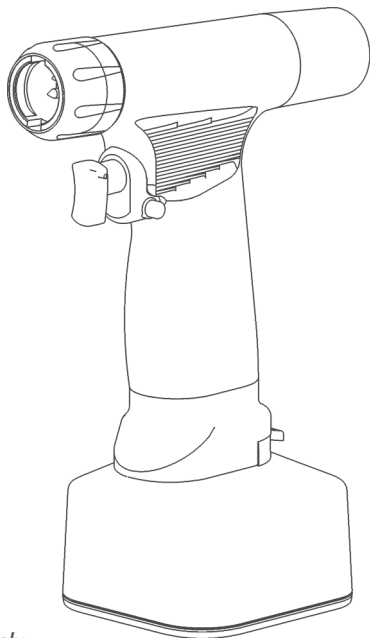




BRASSELER USA[®]
SURGICAL POWER & ACCESSORIES



Rx Only

BSP MAX[™] II

**MODULAR
DRILL/REAMER**

PM-X08-700

Instructions for Use

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Introduction

Thank you for choosing Brasseler USA® Surgical Power & Accessories as supplier of your large bone power system.

The information and procedures described in this manual are intended to assist medical professionals in the safe and effective use, care, cleaning, sterilization and long-term maintenance of BSPMAX™ II Large Bone Power System.

Intended Use

The BSPMAX™ II handpieces are designed for surgical applications in: Orthopaedics, Total Joint Reconstruction, Osteotomies, Trauma and Thoracic.

The BSPMAX™ II Modular Drill/Reamer, PM-X08-700, along with an assortment of attachments is designed for cutting bone, reaming, drilling, wires and pins most common to large bone orthopaedic surgical procedures.

Warnings

- Only trained and experienced medical professionals should use this equipment. Failure to comply with the BSPMAX™ II Instructions for Use may result in patient and/or medical staff injury.
- Use of eye protection is required while operating equipment.
- To prevent accidental activation of the handpiece, the trigger should always be in the SAFE mode when attachment, battery pack and cutting accessory (drill, pin, wire and reamer) are being installed or removed.
- To ensure safety and optimum performance, use Brasseler USA® Surgical Power & Accessories cutting accessories (drills, wires and pins).
- Before each use, test the equipment and inspect each device (handpiece, attachment and accessory) for damage. Do not use any device if damage or malfunctioning is apparent. Return device for service.
- Continually check handpiece and attachments for excessive heat. If overheating is noticed, discontinue use and return device for service.
- Clean and sterilize handpiece, attachments, battery packs and accessories before every use.
- Perform recommended preventive maintenance as indicated in the Care and Maintenance section.

Warnings (continued)

- Do not sterilize 4-Bay Power Unit, Charging Bay Cover and Charging Bay.
- DANGER - Explosion Hazard. DO NOT use in atmospheres containing flammable gasses (anesthetics, etc) with concentrations within explosive limits.
- DO NOT expose battery packs to fire or incineration.
- DO NOT allow battery pack contacts to contact metal objects. Contact with metal objects may result in an electrical shock or a burn injury to the user.
- DO NOT install or remove attachment or cutting accessory while the handpiece is operating. Always place the handpiece in the SAFE mode while the handpiece is idle, before installing or removing attachment or cutting accessory (drill, pin, wire and reamer), or when passing the handpiece to another person.
- DO NOT apply excessive force on a cutting accessory (drill, pin, wire and reamer) when installed in the handpiece, such as bending or prying. Using excessive force may damage the device or cutting accessory and may cause injury to patient and/or user.
- DO NOT reuse single use products. Failure to comply may result in patient and/or health care staff injury.
- Inspect cutting accessories (drills, pins, wires and reamers) for damage before each use. Do not attempt to straighten or sharpen.
- Install and place the handpiece into service according to the EMC information in this manual. Portable and Mobile RF communications equipment can affect the function of the handpiece.
- Under certain classifications of risk, the World Health Organization (WHO), or local regulatory authorities recommend special CJD (Creutzfeldt-Jakob Disease) inactivation processing procedures. Consult WHO and local regulations for further information.

