

Versaflo™ 300 Micro-Infusion Syringe Pump

User's Manual

For Veterinary Use Only



Midmark Corporation

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Versaflo[™] 300 Micro-Infusion Syringe Pump Features

✓ Capability to Load 100ml Syringe

With 100ml syringe, you can treat larger animal with larger volumes continuously without changing syringes

- Broad Infusion Applications
 General medication, Analgesics, PCA therapy, parenteral and eternal nutrition
- ✓ Micro to Macro Infusion

Delivers precise infusion at rates from 0.1 to 1500 ml/hr

- Excellent Linearity Performance
 Continuously linear infusion at both low and high infusion rate for the best even medication treatment
- ✓ Alarms/Alert Light

6 alarms using both light and sound

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GENERAL INFORMATION

This Syringe Pump is a conventional device for specialty practices, universities, and general practices. A wide variety of clinical departments, such as internal medicine, cardiology, and oncology require being equipped with this type of syringe pump. This pump is mainly used for intravenous/arterial infusion, anesthetic injection, IV antibiotics, cancer therapy, etc.

This Micro-Infusion Syringe Pump offers a reliable alternative for fluid control, especially suitable for long-term, micro fluid and precise injections.

SIGNS AND SYMBOLS

HEADINGS USED IN THIS MANUAL

THIS GUIDE CONTAINS WARNINGS, CAUTIONS, AND IMPORTANT INFORMATION TO HELP CALL YOUR ATTENTION TO THE MOST IMPORTANT SAFETY AND OPERATIONAL ASPECTS OF THE PUMP. TO HELP IDENTIFY THESE ITEMS WHEN THEY OCCUR 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 THE SAFE AND EFFECTIVE USE OF THE DEVICE.

IMPORTANT

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

PRODUCT FEATURES

Category:	Type I Internal Power Supplied
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:	Single use syringe size 10 ml, 20/30 ml.
	50/60 ml, 100 ml
Power Consumption:	Rated Power 25VA ±25%

(1) This product controls the flow rate of an injection. The rate is not affected by intravenous/artery pressure or by thickness of the fluid.

(2) This product performs a self-diagnose when turn on the power.

(3) This pump automatically recognizes & calibrate for B-D, MONOJECT, Terumo® BRAND SYRINGES, For complete list of authorized syringes see Page 29

(4) Wide range of injection rate: with 100 ml syringe, maximum flow rate setting is 1500 ml/hr.

(5) Settings of last injection are memorized even after pump is power-off.

(6) When unitary error happens, pump stops immediately. No siphon happens. The volume infused at the responding interval between error happening and pump stopping is less than 15 ml.

(7) The product is DC/AC power supplied with rechargeable internal batteries. Product is able to charge the batteries and to operate at the same time. Power sources are:

a. AC input: 100-240AC, 50/60Hz, 25VA;b. DC input: 12VDC, 1.6A;c. Battery power: 12VDC, 1200mA

In event of losing AC power, product will switch to battery power automatically.

FIGURES AND SIGNS

 \triangle WARNINGS: Must operate this pump with Pump-Use syringes. Fail to comply will cause inaccurate infusion result and may harm the patient.

