

QUICK REFERENCE GUIDE

Sonicision™ Curved Jaw Cordless Ultrasonic Dissection System



Medtronic



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IN THE OPERATING ROOM

ASSEMBLY



1

SCRUBBED PERSON

Slide the generator into the opening at the back of the dissector until it makes contact with the front of the dissector opening.

2

SCRUBBED PERSON

Hold the dissector shaft-rotation wheel. Turn the torque knob clockwise until it clicks twice.

Tip: Listen and feel for the two clicks. This will confirm that the generator is properly attached to the dissector.

3

SCRUBBED PERSON

Place the sterile battery insertion guide onto the open dissector handle and hold firmly.

Tip: Make sure the battery insertion guide is completely seated on the dissector. Improper placement will make it difficult to insert the battery.

4

CIRCULATING PERSON

Orient the battery as shown on the battery insertion guide. Insert the battery pack through the battery insertion guide into the handle of the dissector.

Tip: The scrubbed person should provide additional support by holding the battery insertion guide onto the dissector during battery insertion.

5

CIRCULATING PERSON

After the battery pack is seated in the dissector, remove the now contaminated battery insertion guide from the sterile field.

6

SCRUBBED PERSON

Do not touch the battery pack. Close the battery compartment door until there is tactile feedback and an audible click.

Tip: Press down on the top of the battery compartment door directly over the battery compartment door latch for easiest closure.

After assembly

To ensure the device meets required essential performance, it should be tested after assembly as follows:

- With the clamping jaws open, test the minimum power mode (energy button depressed to first position) and maximum power mode (energy button fully depressed).
- If the device generates different pulsating tones for each power mode and a green LED is present, assembly is complete and the device is ready to use.
- If inaudible or undifferentiated tones or a non-green LED are present, troubleshooting must be performed.

CHANGING A BATTERY PACK DURING A PROCEDURE



1

SCRUBBED PERSON

Hold the device with the battery compartment door up. Press the battery door release button to open the compartment.



2

SCRUBBED PERSON

Place the new sterile battery insertion guide over the exposed battery pack. Seat the guide onto the open dissector handle and hold firmly.

Tip: Ensure the battery pack handle is facing towards the jaws of the device and away from the battery door hinge. Do not attempt to place the battery insertion guide while the handle is in the improper orientation. If the battery handle is facing the wrong direction, tilt the jaws of the instrument down towards the floor. This will cause the handle to fall into proper orientation.



3

CIRCULATING PERSON

Grasp the battery pack handle and pull the battery pack through the insertion guide, out of the dissector, and into a clean, nonsterile environment.

Tip 1: Make sure the battery insertion guide is completely seated on the dissector. Improper placement will make the battery difficult to remove.

Tip 2: The scrubbed person should hold the battery insertion guide firmly on the dissector.



4

CIRCULATING PERSON

Orient the new battery pack as shown on the battery insertion guide. Insert the battery pack through the battery insertion guide into the handle of the dissector.

Tip: The scrubbed person should provide additional support by holding the battery insertion guide onto the dissector during battery insertion.



5

CIRCULATING PERSON

After the battery pack is seated in the dissector handle, remove the now contaminated battery insertion guide from the sterile field.



6

SCRUBBED PERSON

Do not touch the battery pack. Close the battery compartment door until there is tactile feedback and an audible click.

Tip: Press down on the top of the battery compartment door directly over the battery door latch for easiest closure.

After changing the battery pack

- With the clamping jaws open, test the minimum power mode (energy button depressed to first position) and maximum power mode (energy button fully depressed).
- If the device generates different pulsating tones for each power mode and a green LED is present, assembly is complete and the device is ready to use.
- If inaudible or undifferentiated tones or a non-green LED are present, troubleshooting must be performed.

DISASSEMBLY, CLEANING, AND DISINFECTING THE BATTERY PACK



1 SCRUB OR CIRCULATING PERSON

Remove the battery pack by holding the device with the battery compartment door up. Press the battery door release button to open the compartment.