Cautions

- Handpieces are factory sealed. Do not disassemble or lubricate handpieces, as this may void warranty. There are no service requirements expected of the medical or bio-med staff.
- DO NOT stall the handpiece, stalling may damage electrical and/or mechanical components. If the handpiece stalls, release the trigger immediately and remove any obstructions before continuing.
- DO NOT use the oscillate mode with the reamer, keyless chuck or other large mass attachments.
- DO NOT use handpieces or battery packs while warm. Allow adequate time for cooling prior to use. Do not immerse in liquid or cover hand piece with a damp cloth to cool. Cool by exposure to room temperature.
- DO NOT store battery packs on handpieces. Batteries will discharge if they are connected to the handpiece even though the handpiece is not running and may cause irreparable damage to battery packs.
- Handpiece with attachment and/or accessory may cause vibration and fatigue if duty cycle is exceeded.
- Prior to each use, perform the following:
 - Inspect all devices for proper set up and operation.
 - Ensure the attachments install properly.
 - Ensure the battery pack installs properly onto the handpiece.
 - Ensure that drills, pins, wires and reamers work properly with attachments.
 - Ensure there are no loose or missing components.
 - Ensure there are no cracks in the battery pack case.
 - Test the handpiece and battery pack to ensure that they are working properly.
 - Check all moving parts for free movement.
 - Check for unusual sounds or vibrations.
 - Check for proper operating speed.
 - Check for rapid temperature rise or unacceptable heat with handpiece and attachments.
- After each use, perform the following:
 - Remove battery pack from handpiece. If battery is not removed, the charge will be depleted and irreparable damage to battery cells may occur.
 - Thoroughly clean and disinfect all devices.
 - Sterilize handpiece and attachments.

Explanation of Symbols



Catalog number.



Interference.



Caution.



Manufacturer.



Date of manufacture.



Serial Number.



Do not discard. Dispose of product or recycle in accordance with local laws and regulations.



Steam sterilizable.

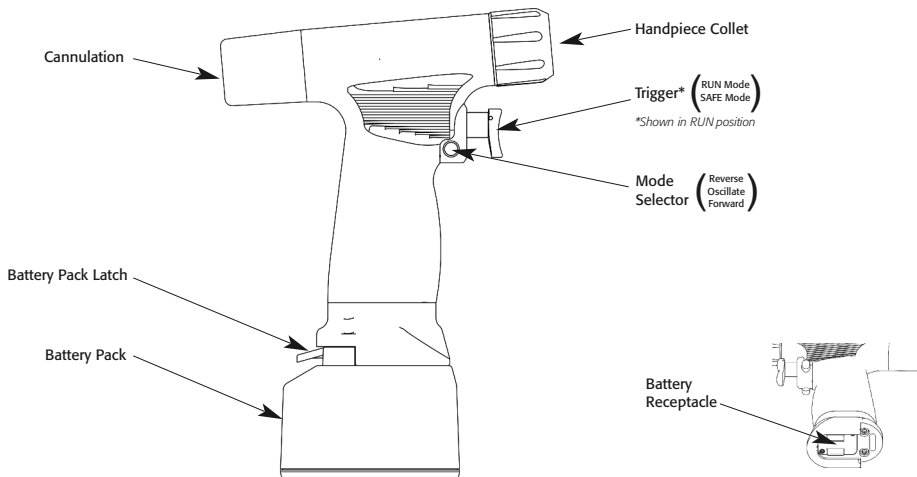


Do not immerse.



Temperature limit.

