - Select **AAI** mode if only the atrial channel is connected
 - Select **VVI** mode if only the ventricular channel is connected
6. Navigate to the Sensitivity settings.
 - a. Complete steps 7 thru 9 for the **A Sensitivity** setting, if the atrial channel is connected.
 - b. Complete steps 7 thru 9 for the **V Sensitivity** setting, if the ventricular channel is connected.

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SENSING THRESHOLDS

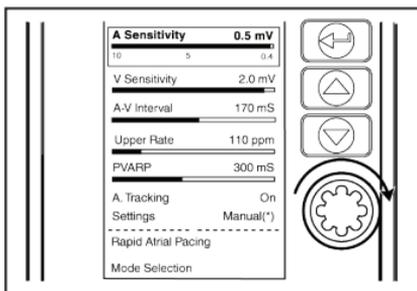
7. Decrease **Sensitivity**: Slowly turn the MENU PARAMETER dial counterclockwise (increase mV value) until the sense indicator stops flashing.

The pace indicator flashes continuously, but capture is not likely because the output value is set to minimum.



8. Increase **Sensitivity**: Slowly turn the MENU PARAMETER dial clockwise (decrease mV value) until the sense indicator starts flashing.

- The pace indicator stops flashing
- This value is the sensing threshold



9. Set **Sensitivity** to half (or less) the threshold value. This setting provides at least a 2:1 safety margin.
10. Restore **Rate**, **A Output**, or **V 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 Threshold

1. Verify that the patient is connected to the temporary pacemaker and is being monitored on the ECG.
2. Set **Rate** at least 10 min^{-1} (ppm) above the patient's intrinsic rate.

This adjustment ensures pacing. The pace indicator flashes.

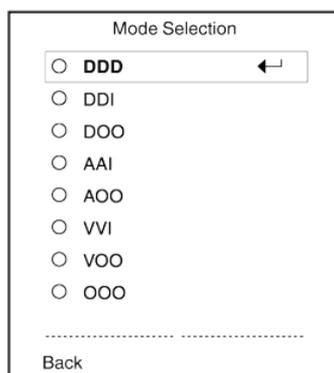
3. Decrease **Output**: Slowly turn the OUTPUT dial counterclockwise until ECG shows loss of capture.
 - Pace and sense indicators flash intermittently
4. Increase **Output**: Slowly turn the OUTPUT dial clockwise until ECG shows consistent capture.
 - The pace indicator flashes continuously; the sense 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 a 2:1 safety margin.
6. Restore **Rate** to the previous value.

PACING SETUP

Notes

- The Pacing Setup Table on the other side of this card provides a reference to output and sensitivity settings for each available pacing mode
 1. Verify Output.
 2. Verify Sensitivity.
 3. Verify Atrial Tracking.
 4. Verify Pacing Setup Indicators.
- The RAP (Rapid Atrial Pacing) card describes how to deliver rapid atrial pacing
- The Pacing Parameter Adjustments card describes how to manually adjust pacing parameters

To Dial-A-Mode (DDD, DDI, DOO, AAI, AOO, VVI or VOO pacing modes, or OOO for no pacing therapy)



1. Navigate to the MODE SELECTION menu.
2. Press the UP or DOWN ARROW keys to highlight a pacing mode.
3. Press the ENTER key to select the pacing mode.

Pacing in the selected mode begins as follows:

Rate, Output and Sensitivity values are set to the nominal values when a pacing mode is selected, unless they have been manually adjusted before the pacing mode was selected. If they have been manually adjusted before the pacing mode was selected, the new pacing mode retains these values.

Note: Manually-set pacing parameter values are not retained when the temporary pacemaker is turned off, and then turned back on.

