

LEVEL 1

LEVEL 1® H-1200 FAST FLOW FLUID  
WARMER WITH H-31B AIR DETECTOR/CLAMP

# QUICK REFERENCE GUIDE

This Quick Reference Guide is intended to provide abbreviated instructions and warnings for reference by users familiar with the Level 1® H-1200 Fast Flow Fluid Warmer with H-31B Air Detector/Clamp.

Complete instructions including warnings, cautions and other important information for the safe and proper use of this product are provided in the Operator's Manual supplied with each device.

SET UP

**READ AND FOLLOW ALL INSTRUCTIONS, LABELING AND ACCOMPANYING DOCUMENTS SUPPLIED WITH THIS MEDICAL DEVICE. FAILURE TO FOLLOW INSTRUCTIONS, INCLUDING ALL WARNINGS AND CAUTIONS, COULD RESULT IN DEATH OR SERIOUS INJURY TO THE PATIENT OR USER.**

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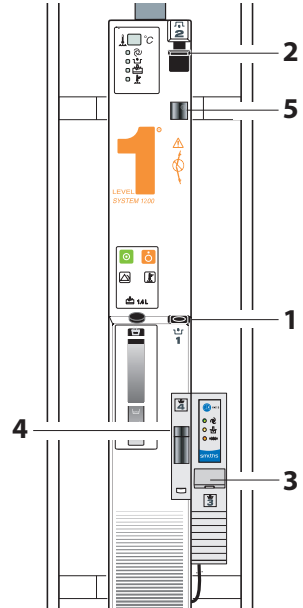
# INSTALL THE DISPOSABLE ADMINISTRATION SET

The installation sequence for the Disposable Administration Set corresponds to the numbered Blocks marked 1-2-3-4 on the Fluid Warmer.

**Note:** Inspect the disposable set prior to use and confirm Luer connections are secure. D/DI-60HL and D/DI-65HL Disposable Sets require the Heat Exchanger to be placed with the Patient Line extending to the left.

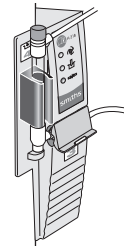
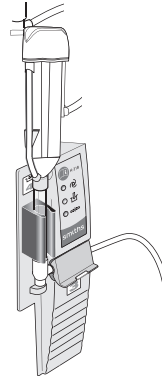
- 1** Push the bottom end of the Heat Exchanger [the end near the Gas Vent/Filter Assembly] into **1** Block. Press the Heat Exchanger down firmly to properly seat in the block.
- 2** Slide **2** Block up. Snap Heat Exchanger into guide **5**. Press firmly into place to ensure it is properly seated. Slide **2** Block down, push down firmly to secure.
- 3** Move the pinch clamp on the Patient Line of the Gas Vent/Filter Assembly next to the Luer connector. Close the pinch clamp.

**Note:** Disposable Sets use two types of Gas Vent/Filter Assemblies. Step **4**, which describes how to install the Gas Vent/Filter Assembly, is different for each type of Disposable Set. Continue with the appropriate step **4** that applies for your specific Disposable Set.



## PRIME THE DISPOSABLE ADMINISTRATION SET

- 4** Install the Gas Vent/Filter Assembly for **DI-55**, **D/DI-65HL**, **D/DI-75**, **D/DI-150**, and **D/DI-350** Disposable Sets.
  - a** Open the **3** Clamp Slot door.
  - b** Align the Gas Vent/Filter Assembly to the **4** Block, and press it into place.
  - c** Press the clip at the top of the Gas Vent Vent/Filter Assembly to the bottom of the Heat Exchanger.
  - d** Insert the Patient Line in the Clamp Slot and push it back into the slot.
  - e** Hold the Patient Line in the Clamp Slot and push the door up to engage the top hinge. Then push the front of the door down to close it.
  
