Medtronic

REF EC300

User's Guide

Integrated Power Console (IPC™) System

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Location: Moldova
MOLDOVA EUROPEANĂ

℞Only

Symbols

On/Off Button

Package Contents

Follow Instructions For Use

Conforms to ANSI/AAMI ES60601-1, Certified to CAN/CSA-C22.2 No.60601-1, IEC/EN 60601-1

EMC Compliance Mark

Do Not Oil

Do Not Immerse

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

Fuse

IPX1

Protected Against Vertical Water Drops

Oscillate

Authorized Representative in the European Community

Use By Date

IPX7

Protected Against The Effects Of Temporary Immersion In Water

F

Forward

Precaution: Pinch Hazard. Keep Fingers Clear Of Rollers

ACC

Accessory

IPX8

Protected Against The Effects Of Temporary Immersion In Water

R

Reverse

PHT DEHP

Contains DEHP (di-2-ethyl hexyl phthalate)

AC Power

Type BF Applied Part

Foot Pedal Connector

Protective Earth

Output

Start/Stop

Fine Irrigant Adjustment

Equipotential Ground Connector

Is Approximately Equal To

RF Transmitter (Interference May Occur)

Left Foot Control Unit Button / Mode Button

Use With

STERILE

Non-Sterile

Consult Instructions for Use

Right Foot Control Unit Button / Control Button

RoHS - Environmental friendly use period - China (SJ/T11364-2006)

NON STERILE

Non-Sterile

BUR

Stim Bur Connector

Quantity

NIM

NIM Console Connector

Top Foot Control Unit Button / Handpiece Button

Do Not Dispose Of This Product In The Unsorted Municipal Waste Stream. Dispose Of This Product According to Local Regulations. See **Recycling.Medtronic.com** for Instructions On Proper Disposal Of This Product.

>120 VAC

Not Greater Than 120vac

EHS

Electrical High Speed Handpiece Connector

Locked

If the single use symbol is on the device label then this device is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.

Caution

Fr

World Wide Standard for Medical Tubing Diameter

Unlocked

ON <120s OFF >180s

Applied Part Duty Cycle

Date of Manufacture

Handpiece

Accessory

Adapter

Attachment

Bone Mill

Brush

Control Unit

Dissecting Tool

Instrument Case

Lubricant/Diffuser

Motor

Multi-Use Disposable Attachment

Regulator

REF

Catalog Number

Manufacturer

1

Pump Head 1

LOT

Lot Number

Temperature Limitation

Outer Limits = Transport

Inner Limits = Use

2

Pump Head 2

SN

Serial Number

Ergonomically Engineered

REFURBISHED

Refurbished

!USA

USA Only

Speed Range

<NNNN min

For use up to "NNNN" RPM

Table of Contents

IPC™ System

Glossary

The following words and acronyms may be used in this guide.

FCU	Foot Control Unit
FWD	Forward - Rotation is clockwise
I.V.	Intravenous
IPC™	Integrated Power Console
OSC	Oscillate
REV	Reverse - Rotation is counter-clockwise
Tool	Surgical cutting device
Motor	Handpiece/drill
Accessory	Any compatible product that can be used with the IPC™
Attachment	Any compatible product that can be secured to a handpiece

Indications for use

The IPC™ is indicated for the incision/cutting, removal, drilling, and sawing of soft and hard tissue and bone, and biomaterials in Neurosurgical (Cranial, Craniofacial), Orthopedic, Arthroscopic, Spinal, Sternotomy, and General surgical procedures.

Device description

The IPC™ System is a powered drill and saw system that will remove soft tissue, hard tissue and bone during surgical procedures. The system consists of a power control console, foot pedal, connection cables and assorted handpieces to drive various burs, blades, drills, rasps, cannulae and saws. It includes integrated irrigation pumps for irrigation of blades, burrs and for motor or attachment coolant.

Contraindications

The IPC™ System is contraindicated for arthroscopic microdiscectomy in individuals with the following:

- Severe/progressive neurological deficits
- Cauda equine syndrome
- Active infection

Arthroscopic microdiscectomy is not indicated for individuals with sequestered disc fragments, discogenic pain, internal disc destruction, or lumbago.

Additional IPC™ configurations

Additional IPC™ configurations are available. Refer to the following User's Guides for related information.

- IPC™ System Model: 1898001 (CFN 1898851)
- IPC™ System Model: 2340000 (User's Guide M976332A001)

Consult the appropriate User's Guide for indications, contraindications, warnings, and component information specific to each system.

Warnings

System warnings

W1 It is important that the IPC™ system operator be familiar with the system User's Guide, its precautions, procedures and safety issues.

W2 Do not use the IPC™ system in the presence of flammable anesthetics. Avoid potential ignition or explosion of gases.

W3 To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.

W4 To avoid the risk of electrical shock, achieve electrical grounding reliability with proper connections. Connect the IPC™ system to hospital grade receptacles only.

W5 Do not attach any system component or accessory other than Medtronic approved components to the IPC™ system as this may result in electrical shock, component damage, substandard performance, increased emissions, or decreased immunity.

W6 Disconnect power to the IPC™ system before cleaning the unit to avoid electrical shock.

W7 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 the anesthetized patient.

W8 Do not operate the IPC™ system in the presence of Magnetic Resonance Imaging devices.

W9 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.

W10 The IPC™ system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the IPC™ system should be observed to verify normal operation in the configuration in which it will be used.

W11 Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

W12 Keep NIM™ Muting Probe cable away from IPC™ system cables to prevent unintended EMG interference or muting.

W13 After each procedure, properly clean all reusable system components.

W14 All service must be performed by Medtronic qualified personnel only. Repair and/or modification to the IPC™ system by anyone other than qualified service personnel may significantly compromise the unit's ability to perform effectively and/or void the equipment warranty.

