



Medtronic

5348

Single Chamber Temporary PaceMaker (AAI/VVI)

Technical Manual

! USA

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



MEDTRONIC MODEL 5348

Technical Manual

Single Chamber Temporary Pacemaker

Explanation of symbols



Consult instructions for use



Type CF applied part



Conformité Européenne

This symbol means that the device fully complies with European Directive 93/42/EEC.



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



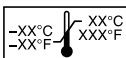
Temporary pacemaker



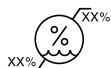
Product documentation



Accessories



Storage temperature limitation



Humidity limitation



Battery



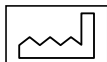
Reorder number



Authorized representative in the European Community



Manufacturer



Date of manufacture



Serial number

Contents

1	General description	11
	Package Contents	12
	Safety Features	12
	Registration Card	12
	Medtronic Warranty	13
2	Intended use	15
3	Contraindications	17
	Atrial Pacing	17
	Asynchronous Pacing	17
	High-Rate Burst Therapy	17
4	Warnings	19
	Equipment Modification	19
	Line-powered Equipment	19
	Electrosurgery	19
	Electromagnetic Interference (EMI)	19
	Defibrillation/Cardioversion	20
	High-Rate Burst Therapy	20
	Connecting the Lead System	20
	Handling Indwelling Leads	21
	Turning the Device On	21
5	Precautions	23
	Random Failures	23
	Pacing Leads and Cables	23
	Pacing System Adjustments	23
	Unipolar Lead Systems	24
	Sensitivity Settings	24
	Electrostatic Discharge (ESD)	24
	Termination of Pacing	24
	Battery	24
	Unauthorized Changes of Pacemaker Settings	25
6	Environmental precautions	27
7	Potential adverse effects	29
	Pacemakers	29

High Rate Pacing	29
Lead Systems	29
8 Controls, indicators, and other features	31
Base Level Pacing Controls	31
RATE	31
OUTPUT	31
SENSITIVITY	31
ON and OFF	33
Rapid Atrial Pacing (RAP) Controls	33
ENABLE/DISABLE	33
HOLD TO DELIVER	34
OUTPUT	34
Indicators	34
PACE	35
SENSE	35
LOW BATT.	35
Physical Features of the Model 5348	35
Control Covers	35
Battery	35
Connector Block	36
Attachment Ring and Bails	37
Functional Features of the Model 5348	37
Self-Testing	37
RAP Standby	38
Rate-Runaway Protection	38
Pulse Width	38
Synchronous (Demand) Modes (AAI/VVI)	38
Asynchronous Modes (AOO/VOO)	39
Blanking Periods	39
Refractory Periods	39
Reversion Response	39
Cables	40
Medtronic Models 5433A and 5433V Patient Cables	40
Medtronic Surgical Cable Models 5832 and 5832S	41
The Model 5409 Disposable Pouch	41
Description	41
Procedure for use	42
9 Preparation for use	43
Battery Installation	43

Connecting the Model 5433A or 5433V Patient Cable to the Model 5348 44

Connecting the Pacing Lead System to the Model 5433A or 5433V Patient Cable 45

Connecting the Pacing Lead System Directly to the Model 5348 Pacemaker 46

10 Instructions for use 49

Turning the Model 5348 On and Off 49

Power-on Self-test 49

Procedures for Basic Pacing 50

Determining the Pacing Mode 50

Adjusting the Pacing Parameters 51

Determining Sensing Potentials 51

Determining Stimulation Thresholds 52

Procedure for Rapid Atrial Pacing (RAP) 53

Verify Connections 53

Enable the RAP Standby State 53

Adjust the RAP Rate 53

Delivering a RAP Burst 53

Adjusting Parameters During RAP Delivery 54

Returning to Basic Pacing Operation (Disabling RAP Standby) 54

11 Service information 55

Cleaning and Disinfection 55

Model 5348 Temporary Pacemaker 55

Model 5433A and 5433V Patient Cables 55

Safety and Technical Checks 56

Visual Inspection: 56

Functional Inspection: 56

Practical Measurements: 56

Service 57

12 Specifications 59

General description 1

The Medtronic® Model 5348 is a temporary, battery-powered, single chamber pacemaker designed primarily for temporary antibradycardia pacing therapy in asynchronous or demand (synchronous) modes. High-rate burst pacing therapy up to 800 min^{-1} (reciprocal minutes) (ppm [pulses per minute]), for tachyarrhythmias, is available in the asynchronous mode¹.

The device is typically connected to temporary transvenous, epicardial or myocardial pacing leads, in a bipolar configuration, using a patient cable (Medtronic Model 5433A or 5433V) or a surgical cable (Medtronic Model 5832 or 5832S).

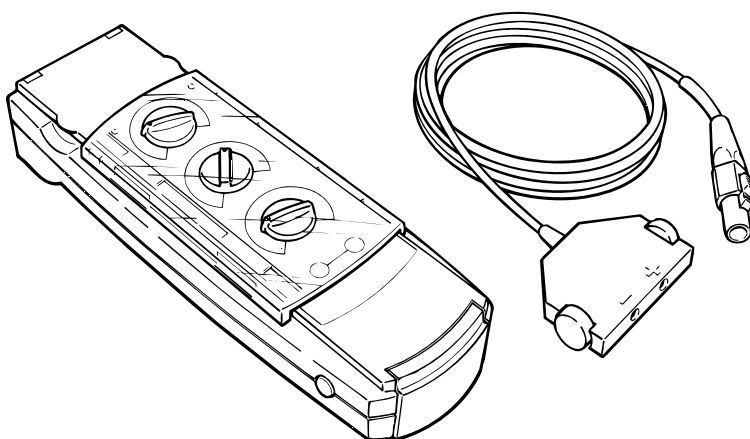


Figure 1-1. The Medtronic Model 5348 Single Chamber Temporary Pacemaker and the Model 5433A or 5433V Patient Cable.

The device operates using a 9-volt alkaline or lithium battery, which is installed in a battery drawer at the bottom end of the pacemaker.

Note: The Model 5348 is a constant current device; it emits a pulse with a current output that is maintained at a constant value. This value is set by the output control and does not vary with respect to the myocardium/lead impedance (as long as the myocardium/lead impedance stays between $200 \, \Omega$ and $1000 \, \Omega$).

¹ For atrial use only.

Package Contents

The Model 5348 is supplied with a 9-volt alkaline battery, technical literature, one Model 5409 disposable pouch, one Model 5433A atrial patient cable, one Model 5433V ventricular patient cable, a package of heartwire seals, and a carrying case. Check the package prior to use. Damaged packages should be returned to Medtronic (see back cover for the address).

Safety Features

The Medtronic Model 5348 is designed to be reliable, simple to operate, and comfortable to hold. Safety features of the Model 5348 include:

- Self-tests;
- Low Battery indicator;
- Continuous operation during battery replacement (at 80 min⁻¹ [ppm], 10 mA) for a minimum of 15 seconds;
- Reversible battery polarity;
- Protective covers over the controls and a rubber seal covering the heartwire receptacles;
- Safe “power-off” operation (Two buttons must be pressed simultaneously to turn the device off.);
- Cautionary label at the Rapid Atrial Pacing (RAP) controls;
- Detents (mechanical restrictions of dial movement) on the RATE and SENSITIVITY dials to highlight extremes or potentially hazardous settings;
- Safety cables (recessed pins);
- Runaway rate protection;
- Protection from defibrillation shock up to 360 watt-seconds;
- Electrostatic protection; and
- Minimized susceptibility to electromagnetic and magnetic interference.

