DIXION VERTRIEB MEDIZINISCHER GERÄTE GMBH

CE 0483

DIXION

Volumetric Infusion Pump

Instilar 1488

Operation Manual

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Version No.: V1.3
Release Date: August 2015
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GENERAL INFORMATION

INTENDED USE

INSTILAR 1488 INFUSION PUMP IS INTENDED FOR DELIVERY OF INTRAVENOUS MEDICATION AND/OR FLUIDS INTO PATIENTS AT PRESET RATES AND VOLUMES WITH STANDARD PUMP-USE IV ADMINISTRATION SETS FOR PRESCRIPTIVE TREATMENT BY A PHYSICIAN.

INDICATIONS FOR USE

THE DEVICE IS A REGULAR INFUSION PUMP INTENDED FOR USE IN EMERGENCY MEDICAL SERVICES AND IN AMBULATORY INSTITUTIONAL CARE IN SURGERY, INTERNAL MEDICINE, OBSTETRICS AND GYNECOLOGY, AND PEDIATRICS.

THE DEVICE SHOULD ONLY BE OPERATED BY MEDICAL PROFESSIONALS. OPERATION OF THE PUMP BY PATIENTS IS PROHIBITED.

INSTILAR 1488 INFUSION PUMP IS NOT FOR SINGLE-USE. IT IS A RE-USABLE DEVICE.

THIS DEVICE CAN BE POWERED BY AC 100-240V OR DC 12V POWER SUPPLY. IT ALSO COMES WITH INTERNAL POWER SOURCE, WHICH IS AN INTERNAL RECHARGEABLE NIMH BATTERY. THE DEVICE CAN BE POWERED BY THE INTERNAL BATTERY WHENEVER EXTERNAL POWER SUPPLY IS NOT AVAILABLE.

THE INFORMATION CONTAINED ON THE LABELING OF INSTILAR 1488 INFUSION PUMP COMPLIES WITH THE REQUIREMENTS OF HARMONIZED STANDARDS EN ISO 15223-1 AND BS EN 1041: 2008. DETAIL EXPLANATIONS OF THE ICONS/SYMBOLS ON THE PRODUCT LABELS ARE PROVIDED IN THE OPERATION MANUAL.

THE FOLLOWING SAMPLE EXPLAINS THE COMPOSITION OF THE SERIAL NUMBER ON INSTILAR 1488 INFUSION PUMP:

SERIAL NUMBER CONSISTS OF 12 NUMBERS XX|XX|XXXX|XXXX; WHERE 1ST XX MEANS GROUP NUMBER, 2ND XX MEANS MODEL NUMBER, NEXT 4 XXXX MEANS YEAR AND MONTHS OF MANUFACTURING AND LAST 4 XXXX MEANS ORDER NUMBER OF THE DEVICE

BEFORE USING THE PUMP, BE SURE TO READ CAREFULLY AND UNDERSTAND ALL SECTIONS OF THIS USER MANUAL. FAILURE TO READ AND UNDERSTAND THE INSTRUCTIONS MAY LEAD TO MISUSE OF THE PUMP, WHICH MAY HARM THE PATIENT.

PRODUCT FEATURES

INSTILAR 1488 Infusion Pump is Peristaltic Volumetric Pump.

A. Safety Signs

THIS GUIDE CONTAINS WARNINGS, CAUTIONS, AND IMPORTANT INFORMATION TO HELP CALL YOUR ATTENTION TO THE MOST IMPORTANT SAFETY AND OPERATIONAL ASPECTS OF THE PUMP. MEDICAL PERSONNEL AND PATIENTS SHOULD READ THIS MANUAL AND UNDERSTAND ALL WARNING AND CAUTION SIGNS BEFORE OPERATING THE PUMP. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT YOUR LOCAL DISTRIBUTOR OR CONTACT THE MANUFACTURER DIRECTLY.

TO HELP IDENTIFY THESE ITEMS WHEN THEY APPEAR IN THE TEXT, THEY ARE SHOWN USING THE FOLLOWING HEADINGS:

⚠**WARNING**
STATEMENTS THAT DESCRIBE SERIOUS ADVERSE REACTIONS AND POTENTIAL SAFETY HAZARDS.

CAUTION
STATEMENTS THAT CALL ATTENTION TO INFORMATION REGARDING ANY SPECIAL CARE TO BE EXERCISED BY THE PRACTITIONER FOR SAFE AND EFFECTIVE USE OF THE DEVICE.

IMPORTANT
STATEMENTS THAT CALL ATTENTION TO ADDITIONAL SIGNIFICANT INFORMATION ABOUT THE DEVICE OR A PROCEDURE.

Category:	**AC Power or Internal Battery Power Supply**
Type of Protection Against Electric Shock:	 **Type CF**
Degree of Protection Against Ingress of Fluids	**Drip-Proof IPX1**
Mode of Operation:	**Continuous operation**
Power Supply:	**AC100-240V or DC12V or Internal rechargeable battery**
Application:	**I.V Administration set (Pump USE ONLY)**
Power Input:	**Rated Power 58VA ±25%**

⚠**WARNING:** Gravity infusion I.V set cannot be used on this infusion pump. Fail to comply will cause inaccurate infusion result and may harm the patient.

B. Features

a) Automatic control of flow rate regardless of the fluid level and viscosity of the solution.
b) This product performs a self-diagnosis test when power is turned on.
c) Range of flow rate allows for setting and display: 1-9999ml/h. When the infusion is completed, the pump will automatically switch to a KVO (Keep Vein Open) mode.
d) Volume limit (Volume to be delivered) allows for setting and display: 1-9999ml.
e) The product comes with 2 infusion modes: ml/h; drop/min.
f) Accuracy calibration function: manual adjustment or self-correction (Drop sensor must be installed).
g) Program memory retained when pump is turned off.
h) When any error occurs, the pump stops infusion immediately. The maximum infusion volume between occurrence of the error and termination of infusion is controlled to less than 0.15ml.
i) The product is AC or DC powered and is supplied with rechargeable internal battery. The battery can be charged while the pump is operating. Power sources are:
    I. AC input: 100-240AC, 50/60Hz, 58VA
    II. DC input: 12VDC, 1.6A;
    III. Battery power: 12VDC, 2000mA

   In time of losing AC power, product will switch to battery power automatically. When the pump is running on AC power, it can provide 12VDC, 1.5A DC voltage output as the power supply for FW-300 Fluid Warmer.
j) The product can record up to 440 data of infusion status including time, infusion parameters and error codes. It supports data transmission with computer via RS232 (the pump must be under non-infusion status while it is connected to computer via RS232).

C. Symbol Identification

Symbols	Definitions
CE 0483	This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community.
	Protection Against Electric Shock: Type CF, Defibrillator Proof
IPX1	Protection Against Vertically Falling Water Drips
	Attention, Consult User's Manual
	Manufacturer's Information
SN	Product Serial Number
	Manufacturing Date
EC REP	EU Representative
	AC Power Supply
	DC Power Supply
FUSE:(T 1AL 250V)	Fuse And Type
 ON	Power Switch
 OFF	

⚠ GERNERAL SAFETY SUMMARY

IMPORTANT: USER SHOULD READ THIS MANUAL THOROUGHLY BEFORE OPERATING THIS INFUSION PUMP.

WARNINGS OVERVIEW
CRITICAL! POSSIBLE EXPLOSION HAZARD IF USED IN THE PRESENCE OF FLAMMABLE ANESTHETICS!

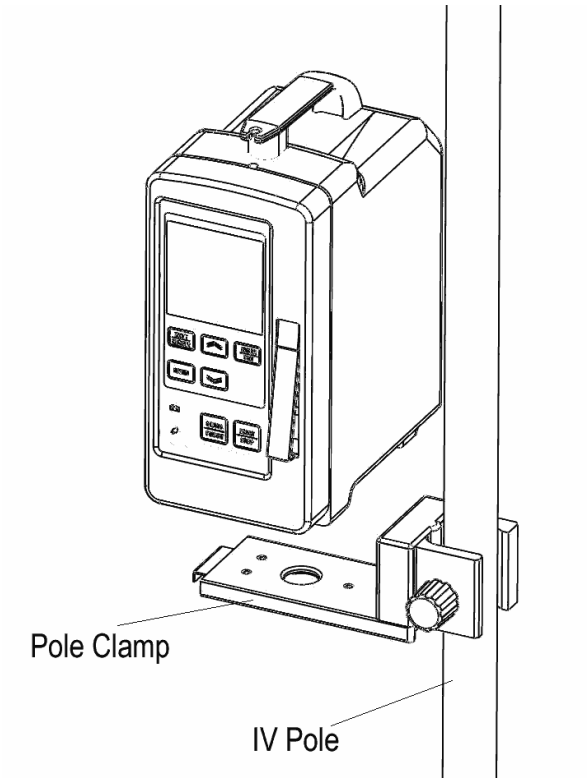
⚠ **WARNINGS:**

1. A SHORT CIRCUIT CAN HAPPEN WHENEVER ANY LIQUIDS COME INTO CONTACT WITH THE AC POWER OUTLET; WHEN CONNECTING THE PUMP TO AC POWER SUPPLY, MAKE SURE THE AC PLUG AND THE POWER OUTLET ARE NOT WET.

2. DO NOT USE THIS PUMP IN THE ENVIRONMENT OF FLAMMABLE ANESTHETIC MIXTURE OF AIR, OXYGEN, NITROGEN AND OXYGEN COMPOUNDS.

3. DO NOT USE A PUMP, INFUSION SET, OR ACCESSORY THAT SHOWS ANY SIGN OF DAMAGE.

4. THIS PUMP IS DESIGNED TO BE USED EITHER IN A STATIC OR MOBILE ENVIRONMENT. WHILE BEING USED IN MOBILE ENVIRONMENT, THE PUMP MUST BE ATTACHED TO AN I.V POLE WITH THE ACCOMPANYING POLE CLAMP.

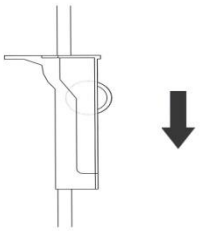


5. THE PUMP DOES NOT DETECT AIR BUBBLES OR OCCLUSION WHEN PURGING. WHEN PURGING, DO NOT CONNECT THE INFUSION SET TO THE PATIENT.

6. DO NOT IMMERSE THIS PUMP IN WATER OR OTHER LIQUIDS.

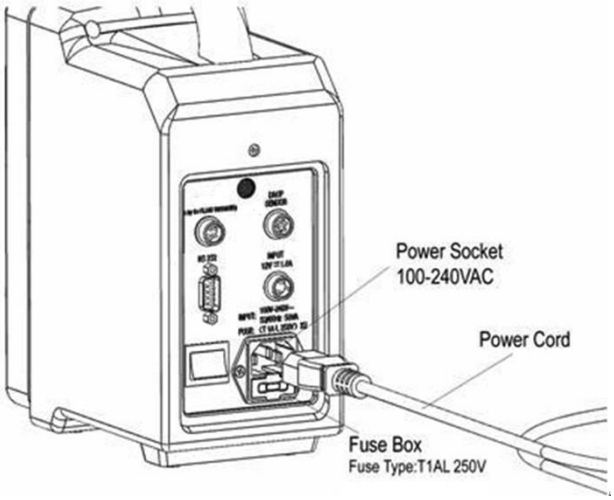
7. BEFORE STARTING AN INFUSION, CAREFULLY MAKE SURE THAT THE I.V SET IS LOADED IN THE PUMP, CONFIRM THE DIRECTION OF THE FLOW IS NOT REVERSED AND THE ROLLER CLAMP IS OPEN, VERIFY THERE IS NO FREE-FLOW IN THE INFUSION SET. ALSO CHECK THAT THE PROGRAMMED INFORMATION IS CORRECT.

8. CLOSE THE ROLLER CLAMP ON THE INFUSION SET BEFORE AND AFTER REMOVING THE INFUSION SET FROM THE PUMP TO PREVENT FREE-FLOW.



9. BEFORE CONNECTING THE I.V SET TO THE PATIENT, THE USER MUST PURGE THE I.V SET TO PREVENT AIR TO THE PATIENT.

10. TO PREVENT ELECTRIC HAZARDS, UNPLUG THE PUMP BEFORE CLEANING. DO NOT SPRAY CLEANSERS TO THE I.V SET OR POWER CORD RECEPTACLES. DO NOT IMMERSE THE PUMP IN ANY LIQUIDS.

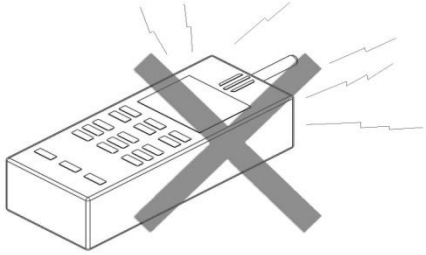


11. DO NOT USE ANY INFUSION SET IF ITS PACKAGING APPEARS TO BE DAMAGED OR OPENED.

12. DO NOT CONNECT THE PUMP TO UNSPECIFIED/UNAUTHORIZED GRAVITY-CONTROLLED I.V SET, AS THIS MAY AFFECT THE ACCURACY OF INFUSION AND MAY TRIGGER FALSE ALARMS, WHICH COULD RESULT IN SERIOUS INJURY TO THE PATIENT. CONTACT YOUR AUTHORIZED DISTRIBUTOR FOR INFORMATION ON HOW TO CHOOSE APPROPRIATE PUMP-USE I.V SETS AND HOW TO CALIBRATE THE PUMP FOR AN ACCURATE INFUSION.