W15 Auxiliary Power Outlet with protective cover is for use with the Hydrodebrider or Bone Mill only. Consult Hydrodebrider and Bone Mill instructions prior to use.

Precautions

P1 Do not kink cables. Inspect cables and pins for cracks, tears or corrosion.

P2 When using a Y-Splitter, only one multifunction foot pedal shall be active at a time.

P3 Do not connect multiple Y-Splitters.

P4 Remove and discard accessories following local regulations for proper disposal of contaminated materials.

System requirements and specifications

Console Specifications

Functional Standards for Electrical Systems

ANSI/AAMI ES60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2005, 2012
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2005, 2012
EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2006, 2014
IEC 60601-1-4	Medical electrical equipment - Part 1: General Requirements for Safety, Part 4: Programmable Electrical Medical Systems	1996, 1999
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	2007, 2014
CAN/CSA C22.2 #60601-1	Medical Electrical Equipment - Part 1: General Requirements for basic safety and essential performance	2005, 2014

Physical Dimensions

Size	277 mm Width x 353 mm Height x 267 mm Depth
Weight	7.3 kg

Operational Environment

Temperature	+10 °C to +33 °C
Humidity	30 % to 75 % RH
Barometric Pressure	700 - 1060 hPa

Transport and Storage Environment

Temperature	-40 °C to +70 °C
Humidity	10 % to 95 % RH
Barometric Pressure	500 to 1060 hPa

Display / Touchscreen

Type	High contrast, digital, graphic color, visible in complete darkness
Resolution	Display 21 cm diagonal, resolution 480 X 640 pixels

Audio Output

Baseline Audio Sound Level 60 dBA minimum SPL (1 m)

Electrical

Input Voltage	100 V-240 V ± 10%
Frequency	50/60 Hz
Power Consumption	500 VA
Auxiliary AC output	200 VA Max.
Internal Fuse	5 x 20 mm T. L. 5 A, 250 V
	Medtronic Xomed P/N 11270066
Duty Cycle for Applied Part	Maximum On Time 120 Seconds
	Minimum Off Time 180 Seconds

System power cords

Region	Part Number	Region	Part Number	Region	Part Number
USA, Barbados, Belize, Bolivia, Canada, Colombia, Ecuador, Venezuela	Standard EA600 or 1895820 6 meter EA650 or 1897821	United Kingdom, Ireland, Hong Kong, Malaysia, Singapore	EA606	Austria, Belgium, Finland, France, Germany, Greece, Korea, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden	EA602 or 1895822
China	EA604	India, South Africa	EA607	Switzerland	EA601
Argentina	EA608	Israel	EA609	Denmark	EA610
Australia, New Zealand	EA605	Japan	EA603 or 1895823	Italy, Chile	EA611

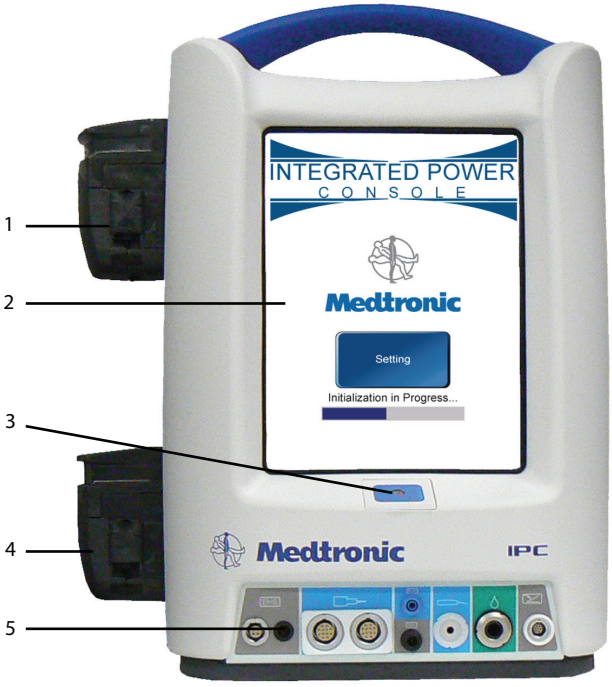
System sounds

The following tones can sound while using the IPC™ Console.

IPC™ Tone	Cause(s)
1 Tone	• Confirmation of change button pressed. • Change from Forward to Oscillate. • Change of active handpiece.
2 Tones	Change from Oscillate to Forward.
3 Tones	• **Audible Alarm. Error detected. See screen for error message.** • Active handpiece is in Reverse and foot pedal pressed. • First time accessory changes from Forward to Reverse.
Long Tone	Change from handpiece to drill.

