MICROPUMP MP*mlh*+
“ Multi Syringe”

Directions For Use

ML173DFU110919GB

Published by Micrel Medical Devices

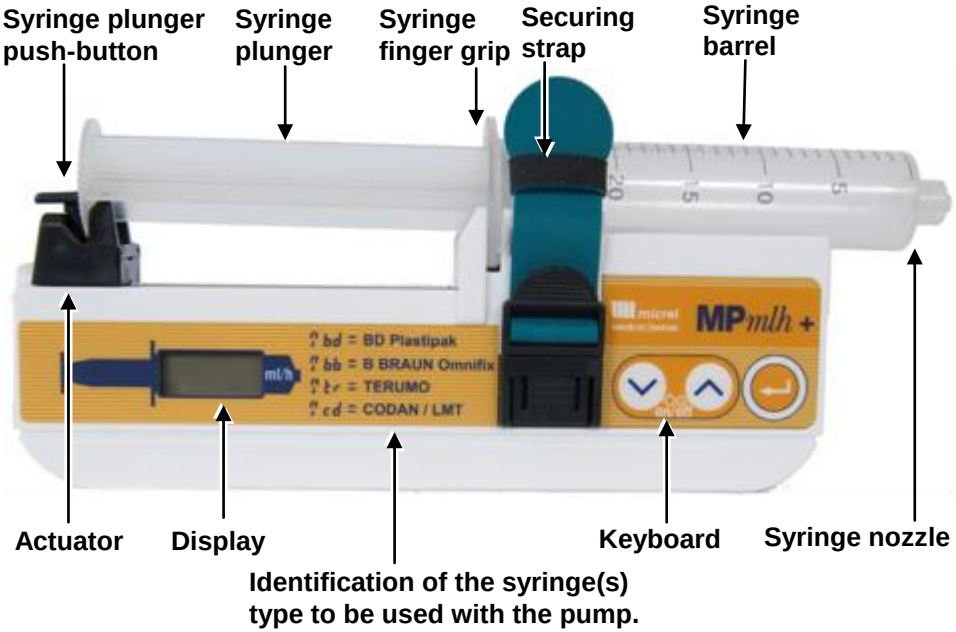
Contents

Introduction

In this manual, you will find instructions on:

- How to use the syringe driver safely
- Care and Maintenance
- What to do if your driver malfunctions

Please take time to read all the information before you start to use the syringe driver, and follow all the **warnings** given. The **Warnings** are listed on page 36, and are also repeated at the appropriate places in the Manual.
Micropump™ MPmlh+ "Multi Syringe" is a technologically advanced, easy to use infusion pump. It completely fulfills EN60601-2-24 standard. It is designed for precision, safety and durability for many years to come.



MPmlh+ "Multi Syringe" gives the ability to select various brand name and volume of syringe to allow accurate flow rate setting in milliliters per hour (ml/hr).

IMPORTANT:
Use only the syringe model and capacity mentioned on the syringe driver in order to avoid any risks of either partial or non-delivery of medication.

Thanks to their high contrast LCD display and membrane keyboard MPmlh+ Multi syringes allows you to set rate with three digit accuracy and efficiently manage the infusion events.

The syringe driver is a medical device that has been carefully designed and made to achieve a high level of safety protection.
In making a decision as to whether this syringe driver is a suitable aid for a particular treatment, the following performance specifications should be considered:

- If used incorrectly, the driver could pose a serious risk to human life
- Driver should only be used by or under the supervision of a medical professional.

The MPmlh+ “Multi Syringe” offers many quality features that make it highly suitable for today’s hospital and home care treatments.
The MPmlh+ “Multi Syringe” has been designed for ambulatory use, enabling it to be carried by the patient during treatment. It is equally suitable for adults or for pediatric use.
Please make sure the Instruction Manual is given to the person who is responsible for using the syringe driver.

The driver is thus able to act as an aid in administering medicinal preparations in liquid form over much longer periods than could be achieved by injecting by hand. In addition to the driver, all that is usually required is a suitable sterile syringe, together with a sterile pathway to deliver the medication to the patient.

Intended Use

The device “MICROPUMP MP+” is intended for controlled infusion of liquids into the patient by means of one single action syringe and is indicated for intravenous, intra-arterial, subcutaneous, intraperitoneal, in close proximity to nerves, into an intraoperative site (soft tissue, body cavity /surgical wound site), epidural space, or subarachnoid space infusion.

Indications

The device “MICROPUMP MP+”, used with the appropriate administration set, is indicated for intravenous, intra-arterial, subcutaneous, intraperitoneal, in close proximity to nerves, into an intraoperative site (soft tissue, body cavity /surgical wound site), epidural space, or subarachnoid space infusion.

Contraindications

The device “MICROPUMP MP+” is not indicated for delivery of blood or insulin.

DO's and Don'ts

DON'T- use the driver without understanding all the instructions.

DON'T- use the driver without the syringe attached on it.

DON'T- use the driver if the plastic covers are damaged.

DON'T- get the driver wet. It is not waterproof and the performance could be affected.

DON'T- take the driver from a cool place and put it into a warm, very humid one (e.g. an incubator) or take it from there into a cooler one. Condensation will form and the inside will get wet.

DON'T- open the driver to look inside. The performance will be affected.

DON'T- use the driver in or near strong magnetic fields, Nuclear Magnetic Resonance (NMR) scanners or MRI for example.

DON'T- use the driver in the presence of flammable anesthetic gases or in an oxygen enriched atmosphere. It may increase the risk of fire or explosion.

DON'T- use the driver outside its temperature range. The performance could be affected.

DON'T- wipe the driver with organic cleaning solvents or strong disinfectants. The plastic case may be damaged.

DO- avoid using Cell Phones within 1 meter of the driver. Although there have been no confirmed reports of mobile telephones interfering with the operation of the driver, following this advice will help to reduce any risk.

DO- check the battery compartment and the batteries daily

Installation

When unpacking, check that the system is complete, according to the below table:

Directions for Use	MP carrying bag with transparent window 20-50ml
Short directions for use	
Set of 6 AAA size Batteries	

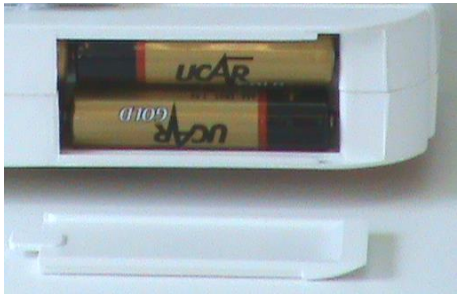
Before use, always inspect the pump for damaged plastic covers. If the plastic covers are damaged, return the pump to service.

Should the instrument fail to perform correctly, contact our distributor immediately for technical support.

Installing/Replacing the Batteries

Micropump™ MPmlh+ "Multi Syringe" uses six Alkaline batteries 1.5V type LR03, AAA size.

Before use, always inspect the battery compartment. In case of presence of battery liquids inside battery compartment, please follow cleaning procedure described in section *'Cleaning and disinfection procedure for pump*" pag. 32. In cases of traces of corrosion on battery contacts, please return the pump to service.