Features

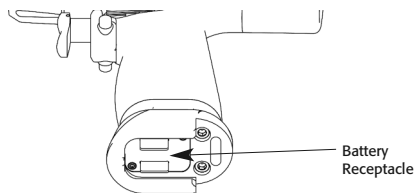
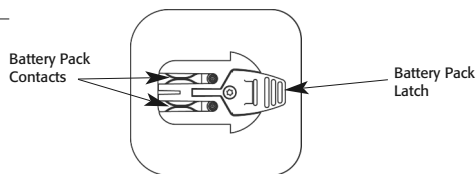


- **Battery Pack** - Rechargeable sterilizable battery pack provides power to the handpiece.
- **Battery Pack Latch** – Secures the battery pack to the handpiece. Depress the battery latch to release the battery pack from the handpiece.
- **Battery Receptacle** – Battery pack connecting location.
- **Cannulation** – Accepts wires/pins/drill bits up to .156 in (4.0 mm) diameter.
- **Handpiece Collet** – Attachment connecting location.
- **Mode Selector** – Selector button allows the modular handpiece to operate in REVERSE (REV), OSCILLATE (OSC) or FORWARD (FWD) modes .
- **Trigger** – Pressure sensitive switch for variable speed operation.
 - (RUN Mode) – Rotate the trigger to the vertical position. Depress trigger to operate handpiece.
 - (SAFE Mode) – Rotate the trigger to the horizontal position. Trigger cannot be depressed to activate the handpiece.

Battery Pack - Installation & Removal

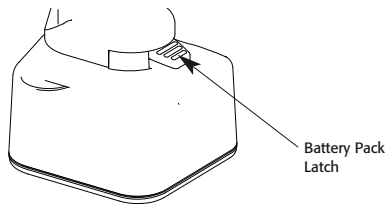
Battery Pack Installation:

- Rotate trigger to the SAFE mode.
- Align the battery pack contacts on the top of the battery pack with the battery receptacle on the handpiece.
- Slide a battery pack into the battery receptacle until the battery latch snaps indicating the battery pack is secure.
- For Modular Drill/Reamer handpiece, position the mode selector in the desired mode to operate the handpiece.
- Rotate trigger to the RUN mode.
- Test the handpiece and battery pack by depressing the trigger.
- Rotate trigger to the SAFE mode when not in operation.



Battery Pack Removal:

- Rotate trigger to the SAFE mode.
- Press down on the battery pack latch and slide battery pack out of the handpiece.
- Always remove battery pack when not in use.



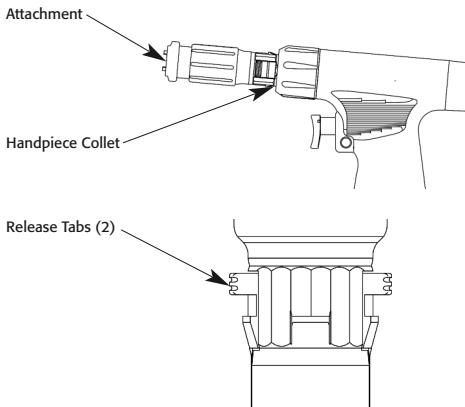
Attachment - Installation & Removal

Attachment Installation:

- Rotate trigger to the SAFE mode.
- Insert attachment into handpiece collet, aligning the release tabs on the attachment with the two notches in the handpiece collet; press firmly until the attachment locks into the handpiece.
- Tug firmly on the attachment to make sure it is installed properly.

Attachment Removal:

- Rotate trigger to the SAFE mode.
- Depress both release tabs fully on the attachment and pull the attachment out of the handpiece.

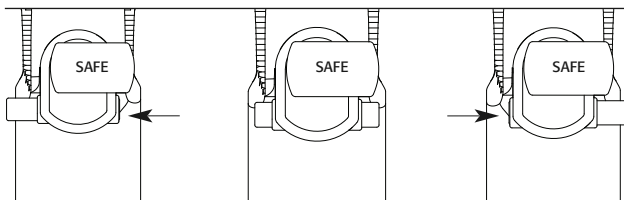


Handpiece Operation

- Rotate trigger to the SAFE mode.
- Install battery pack, attachment and cutting accessory (drill, pin, wire and reamer).
- Position the mode selector in the desired mode to allow the handpiece to operate in the REVERSE (REV), OSCILLATE (OSC) or FORWARD (FWD) modes.

View of Mode Selector Facing Front of Handpiece

(Trigger shown in SAFE mode)



Markings on Top of Handpiece

Reverse (R)



Oscillate



Forward (F)



- Rotate trigger to the RUN mode.
- Depress trigger to operate the handpiece.
- If power loss occurs during use, replace the battery pack with a fully charged sterilized battery pack.
- Rotate trigger to the SAFE mode when not in operation.