PRECAUTIONS OVERVIEW

1. TO AVOID A MALFUNCTION CAUSED BY ELECTROMAGNETISM DISTURBANCE, PUMP SHALL OPERATE AWAY FROM DEVICES SUCH AS ELECTROCOAGULATOR AND DEFIBRILLATOR, WHICH MAY CREATE A STRONG ELECTROMAGNETIC FIELD. DURING OPERATION, PLEASE NOTICE THAT USER:
    i. MUST KEEP THE PUMP AT ENOUGH DISTANCE FROM ELECTROCOAGULATOR AND/OR DEFIBRILLATOR;
    ii. MUST NOT SHARE THE SAME POWER OUTLET WITH ELECTROCOAGULATOR AND/OR DEFIBRILLATOR;
    iii. MUST NOT USE THE PUMP IN THE MRI ROOM OR HIGH PRESSURE ROOM THAT CREATES A STRONG ELECTROMAGNETIC FIELD;
    iv. MUST OPERATE THE PUMP UNDER SUPERVISION;
    v. DO NOT USE DEVICES THAT MAY EMIT HIGH-FREQUENCY SIGNALS SUCH AS CELLPHONE AND RADIO IN PLACE WHERE THE PUMP OPERATES. KEEP THE PUMP AWAY FROM THE MENTIONED DEVICES;

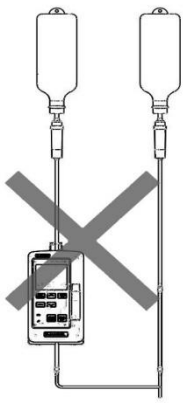


2. USE THE MANUFACTURER RECOMMENDED I.V SET FOR SAFE AND ACCURATE INFUSION. FOR PATIENT SAFETY, IN CASE ANY NEW TYPE OF I.V SET IS USED, USER MUST CALIBRATE THE I.V SET BEFORE STARTING INFUSION. ACCURACY OF THE INFUSION AND CORRECT OCCLUSION LEVEL WITH THIS NEW I.V SET SHALL BE ENSURED.

3. BEFORE STORAGE, MAKE SURE THE BATTERY IS FULLY CHARGED. BATTERY MAY BE DAMAGED IF LEFT UNCHARGED FOR A LONG PERIOD OF TIME.

4. USE THE PUMP AFTER MIN. 3 MONTHS OF STORAGE, THIS PUMP MUST BE CALIBRATED FOR INFUSION ACCURACY, AND TESTED FOR BATTERY POWER AND ALL ALARM FUNCTIONS. ENSURE THE BATTERY IS FULLY CHARGED BEFORE USE.

5. NEVER CONNECT PUMP-CONTROLLED I.V SET TO ANOTHER GRAVITY-CONTROLLED/MANUALLY-CONTROLLED I.V SET. THE PUMP GENERATES POSITIVE PRESSURE TO DRIVE THE FLUID INTO PATIENT'S BODY. IT CANNOT DETECT THE DAMAGE OF I.V TUBE CAUSED BY OVERPRESSURE, SUCH AS FLUID LEAKING OR DAMAGE OF THE FILTER. REGULARLY CHECK ANY POSSIBLE DAMAGE OF THE I.V SET WHEN THE PUMP IS IN OPERATION.



6. WHILE PUMP IS RUNNING ON AC POWER, PLEASE ENSURE THE POWER OUTLET IS PROPERLY GROUNDED.

7. ALWAYS OPERATE THE PUMP WITH AC POWER CONNECTED, UNLESS AC POWER IS NOT AVAILABLE. WHENEVER AC POWER IS AVAILABLE, CONNECT THE PUMP TO AN AC POWER SOURCE AND CHARGE THE BATTERY. IN THIS WAY, BATTERY POWER CAN BE WELL PRESERVED FOR EMERGENCY USE.

8. USE THE PUMP WITH DISPOSABLE I.V SETS RECOMMENDED BY MANUFACTURER (SEE RECOMMEND I.V SET BRAND ON PAGE 41).

9. REPLACE DISPOSABLE I.V SETS ACCORDING TO HOSPITAL POLICIES. USED I.V SETS SHOULD BE STORED IN A SAFE PLACE, AND DISPOSED OF ACCORDING TO GOVERNMENT REGULATIONS AND LOCAL PROTOCOL.

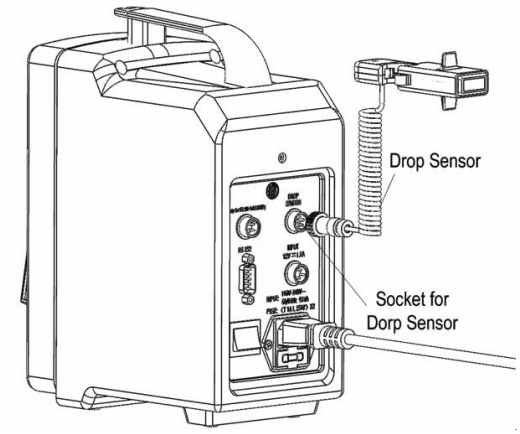
10. THE CIRCUIT DIAGRAM AND PARTS LIST WILL ONLY BE PROVIDED TO THE MANUFACTURER'S AUTHORIZED TECHNICIANS.

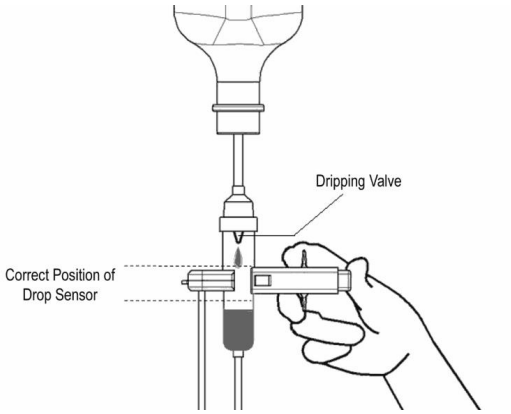
11. THE ACCESSORIES INCLUDE A DROP SENSOR. THE DROP SENSOR IS AN ACCESSORY USED TO DETECT WHETHER THERE IS FLUID LEFT IN THE RESERVOIR. THE DROP SENSOR FUNCTIONS AS A DROP-COUNTING TOOL AND CAN EXECUTE SELF-CORRECTION FOR FLUID VOLUME WHEN THE INFUSION MODE IS SET AS "DROP/MIN". WHEN THE DROP SENSOR IS USED UNDER OTHER INFUSION MODES, IT IS INTENED TO TRIGGER THE "COMPLETE" ALARM WHEN THERE IS NO FLUID LEFT IN THE RESERVOIR.

12. INSTALL AND USE THE DROP SENSOR:
    a) THE DROP SENSOR CAN ENSURE THAT THE PUMP STOPS AND THE ALARM IS TRIGGERED WHEN:
        i. THERE IS AN UNEXPECTED FLUID LEAKING;
        ii. THE FLOW IS REVERSED;
        iii. THE FLUID BAG IS EMPTY.
    b) IF CHOOSE TO USE THE DROP SENSOR, INSTALL IT WITH CARE: CHECK WHETHER THE DROP SENSOR IS PROPERLY PLUGGED TO THE SOCKET ON THE BACK OF THE PUMP; THE DROP SENSOR MUST BE PLACED VERTICAL TO THE INFUSION BAG AND ABOVE THE FLUID SURFACE ON THE DRIP CHAMBER (ENSURE THE FLUID SURFACE IS BELOW THE MID-LINE OF THE DRIP CHAMBER); PROPERLY CLAMP THE SENSOR TO THE DRIP CHAMBER ABOVE THE FLUID SURFACE;
    c) THE PUMP CAN ONLY DISPLAY AND ENABLE THE "DROP/MIN" MODE SETTING WHEN

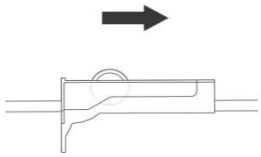
THE DROP SENSOR IS PROPERLY CONNECTED.

d) DO NOT UNPLUG THE DROP SENSOR FROM THE PUMP DURING INFUSION, OR THE PUMP WILL STOP WORKING AND THE ALARM WILL BE TRIGGERED.





13. IN SITUATION WHERE OCCLUSION HAPPENS, CLEAR THE OCCLUSION IMMEDIATELY TO AVOID EXCESSIVE LIQUID OCCLUDED IN THE SYSTEM. PROPER METHOD OF CLEARING AN OCCLUSION IS TO CLOSE THE ROLLER CLAMP FIRST, THEN TO CLEAR THE OCCLUSION. THIS IS TO AVOID EXCESSIVE FLUID THAT IS OCCLUDED IN THE SYSTEM INFUSING INTO THE PATIENT IN A SHORT PERIOD OF TIME. (WHEN THE PRESSURE IN THE TUBING REACHES 0.04 – 0.16MPA, THE PUMP WILL STOP AND SET OFF OCCLUSION ALARM)



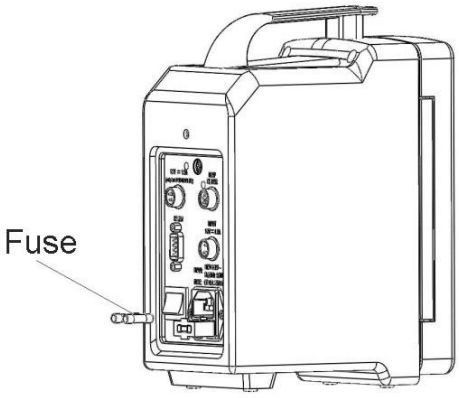
14. THE TUBE PLACED ON PERISTALIC PART OF THE PUMP MIGHT BE ALTERED AFTER 24 HOURS RUNNING; IT IS SUGGESTED TO REPLACE THE I.V SET OR CHANGE THE TUBE AREA PLACED ON THE PUMP'S PERISTALTIC PART TO ENSURE ACCURATE INFUSION.

15. WHEN RELOCATING THE PUMP, PLEASE HANDLE THE INFUSION BAG WITH CARE TO AVOID ANY EXCESSIVE SWING OF THE BAG (WHEN THE DROP SENSOR IS CONNECTED, VIOLENT SHAKING OF THE INFUSION BAG MAY TRIGGER FALSE ALARM).

16. THE PUMP CAN BE USED ON A HORIZONTAL PLATFORM OR ATTACHED TO AN I.V POLE WITH THE I.V POLE CLAMP. BEFORE ATTACHING THE PUMP TO AN I.V POLE, PLEASE MAKE SURE THAT THE I.V POLE IS VERTICALLY STABLE AND WILL NOT FALL WITH THE WEIGHT OF THE PUMP.

17. THE PUMP USES A STEPPER MOTOR DRIVER. ITS SPECIFIC DRIVING MODE PREVENTS THE INCIDENCE OF OVER-FLOW WITHIN AN INFUSION.

18. DISCONNECT THE PUMP WITH AC POWER WHEN REPLACING THE FUSE.



19. THE PUMP MUST BE OPERATED UNDER THE SUPERVISION OF MEDICAL PROFESSIONALS.

20. THE PUMP HAS SELF-DIAGNOSTIC FUNCTION. THE PUMP WILL INITIATE A SELF-DIAGNOSTIC TEST TO GO THROUGH KEY COMPONENTS EVERY TIME THE PUMP IS TURNED ON. WHEN THE AIR-IN-LINE DETECTION SYSTEM IS NOT FUNCTIONING PROPERLY, THE INITIATION WILL FAIL AND THE SCREEN WILL DISPLAY “AIR ALARM SYS. ERROR”. IN THIS SITUATION, THE PRODUCT SHOULD NOT BE USED UNTIL IT IS INSPECTED BY AUTHORIZED SERVICE PERSONNEL.

21. WHEN OPERATING THE INFUSION PUMP, PLEASE READ THIS MANUAL THOROUGHLY, AND STRICTLY FOLLOW THE INSTRUCTION GUIDELINES TO OPERATE THE PUMP.

22. IT IS SUGGESTED TO USE LUER LOCK I.V SET WITH THE PUMP.

23. DO NOT CLEAN, DISINFECT OR STERILIZE ANY PART OF THE PUMP WITH ETHYLENE OXIDE GAS OR BY AUTOCLAVING. THIS MAY DAMAGE THE PUMP AND WILL VOID THE WARRANTY; DISINFECT THE PUMP’S EXTERNAL PARTS ONLY, USING APPROVED CLEANSERS OR DISINFECTANTS.

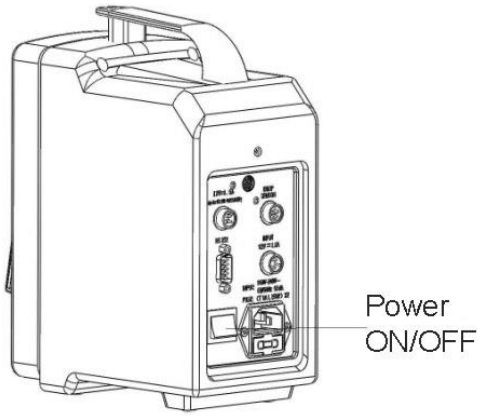
24. THE FOLLOWING CHEMICALS MAY DAMAGE THE PUMP’S FRONT PANEL: ACETALDEHYDE, ACETONE, AMMONIA, BENZENE, HYDROXYTOLUENE, METHYLENE CHLORIDE, OR OZONE. DO NOT USE THOSE CHEMICALS OR CLEANSERS CONTAINING N-ALKYLDIMETHYLBENZYLAMMONIUM CHLORIDE.