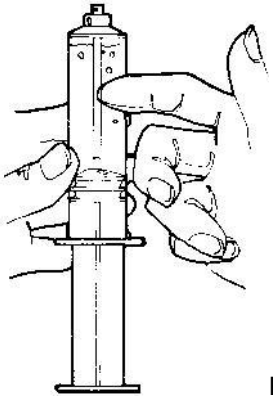


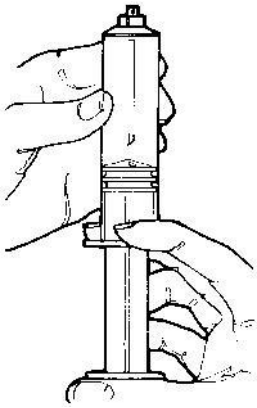
Slide the battery compartment lid towards the rear of the casing.
Insert the batteries within the compartment, observing the correct polarity as shown by the illustration within the battery compartment.
Slide the lid back in place.

Important:
Do not remove the batteries while the pump is switched ON as this may damage the pump.
Check that the polarity of the batteries is correctly oriented.
The pump cannot be damaged if the batteries are incorrectly oriented.
Remove the batteries if the pump is to be stored for more than six months.

Preparing an Infusion

Prepare the medication for treatment.
Draw-up the syringe with the medication according to the instructions of your doctor.





Remove air bubbles

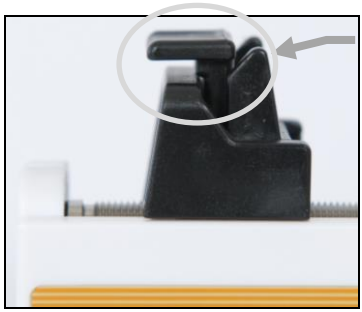
Connect the infusion set to the syringe, prime it and clamp the infusion set.
The set will be connected to the patient and unclamped only after the complete syringe installation.
For syringe replacement, clamp the infusion set at the pump end prior to disconnected the syringe from the infusion set.

Important:
Use only the syringe model and capacity mentioned on the syringe driver in order to avoid any risks of either partial or non-delivery of medication.

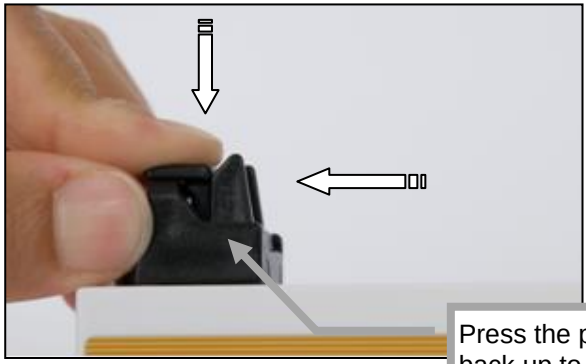
Fitting the syringe

Important:
Ensure that the pump is OFF during removal and placement of the syringe.

Press the center of the clip and pullout the syringe retainer to open it. Remove the syringe that might already be in place.



2) Remove the syringe that might already be in place before trying to disengage the drive mechanism.
The mechanical system prevents the release of the drive mechanism when it is under pressure. This is to prevent wear on the lead screw and to extend the product's mechanical life.



Press the plunger driver button, to pull it back up to the end of the lead screw.

Insert the syringe plunger end in the pusher, between button and edge.

Move the plunger driver as close as you can to the syringe plunger head by depressing the button down. Be careful not to push the plunger forwards.

Insert the syringe flanges in the appropriate slot.

Secure the syringe with the syringe securing strap. Do not over tighten the syringe retainer too much, in order not to deform the barrel of the syringe. This may cause the pump to stop at the deformation point, activating an alarm.

Turn the Pump ON /OFF

Turn the pump ON by pressing

& keys simultaneously for 3 seconds. At any time, the pump can be turned OFF using the same procedure.

While keeping keys pressed down, you can test the display and watch the numbers, decimal point, low battery, bell symbols and the infusion symbol (ellipse).

After switching ON, the pump is on hold. The last brand of syringe used flashes and a warning beep is emitted every minute.

The symbol represents syringe selection symbol for both brand and volume.

Press the up chevron to set the brand of the syringe. Press the Enter to confirm the changed brand and pass to syringe volume selection. Four brands are available:

= BD Plastipak ™

= B BRAUN Omnifix®

= TERUMO®

= CODAN /LMT

as shown in the front label of the pump.

The last volume of syringe used flashes and a warning beep is emitted every minute. Press the up chevron to set the volume of the syringe. Press the Enter key to confirm the volume of the syringe and pass to the rate selection. Four volumes are available 10ml, 20ml, 30ml and 50ml.

Warning: the volume of the syringe relates to the nominal volume of a full syringe. It is not related to the volume of medication to infuse.

[1] Plastipak is a trade mark of Becton Dickinson

[2] Omnifix is a registered trade mark of B.Braun

Important

Volume selection for Terumo brand is 60ml instead of 50ml. To use a Terumo 60 ml syringe, select 50 on the pump display.
The displayed syringe brands and volumes are the only ones selected at the configuration menu. So, it is possible to have only one brand and volume selection.

All brand syringes of 20ml fill fully to 20ml.
The selection of the brand and the volume of the syringe to be used is only available before initiating the infusion.

The last rate used flashes and a warning beep is emitted every minute.

Prime function

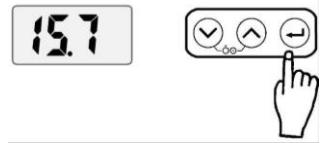
When enabled, this function allows the user to precisely finish the priming of the infusion set. It could be useful to use it to speed up the starting time for the infusion as it reduces the mechanical backlash that may appear during syringe installation.
The Prime function is only available after power on, before initiating the infusion.

To prime, press and simultaneously. The pump displays pr and starts priming as long as the keys are held down.
Prime stops when both keys are released.
To disable the access to this facility, please, refer to the Configuration chapter.

Edit Rate and infuse

Set the Rate using the up ⌃ / down ⌄ chevrons.
Pressing once, the Rate changes by 0.1 ml/HR.

Start the infusion, or confirm the changed rate, by pressing ENTER ↵ for 1 second, until the pump displays CAL and starts the infusion.



During infusion, the syringe brand, the syringe volume and the rate are displayed sequentially and also an ellipse symbol rotates.

The rate, the syringe type and also the syringe's size are saved and not lost by turning the pump OFF, or even after changing the batteries.

Rate can be set from 0.1 ml/hr.
Rate range can be restricted using the **min - max hard limits**, or even can be limited to one single flow rate, as described in the configuration chapter.

Important:
Rate on the display is expressed in ml/hr. Rate in ml/hr depends on syringe's size and brand.
Zero Rate is not permitted and the pump bypasses this number while editing.

Bolus function

When enabled from configuration, this function allows during the course of the infusion, to deliver a dose that has been previously preset in tenth of ml.
Bolus can only be infused if Rate is equal or less than the half of the max rate e.g for BD20 is 16.5 ml/hr.
The bolus dose is delivered at maximum rate.

