

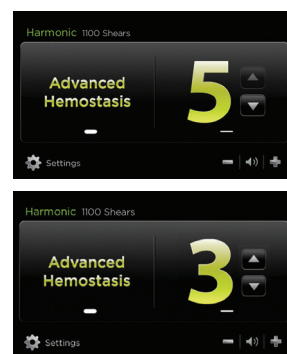


HARMONIC® 1100 Shears

Optimized Device Performance Guide

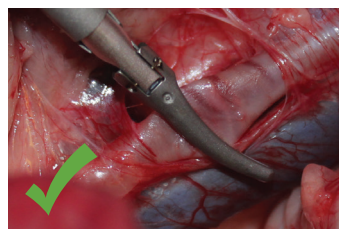
Generator setup

- The Energy button is indicated for vessels up to 5mm in diameter and can be adjusted (1-5). The system defaults to power level 5. For greater tissue cutting speed, use a higher generator power level, and for greater coagulation use a lower generator power level.
- For thicker tissue types, such as liver parenchyma, the recommended generator power setting is power level 3 when activating HARMONIC® 1100 Shears while gradually closing the jaws.
- Designed for use exclusively with the Generator G11 (GEN11) software version 2018-1 or later.

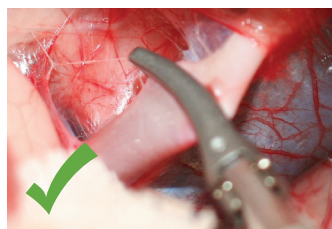
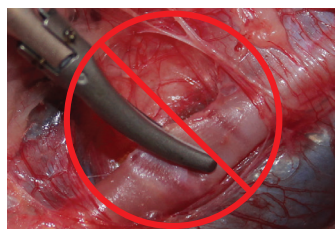


Advanced Hemostasis

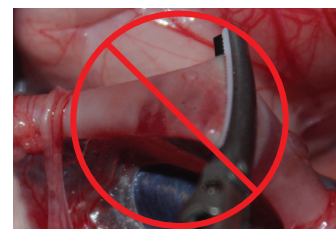
- Advanced Hemostasis mode provides hemostasis for vessels up to and including 7mm in diameter.
- Energy is not delivered using the Energy button with Advanced Hemostasis until the jaws are completely closed.
- Using the Energy button with Advanced Hemostasis without full trigger closure may result in lack of hemostasis.



Fully place tissue in jaws



Minimize tissue tension



Caution

- Tissue pad damage may occur if device is activated without tissue in the closed jaws. Activation without tissue between the jaws will cause tissue pad degradation.
- Avoid contact with any and all metal or plastic instruments or objects such as graspers, uterine manipulators, etc.



HARMONIC® 1100 Shears

Cleaning instructions and troubleshooting

Proactive cleaning throughout the procedure

Expected device performance can be achieved by proactively cleaning the jaw and blade before any generator alert screens can occur.

For optimal performance and to avoid tissue sticking, clean the instrument blade, clamp arm, and distal end of the shaft throughout the procedure.

Cleaning with moist gauze

1. Do not clean the blade tip with abrasives. It can be wiped with a moist gauze sponge to remove tissue, if necessary.
2. If tissue is still visible in the clamp arm, use hemostats to remove residue, taking care not to actuate the instrument.
3. Do not touch the instrument to the hemostats while activated. Scratches on the blade may lead to cracked or broken blades and premature blade failure.



Cleaning with saline

1. Activate the instrument with the jaws open while the blade, clamp arm and distal end of the shaft are in a bowl of sterile saline.
2. Be careful not to make contact between the active blade and any container during the saline wash.

Troubleshooting the “Remove Instrument From Patient” alert screen sequence



When this screen appears on the generator, it is a prelude to further Diagnostics.

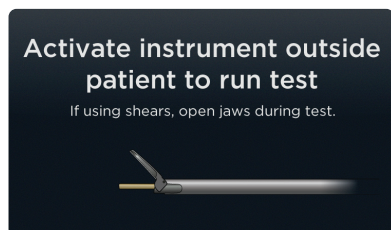


After pressing Next, the GEN11 will prompt the user to “Clean Blade.”

Remove any tissue which may be lodged inside the end of the instrument sheath. Do not clean the blade tip with abrasives. It can be wiped with a moist gauze sponge to remove tissue, if necessary.

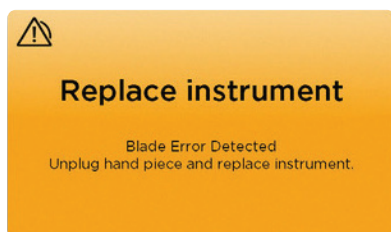
If tissue is still visible in the clamp arm, use hemostats to remove residue, taking care not to actuate the instrument. Do not touch the instrument to the hemostats while activated.

After thorough cleaning, press Next on the GEN11 screen.



Activate instrument outside patient to run test.

If the test is completed successfully, the procedure may continue as planned.



If the test is not completed successfully, the GEN11 screen will display the “Replace Instrument” alert screen.

The HARMONIC® instrument may be damaged and cannot be activated. Discontinue use and replace the instrument.