



# Medtronic

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## MIDAS REX<sup>®</sup> ELECTRIC BONE MILL BM110 & BM120



### User's Guide

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Rx Only

The information contained in this document was accurate at time of publication. Medtronic reserves the right to make changes in the product described in this manual without notice and without incorporating those changes in any products already sold.













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### NOTICE

It is important that you read this entire manual before you use the Midas Rex® Electric Bone Mill. It is unsafe to use this device before you have read and are thoroughly familiar with this document.

## SYMBOLS

	ATTENTION, SEE INSTRUCTIONS FOR USE
<b>REF</b>	CATALOG NUMBER
<b>SN</b>	SERIAL NUMBER
	DATE OF MANUFACTURE
	MANUFACTURER
	FUSE
	DO NOT REUSE
<b>STERILE EO</b>	STERILIZED BY ETHYLENE OXIDE. DO NOT USE IF PACKAGE IS OPENED OR DAMAGED.
<b>LOT</b>	LOT NUMBER
	OFF POSITION OF ON-OFF SWITCH
	RUN
	TYPE B APPLIED PART
	RF TRANSMITTER (INTERFERENCE MAY OCCUR)
	DO NOT DISPOSE OF THIS PRODUCT IN THE UNSORTED MUNICIPAL WASTE STREAM. DISPOSE OF THIS PRODUCT ACCORDING TO LOCAL REGULATIONS. SEE <a href="http://recycling.medtronic.com">HTTP://RECYCLING.MEDTRONIC.COM</a> FOR INSTRUCTIONS ON PROPER DISPOSAL OF THIS PRODUCT.
<b>EC REP</b>	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	THIS DEVICE COMPLIES WITH MEDICAL DEVICE DIRECTIVE 93/42/EEC
	THIS DEVICE COMPLIES WITH UL2601-1, CSA 22.2 NO. 601.1, AND EN60601-1
<b>Rx Only</b>	CAUTION: FEDERAL LAW IN THE U.S.A. RESTRICTS THE SALE, DISTRIBUTION OR USE OF THIS DEVICE TO, BY OR ON THE ORDER OF A LICENSED MEDICAL PRACTITIONER.
IPX1	PROTECTED AGAINST VERTICALLY DRIPPING WATER
IPX2	PROTECTED AGAINST VERTICALLY DRIPPING WATER WHEN THE ENCLOSURE IS INCLINED 15°
Max ON 45 s / Min OFF 10 mins	EN60601-1 DUTY CYCLE - MAXIMUM ON TIME 45 SECONDS / MINIMUM OFF TIME 10 MINUTES

## WHEN THE SYSTEM ARRIVES

### Unpacking and Inspection

As the box is unpacked, check off the contents of the box against the items listed on the packing slip. If the contents are incomplete or if there is damage, notify Customer Service. If the shipping container is damaged, or the cushioning material shows signs of stress, notify the carrier as well. Keep the shipping materials for carrier inspection. After unpacking your new Midas Rex® Electric Bone Mill, save the cartons and packing material. If the instrument is to be shipped from

one location to another, the carefully designed shipping package will provide proper protection.

## WARNINGS AND PRECAUTIONS

It is important that the Midas Rex® Electric Bone Mill operator be familiar with this manual: its precautions, procedures and safety issues. Four labels are used in this manual to identify important concerns, conditions, or procedures:

- **Warnings:** Describes serious adverse reactions and potential safety hazards that can occur during the proper or improper use of a device.
- **Precautions:** Any special care to be exercised by a practitioner or patient for the safe and effective use of the device.
- **Important:** Identifies conditions or practices which require attention for most desirable results.
- **Note:** Identifies special information or to clarify / emphasize important instructions.