Tip: Remember to remove the battery pack prior to discarding the dissector.



2 SCRUB OR CIRCULATING PERSON

Use the battery pack handle to pull the battery pack out into a clean environment.

Tip: The battery pack should be cleaned and disinfected after each use.



3 SCRUB OR CIRCULATING PERSON

Hold the shaft rotation wheel firmly with one hand and begin loosening the torque knob by turning it counterclockwise with the other hand.



4 SCRUB OR CIRCULATING PERSON

Continue to turn the torque knob counterclockwise until the generator can be removed from the dissector.

Tip: Reprocess the generator and battery insertion guides as soon as possible following use. If reprocessing cannot be performed immediately, cover the components with a moist towel.








CLEANING THE BATTERY PACK





1. Moisten a lint-free cloth with a disinfectant solution or use a disinfectant wipe. Use one of the following disinfectants: Ethyl alcohol, isopropyl alcohol (70%), or hydrogen peroxide wipes (e.g., Oxivir™). Do not use CaviWipes™ to clean or disinfect the battery pack.
2. Wipe all external surfaces of the battery pack until visually clean. Make sure the surface remains thoroughly wet by continuously wiping for the contact time recommended per the manufacturer's instructions. Remember to:
 - Ensure a contact time of 1 minute when using 70% ethyl alcohol or isopropyl alcohol
 - Pay special attention to the battery pack handle
 - Avoid contact with the battery pack connector
 - Use additional wipes if needed
3. Use a lint-free cloth to dry all exposed surfaces of the battery pack. Take care to avoid damage to the battery pack connector.
4. Visually inspect the battery pack. If it is not clean, repeat the cleaning steps above.

DISINFECTING THE BATTERY PACK







Repeat the four steps described above.

DEVICE STATUS AND TROUBLESHOOTING

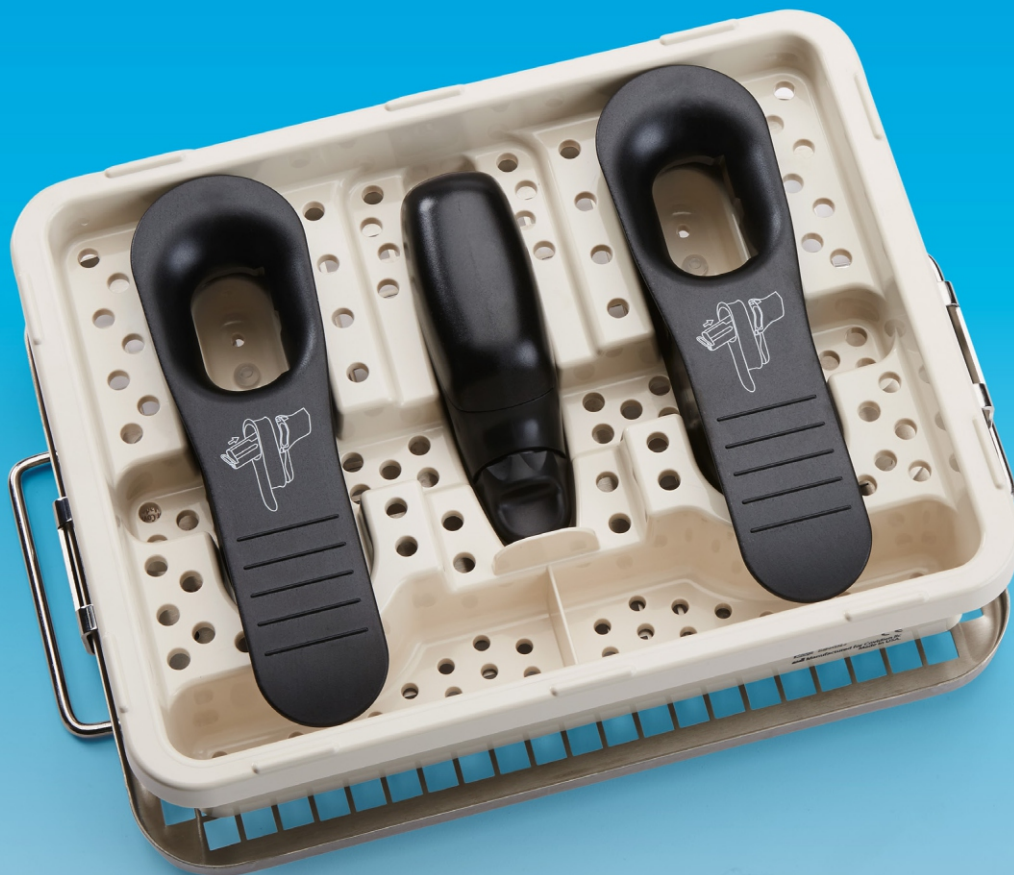
Device Status & Troubleshooting During Setup			
LED INDICATOR COLOR	STONE	STATUS	TROUBLESHOOTING
Green 	Six pulses — start-up tone	System is ready.	NA
	No audio	Device is not functional.	Replace the dissector.
Purple and Green alternating (flashing) 	Six pulses — start-up tone	Generator is on its last surgical use.	Press activation button to begin use.
Purple (flashing) 	Three pulses	Generator has reached its maximum use life and is no longer functional.	Replace the generator.
Red (during assembly) 	Three pulses	System error during assembly. Device is not functional.	<ol style="list-style-type: none"> 1. Fully detach and reattach the generator. Ensure two clicks occur when tightening the generator. 2. Replace the battery pack. 3. Replace the generator. 4. Replace the dissector.
LED not illuminated (during assembly) 	No audio	Device is not functional.	<ol style="list-style-type: none"> 1. Replace the battery pack. 2. Replace the generator.
	Six pulses — start-up tone	Device is not functional.	<ol style="list-style-type: none"> 1. Replace the generator. 2. Replace the dissector.

