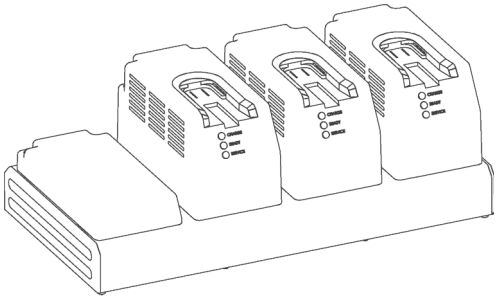
TAVA SURGICAL™
SURGICAL POWER & ACCESSORIES

OPS GEN II™

FOUR STATION MODULAR BATTERY CHARGER



4-BAY POWER UNIT

PM-X00-520

Standard Battery Pack Charging Bay

PM-X00-731

CE 0470

Instructions for Use

R_x Only

Table of Contents

Introduction

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 Tava™ OPS Gen II™ Large Bone Power System.

Intended Use

The OPS Gen II™ 4-Bay Power Unit, PM-X00-520 is a unit designed to accept up to four modular Standard Battery Pack Charging Bays, PM-X00-731. The modular standard battery pack charging bay is intended to charge OPS Gen II™ 9.6V Battery Pack, PM-X00-710 and 12V Battery Pack, PM-X00-715.

Warnings ⚠

- Only trained and experienced medical professionals should use this equipment. Failure to comply with the OPS Gen II™ Instructions for Use may result in patient and/or medical staff injury.
- DO NOT use if damage is apparent.
- Use of Eye protection is required while operating equipment.

- DANGER - Explosion Hazard. DO NOT use in atmospheres containing flammable gasses (anesthetics, etc) with concentrations within explosive limits.
- Clean 4-Bay Power Unit and Charging Bay before use.
- DO NOT modify the 4-Bay Power Unit or the Charging Bay.
- DO NOT use 4-Bay Power Unit in the presence of explosive gases.
- DO NOT use this equipment in the presence of flammable anesthetic and air, or with oxygen or nitrous oxide.
- Always use the appropriate charging bay when charging battery packs. Failure to comply may result in patient and/or medical staff injury.
- DO NOT operate the 4-Bay Power Unit with a damaged power cord or plug.
- DO NOT modify the ground of the 4-Bay Power Unit power cord.
- Install the power cord of the 4-Bay Power Unit directly into electrical outlet.
- DO NOT disassemble or service the 4-Bay Power Unit or Charging Bay. Return to Tava™ for service or repair. Failure to comply may result in electric shock or fire.

- Always disconnect the power cord from the 4-Bay Power Unit before performing cleaning to reduce the risk of electric shock.
- Install and place the 4-Bay Power Unit into service according to the EMC information in this manual. Portable and Mobile RF communications equipment can affect the function of the 4-Bay Power Unit.

Cautions

- DO NOT sterilize the 4-Bay Power Unit or Charging Bays.
- DO NOT connect 4-Bay Power Units in series.
- REMOVE battery packs from Charging Bays when 4-Bay Power Unit is off to avoid battery discharge.

Explanation of Symbols

Attention, refer to instructions for use.

Eye Protection required.

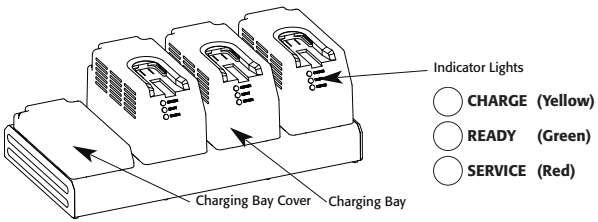
Indicates product should not be immersed in any fluid.

Interference.

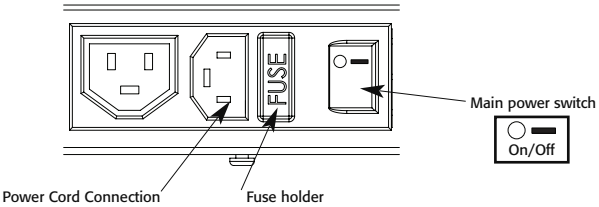
No user service recommended. Refer to Repair Service.

Temperature Ranges.

Features



Power Connection



- Power Connection – Connects and disconnects Power Unit from facility power. Power connection contains:
  - *Fuse Holder*
  - *Main Power Switch*
  - *Power Cord Connection*
- Charging Bay – Modular battery charging bay for OPS Gen II™ battery packs. Power Unit will accept up to four (4) Charging Bays.
- Charging Bay Cover – Shields Power Unit's cooling fan and Charging Bay connector when not in use. Cover should only be removed when installing a Charging Bay.
- Indicator Lights – Provide battery status information when illuminated.
  Charge - Yellow – Battery Pack is charging.
  Ready - Green – Battery Pack is fully charged and ready for use.
  Service - Red – Charging cycle failed.