Signs/Symbols	Definitions
((0197	Meet MDD 93/42/EEC Requirement and
	certified by the notified body 0197 Protection Against Electric Shock: Type CF, defibrillator proof
IPX1	Protection Against vertically falling water drips
\triangle	Attention, consult user's manual
	Manufacturer's information
SN	Product Serial Number
~~~	Manufacturing Date
EC REP	EU Representative
$\sim$	AC Power
	DC Power
FUSE:(T 1AL 250V)	Fuse & Fuse Type
1	ON
0	OFF

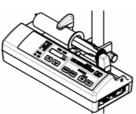
### **PRECAUTIONS & NOTES**

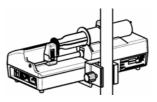
#### SAVE THIS MANUAL FOR YOUR FUTURE REFRENCE!

IMPORTANT: USER SHOULD READ THIS ENTIRE MANUAL BEFORE OPERATING THIS SYRINGE THIS DEVICE SHALL BE OPERATED BY AUTHORIZED PERSONNEL. THE RUNNING PUMP. OF THE DEVICE SHALL BE CONSTANTLY SUPERVISED BY AUTHORIZED PERSONNEL.

WARNINGS: CRITICAL EXPLOSION HAZARD! DO NOT USE IN THE PRESENCE OF Inflammable and explosive materials!

- (1) ONLY USE THE 3-CORE AC (MAINS) POWER CORD INCLUDED WITH THIS PUMP. USE OF ANY OTHER CORD PRESENTS SHOCK OR DEATH HAZARD TO PATIENTS. THE AC MAINS OUTLET MUST BE PROPERLY GROUNDED (EARTHED) TO PREVENT SHOCK HAZARDS TO PATIENT. THE MAINS OUTLET AND THE GROUND (EARTH) SHOULD BE TESTED ON A REGULAR BASIS TO ENSURE PATIENT SAFETY. OPERATE AWAY FROM STRONG MAGNETIC FIELDS (LARGE EQUIPMENT OR BIG MOTORS).
- (2) DO NOT OPERATE THIS DEVICE IN THE PRESENCE OF FLAMMABLE ANESTHETISCS (A MIXURE OF Air, oxygen, nitrogen oxides.
- (3) DO NOT USE A PUMP, SYRINGE, OR ACCESSORY THAT SHOWS ANY SIGN OF DAMAGE.
- (4) This pump is not a portable device. To use this pump in a mobile environment, attach the pump onto an I.V pole with a pole clamp which is included in the accessories.





- (5) DO NOT CONNECT THE DEVICE TO THE PATIENT, WHILE PURGE THE TUBING.
- (6) BEFORE CONNECTING THE TUBING TO THE PATIENT, THE USER MUST PRIME THE TUBING TO PREVENT AIR FROM MOVING INTO THE PATIENT.
- (7) TO CLEAN THE PUMP, USE A DAMP (NOT WET) CLOTH OR SPONGE. DO NOT IMMERSE PUMP OR POWER CABLE INTO WATER OR OTHER CLEANING SOLUTIONS.
- (8) BEFORE START AN INJECTION, CHECK THE EXTENSION TUBING TO MAKE SURE IT IS NEATLY PLACED. MAKE SURE THERE IS NO AIR IN THE SYRINGE AND EXTENSION TUBING. CHECK ALL SETTINGS ON THE SYRINGE PUMP.
- (9) TO AVOID ELECTRIC SHOCK, UNPLUG THE POWER CORD FROM THE PUMP AND THEN CLEAN THE DEVICE. MUST NOT SPRAY THE CLEANSER ON THE EXTENSION TUBING OR THE POWER CORD. DO NOT IMMERSE THE PUMP INTO ANY SOLUTION.
- (10) IF THE PACKAGE OF SINGLE USE SYRINGE IS DAMAGED, MUST NOT USE THIS SYRINGE.
- (11) USE ONLY AUTHORIZED SYRINGES, SEE PAGE 29. CONTACT MANUFACTURER FOR THE

AUTHORIZED CALIBRATION VALUE BEFORE USING SYRINGES NOT LISTED ON PAGE 29. DO NOT CALIBRATE UNAUTHORIZED SYRINGES WITHOUT MANUFACTURERS AUTHORIZATION

#### PRECAUTIONS:

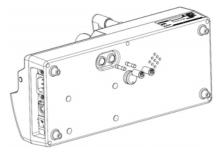
(1) TO AVOID A MALFUNCTION CAUSED BY ELECTROMAGNETISM DISTURBANCE, PUMP SHALL OPERATE AWAY FROM DEVICES SUCH AS ELECTROCOAGULATOR AND DEFIBRILLATOR WHICH MAY CREATE A STRONG ELECTROMAGNETIC FIELD. DURING OPERATION, PLEASE NOTICE THAT THE PUMP:

- a. MUST KEEP ENOUGH DISTANCE FROM ELECTROCOAGULATOR AND/OR DEFIBRILLATOR;
- b. DO NOT SHARE SAME POWER OUTLET WITH ELECTROCOAGULATOR AND/OR DEFIBRILLATOR;
- c. MUST OPERATE UNDER CONTINUOUS SUPERVISION;
- d. DO NOT USE THE PUMP IN THE MRI ROOM OR HIGH PRESSURE ROOM THAT CREATES A STRONG ELECTROMAGNETIC FIELD;
- e. DO NOT USE CELLULAR PHONES, RADIOS, AND DEVICES WHICH MAY EMIT HIGH-FREQUENCY SIGNAL. KEEP THE SYRINGE PUMP AWAY FROM THE MENTIONED DEVICES;
- (2) USE ONLY AUTHORIZED SYRINGES, SEE PAGE 29. CONTACT MANUFACTURER FOR THE AUTHORIZED CALIBRATION VALUE BEFORE USING SYRINGES NOT LISTED ON PAGE 29. DO NOT CALIBRATE UNAUTHORIZED SYRINGES WITHOUT MANUFACTURERS AUTHORIZATION



- (3) TO STORE THE PUMP, MAKE SURE THE BATTERIES ARE FULLY CHARGED BEFORE STORAGE. BATTERIES MAY BE DAMAGED IF LEAVE UNCHARGED FOR A LONG PERIOD OF TIME;
- (4) USE THE PUMP AFTER MIN. 3 MONTHS OF STORAGE, THIS PUMP MUST BE TESTED AND CALIBRATED FOR ACCURACY, BATTERY POWER AND ALL ALARM FUNCTIONS. ENSURE THE BATTERIES ARE FULLY CHARGED BEFORE USE;