25. THE USE OF NON-RECOMMENDED ACCESSORIES MAY RESULT IN INCREASED EMC EMISSIONS OR DECREASED EMC IMMUNITY OF THIS INFUSION PUMP.

26. WHEN USING THIS INFUSION PUMP WITH LIFE-SUSTAINING MEDICINES, ENSURE THERE ARE BACKUP PUMPS AND INFUSION SETS.

IMPORTANT

1. THE PUMP AND DROP SENSOR NEED TO BE CLEANED AND DISINFECTED PERIODICALLY. USE A DAMP (NOT WET) PIECE OF CLOTH OR GAUZE MOISTENED WITH 70% RUBBING ALCOHOL TO GENTLY WIPE OFF THE SHELL AND CONTROL PANEL OF THE PUMP. DO NOT IMMERSE PUMP OR POWER CORD INTO WATER OR OTHER CLEANING LIQUIDS.



2. THE PRODUCT USES RECHARGEABLE NiMH BATTERY, THE MODEL NUMBER IS TMK-AA200E (AA×10/2000mAh). BEFORE RUNNING ON THE INTERNAL BATTERY, CHECK THE BATTERY CAPACITY TO ENSURE THAT THE BATTERY HAS ENOUGH POWER TO SUPPORT THE PUMP TO WORK PROPERLY. IF THE BATTERY WORKING TIME IS SIGNIFICANTLY SHORTER AFTER REGULAR CHARGING, THE BATTERY SHOULD BE REPLACED. TO ENSURE THE BATTERY WORKS WELL WITHIN ITS LIFE SPAN, OPERATE THE PUMP WITH BATTERY POWER OCCASIONALLY TO EXAMINE WHETHER THE BATTERY WORKS PROPERLY. IF THE BATTERY IS NOT USED FOR A PERIOD OF TIME, CHARGE THE BATTERY AT LEAST EVERY THREE MONTHS. WHEN CONNECTING THE PUMP WITH AC POWER, MAKE SURE TO USE THE POWER CORD PROVIDED IN THE ACCESSORIES. IF THERE IS QUESTION ABOUT THE POWER CORD, PLEASE USE THE BATTERY TO OPERATE THE PUMP AND STOP CONNECTING THE PUMP TO AC POWER.

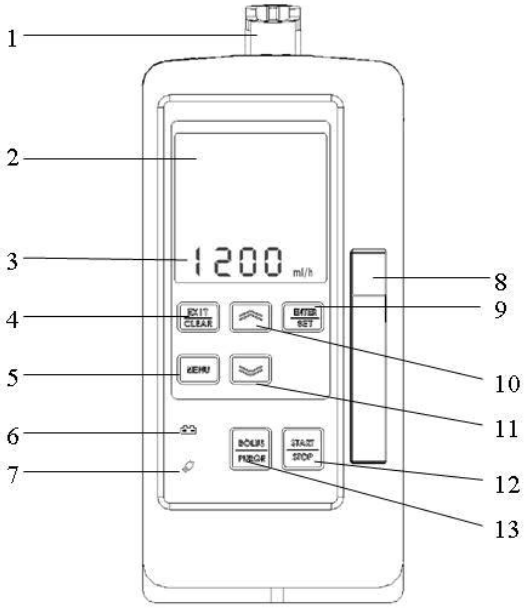
3. IF THE PUMP FAILS, CONTACT THE MANUFACTURER AND PROVIDE DETAILED SYMPTOM DESCRIPTION. ONCE THE PUMP IS ALTERED OR USED BEYOND THE PURPOSES DESCRIBED IN THE MANUAL, THE MANUFACTURER WILL NOT BE HELD RESPONSIBLE.

4. IF THE PUMP IS EXCESSIVELY KNOCKED, IS DROPPED, OR SUFFERS A HIGH-PRESSURE SHOCK, IT MAY BE DAMAGED INTERNALLY WITH NO EXTERNAL SIGN OF DAMAGE. IN SUCH SITUATION, THE PUMP PERFORMANCE MAY BE AFFECTED. DO NOT USE THE PUMP, AND CONTACT AUTHORIZED DISTRIBUTORS FOR SERVICE.

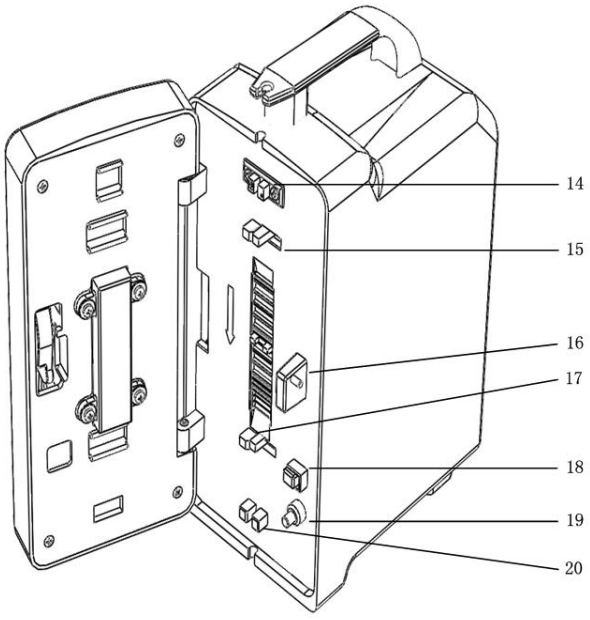
5. BEFORE USING THE PUMP FOR THE FIRST TIME, CONNECT THE PUMP TO THE AC POWER OUTLET. THE BATTERY WILL BE CHARGED WHEN THE PUMP IS TURNED ON; THE CHARGING AND OPERATING CAN RUN SIMULTANEOUSLY. WHEN THE AC POWER IS NOT AVAILABLE, THE PRODUCT WILL RUN ON THE INTERNAL BATTERY. AFTER A CONTINUOUS CHARGE OF 8 HOURS, THE BATTERY CAN SUPPORT THE PUMP TO RUN UP TO 3 HOURS AT A RATE OF 25 ML/H.

6. IF THE INTERNAL BATTERY IS NOT FUNCTIONAL, PLEASE CONTACT THE MANUFACTURER OR LOCAL DISTRIBUTORS FOR A REPLACEMENT.

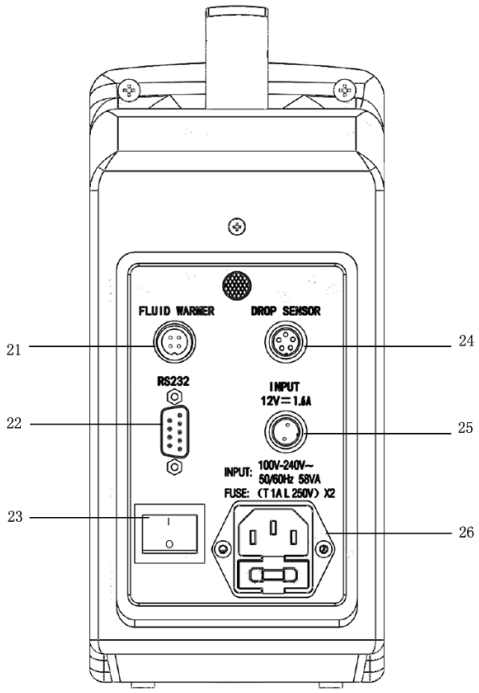
OVERVIEW OF THE INFUSION PUMP



1. **Visual Alarm:** The light will flash with sound if the alarm are triggered
2. **Display Screen:** Display pump and infusion status.
3. **LED Rate Display :** 0.1 to 1200 ml/h or drop/min
4. **EXIT / CLEAR button:** returns to previous screen; zeros the displayed value during programming, erases the last digit during programming
5. **MENU:** Go to the MENU options
6. **Battery Indicator:** The battery indicator in red means that the internal battery is being used
7. **AC Power Indicator :** The AC power indication in green means that the AC power is connected.
8. **Door Open Handle:** Push the top part of the handle then pull handle to open the door; slide down the handle to close the door
9. **ENTER / SET button:** Confirms selecting and setting
10. **Up Arrow:** Scrolls up through options
11. **Down Arrow :** Scrolls down through options
12. **BOLUS / PURGE button:** Hold to enter BOLUS setup when the pump is running; hold to start PURGE when the pump is stopped.
13. **START / STOP button:** starts infusion; stops infusion; silence an alarm condition



14. **Air Detector :** Infrared air detector detects air in the line
15. **Up Tube Clamp :** Guides the Administration Set and detects the downstream occlusion
16. **Door holder :** Holds the door
17. **Down Tube Clamp / Occlusion sensor :** Guides the Administration Set and detects the downstream occlusion in the line
18. **Tube Clamp Opener** : Push to open the down tube clamp
19. **Door Open Detector:** Closes the down tube clamp to prevent free flow when the door is open.
20. **Tube Retainer :** Guides the Administration Set



21. **Fluid Warmer:** Plug Fluid Warmer(optional)
22. **RS 232 Data Port:** For data communication
23. **Power Switch:** Main ON/OFF power switch
24. **Drop Sensor Plug:** Drop Sensor Socket
25. **DC 12V Plug :** Plug DC 12V car charger adapter (optional)
26. **Main Power Plug :** Plug Wall-to-Pump power cord (included)

OPERATING INSTRUCTIONS

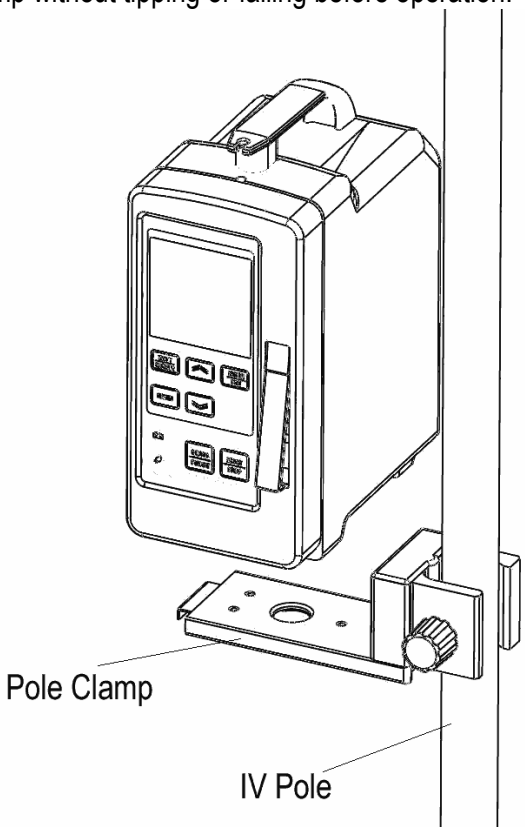
A. MOUNTING THE PUMP ON I.V POLE

This pump can be mounted on the I.V pole with the pole clamp designed for this pump.

1. Turn the pole clamp knob counter clockwise until it fits in the I.V pole.
2. Locate right height of the pump then turn the pole clamp knob clockwise to tighten and secure the pole clamp on the I.V pole.
3. Pull out the secure plate from the side of the holding plate of the pole clamp.
4. Place the center knob on the bottom of the pump to the hole of the pole clamp.
5. Push back the secure plate to secure the pump on the I.V pole.

⚠Cautions

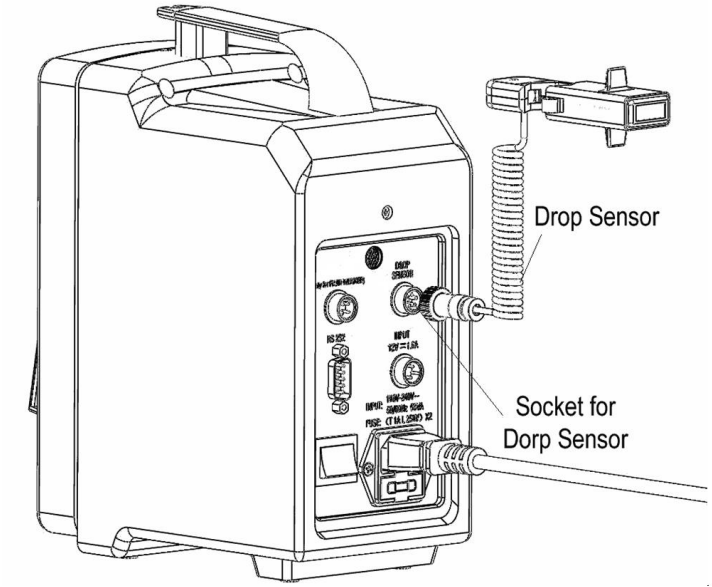
- Ensure the pump is mounted at the height where the main screen and control panel is easily accessible and I.V set can be loaded without being stretched or kinked.
- Make sure the I.V pole is stable and secure to avoid personal injury. Ensure the I.V pole is able to support the pump without tipping or falling before operation.