- 4** Install the Gas Vent/Filter Assembly for **DI-50**, **D/DI-60HL**, **D/DI-70**, **D/DI-100**, and **D/DI-300** Disposable Sets.
  - a** Open the **3** Clamp Slot door.
  - b** Insert the Patient Line in the Clamp Slot and push it back into the slot.
  - c** Hold the Patient Line in the Clamp Slot and push the door up to engage the top hinge. Then push the front of the door down to close it.
  - d** Pull the Patient Line to the right to align it in the Clamp Slot without kinking.
  - e** Align the Gas Vent/Filter Assembly to the **4** Block, and press it into place.

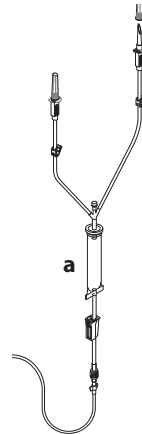


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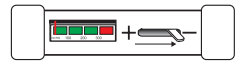
# PRIME THE DISPOSABLE ADMINISTRATION SET

- 1 Close the Disposable Set clamps above the Heat Exchanger.
  - For **DI-50, DI-55, D/DI-60HL, D/DI-65HL, D/DI-70, and D/DI-75** Disposable Sets,
    - close pinch clamps below the bag spikes, and
    - close roller clamp below the drip chamber (**a**).
  - For **D/DI-100, D/DI-150, D/DI-300, and D/DI-350** Disposable Sets,
    - close pinch clamps below the drip chambers.



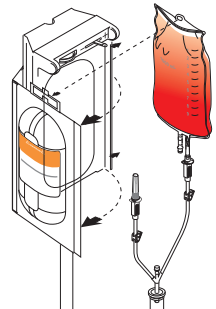
- 2 Remove all air from the fluid bag:
  - a Invert fluid bag.
  - b Use aseptic technique. Pierce membrane of bag port with spike of Disposable Set. Then withdraw spike.
  - c Squeeze bag to exhaust ALL air.
  - d Place spike in bag port. Do not allow air to re-enter bag. Repeat this step for each fluid line to be used.

- 3 Slide lever on H-2 Pressure Chamber to the minus (-) unpressurized position.



- 4 Hang spiked fluid bag/s in Pressure Chamber:
  - a Release hinged latch, open door and hang fluid bag inside on tab appropriate for bag size.
  - b Close the door and secure latch.
  - c Injection and Spike ports on the fluid bag should extend from opening at the bottom of the Pressure Chambers without being obstructed.

**Note:** When installing Level 1® **D/DI-300** and **D/DI-350** Disposable Sets, hang the third fluid bag from the I.V. pole.



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## PRIME THE DISPOSABLE ADMINISTRATION SET (CONT'D)

- 5 Open clamps above Drip Chamber(s) – (not necessary with D/DI-100, D/DI-150, D/DI-300, and D/DI-350).
- 6 Squeeze the Drip Chamber until one-half to three-quarters full of fluid.
- 7 Open remaining clamps above Heat Exchanger. Fluid flows into the Gas Vent/Filter Assembly.
- 8 For D/DI-50, D/DI-60HL, D/DI-70, D/DI-100, and D/DI-300 vigorously tap the Gas/Vent Filter Assembly to dislodge any air bubbles from the filter screen.
- 9 Turn power ON.
  - Air Detector/Clamp enters a Power ON test. All indicators illuminate and the audible warning beeps. If not, remove from service.
  - Upon completion of the Power ON test, the green Automatic Operation LED illuminates.
- 10 Remove male Luer cap from distal end of Patient Line.

**Note:** With D/DI-60HL and D/DI-65HL Disposable Sets, verify that no recirculating solution comes out of the distal end of the Patient Line.
- 11 Open pinch clamp just below the Gas Vent/Filter Assembly and complete priming of Patient Line.
- 12 Allow fluid to flow until no air is observed in the Patient Line and the line is primed with fluid. Then, close the roller clamp on the Patient Line.