Device Status & Troubleshooting Within a Procedure			
LED INDICATOR COLOR	STONE	STATUS	TROUBLESHOOTING
Yellow (flashing) 	Nine pulses	Battery charge is low (less than 15%).	Replace the battery pack.
	Four descending tones	Low-battery reminder.	
	Twelve pulses followed by a constant tone	Battery pack is depleted. Device is not functional.	
Red (during activation) Green (after activation) 	Three pulses during activation	System error during use. Device is not functional.	<ol style="list-style-type: none"> 1. Clean the jaw and blade. Test with an open jaw. 2. Fully detach and reattach the generator. Ensure two clicks occur when tightening the generator. 3. Replace the dissector. 4. Replace the generator.
Red (during use) 	No audio	System error during use. Device is not functional.	Replace all components: dissector, generator, and battery pack.
LED not illuminated (during use) 	Audio may or may not occur	Device is not functional.	<ol style="list-style-type: none"> 1. Replace the battery pack. 2. Replace the dissector. 3. Replace the generator.

CHARGER INDICATIONS AND TROUBLESHOOTING

SYMBOL	MEANING
	Flashing green bars: Active charging. Five solid bars indicate a full charge
	Flashing green bars with a number: The white number shows the remaining surgical uses. This number is present when there are 20 or fewer surgical uses remaining for the battery pack.
	White battery with a line through it and a 0: The battery pack has exceeded the number of surgical uses and has reached its end of life. The battery pack must be replaced. Dispose of the old battery pack as required by local, state, and federal regulations.
	Red battery: The battery pack has a fault and is nonfunctional. Troubleshooting: Reinsert the battery pack into a different charger bay. If the error indication remains, then the battery pack is nonfunctional and must be replaced. Contact Medtronic customer service.
	Yellow caution: The charging bay has a fault and is nonfunctional. Troubleshooting: Unplug and replug the battery charger power cord. If the error indication remains, that battery charger bay is nonfunctional. Contact Medtronic customer service.
	Yellow caution on all bays and red power-status light: The battery charger has a system fault and is nonfunctional. Troubleshooting: Unplug and replug the battery charger power cord. If the error indication remains, the battery charger is nonfunctional. Contact Medtronic customer service.