### Warnings

1. It is important that the Bone Mill operator be familiar with this manual, its precautions, procedures and safety issues.
2. This medical device complies with EN60601-1-2 safety standard for electromagnetic compatibility, requirements and test. However, if this equipment is operated in the presence of high levels of electromagnetic interference (EMI) or highly sensitive equipment, interference may be encountered and the user should take whatever steps are necessary to eliminate or reduce the source of the interference. Diminished performance may lengthen operating time for anesthetized patient.
3. Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this Guide.
4. Portable and mobile RF communications equipment can affect Medical Electrical Equipment.
5. Use of accessories and cables other than those specified and sold by Medtronic may result in increased emissions and decreased immunity of this unit.
6. A system that is not functioning properly should not be used until all necessary repairs have been made and the unit is tested to ensure that it is functioning in accordance with Medtronic specifications.
7. Always inspect the components before and after use for any damage. If damage is observed, do not use the damaged part until it is repaired or replaced.
8. DO NOT operate the Midas Rex® Electric Bone Mill base without the bowl and cap secured in place.
9. Verify reusable device was sterilized prior to use. If not sterilized, do not use.
10. Achieve electrical grounding reliability with proper connections. Connect the Bone Mill to hospital grade receptacles only.
11. DO NOT operate the Midas Rex® Electric Bone Mill in the presence of flammable anesthetics. Avoid potential ignition or explosion of gases.
12. Take care to process bone to the desired partial size. DO NOT over process bone.
13. The Midas Rex® Electric Bone Mill bowl, cap, and spatula are provided STERILE and are intended for SINGLE PATIENT USE ONLY. DO NOT RSTERILIZE THESE COMPONENTS. MEDTRONIC ASSUMES NO LIABILITY FOR PRODUCTS WHICH HAVE BEEN RSTERILIZED BY HEALTH CARE FACILITIES. In discarding the disposables, follow health-care facility guidelines on proper disposal of contaminated materials.
14. Disconnect power to the Midas Rex® Electric Bone Mill base before cleaning the unit to avoid electrical shock.
15. After each procedure, properly clean all reusable system components.
16. Sterilizing and drying the Midas Rex® Electric Bone Mill Base before storing decreases the likelihood of cross-contamination.
17. All service must be performed by Medtronic-qualified personnel only.
18. DO NOT operate the Midas Rex® Electric Bone Mill before

following proper cleaning and sterilization protocols.

19. Properly dispose of single-use devices removed from sterile packages. Devices lose sterility upon removal from packaging.
20. DO NOT come in contact with the interior of the disposable bowl or cap during the milling of bone.
21. DO NOT operate the Midas Rex® Electric Bone Mill in the presence of Magnetic Resonance Imaging Devices.
22. DO NOT operate the Bone Mill without eye wear protection.
23. DO NOT use any other components except for Medtronic Midas Rex® Electric Bone Mill disposables.
24. Do not use accessory if package is opened or damaged. A broken seal offers no protection against cross-contamination.
25. DO NOT modify accessories. Performance could be diminished with modified accessories.

**Precautions:**

1. The addition of any liquid to the milling process should be administered in small volume to prevent leakage.
2. DO NOT use Midas Rex® Electric Bone Mill Disposables to process more than 6 bone pieces approximately 1.5 cm3 in size at one time.
3. DO NOT use Midas Rex® Electric Bone Mill Disposables to process more than a total of 40 cc of bone during any one surgical procedure.
4. DO NOT immerse and/or soak the Bone Mill Base or Console.
5. DO NOT use chlorine based or corrosive cleaning agents such as bleach, acetone, solutions containing glutaraldehyde, etc.
6. The equipment should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.
7. Take care when placing base unit on a surgical drape, that the base is in a stable position and that the cable is safely routed.

**SYSTEM DESCRIPTION**

The Midas Rex® Electric Bone Mill is composed of a non sterile console and base with sterile single use disposable components. The sterile single use disposable components consist of one bowl, one cap, and one spatula. A Midas Rex® Electric Bone Mill Console provides the power to drive the base and disposable components.

**INDICATIONS**

The Midas Rex® Electric Bone Mill is intended to mill bone, producing bone particles 1 to 5 mm in size.

**CONTRAINDICATIONS**

There are no known contraindications.