To start immediately the bolus, press and hold the enter key ↵ and make a simple push to the Up key ⌃.

Release the Enter key ↵ when you hear the starting beep. The pump will start delivering programmed bolus dose.

The pump displays the bolus dose in ml eg: D 0.5

…/..

Changing the bolus dose within limits.
If the bolus range has been set to allow various bolus settings , the last bolus dose is recorded until the pump is turned OFF.
To change the bolus dose within the preset limits:

Press and hold the enter key, then make a simple push to the Up key and immediately release the Enter key.

The bolus dose in ml eg: D 0.5 is displayed. Use the / keys to set the new bolus value. Press the Enter key to initiate the bolus injection.
It is possible to stop the injection of a bolus at any time by pressing the enter key or switching Off the pump.

Bolus Lockout Time **NO**

Bolus lockout time in minutes disables repeating bolus demands. Lockout time zero means repeated bolus enabled without limitation. After delivering a Bolus, a lockout time in minutes as programmed at configuration, starts to count. Attempt to get Bolus within this lockout time, will display No and Bolus will not be delivered. Bolus Lockout time stops counting when the pump is turned OFF.
The Bolus function is only available after initiating the infusion.
To disable the access to this facility, please, refer to the Configuration chapter.
Warning: Bolus function needs full understanding and training of the user. Please make sure that the end user fully understands this functionality.

Syringe misplacement detection

This function warns the user in case of misplacement of syringe barrel or plunger, to avoid any siphoning of drug. The pump during standby warns for misplacement with symbol and during infusion with an alarm, displaying 

. You can silence alarm sound by momentarily pressing ENTER or resume infusion pressing the same key firmly till the infusion starts.

To disable the access to this facility, please, refer to the Configuration chapter.

Fitting pump into carrying bag and wearing

If the driver is to be carried then the MP carrying bag must be used.
Put the pump inside the MP carrying bag, as shown in the picture below.

Make sure that the syringe tip will be placed in the appropriate space inside the carrying bag, in order to protect the syringe tip and also the catheter connection. Pay attention not to trap the infusion line and secure the pump inside the carrying bag using clips.

The MP carrying bag protects the syringe to be dislodged and also the patient from any moving parts.
MP carrying bag can be worn on the shoulder or the waist.

Important
Do not wear in direct contact of the skin or in contact of injured skin. Ensure that the syringe has been secured with the strap.

Alarms and Troubleshooting

The Micropump™ MPmlh+ “Multi Syringe” has two alert modes; alarms and warnings.

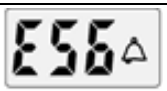
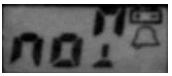
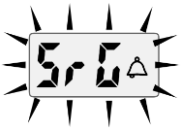
Alarms

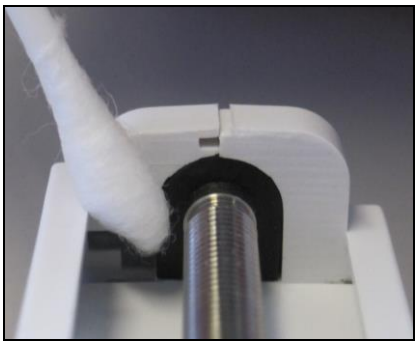
On alarm, the infusion stops, the  symbol is displayed concurrently to the alarm identification message. The instrument will sound intermittently, except for the End of infusion alarm when the Silent End of infusion mode is enabled.
Turn the pump OFF to cancel the alarm.

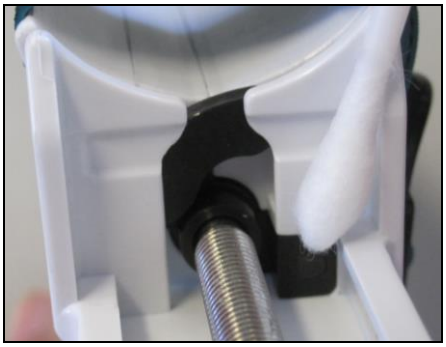
In the unlikely event that instrument indicates an internal error, note the error code, withdraw the instrument from service and have the instrument inspected by a qualified service engineer.

Action to be taken	Display During Alarm
OCClusion or end of plunger travel. Pressing any key will silence the alarm for one hour, Remove the syringe or disconnect the extension set to release the pressure, remove the obstruction and resume the infusion by pressing the ENTER ↵ key.	
Depleted battery. Turn the pump OFF and replace the batteries	
One Hour on Hold Alarm. Turn pump ON again	
End of Infusion. The infusion is finished. Remove the syringe, turn OFF the pump. The End message is displayed when an occlusion is detected after about 24 hours of infusion or a full infusion stroke. Buzzer of this alarm can be disabled from Configuration.	
Coded message displayed, an internal error has been detected. An alarm may originate from Electromagnetic Interference or extreme vibration. Turn pump OFF then ON again. If the alarm persists, withdraw the unit from service, note the error code and have the unit checked by a qualified engineer.	

Alarms and Troubleshooting

Action to be taken	Display During Alarm
E10, E11 Alarms: Key buttons pressed for long. Turn pump OFF, then ON again. This is a safety feature, to prevent unintentional Rate change.	
E-56 Alarm: The pump is exposed direct to high illuminated sources like sunlight, lamps, etc. Relocation of the pump is needed.	
No syringe brand and / or volume were selected. From the Configuration menu select at least one syringe brand and volume.	
Syringe misplacement . Make sure of the syringe barrel flanges fit in the pump's indentations that plunger round end fits in pusher's slot, and that barrel belt is tight. Clean carefully the surfaces as shown in the pictures below, using a cotton bud damped with water.	

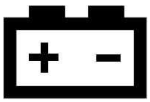




Important:
The occlusion detection activates the alarm with a delay time, which depends on the syringe type, catheter and infusion rate used. Fluid viscosity will not impact the pump accuracy, but high viscosity fluids may result in occlusion alarm depending of the extension set internal diameter and length and the needle gage used.

Warnings

During warnings the infusion continues.
Warnings have audible and sometimes visual signals.
On warning, the pump sounds intermittently and doesn't need to be turned OFF.

Condition	Display	Buzzer
Low battery signal; Change the batteries when the infusion is finished. The first time this warning is triggered, the remaining battery life is about 24hours.To silence the alarm press any key.		One beep every minute
The pump rejects rate change that is not confirmed within 5 seconds by pressing Enter ↵.	Old Rate appears.	Four beeps
At Standby, flashing display, warning that pump is not infusing.		One Beep every minute.
Near end of infusion. The message is displayed when the remaining volume is 10% of the nominal capacity of the syringe.		Three beeps

Syringe selection

There is the ability to select one or more syringe brands and volumes to be displayed at the programming. When enabled, the user has the ability to select the brand and the volume of the syringe before starting the infusion. This feature allows to trim the options for brand and / or volume of the syringe down to one single brand and / or volume. The symbol ⊓ helps to distinguish the syringe brand / volume selection from the rate programming.

