

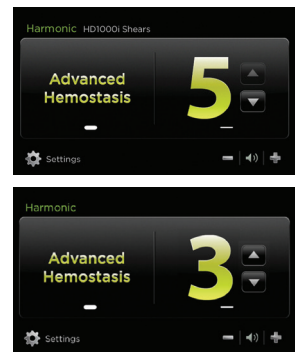


HARMONIC® HD 1000i

Optimized Device Performance Guide

Generator set-up

- Power level 5 is the default setting and will provide hemostasis for vessels up to and including 5mm in diameter; however, it is adjustable 1-5 based on needs of tissue and surgeon preference.
- For thicker tissue types, such as liver parenchyma, the recommended generator power setting is power level 3 when activating HARMONIC® HD 1000i while gradually closing the jaws.
- The device is compatible with standard foot switch.

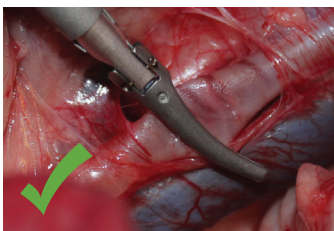


Advanced Hemostasis

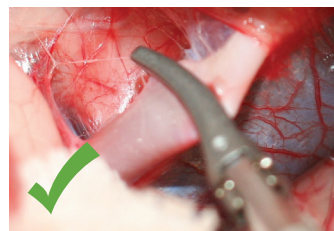
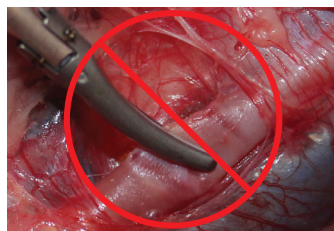
- Advanced Hemostasis mode provides hemostasis for vessels up to and including 7mm in diameter. It is not adjustable.

When using Advanced Hemostasis:

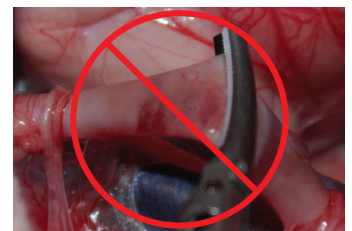
- Trigger must be fully closed to activate.
- Allow entire cycle to complete; this will be indicated by a secondary activation tone.



Fully place tissue in jaws

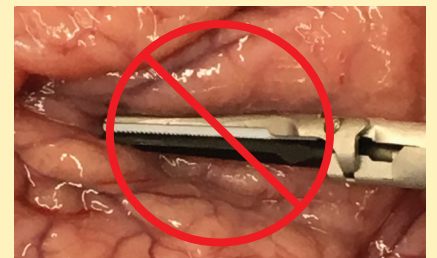


Minimize tissue tension



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® HD 1000i

Cleaning Instructions and Troubleshooting

Proactive cleaning throughout the procedure (no “alert screen” appears on generator)

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

Keeping the jaws and blade clean and free of debris throughout the surgical procedure prevents tissue and debris build-up which may lead to unintended generator errors that may require additional troubleshooting.

Cleaning with moist gauze

1. The jaws should be cleaned with a moist gauze sponge throughout the procedure.
2. If tissue is still visible in the clamp arm, use hemostats to remove residue.



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.
3. The blade and clamp arm can also be cleaned with a moist gauze sponge to remove tissue.
4. If tissue is still visible in the clamp arm use hemostats to remove residue.
5. The device has a unique closure mechanism, so when the trigger is closed, a larger portion of the blade opposite the clamp arm is exposed for cleaning. It is beneficial to remove residue in both the open and closed jaw positions using hemostats.
 - Please ensure that the device is not activated when using hemostats as this could lead to scratches on the blade and potential premature blade failure.

Troubleshooting the “Remove Instrument from Patient” alert screen sequence

The “Remove Instrument from Patient” alert screen is informing the user of an increased load (impedance) on the device.

There are many factors that can lead to an increased load (impedance) on the system, including excessive debris within the jaws, or contact with metal or plastic instruments when the instrument is activated. It is necessary for the GEN11 to monitor device impedance in order to confirm proper device function and blade integrity throughout the surgical procedure.

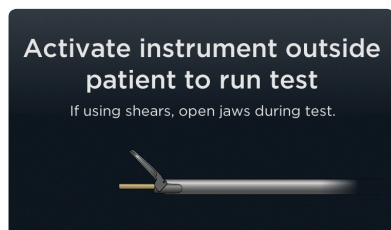


When the GEN 11 identifies high load (impedance), the “Remove Instrument from Patient” alert screen will be displayed.



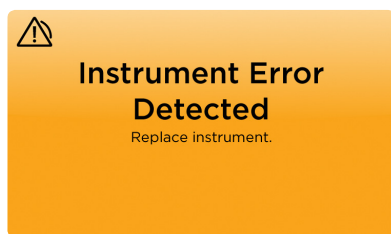
After the Operating Room staff presses Next, the GEN 11 will prompt the user to “Clean Blade; Remove any tissue which may be lodged inside end of instrument sheath.”

At this point the sterile surgical staff should thoroughly clean the device by wiping the blade, tissue pad, and distal shaft with a moist gauze sponge to remove tissue. If tissue is still visible in the clamp arm, use hemostats to remove residue, taking care not to activate the instrument while cleaning.



AFTER thorough cleaning has occurred as instructed, press Next on the GEN11 screen. The GEN11 screen will instruct the user to “Activate instrument outside patient to run test. If using shears, open jaws during test.” This initiates a Blade Integrity Test that will confirm the device will function as intended.

If the test is completed successfully, the procedure may continue as planned. It is important to continue the proactive cleaning of the HDi throughout the remainder of the procedure as previously instructed.



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

Failure of this test most likely means the device was exhibiting a high impedance level caused by excessive tissue buildup within the jaws or a broken/damaged blade. **Failure of the test due to a broken/damaged blade safeguards the user and the patient from further blade damage and additional patient risk.** Failure of this test due to high impedance could also mean that the device could not be cleaned adequately to enable optimized performance.

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