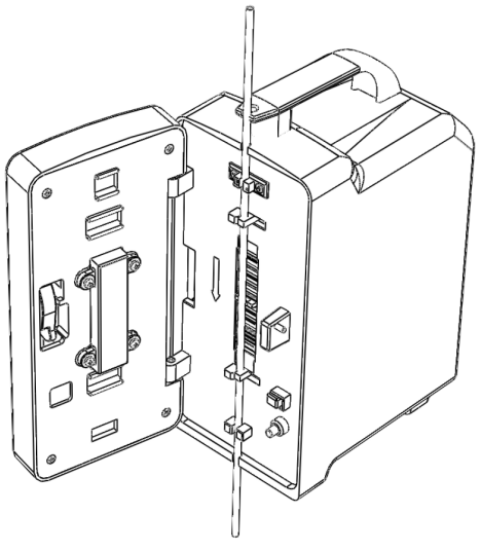
B. PREPARE FOR THE INFUSION

⚠**WARNING:** ONLY USE AUTHORIZED I.V SETS WITH THE APPROPRIATE ACCURACY ADJUSTMENT ON THIS INFUSION PUMP. ANY OTHER GRAVITY USE I.V SET OR UNAUTHORIZED I.V SET MAY AFFECT THE ACCURACY OF INFUSION AND MAY TRIGGER FALSE ALARMS, WHICH COULD RESULT SERIOUS INJURY TO THE PATIENT.

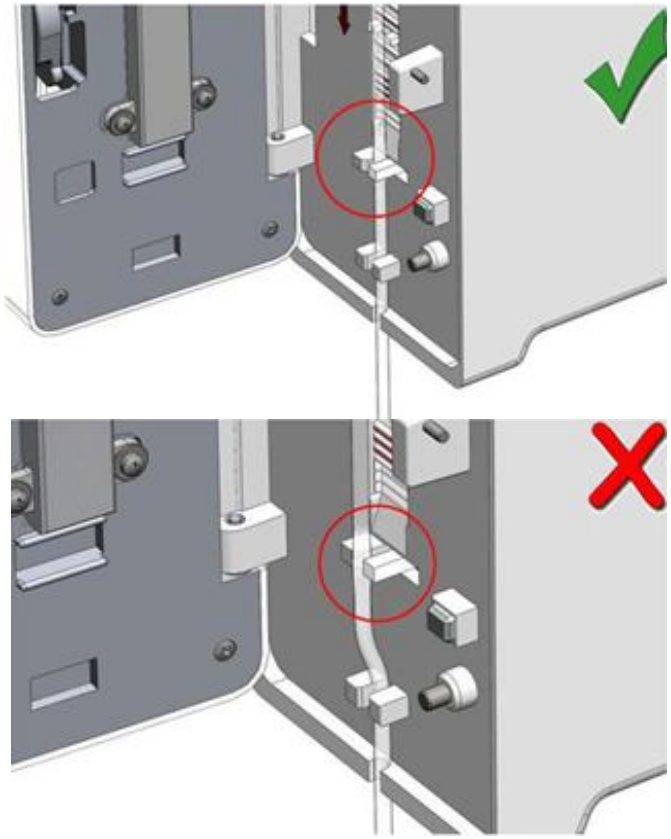
1. Prepare fluid bag and sterilized disposable I.V administration set according to operation instructions on the packaging;



2. Close roller clamp on I.V set, spike and hang the fluid bag to the I.V pole. Open roller clamp to fill the set with fluid;
3. Close roller clamp;
4. Press the top of the grey door latch in front of the pump to lift up the door latch, then open the pump door;
5. Press 'Tube Clamp Opener' to release the " Down Tube Clamp".
6. Guide I.V line through "Air Detector ", "Up Tube Clamp ", "Down Tube Clamp " and "Tube Retainer" as picture below. The tube clamp will be automatically closed while the door is closed.

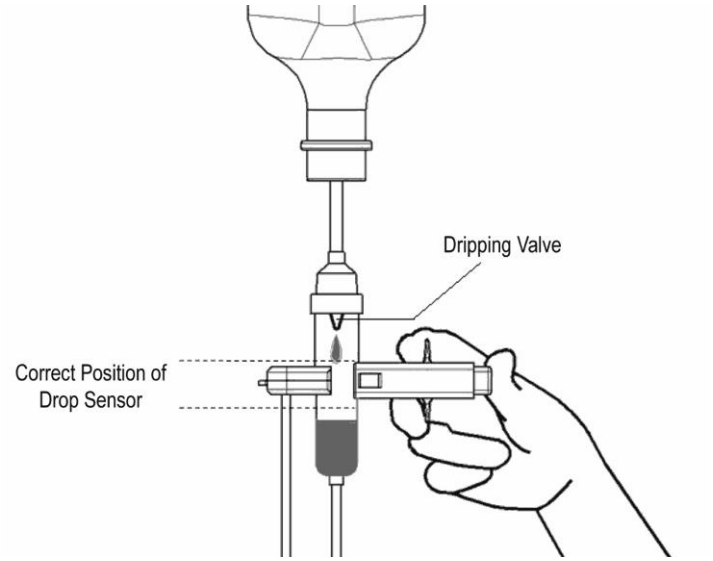


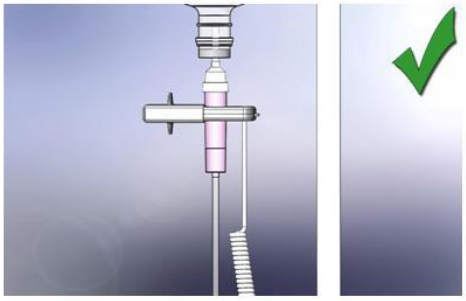
⚠**WARNING:** Once the door is open, the I.V line must be loaded vertically and completely clamped by the bottom clamp as the correct picture below to prevent free flow.



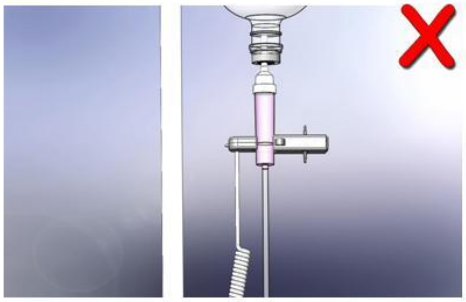
⚠**WARNING:** DO NOT START INFUSION IF ANY UNRESTRICTED FLOW IS OBSERVED! BEFORE STARTING AN INFUSION, OPEN THE I.V SET ROLLER CLAMP. CHECK THE PROGRAMMED INFORMATION AND ENSURE THAT NO DROPS ARE FALLING IN THE DRIPPING CHAMBER FREELY.

7. Close door, open roller clamp.
8. Squeeze drip chamber to make sure it is about one-third (1/3) full.
9. Connect drop sensor to infusion pump; position the sensor horizontally on the drip chamber between the dripping valve and fluid line. Refer to the figures as below to make sure that the drop sensor is installed correctly.

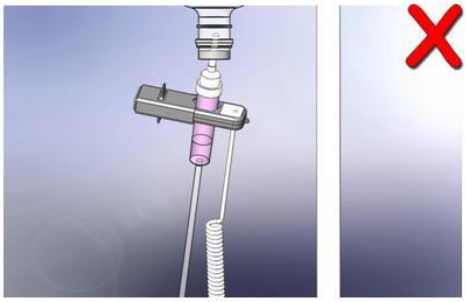




Correct Drop Sensor location!
The Drop Sensor must be placed horizontally above the fluid line, under the dripping valve to detect the drop properly.



Wrong Drop Sensor location!
The Drop Sensor can NOT be placed under or on the fluid line.

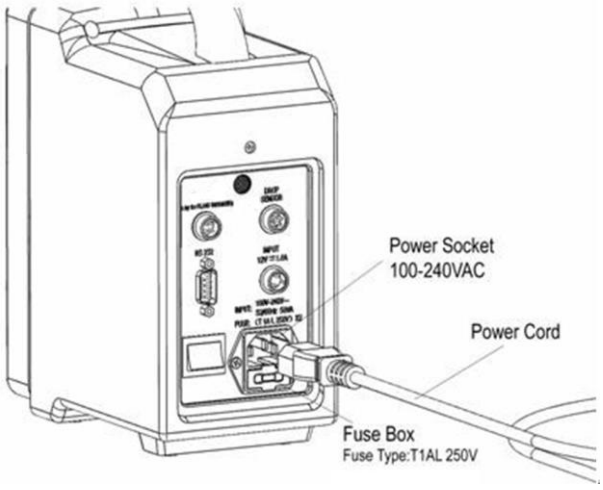


Wrong Drop Sensor location!
The Dripping Chamber and Drop Sensor can NOT be tilted.

Suggested Procedures to replace the I.V set:

1. Close roller clamp on the I.V set.
2. Remove I.V set from patient.
3. Remove drop sensor from the drip chamber of the I.V set.
4. Open the door of the infusion pump.
5. Press tube clamp opener button to release the flow clamp.
6. Remove the I.V set from the pump.
7. Load new I.V set.

C. TURN ON THE PUMP



1. Connect the power cord firmly to the pump and electrical outlet to charge the battery, check the control panel to make sure the green LED power indicator is on.

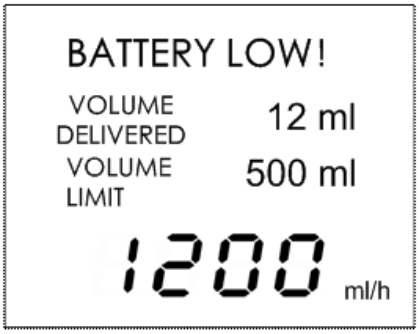
2. The built-in rechargeable batteries will be charged automatically if the AC power is connected. The charging and operating will be running simultaneously. If the plug cord is disconnected during the operation, the pump will automatically switch to internal battery power and will keep a continuous normal operation. After a continuous charge of 8 hours, the battery can support continuous operation for over 3 hours at 25ml/h flow rate. The pump can also be operated with an external 12V DC power supply. The DC power supply has to comply with GB9706.1-2007 Standards.

3. The pump has self-diagnostic function. It will initiate a self-diagnostic program to go through key components every time the pump is turned on. After self-diagnosis is completed successfully, the pump will prompt to main screen. Then this pump is ready for use.

If the self-diagnosis fails:

a. Malfunction of Air-in-Line detecting system: "AIR ALARM SYS. ERROR" will appear. The Pump cannot be used until it is inspected by authorized service personnel.

b. Low Battery alarm at initialization: "BATTERY LOW!" will appear. Pump must be connected to electrical outlet before continuing to operate.



⚠ **WARNING: Do not use the pump with battery if the "BATTERY LOW" alarm message displays, connect the pump to the AC power immediately before use.**

D. FIRST TIME USE

1. Before using this pump for the first time, please make sure that the pump has been connected to electrical outlet (with green LED power indicator ON) to charge internal rechargeable battery for at least 12 hours.
2. Set the date and time to the correct local time.

E. PROGRAMMING A PRIMARY INFUSION

1. Press ENTER SET key once to enter the infusion rate setting screen, press ^ or v key to set desired infusion rate. Press ENTER SET key once to confirm the desired rate and move to volume setting.
2. Press ^ or v key to set desired volume to be infused. Press ENTER SET key to confirm the setting and return to the main screen.
3. Attach infusion set to I.V catheter.
4. Hold BOLUS PURGE key to prime the infusion set.

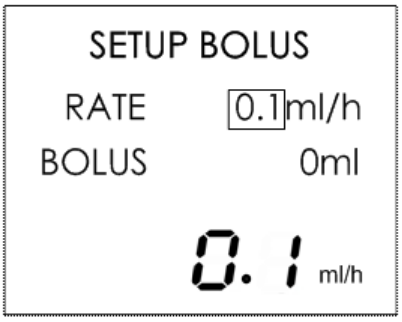
⚠**WARNING: The I.V set must be disconnected from the patient before purging. After the purging is complete, the user can connect the I.V set to the patient again. NEVER start purging the I.V set while the set is still connected with the patient.**

While the pump is not running, user can purge the I.V set by holding BOLUS PURGE key to purge the I.V set. This is for clearing the occlusion or air-in-line conditions.

IMPORTANT: The purge rate is 900 ml/h. PURGE volume will not be counted into VOLUME DELIVERED.

5. Connect the catheter to the patient. Press START/STOP key to begin infusion.
6. To stop infusion, press START/STOP key.
7. To restart or clear the total infused volume, press ON/OFF switch on the back of the pump to restart the pump (minimum 3 seconds interval).

F. PROGRAMMING A BOLUS INFUSION



During primary infusion, the pump can be set to infuse an additional dose of medication or fluids from second source container at a rate and volume different from the current infusion settings. After the BOLUS infusion is completed, the pump will automatically switch to the primary infusion settings.

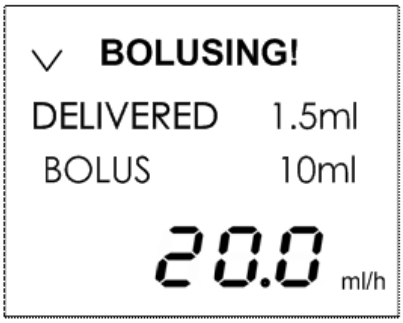
Procedures to program a BOLUS infusion:

1. Holding BOLUS/PURGE key during the primary infusion for 3 seconds to enter **SETUP BOLUS** menu.

IMPORTANT: There will be no interruption for current infusion during the BOLUS setup.

2. Press ∧ or ∨ key to set preferred BOLUS RATE in ml/h then press ENTER/SET key to confirm the rate setting.
3. Press ∧ or ∨ key to set preferred BOLUS VOLUME in ml. Minimum bolus volume is 0.1 ml; maximum bolus volume is 9999 ml. Press ENTER/SET key to confirm the volume setting. Pump will prompt user by asking "BOLUS?"

