



Medtronic

Model 5391

Single Chamber External Pacemaker





PRE-USE	What to do ...	What NOT to do ...
Battery	Replace the battery for each new patient. Use Alkaline or Lithium.	Do NOT reuse battery.
Physical Condition*	Check case for cracks/damage.* Check battery drawer for closure.* Check display for cracks/damage.*	Do NOT ignore 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	Place in an area that minimizes tampering by patient or unauthorized personnel. Use plastic cover to protect against unauthorized access to the controls.	Do NOT place the device in any area where the patient may interact with it.
Replacement	The 5391 does not have pacing continuation during battery replacement. Alkaline batteries last approx. 38 days and Lithium batteries last approx. 53 days.	Do NOT replace the 9-volt battery while device is connected to patient. Device will immediately cease function when battery is removed. Use another temporary pacemaker to support the patient.
POST-USE		
Clean	External surfaces of unit can be cleaned using a sponge or cloth with 70% alcohol or with alhydex or cydex. 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.
If Dropped or 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.

* No RMA or RGA # is required. Questions regarding a device to be returned for service or repair please call 1 (800) 638-1991 or contact your local Medtronic representative.

Safety and technical checks should be carried out at least once every 12 months and after any malfunction or accident. Visit www.MedtronicConnect.com or call 1 (800) 638-1991 to inquire further.

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ON/OFF

Set Sensitivity

- AAI or AOO: Leads/heart wires to atrium
- VVI or VOO: Leads/heart wires to ventricle
- VOO or AOO: Sensitivity dial to Async
- VVI or AAI: Sensitivity dial to detect intrinsic cardiac activity

Set Rate and Output

- Preset rate and output values

Connect to Device

- Connect cables and lead heart wires

Connector setup

NOTE:

- The Model 5433A, 5433V, 5832, 5832S and 5487 cables have an improved connector with protected electrical contacts. A release button on the cable disconnects it from the 53912 extension cable.
- Positive (+) and negative (-) leads connect to positive (+) and negative (-) sockets or clips
- The Model 5433A, 5433V, and 5487 patient cables plug into the 53912 extension cable; then into the sockets on top of unit
- The Model 5832 or 5832S surgical cable plugs into the 53912 extension cable; then into the sockets on top of unit

Turn On

1. Turn "Mode" control knob.
All indicator lights flash briefly.
2. To adjust parameter settings, turn dials.

Turn Off

- Turn "Mode" control knob to "OFF".



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To Replace Battery

NOTE: Do NOT replace the 9-volt battery while connected to patient. The 5391 does not have pacing continuation when battery is removed.

1. On the back of the 5391, open battery compartment by sliding cover to the side.
2. Remove old battery and discard.
3. Connect fresh battery, insuring proper polarity of battery contacts.
4. Slide battery cover inward to close battery compartment.
5. Turn "Mode" control knob to power up.

NOTE: When the 9 volt battery is removed, there is NO pacing continuation. The 5391 will immediately shut down and no longer pace.

Medtronic does not recommend battery replacement with the device connected to the patient.

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Rapid Atrial Pacing (RAP)



CAUTION: RAP is for atrial pacing only.

RAP range: 60 to 700 ppm

1. Verify device is connected to the atrium.
2. Turn "Mode" control knob to either x2 or x4. The 5391 will continue to operate at the basic rate setting until the high-rate button is depressed.
 - x2 = basic rate times 2
 - x4 = basic rate times 4
3. To increase or decrease the rate, turn the "Rate" control knob.
4. Press and hold the "High Rate" button.
Mode changes to AOO, and RAP is delivered.
5. To make adjustments during RAP delivery, continue to press and hold the "High Rate" button and:
 - Adjust RAP rate by turning the "Rate" control knob
 - Adjust output by turning "Output" dial
6. To resume pacing at current mode and dial settings, release "High Rate" button.
7. Basic pacing rate will resume once the "High Rate" button is released.

CAUTION: Rapid atrial pacing may result in tachycardia, acceleration of an existing tachycardia, or fibrillation. Apply high rates under careful patient monitoring and control. Use ECG monitoring and make sure that defibrillation equipment is immediately available.

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Sensing Threshold

NOTE: Use caution in pacing-dependent patients. The sensing threshold is the least sensitive setting at which the intrinsic heartbeat can be detected. (The highest number on "Sensitivity" dial is least sensitive; the lowest number on "Sensitivity" dial is most sensitive.)

To find Sensing Threshold

1. Turn "Rate" dial to set rate 10 ppm below patient's intrinsic rate. This ensures non-pacing. Sense indicator flashes regularly.
2. Turn "Output" dial to 0.3 volts. This prevents risk of competitive pacing.
3. Slowly turn "Sensitivity" dial counterclockwise (to decrease sensitivity) until ECG shows continuous pacing (asynchronous pulses).

Sense indicator stops flashing to indicate loss of sensing. Pace indicator starts flashing, but capture is not likely because output value is at minimum.

4. Slowly turn "Sensitivity" dial clockwise (to increase sensitivity) until ECG shows that sensing has been restored.

Sense indicator starts flashing and the pace indicator stops flashing.

This value is the sensing threshold.

5. Turn "Sensitivity" dial to the value that is half the sensing threshold value. (If threshold is 5.0 mV, set "Sensitivity" to 2.5 mV).

This provides at least a 2:1 safety margin.