Registration Card

Please complete the registration card and return it to Medtronic. Consult the back cover of this manual for the address. U.S. customers: use the address labels provided.

Medtronic Warranty

For complete device warranty and accessories disclaimer of warranty, see the accompanying warranty documents.

Intended use 2

The Medtronic Model 5348 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 Model 5348 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:

- 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 Model 5348 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.

Contraindications

3

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.

Atrial Pacing

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

Asynchronous Pacing

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

High-Rate Burst Therapy

High-rate burst therapy is intended for use in the atrium only. Use in the ventricle could result in life-threatening arrhythmias.

Equipment Modification

Do not modify this equipment. Modifications could impact device effectiveness and adversely affect patient safety.

Line-powered Equipment

An implanted lead or lead with extension cable constitutes a direct, low-resistance current pathway to the myocardium. Due to the danger of fibrillation 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.

Electrosurgery

Electrosurgery can induce ventricular fibrillation, and thus should never be used within 15 cm (6 inches) of an implanted lead system.

Electromagnetic Interference (EMI)

All pacemakers operating in the demand mode respond to intracardiac potentials of a magnitude of a few millivolts. They are inherently sensitive to some external fields. In the presence of excessive levels of interference the Model 5348 may inhibit completely or revert to asynchronous operation, pacing at the rate set by the RATE dial.

It is recommended that the device be set to an asynchronous mode when operated in the presence of strong electromagnetic interference (EMI).

Some sources of excessively strong EMI which may temporarily affect the operation of the Model 5348 are:

- Electrosurgical equipment;
- Diathermy equipment;

- Some medical telemetry equipment (when operated within one meter [several feet] of the pacemaker);
- Communication transmitters such as cellular phones and “walkie talkies”;
- Communication transmitters in emergency transport vehicles (in the presence of an active pacemaker); and
- Magnetic Resonance Imaging (MRI) equipment.

Defibrillation/Cardioversion

Defibrillation discharges of 360 watt-seconds have not affected the Model 5348 in laboratory tests. However, for maximum safety it is recommended that the paddles not be placed near the Model 5348 or the lead system.

Whenever possible, for the safety of the patient, disconnect the pacemaker from the lead system before defibrillating or cardioverting. A relatively low resistance pathway exists between the positive (+) and negative (-) electrodes of the implanted lead system. During defibrillation a large current could flow across this pathway, causing myocardial damage.

High-Rate Burst Therapy

Use of high rates in the atrium could result in high-rate conduction to the ventricle. Defibrillation equipment should be immediately available during high-rate or burst pacing.

Connecting the Lead System

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

Handling Indwelling Leads

When handling indwelling leads, the terminal pins or exposed metal are not to be touched nor be allowed to contact electrically conductive or wet surfaces.

Turning the Device On

All patient, lead, cable and device connections should be made before the pacemaker is powered on.

Precautions **5**

Random Failures

The physician should be aware that the Model 5348 Temporary Pacemaker can fail due to a number of reasons, such as random component failure, battery depletion, and mishandling.

Possible malfunctions of the Model 5348 can include:

- No output;
- No sensing;
- False indicator light signals;
- Increased or decreased rate, output pulse width, or output amplitude;
- Reversion to asynchronous pacing; and
- Loss of control of rate, output, sensitivity or power.

If loss of control of rate, output, sensitivity or power occurs, and it would be appropriate to temporarily stop pacing the patient, attempt to correct the condition by turning the device off and then on. If this does not correct the condition, remove the battery for 30 to 60 seconds, reinsert the battery, and turn the device back on.

Pacing Leads and Cables

Improper connection, displacement or fracture of leads or cables may also result in pacemaker system failure.

Pacing System Adjustments

During stimulation threshold measurements, sensing threshold measurements, and other adjustments, stimuli may be inadvertently delivered into a vulnerable period of the cardiac cycle. Monitor the patient's ECG and keep defibrillation equipment on standby, immediately available for emergency use during pacing lead attachment, pacemaker connection and adjustment, measurements of stimulation thresholds or sensed potentials, and application of burst pacing therapy.

Unipolar Lead Systems

Bipolar lead systems are recommended because they are less susceptible to electromagnetic interference. If a unipolar lead system is used, the pacing electrode should be connected to the negative (-) pacemaker terminal; the indifferent (subcutaneous) lead should be connected to the positive (+) terminal. It is important to observe and match voltage polarity markings of all components when connecting the lead system.

Sensitivity Settings

Since the sensitivity setting determines the smallest signal that can be sensed by the pacemaker, set the sensitivity dial to at least one-half the mV value of the patient's sensitivity threshold (see "Determining Sensing Potentials"). This will provide an adequate safety margin to ensure proper sensing. Be aware that setting the sensitivity value extremely low (the most sensitive) could result in inappropriate sensing of far field signals (e.g., sensing of R or T waves on the atrial lead or P waves on the ventricular lead), leading to inappropriate inhibition of pacing pulses.

Electrostatic Discharge (ESD)

The pacing lead(s) provides a low-impedance pathway to the heart. Therefore, it is recommended that the attending health professional discharge any personal static electricity immediately prior to touching the patient, the cable, leads or pacemaker.

Termination of Pacing

Abrupt termination of pacing stimuli may result in periods of asystole before an intrinsic rhythm is established. Prior to terminating pacing, a gradual reduction in pacing rate, using the demand mode, is recommended.

Battery

Replace the battery for each new patient, and when the low battery indicator appears during device operation.

Check the battery status at least twice daily. Replace alkaline batteries no less than every seven days during continuous use of the temporary pacemaker.

Use of batteries with different physical dimensions from that of the recommended batteries may result in erratic, or no pacing output.

Inspect the contacts on the battery for visible signs of contamination prior to use. Use of batteries with contamination on the contacts may result in erratic, or no output.

Failure to ensure that the battery drawer is fully latched may result in a loss of power. Continued device operation IS NOT an indication that the battery drawer is properly latched.

Unauthorized Changes of Pacemaker Settings

Do not place the Model 5348 in any area where patients may interact with it. The temporary pacemaker should be placed in an area that minimizes tampering with the device by unauthorized personnel (patients, visitors, etc.).

Environmental precautions 6

The Model 5348 has been carefully designed and tested to ensure reliability during normal use. However, electronic devices are susceptible to many environmental stresses. Precautions should be taken to avoid damage to the unit, including (but not limited to) those listed in this chapter.

- Do not drop the unit or mishandle it in a way that might physically damage the device. Even if the device appears to work immediately after being dropped or damaged, operational damage may have occurred.
- Avoid spilling fluid on the unit. The Model 5348 was carefully designed to minimize leakage, but fluid incursion still may occur. Medtronic recommends the use of a protective device such as the Model 5409 plastic pouch. However, a plastic pouch may not completely prevent fluid incursion.
- Avoid contaminating the safety cable receptacle and heartwire receptacles with blood or other body fluids.
- Always use safe electrostatic discharge (ESD) procedures; this device could be adversely affected by ESD.
- Do not open the device. The seam joining the unit is designed to minimize fluid incursion and may not be effective if improperly opened and resealed. Furthermore, breaking the label on the unit may compromise the ESD barrier. Opening this unit will void the warranty (see "Medtronic Warranty" in Chapter 1 for more information).
- Do not sterilize the Model 5348 by gamma irradiation and do not steam-sterilize (autoclave) the device. See "Cleaning and Disinfection" in Chapter 11 for more information.
- Rapid temperature changes may affect proper operation. Always allow the temperature to stabilize in the environment in which the device will be used before attachment and operation of the device (see "Specifications" for recommended storage and operation temperatures).
- Prolonged storage or operation of the device in high humidity may affect proper operation. Allow the device to completely dry after exposure to humidity.