Charging Bay – PM-X00-731

The 4-Bay Power Unit can be configured with a combination of Charging Bay(s) and Bay Cover(s). The 4-Bay Power Unit (PM-X00-520), Standard Battery Pack Charging Bay (PM-X00-731) and Charging Bay Cover (PM-X00-521) are sold separately. The power unit charges up to four battery packs simultaneously.

Cautions:

- DO NOT over tighten screws.
- DO NOT connect power cord to the electrical connector inside the charging bay.

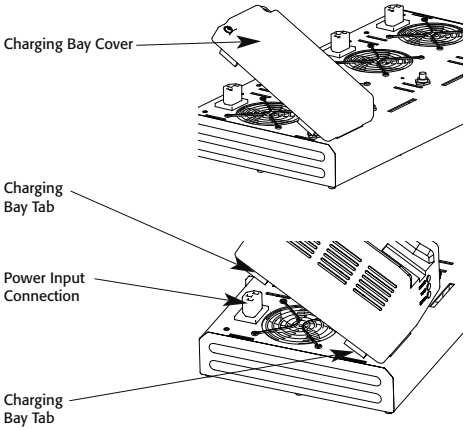
Tool Required:

- Standard Phillips #2 (medium size) Screwdriver.

Installation & Removal

Charging Bay Installation:

- Loosen screws and remove Charging Bay Cover.
- Align front Charging Bay tab with Power Unit slot.
- Lower the Charging Bay into the corresponding side slots and power input connection. Ensure Charging Bay tabs are aligned with Power Unit slots.
- Apply light force to seat fully.
- Tighten screws with screwdriver.
- Verify that the Charging Bay is flush with the top surface of the 4-Bay Power Unit and that the front tab is engaged into power slot.
- Standard Phillips #2 (medium size) Screwdriver.



Charging Bay Removal:

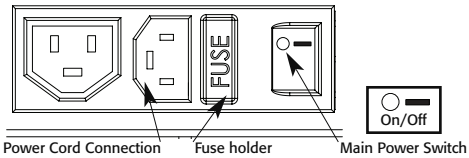
- Loosen Screws.
- Remove Charging Bay.
- Install Charging Bay Cover (PM-X00-521).

4-Bay Power Unit – PM-X00-520

The 4-Bay Power Unit can be configured with a combination of Charging Bay(s) and Bay Cover(s). The 4-Bay Power Unit (PM-X00-520), Standard Battery Pack Charging Bay (PM-X00-731) and Charging Bay Cover (PM-X00-521) are sold separately. The power unit charges up to four battery packs simultaneously.

4-Bay Power Unit Fuse Replacement

1. Set the main power switch to OFF (O).
2. Disconnect the power cord.
3. Squeeze and pull out the fuse holder.
4. Replace with two (2) T6.3A (250V) fuses.
5. Replace fuse holder.
6. Connect the power cord.
7. Set the main power switch to ON (-).



4-Bay Power Unit Operation

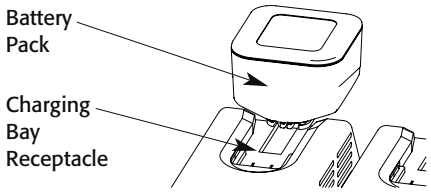
1. Set the main switch to the OFF position (O).
2. Connect the female end of the power cord to the power cord connection on the back of the power unit.
3. Connect the male end of the power cord to the wall outlet.
4. Activate 4-Bay Power Unit by depressing the main power switch to the ON position (-). Indicator lights will pulse when Power unit is activated. Indicator lights will illuminate when a Batter Pack is inserted.

Battery Pack Charging

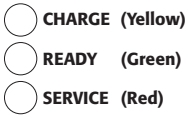
1. Insert battery pack into a charging bay receptacle.

2. Follow warnings, cautions and notes in OPS Gen II™ PM-X00-710 (9.6V) & PM-X00-715 (12V) Battery Packs Instructions for Use.

3. A single light will illuminate to indicate battery pack status.



- All pulse - System is powered on.
- Yellow (pulsing) - Primary diagnostic test to determine voltage level.
- Yellow (solid) - Battery Pack is charging.
- Green (solid) - Battery Pack is charged and ready for use.
- Red (pulsing) - Secondary diagnostic test to determine charging capacity.
- Red (solid) - Charging cycle failed and battery pack should be discarded.



