C-32.

अखिल भारतीय आयुर्विज्ञान संस्थान (एम्स) कल्याणी
All India Institute of Medical Sciences (AIIMS) Kalyani
(स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार के तत्वावधान में एक सांविधिकनिकाय)
(A Statutory Body under the Aegis of Ministry of Health and Family Welfare, GOI)
राष्ट्रीय राजमार्ग – 34, बसन्तपुर, सागूना, कल्याणी, ज़िला – नदिया, पश्चिम बंगाल - 741245
NH-34 Connector, Basantapur, Saguna, Kalyani, District Nadia, West Bengal 741245

WEB CHALLENGE NOTICE

Dispatch No. 892/16023/1/21-22/Single Source/CTVS **Dispatch Date:** 20/7/202

The notice is being uploaded on the web site www.aiimakalyani.edu.in and CPPP.

Sub: Verification and Justification of proprietary nature of the items through 21 days WEB Challenge on the official website of AIIMS. Kalyani and CPPP before Procurement of Single Chamber External Pacemaker against proprietary article certificate of the manufacturer.

Inviting Comments thereon.

Department of CTVS, AIIMS, Kalyani has raised an indent for procurement of Single Chamber External Pacemaker (Model: 53401) make by Medtronic Inc., Supplied by M/s. India Medtronic Pvt. Ltd. 1241, Solitaire Corporate Park, Bldg. No.12, 4-6th Floor, Andheri-Ghatkopar Link Road, Andheri (East), Mumbai-400093, India, a fully owned subsidiary of the Original Equipment Manufacturer (OEM), Medtronic Inc.

The details of the complete set of Single Chamber External Pacemaker (model: 53401) with Cables are as under:

Sl. No.	External Pacemaker	Model no.	Quantity
1.	Single Chamber 53401 (EPG 53401 MKT US)	53401	01
2.	Patient Cable Model 5492VL (Cable 5492VL Molded Connector Intl L	5492VL	01

India Medtronic Pvt. Ltd. has declared in the Proprietary Certificate provided in company's letter head that Medtronic Inc. with its operational headquarters in USA is the only manufacturer of the Single Chamber External Pacemaker (Model: 53401) which is manufactured with Constant Current design and high quality components and is US FDA and CE certified.

P.T.O.

अखिल भारतीय आयुर्विज्ञान संस्थान (एम्स) कल्यानी
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(स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार के तत्वावधान में एक सांविधिकनिकाय)
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NH-34 Connector, Basantapur, Saguna, Kalyani, District Nadia, West Bengal 741245

Continue from page no.01.

The notice is being uploaded for general information of prospective Manufacturer/ Authorized Distributor/Dealer to submit their objection/ comments, if any, on proprietorship of the equipment mentioned above, they may submit their proposal along with specifications meeting point by point and supported by all documentary evidence along with a price quotation for the above said items.

The objection/proposal/comments, if any should be sent in sealed cover to the office of Chairman, Procurement Cell, AIIMS, Kalyani, P.O.- Ghoragacha, NH 34 Connector, Basantapur, Saguna, Kalyani, District-Nadia, West Bengal 747245. Or through email to

e-tender@aiimskaiyani.edu.in, so as to reach on or before Dated. On 10.08.2022. Failing which it will be presumed that no other firm is interested to offer comments/protest/object and case will be decided on its merits.

The Ref" No. P-16023/1/21-22 /Single Source/ CTVS, due on 10.08.2022 should be superscripted on sealed envelope

Enclosures:

1.) Details Specification sheet of OEM provided by M/s. Medtronic
2.) Proprietary Certificate provided by M/s. India Medtronic Pvt. Ltd.

Copy to:

1. Indenting Officer : For kind information please.
2. PS To ED : For kind information please.
3. FIC Website : For kind information please.

Member of Procurement Committee

AIIMS, Kalyani.

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Medtronic

India Medtronic Pvt. Ltd.
CIN: U33110MH1993PTC204814
1241, Solitaire Corporate Park,
Bldg. No. 12, 4th Floor,
Andheri - Ghatkopar Link Road,
Andheri (East), Mumbai - 400093, India.
www.medtronic.co.in

tel +91-22 3074700/1/2/3
fax +91-22 33074704

30th March 2022

Proprietary certificate

From - India Medtronic Pvt. Ltd.

Full address- 1241, Solitaire Corporate Park, Bldg. No. 12. 4th Floor, Andheri- Ghatkopar Link Road, Andheri (East), Mumbai- 400093, India.

To - The Director, All India Institute of Medical Sciences, Kalyani

Dear Sir,

This is to certify that Medtronic with its operational Headquarters in USA is the only company that manufactures Single and Dual Chamber Temporary pacemakers with constant current pacing technology. We confirm that the manufacturing is done with high quality components and our single and dual chamber Temporary pacemakers are USFDA and CE certified.

For India Medtronic Pvt. Ltd.