Other environmental factors may impact proper performance of the unit in the hospital setting. Use of good health management practices will help to prevent environmental damage to the unit.

Pacemakers

Potential adverse effects related to the use of temporary external pacemakers such as the Model 5348 include, but are not limited to:

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

High Rate Pacing

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

Lead Systems

Potential adverse effects related to the use of pacing lead systems used in conjunction with the Model 5348 Pacemaker include, but are not limited to:

- Inappropriate lead connections;
- Inadvertent disconnection of the lead system;
- Lead fracture or displacement causing intermittent or complete loss of capture and/or sensing;
- Myocardial irritability resulting in fibrillation;
- Perforation and tamponade;
- Infarction; and
- Pericarditis.

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

- Body rejection phenomena (local tissue reaction);
- Muscle and nerve stimulation; and
- Infection.

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.

Controls, indicators, and other features

8

This chapter describes the functions of the dials, keys, and indicator lights of the pacemaker. An illustration of the device is included, with all controls, indicators, and physical features labeled. Descriptions of additional functional features and accessories are included at the end of the chapter.

Base Level Pacing Controls

The dials and keys used to control the base level pacing parameters of the device are listed below, along with a brief description of the function of each control.

RATE

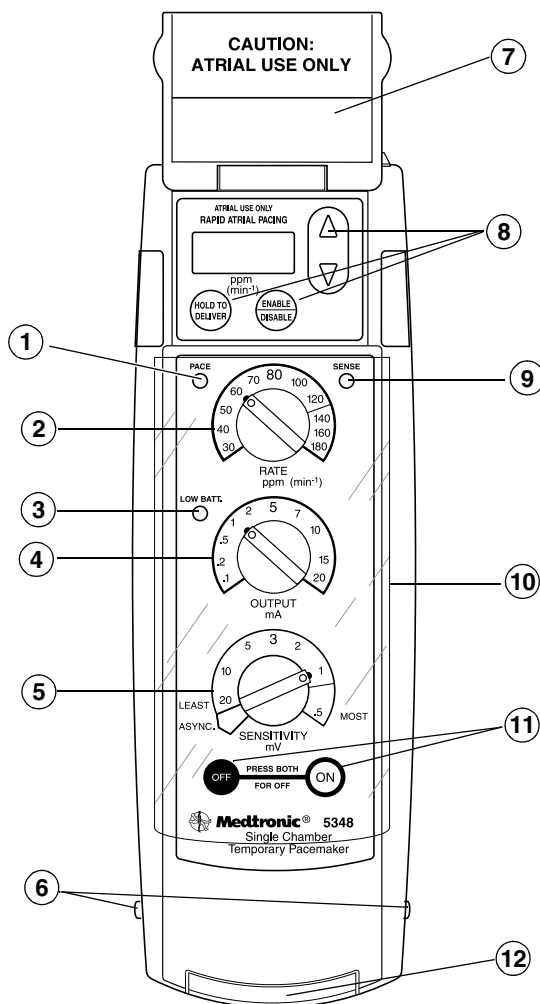
This dial is used to set the rate, in reciprocal minutes (min^{-1}) (pulse per minute [ppm]), at which pacing pulses are delivered. It allows continuous adjustment of the rate from 30 to 180 min^{-1} (ppm). The higher rate range is color-coded and separated from the lower rates by a detent (mechanical restriction of dial movement).

OUTPUT

This dial is used to set the amplitude, in milliamperes (mA), of the pacing pulse. It allows continuous adjustment of the stimulus current amplitude from 0.1 to 20 mA.

SENSITIVITY

This dial is used to enable and adjust the sensitivity, in millivolts (mV), of the sensing circuitry. When enabled, the sensitivity can be adjusted from 0.5 to 20 mV.



- | | |
|---------------------------------|---|
| 1 PACE indicator | 7 Flip-up cover (conceals RAP controls) |
| 2 RATE dial | 8 Rapid Atrial Pacing (RAP) controls |
| 3 LOW BATTERY indicator | 9 SENSE indicator |
| 4 OUTPUT dial | 10 Control cover |
| 5 SENSITIVITY dial | 11 ON/OFF controls |
| 6 Battery drawer release button | 12 Battery drawer |

Figure 8-1. Controls, indicators, and features of the Model 5348.

Turning the SENSITIVITY dial fully counterclockwise to the ASYNC. position disables the sensing circuitry, allowing the device to pace asynchronously. The ASYNC. position is separated from the sensitivity settings by a dial detent (a mechanical restriction of dial movement).

The settings below 1.0 mV are color-coded and are also separated by a dial detent.

ON and OFF

The device is turned on by pressing the ON key. The device is turned off by pressing the ON and OFF keys simultaneously.

Rapid Atrial Pacing (RAP) Controls

ENABLE/DISABLE

Pressing this key enables RAP Standby. RAP Standby is the condition in which all RAP controls are functional and the RAP rate setting is displayed, but the device continues to pace as set by the Base Level Pacing controls. When RAP Standby is enabled, the device checks that all other RAP keys are operational and activates the RAP display.

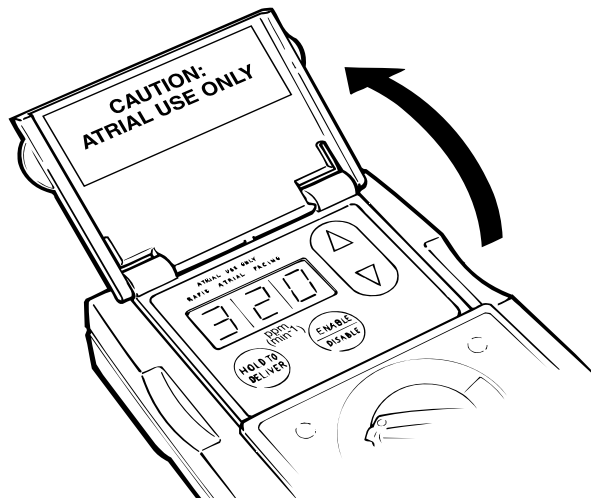


Figure 8-2. RAP controls and screen are located underneath a flip-up cover.

Pressing the ENABLE/DISABLE key during RAP delivery or RAP Standby disables RAP delivery and RAP Standby. Turning the Model 5348 off also disables RAP delivery and RAP Standby.

Note: RAP Standby is automatically disabled if no RAP controls have been used for 5 minutes.

HOLD TO DELIVER

Press and hold this key (when the device is in RAP Standby) to deliver pacing pulses at the set RAP rate.

^ (Increase) and v (Decrease)

Press and hold these keys to adjust the RAP rate before or during delivery of a RAP burst. The ^ key increases the RAP rate, the v key decreases the RAP rate.

When the RAP rate is between 80 and 380 min⁻¹ (ppm), the rate will change in 5 min⁻¹ (ppm) increments. When the RAP rate is between 380 and 540, the rate will change in 10 min⁻¹ (ppm) increments. When the RAP rate is over 540 min⁻¹ (ppm), the rate will change in 20 min⁻¹ (ppm) increments.

Initially the rate will change 2 increments per second. If the increment/decrement key is held down for more than 2 seconds, the speed at which the rate changes increases to 8 increments per second.

OUTPUT

The OUTPUT dial used to adjust base level pacing amplitude also adjusts the amplitude, in mA, of pulses during RAP delivery.