Warning:

- Irrigation is required during resection in order to prevent heat buildup which could cause bone necrosis.

Troubleshooting

Symptom	Potential Cause	Solution
Handpiece does not start.	Trigger is in safe mode.	Rotate trigger to run mode.
	Battery pack is not installed.	Install battery pack.
	Battery pack is not installed fully.	Remove and reinstall battery pack.
	Battery pack is discharged.	Charge or replace battery pack.
	Mode selector is not engaged.	Position mode selector in REV, OSC or FWD mode.
	Trigger is activated too slowly.	Increase activation rate.
	Handpiece has electrical/mechanical malfunction.	Send handpiece to Brasseler U.S.A. Medical, LLC, for service.
Handpiece lacks power.	Battery pack is discharged.	Charge battery pack.
	Battery pack is malfunctioning.	Replace battery pack.
	Reaming attachment is malfunctioning; has faulty bearings.	Replace attachment.
	Variable speed throttle is out of adjustment.	Send handpiece to Brasseler U.S.A. Medical, LLC, for service.
	Drill attachment used for reaming applications.	Use reamer attachment.
Handpiece stops during use.	Battery pack is discharged.	Charge or replace battery.
	Circuit protection is activated due to excessive loading.	Release trigger to reset circuit protection.
Handpiece runs after trigger is released.	Trigger is malfunctioning.	Send handpiece to Brasseler U.S.A. Medical, LLC, for service.

Troubleshooting (continued)

Symptom	Potential Cause	Solution
Attachment will not connect properly to handpiece.	There is debris in the handpiece collet.	See cleaning recommendations.
	Attachment release tabs are damaged.	Replace attachment.
Difficulty/Cannot remove attachment from handpiece.	Attachment release tabs are not fully depressed.	Depress both release tabs fully.
	Handpiece was sterilized with attachment installed.	See cleaning recommendations. If condition continues, send handpiece to Brasseler U.S.A. Medical, LLC, for service.
Attachment will not hold reamers or drills.	Attachment collet is worn.	Replace attachment.
	There is debris in the attachment collet.	See cleaning recommendations.
	Wrong attachment.	Use correct attachment.
Attachment and/or cutting accessory wobbles in handpiece.	Incorrect attachment used.	Insert correct attachment.
	Cutting accessory or wire/pin is bent, extends too far from the distal end of attachment, is the wrong size, is worn or is not properly centered in the attachment.	Reinsert the cutting accessory, wire or pin. If condition continues, send handpiece and attachment to Brasseler U.S.A. Medical, LLC, for service.
Pin/Wire slips or will not advance.	The pin/wire size is incorrect.	Check that pin/wire size is correct size for pin/wire driver.
	The attachment collet is worn.	Send attachment to Brasseler U.S.A. Medical, LLC, for service.
	The lever force is inadequate.	Pull driver lever fully for maximum gripping force.
Pin/Wire driver lever won't depress.	There is debris in the attachment collet.	Send attachment to Brasseler U.S.A. Medical, LLC, for service.

Troubleshooting (continued)

Symptom	Potential Cause	Solution
Pin/Wire is not retained in the attachment.	The pin/wire size is incorrect.	Check that pin/wire size is correct size for pin/wire driver.
	The attachment collet is worn.	Send attachment to Brasseler U.S.A. Medical, LLC, for service.
	There is debris in the attachment collet.	See cleaning recommendations.
Battery pack will not connect properly to handpiece.	There is debris in the battery receptacle.	See cleaning recommendations.
	Battery pack contacts are damaged.	Replace battery pack.
	Battery pack latch is damaged.	Replace battery pack.
	Handpiece battery receptacle is damaged.	Send handpiece to Brasseler U.S.A. Medical, LLC, for service.
Battery pack cannot be removed from handpiece.	Battery pack latch is damaged.	Send handpiece and battery pack to Brasseler U.S.A. Medical, LLC, for service.
	Handpiece battery receptacle is damaged.	Send handpiece and battery pack to Brasseler U.S.A. Medical, LLC, for service.