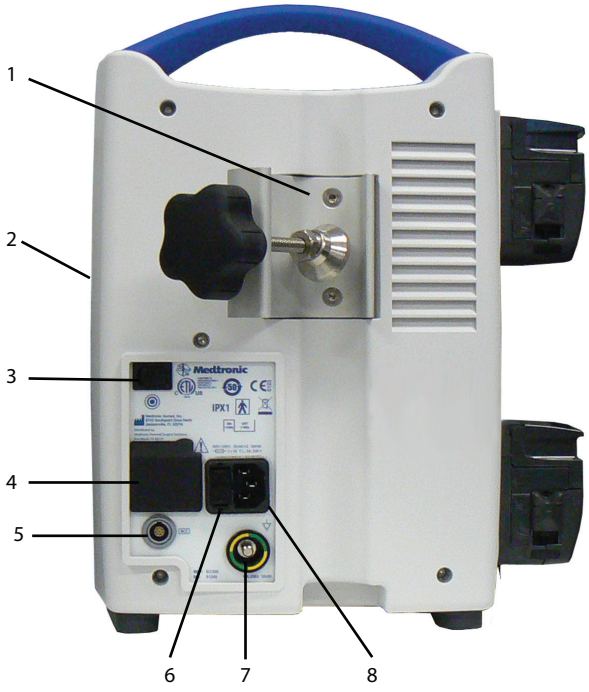
System figures

Figure 1-1. IPC™ Console Front



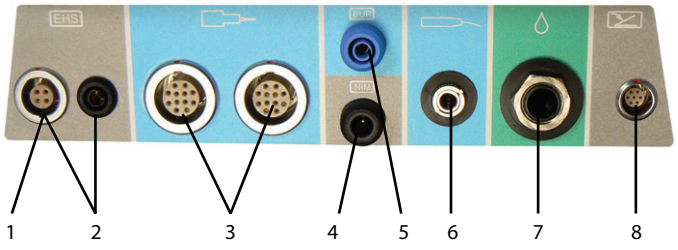
1 Pump 1: Coolant, irrigation
2 Touchscreen
3 Power on/off
4 Pump 2: Irrigation
5 Console connector panel for peripheral devices

Figure 1-2. IPC™ Console Back



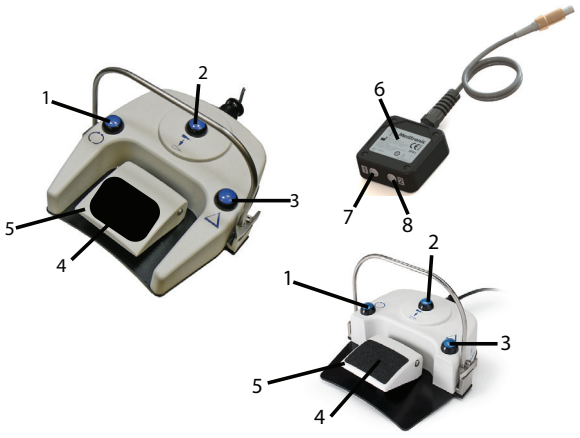
1 Pole clamp
2 Compact flash card port (Medtronic Use)
3 Manual start/stop
4 Auxiliary power outlet
5 Endo-Scrub 2 connector
6 Fuse access
7 Equipotential Ground Connector.
Apply potential equalization conductor.
8 Hospital grade power cord connector

Figure 1-3. IPC™ Console Connector Panel



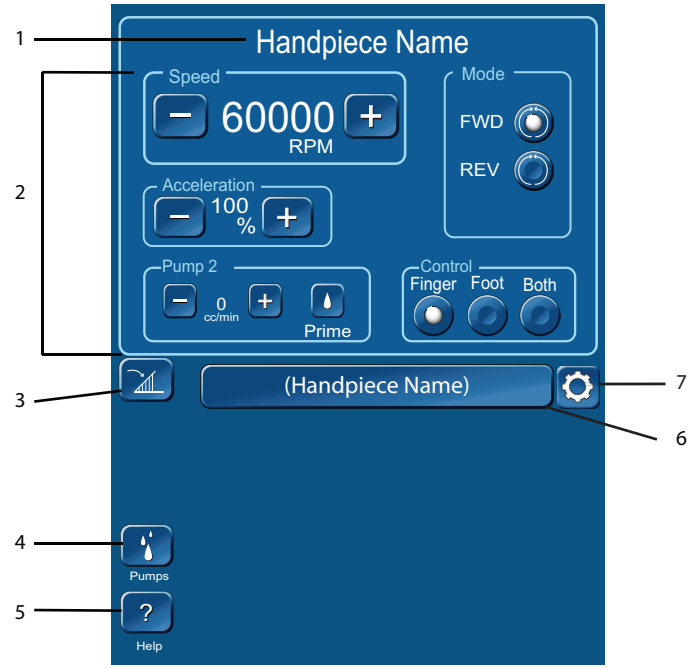
1 Legend EHS™
2 Legend EHS™ Stylus, Stealth-Midas™
3 Midas Rex™ Stylus Touch™ motor, Microsaws, High-torque handpiece, and MR8 motors
4 Stimulus input from patient interface (NIM™ or NIM-Eclipse™)
5 Stimulus output to stim bur guard or POWEREASE™
6 Not applicable
7 IntelliFlow™ irrigation remote control
8 Multifunction foot pedal

Figure 1-4. Multifunction Foot Pedal & Y-Splitter



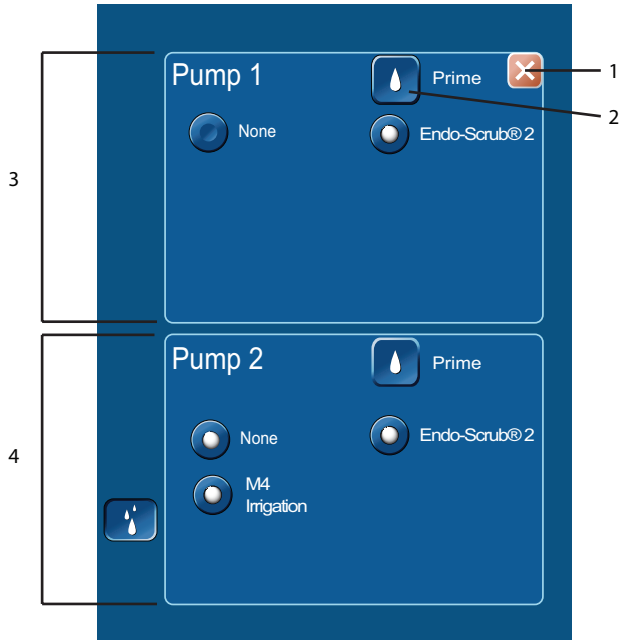
1 Mode button
2 Handpiece button
3 Control button
4 Slip-resistant foot pad
5 Foot pedal
6 Y-Splitter
7 Port 1
8 Port 2

