micrel
Medical Devices

Rythmic™ evolution

ready to connect

Instructions For Use

This Instructions for Use (IFU) is applicable for the following equipment:

Rythmic™ Evolution
Mini Rythmic™ Evolution
Rythmic™ Evolution Rechargeable
Mini Rythmic™ Evolution Rechargeable
Rythmic™ Evolution Organiser 500/100
Rythmic™ Evolution Organiser 501/101 Rechargeable

Important

Read the entire IFU before operating the Rythmic™ pump. Failure to properly follow warnings, cautions and instructions could result in death or serious injury to the patient.

Keep for future reference

Technical Assistance

If you have comments or questions concerning the operation of your Rythmic™ pump or you need technical assistance, please contact your local Micrel's Authorized Distributor or contact Micrel Customer Support at info@micrelmed.com or call at +30 210 6032333-4.
Pump serial number and software version should be provided at any communication.

Terms used in IFU

Warning: A warning contains safety information that could result to death or serious injury of patient or operator.

Caution: A caution contains information that could result to product damage.

The use of terms "infusion set" and "administration set" are interchangeable with the product name "Rythmic™ Administration Set".

Warnings

- The supervisor of the infusion must decide whether the Configuration chapter should be kept in the present IFU.
- We recommend the default codes of the pump to be changed (through the configuration menu) in order to secure the access to different actions related to each code.
- The supervisor of the infusion should decide to whom each code and its related actions should be distributed. Incorrect pump programming could result in death or serious injury to the patient.
- For those patients who are likely to be adversely affected by unintended operations and failures, including interrupted medication or fluid delivery from the device, close supervision and provision for immediate corrective action should be provided.
- The Rythmic™ Evolution is not to be used to deliver blood.
- Always inspect the Rythmic™ Evolution pump and its accessories for damaged plastic parts, wires and presence of liquids on its surface, prior to use. If the pump or accessories are dropped, hit, subjected to excessive moisture and/ or beyond temperature limits, immediately take it out of use and return it to authorized service department for inspection.
- Infusion system characteristics, such as medication viscosity, catheter size and high delivery rate may affect delivery accuracy.
- Only Rythmic™ Administration sets shall be used with the pump. Use of other than Rythmic™ Administration sets may impair the operation of the pump and the accuracy of the infusion.
- Always inspect the integrity of the package and the administration set included.
- Frozen medication must be thawed at room temperature only. Do not heat medication and administration set in an oven as this may damage the medication, the Rythmic™ Administration set and, cause leakage.
- Ensure that the medication administered is indicated for the therapy / route and in accordance to healthcare provider drug / medication protocol and official drug prescribing information.
- Ensure that the administration set used to deliver medication is the appropriate one for the specific medication and for the therapy that will be used.
- When using the pump for secondary delivery, ensure that the fluids being administered are chemically and physically compatible with each other.
- When additional medication is infused through Y connector then over delivery of medication may occur.
- Ensure that during delivery the vertical distance between the pump and the injection site should be one meter height maximum.
- When using administration set with Y connector ensure a closed cap is used on the Y port when not in use.
- Do not prime the administration set while it is connected to a patient, as this may result in air embolism or over- delivery of medication. Always disconnect the line from patient before priming.

Warnings

- Ensure that air has been purged from the administration set before connecting it to a patient to prevent air embolism.
- Ensure that air has been removed from Y connector. Air embolism could result in death or serious injury to the patient.
- Periodically inspect the fluid path for air. If air is seen stop infusion. Air infusion could result to under or non-delivery of medication.
- Always inspect for marks, dust, dirt, particles or substance that exist underneath the tubing cover or in the mechanical pumping area before use.
- Ensure that the administration set has been properly installed and has not been trapped in transparent covers or in carrying bag, as this may result in under or non-delivery of medication.
- Ensure that the release lever is locked in closed position and the tubing cover is closed firmly. If the release lever or the tubing cover become loose, may result in under on non-delivery of medication.
- Ensure that the transparent covers are securely closed, to prevent patient access to medication container.
- Periodically inspect the fluid container for decreasing volume, inspect the fluid path for kinks, a closed clamp or other upstream obstruction. Upstream occlusions could result in under or non-delivery of medication.
- Extra care when using the clinician bolus function. There is no limit, or frequency limit in the use of the override bolus function. Incorrect programming could result in death or serious injury to the patient.
- Do not leave the pump unattended while is on Clinician Bolus screen.
- Ensure that the spike connector is properly attached to the external medication container.
- When rigid- non collapsible external medication containers (e.g. glass bottles, hard plastic bag) are used with a Rythmic™ Spike set, then the air vent on the spike must be opened and the container must be suspended from a pole.
- When collapsible external medication container are used in ambulatory infusion (infusion during transportation) ensure that all air has been removed from the external container. If air remains may result in under or non delivery of medications which could result in death or serious injury to the patient.
- Ensure that the slide clamp is closed before removing the administration set from the pump, to prevent free flow of medication.
- Ensure the battery door has been locked in position. If the battery door becomes loose, then the battery can be removed, which could result in loss of power and non-delivery of medication.

