SYMPHION®
Operative Hysteroscopy System

QUICK REFERENCE GUIDE

This Quick Reference Guide is applicable to Symphion controller with Software Version 3.0.0 or higher, which includes EXPRESS Fluid Management Accessory, INFINITY Fluid Management Accessory (FG-0204), and optional Fluid Deficit Readout (FG-FDR1).

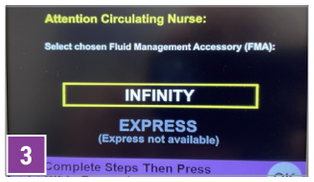
minerva®
The Uterine Health Company

Set-up

Note: EXPRESS Fluid Management Accessory, currently NOT AVAILABLE. The original FMA (FG-0202) is not designed to be used with Software Version 3.0.0 or higher.

Circulating Nurse - If using the Fluid Deficit Readout (FDR) accessory, place the FDR on the Saline Pole. Connect power cord accordingly.

Circulating Nurse - Plug in the controller, connect footswitch, and turn on power. Verify that version 3.0.1 is displayed.

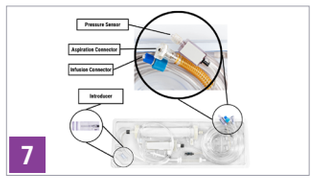


Circulating Nurse - Select the INFINITY Fluid Management Accessory (FMA) on the touch screen.

Circulating Nurse - Hang 2 or 3 Liter bag of saline on IV bag hook. Apply BIOHAZARD label to the bag of saline.

Circulating Nurse - If using the FDR, power on. When "HANG BAG" is displayed, hang the single saline bag on the FDR hook. The word "SET" will appear on display.

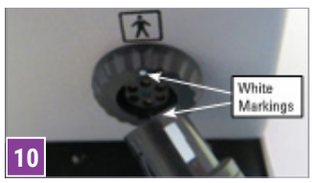
Circulating Nurse - Remove protective cover from INFINITY FMA tray.



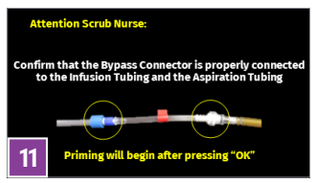
Scrub Nurse - Remove Introducer and tubing from the FMA tray by grabbing distal ends of Infusion, Aspiration tubing, and Pressure Sensor.

Circulating Nurse - Insert tubing into color coded Pump Heads and close.

Circulating Nurse - Spike the Infusion port on saline bag with the saline spike on the end of the Infusion and Filter Tube. De-air the drip chamber until blue ball is at the top.

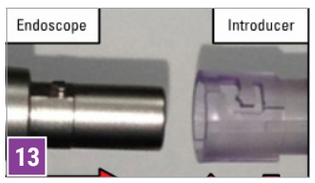


Circulating Nurse - Connect the Pressure Sensor to the Controller.

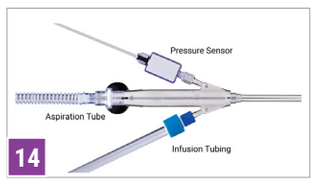


Scrub Nurse - Confirm that the Bypass Connector is properly connected to the Infusion and Aspiration Tubing. Wait for the system to complete priming, which may last up to 40 seconds. Remove and discard the Bypass Connector.

Circulating Nurse - If using FDR, set the desired Fluid Deficit Limit.



Scrub Nurse - Connect Introducer to scope and twist to lock on.



Scrub Nurse - Connect the Aspiration Tubing to Introducer. Connect Infusion Tubing and Pressure Sensor to the scope.

System Operation

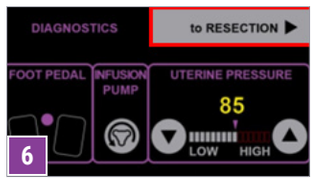
Set cavity pressure. Immediately before insertion, start infusion by pressing the Infusion pump on-screen icon.

Aspiration can be activated by pressing the center button.

Following sterile practice, peel off protective cover and remove Resecting Device.

Connect resecting device to controller.

Connect Aspiration Tubing to Resecting Device and insert into working channel of endoscope. Follow standard operative hysteroscopy practices.



Press "to RESECTION" on controller screen. The yellow RESECT foot pedal activates RF resection as indicated on the display.

The blue COAG foot pedal activates coagulation as indicated on the display.

FDR Recall Mode

If the optional Fluid Deficit Readout is being used and is turned off or loses power, the FDR will store the last displayed deficit volume.

- Remove saline bag from hook.
- Power System on and wait for "HANG BAG" prompt, indicating completion of system initialization. DO NOT HANG SALINE BAG WHEN PROMPTED.
- Press Recall Button on the rear panel.

The recall value will be displayed in the Initial Value/Deficit display. To exit recall mode and resume typical functionality, power the system off and back on.