Anuradha Desai
2022.03.30
11:37:46
+05'30'

Anuradha Desai
Country Sales Manager | Response Care

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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.

Medtronic

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Reference

[1]Behm 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 never 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, 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.

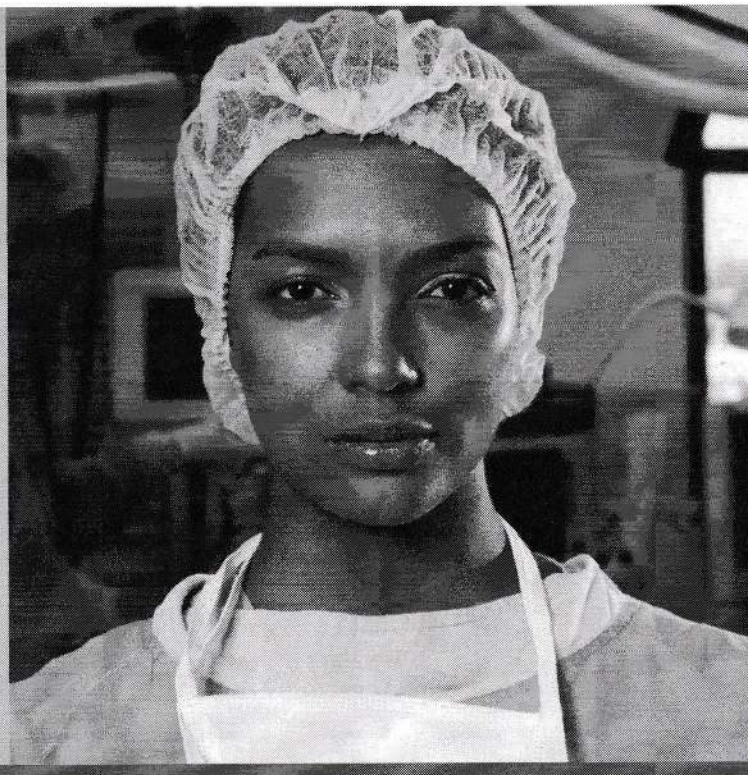
Medtronic
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

Toll-free in USA: 800.633.8766
Worldwide: +1.763.514.4000

medtronic.com

Medtronic

Dr Akhilesh Arumalla
FIC Department of CTVS
AIIMS Kalyani



INTUITIVELY DESIGNED, INSTINCTIVELY FUNCTIONAL

Model 53401
Single Chamber Temporary External Pacemaker

Medtronic

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Model 53401 is a battery powered, external single chamber pacemaker for temporary use. It provides four common pacing modes including on-demand VVI/AAI (synchronous) and VOO/AOO (asynchronous) as well as burst functionality for managing atrial tachyarrhythmias.

THE NEXT GENERATION EXTERNAL TEMPORARY PACEMAKER

- Easy to configure and operate
- Reliable and proven design
- Seven year service life
- Leverages personnel's device familiarity and experience

BENEFITS OF CONSTANT CURRENT DESIGN

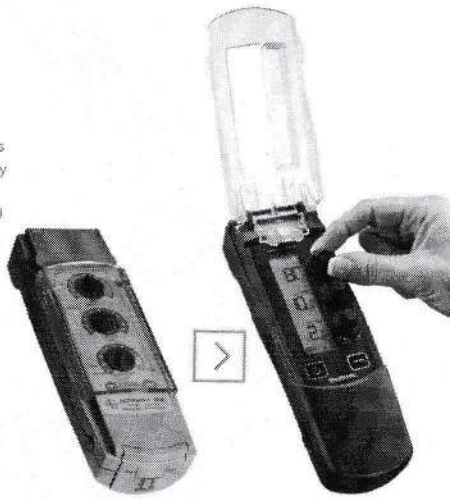
- Adjusts pacing output voltage in response to changes in lead impedance*
- Consistently maintains stable output
- Requires fewer manual device adjustments

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

EASE OF USE — SIMPLICITY AND TECHNOLOGY

Providing a simple and familiar user experience with technological improvements, such as digital display and precision.

- Intuitive three dial design; no submenus
- Easy to view rate, output, and sensitivity settings
- User interface requires minimal training
- Ergonomically grip with one hand



THE MOST EXTENSIVE TEMPORARY EXTERNAL PACEMAKER PORTFOLIO

Patient Cables
- Model 5433A and 5433V — Reusable
- Model 5846A and 5846V — Disposable
- Model 5487 (A or V) — Disposable (IS-1 or exposed pin connectors)

Surgical Cables
- Model 5833 (A or V) — Disposable
- Model 5832 (A or V) — Reusable
- Model 5487 (A or V) — Disposable (IS-1 or exposed pin connectors)

59 YEARS
of proven battery-powered temporary pacemaker experience

Dr Akhilesh Arumalla
FIC Department of CTVS
AIIMS Kalyani

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