⚠**WARNING:** If the Bolus volume exceeds the remaining volume to be infused on main setup screen, the pump will display 'BOLUS TOO MUCH!' and return to the main screen. The current bolus setup will be cancelled!



4. To start a bolus, press BOLUS/PURGE key. Bolus infusion will start at the preset rate and volume. The screen will display delivered bolus volume and bolus rate. Once the delivered bolus volume reaches the preset bolus volume, the pump will automatically switch back to the primary infusion rate.

⚠**WARNING:** BOLUS volume will be added into TOTAL VOLUME DELIVERED.

To Stop the BOLUS infusion:

Press START/STOP key to stop the current bolus infusion and return to the main screen.

To repeat last BOLUS infusion:

The latest BOLUS infusion rate will be kept in the memory of the pump. If the user wants to restart the same bolus infusion, please hold BOLUS/PURGE key for 3 seconds to enter **SETUP BOLUS** screen, then press

ENTER SET key twice, and start the same bolus by pressing BOLUS PURGE key once.

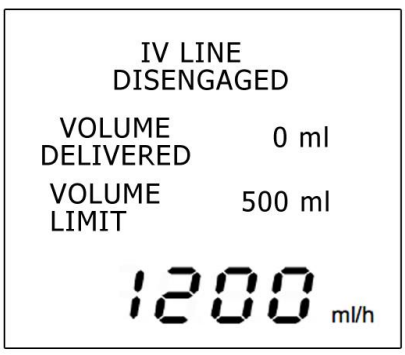
G. ALARM AND PROMPT FUNCTION

Model INSTILAR 1488 Infusion Pump comes with alarm and prompt function. During the operation, the alarm might be triggered automatically as a way to inform the operator of abnormal parameters. Except for a delay in the Occlusion alarm, the trigger time for other alarms are all precise (under 10s). All alarms reflect the mechanical status of the device and do not reflect the vital signs of the patient.

Alarm Categories and Priorities

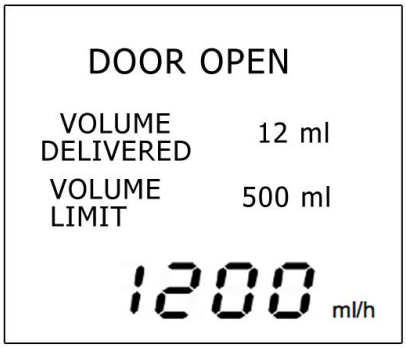
Alarm Category	Priority	Alarm mode
I.V line not loaded	Low	Low, Medium level alarm sound, accompanied by a flashing yellow light
Start reminder	Low	Low, Medium level alarm sound, accompanied by a flashing yellow light
Door open	High	High-level alarm sound, accompanied by a flashing red light
Air in line	High	High-level alarm sound, accompanied by a flashing red light
Occlusion in line	High	High-level alarm sound, accompanied by a flashing red light
Empty	High	High-level alarm sound, accompanied by a flashing red light
Infusion complete	High	High-level alarm sound, accompanied by a flashing red light
Low battery Reminder	Medium	Low, Medium level alarm sound, accompanied by a flashing yellow light
Low battery: infusion stops in 3 minutes	High	High-level alarm sound, accompanied by a flashing red light
Low battery: infusion stops	High	High-level alarm sound, accompanied by a flashing red light
Drive mechanism error	High	High-level alarm sound, accompanied by a flashing red light

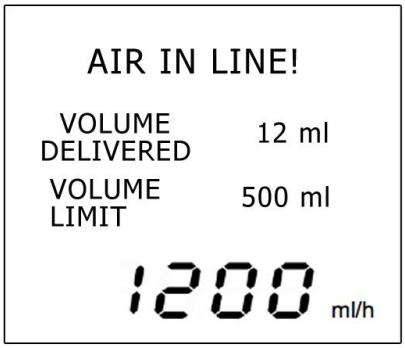
1. **I.V LINE NOT LOADED---** If the device is powered on without the I.V line being loaded in the pump, a low or medium-level alarm sound is activated with an interval of 15 seconds. The indicator is on with a yellow flashing light light at 0.5 Hz, 25% duty cycle. The screen displays “IV LINE DISENGAGED”.



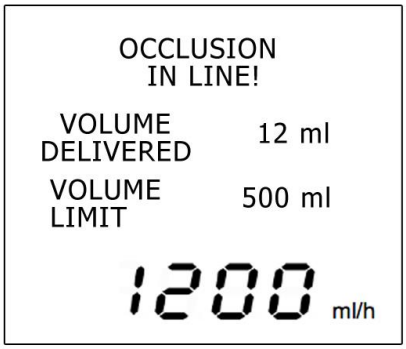
2. **START REMINDER---** If all the necessary settings for a regular infusion are completed but user did not start the infusion within 3 minutes, a low or medium-level alarm sound is activated with an interval of 15 seconds. The indicator is on with a yellow flashing light at 0.5 Hz, 25% duty cycle. The pump prompts user to "PRESS START KEY!".

3. **DOOR OPEN---** If the door is accidentally opened during a regular infusion, the pump stops infusing immediately. A high-level alarm sound is activated with an interval of 5 seconds. The indicator is on with a red flashing light at 2Hz, 40% duty cycle. The screen displays "DOOR OPEN!".

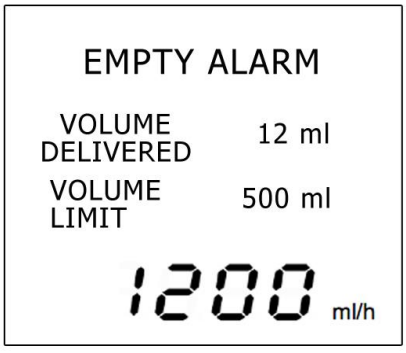




4. **AIR IN LINE---**
   1) If any air bubble is detected in the I.V set during a regular infusion, the **AIR-IN-LINE** alarm will be triggered. A high-level alarm sound is activated with an interval of 5 seconds. The indicator is on with a red flashing light at 2Hz, 40% duty cycle. The pump will stop regular infusion and switch to a KVO (Keep Vain Open) infusion mode. Press EXIT CLEAR key to silence the alarm buzzer. Infusion can be resumed ONLY after the AIR IN LINE condition is cleared.
   2) If user does not purge the I.V set before pressing the START key, the high-level alarm sound is activated with an interval of 5 seconds. The indicator is on with a red flashing light at 2Hz, 40% duty cycle. The screen displays "AIR IN LINE". User should remove the I.V set from the pump and open the roller clamp, let the solution fill the I.V set; then turn off the roller clamp and reload the I.V set to the pump.



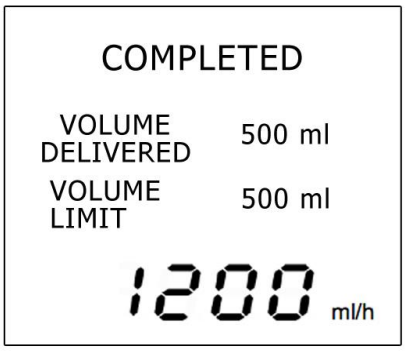
5. **OCCLUSION IN LINE---** If an occlusion occurs in the I.V set or in the needle area during a regular infusion, the **OCCLUSION-IN-LINE** alarm will be triggered. A high-level alarm sound is activated with an interval of 5 seconds. The indicator is on with a red flashing light at 2Hz, 40% duty cycle. The screen displays "OCCLUSION IN LINE". Infusion can be resumed ONLY when the OCCLUSION is cleared.



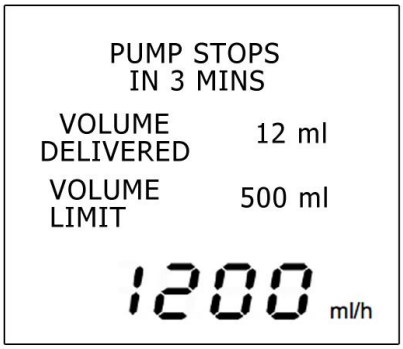
6. **EMPTY ALARM---** To use the drop sensor during an infusion, user must pay attention to the sensor installation requirements. Read the instructions carefully and install the drop sensor accordingly. During a regular infusion, while there is no solution

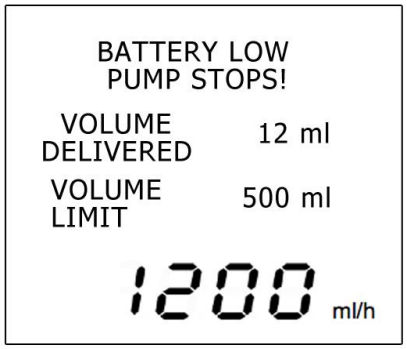
left in the fluid bag or the drop sensor is dislodged, an **EMPTY ALARM** will be triggered to remind the user that the fluid bag is empty. A high-level alarm sound is activated with an interval of 5 seconds. The indicator is on with a red flashing light at 2Hz, 40% duty cycle. The screen displays "EMPTY ALARM".

7. **COMPLETE ALARM---** During a regular infusion, when the VOLUME DELIVERED matches the VOLUME LIMIT (volume to be infused), pump stops the regular infusion and switches to a KVO (Keep Vain Open) infusion mode (KVO rate is 0.1 ml/h at micro infusion; 1ml/h or 2 ml/h at macro infusion). A high-level alarm sound is activated with an interval of 5 seconds. The indicator is on with a red flashing light at 2Hz, 40% duty cycle. The screen displays "COMPLETED".

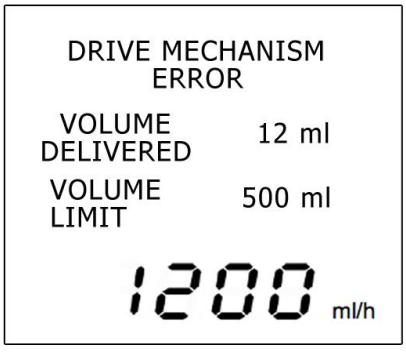


8. **LOW BATTERY REMINDER AND ALARM---** If the battery capacity runs lower than the required working power, a low or medium-level alarm sound is activated with an interval of 15 seconds. The indicator is on with a yellow flashing light at 0.5 Hz, 25% duty cycle. The screen displays "BATTERY LOW". In this situation, the user shall connect the pump to an electrical outlet immediately to work under plug-in power and charge the internal battery. Otherwise, the battery will only support the pump for another 30 minutes. After 30 minutes, the screen displays "PUMP STOPS IN 3 MINS". After 3 minutes, the screen displays "BATTERY LOW, PUMP STOPS", and pump stops the infusion. During the 3-minute period, a high-level alarm sound is activated with an interval of 5 seconds. At the same time, the indicator is on with a red flashing light at 2 Hz, 40% duty cycle.





9. **DRIVE MECHANISM ERROR---** If a mechanism error is detected during an infusion, **DRIVE MECHANISM ERROR** alarm will be triggered. A high-level alarm sound is activated with an interval of 5 seconds. The indicator is on with a red flashing light at 2Hz, 40% duty cycle. Pump stops and displays error message on the screen. Once this message is displayed, the user should disconnect the I.V set from the patient immediately. Then press ON/OFF switch on the back of the pump to turn off the pump completely. User should connect the pump to an electrical outlet and make sure the power indicator on the front of the pump is on with a green light. Wait for 30 seconds. Then press the ON/OFF switch on the back of the pump to turn on the pump again.



IMPORTANT: If the pump displays "PUMP STOPS IN 3 MINS", it will then display "DRIVE MECHANISM ERROR" alarm. In this situation, user should first confirm that the pump is connected to an electrical outlet and make sure the power indicator on the front of the pump is green. Wait for 30 seconds. Then press the ON/OFF switch on the back of the pump to turn on the pump again.

⚠**WARNING:** If the DRIVE MECHANISM ERROR alarm still occurs in the start-up procedure, the pump will not finish the normal operation. Pump cannot be used anymore unless inspected by authorized service personnel!

IMPORTANT: If a high-level alarm occurs when the pump is processing a low, medium level alarm, the pump will assign priority to the high-level alarm.

IMPORTANT: User can select the alarm sound from three levels: high, medium and low. The sound pressure for high-level alarm sound is greater than 65dB; the sound pressure for low-level alarm sound is greater than 45dB.

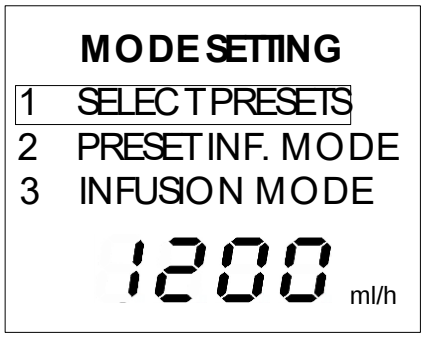
CAUTION:

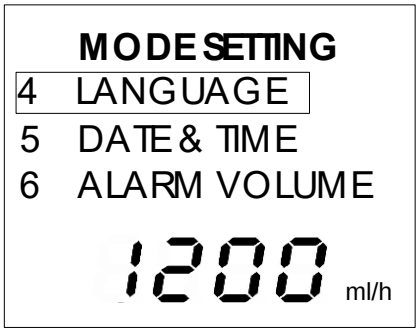
- To silence the alarm buzzer, press EXIT/CLEAR key.
- Once the flashlight and the audio alarm are triggered, please note the alarm messages on the screen and the cause of alarm/problem.