**SETUP AND OPERATION**

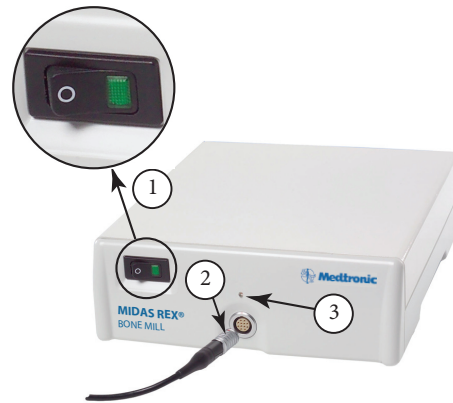
**BASE with BOWL and CAP.**



1. Cap
2. Bowl
3. Base
4. Run switch

5. Disposable bowl release buttons.

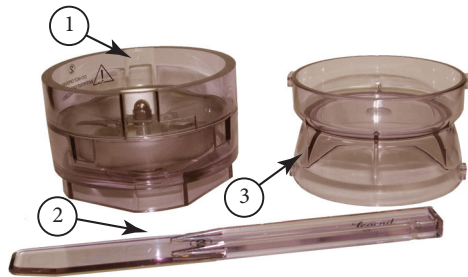
**CONSOLE**



1. Power Switch (lighted indicator = On / O = Off).
2. Bone mill base to console control cable.
3. LED (illumination indicates “mill present”).

**DISPOSABLES**

Midas Rex® Electric Bone Mill disposable components

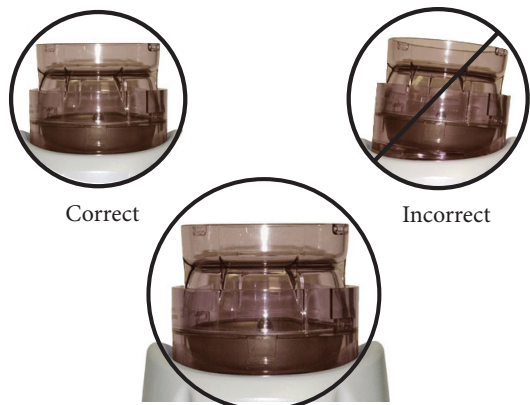


1. Bowl
2. Spatula
3. Cap

**OPERATIVE PROCEDURE**



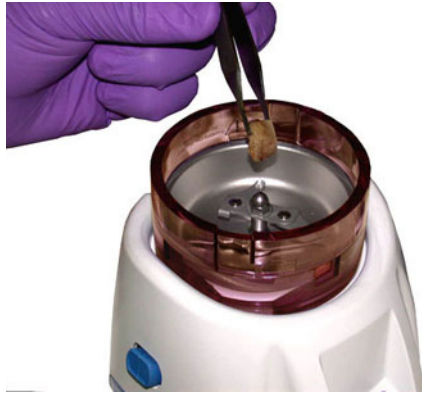
1. Connect the base cable to console.



2. Press bowl “**firmly**” onto Midas Rex® Electric Bone Mill Base until

an audible click (lock) is heard. **“Observe”** that both of the **“Release Buttons”** are fully out.

**Note:** BM200 bowl and cap are not compatible with this unit.



3. Lay harvested bone specimens into bowl.

**Precaution:** Please see Precautions 1, 2 and 3.



**CRITICAL STEP**

**Warning:** DO NOT operate the Midas Rex® Electric Bone Mill base without the bowl and cap secured in place.

4. Secure Cap onto Bowl by rotating counterclockwise. DO NOT activate Bone Mill without securing Cap.
5. To process bone, press the Midas Rex® Electric Bone Mill run switch.
  - Continue to run until desired bone particle size is achieved.

**Important:** Milling time is dependent on the density of the patient’s bone, the ratio of cancellous and cortical bone, the size of the individual particles and the batch amount of the bone to be processed. Always check bone after 10-15 seconds to gauge quality of milling.

**Warning:** Take care to process bone to the desired partial size. DO NOT over process bone.

**Note:** If the blade becomes inoperable, (jams or runs very slowly) stop operation of the Midas Rex® Electric Bone Mill and remove bowl cap and use the spatula to free the bone and blade. Remove some of the bone if needed to obtain proper operating speed.

**Precaution:** Please see Precautions 1, 2 and 3.



6. To remove bone particles:
  - stop operation of the Midas Rex® Electric Bone Mill

- press release buttons and remove bowl and cap from base.
- remove cap from bowl
- use spatula to remove bone particles from bowl and cap.

**Note:** After removing bone particles from Bowl, the milling process may be repeated with additional bone specimens, as needed, (Up to a total of 40 cc of bone may be processed by the Bone Mill Disposable during any one surgical procedure.)