Warnings

- Ensure that the battery placed in the pump is in good condition and the remaining battery power is enough for the infusion that is going to start. If the battery is not likely to finish the infusion, replace it before infusion starts. Loss of power may result in non-delivery of medication.
- Always inspect the battery compartment for fluid or debris before inserting the batteries. Fluid or debris in the battery compartment may damage the battery terminals and could result in loss of power and non delivery of medication.
- Always inspect the battery terminals for debris, grime and damages. If debris or grime exists, clean the terminals according to cleaning instructions. If the debris or grime persists or damage exists remove the device from service. Debris, grime or damage of the battery contacts could result in loss of power and non delivery of medication.
- Always have a new battery available for replacement to ensure that the pump can continue its operation for the time specified.
- Do not use rechargeable NiCd or NiMH batteries. Do not use carbon zinc batteries.
- Only accessories supplied from Micrel shall be used with the pump. Use of non-specified accessories may impair the operation of the pump.
- Ensure that IP Connect Pack if used is ON to supply power to the pump.
- Do not pull out the bolus handset at an angle, bolus may be damaged.
- Do not remove the bolus handset by pulling the cable, bolus may be damaged.
- Do not rotate the bolus connector while removing the bolus handset.
- Do not use other external power adaptor than the ones supplied by Micrel.
- Do not plug the Micrel power adaptor to the Mains with wet / moist hands.
- The pump should be disconnected from the patient prior to being connected to a computer.
- Do not perform uploading procedure in the presence of a patient.
- Do not connect cords supplied from Micrel to other devices rather than the ones that are intended to be used with.
- External power adaptor should be used only indoors.
- The external power adaptor should no longer be used if the housing or cable becomes damaged.
- Ensure that the external power adaptor is not covered when in operation, is not in close proximity to a heating source and is not exposed to direct sunlight.
- The external power adaptor must not come into contact with liquids.
- Ensure that the pump is OFF and disconnected from any power supply before commencing the cleaning / disinfection procedure.

Warnings

- Ensure that accessories are not attached to the pump, are not ON or connected to the Mains before commencing the cleaning / disinfection procedure.
- Always validate infusion protocol values by checking all parameters, prior to start the infusion.
- There are no user serviceable parts or user replaceable parts within the pump, except 9V alkaline disposable battery.
- Equipment can be modified as described in service manual by trained service personnel with valid certificate. Appropriate inspection and testing according to service manual, must be conducted to ensure safe use of the equipment.
- Do not attempt to service the pump, only qualified service personnel can perform service / preventive maintenance.
- During cleaning / disinfection procedure, pay attention that disinfectant solution does not go inside connectors.

Cautions

- Do not use the equipment outside its temperature range. The performance could be affected.
- Do not expose the equipment to humidity levels below 15% or above 93% relative humidity.
- Do not expose the equipment directly to irritation by therapeutic levels of ionizing radiation because the equipment may be permanently damaged.
- Do not operate the equipment in a MRI environment, in the vicinity of high-frequency surgical diathermy equipment, defibrillators, short-wave therapy equipment, strong magnetic fields or Nuclear Magnetic Resonance (NMR) scanners.
- Do not expose the equipment to ultrasound energy because it may be permanently damaged.
- Do not use the equipment in the presence of flammable anesthetics or explosive gases, to avoid explosion hazard.
- Do not expose the equipment to direct sunlight or high temperature or in a closed car in hot days for a long time, since it affects the lifetime of the batteries.
- Do not sterilize the equipment under any circumstances.