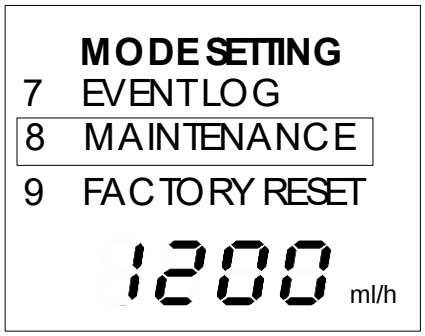
MENU OPTIONS

After the self-diagnosis is completed successfully, press MENU key to enter MODE SETTING.

Press ^ or v key to select from 1-9 different mode settings.







1 SELECT PRESETS — select present frequently used rate and volume combinations stored in the pump memory.

2 PRESET PROGRAM — input and store frequently used rate and volume combinations in one of ten memories.

3 INFUSION MODE — select to infuse by ML/H or DROP/MIN.

NOTE: drop/min mode will only be available after user enables the mode under MODE SETTING item NO.8 MAINTENANCE.

4 LANGUAGE — select preferred operation language.

5 DATE & TIME — set real date & time and define the date format.

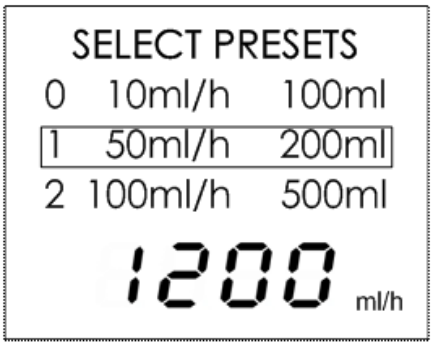
6 ALARM VOLUME — adjust 3 levels of alarm sound.

7 EVENT LOG — review the infusion history including infusion parameters and alarms along with the date and time of occurrence.

8 MAINTENCE— set occlusion sensitivity; perform I.V set accuracy calibration; select type of I.V set, enable/disable DROP/MIN mode.

9 FACTORY RESET — restore to original factory settings.

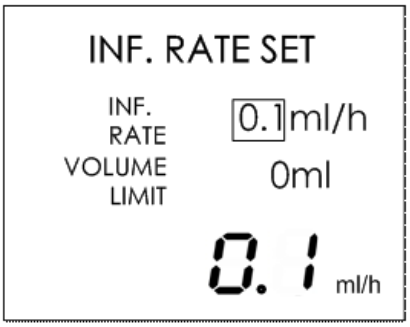
A. SELECT PRESETS



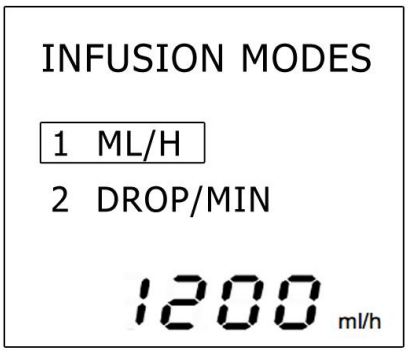
1. Press MENU key to enter MODE SETTING status.
2. Select item No.1 **SELECT PRESETS**;
3. Press ENTER SET key to enter.
4. Press ^ or v key to select preferred infusion data from 0-9 memories.
   Press ENTER SET key to confirm selection, and then return to main screen.
5. If preset infusion data is not selected, press EXIT CLEAR key to return to main screen.

B. PRESET PROGRAM

1. Press MENU key to enter MODE SETTING status.
2. Press ^ or v key to select item No.2 **PRESET PROGRAM.**
3. Press ENTER SET key to enter. Press ^ or v key to select a memory from 0-9 directory to store pre-programmed infusion rate and volume.
4. Press ENTER SET key to confirm selection and enter.
5. Press ^ or v key to set the desired infusion rate, then press ENTER SET key to confirm.
6. Press ^ or v key to set the desired volume limit, then press ENTER SET key to confirm and return to memory directory screen. Pre-programmed infusion combination will be stored in the memory.
7. Press EXIT CLEAR key to return to MODE SETTING screen.
8. Press EXIT CLEAR key again to return to main screen.



C. INFUSION MODE



1. Press MENU key to enter MODE SETTING status.
2. Press ^ or v key to item No.3 **INFUSION MODE**.
3. Press ENTER SET key to enter INFUSION MODES menu.

1) **ML/H** INFUSION MODE

a) Press ⌃ or ⌄ key to choose **ML/H**.

b) Press ENTER SET key to confirm selection and return to MODE SETTING screen.

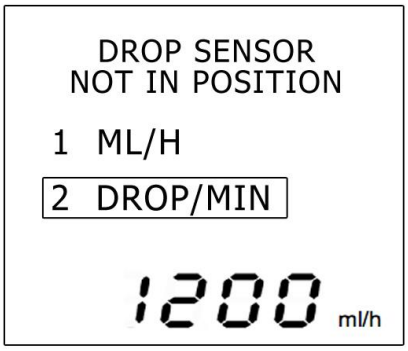
2) **DROP/MIN** INFUSION MODE

NOTE: DROP/MIN mode will only be available after user enables the mode under MODE SETTING item NO.**8 MAINTENANCE**.

⚠**WARNING**: Do **NOT** use the pump under DROP/MIN mode in a mobile environment. The drop sensor cannot count the drops properly in shaking or vibration status.

IMPORTANT: If the infusion mode is set as DROP/MIN, the drop sensor **MUST** be connected to the pump and clamped on the drip chamber properly.

IMPORTANT: The drop sensor **MUST** be clamped above the fluid surface on the drip chamber.



IMPORTANT: If the drop sensor is not installed correctly, the pump **CANNOT** start in DROP/MIN mode. The alarm will be triggered with "DROP SENSOR NOT IN POSITION" message shown on the screen.

a) Press ⌃ or ⌄ key to choose infusion mode 2 **DROP/MIN**.

b) Once **DROP/MIN** is selected, the screen will prompt to DROP SEIZE SELECTION menu.

c) Please verify the I.V set drop size on the I.V set's packaging then press ⌃ or ⌄ key to select the correct drop size setting.

d) Press ENTER SET key to confirm selection and return to MODE SETTING screen.

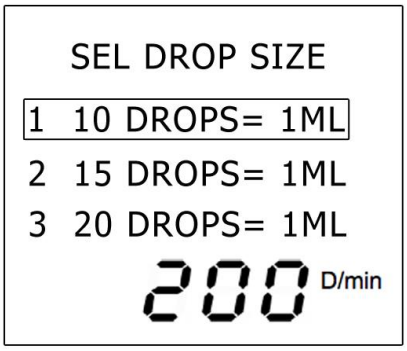
e) Press EXIT CLEAR key to return to main screen

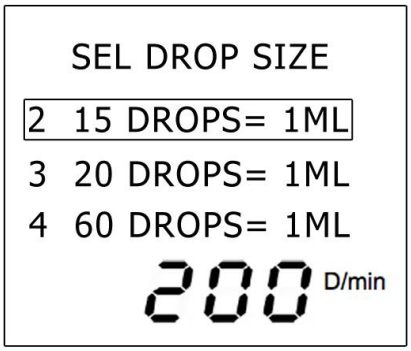
⚠**WARNING:** Failure to select correct I.V set drop size will result inaccurate infused volume counting under **DROP/MIN** mode.

IMPORTANT: Due to the design of the I.V set, the minimum flow rate and maximum drop rate vary between different I.V sets under **DROP/MIN** mode, check the following conversion table:

I.V Set Drop Size	DROP/MIN Rate Range	Equivalent ML/H Rate Range
10 drops/ml	1—200 drops/min	6—1200 ml/h
15 drops/ml	1—200 drops/min	4—800 ml/h
20 drops/ml	1—200 drops/min	3—600 ml/h
60 drops/ml	1—180 drops/min	1—180ml/h

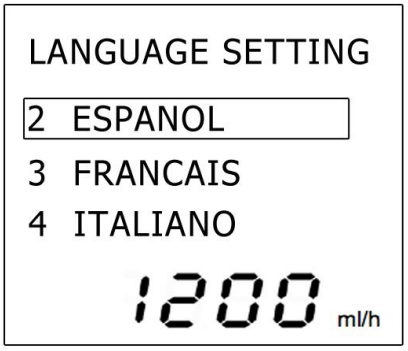
IMPORTANT: For 60 drops / ml IV set, the maximum drop rate is 180 **drop/min**; the maximum flow rate is 180 **ml/h.**



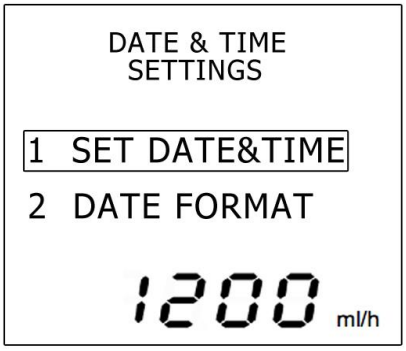


D. LANGUAGE SETTING

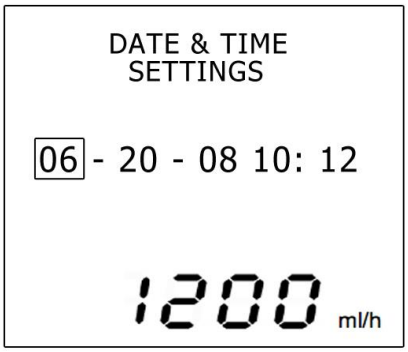
1. Press MENU key to enter MODE SETTING status.
2. Press ^ or v key to select item No.4 **LANGUAGE**
3. Press ENTER SET key into LANGUAGE SETTING menu.
4. Press ^ or v key to select preferred operating language.
5. Press ENTER SET key to confirm selection, and return to MODE SETTING screen.
6. Press EXIT CLEAR key to return to main screen.



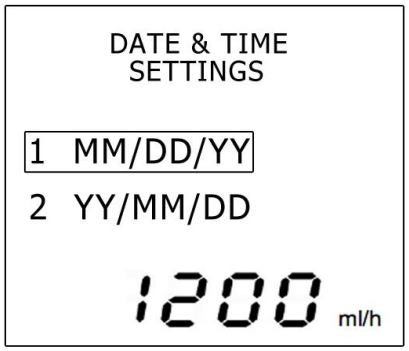
E. DATE & TIME



1. Press MENU key to enter MODE SETTING status.
2. Press ^ or v key to item No.5 **DATE & TIME.**
3. Press ENTER SET key to enter **SET DATE & TIME** SETTING menu.
4. Press ^ or v key to set current date and time (24 hours format only).
5. Press ENTER SET key to confirm selection, and return to MODE SETTING menu.
6. Press ENTER SET key to re-enter DATE & TIME menu, and press v key to select No. 2 **DATE FORMAT**;

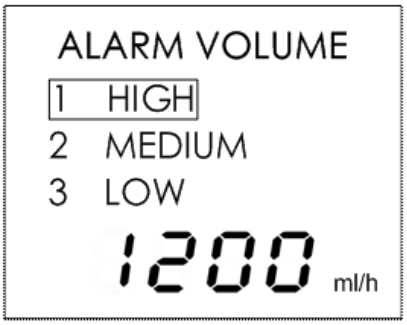


7. Press ENTER SET key to enter; two date formats are available:
   1) month / date / year: MM/DD/YY
   2) year / month / date: YY/MM/DD
8. Press ENTER SET key to confirm selection and return to MODE SETTING screen.
9. Press EXIT CLEAR key to return to main screen.



F. ADJUST ALARM VOLUME

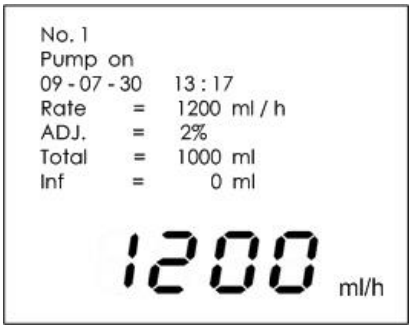
1. Press MENU key to enter MODE SETTING status.
2. Press ^ or v key to select No.6 **ALARM VOLUME**
3. Press ENTER SET key to enter **ALARM VOLUME** menu, there are three levels of alarm volume to select:
   1) HIGH：Maximum alarm volume
   2) MEDIUM：Medium alarm volume
   3) LOW：Lowest alarm volume
4. Press ^ or v key to adjust the alarm volume, then press EXIT CLEAR key to return to the main screen.



⚠**WARNING**: The default alarm volume setting is HIGH. Set the alarm volume to MEDIUM or LOW may cause the alarm not heard in distance. Always check the alarm volume before new infusion.