Rate range limitation

In order to help prevent misprogramming, it is possible to restrict the Rate range to the highest and lowest possible rate you use for a given application.
This feature allows you to even trim the rate range down to one single value and turn the pump into a single Rate pump.

High and low flow rate limits

High and low flow rate limits could be configured in the pump.
The Up / Down chevron increment /decrement the flow rate between these two limits. For the possible Up/down limit values and configuration procedure, refer to the Configuration chapter.

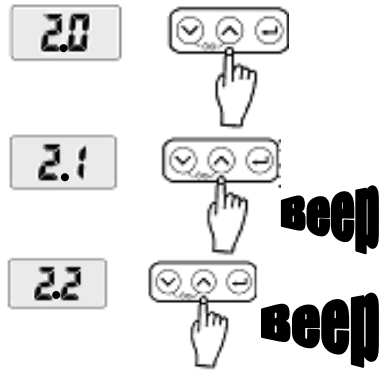
Unusual Rate warning.

High rate zone, Low rate zone

It is possible to configure the pump to get a warning beep when programming a rate that is outside the rate range you commonly use.
It doesn't prevent you from selecting this rate.
For the possible soft limit values and configuration procedure, refer to the Configuration chapter.

Inside the high or low rate zones, no beep is heard Eg: 2.0 ml/hr

A warning beep will be heard to warn you that your setting is above or below what you have defined as your High or low rate zone.



Rate titration

Certain applications may require rate change during the course of the infusion. It is possible to unlock the Rate titration mode to allow to change the Rate whenever you need during the course of the infusion.
When Rate Titration mode is ON, use the Up/down chevron to adjust the Rate and press Enter until **CAL** is displayed. The new rate is validated.
To enable this function please, refer to the Configuration chapter.
Until the rate is confirmed, the pump continues to infuse at the previous rate.

If rate change is not confirmed by pressing  key, within 2 seconds the display shows the actual rate and warns you by four consecutive beeps.

Silent End Of Infusion

Depending of the infused drug, it is sometimes not necessary and potentially stressful to have an audible alert at the end of the infusion.
The Silent End OF Infusion mode provides the capability to disable the buzzer at the End Of Infusion.

When the silent EOI is enabled, the pump will show  at the end of infusion and stops without a beep sound.
We do not recommend to use this function if the infusion is supposed to last more the 24Hours.
Always turn Off the pump after the end of infusion.
To enable this function, please refer to the Configuration chapter.

Display Backlight

The pump has an LCD display backlight for night view. The backlight slightly increases power consumption, so this function can be configuration enabled only when it is necessary: always on (**A**) or just be turned on when a key is pressed or the pump going on alarm (**Y**), or always Off (**n**).

Bolus Configuration

The bolus function can be enabled or disabled in the configuration menu. When enabled,(b-y) the bolus function is accessible during the course of the infusion.
It is possible to preset the accessible range for this bolus dose up to the point that it can be set to a fixed value when the upper bolus limit value is set equal to the lower bolus limit value.

Configurable Options

The bolus lockout time in minutes from 00 to 99 is also preset at configuration. When t=00 then no lockout time is set, and bolus can be given just after preceding one.

Occlusion pressure level

It is possible to lower the occlusion pressure alarm level.
Lowering the occlusion alarm level may generate unintended occlusion alarm particularly when used with viscous drug.
When occlusion alarm level is selected at a lower level than PL3, the device inform the user after power On by displaying the selected level eg PL1 or PL2 before displaying the rate.
Ensure that the selected occlusion pressure level of the pump is the appropriate for the therapy that will be used.

Near End of Infusion

When enable from configuration, this function warns the user of finishing the infusion. The pump beeps and displays the N.O.E.I message  when the volume is dropped down to 10% of the nominal volume, e.g. for a BD20 syringe the NEOI

message will be displayed when the remaining volume is 2ml. The message is displayed alternately with the rate screen, every two seconds.

Syringe Detection

The Syringe Detection function can be enable or disabled in the configuration menu. When enable, this function warns the user in case of misplacement of syringe barrel or plunger, to avoid any siphoning of drug. The pump during standby warns for misplacement with  symbol and during infusion with an alarm, displaying  .

To disable the access to this facility, please refer to the Configuration chapter.

Configurable Options

Warning:
The next page explains how to access the configuration. You may wish to remove the next page to secure the access of this programming option.
May you need a copy, please contact your manager.

Configurable Options

Configuration MPmlh+ "Multi Syringe"

To access the configuration menu of the pump, Turn the pump ON and hold the two chevron keys down. When all segments of the display are on, maintaining the down key pressed, press and release the ENTER key. Then release the down key. You entered the configuration menu, bd— is displayed.

Pressing Enter key, scrolls along the parameters list to give access to the value of the parameter that needs to be changed.

The chevron keys change the values.

The Enter key, stores the value and scrolls to the next parameter.

At the beginning of the configuration menu, the brands of the syringes are being displayed and then the volumes. The ones with Y will be shown at programming before infusion start. At least one brand and one syringe must be selected.

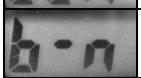
The four limit parameters U,d,H,L, adjust 2 digits of the 3 digit Rate. When decimal point is shown, most significant digit is set to 0. When decimal point is not shown, decimal digit is set to 0.

Press simultaneously the two chevrons to turn the pump off and save the settings.

The default values of the below configuration may differ according to customer request.

Display	Parameter	Numerical limits	Mfg default setting	Ward settings
bdY	BD Plastipak syringe	n or Y	**Yes**	
bbY	Bbraun Omnifix syringe	n or Y	**Yes**	
trY	Terumo syringe	n or Y	**Yes**	
cdY	Codan / LMT syringe	n or Y	**Yes**	
10Y	10 ml syringe volume	n or Y	**Yes**	
20Y	20 ml syringe volume	n or Y	**Yes**	
30Y	30 ml syringe volume	n or Y	**Yes**	

Configurable Options

	50 ml syringe volume	n or Y	**Yes**	
	High flow rate limit Upper Rate limit	up to Max Rate	**Max Rate**	
	Low flow rate limit Down Rate limit	0.1 up to upper rate limit or Max Rate	**0.1**	
	High rate zone above	0.1 up to upper rate Limit	**Max Rate**	
	Low Rate zone	1 up to high rate zone	**0.1**	
	Rate Titration enabled (yes –no)	n or Y	**Yes**	
	Prime function enabled (yes –no)	n or Y	**Yes**	
	Buzzer On at end of infusion (yes –no)	n or Y	**Yes**	
	Display Backlight	n or Y or A	**No**	
	Bolus Enable	n or Y	**No**	
	Bolus Max Volume	Min up to 20 ml	**2.0**	
	Bolus Min Volume	0.1 to Max ml	**0.1**	
	Bolus Lockout Time	01 to 99 min	**00**	
	Occlusion Pressure Level	1 to 3	**3**	
	Near End of Infusion	n or Y	**No**	
	Syringe Detection	n or Y	**Yes**	

Configured by: according to the prescription of:

Date:

Pump SN:_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ to _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Configurable Options

Remove and store the above two pages, if you need to secure the access to this configuration program.