Care & Maintenance

Brasseler USA® Surgical Power & Accessories recommends that all BSPMAX™ II components (handpieces, attachments and accessories excluding battery packs) be returned to Brasseler U.S.A. Medical, LLC, Service Department for routine preventative maintenance every twelve (12) months.

Follow a regular care regimen that includes routine cleaning and a thorough inspection for damage.

Routine preventive maintenance performed every twelve (12) months by the Brasseler U.S.A. Medical, LLC, Service Department can increase the reliability and extend the life of your BSPMAX™ II Large Bone Power System.

Checklist:

- Inspect all BSPMAX™ II components (handpieces, attachments and accessories) to verify all components are present.
 - Ensure all handpieces, attachments and accessories have been properly cleaned as outlined in the Cleaning Recommendations section.
 - Inspect all devices for proper set up and operation.
 - Ensure all attachments install properly.
 - Ensure the battery pack installs properly onto the handpiece.
 - Ensure the drills, pins, wires and reamers work properly with attachments.
 - Ensure there are no loose or missing components.
 - Ensure there are no cracks in the battery pack case.
 - Test* the handpiece and battery pack to ensure that they are working properly.
 - Check all moving parts for free movement.
 - Check for unusual sounds or vibrations.
 - Check for proper operating speed.
 - If the recommended solutions provided in the Troubleshooting section do not solve problem(s), send the device(s) to Brasseler U.S.A. Medical, LLC, Service Department as outlined in the Repair Service section.
 - Remove battery pack from handpiece when test is completed.
- * This maintenance test may be completed under non-sterile conditions with a battery pack that has not been sterilized.

Cleaning Recommendations

Warnings:

- Clean and sterilize handpieces, attachments, battery packs and accessories before every use.
- Remove attachment and battery pack from handpiece prior to cleaning and sterilization.
- DO NOT sterilize 4-Bay Power Unit, Charging Bay Cover and Charging Bay.
- Prior to cleaning and sterilization, remove cutting accessory (drill, pin, wire and reamer) from attachment and remove attachment and battery pack from the handpiece.
- DO NOT use solvents, lubricants, or other chemicals, unless otherwise specified.

Cautions:

- Follow universal precautions and protective apparel when handling and cleaning contaminated instruments.
- Dispose of all cutting accessories properly after each use.
- DO NOT lubricate handpieces or attachments.
- DO NOT immerse handpieces, attachments and battery packs in liquid. Contaminants will enter the equipment and damage the device.
- DO NOT clean handpieces, attachments or battery packs in an automated washer or ultrasonic cleaner.
- DO NOT clean handpieces with bleach, chlorine-based detergents, liquid or chemical disinfectants, or any products containing sodium hydroxide (e.g. INSTRU-KLENZ® or Buell® Cleaner). They will degrade the anodized aluminum coating.

Cleaning Recommendations (continued)

Cleaning Procedures:

1. Remove battery pack and attachment from the handpiece.
2. Remove cutting accessories from attachment.
3. Scrub debris from the handpiece using a brush with stiff, non-metallic bristles and mild, pH balanced enzymatic cleaner. Manipulate all moving parts of the handpiece to ensure all debris is removed. Use a bottle brush to clean the entire cannula in the handpiece. Pull the wire end of the bottle brush through the cannula and repeat until all debris is removed.
4. Rinse all external surfaces of the handpiece under running tap water. Hold the handpiece upright to prevent water from running into the battery receptacle. Flush the cannula in the handpiece with running tap water.
5. If water leaks into the handpiece, hold handpiece upright to allow drainage from the battery receptacle area.
6. Visually inspect the handpiece for any remaining debris. If any debris is present, repeat the cleaning and rinsing procedure.
7. Gently shake the handpiece free of water.
8. Dry the handpiece with a clean lint-free soft cloth.
9. Inspect handpiece for damage and malfunctioning. Return damaged components to Brasseler U.S.A. Medical, LLC, Service Department.
10. Place handpieces, attachments and chuck keys into designated locations in the tray and place tray into sterilization case. Fasten sterilization case lid.
11. Sterilize as directed. See Sterilization Recommendations section.