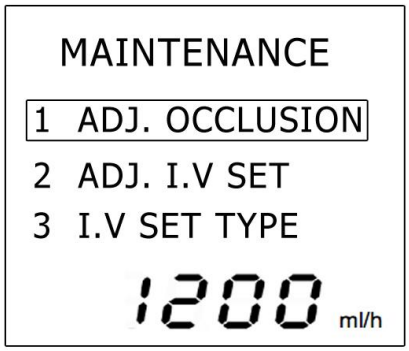
G. EVENT LOG

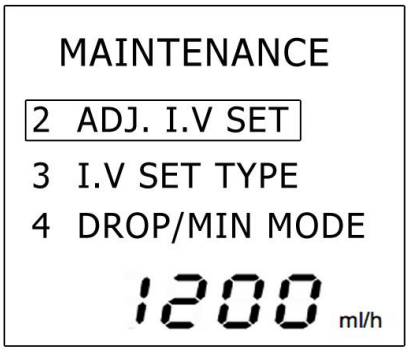
1. Press MENU key to enter MODE SETTING status.
2. Press ^ or v key to No.7 **EVENT LOG**
3. Press ENTER SET key to enter **EVENT LOG** menu, ^ or v key to review the event logs.
4. Press EXIT CLEAR key to return to main screen



H. MAINTENANCE

1. Press MENU key to enter MODE SETTING status.
2. Press ^ or v key to select No.8 **MAINTENANCE.** There are 4 different setting programs:



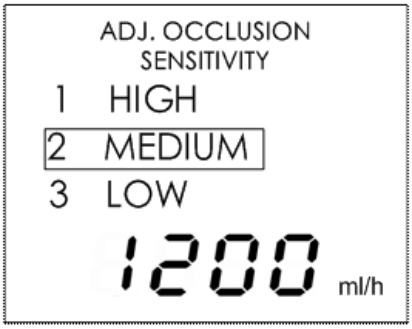


1) ADJUST OCCLUSION PRESSURE (SENSITIVITY).

a. Press  or  key to select item No.1 **ADJ. OCCLUSION**.

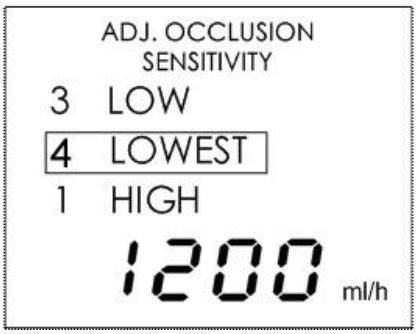
b. Press  key to enter **ADJ. OCCLUSION SENSITIVITY** menu.

c. There are 4 levels of occlusion sensitivity to adjust:



a) HIGH
If the pump is not sensitive enough to trigger occlusion alarm with certain I.V sets, HIGH occlusion sensitivity level should be selected.

b) MEDIUM
MEDIUM occlusion sensitivity level is the factory default setting. This occlusion sensitivity level is preferred for most scenarios.



c) LOW
If the pump is very sensitive to trigger occlusion alarm, LOW occlusion sensitivity level shall be selected.

d) LOWEST
If the pump is still too sensitive and frequently sets off occlusion alarm with other I.V sets, LOWEST occlusion sensitivity level shall be selected.

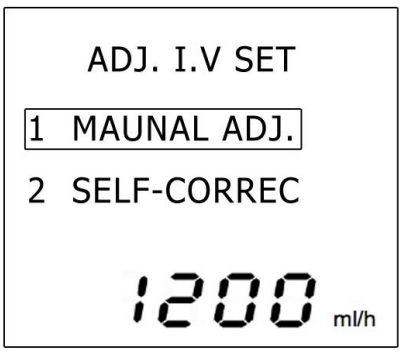
Note: When the setting of sensitivity level is completed, the set sensitivity level will be displayed on the main screen.

⚠**WARNING:** Set the sensitivity level at **LOWEST** is not recommended. The occlusion alarm will not be triggered under the **LOWEST OCCLUSION SENSITIVITY LEVEL** for most pump-use I.V sets.

2) ACCURACY CALIBRATION

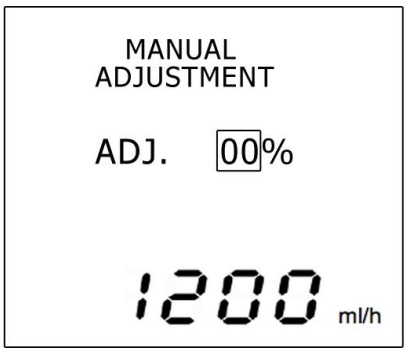
a. Press  or  key to item No. 2 **ADJ. I.V SET.**

b. Press  key to enter ADJ. I.V SET menu. There are two options for accuracy calibration:



a) MANUAL ADJUSTMENT (For ml/h or DROP/MIN mode)

a. Press ENTER/SET key to choose manual calibration.
b. Press ∧ or ∨ key to change calibration volume in percentage.
c. Press ENTER/SET key to confirm the adjustment and return to the MODE SETTING status.



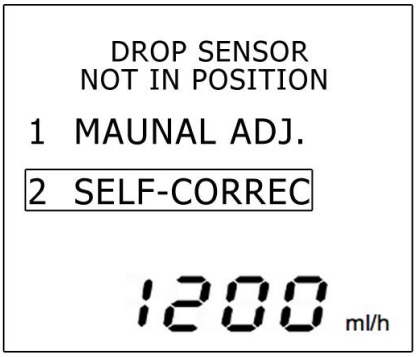
⚠**WARNING:** The manual adjustment range is: -30% to +30% at the current flow rate from 0.1 to 1000 ml/h. The pump will **NOT** respond to the manual adjustment if the current flow rate is set from 1001 to 1200 ml/h.

⚠ **WARNING: THE ACCURACY OF THE PUMP HAS BEEN CALIBRATED TO THE I.V SETS PACKAGED WITH THIS PUMP.** The default setting is 0%. When other I.V set is used, user must test the pump accuracy to verify the infusion result before connecting the I.V set to patient.

⚠ **WARNING:** Failure to adjust the accuracy for other I.V sets may result in an inaccurate infusion, which **COULD CAUSE SERIOUS INJURY TO PATIENT. CONTACT YOUR DISTRIBUTOR FOR THE AUTHORIZED PUMP-USE I.V SETS WITH THE APPROPRIATE ADJUSTMENT.**

b) SELF-CORRECTION (For DROP/MIN mode ONLY)

If the self-correction function is selected to calibrate the accuracy automatically, the drop sensor MUST be connected to the pump and clamped on the drip chamber. The **SELF-CORRECTION ONLY** works under **drop/min** mode; it will adjust the drop rate automatically according to the preset drop rate. The **SELF-CORRECTION DOES NOT** work under ml/hr mode, the pump will **NOT** adjust the flow rate automatically.

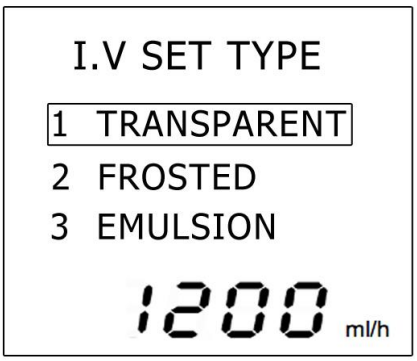


IMPORTANT: If drop sensor was not installed properly, self-correction function will not start.

IMPORTANT: After entering SELF-CORRECTION menu, correct drop size should be selected (see DROP/MIN infusion mode chapter on page 27).

3) I.V SET TYPE

INSTILAR 1488 infusion pump can recognize pump-use I.V sets from major brands. Before infusion, please select the correct I.V set type according to the I.V set that is in use. There are two main types of I.V set: Transparent I.V set and Frosted I.V set (including Opaque I.V set). The default setting is TRANSPARENT. If the selection of I.V set type is not appropriate, the infusion will not start.



a. The user can perform following test to confirm the I.V set type (fluid used for the this test should be regular transparent fluid; medical distilled water is suggested):

a) Press START/STOP key while the I.V line is empty, the screen should display “AIR IN LINE”, the infusion wouldn’t start. Prime the tube with fluid and press

START/STOP key again, the infusion starts normally.
This situation indicates that the I.V set type is compatible with the default setting, user can confirm the selction and quit the menu.

b) The following two situations indicate that the setting of the I.V set type is incorrect:
   i. User press START/STOP key while the I.V line is empty, the pump starts normally;
   ii. User press START/STOP key after the I.V line is primed, but the screen displays "AIR IN LINE" and the pump wouldn't start.

If either of these two situations occurs, please adjust the I.V set type to No. 2 FROSTED.

b. When the medication/fluid infused is milky white liquid or blood, please select No. 3 EMULSION.

Setting steps:

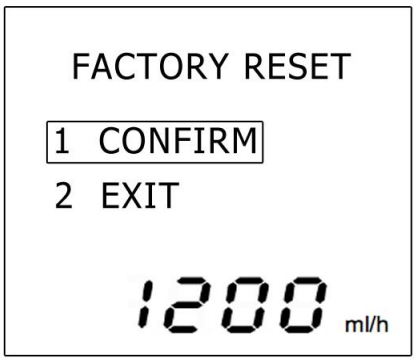
a. Press ∧ or ∨ key to select item No. 3 **I.V SET TYPE.**
b. Press ENTER/SET key to enter I.V SET TYPE menu.
c. Press ∧ or ∨ key to choose between:
   a) TRANSPARENT
   b) FROSTED
   c) EMULSION
d. Press ENTER/SET key to confirm selection and return to MODE SETTING menu.
e. Press EXIT/CLEAR key to return to main screen.

4) DROP/MIN MODE

a. Press ∧ or ∨ key to select item NO. 4 **DROP/MIN MODE**.
b. Press ENTER/SET key to enter DROP/MIN MODE menu.
c. Press ∧ or ∨ key to turn ON or turn OFF DROP/MIN mode.
d. Press ENTER/SET key to confirm selection and return to MODE SETTING menu.
e. Press EXIT/CLEAR key to return to main screen.

I. FACTORY RESET

1. Press MENU key to enter MODE SETTING status.
2. Press ∧ or ∨ key to select item No.**9 FACTORY RESET**.



3. Press ENTER/SET key to enter **FACTORY RESET** menu.
4. Select CONFIRM, press ENTER/SET key to reset the pump.
5. Select EXIT, press ENTER/SET key to quit FACTORY RESET and return to MODE SETTING menu.
6. Press EXIT/CLEAR key to return to main screen.

⚠**WARNING:** Once pump is reset, all settings will return to factory default as following:

1) All current and pre-set data and pre-programmed infusion modes will be cleared.
2) Language will be reset to ENGLISH
3) Time format will be reset to MM/DD/YY
4) The occlusion level will be reset to MEDIUM.
5) The accuracy calibration mode will be reset as MANUAL and the accuracy will be reset to 0%
6) The alarm volume will be reset to HIGH
7) The current date & time will be kept.
8) The event log will be kept.

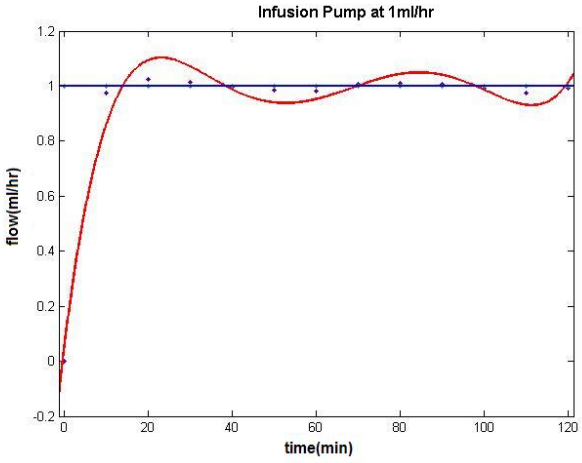
TROUBLESHOOTING

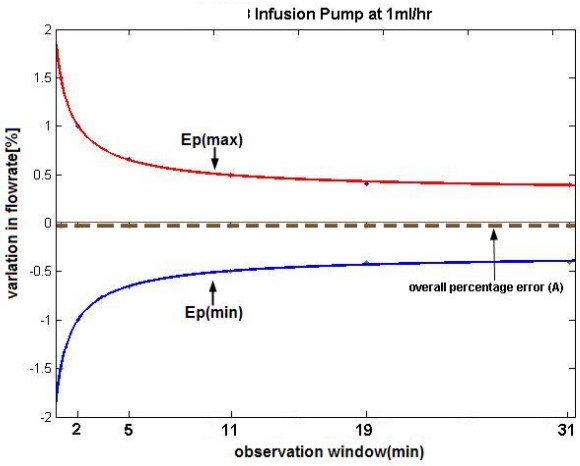
Description	Possible Cause	Required Actions
EMPTY alarm while the fluid bag is not empty	The drop sensor is not plugged to the back of the pump or not installed on the drip chamber properly.	Plug the drop sensor to the back of the pump and clamp the sensor to the drip chamber properly according to the manual.
OCCLUSION alarm but no block in the I.V line	1. There is a hidden occlusion that can't be seen. 2. The pump was set at HIGH occlusion sensitivity.	1. Examine the I.V line connection to the patient carefully then resume the infusion. 2. Change the pump to lower Occlusion sensitivity setting.
AIR-IN-LINE alarm but no air bubble is observed	1. There are very small bubbles or dust in the I.V line. 2. The I.V line in the AIR sensor is tangled.	1. Remove the small bubble / dust or change the I.V. set. 2. Move the I.V. line to make sure the tubing is neatly placed around the Air Detector.
Pump can't be turned on	1. Circuit overload. 2. Power cord is damaged.	3. Unplug the pump from the main power, check/change fuses. 4. Contact authorized distributor to replace the main power supply.
Pump does not charge the battery	1. Circuit overload. 2. The rechargeable main battery wasn't replaced within last 24 months according to service protocol.	1. Unplug the pump from the main power, check/change fuses. 2. Contact authorized distributor to replace the main battery.
Alarm does not sound	Speaker problem.	Stop using the pump. Contact authorized distributor for maintenance service.
Over/under infusing over +/- 5%	1. User did not perform the accuracy calibration when different I.V sets are used. 2. The pump wasn't sent for calibration within the last 24 months as per maintenance instructions.	1. Stop using the pump. Perform an I.V set calibration to verify the pump accuracy according to the manual instructions. 2. Stop using the pump. Contact authorized distributor for maintenance
Time and Date displays: 00:00 01-01-00	1. Pump was reset but didn't set the current time. 2. The rechargeable battery has not been replaced for the last 2 years as per maintenance instructions.	1. Set the current time & date, turn off the pump. Wait for 10 minutes then turn on again to make sure the time is running properly. 2. Stop using the pump. Contact authorized distributor for maintenance.
Noise line on the main screen, no data displayed.	1. The power supply is not stable. 2. The display board is dead.	1. Switch to stable power supply. 2. Stop using the pump. Contact authorized distributor for maintenance.
Keypad locked/frozen	1. Keypad is locked for safety purpose when the pump is infusing. 2. The control buttons are dead.	1. Stop the infusion to unlock the keypad and change the infusion settings. 2. Stop using the pump. Contact authorized distributor for maintenance.