- (5) AVOID CONNECT TUBING OF PUMP-CONTROLLED SYRINGE WITH TUBING OF MANUAL-CONTROLLED SYRINGE. IT MAY AFFECT THE INFUSION ACCURACY AND ACTIVATE FALSE ALARMS. THE SYRINGE PUMP WILL GENERATE A PRESSURE DRIVING MEDICATION INTO THE PATIENT, BUT THE PUMP CAN NOT DETECT THE DAMAGE OF SYRINGE CAUSED BY OVERPRESSURE, E.G. LEAKING IN THE TUBING, DISENGAGEMENT OF SYRINGE AND EXTENSION TUBING. DURING THE OPERATION, CONSTANTLY CHECK FOR THE DAMAGE OF TUBING SYSTEM;
- (6) WHILE PUMP IS USING 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) DISPOSABLE SYRINGE USED IN THE PUMP SHOULD COMPLY WITH THE GOVERNMENT REGULATIONS AND HAS TO BE DESIGNED FOR PUMP-USE;
- (9) USE AND CHANGE SYRINGES AND EXTENSION TUBING ACCORDING TO HOSPITAL REGULATIONS. SINGLE USE SYRINGE AND TUBING SHALL BE STORED IN A CENTRALIZED STORAGE AFTER USE, AND BE DISPOSED ACCORDING TO REGULATIONS OF DISPOSAL OF MEDICAL WASTE;
- (10) THE CIRCUIT DIAGRAM AND PARTS LIST WILL ONLY BE PROVIDED TO MANUFACTURER ASSIGNED TECHNICIANS;

- (11) THE PUMP CAN BE USED ON A HORIZONTAL PLATFORM OR ON THE IV STAND WITH THE IV POLE CLAMP. BEFORE SECURING THE PUMP ON THE IV POLE, PLEASE MAKE SURE THAT THE IV STAND IS SOLID VERTICALLY AND WON'T FALL WITH THE WEIGHT OF THE PUMP;
- (12) TO CHANGE THE FUSE, MUST DISCONNECT THE PUMP WITH AC POWER;
- (13) DURING THE OPERATION, THIS SYRINGE PUMP SHALL BE CONSTANTLY MONITORED BY MEDICAL PERSONNEL;
- (14) THE PUMP WILL GO THROUGH A SELF DIAGNOSTIC PROGRAM WHEN THE POWER SWITCH IS TURNED ON. IF AN "ERR" IS SHOWN IN THE DISPLAY, REBOOT THE PUMP. IF THE ERROR CONDITION STILL EXISTS, DO NOT



CONTINUE OPERATION AND CONTACT DISTRIBUTOR OR MANUFACTURER FOR TECHNICAL SERVICE IMMEDIATELY;

- (15) READ MANUAL OF SYRINGES CAREFULLY BEFORE OPERATING THE SYRINGE. STRICTLY FOLLOW THE MEDICAL RULES AND REGULATIONS DURING OPERATION;
- (16) ONLY AUTHORIZED PERSONNEL SHALL OPERATE THIS SYRINGE PUMP;
- (17) LUER LOCK SYRINGES SHOULD ALWAYS BE USED TO ENSURE SECURE CONNECTION OF THE EXTENSION TUBING;
- (18) 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;
- (19) THESE 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:
- (20) THE USE OF NON-RECOMMENDED ACCESSORIES MAY RESULT IN INCREASED EMC EMISSIONS OR DECREASED EMC IMMUNITY OF THIS SYRINGE PUMP.
- (21) USE THIS PUMP FOR INJECTION OF LIFE-SUSTAINING MEDICATION, MAKE SURE THERE IS AN EXTRA PUMP STANDBY AND THERE ARE ENOUGH SYRINGES STANDBY;

#### IMPORTANT:

- (1) TO PREVENT ELECTRIC HAZARDS, BEFORE CLEANING, TURN OFF THE PUMP AND THEN UNPLUG THE POWER CORD FROM THE PUMP. USE 70% ALCOHOL ON A SOFT CLOTH TO WIPE OUT ANY FLUID ON THE PUMP. KEEP THE PUMP CLEAN AND DO NOT IMMERSE THE PUMP INTO ANY LIQUID FOR CLEANSING PURPOSE;
- (2) BATTERIES USED IN THIS PUMP ARE HYNB-762(AA×10/1200MAH). TO ENSURE THE PERFORMANCE OF THE SYRINGE PUMP, MAKE SURE THE BATTERIES ARE FULLY CHARGED BEFORE OPERATE THE PUMP ON BATTERY POWER. ALWAYS CHECK THE BATTERY PERFORMANCE BEFORE OPERATE ON BATTERY POWER. AFTER A FULL BATTERY-CHARGING CYCLE, IF THE BATTERIES ARE STILL DEPLETED, CHANGE THE BATTERY PACK IMMEDIATELY; THE BATTERIES MUST BE CHARGED FOR ONCE AT EVERY 3 MONTHS OF STORAGE. WHILE CONNECT THE PUMP TO AC POWER, MAKE SURE THE POWER IS PROPERLY GROUNDED. IF AC POWER IS NOT RELIABLE, USE INTERNAL

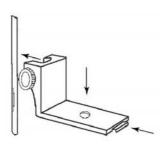
BATTERIES TO OPERATE THE PUMP;

- (3) TO CHANGE THE FUSE OF THE PUMP, DISCONNECT THE AC POWER;
- (4) ONLY AUTHORIZED SERVICE PERSONNEL SHOULD REPAIR THIS PUMP. THE MANUFACTURER ASSUMES NO RESPONSIBILITY FOR INCIDENTS THAT OCCUR IF THE PUMP IS NOT REPAIRED ACCORDING TO MANUFACTURER-AUTHORIZED PROCEDURES;
- (5) IF THE PUMP FALLS OFF ON THE GROUND, OR HAS IMPACT, IT MAY BE DAMAGED INTERNALLY WITH NO SIGN OF BROKEN EXTERNALLY. IN SUCH SITUATION, THE PUMP PERFORMANCE MAY BE AFFECTED. DO NOT USE THE PUMP, AND CONTACT AUTHORIZED DISTRIBUTORS FOR SERVICE;
- (6) THIS PUMP HAS BUILT-IN BATTERIES. WHEN AC POWER IS DISCONNECTED, THE PUMP SWITCHES TO BATTERY POWER AUTOMATICALLY. BEFORE INITIALLY POWERING ON THE PUMP, CHARGE THE BATTERY FOR AT LEAST 8 UNINTERRUPTED HOURS.

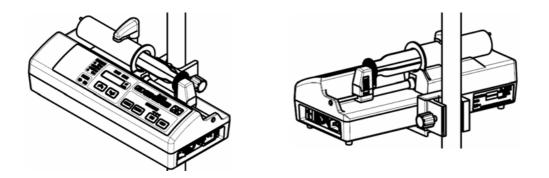
# SPECIFICATIONS

1. Environmental Temperatures of Operation:		5℃ ~40℃ /41 F – 104 F	
2. Relative Humidity:		Less than 90%	
3. Atmospheric	Pressure:	700hPa-1060hPa	
4. Power Sourc	e:	(1) AC Input: 100-2	40AC, 50/60Hz, 25VA
		(2) DC Input: 12VD	C, 1.6A
5. Power Consu	umption:	No More Than 25 V	/A
6. Volume To B	e Infused:	1–999 ml	
7. Compatible S	Syringe Size:	10ml, 20/30ml, 50/6	50ml, 100ml
8. Flow Rate Ra	ange:	10ml syringe	0.1ml/h-300ml/h;