Sterilization Recommendations

Steam sterilization has been found both safe and effective for the sterilization of Brasseler USA® BSPMAX™ II Large Bone Power System handpieces, attachments and battery packs. The instruments are capable of withstanding the recommended exposure times and temperatures of steam sterilization.

Warnings:

- The use of disinfecting solutions for an exterior instrument wipe will not sterilize equipment and is not recommended.

Cautions:

- DO NOT sterilize handpieces with Ethylene Oxide (ETO).
- DO NOT sterilize handpieces in a STERIS® System, STERRAD® System or comparable sterilization methods.
- DO NOT sterilize handpieces in cold sterilization like CIDEX®.
- DO NOT “peel pack” handpieces or attachments for sterilization. Sterilization in a sealed pouch traps moisture which can cause damage.
- DO NOT sterilize attachment while connected to the handpiece.
- DO NOT sterilize battery pack while connected to the handpiece.
- Do not Flash Sterilize. It can decrease the life of the device and may cause premature failure of the device. Flash sterilization will void the warranty.

Notes:

- These processes have been validated as being capable of cleaning and sterilizing the BSPMAX™ II Drill Reamer.
- The sterilizer manufacturer’s written instruction for cycle parameters, load configuration and AAMI guidelines for steam sterilization should be followed.

Sterilization Recommendations (continued)

Parameters for Sterilizing BSPMAX™ II Modular/Drill Reamer

Sterilization Type	Minimum Temperature	Minimum Exposure Time	Dry Time
Pre Vacuum (Wrapped)	270° F (132° C)	4 Minutes	15-30 Minutes
Pre Vacuum (Wrapped)	273° F (134° C)	3 Minutes	15-30 Minutes
Gravity (Wrapped)	250° F (121° C)	100 Minutes	15-30 Minutes
Gravity (Wrapped)	270° F (132° C)	60 Minutes	15-30 Minutes

To Sterilize Battery Packs

See instructions for use provided with battery packs.

Specifications

1. Performance

	With 9.6V Battery Pack PM-X00-710	With 12V Battery Pack PM-X00-715
Drill Speed Range	0-900 rpm	0-1200 rpm
Drill Stall Torque	40 in.-lb. (4.5 Nm)	40 in.-lb. (4.5 Nm)
Reamer Speed Range	0-290 rpm	0-390 rpm
Reamer Torque	100 in.-lb. (11.3 Nm)	100 in.-lb. (11.3 Nm)
Duty Cycle	1 minute ON/ 5 minutes OFF, 5 times with a 3 hour rest.	
Electrical Safety	Internally powered equipment.	

2. Physical Characteristics

Size (L x W x H)	5.75 x 1.25 x 5.9 in. (146 x 32 x 150 mm)
Weight	2.0 lb. (.9 kg)

3. Environmental Requirements

Operating:



- Ambient temperature : 50°F to 70°F (10°C to 21°C)
- Relative Humidity 30% - 75%
- Atmospheric Pressure: 700hPa to 1060hPa

Transport :



- Ambient temperature : -4°F to 158°F (-20°C to 70°C)
- Relative Humidity 10% - 100%
- Atmospheric Pressure: 500hPa to 1060hPa

Specifications (continued)


4. Electromagnetic Compatibility Requirements

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

<p>The BSPMAX™ II handpiece is intended for use in the electromagnetic environment specified below. The user of the BSPMAX™ II handpiece should assure that it is used in such an environment.</p>		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The BSPMAX™ II handpiece 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 BSPMAX™ II handpiece 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 used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations Flicker emissions IEC 61000-3-3	N/A	

Specifications (continued) 4. Electromagnetic Compatibility Requirements continued

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 KHz to 80 MHz</p> <p>3 V/m 80MHz to 2.5 GHz</p>	<p>N/A N/A</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the BSPMAX™ II handpiece, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d=1.67\sqrt{P}$ <p>80 MHz to 800 MHz</p> $d=2.33\sqrt{P}$ <p>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>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1: At 80MHz and 800MHz 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.