Figure 1-5. IPC™ Touchscreen



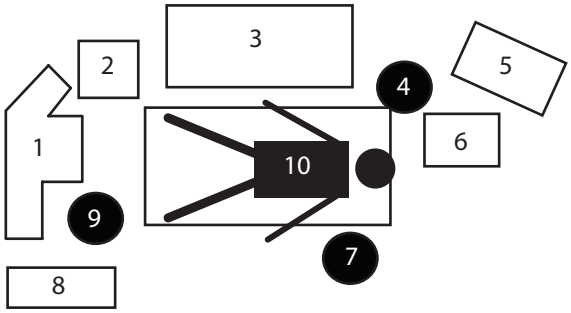
1 Displays active handpiece
2 Accessory control panel
3 Foot pedal variable control
4 Opens Pumps screen
5 Opens Help screen
6 Inactive handpiece
7 Set active handpiece settings as default

Figure 1-6. IPC™ Pumps Screen



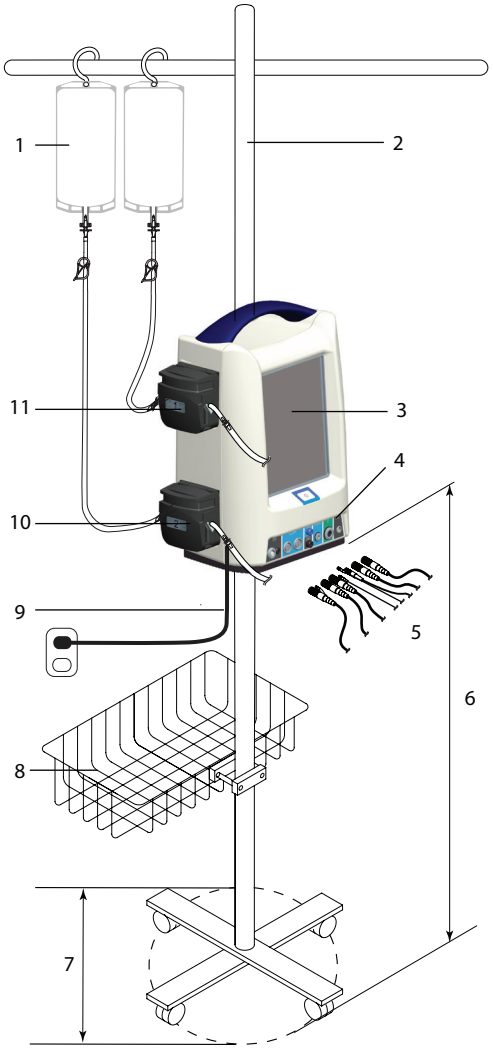
1 Close Pumps screen
2 Prime/Flush pump
3 Pump 1 panel available accessories
4 Pump 2 panel available accessories

Figure 1-7. Operating Room Setup



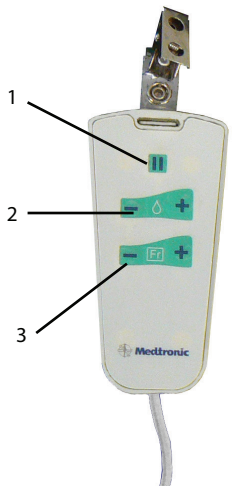
1 Mode anesthesia equipment
2 IPC™ system
3 Nursing supplies/Surgical instruments
4 Scrub nurse
5 NIM™ Monitor
6 Microscope
7 Surgeon
8 Electro-Surgical unit
9 Anesthesiologist
10 Patient

Figure 1-8. IPC™ System Configuration



1	Irrigation and coolant bags	7	Irrigation pole base diameter
2	Irrigation pole	8	Irrigation pole basket
3	IPC™ console	9	Power cord
4	Console connector panel	10	Pump 2
5	Accessory cables	11	Pump 1
6	Console height		

Figure 1-9. IntelliFlow™ Remote Control



1	Pause/On-Off
2	Increase/Decrease Fine Adjustment
3	Increase/Decrease Coarse Adjustment OR Select stainless steel tubing size (French size) for suction irrigator.

Pre-and Post-operating instructions

The following are general IPC™ pre- and post-operating instructions. Refer to other sections of this User's Guide for operating instructions specific to individual handpieces or accessories.

When the system arrives

- Verify the contents of the box match the packing slip. If incomplete or damaged, notify Medtronic Customer Service.
- If container is damaged, or cushioning material shows stress, notify carrier and Medtronic Customer Service. Keep shipping materials for carrier inspection.
- Save the cartons and packing material. If the instrument is to be shipped the shipping package will provide proper protection.

Set up the IPC™

Refer the related topics for detailed instruction.

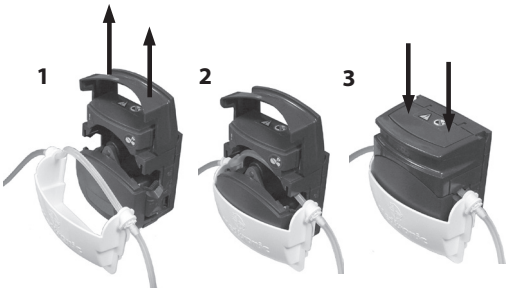
1. Install pump cartridges or irrigation tubing.
2. Prepare IPC™ for use.
3. Calibrate touchscreen, if necessary.
4. Change system settings, if necessary.
5. Set up and prime pumps.
6. Confirm system operation.
7. Press the manual start/stop button on the back of the console (Figure 1-2) and verify you can start/stop the handpiece, irrigation and/or coolant flow.