		20/30ml syringe	0.1ml/h-500ml/h;
		50/60ml syringe	0.1ml/h-1200ml/h;
		100ml syringe	0.1ml/h-1500ml/h
9. Accuracy:		± 5% with syringe	
10. Alarms:		Audible alarms	
			"COMPLETE", "OCCLUSION",
		and "LOW BATT"	
11. Maximum Infusion Pressure:		•	a with 50ml syringe
12. Occlusion Alarm Pressure:		0.03 Mpa – 0.07 M	pa wit 50ml syringe
	ond Time and Bolus Rate:	With 50ml syringe	Γ
Infusion Rate	Occlusion Alarm Pressure	Respond Time	Bolus Rate
Min. 1 ml/h	Low $(0.03 \pm 0.02 \text{ MPa})$	1:45'	0.77ml
	Mid $(0.05 \pm 0.02 \text{ Mpa})$	3:05'	0.62ml
	High (0.07 $\pm$ 0.02 Mpa)	4:10'	0.50ml
Mid. 5 ml/h	Low $(0.03 \pm 0.02 \text{ MPa})$	18'	0.70ml
	Mid $(0.05 \pm 0.02 \text{ Mpa})$	31'	0.61ml
	High (0.07 $\pm$ 0.02 Mpa)	41'	0.63ml
14. Net Weight:		2.5 Kg / 5.5 lbs	
15. Dimension:		335(L)x142(B)x120	
		13" x 5 1/2" x 4 3/4	"

### PREPARING FOR THE INFUSION

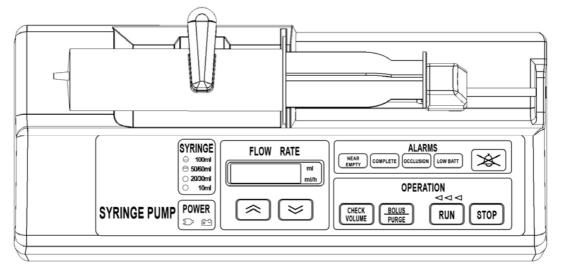


- 1. Keep the pump horizontally before use. The pump can be used either on horizontal table or on the IV pole with the designated pole clamp packaged with the pump.
- Prepare the disposable syringe and extension tube according to its accompanying instructions. ONLY use syringes and extension tube with a luer-lock connection. This connection guarantees that the drain will not slip off due to a rise in pressure during the infusion.



▲ WARNINGS: THIS SYRINGE PUMP HAS BEEN PROGRAMMED TO USE BD PLASTIPAK SYRINGE BY DEFAULT. ALWAYS CHECK THE ACCURACY CALIBRATION SETTING EVERY TIME BEFORE USING A NEW/DIFFERENT SIZE/BRAND SYRINGE. USING A NEW/DIFFERENT SIZE/BRAND SYRINGE WITHOUT CORRECT CALIBRATION SETTING WILL CAUSE INACCURATE INFUSION RESULT!

。 For use in USA, B-D, Monoject, TERUMO brand syringe can be used without calibration.



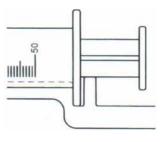
# STARTING AN INFUSION

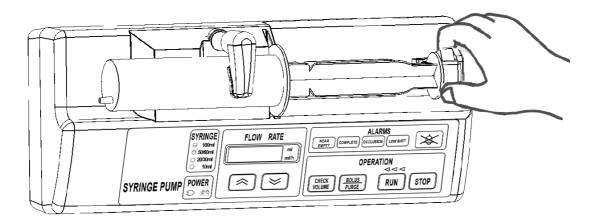
MARNINGS: The user must read this manual carefully before first-time use.

- Plug the power cord into a wall outlet to charge the internal battery. The pump can be used normally during the charging or use the DC 12V built-in battery power. Under battery operation, charge battery at least 8 hours before use. A fully charged NEW battery can support continuous running up to 3 hours at a flow rate of 25 ml/hr. If the power cord is unplugged during the operation, the pump will switch to the built-in battery automatically.
- 2. Load syringe with medication or desired fluid, then purge the syringe to expel the air. Lift up the syringe securing bar and rotate 90 degrees counter-clockwise to make it hold the position. Place the syringe on the top of the pump. Be sure to insert the syringe flange firmly into the flange slot on the pump firmly so the syringe won't be able to move during the infusion.

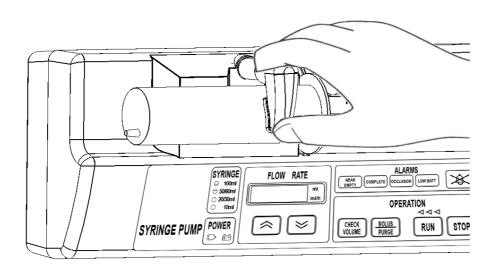
**WARNINGS**: A loose installation of the syringe will cause inaccurate infusion result.

3. Press the release button on the plunger driver block and slide the driver-block into position so that the end of the syringe plunger can be placed into the slot in the driver block. Make sure the syringe plunger is properly seated in the plunger driver block.

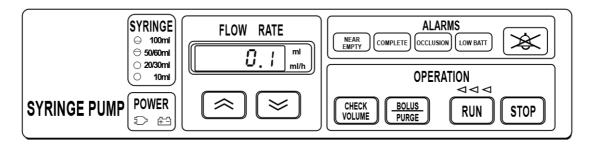




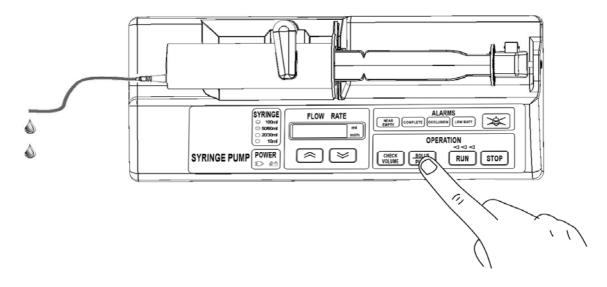
4. Turn the syringe securing bar 90° clockwise to secure the syringe barrel. Make sure the syringe barrel is secured so the syringe won't move during the infusion.



5. Turn the power switch ON. ON/OFF switch is located on the right side of the pump. When it is initialized, the pump will go through a Self Diagnostic program. After the pump passes the Self Diagnostic tests, previous infusion rate setting will appear on the display. The pump is then ready to be programmed for an infusion.



6. Press and hold the **BOLUS** button to purge air from the syringe and associated extension tube before connecting to patient.

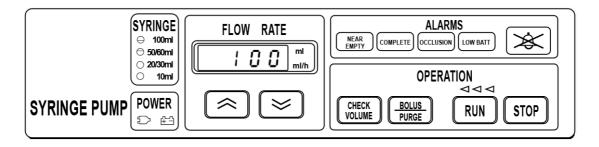




**IMPORTANT:** If the syringe was not installed or not installed properly, the syringe size indicators will keep flashing. After the syringe was installed, the corresponding LED light will keep ON indicating the syringe size (e.g. 100ml as below sample)

7. Press or or to set the desired flow rate. You can also hold the button or or

to accelerate the rate changing.



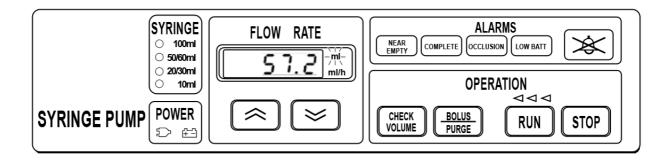