**Note:** On D/DI-60HL and D/DI-65HL Disposable Sets, close the roller clamp below the drip chamber.

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## TEST THE AIR DETECTOR/CLAMP

**This step is to be performed with the H-1200 in Automatic Operation mode with a primed Disposable Set in place.**

- 1 Slide the lever on the Pressure Chambers to the plus (+) position.
- 2 Move the Gas Vent/Filter Assembly away from the Air Detector sensor as shown.
- 3 The following occurs:
  - The Air Detector clamp closes.
  - The red Clamped LED illuminates.
  - The audible warning signal beeps.
  - Fluid Warmer disposable alarm activates.

If any of the above does not occur, remove the device from service.

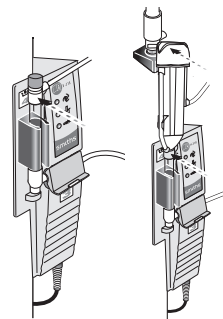
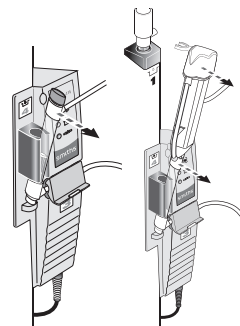
- 4 Open the roller clamp on the Patient Line to verify that fluid does not flow. After verifying that no fluid is flowing, close the roller clamp completely.

If fluid flow is observed, remove the device from service.

- 5 Return to normal operation by placing the Gas Vent/Filter Assembly back into the #4 block as shown.

The green Automatic Operation LED on the Fluid Warmer Display Panel and on the Air Detector/Clamp Control Panel illuminate.

- 6 Establish patient connection and begin infusion.



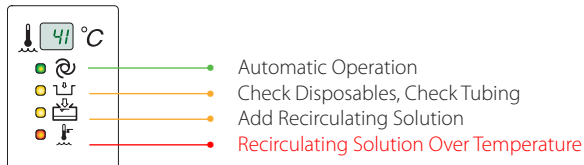
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# ALARMS: FLUID WARMER

For complete information regarding all alarms, please consult Operator's Manual.

## FLUID WARMER DISPLAY PANEL



### HIGH PRIORITY ALARM

#### ● **Recirculating Solution Over Temperature**

**Alarm Condition:** Recirculating solution temperature has exceeded acceptable temperature for safe use.

**Action Required:**

- If connected to patient, close all clamps.
- Turn Fluid Warmer OFF.
- Turn Fluid Warmer back ON.
- If alarm condition clears, open all clamps.
- If alarm persists, remove device from service.

### MEDIUM PRIORITY ALARMS

#### ● **Check Disposable, Check Tubing**

**Alarm Condition:** Disposable Set is missing or not fully seated in the Fluid Warmer.

**Action Required:**

- Verify disposable is secured in:
  - **1** Block.
  - **2** Block - Press Interlock down firmly to engage. (O-Rings may require lubrication. Refer to Maintenance section of Operator's Manual).
  - Heat Exchanger Guide (**5**). Firmly press into Guide **5**.
  - **4** Block - Firmly press Gas/Vent Filter Assembly into Block **4**.

#### ● **Add Recirculating Solution**

**Alarm Condition:** Recirculating Solution level is below minimum level.

**Action Required:**

- Fill reservoir to maximum level with either:
  - Distilled water; or
  - 0.3% Hydrogen Peroxide/distilled water solution.



Sequential  
Block Locations

ALARMS

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# ALARMS: AIR DETECTION

For complete information regarding all alarms, please consult Operator's Manual.

## AIR DETECTOR/CLAMP CONTROL PANEL



Automatic Operation

Check Disposables, Check Tubing

Air Detected/Clamped

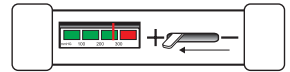
### HIGH PRIORITY ALARM

**Clamped**

Alarm Condition: Air detected in Gas Vent/Filter Assembly.