CLEANING AND STERILIZATION

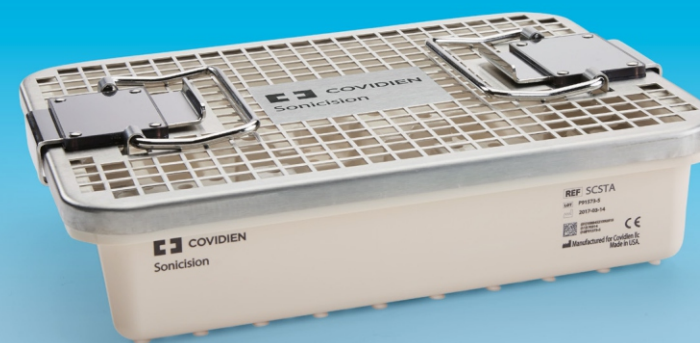
CLEANING THE GENERATOR, BATTERY INSERTION GUIDES, AND STERILIZATION TRAY

Preparation for cleaning — gross decontamination

1. Visually inspect the battery insertion guides, generator, and sterilization tray. Do not use the components if they are broken, cracked, nicked, or have any other damage. Do not use if the sterilization tray latches do not secure the base to the lid. Replace damaged components.
2. Under warm (32–40°C; 90–104°F) running tap water scrub all components with a small, soft, nylon-bristle, general instrument cleaning brush to remove surgical debris. For hard to reach crevices, use a 4.0 mm soft nylon-bristle brush for the battery insertion guide, and use a 12.0 mm soft nylon-bristle brush for the generator and sterilization tray.
3. Rinse under warm (32–40°C; 90–104°F) running tap water for a minimum of one minute.
4. Prepare a cleaning solution according to the manufacturer's instructions. Use a cleaning solution of pH-neutral, pH-neutral enzymatic, or alkaline detergent to clean the generator, battery insertion guides, and sterilization tray.

Note: Cleaning was validated with the following cleaning agents:

- Steris Prolystica™ 2x concentrate neutral detergent, Metrex MetriWash™ neutral detergent, Steris ValSure™ neutral detergent.
 - Steris Prolystica™ 2x concentrate enzymatic presoak and cleaner, United Biotech Tri-Power™ enzymatic cleaner, ASP Enzo™ enzymatic cleaner
 - Dr. Weigert neodisher™ MediClean forte alkaline detergent, Steris Prolystica™ 2x concentrate alkaline detergent, Steris Valsure™ alkaline detergent
5. Choose manual cleaning or automatic cleaning.



CLEANING THE GENERATOR, BATTERY INSERTION GUIDES, AND STERILIZATION TRAY

Manual Cleaning

1. Immerse the battery insertion guides, generator, and sterilization tray in a warm (32–40°C; 90–104°F) detergent bath for 10 minutes.
2. Use a small, soft nylon-bristle, general instrument cleaning brush to scrub each component in the detergent bath for a minimum of 1 minute. For hard to reach crevices, use a 4.0 mm soft nylon-bristle brush for the battery insertion guide, and use a 12.0 mm soft nylon-bristle brush for the generator and sterilization tray.
3. Rinse each components under warm (32–40°C; 90–104°F) running tap water for a minimum of 1 minute.
4. Perform a final rinse under warm purified water for a minimum of 1 minute for each component.
5. Use a clean, soft, lint-free cloth to dry the components.

Automatic Cleaning

Run the automatic cleaning cycle. Refer to the Automatic Cleaning Recommendations table below.