Specifications (continued) 4. Electromagnetic Compatibility Requirements continued

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The BSPMAX™ II handpiece is intended for use in the electromagnetic environment specified below. The user of the BSPMAX™ II handpiece 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	±2, 4, 6 KV contact ±2, 4, 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	n/a n/a	
Surge IEC 61000-4-5	±1 KV differential mode ±2 KV common mode	n/a n/a	

Specifications (continued) 4. Electromagnetic Compatibility Requirements continued

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) For 0.5 cycle	n/a	
	40% U_T (60% dip in U_T) For 5 cycles	n/a	
	70% U_T (30% dip in U_T) For 25 cycles	n/a	
	<5% U_T (>95% dip in U_T) For 5 sec	n/a	
Power frequency (50/60Hz) 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 1: U_T is the alternating current mains voltage prior to application of the test level.

Specifications (continued) 4. Electromagnetic Compatibility Requirements continued

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Recommended separation distances between portable and RF communications equipment and the BSPMAX™ II handpiece.			
The BSPMAX™ II handpiece is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The user of the BSPMAX™ II handpiece can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BSPMAX™ II handpiece as recommended below, according to the maximum output power of the communications equipment.			
Related maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 KHz to 80 MHz $d = \left[\frac{3.5}{V_f} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_f} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_f} \right] \sqrt{P}$
0.01	n/a	0.12	0.23
0.1	n/a	0.37	0.74
1	n/a	1.17	2.33
10	n/a	3.70	7.37
100	n/a	11.70	23.30

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.

Repair Service

Brasseler USA® Surgical Power & Accessories recommends that the BSPMAX™ II handpieces, attachments and accessories (excluding battery packs) be returned to Brasseler U.S.A. Medical, LLC, Service Department for routine preventive maintenance every twelve (12) months. Follow a regular care regimen that includes routine cleaning after each use, strict adherence to sterilization recommendations and a thorough inspection for damage of all devices after each use. Routine preventive maintenance performed by the Brasseler U.S.A. Medical, LLC, Service Department can increase the reliability and extend the life of your BSPMAX™ II Large Bone Power System.

Brasseler USA® Surgical Power & Accessories warrants any service or repair work performed will be free from defects in material or workmanship for the period of ninety (90) days from date of service or repair. This warranty applies to the actual work performed.

Products must be decontaminated and sterilized before returning.

Note: It is unlawful to ship contaminated non-sterilized products.

Contact a Customer Service Representative at Brasseler USA® Surgical Power & Accessories at 877-834-7133 to request repair, preventive maintenance, or a loaner instrument. If available, loaner instruments will be supplied in accordance with the Brasseler USA® Surgical Power & Accessories Loaner Program.

Please include the following information with the returned product(s):

- Indicate on the paperwork or the box the designated call ID number.
- When returning products from outside the U.S. please indicate on shipping documents per Customs requirements the following: "U.S. manufactured goods returned for factory service/repair".
- Catalog number, serial number and lot number (if applicable) of device.
- Customer name, address and account number.
- Itemized packing list.
- Brief statement describing reason for product repair or requesting preventive maintenance.

Return to:

***Brasseler U.S.A. Medical, LLC
4837 McGrath Street
Ventura, CA 93003***

Warranty

Brasseler USA® Surgical Power & Accessories warrants all BSPMAX™ II Handpieces, Attachments and Accessories excluding Battery Packs to be free from defects in material and workmanship for a period of one (1) year from the invoice date. Battery Packs are warranted to be free from defects in material and workmanship for a period of ninety (90) days from the invoice date. The warranty is limited to the repair of the product without charge. This warranty is nontransferable. In addition, this warranty is void in the event of any of the following: abuse, misuse, neglect or use in other than normal surgery environment, disassembly, alteration or unauthorized repair, or in the event that the product has not been used in reasonable manner and in compliance with the written instructions provided by Brasseler USA® Surgical Power & Accessories.