Indicators

The indicators are LEDs (light emitting diodes) that provide feedback about the electrical functioning of the device. The Model 5348 pacemaker has three indicators, labeled PACE, SENSE, and LOW BATT.

Note: All three indicators illuminate during the Power-on Self-test (see “Self-testing”), and again as the device is turned off.

PACE

This green light flashes each time a pacing pulse is generated by the device. It does not, however, indicate that the pacing pulse has initiated cardiac stimulation.

SENSE

This orange light flashes each time a sensed-outside-refractory¹ event is detected by the device.

LOW BATT.

This yellow light begins flashing in unison with the PACE or SENSE indicator when the battery level drops below 7.2 volts (approximately). This indicator changes from flashes to continuous illumination after 24 hours, as the battery voltage continues to drop. (There is no change in the pacing or sensing characteristics of the device.) The device shuts itself off after another 2 or 3 pacing cycles if the battery is not replaced. The only way to extinguish the LOW BATT. indicator is by replacing the low battery with a new battery² (see “Battery Installation”).

Physical Features of the Model 5348

Control Covers

The Base Level Pacing controls are protected by a clear plastic cover. Sliding the cover downward provides access to the pacing controls and the ON and OFF keys. The RAP controls are protected by an opaque plastic cover. Flipping the cover up provides access to the RAP controls. Replacement control covers are available from Medtronic.

Battery

The battery drawer, located on the bottom end of the device, accepts a standard 9-volt alkaline or lithium battery (see “Specifications”).

¹ This indicator light only flashes for cardiac events sensed outside the refractory period.

² The new battery voltage level must be approximately 8.0 V.

Battery Life - When the device is set to 80 min^{-1} (ppm) and 10 mA, battery life is typically 12 days or approximately 300 hours. continuous operation for an alkaline battery, or typically 27 days or approximately 650 hours of continuous operation for a lithium battery.

Battery Drawer Release Mechanism - To open the battery drawer, simultaneously press the two buttons on either side of the device (see Figure 9-1).

Reversible Battery Polarity - The polarity is marked inside the battery drawer, but the device will operate appropriately if the battery is installed with the polarity reversed.

Continued Operation During Replacement - When the battery is removed, the device will continue to operate at the set parameters for a minimum of 15 seconds when parameters are set at, or below, 80 min^{-1} (ppm) and 10 mA. Medtronic does not recommend replacing the battery while the pacemaker is turned on.

Connector Block

Located at the top end of the device, the connector block accepts safety cables (Medtronic Patient Cable Models 5433A and 5433V and Medtronic Surgical Cable Models 5832 and 5832S). The connector block also has openings for the direct connection of heartwires from 0.38 mm to 2.28 mm (0.015 inch to 0.09 inch) in diameter and from 12.67 mm to 22.8 mm (0.5 inch to 0.9 inch) in length. These receptacles are covered with a rubber seal to keep out contaminants.

Note: The heartwire openings are to be used in emergency situations only. They have no gripping mechanism, so the retention force within the receptacles varies with pin diameter.

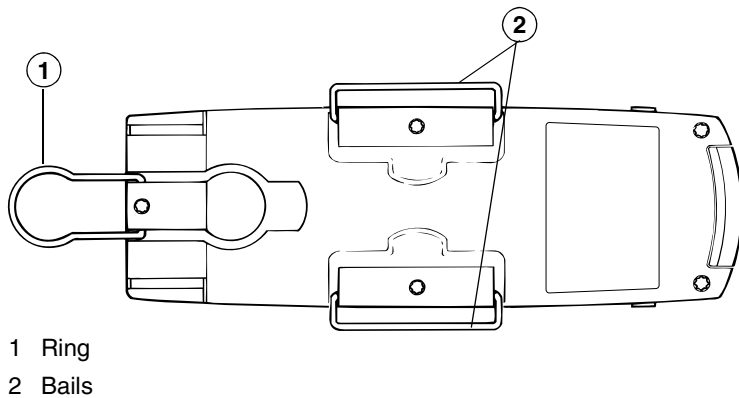


Figure 8-3. The attachment ring and bails.

Attachment Ring and Bails

The attachment ring and bails are located on the back of the device. The ring is used to attach the device to an IV pole. The bails should only be used to temporarily secure the device to the patient or bed rail when the patient is in transit. When not in use, the ring and the bails fold flat against the back of the device.

Note: To prevent unauthorized changes to pacemaker settings, do not place the device in any area where patients may interact with it. The temporary pacemaker should be placed in an area that minimizes tampering with the device by unauthorized personnel such as patients or visitors.

Functional Features of the Model 5348

Self-Testing

When the Model 5348 is turned on, the device takes approximately one second to check the OFF key, the RAP ENABLE/DISABLE key, and the battery, as well as the conditions of ROM, RAM, and the analog-to-digital converter. The PACE, SENSE, and LOW BATT. indicators will come on and stay illuminated during the self-test.

If the OFF key fails the self-test, the device turns itself off immediately. If the device fails the self-test for another reason, the LEDs will remain on. Turn the device off by pressing the ON and OFF keys simultaneously, or by removing the battery. Return the device for servicing.

RAP Standby

When the RAP Standby state is enabled, the device begins to monitor the use of the RAP feature. If the RAP feature has not been used for 5 minutes, the device automatically disables the RAP Standby state as a safety precaution.

Rate-Runaway Protection

A rate-runaway protection circuit continually monitors the crystal rate, which controls the pacing rate of the Model 5348 temporary pacemaker. If the crystal rate deviates from the appropriate value, the rate-runaway protection circuit initiates a restart of the system. The PACE and SENSE indicators illuminate for less than a second while a self-test is performed. If the crystal rate remains incorrect, the rate-runaway protection circuit turns the device off.

Pulse Width

The pacing pulse width is fixed at 1.8 ms.

Synchronous (Demand) Modes (AAI/VVI)

This mode provides demand (R-wave inhibited) pacing stimuli of 1.8 ms in duration, at rates of 30 to 180 min⁻¹ (ppm) and current amplitudes of 0.1 to 20 mA, in either the atrium or ventricle, depending upon which chamber the leads are in contact with. This mode is selected by setting the SENSITIVITY dial to a setting that is twice the mV value of the patient's sensing threshold (see "Determining Sensing Potentials"). The pacemaker is then able to sense intrinsic or ectopic activity, minimizing competition between pacing pulses and intrinsic heart activity.

Asynchronous Modes (AOO/VOO)

This mode provides fixed-rate pacing stimuli of 1.8 ms in duration, at rates of 30 to 180 min⁻¹ (ppm) and current amplitude of 0.1 to 20 mA, in either the atrium or ventricle, depending upon which chamber the leads are in contact with. This mode is selected by turning the SENSITIVITY dial fully counterclockwise to the ASYNC. position. At this position the device's sensing circuitry is turned off.

Blanking Periods

Blanking is the period following a paced or sensed event during which the device sense amplifier is disabled. Pace Blanking begins 10 ms before a pacing pulse is delivered. Sense Blanking begins after a sensed event.

Refractory Periods

Refractory is the period during which a sensed event does not cause the SENSE indicator to flash and does not restart the escape interval. An event sensed inside refractory but outside blanking (i.e., the reversion window) does restart the blanking and refractory periods.

Note: When the device is in low battery operation, an event sensed inside the reversion window will also illuminate the LOW BATT. indicator.

Pace Refractory is started by a paced event while Sense Refractory is started by a sensed event.