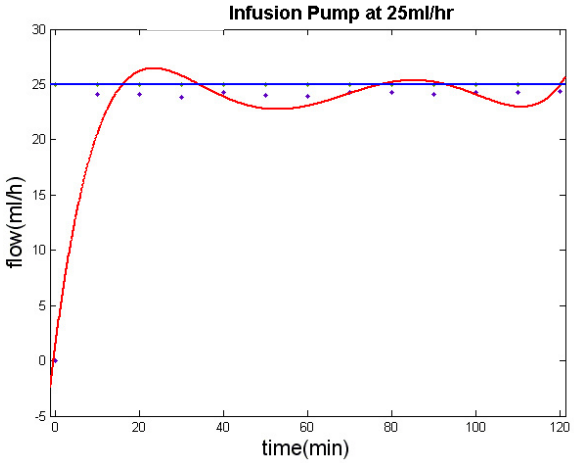
TECHNICAL SPECIFICATIONS

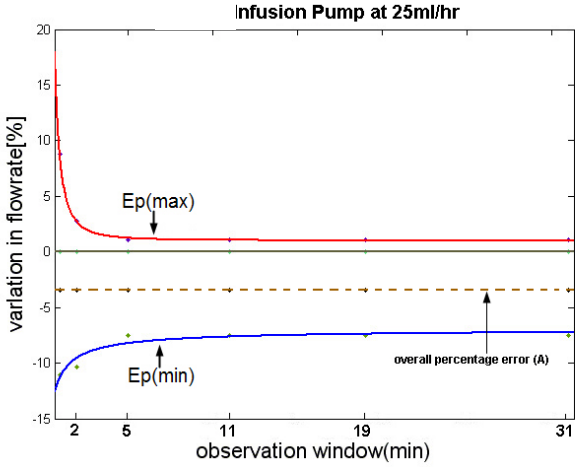
a) Ambient Temperature		5 ~ 40°C	
b) Relative Humidity		≤ 90%	
c) Atmospheric pressure		700hPa - 1060hPa	
d) Operation Power		AC power: 100-240AC, 50/60Hz, 58VA DC power: 12VDC, 1.6A	
e) Power Consumption		≤58VA	
f) Total Volume Delivered Display		1 - 9999ml	
g) Flow Rate Range		1 - 1200 ml/h	
h) Volume Limit Range		1 - 9999 ml	
i) Infusion Accuracy		± 5% (the accuracy is related to I.V set used)	
j) Dimension l × b × h (mm)		172 × 105 × 240	
k) Weight		≤ 3.2kg	
l) Air detector sensitivity		≥ 3mm	
m) Disposable I.V set		I.V set brands recommended in the manual with an inner diameter of φ2.9±0.1	
n) Maximum Delivery Pressure		≥ 0.16Mpa	
o) Occlusion Pressure		0.04 ~ 0.16Mpa	
p) Occlusion Alarm Trigger Time And Dose Infused			
Flow Rate	Occlusion Pressure	Response Time	Dosage
Minimum flow rate (1ml/h)	Low (0.04Mpa)	1:13’57”	1.20ml
	High (0.16Mpa)	2:50’55”	2.43ml
Medium flow rate (25ml/h)	Low (0.04Mpa)	2’26”	1.00ml
	High (0.16Mpa)	6’30”	2.52ml

INFUSION ACCURACY OF THE SYSTEM









REGULATORY INFORMATION

INSTILAR 1488 infusion pump complies with the following standards:

- 93/42/EEC European directive for medical devices including EN 60601-1-2: 2007 + AC: 2010 standards and collaterals.
- Electrical Safety (IEC) and Electromagnetic Compatibility standards (CEM)
- Guidance and Manufacturer's Declaration—Electromagnetic Emissions

Electromagnetic Compatibility Precautions

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC). Medical equipment must be installed and put into service according to the EMC information provided in the following documentation.

Guidance and Manufacturer's Declaration—Electromagnetic Emissions

Tablet 1-1

Guidance and Manufacturer's Declaration—Electromagnetic Emissions		
INSTILAR 1488 infusion pump is intended for use in the electromagnetic environment specified below. The customer or the user of this infusion pump should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment- Guidance**
RF emissions CISPR 11	Group 1	INSTILAR 1488 infusion pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	INSTILAR 1488 infusion pump is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Tablet 1-2

Electromagnetic Immunity for Equipment and Systems Fully Compliant with EN 60601-1-2:2007			
INSTILAR 1488 infusion pump is intended for use in the electromagnetic environment specified below.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment- Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material. The relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines ± 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	± 1kV line(s) to line(s) ± 2kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the INSTILAR 1488 infusion pump requires continued operation during power mains interruptions, it is recommended that the INSTILAR 1488 infusion pump be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location, in a typical commercial or hospital environment.

Tablet 1-3

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">INSTILAR 1488 infusion pump is intended for use in the electromagnetic environment specified below. The customer or the user of this infusion pump should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity Test</th><th>IEC 60601
Test Level</th><th>Compliance
Level</th><th>Electromagnetic Environment- Guidance</th></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3V/m
80MHz to 2.5GHz</td><td>[E1] V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any part of INSTILAR 1488 infusion pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance

d = [3.5/E1]√P 80MHz to 800MHz
d = [7/E1]√P 800MHz to 2.5GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.
Interference may occur in the vicinity of equipment marked with the following symbol

  </td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which INSTILAR 1488 infusion pump is used exceeds the applicable RF compliance level above, INSTILAR 1488 infusion pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating INSTILAR 1488 infusion pump.</td></tr>
</table>

Tablet 1-4

Recommended separation distances between portable and mobile RF communications equipment and INSTILAR 1488 infusion pump		
INSTILAR 1488 infusion pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the INSTILAR 1488 infusion pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the INSTILAR 1488 infusion pump as recommended below, according to the maximum output power of the communications equipment.		
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m	
	80 MHz to 800 MHz d = [3.5/E1]√P	800 MHz to 2.5 GHz d = [3.5/E1]√P
0.01	0.117	0.233
0.1	0.37	0.737
1	1.17	2.33
10	3.7	7.36
100	11.7	23.3
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 900 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

ACCESSORIES

Every new pump's package includes:

1. 3-core standard power cord x 1
2. Drop Sensor x 1
3. Pole Clamp x 1
4. Disposable IV set (for testing) x 2
5. 2-pin 12V Plug x 1
6. Fuse (T 1AL 250V) x 2
7. User's manual x 1
8. Quality Certificate x 1

Optional accessories:

1. Fluid Warmer (FW-300), optional, sold separately x 1
2. Power cord for fluid Warmer, optional, sold separately x 1
3. Power adaptor for fluid Warmer, optional, sold separately x 1

NOTE: In order to ensure patient safety and long-lasting performance of the pump, ONLY use power cord for fluid warmer supplied by DIXION VERTRIEB MEDIZINISCHER GERÄTE GMBH to connect the fluid warmer to the infusion pump.

NOTE: RS232 port is used for data transmission only.

PACKAGING, TRANSPORTATION AND STORAGE

1. **Packaging:** Please retain and use the original packing carton and foam storage; place the infusion pump in this specialized package with manual, certificate and accessories, and then seal the box.
2. **Transportation:** Avoid intense vibration, shock and rain (snow).
3. **Storage Condition:**
    - **a.** If the pump is to be stored for an extended period, please charge the battery for at least 8 hours in advance. Store the pump in an environment with ambient temperature range from -10°C ~ +55°C, relative humidity below 93%, and Atmospheric pressure from 500hPa to 1060hPa. Do not store close to corrosive vapour and/or harmful impurities. Leaving the battery in an uncharged state for a long period of time may discharge completely and damage the battery permanently.
    - **b.** Perform operational and safety standard checkout to ensure the pump works properly and delivers accurately before use if the pump is stored over 3 months.
    - **c.** Perform operational and safety standard checkout and fully charge the battery every 3 months.

MAINTENANCE

Maintenance of this infusion pump must be conducted by technical personnel that authorized by DIXION VERTRIEB MEDIZINISCHER GERÄTE GMBH or personnel trained by DIXION VERTRIEB MEDIZINISCHER GERÄTE GMBH. If the infusion pump is disassembled for maintenance purpose by not-trained personnel or is used beyond the purposes described in the manual, the manufacturer does not have the responsibility and obligation for the degradation and lose of effectiveness of the infusion pump

SUGGESTED CLEANING, STERILIZATION GUIDELINES:
Always keep the pump clean, use a soft cloth dampened with 70% alcohol to wipe out any fluid on the pump.
Use EOG (Ethylene oxide gas) to sterilize the pump under the following conditions:
Environmental temperatures: under 58°C
Relative Humidity: Less than 60%
After sterilization, keep the room ventilated for 24 hours or longer, or leave the pump in the ventilation device for 8 hours or longer.

NOTE:
Avoid using solvents and thinners to clean the pump
Before cleaning, turn off the power and disconnect the power cord.

⚠**WARNING:** The operational and safety standard checkout must be performed at least every 24 month by the factory authorized service representative to ensure the pump works properly and infuses accurately. (Not covered by the warranty, service charges may apply)

⚠**WARNING:** Perform functional tests and ensure that the battery is fully charged once every three months.

⚠**WARNING:** Replace the rechargeable main battery and lithium cell button battery every two years.
Pollution-Free Treatment and Recycling
1) Remove the Ni-MH before recycling or disposal.
2) Your local distributor will accept any used INSTILAR 1488 infusion pump for proper pollution-free treatment and recycling.

MAINTENANCE SERVICE RECORD

Serial Number: _____ **Date of Purchase:** _____

Date of Service:_____ ☐ Accuracy Calibration ☐ Functional tests
Maintenance Detail:

_____

_____

_____

Serviced by (Print Technician Name): _____ Signature:_____
Service Company Name (Print):_____ Tel:_____

Date of Service:_____ ☐ Accuracy Calibration ☐ Functional tests
Maintenance Detail:

_____

_____

_____

Serviced by (Print Technician Name): _____ Signature:_____
Service Company Name (Print):_____ Tel:_____

DIXION VERTRIEB MEDIZINISCHER GERÄTE GMBH

Couvenstr. 6, 40211, Dusseldorf, Germany
Tel: +4921138838868, Fax: +4921138838697

LIMITED WARRANTY

The INSTILAR 1488 Infusion Pump has been carefully manufactured from the highest quality components. The pump is guaranteed against defects in material and workmanship for twenty-four (24) months from date of shipment from the manufacturer. User should always comply with the transportation, storage and operation rules specified in this manual for the use of device. User should keep the service record according to manufacturer's instruction to keep the warranty valid.

Manufacturer's obligation, or that of its designated representative under this Limited Warranty, shall be limited, at our option, to repairing or replacing the pump, which upon examination, is found to be defective in material or workmanship. The repair or replacement of any product under this Limited Warranty shall not extend the above-mentioned Warranty period.

All repairs under this Limited Warranty should be undertaken only by qualified, trained service personnel. In the event that a pump is found to be defective during the warranty period, the purchaser shall notify manufacturer or its designated representative within thirty (30) days after such defect is discovered. The defective pump should be sent immediately to the manufacturer or its designated representative for inspection, repair or replacement.

Material returned should be properly packaged to avoid shipping damage.

This Limited Warranty shall not apply to defects or damage caused, wholly or in part, by negligence, spilt fluids, dropping of the pump, misuse, abuse, improper installation or alteration by anyone other than qualified, trained personnel; or to damage resulting from inadequate packaging in returning the pump.

This Limited Warranty is the sole and entire warranty pertaining to manufacturer's products and is in lieu of and excludes all other warranties of any nature whatsoever, whether stated, or implied or arising by operation of law, trade, usage or course of dealing, including but not limited to, warranties of merchantability and warranties of fitness for a particular purpose. Purchaser expressly agrees that the remedies granted to it under this limited warranty are purchaser's sole and exclusive remedies with respect to any claim of purchaser arising under this Limited Warranty.

EXCLUSIONS (WHAT IS NOT COVERED)

1. Accessories used with this pump, such as pole clamp, power cord etc. are not covered under this limited warranty policy.
2. The rechargeable battery is not covered under this limited warranty policy.
3. This warranty becomes void if the pump is opened or serviced by un-authorized personnel.
4. This warranty does NOT cover freight cost, insurance and any other incidental charges.
5. Failure to service the pump periodically as scheduled will void this warranty policy.
6. This warranty becomes void if the pump shows evidence of having been dropped, impact, sand and/or water damage, mishandling, tampering, battery or chemical corrosion, use contrary to this instruction manual.

DIXION

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