Action Required:

- Immediately Close ALL clamps on Disposable Set.
- Release pressure: Move lever to minus (-) position.
- Find and remove source of air.
- Spike an air-free bag of I.V. solution, place bag in Pressure Chamber, close and secure door and move lever to plus (+) position.
- Prime drip chamber and open clamps above Gas Vent/Filter Assembly. Fluid should freely flow as air is vented out Gas Vent/Filter Assembly.
- If fluid does not freely flow, replace Gas Vent/Filter Assembly.
- When air is not present in the Gas Vent/Filter Assembly, the clamp will open and resume Automatic Operation mode.
- If no warning signals are active, the Fluid Warmer is ready for use.
- Open remaining clamp(s) and resume infusion.



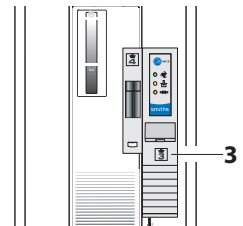
### MEDIUM PRIORITY ALARM

**Check Disposables, Check Tubing**

Alarm Condition: Tubing is not fully in Clamp Slot or clamp door not fully closed.

Action Required:

- Open Air Detector door located in **3** Block.
- Check Tubing is fully seated in Clamp Slot.
- Close door (**3**). Ensure the tab on top of the door is fully inserted.



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# CONTRAINDICATIONS, WARNINGS & CAUTIONS

For a complete list of Contraindications, Warnings & Cautions, please consult Operator's Manual.

## CONTRAINDICATIONS

- Not for use in warming platelets, cryo-precipitates, or granulocyte suspensions.

## WARNINGS

Death or serious injury may occur to the patient or user if these warnings are not followed:

### Setup

- Remove all air from the fluid bags before spiking and fluid lines before connecting to the patient. Failure to do so can result in infusion of air into the patient.
- Do not bend the heat exchanger. Bending may damage the heat exchanger allowing communication between the recirculating solution and I.V. fluid path, resulting in the I.V. delivery of inappropriate fluids.
- When injecting medications into the fluid path, do not inject through the triple lumen tubing of the **D/DI-60HL** and **D/DI-65HL** Disposable Set. This may allow communication between the recirculating solution and I.V. fluid path.
- Do not re-use partially full fluid bags. Fluid bags that have been partially drained, un-spiked, and then reinstalled may contain air, which if used can result in infusion of air into the patient. Use only new fluid bags from which the air has been removed.
- Disposable Sets are supplied with a sterile fluid path which may be compromised if the caps are not in place. Do not use Disposable Sets if Luer and spike caps are not securely in place, or if Luer connections are not secure as the fluid path may not be sterile and may cause death or serious injury to the patient.

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## CONTRAINDICATIONS, WARNINGS & CAUTIONS (CONT'D)

For a complete list of Contraindications, Warnings & Cautions, please consult Operator's Manual.

- Blood and blood products could contain pathogenic organisms. Failure to follow institutional policy and procedures for biomedical-hazardous materials could lead to exposure to harmful pathogens
- Use of a bedside leukocyte reduction filter may cause a sudden precipitous drop in blood pressure resulting in respiratory distress, facial flushing, abdominal pain and nausea, and loss of consciousness. Immediately stop transfusion, and follow institution's protocol for treatment of transfusion reactions.
- Disposable Sets are for single use only. To reduce the risk of cross contamination, do not reuse Disposable Sets.

### Air Detector

- The functional test for the Air Detector/Clamp accessory must be performed before each use. If the device does not function correctly, air in the I.V. line may not be detected, and the patient line may not be clamped. Remove the device from service immediately.
- The tubing must be properly placed in the Clamp Slot of the Air Detector/Clamp. Failure to ensure that the tubing is correctly positioned in the Clamp Slot may result in failure to stop air infusion.
- Do not turn OFF the Fluid Warmer when the Air Detector alarm is active. If the Fluid Warmer is powered OFF in an active alarm state, the Air Detector/Clamp will open and the Air Detector will become disabled. This could allow any air within the Patient Line to be delivered to the patient resulting in serious injury or death.
- Activation of the Air Detector/Clamp alarm during infusion indicates that fluid flow has stopped and that immediate operator intervention is required to restore fluid flow. Failure to reinstate flow (after purging any air or foam) may result in death or serious injury to the patient.