Reversion Response

This safety feature is designed to prevent a loss of pacing therapy during continuous electromagnetic interference. The Reversion Window is the period between the end of Blanking and the end of Refractory.

If the device is pacing in the demand mode and begins to sense events continuously (e.g. arrhythmias or ambient electromagnetic noise) within successive Reversion Windows, the device reverts to asynchronous pacing at the rate set by the RATE dial. The device resumes pacing in the demand mode when the interference is no longer sensed.

Cables

Medtronic Models 5433A and 5433V Patient Cables

The Patient Cable Models 5433A and 5433V are designed to connect atrial and ventricular pacing lead systems to the Medtronic Model 5348 Temporary Pacemaker for temporary, external pacing.

The Patient Cable Models 5433A and 5433V are safety cables (i.e., they have recessed or non-exposed pins). They are reusable and are supplied non-sterile, but should be sterilized prior to use using steam (reliable up to 25 autoclave cycles) or ethylene oxide.

The lead connector assembly at one end of each cable accepts endocardial or myocardial pacing lead connector pins 0.38 mm to 2.41 mm (0.015 inch to 0.095 inch) in diameter. The terminal connector at the other end of each cable is designed to mate with the output terminal on the Model 5348 pacemaker.

The two cables are identical except for color coding and markings:

- The Model 5433A, for atrial use, has a blue connector block and blue band around the terminal pin block. The connector block has a symbol denoting Atrial Use printed on one face (see Figure 8-4).
- The Model 5433V, for ventricular use, has a white connector block and white band. The connector block has a symbol denoting Ventricular Use printed on one face (see Figure 8-4).

Do not expose the cables to storage temperatures above 66°C (150°F) or below -40°C (-40°F).

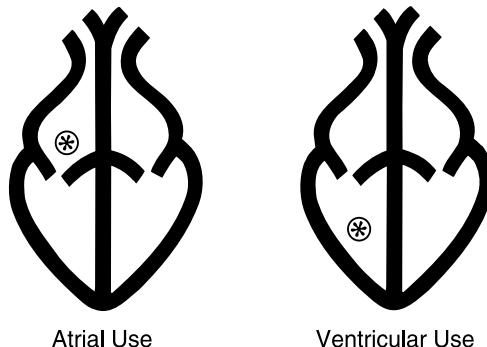


Figure 8-4. The Model 5433A Atrial Use Symbol and the Model 5433V Ventricular Use Symbol.

Medtronic Surgical Cable Models 5832 and 5832S

The Models 5832 and 5832S Surgical Cables are designed to connect a cardiac pacing lead to the Model 5348 temporary pacemaker. They are safety cables (i.e., they have recessed or non-exposed pins).

The cable bifurcates at its distal end and terminates in two alligator clips that attach to the connector pins of the cardiac lead. The Model 5832S cable, which has smaller alligator clips than the Model 5832, is designed for use with IS-1¹ style leads.

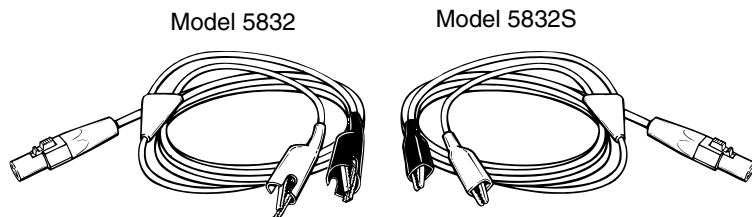


Figure 8-5. Models 5832 and 5832S Surgical Cables.

The Model 5409 Disposable Pouch

Description

The Model 5409 Disposable Pouch is designed to protect and hold the Model 5348 Temporary Pacemaker. The pouch consists of a see-through plastic pocket mounted on an attachment panel. The pouch should be disposed of after each patient use. The pouch can be hung from an IV stand. It can also be secured to an ambulatory patient or attached to other surfaces such as a bed, with the addition of a velcro strap which can be ordered (see the accessories catalog).

¹ IS-1 refers to the International Connector Standard (ISO 5841-3: 1992) whereby pulse generators and leads so designated are assured of a basic mechanical fit.

Procedure for use

Insert the temporary pacemaker into the pouch, bottom end first, with the pacemaker's front facing away from the attachment panel. Fold the flip-over top over itself to secure the temporary pacemaker in the pouch. Insert the patient cable connector plug through the slits in the pouch and insert it into the temporary pacemaker.

Preparation for use 9

Caution: Use ECG monitoring and keep defibrillation equipment on standby, immediately available for emergency use during pacing lead insertion and pacemaker connection.

Caution: Properly ground all line-powered equipment used on or in the vicinity of the patient (see “Warnings”).

Battery Installation

Replace the battery for each new patient, and when the low battery indicator appears during device operation.

Check the battery status at least twice daily. Replace alkaline batteries no less than every seven days during continuous use of the temporary pacemaker.

To install (or replace) the battery, press both battery drawer release buttons simultaneously until the battery drawer opens (see Figure 9-1). Remove the old battery and replace it with a new 9-volt type 6LR61 or type 6F22E, or NEDA 1604A (Eveready Energizer 522 or equivalent) alkaline battery or a NEDA 1604LC (Ultralife U9VL or equivalent) lithium battery.

Note: Use of other than the recommended batteries may result in one of the following conditions: (1) a very short battery life after the low-battery indicator comes on, (2) degraded pulse generator performance, and/or (3) overall reduced battery life. Use of batteries with different physical dimensions from that of the recommended batteries may result in erratic or no pacing.

Medtronic does not recommend replacing the battery while the pulse generator is connected to a patient.

Note: The battery should be removed when the device is not in use.

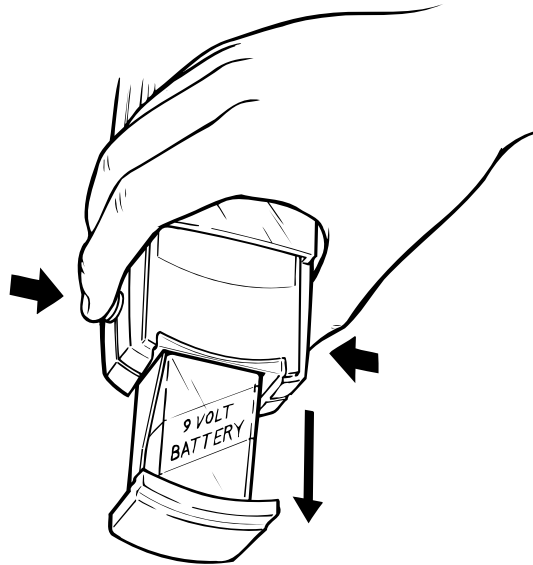


Figure 9-1. Press battery drawer release buttons simultaneously.

Note: Battery drawer latching can be verified by observing that the battery drawer is in its closed position and neither drawer release button is still pressed into the device. An audible click may also occur when the buttons pop out as the battery drawer latches.

Caution: Continued device operation IS NOT an indication that the battery drawer is properly latched.

Connecting the Model 5433A or 5433V Patient Cable to the Model 5348

Warning: Connect the patient cable to the temporary pacemaker before connecting the leads to the patient cable.

Caution: Do not hang the Model 5348 by the cables. The attachment ring or bails should be used when mechanical support of the pacemaker is necessary.

Note: The Patient Cable Models 5433A and 5433V are supplied non-sterile. They should be cleaned and sterilized according to the instructions supplied with each cable.

Connecting the Pacing Lead System to the Model 5433A or 5433V Patient Cable

Note: Carefully inspect the patient cable for visible signs of wear or damage.