Important:
After configuration, is the last used rate was out of the limits, it will be reset down to the lowest possible rate.
It is this rate that you will retrieve after power On.

Configurable Options

Parameter	Last settings	Last settings	Last settings
bd (yes –no)			
bb (yes –no)			
tr (yes –no)			
cd (yes –no)			
10 (yes –no)			
20 (yes –no)			
30 (yes –no)			
50 (yes –no)			
Upper Rate limit			
Down Rate limit			
High rate zone above			
Low Rate zone			
Rate Titration enabled (yes –no)			
Prime function enabled (yes –no)			
Buzzer On at end of infusion (yes –no)			
Display Backlight (yes –no)			
Bolus Enable (yes –no)			
Bolus Max Volume			
Bolus Min Volume			
Bolus Lockout time			
Occlusion Pressure			
Near End of Infusion			
Syringe Detection			
Pump SN;			
Comments:			
Date:			
Signature:			

Symbol Definition

Attention (Consult accompanying documents)	
Pump is classified as Internally Powered Equipment, Type CF Applied Part as per EN60601-2-24.	
Protected against splashing fluid (Degree of protection against fluid ingress) when fitted in protective cover and holster.	IPX4
Device complies with requirements of Medical Device Directive 93/42/EEC. Registered with the CE Mark.	CE 0120
Manufacturer's name and address	
ENTER Button	
UP Button	
DOWN Button	
According to WEEE Directive to remind consumers to properly dispose of used batteries and dispose of the product at the end of its useful life in an environmentally safe manner and according to any regulations which may apply.	
Serial number with year code. The first two digits (YY) represent the production year of the pump.	YYXXWWAAABBB

Regulatory Compliance

Electrical /Mechanical Safety

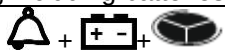
Device complies with EN60601-1 Classified as ambulatory type 4 as per EN60601-2-24	
Device is classified as Type IIb as per Medical Device Directive 93/42/EEC	**Type IIb**
Complies with EN60601-2-24.	
Safety Measures: Dual micro controller - dual clock redundant architecture for highest safety, exceeding EN60601-1 requirements.	
Declaration of Conformity can be available upon request.	

Environmental Conditions

	Operating
Ambient Temperature	+5ºC - +40ºC
Relative Humidity	20% - 90%
Atmospheric Pressure	8.4 PSI (600 hPa) – 14 PSI (1060 hPa)
	Transport / Storage
Ambient Temperature	-15ºC - +50ºC
Relative Humidity	5% - 95%
Atmospheric Pressure	9.8PSI (700 hPa) – 14 PSI (1060 hPa)

Exceeding those environmental conditions may damage the device or be harmful to the patients.

Structural

Dimensions:	170 x 61 x 32 mm
Weight:	220g including batteries
LCD Display	3 digits + 

Performance

Specifications	BD Plastipak 10mL Syringe 3 Pieces Luer Lok™	BD Plastipak 20mL Syringe 3 Pieces Luer Lok™	BD Plastipak 30mL Syringe 3 Pieces Luer Lok™	BD Plastipak 50mL Syringe 3 Pieces Luer Lok™
Flow rate increment step 0,1 ml/hr	0.1 – 19.0ml/hr	0.1 – 33.0ml/hr	0.1 – 43.0ml/hr	0.1 – 65.0ml/hr
Prime rate	19.0ml/hr	33.0 ml/hr	43.0ml/hr	65.0ml/hr
Max time to occ @ 5ml/hr	8min	10min	18min	27min
Bolus at occ release	0.5ml	0.7ml	1,3ml	1,8ml

Performance cont.

Specifications	Terumo 3-part 10 cc syringe Luer Lock tip	Terumo 3-part 20 cc syringe Luer Lock tip	Terumo 3-part 30 cc syringe Luer Lock tip	Terumo 3-part 60 cc syringe Luer Lock tip
Flow rate increment step 0,1 ml/hr	0.1 – 23.0ml/hr	0.1 – 37.0ml/hr	0.1 – 50.0ml/hr	0.1 – 78.0ml/hr
Prime rate	23.0ml/hr	37.0 ml/hr	50.0ml/hr	78.0ml/hr
Max time to occ @ 5ml/hr	9min	10min	17min	28min
Bolus at occ release	0.6ml	0.5ml	1.3ml	1.8ml

Specifications	BBraun Omnifix™ 10mL Syringe 3 Pieces Luer Lock	BBraun Omnifix™ 20mL Syringe 3 Pieces Luer Lock	BBraun Omnifix™ 30mL Syringe 3 Pieces Luer Lock	BBraun Omnifix™ 50mL Syringe 3 Pieces Luer Lock
Flow rate increment step 0,1 ml/hr	0.1 – 23.0ml/hr	0.1 – 37.0ml/hr	0.1 – 45.0ml/hr	0.1 – 72.0ml/hr
Prime rate	23.0ml/hr	37.0 ml/hr	45.0ml/hr	72.0ml/hr
Max time to occ @ 5ml/hr	10min	10min	18min	23min
Bolus at occ release	0.7ml	0.7ml	1.3ml	1.5ml

Specifications	Codan 3-part 10 cc syringe Male Luer Lock	Codan 3-part 20 cc syringe Male Luer Lock	Codan 3-part 30 cc syringe Male Luer Lock	Codan 3-part 50 cc syringe Male Luer Lock
Flow rate increment step 0,1 ml/hr	0.1 – 22.0ml/hr	0.1 – 41.0ml/hr	0.1 – 43.0ml/hr	0.1 – 71.0ml/hr
Prime rate	22.0ml/hr	41.0 ml/hr	43.0ml/hr	71.0ml/hr
Max time to occ @ 5ml/hr	7min	10min	14min	22min
Bolus at occ release	0.4ml	0.8ml	0.6ml	1.1ml

Important

- USE ONLY 3 PIECES AND LUER LOCK SYRINGE.
- USE ONLY THE DEDICATED SYRINGES WITH THE PUMP.
- ALL BRAND SYRINGES OF 20ML FILL FULLY TO 20ML.

Specifications

Specifications	LMT 3-part 10 cc syringe Male Luer Lock	LMT 3-part 20 cc syringe Male Luer Lock	LMT 3-part 30 cc syringe Male Luer Lock	LMT 3-part 50 cc syringe Male Luer Lock
Flow rate increment step 0,1 ml/hr	0.1 – 22.0ml/hr	0.1 – 41.0ml/hr	0.1 – 43.0ml/hr	0.1 – 71.0ml/hr
Prime rate	22.0ml/hr	41.0 ml/hr	43.0ml/hr	71.0ml/hr
Max time to occ @ 5ml/hr	7min	10min	14min	22min
Bolus at occ release	0.4ml	0.8ml	0.6ml	1.1ml

Occlusion Alarm	10cc syringe	20cc syringe	30cc syringe	50/60cc syringe
Level **1**	2.00 bar	1.10 bar	0.90 bar	
Level **2**	2.80 bar	1.60 bar	1.30 bar	
Level **3**	3.60 bar	2.10 bar	1.70 bar	1.0 bar
Accuracy	+0.8 / - 0.8	+0.7 / - 0.4	+0.6 / - 0.6	+0.4 / - 0.4

Rate linear displacement accuracy	± 2%
Volumetric Accuracy including syringe accuracy	± 4%
Battery Life	approx. 2 months with 50 mm per day infusion
Eventlog	500 events
Memory retention	10 years
Maximum over displacement infusion under single fault condition	0.2 ml
Max Accuracy error (pump speed) under single fault condition	± 5%

Batteries Type

Set of 6 Alkaline batteries, 1,5V IEC Type LR03, AAA size.