Troubleshooting

Symptom	Potential Cause	Solution
Fans and indicator lights do not function.	Power cord not connected.	Connect power cord.
	Power unit is turned OFF (O).	Turn power switch On (-).
	Fuses are open/blown or missing.	Replace with appropriate rated fuses. See 4-Bay Power Unit fuse replacement.
	No power at electrical outlet.	Check circuit breaker.
Charging bay fan does not function.	Charging bay is not installed correctly.	See installation and removal.
Indicator lights do not function on charging bays.	Charging bay is not installed correctly.	See installation and removal.
	Power unit fuses are open/blown.	Send charging bay to Tava™ for service.
	Battery pack is not seated properly or is not aligned with contacts.	See Instructions for Use.
	Charging contacts are dirty.	See cleaning recommendations.
	Battery pack malfunctions.	Replace battery pack.

Troubleshooting (continued)

Symptom	Potential Cause	Solution
After inserting battery pack into charging bay, red light illuminates.	Charging contacts are dirty.	See cleaning recommendations.
	Battery pack is at elevated temperature.	Allow to cool for 20 minutes, then reinsert into charging bay.
	End of life cycle for battery pack.	Replace battery pack.
	Battery pack is improperly sterilized.	Replace battery pack.
Charging bay will not fully connect onto power unit.	Misalignment of electrical plug.	Send power unit and charging bay to Tava™ for service.
	Electrical plug blades bent.	Send charging bay to Tava™ for service.
Indicator lights remain illuminated when battery pack is not installed.	Charging bay malfunctioned.	Send charging bay to Tava™ for service.
There is a recurring power unit open/blown fuses.	Charging board circuit failed.	Send power unit to Tava™ for service.
	Fuses have wrong rating.	Replace with appropriate rated fuses. See 4-bay power unit fuse replacement.
	A power surge occurred.	Install power surge suppressor.
Indicator light does not illuminate when battery pack is installed.	Charging bay malfunctioned.	Send charging bay to Tava™ for service.
	Fuses are open/blown or missing.	Replace with appropriate rated fuses. See 4-bay power unit fuse replacement.
	Power cord not connected.	Connect power cord.
	Power unit is turned off (o).	Turn power switch on (-).
	No power at electrical outlet.	Check circuit breaker.

Care & Maintenance

Tava™ recommends that all OPS Gen II™ components (handpieces, attachments and accessories excluding battery packs) be returned to Tava™ Service Department for routine preventive 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 Tava™ Service Department can increase the reliability and extend the life span of your OPS Gen II™ Large Bone Power System.

Cleaning Recommendations

General Cleaning Precaution:

- Follow universal precautions and protective apparel when handling and cleaning contaminated instruments.

Warnings: ⚠

- DO NOT use if damage is apparent.
- DO NOT use 4-Bay Power Unit in the presence of explosive gases.
- Always use the appropriate Battery Pack Charging Bay when re-charging battery packs.
- DO NOT operate the 4-Bay Power Unit with a damaged power cord or plug.
- DO NOT disassemble or service the 4-Bay Power Unit. Return to Tava™ Service Department.

Cautions:

- DO NOT immerse the 4-Bay Power Unit or Charging Bays in liquid.
- DO NOT use solvents, lubricants, or other chemicals to clean the 4-Bay Power Unit or Charging Bays unless otherwise directed.
- DO NOT allow water to collect on the 4-Bay Power Unit or Charging Bays.
- DO NOT sterilize the 4-Bay Power Unit or Charging Bays.
- DO NOT clean the charging contacts with abrasives.
- Prior to changing fuses, set power unit main switch to OFF (O), then disconnect power cord.
- DO NOT use in operating rooms or locations with explosive gases.
- DO NOT connect 4-Bay Power Unit in series.

Notes:

- Remove battery packs from charging bays when 4-Bay Power Unit is off to avoid battery discharge.

Cleaning Recommendations (continued)

Cleaning Procedures:

1. Set the main power switch to OFF(O).
2. Remove all battery packs.
3. Disconnect the 4-Bay Power Unit power cord from the outlet.
4. Wipe the external surfaces of the 4-Bay Power Unit and Charging Bays with a clean lint-free soft cloth lightly dampened with a non-abrasive hospital disinfectant.
5. Dry immediately with a clean lint-free soft cloth.
6. Clean charging contacts using a cotton swab lightly with isopropyl alcohol. DO NOT clean the charging contacts with abrasives.
7. Ensure equipment is completely dry before reconnecting to power.
8. Inspect for damage or malfunctioning.
   Return damaged components to Tava™ Service Department.