Install the pump cartridges or irrigation tubing

The pumps are available for use with accessories requiring irrigation or cooling.

1. Locate the correct pump and lift up the lock (Figure 1-10).
   Pump 1: Coolant, lens cleaning or irrigation
   Pump 2: Irrigation
   Note: The number on the pump must match the number on the cartridge (either 1/1 or 2/2). If the cartridge does not have a pump designator number, use the Pump Setup Screen to install the pump cartridge.
2. Insert the pump cartridge.
3. Snap the pump lock shut.
   Note: Ensure the pump cartridge does not crimp the tubing.

Figure 1-10. Install Pump Cartridge



Prepare IPC™ for use

1. Verify Operation Room set up (Figure 1-7). The surgeon may have preferences to the location and visibility.
2. Verify the wheels are locked on the IPC™ cart.
3. Inspect all components for damage and determine if the system is ready for use.
4. Mount the IPC™ and irrigation/coolant bags on the I.V. pole (Figure 1-8).
   Notes:
   - Mount irrigant and coolant bags above the IPC™ to ensure adequate flow.
   - It is recommended to use an irrigation pole with minimum base diameter of 53 cm and to mount all items as low as possible to increase stability during use.
   - For transport or uneven floor conditions greater than 10 degrees, maximum height to mount the console is 38 cm if irrigation and coolant bags are at fully extended pole height.
5. Plug the IPC™ into the power source. Position the IPC™ so that it does not obstruct the power source for the purpose of disconnecting the Main voltage by the power cord.
6. Locate the correct foot pedal or accessory connection port on the connector panel (Figure 1-3), align the mark on the connector to the mark on the console, and then insert the connector.
7. Connect suction, cooling and/or irrigation tubing.
8. Turn on the IPC™ and verify the system passes the self-test and the accessory screen appears on the IPC™ monitor.
   Note: If the IPC™ does not detect a handpiece or foot pedal the Connect Handpiece/Connect Foot Switch screen appears. Do the following:
   - Verify the cable is connected to the correct connection port.
   - Press **[OK]** in the Connect Handpiece/Connect Foot Switch message window to continue use of the IPC™ without the handpiece or foot pedal.

Calibrate touchscreen

Note: This step is optional.

1. Turn on the IPC™ console.
2. When the system starts, on the Splash screen, press **[Settings]**.
3. On the Settings screen, press **Touch Screen Calibration** and follow the screen prompts.

Change system settings

Note: During surgery, system settings can be overwritten.

1. Turn on the IPC™ console.
2. While the system starts, on the Splash screen, press **[Settings]**.
3. To change the language, press the appropriate language.
4. To change the default settings, press **[Default]**.
   - On the Default screen, press the Forward or Backward arrow to change the accessory.
   - Make changes to the default settings.
   - To confirm system settings and return to the Splash screen, press **[OK]**.
5. For accessories with audible tones, press the REV Audible Tones button to control the following:
   - The system delivers one set of reverse beeps when the Reverse mode is activated.
   - The system delivers one set of reverse beeps the first time the drill is used in Reverse mode after the Reverse mode has been activated.
6. To confirm system settings and continue to the IPC™ touchscreen, press **[OK]**.
7. To restore settings to factory default, press **[Restore]**.

Set up and prime pumps

- The IPC™ turns on pump 1 and/or 2 long enough to purge air out of the tubing set(s) the first time the prime button is pressed.
- The IPC™ resets the prime feature when you turn IPC™ power Off and On.
- After you prime the pump, the prime button and functionality become flush functionality.

1. Connect tubing from an IPC™ cartridge to irrigation or coolant port on an accessory.
2. On the irrigation tubing, turn the clamp to OPEN.
3. If an accessory uses the clear drip chamber (Visao), fill the clear drip chamber with coolant. To fill, squeeze and release the chamber until full.
4. On the IPC™ touchscreen (Figure 1-5), press the pumps button.
   Note: The IPC™ pumps screen is also available from the Connect Handpiece/Connect Foot Switch screen which the system displays during IPC™ preparation for use if a handpiece or foot switch is not detected by the system.
5. On the IPC™ pumps screen (Figure 1-6), select the accessory for each pump.
6. For each pump, press the prime button and verify the following:
   - Pump(s) run until air is completely purged from tubing.
   - Small amount of lubricant flows at the tip of the irrigation device.
   - Pump(s) turns off.
7. Press the close button.

Pump default configurations

The pump configuration is dependent on the handpiece(s) connected to the console. The following table defines the pump default settings (X) and default options (O).

Table 2. IPC™ Pumps Screen Default Configurations

	Pump 1		Pump 2	Endo-Scrub 2		Suction Irrigator	
Handpiece	**Cooling**	**Irrigation**	**Irrigation**	**Pump 1**	**Pump 2**	**Pump 1**	**Pump 2**
Stylus Touch™		X	O	O	O	O	O
Legend EHS™, Legend EHS™ Stylus, Stealth-Midas™ and MR8 motors		X	O*	O	O	O	O
Midas Rex™ Microsaws		O	X	O	O	O	O

* When the IPC™ detects both the Endoscrub 2 and the Stylus Touch™, and the Legend EHS Stylus, or Midas Rex™ MR8, Midas Rex™ MR8 Plus, Midas Rex™ MR8 Touch, or Stealth-Midas™ MR8, by default, the system sets pump 2 as a "shared" irrigation pump. You must manually connect the irrigation tubing to the active handpiece.