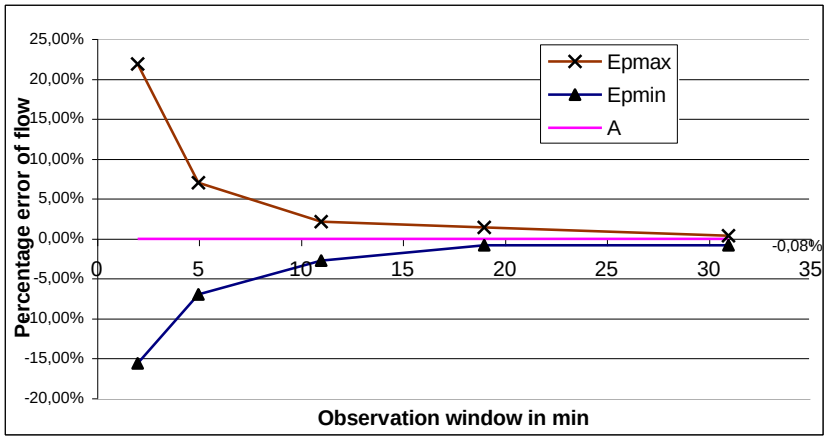
Event Log

The pump has an event log, storing pump events such as infusion Rate, titrated Rate, Bolus, Alarms, Configuration and each event time after pump is turned ON, on a Memory that can store about 500 events.
The event log can be stored on a PC with an "MPMicrelCom Cord" RS232 output accessory KS1.10.020.X.

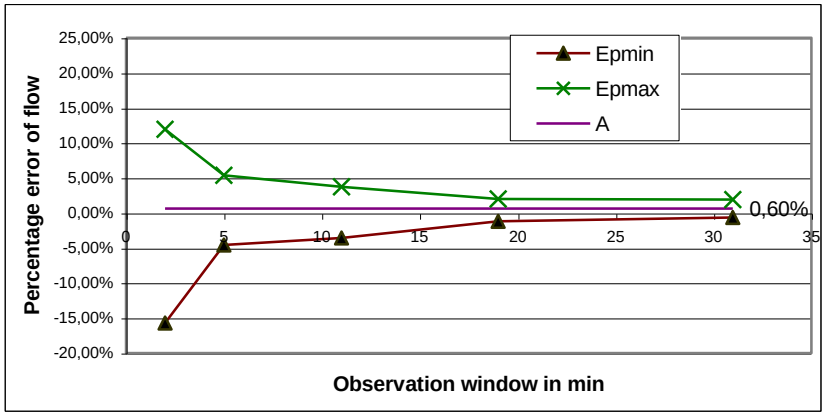
Trumpet Curves

Trumpet curves demonstrate the evolution of the minimum and maximum variance of the Syringe/Syringe-Pump combination.
The test protocol used to obtain these results is described in the EN 60601-2-24. For further information, please refer to this publication.
This graph is therefore representative of syringes used during trials and serve as an indication only of the pump's overall performance. Please contact our After-Sales Department for the other curves.

Trumpet Curve @ 1ml/HR & BD-20ml syringe



Trumpet Curve @ 15ml/HR & BD-20 ml syringe



Routine Maintenance Procedures

To insure that the instrument remains in good operating condition, it is important to keep it clean as described below. All servicing should be performed by a qualified service engineer with reference to the MICREL Service Manual.
A comprehensive service manual containing circuit descriptions, servicing and testing information is available for this unit. It can be ordered from Micrel Medical Devices or Micrel Medical Devices authorized distributor.

At least once every 3 years: Perform a functional test as outlined in the Technical service manual.

Important:
If the instrument is dropped, damaged, subject of excessive moisture or high temperature, immediately take the instrument out of service for examination by a qualified service engineer.
There are no user serviceable parts or user replaceable parts within the instrument.

Cleaning and disinfection procedure for pump

To insure that the pump remains in good operating condition, it is important to keep it clean. Clean the pump periodically following the below described procedure. Disinfection must take place regularly and always when the user is changed.

- Wear a new pair of protective sulphur free gloves and eye protection if splashing is likely to occur.
- Slightly damp a clean, soft, lint -free cloth (microfiber) with solution of mild soap (pH 7-8) and warm water (up to 30^{o}C/86^{o}F) and wring thoroughly. Make sure that it is not dripping.
- Wipe the pump using the damped cloth.
- Clean moving parts and especially the two elongated guide slots with a damp tooth brush so that driver is moving freely when the button is pressed.
- Let air dry. Do not use compressed air to dry the pump.
- Use the recommended disinfectant solution to spray 2 or 3 times on a clean, soft, lint-free cloth (microfiber). The cloth must be slightly damp with the sprayed disinfectant.
- Wipe the pump using the damped cloth and repeat wiping for 2-3 times.
- Let air dry. Do not use compressed air to dry the pump.

After removing protective equipment on completion of task, thoroughly wash and dry hands.

Do not use solutions that contain: ammonia, amines, aldehyde,

ammonium compounds, alcohol, phenols, ethers, ketones, esters, aromatic H/C (benzene, xylene, toluene, chlorobenzene, white spirit, paint thinner, e.t.c.), benzoic acid and benzoates, chlorinated H/C solvents (trichlorethane, methylene chloride, chloroform, ethylene chloride, e.t.c.), phosphoric acid in concentration above 10%, phosphates, acid solutions (citric acid, sulphurous acid, acetic acid, hydrochloric acid) alkali bases (caustic potash, caustic soda, ammonium hydroxide, e.t.c.), sodium hypocloride (bleach) solutions, ozone, acetylene, loctite adhesives, varnish, gasoline, kerosene, naphtha, heptane, hexane, essential oils, silicone fluid and iodine.

Wipe Information

material and weight:	Non-woven PET (30%) / viscose (70%) blend, 50g/m^2
size:	100 x 150 mm or 100 x 200 mm

Important:

- The use of non reccomended cleaning solutions and disinfectants and the failure to follow Micrel cleaning and disinfection procedure may result in product damage.
- To avoid pump damage, cleaning / disinfectant solutions must be used according to the below table and manufacturer reccommendations.
- Do not use hard or pointed objects to clean any part of the pump.
- Do not spray directly cleaning fluids on the pump.
- Do not steam autoclave or ethylene oxide sterilise this Micropump.
- Do not use UV radiation to disinfect the pump.
- Do not use compressed air to dry the pump.
- Do not mix the disinfectant with any other product or chemical.
- Dirty moving parts will cause an occlusion alarm during infusion.