Flow rate range for different size of syringe:

Syringe Size (ml)	Infusion Rate Range (ml/h)
10	0.1-300
20/30	0.1-500
50/60	0.1-1200
100	0.1-1500

CHECK

User can check the infused volume by pressing

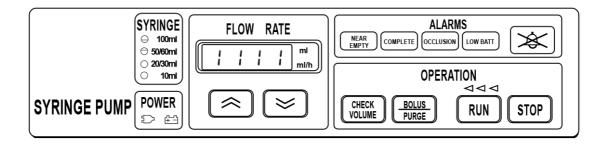
button. The 'ml/h' LED light will switch to 'ml'.



9. To stop an infusion, press

Reason for the failure of the Self Diagnostic program

If the pump fails the start-up/initial Self Diagnostic program, the LED screen will display '1111' indicating that the pump did not pass the Self Diagnostic program. Stop using the pump until the it is serviced by authorized personnel.



button.



**WARNINGS**: If the pump's LOW BATT alarm is ON after the pump is turned on, the user must connect the pump to/into an AC power outlet immediately. DO NOT use the pump if the LOW BATT alarm is ON. The pump may stop during the infusion if the LOW BATT alarm is ON after the pump was turned on.

# PURGE FUNCTION

#### **WARNINGS**:

The extension line must be disconnected or clamped before removing the syringe to prevent free flow to the patient. The user must purge the syringe to expel the air completely from the syringe and the associated tubing every time before connecting to the patient. Failure to do so may cause the patient's blood to drain backward at a low rate.

WARNING: Do not remove a syringe from the pump while connected to a patient.

To purge the syringe, stop the pump first if the pump is running. Hold the **BOLUS** button to expel the air or fluid from the syringe.

**IMPORTANT:** Depending on the syringe size, the pump will purge the syringe at different rates for different size of syringe:

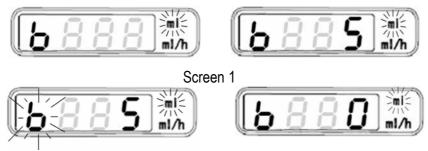
Syringe Size (ml)	BOLUS/Purge Rate (ml/h)
10	240
20/30	400
50/60	960
100	1200

### **BOLUS SETTING**

1. During an injection, use bolus to give extra dose to the patient. If you press for 2 times, pump enters Bolus settings. First numeric sign will display "b", unit indicator "ml" is on at the same time./ The screen will display "b" with unit indicator "ml". (Screen 1)

2. Press or or to set the desired bolus volume. Maximum bolus volume is 10 ml. Bolus volume will be displayed. The pump will automatically calculate the bolus rate according to the syringe size and the bolus volume.

3. Press **RUN** to confirm the bolus setting and to start the bolus. The pump will give a short buzz, reminding user of initialing bolus has started. Numeric sign "b" is flashing. (Screen 2) The displayed bolus volume will decrease as the bolus injection goes on. When the displayed bolus volume reaches "0", the pump will give a short buzz, reminding user of the bolus completion. Then the pump will go back to original injecting mode.





When the bolus is completed, the pump goes back to the original injecting/infusion rate/mode.

**CAUTION:** When the user enters the Bolus Setting screen, original infusion rate and volume are not affected. Each bolus shall not exceed 10 ml.

**CAUTION:** Press in case bolus infusion needs to be stopped; the pump will stop bolus injection and will return to original infusion mode.

IMPORTANT: Bolus volume will be included into the total volume infused.

**WARNINGS**: Before starting a bolus infusion, the user shall confirm the bolus volume and make sure the additional volume is safe for the patient.

Environment :

Condition	Operating	Transportation / Storage
Relative humidity	≤90 %	≤93 %
(non-condensing)		
Temperature	5℃ to + 40℃	-10℃ to + 55℃
	41°F to + 104°F	14°F to + 131°F
Atmospheric	700 to 1060 hPa	500 to 1060 hPa

# ALARMS

**OCCLUSION** — When an occlusion occurs, the infusion stops. Press MUTE button to silence the alarm buzzer. User can only resume the after the alarm condition is cleared.



**COMPLETE** — When an infusion is completed, the operation stops and audible and visual alarms are activated. Press MUTE button to silence the alarm buzzer.



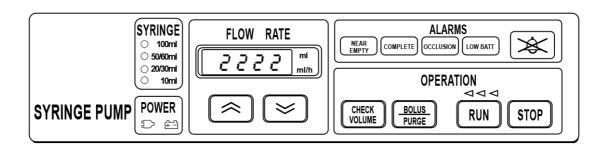
LOW BATTERY — Audible and visual alarms are activated if the battery runs low. In such

situation, the pump should be connected to an AC or DC power supply immediately to charge the battery. The pump will continue to operate while recharging the battery. The LOW BATT alarm will keep 30 minutes if pump wasn't not plugged in the power supply/will remain activated during 30 minutes if the pump is not plugged into a power outlet. Pump will stop if the battery will be depleted in 3 minutes.