Confirm system operation

1. Confirm the irrigation pedal starts handpiece and irrigation flow. Verify the speed changes from white to yellow in the Speed box on the touchscreen.
2. Confirm the foot pedal buttons operate. Refer to **Multifunction foot pedal** for details.
3. On the touchscreen, verify you can do all of the following:
   - Adjust Speed: In the Speed box, press the plus and minus buttons. 
   - Change Modes: In a Mode box, press any mode button. 
   - Adjust Flow Rate: In the Irrigation box, press the plus and minus buttons. 

Disassemble the IPC™

1. Remove irrigation tubing or cartridge from IPC™ pump.

   Note: Before removing the tubing from the pump, adjust the clamp on the intravenous tubing to the CLOSED position to prevent excessive drainage of irrigant from the intravenous bag.
2. Disconnect components and cables. To disconnect non-silicone multi-pin cables from the console, push the cable toward the console and then pull out by the lock ring.

   Note: Silicone insulated multi-pin and single pin cable connectors do not have a lock ring. Remove these types of cable connectors straight from the connector panel.
3. After disconnecting insulated connectors from the console, connectors that have debris under the insulator must be cleaned according to **Cleaning and Sterilization** instructions. If debris is still present after cleaning and sterilization, return for warranty servicing.
4. See **Cleaning and sterilization** section of this User's Guide for instructions.

IPC™ components

Auxiliary power to console

Note: The auxiliary power outlet is available for use with the Hydrodebrider™ and Bone Mill consoles only.

The auxiliary power outlet is for use at grid voltage ≤120 VAC only.

Multifunction foot pedal

You can use the multifunction foot pedal (Figure 1-4) to start/stop the handpiece, control handpiece speed, handpiece selection and mode of operation. Refer to the **Multifunction foot pedal controls** topic for each handpiece for specific use and control.

Y-Splitter

Y-Splitter (Figure 1-4) allows using a maximum of two multifunction foot pedals connected to a single IPC™. In this configuration, the Y-Splitter shall be connected to the IPC™, and the multifunction foot pedal(s) shall be connected to the Y-Splitter. When connecting a single foot pedal to the Y-Splitter, you may connect to either Port 1 or 2.

IntelliFlow™ irrigation remote control

Use the IntelliFlow™ irrigation remote control (Figure 1-9) to start/stop and change irrigation flow while in the sterile field.

If you are using handpiece irrigation:

- To pause irrigation flow, press the Pause/On-Off button.
- To adjust flow rate, press the Fine Adjustment or Coarse Adjustment Increase/Decrease button.

If you are using the Suction Irrigator:

- To pause or turn on/off the Suction Irrigator, press the Pause/On-Off button.
- To adjust flow rate, press the Fine Adjustment Increase/Decrease button.
- To select the stainless steel tubing size (French size), press the Stainless Steel Tubing Size button.

Electromagnetic compatability

Environment of Intended Use: Professional healthcare facility environment

Guidance and manufacturer's declaration – electromagnetic emissions		
The IPC™ System is intended for use in the electromagnetic environment specified below. The customer or the user of the IPC™ System should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The IPC™ System 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 IPC™ Systems suitable for use in all establishments, ther than domestic 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 6100-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunities - part I			
The IPC™ System is intended for use in the electromagnetic environment specified below. The customer or the user of the IPC™ System should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	The relative humidity should be at least 5% Note-1.
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 line to line ± 2 kV line to earth	± 1 kV line to line ± 2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T (100% dip in U_T) for 1 cycle at 0° 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 0.5 sec 0% U_T (100% dip in U_T) for 5 sec	0% U_T (100% dip in U_T) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T (100% dip in U_T) for 1 cycle at 0° 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 0.5 sec 0% U_T (100% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the IPC™ System requires continued operation during power mains interruptions, it is recommended that the IPC™ System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTES:

1. U_T is the mains voltage prior to application of the test level.
2. When the console is powered and connected to the footswtich, application of -15KV air discharge onto the footswitch buttons may cause the console to freeze. Power cycle the console to re-establish normal operation.

Guidance and manufacturer's declaration – electromagnetic immunities - part II

The IPC™ System is intended for use in the electromagnetic environment specified below. The customer or the user of the IPC™ System should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz in ISM bands and amateur radio bands	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz in ISM bands and amateur radio bands	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the IPC™ System, including cables specified by the manufacturer. Othewise, degradation of the performance of this equipment may result.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 9–28 V/m Spot frequencies 385 MHz–5.785 GHz Pulse modulation	3 V/m 80 MHz to 2.7 GHz 9–28 V/m Spot frequencies 385 MHz–5.785 GHz Pulse modulation	Portable and mobile RF communications equipment should be used no closer to any part of the IPC™ System including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = (6/E)\sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, E is the immunity test levels in volt per meter (V/m), and d is the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with the following symbol: 

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

Recommended separation distances between portable and mobile RF communications equipment and the IPC™ System

The IPC™ System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the IPC™ System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the IPC™ System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter P(W)	Separation distance according to frequency of transmitter m						
	380 MHz–390 MHz $d = 0.22\sqrt{P}$	430 MHz–470 MHz $d = 0.22\sqrt{P}$	704 MHz–787 MHz $d = 0.67\sqrt{P}$	800 MHz–960 MHz $d = 0.22\sqrt{P}$	1.7 GHz–1.99 GHz $d = 0.22\sqrt{P}$	2.4 GHz–2.57 GHz $d = 0.22\sqrt{P}$	5.1 GHz–5.8 GHz $d = 0.67\sqrt{P}$
0.01	0.03	0.03	0.07	0.03	0.03	0.03	0.07
0.1	0.07	0.07	0.21	0.07	0.07	0.07	0.21
1	0.22	0.22	0.67	0.22	0.22	0.22	0.67
10	0.7	0.7	2.12	0.7	0.7	0.7	2.12
100	2.2	2.2	6.7	2.2	2.2	2.2	6.7