Recommended Cleaning solutions and Disinfectants for Micropump pumps' exterior surface

	Chemical type	Trade name / Manufacturer
1	Isopropyl alcohol 70%	IPA 70%
2	Mild solution of soap water (PH:7-8)	

Cleaning and disinfection procedure for MP Carrying bag

In order to clean the carrying bag ,please follow the below procedure:

1. Wash carrying bag with cold water either in wash machine or hand wash.
2. Do not use bleach.
3. Dry it in shade, do not use dryer and do not wring.
4. Do not iron the carrying bag.

In order to disinfect the carrying bag, please follow the below procedure:

1. Wear a new pair of protective sulphur free gloves and eye protection if splashing is likely to occur.
2. Use one of the recommended disinfectant solutions to spray on a clean, soft, lint-free cloth (microfiber). The cloth must be slightly damp with the sprayed disinfectant.
3. Wipe the carrying bag using the damped cloth and **repeat wiping 2-3 times.**
4. Be careful not to clean the metal parts of the carrying bag.
5. Wipe the surface to dry using a clean, soft, lint-free cloth damped with water.
6. Let air dry.

After removing protective equipment on completion of task, thoroughly wash and dry hands. The disposable equipment must be discarded according to local regulations.

Storage

If the pump is to be stored, it should be cleaned and the batteries removed. Store in a clean dry atmosphere at room temperature and if available, employ the original packaging for protection.

Useful Recommendations

Do not expose the Micropump to direct sunlight or high temperature, or in a closed car in hot days for a long time, since this affects the life of the batteries.

Do not expose the pump direct to high illuminated sources like sunlight or lamps. False alarms may occur.

Do not leave the batteries inside the pump without using it for a long time.

Do not immerse the Micropump into the water. Your Micropump is not waterproof and it will be seriously damaged.

Warnings & Operating Precautions

Do not use two parts syringes (syringes without black seal) as they might leak during long infusions.

Always use Luer Lock Syringes for safe infusion set attachment. Tighten the tip of the catheter to the syringe luer lock to prevent leaking.

Do not tighten the shelf adhesive strap too much, in order not to deform the barrel of the syringe. This may cause pump's stopping at the deformation point, activating alarm.

Fill the syringe with medication volume as close as possible to the predetermined one in order to increase the accuracy of dose.

Prime the syringe and catheter before use to remove any air. Priming the line ensures that the medicine delivery will start immediately after start of the infusion.

Disposal

The MICROPUMP instrument should be disposed of, taking environmental factors into consideration.
Batteries should be disposed according to government or local regulations.
The pump should be disposed according to government or local regulations.

Spare Parts

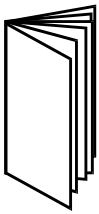
A comprehensive list of spare parts for the MICROPUMP is included with the service manual. This can be ordered from Micrel Medical Devices, or from our authorized distributor. For driver holster and driver protective cover contact your nearest dealer.

Accessories

The accessories for Micropump MP+ pumps are:

Code	Description
KM1.YY.604.x	MP+ Carrying bag with transparent window 20-50ml
KS1.12.164.x	MP+ Soft Locker box 20 ml
KS1.12.165.x	MP+ Soft Locker box 50 ml
KM1.EE.121.x	MP+ Pole Clamp
KM1.YY.561.x	Disposable bag for MP+ pumps

Warnings & Operating Precautions



Warnings and cautions tell you about dangerous conditions that may occur if you do not obey all of the instructions in this manual.
These warnings and cautions tell you about certain conditions that could lead to serious injury or death to the patient.

Warnings

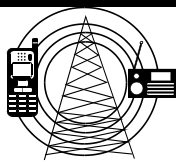
The correct desired rate is essential to prevent serious injury or death to the patient.
The rate setting used may need to be recalculated and changed so that the dose is administered in the required time, thus preventing serious injury or death to the patient.

Completely prime the administration set and also remove all air from both the administration set and the syringe before measuring the mm of fluid length, otherwise the rate calculation will be incorrect.
Syringe and administration set must be free from air bubbles to prevent air embolism.

To prevent serious damage to the driver it must not be immersed in any liquids or exposed to strong organic solvents. Wipe off all spills immediately. The driver is not designed to be sterilized. Failure to observe the above may cause internal damage to the driver resulting in patient injury or death.

If the driver gets wet, do not just try to dry the outside and then continue to use it. Liquid may have leaked inside and caused damage. Follow the advice given on page 32.
Do not expose the Micropump to direct sunlight or high temperature or in a closed car in hot days for a long time, since this affects the life of the batteries.
Do not leave the batteries inside the pump if not using it for a long time.
Portable and mobile RF communications equipment can affect the pump, according to EN60601-1-2. Medical Electrical Equipment needs special precautions regarding EMC and needs to be put into service according to the following EMC information: If the unit interacts with other equipment, it may alarm, measures should be taken to minimize the effects, for instance by repositioning or relocation.

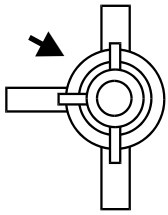
Warnings & Operating Precautions



According to EN60601-2-24 , this instrument is protected against the effects of external interference and is designed to fail-safe if unreasonable levels of interference are encountered. Should false alarm conditions be encountered, either remove the source of the interference, or regulate the infusion by another appropriate means.

This unit emits a certain level of electromagnetic radiation, which is within the levels specified by EN60601-2-24 and EN60601-1-2. If however the unit interacts with other equipment, measures should be taken to minimize the effects, for instance by repositioning or relocation.

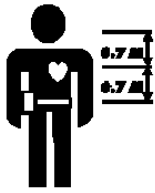
An explosion hazard exists if the instrument is used in the presence of flammable anaesthetics. Exercise care to locate the unit away from any such hazardous sources. Refer all servicing to qualified service personnel.



When combining several apparatus and/or instruments with administration sets and other tubing, for example via a 3-way tap, the performance of the pump may be compromised and should be monitored closely. Several alarm conditions detected by this pump will stop the infusion and generate audible alarms. Users must perform regular checks to ensure that the infusion is progressing correctly and no alarms are operating

Use only sterile catheter infusion sets that can resist pressures of up to 42 PSI (3000 Hpa). The maximum occlusion force as described in this document can generate higher pressure when using very small syringes. Verify infusion set maximum pressure compatibility depending on syringe size used. Tighten the tip of the catheter to the syringe luer lock to prevent leaking.

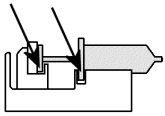
The device is designed to infuse any medical substance that can be injected. The physiological effects of medicine can be influenced by the characteristics of the device and disposable syringe. Check that they are compatible with prescriptions, the characteristics of trumpet curves and occlusion alarm setting times in relation to the programmed flow rate.



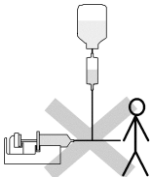
When fitting the holster to the patient ensure that the pump is not located 0.7m above or below the injection point and patients heart.

Uncontrolled flow or siphoning may result if the administration line is removed from the instrument before it is properly isolated from the patient. Isolation may include activating a flow stop clamp.