**POST-OPERATIVE PROCEDURE**

1. Turn power Off at console and disconnect power cable.
2. Press release buttons and remove bowl from base.
3. Discard bowl, cap and spatula.
4. Clean and sterilize Midas Rex® Electric Bone Mill Base according to directions in cleaning section of manual.
5. Clean console

**CLEANING**

Wipe all surfaces of the Midas Rex® Electric Bone Mill with a cloth dampened with a neutral enzymatic detergent (pH 6.0 - 8.0). Dry thoroughly.

Sterilizing and drying the Midas Rex® Electric Bone Mill Base before storing decreases the likelihood of cross-contamination.

**Precaution:** Please see Precautions 4 and 5.

**STERILIZATION (BM110)**

These sterilization guidelines are only recommended guidelines and may vary among hospitals depending upon the type of sterilization equipment and possible pathogens in their particular areas. These guidelines represent exposure time and not total cycle time. The recommended sterilization parameters may be modified based on standard hospital sterilization protocol.

Sterilization method	Temperature	Time	Wrapped unwrapped	Drying
High Vacuum Steam (pre-vacuum)	270 °F / 132 °C	4 min.	(wrapped/ unwrapped)	> 20 min
Gravity Displacement (steam)	270 °F / 132 °C	10 min.	(wrapped/ unwrapped)	> 25 min
High Vacuum Steam (pre-vacuum)	273-278 °F / 134-137 °C	3 min.	(wrapped/ unwrapped)	> 20 min
Ethylene Oxide (EO)	Not Validated			

**Limitations**

After cleaning and sterilization, verify functionality prior to re-use.

**Reference:** For Items Contaminated With TSE Agents Steam sterilization under a temperature of 273-278 °F/134-137 °C may be repeated for either a total of six 3 minute cycles OR a single cycle for 18 minutes as referenced in NHS Estates HTM 2010 parts 4 & 6: Appendix 2, Items Contaminated With TSE Agents.

Midas Rex® Electric Bone Mill Bowl, Cap and Spatula are single use devices.

Opened but unused Bone Mill Disposables may not be re sterilized under any sterilization method.

## Midas Rex® Electric Bone Mill

### LIMITED WARRANTY\*

(U.S. Customers Only)

A. This Limited Warranty provides the following assurance to the purchaser of a Medtronic Midas Rex® Electric Bone Mill. The Midas Rex® Electric Bone Mill includes the Console, and Base (hereafter referred to as “Components”), and the Disposable Bowl, Cap and Spatula (hereafter referred to as “Accessory”) and jointly referred to as Midas Rex® Electric Bone Mill, unless specifically noted.

- (1) Should a Component fail to function within normal tolerances due to a defect in materials or workmanship within a period of one (1) year from the date of shipment of the new Component, or 180 days from the date of shipment of the serviced or refurbished Component to the purchaser (but not less than the one year period from the date of shipment of the new Component), or
- (2) Should an Accessory fail to function within normal tolerances due to a defect in materials or workmanship within a period of 90 days from the date of shipment of a new Accessory or serviced or refurbished Accessory to the purchaser.
- (3) Medtronic will at its option: (a) issue a credit to the purchaser of the replacement Component or Accessory equal to the Purchase Price, as defined in Subsection A(4), against the purchase of any same Component or Accessory requested as its replacement, or, (b) provide a functionally comparable replacement Component or Accessory at no charge.
- (4) As used herein, Purchase Price shall mean the lesser of the net invoiced price of the original or current functionally comparable, or replacement Component or Accessory.

B. To qualify for this Limited Warranty, these conditions must be met:

- (1) The Midas Rex® Electric Bone Mill must be used in accordance with the labeling and Instruction Manual provided with the products.
- (2) Only Midas Rex® Electric Bone Mill Accessories that are manufactured, authorized, and quality controlled by Medtronic may be used.
- (3) No reprocessed Accessory sets may be used.
- (4) The Midas Rex® Electric Bone Mill may not be damaged by accident, abuse, misuse or tampering.
- (5) The Midas Rex® Electric Bone Mill or Midas Rex® Electric Bone Mill Accessories may not be modified without the written permission of Medtronic.