Temporary External Pacemaker 5392 Setup Table

	AOO	VOO	AAI	VVI	DOO	DDD	DDI
Setup Indicators	<input type="checkbox"/> A <input type="checkbox"/> J <input type="checkbox"/>	<input type="checkbox"/> V <input type="checkbox"/> J <input type="checkbox"/>	<input type="checkbox"/> PACE SENSE <input type="checkbox"/> A <input type="checkbox"/> J <input type="checkbox"/>	<input type="checkbox"/> PACE SENSE <input type="checkbox"/> V <input type="checkbox"/> J <input type="checkbox"/> V <input type="checkbox"/>	<input type="checkbox"/> PACE SENSE <input type="checkbox"/> A+V <input type="checkbox"/> J <input type="checkbox"/>	<input type="checkbox"/> PACE SENSE <input type="checkbox"/> A+V <input type="checkbox"/> J <input type="checkbox"/> A+V <input type="checkbox"/>	<input type="checkbox"/> PACE SENSE <input type="checkbox"/> A+V <input type="checkbox"/> J <input type="checkbox"/> A+V <input type="checkbox"/>
Instructions							
1. Set Output							
A Output	On	Off	On	Off	On	On	On
V Output	Off	On	Off	On	On	On	On
2. Set Sensitivity							
A Sensitivity	ASYNC	NA	On	NA	ASYNC	On	On
V Sensitivity	NA	ASYNC	NA	On	ASYNC	On	On
3. Set							
A Tracking	NA	NA	NA	NA	NA	On	Off

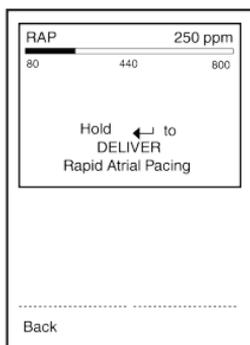


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RAP (RAPID ATRIAL PACING)

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

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

To Deliver RAP:

1. Navigate to the PACING PARAMETERS menu.
2. Press the UP or DOWN ARROW key to highlight **Rapid Atrial Pacing (RAP)**.
3. Verify that the leads are in contact with the atrium and are connected to the atrial channel of the temporary pacemaker through a patient or surgical cable.
4. Press the ENTER key to open the RAP screen. The RAP screen displays the RAP rate [initially the rate of 250 min^{-1} (ppm)]. Pacing continues at currently displayed settings.
5. Adjust RAP rate as needed. Turn the MENU PARAMETER dial clockwise to increase rate, or counterclockwise to decrease rate.

Note: The range for RAP is 80 min^{-1} (ppm) to 800 min^{-1} (ppm).

6. Press and hold the ENTER key to deliver RAP burst. AOO pacing begins at displayed RAP rate and current **A Output**. The **A Pace** LED flashes during delivery of RAP pulses.

Note: RAP delivery stops when either the ENTER key is released, or after 1 min has passed.

To exit the RAP screen, use the UP or DOWN ARROW key to select **BACK**, and then press the ENTER key.



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RAP (RAPID ATRIAL PACING)

Adjusting Rate or Atrial Output during RAP Delivery

The RAP rate and **A Output** can be adjusted during RAP delivery by turning the MENU PARAMETER dial. To adjust **A Output**, do the following:

1. Continue to press and hold the ENTER key.
2. Turn the MENU PARAMETER dial clockwise or counterclockwise to adjust RAP rate.
3. Turn the A OUTPUT dial clockwise or counterclockwise to adjust atrial output.

Resuming Pacing at Previous Settings

- Release ENTER key to resume pacing at the previous settings. The temporary pacemaker stops delivering RAP and resumes operation at the non-RAP settings, within 3 s.

If the **A 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 ENTER key is released, press the ON/OFF key or the DOO/EMERGENCY key to stop RAP. If RAP continues to be delivered, remove the batteries from the temporary pacemaker. Return the temporary pacemaker for service.

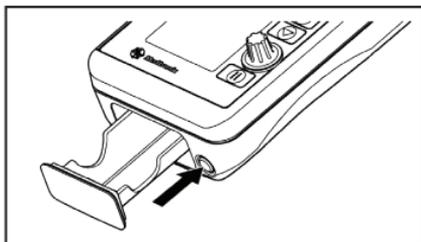
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BATTERY REPLACEMENT

Battery Installation and Replacement

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

1. Press the battery drawer latch release button 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 appears during temporary pacemaker operation
 - Replace the batteries at least once every week when the temporary pacemaker is in continuous use
- Install the batteries with proper polarity. The temporary pacemaker does not turn on or provide pacing therapy with incorrect battery polarity
- 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. Pacing is maintained at the current settings for 30 s, minimum, if the settings are at nominal values.



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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