**NEAR EMPTY**— When there is approximately 5 ml of medication left, an audible and visual alarm is activated. Press the MUTE button to silence the alarm buzzer.



**MALFUNCTION** — If the pump's LED screen displays '2222' during the infusion, it's indicating that the pump has internal mechanism problem. Stop using the pump immediately until the it is serviced by authorized personnel.



**CAUTION:** Alarm can be silenced by pressing alarm condition is not cleared within 2 minutes.



button. However, the alarm will resume if the

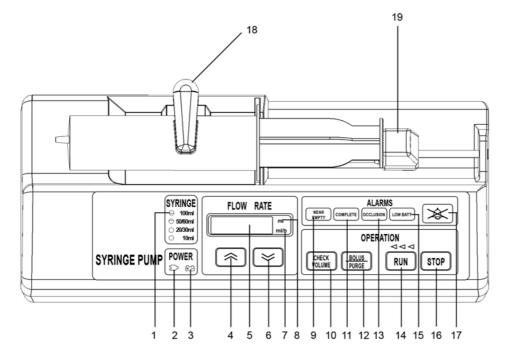
SYRINGE DISENGAGED ALARM ---- If the syringe is disengaged during the

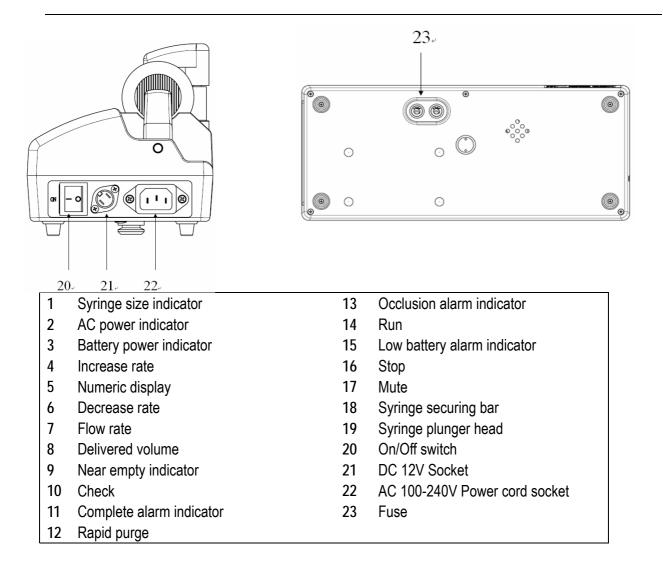
normal infusion, an alarm will sound and both 'NEAR EMPTY' and 'COMPLETE' LED lights will be ON. Only resume the infusion after the syringe is installed properly.

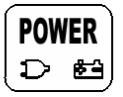


### **KEYPAD DESCRIPTION**

A. Control panel & pump structure







Power supply indicator: Green for external power supply; Orange for battery operation

### **KEYPAD FUNCTIONS**

	INCREASE Button – Increases flow rate. Press to increase the flow rate, hold to accelerate the rate changing		
$\mathbf{\forall}$	DECREASE Button – Decreases flow rate. Press to decrease the flow rate, hold to accelerate the rate changing		
CHECK VOLUME	CHECK VOLUME Button - Press or hold during RUN mode to display the volume delivered. Release to return the current flow rate		
BOLUS PURGE	button for 2 seconds to enter E maximum BOLUS volume is 10 If pump is in STOP mode, this b	this button function as a BOLUS button. Hold this BOLUS infusion setting to infuse at preset flow rate, iml.button function as a PURGE button. Hold this button rate to expel air out of the syringe or to purge theBOLUS/Purge Rate (ml/h)240 400 960 1200	
RUN	RUN Button – Press RUN button to start infusion; the LED indicator flashes during the infusion.		
STOP	STOP Button – Press to stop the pump.		
X	MUTE Button – Press to silence the alarm buzzer when 'NEAR EMPTY', 'COMPLETION/COMPLETE' OR 'OCCLUSION' alarms are sounded. Audible and visual alarms.		

### CALIBRATION SETTINGS

### **ACCURACY CALIBRATION**

**WARNINGS**: Contact manufacturer for authorized calibration value before using syringes not listed on Page 29. Do not calibrate unauthorized syringes without manufacturer's authorization.

- 1. Turn on the power switch
- 2. Load the applicable syringe.
- 3. Press the **STOP** button 4 consecutive times. The pump will enter the calibration model with the first digit displaying 1 on the display screen. (Screen 3)

i. Screen 3

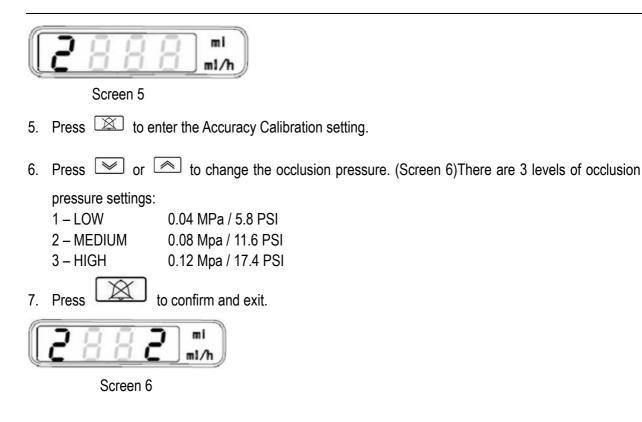
- 5. Press 🖾 to enter the Accuracy Calibration setting.
- 6. Press or for to change the calibration value, the calibration range is -30% ~ + 30%. (-30 represents -30%; 30 represents +30%). (Screen 4)

1. Screen 4

7. Press 🖾 to confirm and exit.

#### ADJUST OCCLUSION PRESSURE

- 1. Turn on the power switch.
- 2. Load the applicable/compatible syringe.
- 3. Press the STOP button 4 consecutive times. The pump will enter the calibration model with the first digit displaying 1 on the display screen.
- 4. Press once and the pump will display 2 in the first digit. (Screen 5)



### **ADJUST ALARM VOLUME**

- 1. Turn on the power switch
- 2. Load the applicable syringe
- 3. Press the STOP button 4 times continuously; the pump will enter the calibration settings with the first digit displaying 1 on the display screen.
- 4. Press button two times and the pump will display 3 in the first digit on the display screen.

(Screen 7)



Screen 7

- 5. Press is to enter the alarm volume setting.
- 6. Press or location to select the alarm volume. (Screen 8) There are three levels of alarm volume

to select:

- LOW: Lowest alarm volume
- MEDIUM: Medium alarm volume
- HIGH: Maximum alarm volume



Screen 8

7. Press 🖾 to confirm and exit.

**WARNINGS**: The default alarm volume setting is HIGH. Set the alarm volume to MEDIUM or LOW may cause the alarm not heard in distance/ If the volume is set to MEDIUM or LOW, the user may not hear the alarm from a distance. Always check if the alarm volume/ that the alarm volume is on HIGH before a new infusion. Make sure the alarm sound at the current volume setting can be heard at any time by the responsible personnel in any situation.

### **RESET TO FACTORY DEFAULTS**

- 1. Turn on the power switch.