Disassembly of Fluid Management Accessory

1

Disable Infusion and remove instruments from the uterine cavity.

2

Wait a minimum of 60 seconds for any fluid pressure to dissipate from the Tubing set. Remove the tissue catch and obtain the tissue specimen.

3

Disconnect Resecting Device and Pressure Sensor from Controller.

4

Disconnect the Tubing and the Pressure Sensor. Unscrew the Introducer. Remove Resecting Device from endoscope and put on top of the FMA tray.

5

Unhook Saline Bag and place it on the FMA Tray.

6

Disconnect Tubing from Pump Heads and dispose of tubing with the FMA tray.

7

Dispose of remainder of the Resecting Device, FMA and Saline Bag per hospital standards concerning BIOHAZARD materials.

Troubleshooting

IMPORTANT: If you cannot eliminate the issue with these most common errors from the help of this table, please contact your representative or the customer service department. There are no user serviceable parts inside of the Controller or Fluid Deficit Readout. Opening the unit may cause electrical shock to user and voids warranty.

CONTROLLER

ERROR CODE DESCRIPTION	DISPLAYED ERROR CODE	REMEDY
Insufficient Aspiration	**Check Aspiration Tubing for Kink Press OK to CONTINUE**	• Check that Aspiration Tubing is properly inserted in pump, check that connections are secure, replace if necessary • Check Aspiration tubing for occlusion • Replace Resecting Device
Kinked Tubing	**Check Infusion Tubing for Kink Press OK to CONTINUE**	• Check Infusion Tubing for kinks and constrictions • Check that Infusion Tubing is properly inserted into pump
Return Fluid Path Obstructed	**Unkink Aspiration Tube or, Replace FMA**	• Replace FMA See section 13.4 (INFINTY FMA) of L0184 IFU above for instructions. If using optional FDR, record deficit value prior to restart. CAUTION: DO NOT HANG A NEW SALINE BAG. HANG THE SAME SALINE BAG USED IN THE BEGINNING OF THE PROCEDURE TO CONTINUE. Note: Priming the FMA results in a loss of 500-600mL of saline from the hanging saline bag. Plan the procedure accordingly based on the remaining fluid within the saline bag. • Check that Aspiration Tubing is properly inserted into pump • Check Tissue Catch/Tissue Catch Tubing/ Filter Tubing for kink or occlusion
No Device Detected	**Device Detected Connect Device to CONTINUE**	• Check Resecting Device connection, replace if necessary • Ensure the Resecting Device is securely plugged into the blue connector
Fluid Leak	**Check System for Leak**	• Check device/tubing connections. Reconnect/replace as needed • Check cervix for leaking, add/adjust tenaculum at the cervix • Check for perforation
Excessive Cavity Pressure	**Excessive Cavity Pressure Relieving Pressure**	• Wait and allow system to clear (<5 secs), check return tubing for occlusion
Cannot RESECT or COAG	**No Device Detected Connect Device to CONTINUE**	• Make sure that the Controller is in Resection mode • Ensure that normal saline [sodium chloride (0.9% w/v; 150mmol/L) is being used as irrigation solution • Ensure that the footswitch is plugged into the gray port on the Controller • Check Resecting Device connection, replace if necessary • Ensure the Resecting Device is securely plugged into the blue connector

FLUID DEFICIT READOUT

DISPLAYED ERROR CODE	ERROR CODE DESCRIPTION	REMEDY
1	**Error captured when a weight is detected at power on**	Remove all weight hanging from system and power cycle device.
2	**Error captured when the 5V internal voltage rail is outside defined ranges**	Confirm that power supply connected to Fluid Deficit Readout Accessory is the Minerva Surgical issued power supply.
3-46	**Software Error (Multiple)**	Power cycle device, if error continues contact Customer Service.

For case support call Customer Service, select option 2: 855-646-7874

Minerva Surgical, Inc.
4255 Burton Dr.,
Santa Clara, CA 95054
www.minervasurgical.com

L0202 Rev. B

INDICATIONS: The Symphion® System is intended for resection and coagulation of uterine tissue such as intrauterine polyps and myomas using a bipolar resecting device by distending the uterus with saline to facilitate viewing with a hysteroscope during diagnostic and operative hysteroscopy and providing fluid management through either the closed loop recirculation of filtered distension fluid or non-recirculating/non-filtered distension fluid.

Consult electronic instructions for use (eIFU) prior to use and a complete list of contraindications, warnings/precautions, and potential adverse events. The Symphion IFU and Quick Reference Guide will be on the Minerva Surgical website and could be subject to periodic updates. Visit **https://minervasurgical.com/ifu_symbol-glossary/** for the most current versions.

℞ Only **CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician. The physician using this device must be trained in diagnostic hysteroscopy and hysteroscopic surgery using powered instruments.