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be determined 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: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Limited warranty

A. This Limited Warranty provides the following assurance for the customer who purchases a Medtronic IPC System. This Limited Warranty is extended only to the buyer purchasing the IPC System directly from Medtronic or from its affiliate or its authorized distributor or representative. The IPC System includes the console, foot control, and Intelliflow remote control (hereinafter referred to as Single Use Components) and jointly referred to as the IPC System, unless specifically noted.
   i. Should a System Component fail to function to Medtronic's published specifications during the term of this Limited Warranty (one [1] year from the date of sale of a new System Component or ninety [90] days from the date of sale of a refurbished or used System Component), Medtronic will either repair or replace the Motor Component or any portion thereof.
   ii. Should a Semi-reusable Component fail to function to Medtronic's published specifications during the term of this Limited Warranty (thirty [30] days from the date of sale of a new Semi-reusable Component), Medtronic will replace the Semi-reusable Component or any portion thereof.
   iii. Should a Single Use Component fail to function to Medtronic's published specifications prior to its "use by" date Medtronic will replace the Single Use Component.

B. To qualify for this Limited Warranty, the following conditions must be met:
   i. The Product must be used on or before its "Use By" or "Use Before" date, if applicable.
   ii. The Product must be used in accordance with its labeling and may not be altered or subjected to misuse, abuse, accident or improper handling.
   iii. Medtronic must be notified in writing within thirty (30) days following discovery of a defect.
   iv. The Product must be returned to Medtronic within thirty (30) days of Medtronic receiving notice as provided for in (3) above.
   v. Upon examination of the Product by Medtronic, Medtronic shall have determined that: (i) the Product was not repaired or altered by anyone other than Medtronic or its authorized representative, (ii) the Product was not operated under conditions other than normal use, and (iii) the prescribed periodic maintenance and services, if applicable, have been performed on the Product.

C. This Limited Warranty is limited to its express terms. THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED WHETHER STATUTORY OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. In no event shall Medtronic be liable for any consequential, incidental, prospective or other similar damage resulting from a defect, failure, or malfunction of the IPC System, whether a claim for such damage is based upon the warranty, contract, negligence or otherwise.

D. 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. Users may benefit from statutory warranty rights under legislation governing the sale of consumer goods. If any part or term of this Limited Warranty is held by any court of competent jurisdiction to be illegal, unenforceable, or in conflict with applicable law, the validity of the remaining portion 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.

For items contaminated with TSE agents

Medtronic recommends incineration of devices that have directly or indirectly contacted patients suspected or confirmed with prions or a Transmissible Spongiform Encephalopathy (TSE) such as Crutzfeld-Jakob disease (CJD).

Troubleshooting

For any troubleshooting items not corrected by the actions below, contact Customer Service.

General system troubleshooting

Issue	Possible Cause	Action
Pump(s) does not run.	Failed internal components.	Contact Customer Service
Little or no irrigation flow.	Tubing Set improperly seated in pump.	Reposition tubing in pump, verify pump lid is fully closed with the fluid flow from left to right.
	Tubing is pinched or kinked.	Check tubing at side of pump, see Irrigation/ Coolant Pumps.
		Check remaining tubing for pinched or kinked areas, if necessary replace tubing.
	Tubing clamps are restricting flow.	Set tubing clamps in "open" position.
	Irrigation flow rate setting low.	Adjust irrigation flow rate.
	Irrigator obstructed.	Replace irrigator.
Pump stall error.	Tubing set improperly placed in pump.	Reposition tubing in pump, verify pump lid is fully closed with the fluid flow from left to right.
	Tubing is pinched or kinked.	Check tubing is not pinched or kinked on side of pump (see section on "Irrigation/Coolant Pumps").
Handpiece connected but console reads "Connect Handpiece."	Moisture in cable conflicts with handpiece recognition.	Run a dry cycle when sterilizing.
Handpiece connected but console displays incorrect handpiece.		
Console does not power up.	Power cord not properly connected.	Connect power cord.
	No power.	Check power available (i.e. power strip is on, circuit breaker is closed, etc.).
	Power Inlet Fuses blown.	Replace fuses with 5.00 A, 250 V, time delayed fuses (P/N 11270066 Fuse Kit 1898125).
	Failed internal components.	Contact Customer Service.
Power switch light is on but Touchscreen does not come on.	Failed internal components.	Contact Customer Service.
Console does not power down.	Power switch failure.	Unplug power cord, Contact Customer Service.
Touchscreen does not respond.	Screen gasket displaced or failed internal components.	Contact Customer Service.
Touchscreen does not work properly.	Touchscreen not calibrated.	Calibrate Touchscreen.
Console displays wrong handpiece / motor type.	Console misidentified the handpiece / motor.	Disconnect and reconnect the motor cable.
		Turn console off then on.
		Change motor, motor cable, or console to isolate the problem.
	Moisture in cable conflicts with handpiece recognition.	Run a dry cycle when sterilizing.

Issue	Possible Cause	Action
Foot control unit buttons or pedal does not respond.	Faulty Y-Splitter.	Disconnect Y-Splitter and connect FCU to IPC directly.
	Incorrect use.	Press and hold buttons for at least 1 second, wait for console confirmation beep.
	Top button does not respond.	One (1) handpiece connected (top button has no function with 1 handpiece connected).
	Connector not fully inserted.	Disconnect and reconnect the FCU cable connector.
		Try different FCU or console to isolate the problem.
	Internal component failure.	Contact Customer Service.
Handpiece fails to rotate.	Failed foot switch.	Disconnect foot switch, use manual start/stop rocker switch on rear of console.
	Failed handpiece motor or motor driver.	Contact Customer Service.
	Cables are not property connected.	Ensure handpiece cable is properly connected.
	Cables are damaged.	Check cables for cracks, splits, or bent connector pins.
Handpiece is too hot to touch/hold.	Blade, bur, and/or attachment transferring heat to handpiece.	Remove and reinstall or change blade, bur, and/or attachment. Ensure the part is properly seated before resuming use.
	Inadequate irrigation and/or coolant.	Ensure adequate irrigation and/or coolant is present.