6. Finally, reset to original "Rate" and "Output".



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Stimulation/Pacing Threshold

The stimulation/pacing threshold is the minimum output pulse needed to consistently capture the heart. To find this threshold, monitor the ECG and gradually reduce the output until capture is lost. Then gradually increase output until consistent capture is regained.

To find Stimulation/Pacing Threshold

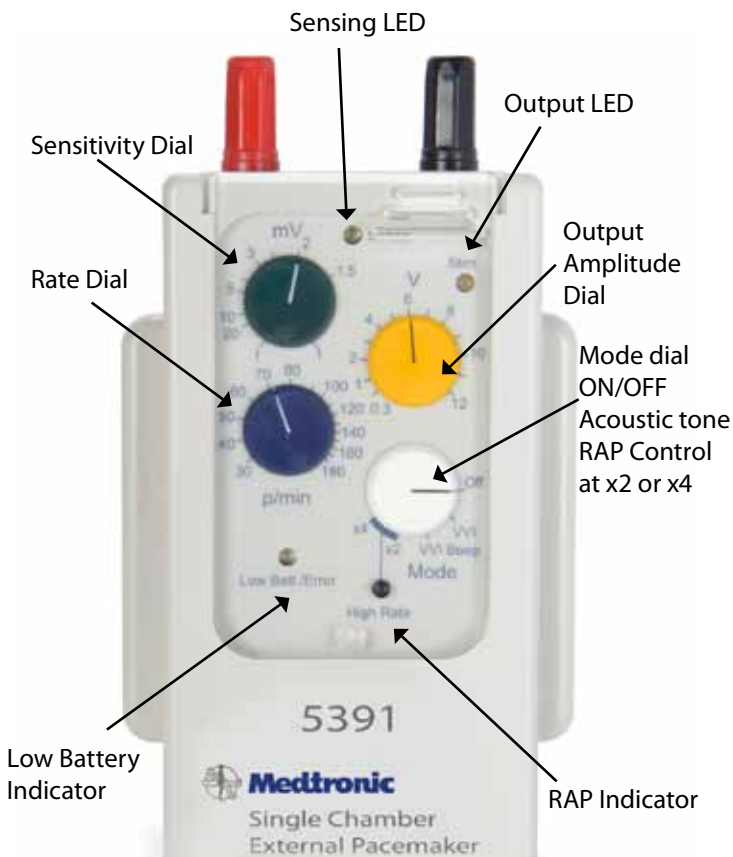
1. Turn "Rate" dial to set rate 10 ppm above patient's intrinsic rate. This ensures pacing. Pace indicator flashes at set rate.
2. Slowly turn "Output" dial counterclockwise (to decrease value) until ECG shows loss of capture. Pace and sense indicators flash intermittently.
3. Slowly turn "Output" dial clockwise (to increase value) until ECG shows capture.

Pace indicator flashes and sense indicator stops flashing.

This value is the stimulation/pacing threshold.
4. Turn "Output" dial to a value that is two to three times greater than the stimulation/pacing threshold value. (If threshold is 2.5, set "Output" to 5.0 to 7.5). This provides at least a 2:1 safety margin.
5. Finally, reset to original "Rate".

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Dials and Indicators





Brief Statement: Model 5391 Single Chamber Temporary Pacemaker

Intended Use: The Medtronic Model 5391 single chamber temporary pacemaker is intended to be used in conjunction with a cardiac pacing lead system for temporary single chamber pacing in a clinical environment by trained personnel. The external pacemaker 5391 is designed for temporary stimulation of the heart in case of rhythm disturbances and conduction defects. According to present clinical experience, the instrument is especially suited for stimulation of the heart in the following cases: • treatment of patients before an operation, whereby an implantable pacemaker is being inserted. • treatment of tachyarrhythmia. • treatment of special cases of acute myocardial infarction. • treatment of patients after heart surgery. 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 contraindications with regards to the use of the 5391 for temporary cardiac stimulation for therapy and prevention of arrhythmia. The state of health of the patient, however, can restrict the choice of operational mode and stimulation parameters. For example, a mode of operation with atrial sensing is not suitable or appropriate when atrial fibrillation occurs. This is due to the excessive and chaotic frequency of detected fibrillation waves. Asynchronous pacing is contraindicated in the presence of intrinsic cardiac rhythms. Overdrive-stimulation therapy must only be used in the atrium. Overdrive-stimulation in the ventricle could cause life-threatening ventricular fibrillation. Medtronic does not recommend high-rate pacing for the treatment of ventricular tachycardia. **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. • **Warning:** The 5391 does not have pacing continuation when the 9-volt battery is removed. • **Warning:** The 5391 must not be connected to the patient during battery replacement. • **External Interference:** The 5391 may be inhibited by strong external interference resembling the signal the pacer is designed to sense. Such interference signals may be produced by a variety of sources including electrocautery, diathermy, and other devices. The 5391 will not be damaged by such interferences and will resume its function as soon as the interference source is removed. • Defibrillation equipment should be at hand while the 5391 and its leads are being introduced into and connected to the patient. • **Warning:** 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. 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 such as the Model 5391 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 Model 5391 include, but are not limited to, myocardial irritability resulting in fibrillation, infarction, pericarditis, rejection, muscle and nerve stimulation, and infection. Complication related 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 or detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential complications/ adverse events. For further information, please call Medtronic at 1 (800) 328-2518 and/or consult Medtronic's website at www.medtronic.com.*

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

www.medtronic.com

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