With the Model 5348 pacemaker turned off, fully insert the patient cable connector plug into the Model 5348 connector receptacle until it “clicks.” Pull gently on the plug after insertion to ensure a good connection.

To disconnect the patient cable from the device, press the connector release button on the patient cable plug (as shown in Figure 9-2) and gently pull the plug out of the receptacle.

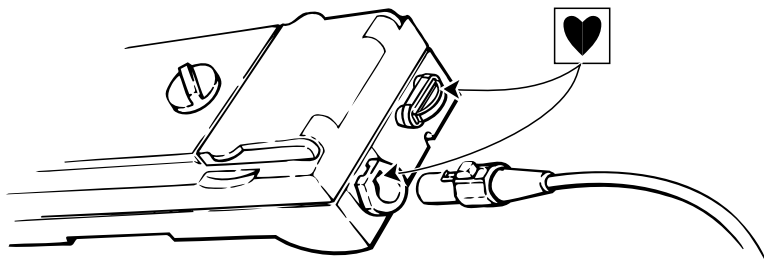


Figure 9-2. Connecting the Model 5433A or 5433V patient cable to the Model 5348 pacemaker.

Caution: It is important to keep hands and gloves free of blood and body fluids while connecting or disconnecting the Model 5433A or 5433V patient cable and/or pacing leads to the Model 5348 pacemaker to avoid getting contaminants in difficult to clean areas.

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

Connecting the Pacing Lead System to the Model 5433A or 5433V Patient Cable

Note: Carefully inspect the leads for visible signs of wear or damage.

1. Loosen the patient cable connector knobs by twisting each knob counterclockwise until resistance is felt.
2. Insert the lead connector pins into the patient cable receptacles as shown (see Figure 9-3).

For bipolar systems: Insert each connector pin into the proper receptacle (marked + and -). Bipolar lead systems may exhibit different threshold values depending on the polarity of the lead connections. This difference is usually negligible for myocardial leads.

For unipolar systems: Insert the connector pin into the negative receptacle. An “indifferent” electrode (or “ground”) should be inserted into the positive receptacle.

Caution: Bipolar lead systems are recommended because they are less susceptible to electromagnetic interference.

3. Finger tighten each terminal knob clockwise until snug. Gentle traction on each lead conductor will verify a secure connection.

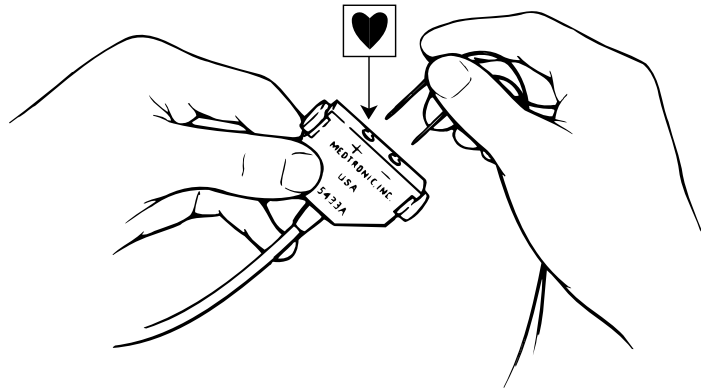


Figure 9-3. Connecting the pacing lead system to the Model 5433A or 5433V patient cable receptacles.

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

Connecting the Pacing Lead System Directly to the Model 5348 Pacemaker

Warning: Do not connect heartwires or leads directly to the Model 5348 except in extreme emergency situations.

Temporary pacing leads, such as the Medtronic Model 6500, can be connected directly to the Model 5348 in extreme emergency situations.

Caution: There is no locking mechanism within the receptacles to hold connector pins securely in place; consequently, use the Model 5433A or 5433V safety patient cable whenever possible (see “Connecting the Pacing Lead System to the Model 5433A or 5433V Patient Cable”).

Caution: Do not allow exposed pins to be touched or to contact electrically conductive or wet surfaces. It is recommended that exposed pins and wires be covered to prevent shorting.

1. Remove the connector pin receptacle seal by gripping the rubber handle and pulling it away from the device.
2. Push the connector pins into the corresponding holes on the connector block as shown (see Figure 9-4).

Caution: DO NOT insert the pins into the receptacle for the patient cable.

Caution: It is important to keep hands and gloves free of blood and body fluids while connecting or disconnecting the temporary pacing leads to the Model 5348 pacemaker to avoid getting contaminants in difficult to clean areas.

For bipolar systems: Insert each pin into the proper receptacle (marked + and -). Bipolar lead systems may exhibit different threshold values depending on the polarity of the lead connections. This difference is usually negligible for myocardial leads.

For unipolar systems: Insert the connector pin into the negative (-) receptacle. An “indifferent” electrode (or “ground”) should be inserted into the positive (+) receptacle.

Caution: Bipolar lead systems are recommended because they are less susceptible to electromagnetic interference.

3. To remove the pins, simply pull them out.

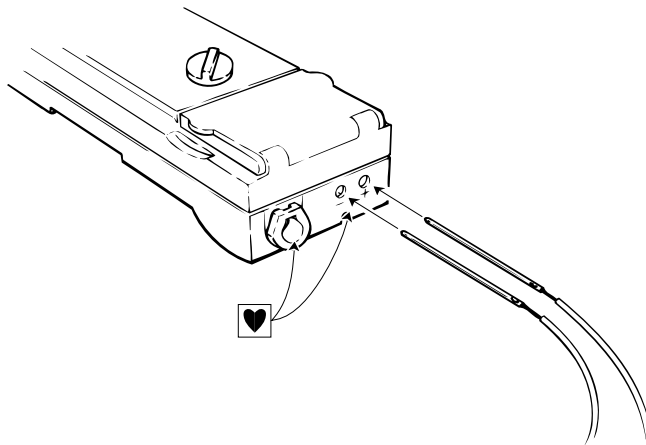


Figure 9-4. Connecting heartwires directly to the Model 5348.

Instructions for use 10

Warning: Make all connections before turning the device on.

Turning the Model 5348 On and Off

To turn on the Model 5348, simply press the ON key. To turn the pacemaker off, press the OFF and ON keys simultaneously.

Caution: Replace the battery immediately if the LOW BATT. indicator illuminates or flashes with the PACE and SENSE indicators when the device is first turned on. Operating life in this low battery condition is unknown, and the device may shut down at any time.

Caution: Medtronic does not recommend replacing the battery while the pacemaker is connected to a patient. The pacemaker will operate satisfactorily for a minimum of 24 hours at settings at, or below, 80 min⁻¹ (ppm) and 10 mA after the first time that the LOW BATT. indicator starts flashing during pacemaker operation.

Note: The Model 5348 will operate in a base level pacing mode as indicated by the settings on the dials when the device is turned on, even if the device was in RAP Standby or RAP delivery state when turned off.

Power-on Self-test

Turning on the Model 5348 initiates a Power-on Self-test (see “Self-Testing”) during which all indicator lights are illuminated. If the device passes the self-test, the indicator lights are extinguished after approximately one second (the PACE or SENSE indicator will then flash accordingly).

If the battery voltage is below the low-battery level, the LOW BATT. indicator begins to flash synchronously with the pace or sense indicators.

Depending upon how low the battery is when the device is turned on, the LEDs may come on and pace or sense for a cycle or two before turning off; or the LEDs may turn on and then turn off immediately. If the battery voltage is too low the LEDs do not come on at all and the device does not turn on.