Error codes

Code #	Title	Cause	Description
1	MCB does not report that it booted within 5 seconds of AI telling it to start and subsequent reattempts fail.	System Error.	Power off. Wait 10 seconds. Power on. If error persists, call Customer Service.
2	NOT USED.	NOT USED.	NOT USED
3	UI-MCB Com Failure - Max resends exceeded.	System Error.	Power off. Wait 10 seconds. Power on. If error persists, call Customer Service.
4	UI-MCB Com Failure - Get answer failed.		
5	UI-MCB Com Failure - No status message received.		
6	UI-MCB Com Failure - Serialization ID error.		
7	UI-MCB Com Failure - Timeout exception.		
8	UI-MCB Com Failure - Variable not recognized.		
9	Pump 1 stalled (no transitions on opto sensor).	Pump #1 stalled.	Check tubing connection.
10	Pump 2 stalled (no transitions on opto sensor).	Pump #2 stalled.	Check tubing connection.
11	Unrecognized/damaged handpiece plugged in on port 1 (first 12 pin).	Handpiece.	Unplug handpiece and plug back in. If error persists, replace handpiece.
12	Unrecognized/damaged handpiece plugged in on port 2 (second 12 pin).		
13	Unrecognized/damaged handpiece plugged in on port 3 (4 pin).		
14	Unrecognized/damaged handpiece plugged in on port 4 (Skeeter).		
15	Handpiece stalled.	Handpiece stalled.	Check accessory.
16	MCB motor overcurrent detected.	Motor overcurrent.	Unplug handpiece and plug back in. If error persists, replace handpiece.
17	Unrecognized/damaged multifunction foot pedal plugged in.	Foot Pedal Connection error.	When using foot pedal only, unplug foot pedal and plug back in. If error persists, replace foot pedal or switch to manual control. When using Y-Splitter, disconnect foot pedal and Y-Splitter, then connect foot pedal directly to IPC™. If after reconnecting foot pedal, the error goes away, replace Y-Splitter with another unit. If error persists, replace foot pedal and reconnect both Y-Splitter and foot pedal or switch to manual control.
18	Damaged handpiece or finger lever base out of position.	Finger Control error.	Stylus Touch™ - A finger control error has been detected. Check that the control lever ring is properly seated in one of the four possible positions. If error persists contact Customer Service. Press OK to use alternate control method. POWEREASE™ - Please check mode select switch to ensure a mode has been selected by rotating mechanism until it rests in a detent. If error persists, contact Customer Service.
19	UI self test failure - culture (language) registry entry.	Self Test Failed.	Power off. Wait 10 seconds. Power on. If error persists, call Customer Service.
20	UI self test failure - sector configuration registry entry.		
21	UI self test failure - corrupt usage data file or unable to create usage data file.		
22	NOT USED.	NOT USED.	NOT USED.

Code #	Title	Cause	Description
23	MCB non-specific self test failure.	Self Test Failed.	Power off. Wait 10 seconds. Power on. If error persists, call Customer Service.
24	MCB self test failure - port 1.		
25	MCB self test failure - port 2.		
26	MCB self test failure - port 3.		
27	MCB self test failure - port 4.		
28	MCB self test failure - bridge transitor 1 shorted.		
29	MCB self test failure - bridge transitor 2 shorted.		
30	MCB self test failure - bridge transitor 3 shorted.		
31	MCB self test failure - bridge transitor 4 shorted.		
32	MCB self test failure - bridge transitor 5 shorted.		
33	MCB self test failure - bridge transitor 6 shorted.		
34	MCB self test failure - A/D converter.		
35	MCB self test failure - motor error.		
36	MCB self test failure - 3.3 volt supply.		
37	MCB self test failure - 12 volt supply.		
38	MCB self test failure - 48 volt supply.		
39	MCB self test failure - FCU port.		

Cleaning and sterilization

Reprocessing Instructions are subject to change. Refer to **manuals.medtronic.com** for current Reprocessing Instructions.

Clean the multifunction foot pedal

- If debris is present under the foot pedal's boot, return for warranty service.
- Do not immerse or sterilize the foot pedal.
- Do not use alcohol, other solvents or abrasive cleaners.

1. On the slip resistant foot pad ONLY, spray a neutral enzymatic detergent, pH 6.0-8.0, or a phenol based disinfectant, mixed according to manufacturer's instructions.
2. Leave the solution on the foot pad for approximately 10 minutes.
3. Dampen a cloth with a neutral enzymatic detergent, pH 6.0-8.0, or a phenol based disinfectant, mixed according to manufacturer's instructions.
4. Wipe the foot pedal with the damp cloth until visually clean.
5. Dry the unit with a clean, non-abrasive cloth.

Clean the Y-Splitter

1. Do not immerse or sterilize the Y-Splitter.
2. Do not use alcohol, other solvents or abrasive cleaners.
3. Dampen a cloth with a neutral enzymatic detergent, pH 6.0 – 8.0, or a phenol based disinfectant, mixed according to manufacturer's instructions.
4. Wipe the Y-Splitter with a damp cloth until visually clean.
5. Dry the unit with a clean, non abrasive cloth.

Customer service

For further information regarding the use of this product or to report any problems, please contact Medtronic using the appropriate information provided on the blue and white contact information card packaged with each device; or contact your local distributor.

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International Service
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