

SINGLE CHAMBER TEMPORARY EXTERNAL PACEMAKER

Model 53401

Specifications

Modes	AAI, AOO, VVI, VOO
Basic Pacing Rates	30 – 200 ppm
Rapid Atrial Pacing Rates	80 – 800 ppm
Output Amplitude	0.1 – 25 mA
Pulse Width	1.5 ms
Sensitivity	0.4 – 20 mV
Blanking	200 ms +5/-30 ms — after pace 120 ms +2/-30 ms — after sense
Height	20.27 cm (7.98 in)
Width	6.68 cm (2.63 in)
Depth	4.14 cm (1.63 in)
Weight	499 g (17.6 ounces)
Battery Type	Two IEC type LR6-sized (AA-sized) 1.5 V alkaline batteries (Duracell MN1500, Eveready E91 or equivalent)
Battery Life	Up to 19 days ¹
Electrode Type	Unipolar or bipolar



Intuitively Designed, Instinctively Functional

- Easy to configure and operate
- Constant current — adjust pacing output voltage in response to changes in lead impedance*
- Leverages personnel's device familiarity and experience
- Reliable and proven design
- Ergonomically grip with one hand
- 7-year service life

*As long as the total voltage capacity of the circuit is not surpassed.

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Reference

¹Behm M, Guillermo R. Battery Longevity/Life for Model 53401 Temporary External Pacemaker. September 2016. Medtronic Data On File.

Brief Statement

Model 53401 Temporary External Pacemaker

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

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

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

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

Whenever possible, for the safety of the patient, disconnect the temporary pacemaker from the implanted lead system before defibrillating or cardioverting. Excessive defibrillation energy can damage the temporary pacemaker. This can result in a large current flowing through the implanted lead system and temporary pacemaker, which could reduce intended defibrillation energy delivered to the patient or cause myocardial damage.

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

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

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

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

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

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Printed in USA. 11/2016

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