Cautions

- Do not clean the equipment using acetone, other plastic solvents or abrasive cleaners as they may damage the equipment.
- Do not use hard or pointed objects to clean any part of the pump and its accessories.
- Do not spray cleaning fluids directly on the pump and its accessories.
- Do not steam autoclave, ethylene oxide sterilise or immerse Rythmic™ Evolution pump and its accessories in any fluid.
- Do not use UV radiation to disinfect the pump and its accessories.
- Do not use compressed air to dry the pump and its accessories.
- Do not mix the disinfectant with any other product or chemical.
- Do not immerse the pump in cleaning fluid or water, it is not waterproof and it can cause serious damage to the pump.
- Do not store the pump with the battery inside for more than three months.
- Do not store the pump with the rechargeable battery depleted. If the pump has to be stored for a long period of time, every three months recharge the battery.
- Check that the polarity of the 9V alkaline battery is correctly oriented.
- Check that the battery door has been closed correctly, otherwise the transparent covers may not close.
- Do not remove the battery while the pump is switched ON as this may damage the pump.
- Prior to using IP Connect Pack accessory for the first time, use the power adaptor to fully charge the internal rechargeable battery.
- Do not remove the internal battery (9V alkaline or rechargeable) from the pump while it is connected to Micrel power adaptor or IP Connect Pack accessory.
- Prior to using pump with rechargeable battery for the first time, use the power adaptor to fully charge the internal rechargeable battery.
- During charging of Rythmic™ Evolution while the pump is switched OFF, there is not any indication of charging progress.
- When handling fluid-path connections always follow aseptic technique protocol.
- Tighten the luer connectors to prevent leakage.
- The administration set is a single use product and must be changed in accordance with the applicable healthcare protocols.
- Prior to administering medication under specific delivery conditions, medication stability for time and temperature must be checked.
- The use of non reccomended cleaning solutions and disinfectants and the failure to follow Micrel cleaning and disinfection procedure may result in product damage.

Contents

IFU Rythmic™ evolution

1. General Description Pump

1.1 Introduction

The Rythmic™ pump is a technologically advanced, easy to use infusion pump, designed to provide best comfort, precision, safety and durability for many years to come.
The Rythmic™ pump offers many quality features that make it highly suitable for today's hospital and home care treatments. The Rythmic™ pump has been specially designed for ambulatory use, but can also be used bedside.
The pump can be powered using battery for full portable use but also can be plugged to the mains. The Rythmic™ pump is a safe pump that incorporates the latest features for medication error prevention and also has lockable covers to achieve drug protection for patient.
Rythmic™ Evolution pumps are available in blue color coded, in yellow color coded and in green color coded, in order to be used for certain therapies according to your physician's or healthcare professional's instructions.

Rythmic™ Evolution range

Please, read the following instructions carefully before using this device.

Rythmic™ Evolution pump is to be used by qualified personnel who have the qualifications required for medical application and act according to these instructions for use. Infusions must be supervised by clinicians.

Intended use

Rythmic™ Evolution pump 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 of use

Rythmic™ Evolution pumps are not to be used for delivery of blood and insulin.

When unpacking, check that the system is complete and undamaged.
Systems include the below:

ITEM	Rythmic™ Evolution & Evolution Organiser 100	Mini Rythmic™ Evolution	Rythmic™ Evolution Organiser 500	Rythmic™ Evolution Rechargeable & Evolution Organiser 101	Mini Rythmic™ Evolution Rechargeable	Rythmic™ Evolution Organiser 501
Protective Packaging	✓	✓	✓	✓	✓	✓
Instructions for Use	✓	✓	✓	✓	✓	✓
Short instructions for Use	✓	✓	✓	✓	✓	✓
Carrying Bag	✓	✓		✓	✓	
Carrying Belt			✓			✓
Bolus Handset	✓	✓	✓	✓	✓	✓
Power Adaptor				✓	✓	✓
9V Alkaline battery	✓	✓	✓			
Keys for transparent covers	2	3	2	2	2	2

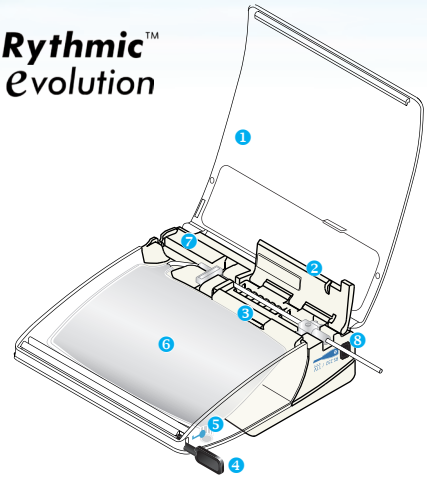
Warning

Always inspect the Rythmic™ Evolution pump and its accessories for damaged plastic parts, wires and presence of liquids on its surface, prior to use. If the pump or accessories are dropped, hit, subjected to excessive moisture and/or beyond temperature limits, immediately take it out of use and return it to authorized service department for inspection.