- 2. Load the applicable syringe.
- 3. Press the STOP button 4 times continuously; the pump will enter the calibration model with the first digit displaying 1 on the display screen. (Screen 9)
- 4. Press 3 times to display 4 in the first digit on the display screen. (Screen 10)



Screen 9

Default settings:

Infusion Rate	0.1ml/h
Accuracy Calibration	0%
Occlusion pressure	2 (Medium)
Alarm volume	3 (High)



Screen 10

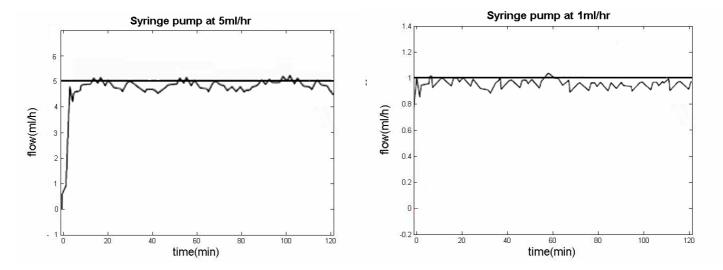
5. Press is to confirm the factory reset and exit. The pump will be restored to the factory default settings.

# TROUBLESHOOTING

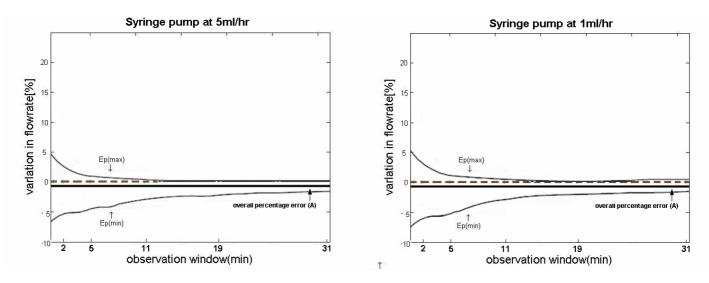
Description	Possible Cause	Required Actions
Pump can't be turned on	<ol> <li>Circuit overload.</li> <li>The power cord is loose or battery is depleted.</li> <li>Pump's power supply/transformer is not working.</li> </ol>	<ol> <li>Unplug the pump from the AC power, Check/change fuses on the bottom of the pump (only use fuse type T 1AL 250V).</li> <li>Make sure the power cord is firmly connected and power switch is turned on.</li> <li>Contact our authorized distributor to replace the main power supply.</li> </ol>
Pump won't charge the battery	<ol> <li>Circuit overload.</li> <li>The rechargeable main battery needs to be replaced.</li> </ol>	<ol> <li>Unplug the pump from the AC power, Check and change fuses</li> <li>Contact our authorized distributor to replace the main battery</li> </ol>
OCCLUSION alarm but no visible block on the IV line	<ol> <li>Hidden occlusion can't be seen</li> <li>The pump was set at HIGH occlusion sensitivity</li> </ol>	<ol> <li>Check carefully the IV line and connection area, and then resume the infusion.</li> <li>Change the pump to lower Occlusion sensitivity setting</li> </ol>
Over/under infusing over +/- 5%	<ol> <li>User uses different brand/size syringe without proper calibration setting.</li> <li>The pump wasn't sent for calibration within last 24 months according to the service protocol.</li> </ol>	<ol> <li>Stop using the pump. Check the pump accuracy with the currently used syringe brand/size and pump calibration setting according to the manual.</li> <li>Stop using the pump. Contact our authorized distributor for the maintenance service.</li> </ol>
Keypad locked/frozen	<ol> <li>The pump is running and most keypads are locked.</li> <li>The control buttons are broken.</li> </ol>	<ol> <li>Stop the pump to change the pump setting on the keypad.</li> <li>Stop using the pump. Contact our authorized distributor for service.</li> </ol>

# INFUSION ACCURACY OF THE SYSTEM

Infusion Accuracy



#### **Trumpet Curve**



# **REGULATORY INFORMATION**

This volumetric syringe pump complies with the following standards:

- 93/42/EEC European directive for medical devices including EN 60601-1-2 and collaterals.
- Electrical Safety and Electromagnetic Compatibility standards (IEC) (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

Tablel-1

Elect		r Equipment and Syst EN 60601-1-2:2007	tems Fully Compliant with
This syringe pump is inf	ended for use in the electrom	agnetic environment speci	fied below.
Immunity Test	IEC 60601	Compliance	Electromagnetic Environment- Guidance
	Test Level	Level	
Electrostatic	± 6kV contact	± 6kV contact	Floors should be wood, concrete or
Discharge (ESD)			ceramic tile. If floors are covered with
	± 8kV air	± 8kV air	synthetic material. The relative humidity
IEC 61000-4-2			should be at least 30%.
Electrical fast	± 2kV for power	± 2kV for power	Mains power quality should be that of a
transient / burst	supply lines	supply lines	typical commercial or clinical
			environment.
IEC 61000-4-4	± 1kV for input / output	± 1kV for input /	
	lines	output lines	
Surge	± 1kV line to line	± 1kV line to line	Mains power quality should be that of a
	± 2kV line to earth		typical commercial or hospital
IEC 61000-4-5		± 2kV line to earth	environment.
Power frequency	3 A/m	3 A/m	Power frequency magnetic fields should
(50/60Hz) magnetic			be at levels characteristic of a typical
field			location in a typical commercial or
			hospital environment.
IEC 61000-4-8			