C. This Limited Warranty is limited to its express terms. In particular:

- (1) Except as expressly provided by this Limited Warranty, MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE OR MALFUNCTION OF THE Midas Rex® Electric Bone Mill TO FUNCTION WITHIN NORMAL TOLERANCES WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, NEGLIGENCE, STRICT LIABILITY, OR OTHER TORT OR OTHERWISE.
- (2) This Limited Warranty is made only to the purchaser. AS TO ALL OTHERS, MEDTRONIC MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM OR OTHERWISE.
- (3) The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Limited Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid. This Limited Warranty gives the purchaser specific legal rights. The

purchaser may also have other rights that vary from state to state.

- (4) No such express or implied warranty to the purchaser shall extend beyond the period specified in A(1) above.
- (5) This Limited Warranty shall be the exclusive remedy available to any person.
- (6) No person has any authority to bind Medtronic to any representation, condition, or warranty, except this Limited Warranty.

\*This Limited Warranty is provided by Medtronic Powered Surgical Solutions, 4620 North Beach Street, Fort Worth, Texas 76137-4116. It applies only in the United States. Areas outside the United States should contact their local Medtronic representative for terms of the warranty.

### SERVICE

The Midas Rex® Electric Bone Mill is not user-serviceable, and no preventive maintenance or calibration procedures are required except for the directions listed in this manual.

**Precaution:** Please see Precautions 6.

### TROUBLESHOOTING

SYMPTOM	ISSUE	ACTION
The blades do not turn with the run switch depressed:	Loose connection	Ensure that the power cable and the control switch cable are fully engaged in the receptacles.
	Bone stuck under blade.	Ensure that power is Off and using spatula rotate blade in a clockwise direction.
If there is still a problem with the Midas Rex® Electric Bone Mill Contact Medtronic Customer Service at 1-800-335-9557 or FAX: 817-788-6441		

### TECHNICAL SPECIFICATIONS

Size	Base	4.95” W x 4.35” H x 5.92” D (126mm x 111mm x 151mm)
	Console	8.00” W x 2.76” H x 9.09” D (204mm x 70mm x 231mm)
Weight	Base	2.73lbs (1.24kg)
	Console	3.60 lbs (1.63kg)
EN60601-1 Duty Cycle		Max ON 45s/Min OFF 10 Mins
Recommended Installation:		Table Top
External Power Source:		100-240VAC, 200 VA Max
Internal Fuse		4A 250V
Front Panel Control:		Power (On-Off) Switch
Front Panel Indicators:		Power, Mill Present
Authorized Service Organization:		Medtronic Xomed, Inc.
Environmental Requirements:		
Operating:		
	Temperature:	+10 °C to +40 °C
	Humidity:	30% to 75% RH
	Barometric Pressure:	700 to 1060 hPa
Storage and Transportation:		
	Temperature:	-40 °C to +70 °C
	Humidity:	10% to 95% RH
	Barometric Pressure:	500 to 1060 hPa
Disposable Components:		Bowl, Cap, and Spatula
This device meets EN 60601-1-2:2001 requirements.		and IEC 60601-1-2:2001 requirements.
This device complies with UL60601-1, CSA 22.2 No. 601.1, and EN60601-1, and is not for continuous operation.		
Medical Equipment Classification		Class II Type B Applied Part
Protection Against Water Ingress		Console, IPX1 Base, IPX2

## Midas Rex® Electric Bone Mill COMPONENTS

BM110	BM110 Midas Rex® Electric Bone Mill Base
BM120	BM120 Midas Rex® Electric Bone Mill Console
BM130	Bone Mill Instrument Tray
EA600	North America 110 VAC Power Supply Cord
EA607	India / South Africa Power Supply Cord
EA608	Argentina Power Supply Cord
EA609	Israel Power Supply Cord
EA503	Japanese Power Supply Cord
EA611	Italian Power Supply Cord
EA604	Chinese Power Supply Cord
EA610	Danish Power Supply Cord
EA606	UK 240 VAC Power Supply Cord
EA602	Continental Europe 230 VAC Power Supply Cord
EA501	International 115/230 VAC Power Supply
EA505	Australia 240 VAC Power Supply Cord
175025EN	Midas Rex® Electric Bone Mill User's Guide, English
175025MLIU	Midas Rex® Electric Bone Mill User's Guide, 15 Language
11270037	Fuse
DISPOSABLES	
BM210	Bowl, Cap and Spatula

## GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

Guidance and manufacturer's declaration – electromagnetic immunity – Part I			
The Midas Rex® Electric Bone Mill is intended for use in the electromagnetic environment specified below. The customer or the user of the Midas Rex® Electric Bone Mill should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5 % UT for 0.5 cycle 40 % UT for 5 cycles 70 % UT for 25 cycles <5 % UT for 5 sec	<5 % UT for 0.5 cycle 40 % UT for 5 cycles 70 % UT for 25 cycles <5 % UT for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Midas Rex® Electric Bone Mill requires continuous operation during power mains interruptions, it is recommended that the Midas Rex® Electric Bone Mill be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the a.c. mains voltage prior to application of the test level.			


Guidance and manufacturer's declaration – electromagnetic emissions		
The Midas Rex® Electric Bone Mill is intended for use in the electromagnetic environment specified below. The customer or the user of the Midas Rex® Electric Bone Mill should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Midas Rex® Electric Bone Mill uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	The Midas Rex® Electric Bone Mill is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purpose.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the Midas Rex® Electric Bone Mill			
The Midas Rex® Electric Bone Mill is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Midas Rex® Electric Bone Mill can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Midas Rex® Electric Bone Mill as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum power of transmitter  W	Separation distance according to frequency of transmitter meters		
	150 kHz to 80 MHz  $d = 1.2\sqrt{P}$	80 MHz to 800 MHz  $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz  $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.10	0.38	0.38	0.73
1.00	1.20	1.20	2.30
10.00	3.80	3.80	7.30
100.00	12.00	12.00	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			



**Guidance and manufacturer's declaration – electromagnetic immunity - Part II**

The Midas Rex® Electric Bone Mill is intended for use in the electromagnetic environment specified below.  
The customer or the user of the Midas Rex® Electric Bone Mill should assure that it is used in such an environment.




Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF</p> <p>IEC 61000-4-6</p> <p>Radiated RF</p> <p>IEC 61000-4-3</p>	<p>3 Vrms</p> <p>150 kHz to 80 MHz</p> <p>3 V / m</p> <p>80 MHz to 2.5 GHz</p>	<p>3 Vrms</p> <p>3 V / m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Midas Rex® Electric Bone Mill, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b></p> <p><math>d = 1.2 \sqrt{P}</math></p> <p><math>d = 1.2 \sqrt{P}</math> 80 MHz to 800 MHz</p> <p><math>d = 2.3 \sqrt{P}</math> 800 MHz to 2.5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

<sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Midas Rex® Electric Bone Mill is used exceeds the applicable RF compliance level above, the Midas Rex® Electric Bone Mill should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Midas Rex® Electric Bone Mill.

<sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

	<p>Medtronic Powered Surgical Solutions 4620 North Beach Street Fort Worth, TX 76137 USA www.medtronic.com</p>			<p>Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands Tel.: 011-31-45-566-8000 Fax: 011-31-45-566-8668</p>
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## U.S. Customers

Medtronic Powered Surgical Solutions  
4620 North Beach Street  
Fort Worth, TX 76137 USA  
www.medtronic.com

Orders:  
Customer Service  
1-800-433-7080  
FAX: 817-788-6489

Repair Department  
1-800-335-9557  
817-788-6440  
FAX: 817-788-6441

Should your console or related equipment malfunction, (please adhere to the following guidelines)

1. A return goods authorization number is required.
2. Please package the console as safely as possible and insure the shipment.
3. A copy of your purchase order is required. Make certain the purchase order includes the following:
  - Shipping and billing information
  - Purchase order number
  - Contact person
  - Phone number
  - Description of malfunction
  - Your Medtronic account number.
4. Please indicate preferred method of return shipment. Otherwise the unit will be shipped back via UPS ground.
5. When the malfunctioning unit is not covered by warranty, Medtronic will contact your facility promptly with a service cost estimate if requested. The customer will be responsible for freight charges on non-warranted units.

## International Customers

International Customers should contact their local Medtronic office or distributor.

Medtronic Powered Surgical Solutions  
4620 North Beach Street  
Fort Worth, TX 76137  
USA  
www.medtronic.com

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