If the Model 5348 fails the self-test, all indicator lights remain on and no pacing or sensing occurs. Turn the device off by pressing the ON and OFF keys simultaneously, or by removing the battery. Return the device for servicing.

Procedures for Basic Pacing

Basic pacing operation provided by the Model 5348 includes demand (synchronous) and asynchronous modes, in either the atrium or the ventricle, at rates from 30 to 180 min⁻¹ (ppm). This section describes procedures for basic pacing operation.

Determining the Pacing Mode

The pacing mode is determined by lead placement and by the sensitivity setting. Position the lead(s) to pace the appropriate chamber (atrium or ventricle), following the instructions provided with each lead.

The sensitivity setting determines whether the pacemaker is in a demand (synchronous) mode or an asynchronous mode.

To select a demand mode, adjust the SENSITIVITY dial to a setting (between 0.5 and 20 mV) that is one-half the mV value of the patient's sensitivity threshold (see "Determining Sensing Potentials").

Note: In the demand pacing mode, pacing output pulses are inhibited when the pacemaker senses intrinsic or ectopic activity, minimizing competition between the paced rhythm and the intrinsic activity of the heart.

To select an asynchronous mode, turn the SENSITIVITY dial fully counterclockwise to the ASYNC. position.

Caution: Asynchronous pacing, because it may compete with the intrinsic activity of the heart, may result in tachyarrhythmias.

Note: The asynchronous mode is best suited to patients whose intrinsic rate during pacing is consistently below the pacing rate and who do not have ectopic activity.

Adjusting the Pacing Parameters

The parameters for basic pacing operation include Rate, Output, and Sensitivity. To adjust any of these parameters, turn the appropriate dial to the desired value. Adjustments of all parameters take effect on the next pacing cycle.

Determining Sensing Potentials

Caution: During sensing threshold measurements, stimulation threshold measurements, and other adjustments, stimuli may be inadvertently delivered into a vulnerable period of the cardiac cycle. Use ECG monitoring and keep defibrillating equipment on standby, immediately available for emergency use during pacing lead attachment, pacemaker connection and adjustment, measurements of stimulation thresholds or sensed potentials, and application of burst pacing therapy.

The purpose of determining sensing potentials is to ensure that the pacemaker (when operating in a demand mode) will sense intrinsic cardiac activity and inhibit pacing stimulus accordingly.

The Model 5348 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 such as the Model 5311 or 5311B.

Note: If a patient does not have adequate intrinsic rhythm, this procedure must be modified by a physician according to the patient's condition.

1. Set the RATE dial to at least 10 min⁻¹ (ppm) less than the intrinsic rate (as determined from the ECG).
2. Set the OUTPUT dial fully counterclockwise to 0.1 mA to avoid the risk of competitive pacing.
3. Set the SENSITIVITY dial fully clockwise to 0.5 mV. (The pacing pulses should no longer capture the heart and the SENSE indicator should be flashing as the unit senses the patient's intrinsic heart rhythm.)
4. Slowly decrease sensitivity by increasing the millivolt value (turn the SENSITIVITY dial counterclockwise) until the PACE indicator begins flashing.
5. Slowly increase the sensitivity by decreasing the millivolt value (turn the SENSITIVITY dial clockwise) until the SENSE indicator begins flashing again.

The millivolt value at which the pacemaker resumes sensing (the sensing “threshold”) is the level at which P- or R-wave potentials are sensed. The threshold should be at least 2 mV for P-waves and at least 4 mV for R-waves.

6. Set the sensitivity to a value that is twice as sensitive as the threshold, i.e., one half the millivolt value to ensure a margin of safety. The appropriate sensitivity setting for a patient with a 3 mV threshold would be 1.5 mV.
7. Turn the RATE and OUTPUT dials to their original values.

Determining Stimulation Thresholds

1. Set the RATE dial to a value at least 10 min⁻¹ (ppm) faster than the patient’s intrinsic rate (as determined from the ECG), and set the sensitivity to the appropriate value (see “Determining Sensing Potentials”).
2. Verify 1:1 capture (via the ECG monitor), then gradually decrease the output current (by turning the dial counterclockwise) until 1:1 capture is lost, as indicated on the ECG monitor. (The PACE and SENSE indicators flash intermittently.)
3. Slowly increase the output current again until 1:1 capture is regained, as indicated on the ECG monitor (PACE indicator flashes; SENSE indicator stops flashing).

The value at which capture is regained is the stimulation threshold. Acceptable stimulation thresholds are 1.0 mA or less for most endocardial and/or myocardial leads and heartwires.

4. Set the OUTPUT to a value that is at least twice the threshold value to ensure a margin of safety. The appropriate Output setting for a patient with a 1 mA threshold would be at least 2 mA.
5. Reset the RATE dial to the proper value.

Procedure for Rapid Atrial Pacing (RAP)

Warning: RAPID ATRIAL PACING IS INTENDED FOR USE IN THE ATRIUM ONLY.

Caution: Use of high rates in the atrium could result in high-rate conduction to the ventricle.

Verify Connections

Verify that the lead(s) are in contact with the atrium, and not the ventricle, before enabling RAP Standby.

Enable the RAP Standby State

RAP Standby is the condition in which all RAP controls are functional and the RAP rate setting is displayed, but the device continues to pace as set by the base level pacing controls.

To enable RAP Standby, flip open the opaque RAP cover and press the ENABLE/DISABLE key. The device will perform a self-test of all the RAP keys and the screen will display the nominal RAP rate of 320 min^{-1} (ppm) (although the device will continue to operate as set by the Base Level Pacing controls). The RAP keys and display will remain in standby state for 5 minutes. If no RAP keys are used within 5 minutes, the RAP functions will turn off.

Note: The Model 5348 will operate in a base level pacing mode when turned on, even if the device was in RAP Standby or RAP delivery state when turned-off.

Adjust the RAP Rate

Press and hold the $\wedge$ key to increase the RAP rate. Press and hold the $\vee$ key to decrease the RAP rate.

Delivering a RAP Burst

To deliver a RAP burst, press and hold the HOLD TO DELIVER key. The device waits for a maximum of two base level pacing cycles, then begins delivering output pulses asynchronously at the selected rate while the HOLD TO DELIVER key is depressed. To end the RAP burst, release the HOLD TO DELIVER key.

Adjusting Parameters During RAP Delivery

The $\wedge$ key and the $\vee$ key remain functional during RAP delivery. The OUTPUT dial is also functional during RAP delivery, allowing the amplitude of the RAP to be adjusted.

Caution: Adjusting the RATE dial and the SENSITIVITY dial has no effect on RAP delivery. If the RATE dial or the SENSITIVITY dial are adjusted during RAP delivery, however, the device will resume basic pacing operation at the new settings when the HOLD TO DELIVER key is released.

Returning to Basic Pacing Operation (Disabling RAP Standby)

As soon as the HOLD TO DELIVER key is released, the device resumes pacing as set by the Base Level Pacing controls, but the device remains in the RAP Standby state. To disable RAP Standby, press the ENABLE/DISABLE key and close the RAP control cover.

Cleaning and Disinfection

Model 5348 Temporary Pacemaker

The Model 5348 pacemaker can be cleaned using a sponge or cloth moistened with water or 70% isopropyl alcohol.

Note: Do not expose the unit to ethers, acetone, or chlorinated solvents as these may damage the case or labels. THE MODEL 5348 MUST NOT BE IMMERSSED IN WATER OR CLEANING AGENTS.