Specifications

1. Performance

Input Voltage	100VAC – 120VAC
Max. Rated Current	10A
Frequency	50 – 60 Hz
Output Voltage Max.	15VDC
Classification	Protection Class 1
Class of Rating	Continuous operation
Socket Outlet	5A 100 – 120V ~ 50/60 Hz

2. Physical Characteristics

4-Bay Power Unit with 4 charging bays

Size	17″ x 8 5/8″ x 6 1/4″
Weight	16.75 lb

Charging Bay

Size	7 1/2″ x 3 1/2″ x 4″
Weight	1.8 lb

4-Bay Power Unit

Size	17″ x 8 5/8″ x 2 1/4″
Weight	9.55 lb

Specifications (continued)

3. Compliance Standards

EMC Compliance Standards: DN60601-1-2; IEC60601-1; CSA 60601.1
Safety Compliance: EN60950-1; IEC60950-1; CSA 60950-1; UL 60950-1
C US

4. Environmental Requirements

Operating:

- Ambient temperature : 50°F to 104°F (10°C to 40°C)
- Relative Humidity 30% - 75%
- Atmospheric Pressure: 700hPa to 1060hPa

Transport :

- Ambient temperature : -04°F to 158°F (-20°C to 70°C)
- Relative Humidity 10% - 100%
- Atmospheric Pressure: 500hPa to 1060hPa

Specifications (continued)

5. Electromagnetic Compatibility Requirements

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The OPS GEN II™ battery charger is intended for use in the electromagnetic environment specified below. The user of the OPS GEN II™ battery charger should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The OPS GEN II™ battery charger 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 A	The OPS GEN II™ battery charger 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	Class A	
Voltage fluctuations Flicker emissions IEC 61000-3-3	Complies	

Specifications (continued) 5. Electromagnetic Compatibility Requirements continued

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

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

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) 5. Electromagnetic Compatibility Requirements continued

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The OPS GEN II™ Battery Charger is intended for use in the electromagnetic environment specified below. The user of the OPS GEN II™ Battery Charger 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	±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.

Specifications (continued) 5. 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	100% Reduction (10 ms)	
	40%U_T (60% dip in U_T) For 5 cycles	60% Reduction (100 ms)	
	70%U_T (30% dip in U_T) For 25 cycles	30% Reduction (500 ms)	
	<5%U_T (>95% dip in U_T) For 5 sec	95% Reduction (5 sec)	
Power frequency (50/60Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m At 50 Hz	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) 5. Electromagnetic Compatibility Requirements continued

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Recommended separation distances between portable and RF communications equipment and the OPS GENII handpiece.			
The OPS GEN II™ Battery Charger is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The user of the OPS GEN II™ Battery Charger can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OPS GEN II™ Battery Charger 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 $d=[\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d=[\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d=[\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	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.

Warranty

Tava™ Surgical Power & Accessories warrants OPS Gen II™ 4-Bay Power Unit and Charging Bay to be free from defects in material and workmanship for a period of two (2) years from the invoice date.

The warranty is limited to the repair of the product without charge.

This warranty is void in the event of any of the following: abuse, misuse 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 Tava™ Surgical Power & Accessories.

Repair Service

Tava™ recommends that OPS Gen II™ 4-Bay Power Unit and Charging Bay be returned to Tava™ Service Department for routine preventive maintenance every twelve (12) months. Follow a regular care regimen that includes routine cleaning after each use and a thorough inspection for damage after each use. Routine preventive maintenance performed by the Tava™ Service Department can increase the reliability and extend the life of your OPS Gen II™ Large Bone Power System.

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

Contact a Customer Service Representative at Tava™ at 800-535-6638 to request repair, preventive maintenance, or a loaner instrument. If available, loaner instruments will be supplied in accordance with the Tava™ Loaner Program.

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

- 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:
Tava™
Service Department
4837 McGrath Street
Ventura, CA 93003

Return Goods Policy

Tava™ unconditionally guarantees the quality of each of our products, their performance and your satisfaction with those products.

If product needs to be returned, the following applies:

Capital Equipment:
Capital equipment returned for credit must be received within thirty (30) days of invoice date and qualifies for resale (prior to a credit being issued) or may be subject to an additional restocking fee. Credit will be issued for incorrectly ordered product and incorrect product shipped. Capital equipment that has been used does not qualify for resale and credit will no be issued.

Packaging and Shipping:
Package items in original packaging, as 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 Tava™ 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:
Tava™
4837 McGrath Street
Ventura, CA 93003

Product Disposal

Contact Tava™ before disposing of any product.

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" JACOBS CHUCK w/ KEY
PM-X08-915	5/32" JACOBS CHUCK w/ KEY
PM-X08-920	HUDSON
PM-X08-925	ZIMMER
PM-X08-930	1/4" KEYLESS CHUCK
PM-X08-935	3MM KEYLESS CHUCK
PM-X08-940	ZHS(Zimmer®/Hudson/Stryker Universal®)

ATTACHMENTS - REAMERS

PM-X08-911	1/4" JACOBS HIGH 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" JACOBS HIGH TORQUE w/ KEY (Standard Length)

ATTACHMENT - STERNUM GUARD

PM-X14-901	STERNUM SAW GUARD

ACCESSORIES

PM-X00-520	4-BAY POWER UNIT
PM-X00-521	CHARGING BAY COVER
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

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