TREATMENT	TIME (MM:SS)	TEMPERATURE	CHEMICAL
Prewash	01:00	Cold tap water	N/A
Wash	03:00	Hot tap water	pH-neutral, pH-neutral enzymatic, or mild alkaline detergent diluted per the manufacturer's specifications
Rinse	00:15	Hot tap water	N/A
Wash	02:00	Hot tap water	pH-neutral, pH-neutral enzymatic, or alkaline detergent diluted per the manufacturer's specifications
Rinse	00:15	Hot tap water	N/A
Thermal rinse	01:00	Heated purified water 82°C (180°F)	N/A
Dry	06:00	High setting 95°C (203°F)	n/a

Note: The components have been qualified to withstand the following parameters: Prewash of 4 minutes, total wash of 10 minutes, hot tap water rinse of 5 minutes, thermal rinse of 95°C (203°F), and dry time of 30 minutes.

Note: Do not use instrument lube within automatic cleaning protocols when cleaning the reusable generator, reusable battery insertion guides, and the reusable sterilization tray. Automatic cleaning of these components has not been validated using instrument lube.

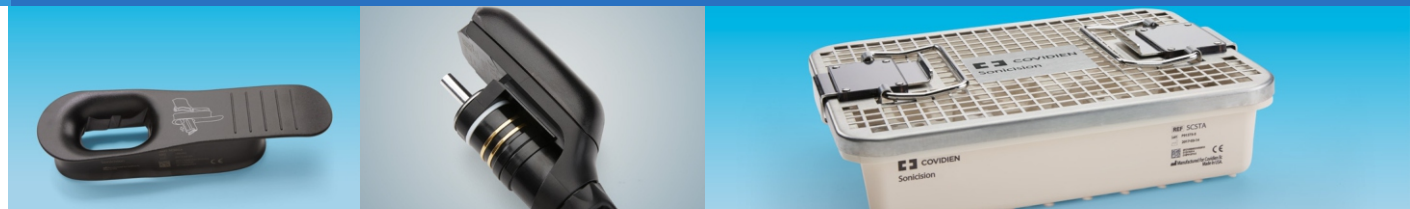
Note: Do not use compressed air to dry the reusable generator after cleaning.

Precaution: To avoid mechanical damage, arrange the contents of the washer so that the components will not contact other items during the wash cycle.

Precaution: Do not wash the battery insertion guides or generator in the sterilization tray. Washing these components while they are in the tray will cause damage and compromise cleaning.

Precaution: Do not wash the generator in an ultrasonic washer.

After either manual cleaning or automatic cleaning, visually inspect the components for cleanliness. Repeat the cleaning cycle if necessary.



STERILIZING THE GENERATOR, BATTERY INSERTION GUIDES, AND STERILIZATION TRAY

Option 1

Sterilization with a Sonicision™ Reusable Sterilization Tray

1. After cleaning, place one generator and as many as two battery insertion guides in the base of the sterilization tray.
2. Place the lid onto the base and push the latches inward to secure the lid.
3. Use the manufacturer's instructions for the sterile barrier selected:
 - **Single polypropylene wrap:** Wrap the sterilization tray in a compatible polypropylene sterilization wrap.
 - **Double polypropylene wrap:** Wrap the sterilization tray in two compatible polypropylene sterilization wraps.
 - **Rigid steam sterilization container:** Place the sterilization tray in a compatible rigid steam sterilization container.
4. Place the loaded sterilization tray into the autoclave. Do not stack the sterilization tray with any other items. When sterilizing multiple instruments in one autoclave cycle, do not exceed the maximum load specified by the manufacturer.
5. Select one of the sterilization cycles in the following Steam Sterilization Cycles table.

Warning: The list of sterilization barriers above have been validated for effective sterilization of the system components. Do not use alternative sterilization barriers or additional absorbent or protective materials as this may compromise sterility or functionality of the components.