The Model 5348 can be placed in ethylene oxide gas for disinfection. Due to the variability between sterilizers, precise sterilization instructions must come from the sterilizer manufacturer. However, the process should not exceed temperatures of 52°C (125°F) nor 103 kPa (15 PSIG). Use an acceptable method such as biological indicators for determining sterilizer effectiveness.

Caution: Do not sterilize the Model 5348 by gamma irradiation and do not steam-sterilize (autoclave) the device.

Model 5433A and 5433V Patient Cables

The Model 5433A and 5433V Patient Cables are supplied non-sterile, but should be sterilized by steam or ethylene prior to use.

Prior to sterilization, the Model 5433A or 5433V Patient Cable should be cleaned thoroughly with a mild detergent or 70% isopropyl alcohol to remove all visible blood and body fluids. The cables may be immersed for cleaning. The cables must be thoroughly dried after cleaning.

Inspection and testing by a qualified technician should be done after cleaning to verify proper cable function.

Either of the following sterilization methods are acceptable; however, repeated steam sterilization typically causes more rapid degradation and is only reliable for up to 25 autoclave cycles.

Steam Sterilization: Remove the cable from the original package and place the cable in a suitable autoclavable packaging material. The packaged cable should be autoclaved at:

- 121°C (250°F) at 103 kPa (15 PSIG) for 30 minutes, or

- 132°C (270°F) at 186 kPa (27 PSIG) for 7 minutes

Ethylene Oxide Sterilization: Remove the cable from the original package and wrap the cable in packaging permeable to ethylene oxide. Follow standard method for ethylene oxide sterilization. Use an acceptable method such as biological indicators for determining sterilizer effectiveness.

Safety and Technical Checks

Safety and technical checks should be carried out on the Model 5348 Single Chamber Temporary Pacemaker at least once every 12 months and after any malfunction or accident. Medtronic recommends that the checks be carried out by qualified engineers and technicians trained in the use of Medtronic products. Below is a brief outline of necessary checks. For service or training contact your Medtronic sales or service representative.

Visual Inspection:

- Technical Manual
- Inscriptions, information and warning signs properly and completely fixed.
- Mechanical damage to the device.
- Inspection of battery compartment and battery connection for corrosion and other contamination.

Functional Inspection:

- Faultless self-test (see “Self-test”).
- Front panel dials, keys, and displays
- Inspection of all connections and cables
- Examination of warnings.

Practical Measurements:

- Rate Test
- Rapid Atrial Pacing
- Pulse Width
- Output

- Sensitivity
- Frequency Response
- Refractory Period
- Off Current Drain (150 microamp maximum)
- On Current Drain (1.5 milliamp maximum when measured away from peaks)
- AC (50 Hz) Interference Rejection of 2.0 mVp-p noise while sensing 3.0 mV, 40 ms sine-squared test pulses
- DC Leakage Current Measurements per IEC 601

Caution: Do not open the device as this will void the warranty (see Medtronic Warranty in Chapter 1 for more information).

Medtronic does not recommend field repair of the device. For service or repair contact your local Medtronic representative at the appropriate address or telephone number listed on the back cover.

Service

Medtronic employs highly trained representatives located throughout the world to serve customers and, upon request, to provide training to qualified personnel in the use of Medtronic products. In addition, Medtronic maintains a professional staff of consultants who provide technical and medical consultation to product users. For supplemental information, contact your local Medtronic representative, or call or write Medtronic at the appropriate address or telephone number listed on the back cover.

The Medtronic Model 5348 Temporary Pacemaker has been carefully engineered, manufactured and quality tested to provide long, trouble-free service. Should service or repair be necessary, contact your local Medtronic representative at the appropriate address or telephone number listed on the back cover.

A serial number identifying each individual pacemaker is printed on the back surface of the device. This serial number should be referenced in any correspondence regarding this device.

Specifications¹ 12

Modes:	Synchronous (AAI/VVI) (demand) and asynchronous (AOO/VOO)
Base level pacing rates:	30 - 180 min ⁻¹ (ppm) (continuously adjustable) ± 10% ^a
Rapid atrial pacing rates:	80 - 380 min ⁻¹ (ppm) (5 min ⁻¹ [ppm] increments) ± 10% 380 - 540 min ⁻¹ (ppm) (10 min ⁻¹ [ppm] increments) ± 10% 540 - 800 min ⁻¹ (ppm) (20 min ⁻¹ [ppm] increments) ± 10%
Output amplitude:	0.1 - 20 mA (continuously adjustable) ± 15% plus ± 0.1 mA ^a
Pulse width:	1.8 ms ± 10% ^b
Sensitivity:	ASYNC., 0.5 to 20 mV (continuously adjustable) ± 25% or ± 0.30 mV (whichever is greater), including polarity disparity ^{a,c}
Refractory:	250 ms ± 5% ^d
Blanking:	Pace: 125 ms (+ 50 ms; - 0 ms) ^d Sense: 75 ms (+ 50 ms; - 0 ms) ^d
Rate limit:	A crystal is used to set the pacing rate. If the crystal rate deviates from the appropriate value, the rate runaway protection circuit resets the device once. If the crystal rate remains incorrect, the rate runaway protection circuit turns the device off.
Height:	approximately 18.8 cm (7.4 inches)
Width:	approximately 6.1 cm (2.4 inches)
Depth:	approximately 4.1 cm (1.6 inches)
Weight:	approximately 283 g (10 oz.) (with battery)
Operating temperature:	10°C to 43°C (50°F to 110°F) ^e
Storage temperature:	-40°C to 70°C (-40°F to 158°F) (without battery)
Storage humidity:	90% maximum
Battery type:	Standard 9 V, Alkaline Type 6LR61 or Type 6F22E, NEDA 1604A (Eveready Energizer 522 or equivalent) or Lithium NEDA 1604LC (Ultralife U9VL or equivalent)

¹ At 20°C (68°F) ± 2°C and with a 500 ohm (± 1%) load.

Battery life: Typical projected battery life is 12 days (approximately 300 hours) for alkaline batteries or 27 days (approximately 650 hours) for lithium batteries, at 80 min⁻¹ (ppm), 10 mA, and 100% pacing into a 500 ohm load, with RAP disabled, using the recommended battery. There is a minimum of 24 hours of pacing between low battery indication and shut-off, at the above parameters.

Operation after battery removal: Minimum of 15 seconds at 80 min⁻¹ (ppm), 10 mA (not in any RAP state)^f

^a When the dial pointer is centered on the number (numbers are unmarked).

^b Pulse width is measured at the 50% amplitude points of the leading and trailing edges, excluding the discharge cycle.

^c When sensing 40 ms-wide Haversine waveform.

^d When tested with a 1 ms square pulse with sufficient amplitude.

^e Within the ranges of 10°C to 17°C (50°F to 64°F) and 33°C to 43°C (92°F to 110°F) the specification for output is derated an additional ± 5%; the specification for sensitivity is derated an additional ± 7%; and the specification for rate is not derated.

^f Medtronic does not recommend replacing the battery while the pulse generator is connected to a patient.



Medtronic

Manufacturer

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

www.medtronic.com
Tel. +1-763-514-4000
Fax +1-763-514-4879

**Medtronic E.C. Authorized
Representative/Distributed by**

Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
Tel. +31-45-566-8000
Fax +31-45-566-8668

Europe/Africa/Middle East**Headquarters**

Medtronic International Trading Sàrl
Route du Molliau 31
Case Postale 84
CH-1131 Tolochenaz
Switzerland
www.medtronic.co.uk
Tel. +41-21-802-7000
Fax +41-21-802-7900

Technical manuals:
www.medtronic.com/manuals

