



Guide to Troubleshooting Common Alarms

This Quick Reference Guide is designed to be used in conjunction with, but not replace, the NovaSure Instructions for Use and Controller Operators Manual. Prior to performing the procedure, the physician must review, and be familiar with, the full operating instructions for the Controller and Disposable Device, as well as any warnings, contraindications, and safety information.

Cavity Assessment LED Illuminated:

Cavity Integrity Assessment (CIA) failure is identified by an audible alarm, coupled with a steady red illumination of the CAVITY ASSESSMENT LED.

If a perforation is suspected, the procedure should be terminated immediately.

What to do:

Step 1: Press the footswitch to silence the alarm.



Step 2: Ensure that the suction line desiccant filter has been installed. Check all tubing and luer connections to ensure that they are tightly connected.



Step 3: Look for visible bubbles and/or listen for a "hissing" sound at the external os of the cervix. Use the tab on the cervical collar to advance the cervical collar towards the external os of the cervix to ensure a tight seal.



HOLOGIC°

Step 4: Test again.

If the CIA LED is illuminated green, begin the ablation cycle.

If the CIA LED remains illuminated red, continue with the troubleshooting steps below:

Step 5: If a CO₂ leak appears to be at the cervix and cannot be resolved by using the cervical collar, use a second tenaculum to grasp the cervix around the sheath.

Step 6: Repeat the assessment test by pressing footswitch.

If the CIA fails after reasonable attempts to implement the troubleshooting procedures, terminate the procedure.

CO₂ Canister Low or Empty:

An audible tone will be heard at a rate of four times per second. Pressing the footswitch will not turn off the audible alarm.

What to do:

Step 1: Replace the CO_2 canister to stop the audible alarm.

Vacuum LED Illuminated:

A vacuum alert is identified by a steady red illumination of the VACUUM LED. No audible tone will occur with a vacuum alert.

*In some Model 09 RF Controllers, a vacuum pre-check occurs automatically prior to initiation of the ablation cycle. The VACUUM LED will flash and an audible tone will be heard for up to 10 seconds during the vacuum pre-check.

What to do:

Step 1: Gently press a 2 mm– 3.5 mm uterine dilator or sound inside the vacuum relief valve.



Step 2: Check the cervical collar position, and

reposition it if necessary. Advance the cervical collar towards the external os to ensure a tight seal to verify that air is not being drawn through the cervix.

- **Step 3:** Ensure the suction canister on the device is vertical and that the device tubing is not draped over the patient's leg.
- Step 4: Check the push-on tubing connectors at the desiccant tube. Replace the desiccant if it is pink. Ensure that the filter located near the disposable connection on the vacuum feedback line is tightened.



Step 5: Press the ENABLE button to reattempt ablation.

If the VACUUM LED is illuminated red, continue with the troubleshooting steps below:

Step 6: Remove the device from the patient.

- Step 7: Call Tech Services (800-442-9892, Option 1)
- **Step 8:** Reinsert the disposable device, press the ENABLE button twice, and step on the footswitch to reattempt the ablation.

If the VACUUM LED is illuminated red, continue with the troubleshooting steps below:

Step 9: Reattempt the ablation with a new device. If a vacuum alarm occurs with the new device, abort the procedure.

Array Position LED Illuminated:

Electrode array position alert is identified by a steady red illumination of the ARRAY POSITION LED. No audible tone will occur.

What to do:

Gently move the proximal end of the disposable device and observe if the ARRAY POSITION LED extinguishes. If it does not, follow the steps below:



- Step 1: Attempt gentle reseating of the disposable device: Partially retract the array into the sheath by releasing the handle lock release button; pull back slightly from the fundus; slowly deploy the device array while gently rocking the device back and forth and locking the handles; reseat the device against the fundus.
- Step 2: If the uterus is retroverted, take special care to avoid perforation. Apply gentle caudad traction to the cervix with the tenaculum, and elevate the disposable device handle in-line with the axis of the uterus while performing the seating procedure.

If the ARRAY POSITION LED remains illuminated red, continue with the troubleshooting steps below:

- **Step 3:** Fully retract the disposable device array and remove from patient.
- **Step 4:** Deploy the device outside of the patient's body; ensure that the electrode array is undamaged and that the ARRAY POSITION LED extinguishes on the RF controller.
- **Step 5:** Attempt reinsertion, redeployment and reseating of the disposable device.

If the ARRAY POSITION LED is illuminated red, continue with the troubleshooting steps below:

Step 6: Replace with a new disposable device.

If the ARRAY POSITION LED remains illuminated red with a new disposable device, terminate the procedure.