CYCLE TYPE	EXPOSURE TEMPERATURE	EXPOSURE TIME (MINUTES)	MINIMUM DRY TIME* (MINUTES)	COMPATIBLE STERILE BARRIERS
Prevacuum	132°C (270°F)	4	40	Wrap(s) and rigid container ^b
Prevacuum	135°C (275°F)	3	40	Wrap(s) and rigid container
Gravity	132°C (270°F)	15	40	Wrap(s)
Gravity	135°C (275°F)	10	30	Wrap(s)

a. Due to variations in autoclave sterilization equipment, actual dry times may vary from the minimum dry times validated for this product.

b. Validated with Asculap™ rigid container model JN741/JK789.

Warning: Generators and battery insertion guides within the sterilization tray cannot be sterilized with rigid containers using a steam sterilization cycle of gravity 132°C (270°F) or gravity 135°C (275°F).

To ensure adequate cool down time to 48°C (118°F) for handling of the sterilization tray and its contents, the sterilization tray should be allowed to cool down on a rack after sterilization for a minimum of 30 minutes.

Warning: Do not use immediate use (flash) steam sterilization, hydrogen peroxide gas plasma technology (such as Sterrad™ systems), ethylene oxide (EO), or gamma sterilization to sterilize any components of the Sonicision™ system. Exposure to these alternative forms of sterilization will damage the equipment and may compromise sterility.



STERILIZING THE GENERATOR AND BATTERY INSERTION GUIDES

Option 2

Sterilization Without a Sonicision™ Reusable Sterilization Tray

- After cleaning, use the manufacturer's instructions for the sterile barrier selected:
 - Single polypropylene wrap:** Wrap each component individually in a compatible polypropylene sterilization wrap.
 - Double polypropylene wrap:** Wrap each component individually in two compatible polypropylene sterilization wraps.
 - Single breathable polyethylene pouch:** Place each component individually in its own single compatible breathable polyethylene pouch and seal. Place the pouch in the autoclave with the breathable side of the pouch facing up.
 - Double breathable polyethylene pouch:** Place each component individually within two compatible breathable polyethylene pouches, and seal. The breathable side of the inside pouch must be aligned with the breathable side of the outside pouch. Place the pouches in the autoclave with the breathable sides of the pouches facing up.
 - Rigid steam sterilization container:** Place the components in a compatible rigid steam sterilization container. Ensure that the individual components are not touching, and the container is loaded according to the manufacture's recommendations.
- Place the generators and battery insertion guides into the autoclave. Do not stack the sterilization tray with any other items. When sterilizing multiple instruments in one autoclave cycle, do not exceed the maximum load specified by the manufacturer.

Warning: The list of sterilization barriers above have been validated for effective sterilization of the system components. Do not use alternative sterilization barriers or additional absorbent or protective materials as this may compromise sterility or functionality of the components.

- Select one of the sterilization cycles in the following Steam Sterilization Cycles table.

CYCLE TYPE	EXPOSURE TEMPERATURE	EXPOSURE TIME (MINUTES)	DRY TIME (MINUTES)	COMPATIBLE STERILE BARRIERS
Prevacuum	132°C (270°F)	4	20–40	Wrap(s), pouches, and rigid container
Prevacuum	135°C (275°F)	3	16–40	Wrap(s), pouches, and rigid container
Gravity	132°C (270°F)	15	15–40	Wrap(s) and pouches
Gravity	135°C (275°F)	10	30	Wrap(s), pouches, and rigid container

Note: The generator and battery insertion guide have been tested to allow exposure to temperatures up to 135°C (275°F) for 18 minutes, in order to allow for variations in local requirements and regulations for sterilization protocols.

Warning: Generators and battery insertion guides cannot be sterilized with rigid containers using a steam sterilization cycle of gravity 132°C (270°F).

Warning: Do not use immediate use (flash) steam sterilization, hydrogen peroxide gas plasma technology (such as Sterrad™ systems), ethylene oxide (EO), or gamma sterilization to sterilize any components of the Sonicision™ system. Exposure to these alternative forms of sterilization will damage the equipment and may compromise sterility.





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