Return Goods Policy

If product needs to be returned, the following applies:

Consumable/Disposable Product:

Any unused consumable/disposable product may be returned for credit within ninety (90) days of invoice date if it qualifies for resale (unopened and unmarked package). Products may be subject to a restocking fee. Credit will not be issued for products that do not qualify for resale.

Capital Equipment:

Any unused capital equipment may be returned for credit within thirty (30) days of invoice date if it qualifies for resale (unopened and unmarked package). Products may be subject to a restocking fee. Credit will not be issued for products that do not qualify for resale.

Packaging and Shipping:

Returned items should be packaged in original packaging. Credit will not be issued for items damaged in return shipment due to packaging inadequacy.

Note: It is unlawful to ship contaminated non-sterilized products.

Contact a Customer Service Representative at Brasseler USA® Surgical Power & Accessories at 800-535-6638 to obtain a "Return Merchandise Authorization" (RMA) number.

Please include the following information with the returned product(s):

- Catalog number, serial number and lot number (if applicable) of device.
- Return Merchandise Authorization (RMA) number noted with the return.
- Original invoice number or copy of original invoice.
- Original invoice date.
- Customer name, address and account number.
- Itemized packing list.
- Brief statement describing reason for product return.

Return to:

***Brasseler U.S.A. Medical, LLC
4837 McGrath Street
Ventura, CA 93003***

Product Disposal

Dispose of product or recycle in accordance with local laws and regulations.

Product Ordering Information

HANDPIECES

PM-X08-700	MODULAR DRILL/REAMER
PM-X12-700	SAGITTAL/OSCILLATOR SAW
PM-X14-700	RECIPROCATOR/STERNUM SAW

ATTACHMENTS - DRIVERS

PM-X08-701	PIN DRIVER
PM-X08-702	WIRE DRIVER

ATTACHMENTS - DRILLS

PM-X08-905	TRINKLE/AO®
PM-X08-910	1/4 IN JACOBS® CHUCK W/ KEY
PM-X08-915	5/32 IN JACOBS® CHUCK W/ KEY
PM-X08-920	HUDSON®
PM-X08-925	ZIMMER®
PM-X08-930	1/4 IN KEYLESS CHUCK
PM-X08-935	3 MM KEYLESS CHUCK
PM-X08-940	ZHS - ZIMMER®/HUDSON®/STRYKER® UNIVERSAL

ATTACHMENTS - REAMERS

PM-X08-911	1/4 IN JACOBS® HI TORQUE W/ KEY - EXTENDED LENGTH
PM-X08-950	HUDSON® - EXTENDED LENGTH
PM-X08-955	ZIMMER® - EXTENDED LENGTH
PM-X08-960	AO® - EXTENDED LENGTH
PM-X08-965	ZHS - ZIMMER®/HUDSON®/STRYKER® UNIVERSAL - STANDARD LENGTH
PM-X08-970	1/4 IN JACOBS® HI TORQUE W/ KEY - STANDARD LENGTH

ATTACHMENT - STERNUM SAW GUARD

PM-X14-901	STERNUM SAW GUARD
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ACCESSORIES

PM-X00-520	4-BAY POWER UNIT 110V
PM-X00-521	CHARGING BAY COVER
PM-X00-522	4 BAY POWER UNIT 230V
PM-X00-710	9.6V BATTERY PACK
PM-X00-715	12V BATTERY PACK
PM-X00-731	STANDARD BATTERY PACK CHARGING BAY
PM-X00-770	STERILIZATION CASE – 3 HANDPIECES
PM-X08-000	1/4 IN JACOBS® CHUCK KEY
PM-X08-001	5/32 IN JACOBS® CHUCK KEY

BRASSELLER USA® SURGICAL POWER & ACCESSORIES OFFERS A COMPLETE LINE OF CUTTING ACCESSORIES (SAW BLADES/RASPS, BURS, K-WIRES, STEINMANN PINS, TWIST DRILLS AND ORTHOPAEDIC PIN PACKS).



Brasseler U.S.A. Medical, LLC
One Brasseler Boulevard • Savannah, GA 31419
800-535-6638 • 912-921-7578 (fax)
BrasselerUSAMedical.com

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