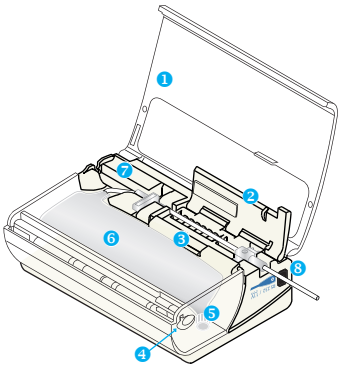
Keep the original packaging for further storage or transportation.

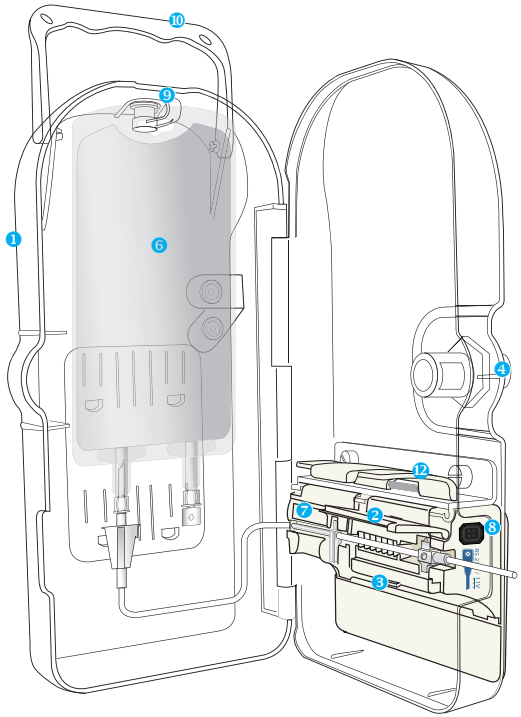
1.2 Pump Layout

Rythmic™ evolution

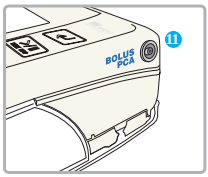


Mini Rythmic™ evolution



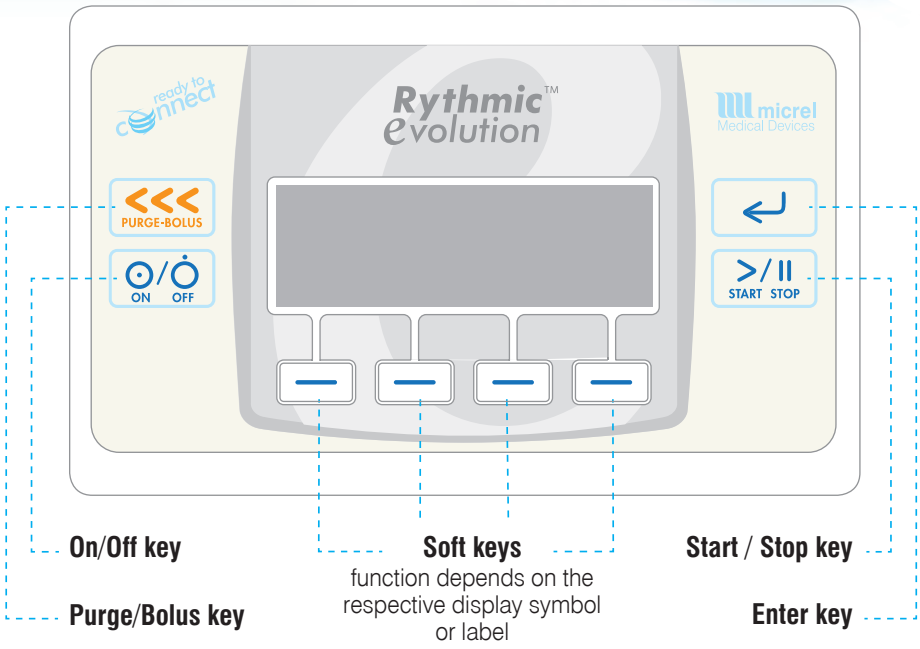


Rythmic™ evolution Organiser



1. Transparent cover
2. Tubing cover
3. Tubing cover release lever
4. Opening system
5. Injection / filling port
6. Reservoir and tubing
7. Battery cover
8. RS232 port – computer port
9. Bag Hook
10. Carrying Handle
11. Bolus handset port
12. Door hood

CONTROLS AND DISPLAY



Turn the pump ON or OFF by pressing and holding the key for 2 sec.