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## CONTRAINDICATIONS, WARNINGS & CAUTIONS (CONT'D)

For a complete list of Contraindications, Warnings & Cautions, please consult Operator's Manual.

### Alarms

- The functional test for the Air Detector/Clamp accessory must be performed before each use. If any visual indicator does not illuminate or the audible signal does not sound, do not use the Fluid Warmer. Remove the device from service immediately. Fully functional visual and audible alarm systems are essential for the safe use of the Air Detector/Clamp.

### Over Temperature

- Activation of the Over Temperature warning signal indicates that warming has stopped and immediate operator intervention is required. Failure to clear the over temperature condition or to take the device out of service may result in death or serious injury to the patient.

### Gas/Vent Filter Assembly

- Replace Gas Vent/Filter Assembly every three hours, or when the filter becomes clogged, or when air is slowly vented. Failure to do so will result in a reduction of flow rate. This may result in inadequate patient treatment.
- The replacement Gas Vent/Filter Assembly must be fully primed before continuing infusion. Failure to do so may allow air to be infused into the patient.

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## CONTRAINDICATIONS, WARNINGS & CAUTIONS (CONT'D)

For a complete list of Contraindications, Warnings & Cautions, please consult Operator's Manual.

### CAUTIONS

- Malfunction, failure, or damage to the device may occur if these cautions are not followed.

#### **Setup**

- Do not use the Fluid Warmer if equipment or Disposable Set malfunction is evident.
- When loading fluid bags into Pressure Chambers, choose a hanging hook that allows the bag port to hang freely in the indented slot at the bottom of the chamber door. If bag ports are positioned above this slot, diminished flow could occur.

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## KEY SYMBOLS

For a complete list of all symbols, please consult Operator's Manual.



Caution



Do not bend heat exchanger



Alarm Test



ON - Only for a part of the equipment.  
MAINS are connected



OFF - Only for a part of the equipment.  
The MAINS are still connected



Automatic Operation



Over Temperature Test  
(Recirculating Solution Over Temperature)



Add Recirculating Solution



Check Disposables, Check Tubing



Clamped



Maximum Reservoir Level

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### Service Contacts

**Contact your Smiths Medical ASD, Inc.,  
Technical Service Department or  
Smiths Medical ASD, Inc., distributor at:**

#### USA/Canada

Smiths Medical ASD, Inc.  
160 Weymouth Street  
Rockland, MA 02370 USA  
USA/Canada 1-800-258-5361  
International +1-781-878-8011  
Fax +1-781-878-8201

#### European Representative

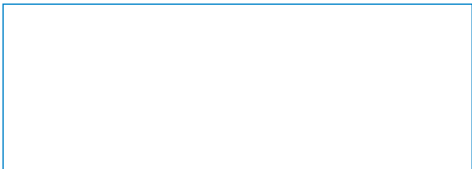
Smiths Medical International Ltd.  
Colonial Way, Watford,  
Herts, WD24 4LG, UK  
Tel +44 (0) 1923 246434  
Fax +44 (0) 1923 240273

#### Australian Representative

Smiths Medical Australasia Pty. Ltd.  
61 Brandl Street, Brisbane Technology Park  
Eight Mile Plains, QLD 4113, Australia  
Tel +61 (0) 7 3340 1300  
Tel NZ (0) 800 444 200  
Fax +61 (0) 7 3340 1399

#### Smiths Medical ASD, Inc.

160 Weymouth Street  
Rockland, MA 02370 USA  
USA/Canada 1-800-258-5361  
International +1-781-878-8011  
Fax +1-781-878-8201  
[www.smiths-medical.com](http://www.smiths-medical.com)



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