NOTE: U _T is the a. c. r	mains voltage prior to applicat	ion of the test level.	

### ACCESSORIES

Every new pump's package includes:

1 x Pole Clamp 1 x 3-core standard power cord 3 x Disposable extension tube (for testing) 2 x Fuse (T1AL 250V) 1 x User's manual

Authorized syringe brands to use with this pump without additional calibration

10ml、20ml、50ml syringes: B-D, Monoject, Terumo® , NIPRO(Europe), JMS 100ml syringe: JMS, KDL

# PACKAGE, TRANSPORTATION AND STORAGE

**1. Package:** Please save the original package and Styrofoam, put the syringe pump in this original package for storage, keep the manuals and all accessories.

**2.Transportation:** Avoid shake and impact during transportation, keep away from moistures (no rain or snow).

#### 3. Storage:

If the pump is to be stored for an extended period, it should be cleaned and the battery fully charged (at least 8 hours). Store in a clean, dry atmosphere.

Environmental temperatures:  $-10^{\circ}C \sim +55^{\circ}C$ Relative Humidity: Less than 93% Atmosphere Pressure:  $500hPa \sim 1060hPa$ 

There should be no erosive air or harmful dust. Leaving the battery in an uncharged state for a long period of time may discharge completely and damage the battery permanently.

Perform operational and safety standard checkout to ensure the pump works properly and infuses accurately before use if the pump is stored over 3 months.

Perform operational and safety standard checkout and fully charge the battery every three months.

### MAINTENANCE

Service of this syringe pump must be done by manufacturer authorized technician.

#### Replacing the fuse:

If the pump can't be turned on when it's plugged in the electrical outlet, please make sure there that the electrical outlet is working. Then unplug the power cord and check the fuses in the fuse box on under the power socket. If the fuse is burned, please replace the fuse.

#### SUGGESTED CLEANING, STERILIZATION GUIDELINES :

Always keep the pump clean, use 70% alcohol soft cloths to wipe out any fluid on the pump.

Use EOG (Ethylene oxide gas) to sterilize the pump under following conditions:

Environmental temperatures: under 58°C

Relative Humidity: Less than 60%

After the sterilization, please keep the room ventilated for 24 hours or longer, or leave the pump in the ventilation device for 8 hours or longer.

#### Important:

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

AWARNING: The operational and safety standard checkout must be performed at least every 24 month by factory authorized service representative to ensure the pump works properly and infuse accurately. (not covered by warranty, paid service)

AWARNING: Perform functional tests and ensure that battery is fully charged at least once every month.

The designed life time of this pump is 6-8 years. After designed life time, please replace all major components by manufacturer authorized technician or stop use.

#### **Pollution-Free Treatment And Recycling**

- 1) Remove the Ni-MH before recycling or disposal.
- 2) Manufacturer will accept used pump for proper pollution-free treatment and recycling

# MAINTENANCE SERVICE RECORD

Serial Number:	Date of Purchase:
Date of Service: Maintenance Detail:	Accuracy Calibration Functional tests
Serviced by (Print Technician Name): Service Company Name (Print):	
Date of Service: Maintenance Detail:	Accuracy Calibration Functional tests
Serviced by (Print Technician Name): Service Company Name (Print):	

Date of Service:	Accuracy Calibration	Functional tests	
Maintenance Detail:			
		-	
Serviced by (Print Technician Name):	Signa	ture:	
Service Company Name (Print):		Tel:	

# LIMITED WARRANTY

This syringe pump has been carefully manufactured from the highest quality components. The pump is guaranteed against defects in material and workmanship for two (2) years from date of purchase by the original purchaser, 6 months (6) for rechargeable battery. 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 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. This warranty becomes void if opened or serviced by un-authorized personnel.
- 3. This warranty does NOT cover freight cost, insurance and any other incidental charges.
- 4. Failure to service the pump periodically as scheduled will void this warranty policy.
- 5. 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.