Start and stops priming the line and during infusion generates patient bolus demands, if bolus handset is not connected.

Scroll down through pump menu, confirms a programmed value or selected option.

Enters codes, sets value during programming, silence the audible alarm for one hour, answer questions on the pump screen, navigates through pump history and protocol.

Starts and stops infusion, by pressing the button twice quickly.

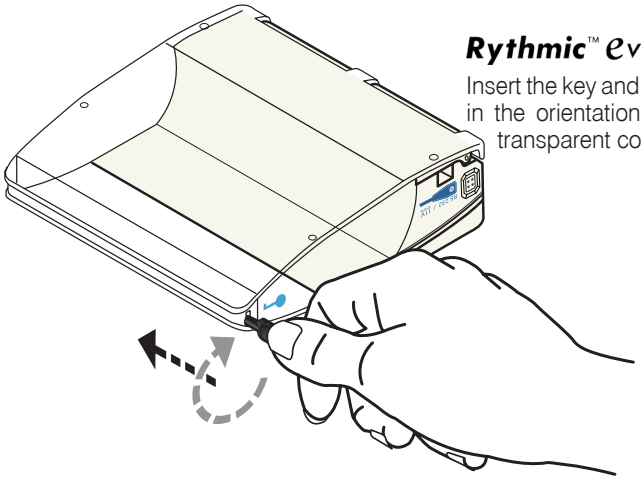
2. Preparation of infusion

2.1 Opening the transparent covers

To open the transparent covers please follow the steps below:

Step 1: Verify that the pump is switched OFF.

Step 2: Remove the pump from the carrying bag or the pole clamp and then follow the procedure as shown for each model accordingly.



Rythmic™ *evolution*

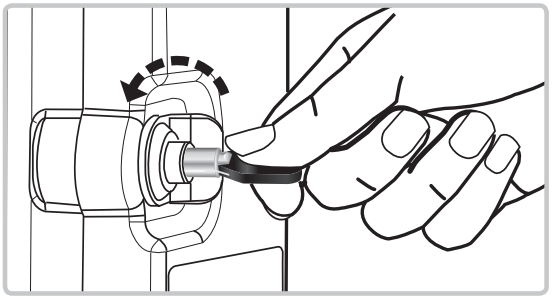
Insert the key and turn gently clockwise in the orientation shown to open the transparent cover.

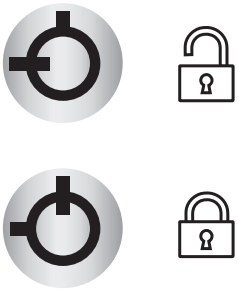
Rythmic™ *evolution* *Organiser* 500/501

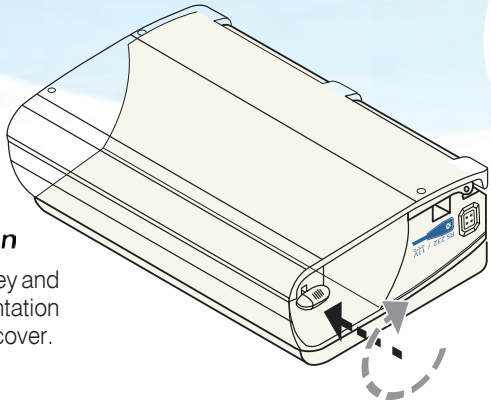
Press the knob and pull the cover using the finger grip to open the cover. If the pump is locked insert the key and gently turn it anti clockwise in the direction shown to unlock the push button.

Rythmic™ *evolution* *Organiser* 100/101

Lift the lever to open the cover.
If the pump is locked, insert the key and turn gently anticlockwise in the orientation shown to unlock the lever and lift to open the transparent cover.