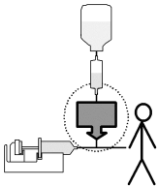
Do not put the holster in contact of injured /broken skin.



While in use, negative pressure variation may occur in the syringe, by the relative height from the device to the injection site or by combined infusion devices such as blood pump, alternative clamp, etc.
When the device is placed higher than the injection site, please pay attention to correctly secure the syringe. The driver must only be used with the syringe-securing strap fixed firmly in place, thus preventing an uncontrolled infusion to the patient that could result in serious injury or death.
Never take a syringe that is not empty off the driver if it is still connected to the patient. The infusion line must be first clamped or disconnected from patient side prior to manipulating the syringe. This could prevent serious injury or death to the patient.
The use of Anti-siphon valves will also contribute to reduce the risk of free flow during syringe changes or if syringe plunger head or flanges is dislodged from their retaining place. An air leakage in a syringe with a line not equipped with an anti-siphon valve may generate an uncontrolled flow delivery.



High vacuum or suction may create syringe siphoning. In this situation, you must check the integrity if the syringe used (possible leakage), and if necessary insert anti-siphon valves.
Pressure variation may generate flow discontinuity mainly noticeable at low flow rates and depending upon the infusion system characteristics such as friction force, stickiness, compliance of syringes and mechanical backlash.



Do not use in conjunction with positive pressure infusion devices that could generate back pressure higher than
42 PSI (3000 HPa) as this could cause damage to the infusion disposables and the device.
Micrel recommends the use of one-way valves or positive pressure infusion devices for multi-line infusions. If there is no one way valve on a gravity infusion line during a multi-line infusion, this will make it impossible to detect occlusions on the patient side, and could result in accumulation of the drug being infused in the gravity line, which could later be infused in an uncontrolled manner when the occlusion is released. Place the connection between the feeder line and the syringe-driver line as near to the start of the catheter as possible in order to minimize the dead space and consequently the impact of any change in flow rate on the feeder line.

Technical Information

Electromagnetic Compatibility (EMC) Information

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC). Portable and radio frequency (RF) communications equipment can affect devices such as Micropump™ pump. As such, the pump should not be adjacent to other equipment. If it is not practical, then observe the pump to make sure it is operating properly after installation.

Important

The use of non-recommended accessories may result in increased EMC emissions or decreased EMC immunity of the Micropump™ pump. Refer to Micropump™'s approved accessories list.

Guidance and manufacturer's declaration: electromagnetic emissions

The Micropump™ pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Micropump™ pump should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment/guidance
RF emissions CISPR 11	Group 1	The Micropump pump uses RF energy only for its internal functioning. 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	The Micropump pump is suitable for use in all establishments, including domestic surroundings.
Harmonic emissions IEC 61000-3-2	Class B	

Precautions & Maintenance

Guidance and manufacturer's declaration: electromagnetic immunity

The Micropump™ pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Micropump™ pump should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment/guidance
Electrostatic discharge (ESD) IEC61000-4-2	±6kV contact ±8kV air	± 8 kV contact ± 15kV air	Floors should be wood, concrete or ceramic tile. If floor is covered with synthetic material, the relative humidity should be at least 30%.

Guidance and manufacturer's declaration: electromagnetic immunity (cont.)

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment/guidance
Radiated RF IEC 61000-4-3	3V/m 80MHz to 2.5GHz	10V/m 80MHz to 1GHz 3V/m 1GHz to 2.5GHz	Portable and mobile RF communications equipment should be used no closer to any part of the Micropump™ pump, including cables, than the recommended separations distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=(3/3.5)\sqrt{P}$ $d=(3/3.5)\sqrt{P}$ 80MHz to 800MHz $d=(7/10)\sqrt{P}$ 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 meters. Field strengths from fixed RF transmitters as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

*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 accurancy. To assess the electromagnetic envirroment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the pump is used exceeds the applicable RF compliance level abive, the pump should be observed to verify normal operation. If abnormal performance is

observed, additional measurements should be taken to minimize the effects, for instance by repositioning or relocation the pump.

**Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the pump.

The Micropump pump is intended for use in an electromagnetic enviroment in which radiated RF disturbances are controlled. The user can help prevent electromagnetic interference by maintaining a minimum distance between portable and RF communications equipment and the pump as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance (m) according to frequency of transmitter		
	150kHz to 80MHz d=[3.5/3]√P	**80MHz to 800MHz** d=[3.5/3]√P	**800MHz to 2.5GHz** d=[7/10]√P
0,01	0,116	0,116	0,07
0,1	0,368	0,368	0,221
1	1,166	1,166	0,7
10	3,689	3,689	2,214
100	11,666	11,666	7

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated 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: At 80MHz and 800MHz, the separation distance applies to the higher frequency range.
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects and people.

Limited Warranty

Micrel Medical Devices (here in after referred to as “Micrel”) warrants that:
It will repair or replace the Micrel Medical Devices Syringe Pump should it fail or malfunction with in twelve months from date of shipment to the original purchaser, because of a manufacturing defect in materials or workmanship.

The forgoing limited warranty is conditioned upon the purchaser’s return of the pump, freight charges prepaid, to Micrel or its authorized representative. The shipment must be within a reasonable time after discovery of failure or malfunction but not later than twelve months (plus normal shipping time) from date of original shipment, together with brief written explanation of the failure or malfunction. The Customer must obtain a return authorization number from or distributor, the authorized service department, prior to shipment. If the returned unit is confirmed on examination to have failed or malfunctioned because of manufacturing defect, the repair or replacement will be performed (at the manufacturer’s option).
Loss or damage in return shipment to Micrel or our distributor shall be at purchaser's risk.
Repair or replacement under the terms and conditions stated herein is the sole liability and the exclusive remedy for failure or malfunction of the external pump.

The limited warranty will not apply if the warranty period has expired; or if the failure or malfunction is caused by damage, accident, misuse, abuse, neglect, unauthorized repair, exposure to extreme temperatures or other adverse environment, or similar causes; to blemishes or cosmetic defects regardless of cause.
In no event shall Micrel be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any Micrel product.
This warranty shall not apply to, and Micrel shall not be responsible for, any loss arising in connection with the purchase or use of any Micrel product which has been altered in any way so as, in Micrel's judgement, to affect its stability or reliability, or which has been subject to misuse or negligence or accident, or which has had the serial or lot number altered, defaced or removed, or which has been used otherwise than in accordance with the instructions furnished by Micrel.
Prices for repair or replacement of units outside this warranty will be furnished on request.
The warranty stated herein is in lieu of all other warranties, express or implied, including but not limited to implied warranties of merchantability and fitness for particular purpose. No liability will be incurred for incidental or consequential damages.

Service Contacts

For service, contact your local Micrel Medical Devices Office or local distributor:

Micrel Medical Devices Service Centre Address and Manufacturer according to Medical Device Directive 93/42/EEC:

Micrel Medical Devices S.A.
42 Konstantinoupoleos Str.,
Karellas 194 41 Koropi
Athens, GREECE
Tel: (+30 210) 6032333-4
Fax: (+30 210) 6032335
Email: customersupport@micrelmed.com
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