QUICK REFERENCE GUIDE

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 Alarm

If the cavity integrity assessment (CIA) fails, then the CAVITY ASSESSMENT LED on the NovaSure RF controller will flash red, and a rapid audible tone will sound at a rate of four times per second. **(Model 09 RF Controller)**.

Model 10 RF Controller: Screen displays "Cavity Assessment Failure" with troubleshooting steps.

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

What to do:

Step 1: For **Model 09** controllers, press the footswitch to silence the alarm.

(On **Model 10** the alarm sounds for a few seconds and then stops by itself. Pressing the footswitch will restart the CIA.)

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.

Desiccant Filter

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.

Step 4: Test again.

Thumb Tab

Model 09: If the CIA LED is illuminated green, begin the ablation cycle.

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

Model 10: If the screen displays "Cavity Assessment complete" begin the ablation cycle.

If the screen displays "Cavity Assessment Failure", 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:

Model 09: An audible tone will be heard at a rate of four times per second. Pressing the footswitch will not turn off the audible alarm.

Model 10: Screen will display "Replace CO2". Audible tone will be heard at a rate of one time per second. Volume can be lowered by pressing button on the screen, but will not turn off completely until the new CO2 canister is fastened to the back of the controller.

What to do:

Step 1: Replace the CO2 canister to stop the audible alarm.

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Troubleshooting Common Alarms *continued*

Vacuum Alarm:

Model 09: 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.

Model 10: Vacuum precheck occurs automatically prior to ablation and failure is indicated on the screen by a "Vacuum Failure" message with troubleshooting instructions.

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.

Vacuum Relief Valve

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.

Desiccant Filter

Step 5: **Model 09:** Press the ENABLE button once to reset the alarm, press ENABLE button again and press foot pedal to continue with ablation.

Model 10: Simply press footswitch to restart vacuum check (and if successful) continue with ablation.

If the VACUUM LED illuminates red again (Model 09) or screen displays "Vacuum Failure" (Model 10), follow the troubleshooting steps below:

Step 6: Reattempt the ablation with a new device. Reseat the device and perform CIA

Step 7: If a vacuum alarm occurs with the new device, abort the procedure.

Array Position Alarm:

Model 09: Electrode array position alert is identified by a steady red illumination of the ARRAY POSITION LED. No audible tone will occur.

Model 10: An "Array Position" message appears on the lower right-hand corner of the screen if an array position short (array closed) is detected.

What to do:
Gently move the proximal end of the disposable device and observe if the ARRAY POSITION LED extinguishes **(Model 09)** or "Array Position" message goes away **(Model 10)**. 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.

Lock Release Button

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 (Model 09) or "Array Position" message remains on screen (Model 10), 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 (Model 09) or "Array Position" message remains on screen (Model 10), continue with the troubleshooting steps below:

Step 6: Replace with a new disposable device.

If the ARRAY POSITION LED remains illuminated red (Model 09) or "Array Position" message remains on screen (Model 10) with a new disposable device, terminate the procedure.

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