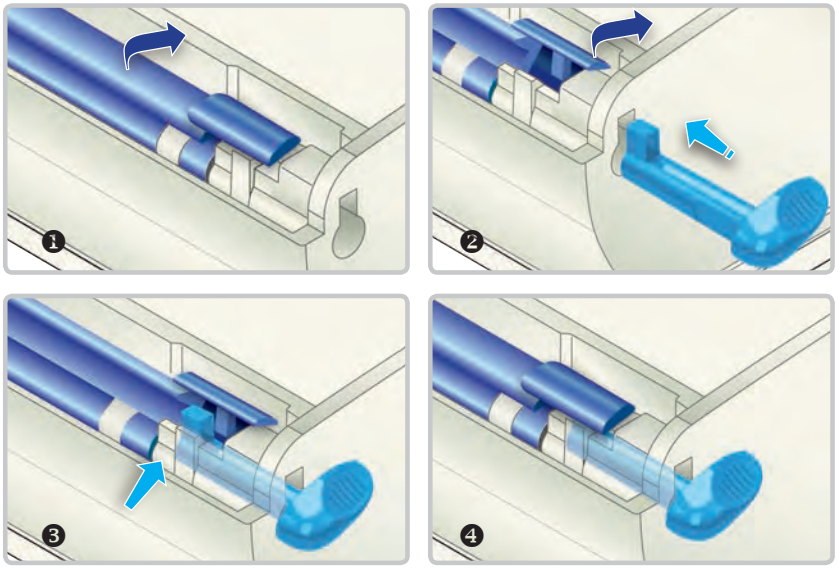


Mini Rythmic™ evolution

Insert the key or the permanent key and turn gently clockwise in the orientation shown to open the transparent cover.

The user can configure the cover so it can be used without being locked.

To insert the permanent key on transparent cover please follow the below steps.



2.2 Locking the transparent covers

For Rythmic™ Evolution Organisers:
Close the transparent covers and turn the key clockwise. Remove the key.

For Rythmic™ Evolution:
Close the transparent covers. The Rythmic™ Evolution pump is now locked.

For Mini Rythmic™ Evolution:
Remove the permanent key and close the transparent covers. The Mini Rythmic™ Evolution pump is now locked.

2.3 Power Supply

2.3.1 For pumps with 9V alkaline battery

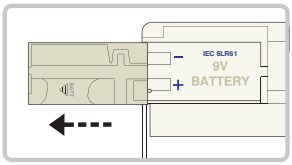
Applies to models: Rythmic™ Evolution, Mini Rythmic™ Evolution, Rythmic™ Evolution Organiser 500/100.

Warning

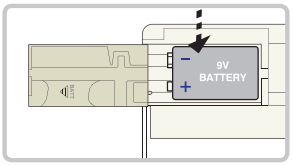
- Do not use rechargeable NiCd or NiMH batteries. Do not use carbon zinc batteries.
- Ensure that the battery placed in the pump is in good condition and the remaining battery power is enough for the infusion that is going to start. If the battery is not likely to finish the infusion, replace it before infusion starts. Loss of power may result in non-delivery of medication which could result in death or serious injury to patient.
- Always have a new battery available for replacement to ensure that the pump can continue its operation for the time specified. Loss of power may result in non-delivery of medication which could result in death or serious injury to patient.
- Ensure the battery door has been locked in position. If the battery door becomes loose, then the battery can be removed, which could result in loss of power and non-delivery of medication which could result in death or serious injury to patient.
- Always inspect the battery compartment for fluid or debris before inserting the batteries. Fluid or debris in the battery compartment may damage the battery terminals and could result in loss of power and non delivery of medication.
- Always inspect the battery terminals for debris, grime and damages. If debris or grime exists, clean the terminals according to cleaning instructions. If the debris or grime persists or damage exists remove the device from service. Debris, grime or damage of the battery contacts could result in loss of power and non delivery of medication.

To access the battery please follow the below procedure:

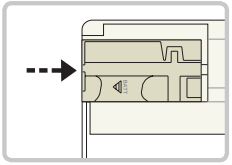
- Verify that the pump is switched OFF.
- Place the pump on a table, with the front panel facing downwards.
- Open the transparent covers as described in chapter 2, paragraph 2.1 "*Opening the transparent covers*".



❶ Slide the battery compartment lid in the direction of the arrow marked BATT.



❷ Insert the batteries within the compartment, observing the correct polarity as shown by the illustration within the battery compartment.



❸ Slide the lid back in place.

Caution

- Check that the polarity of the 9V alkaline battery is correctly oriented.
- Check that the battery door has been closed; otherwise the transparent covers may not close.
- Do not remove the 9V alkaline battery while the pump is switched ON, as this may damage the pump.
- Do not store the pump with the battery inside for more than three months.

2.3.2 For pumps with rechargeable battery

Applies to models: Rythmic™ Evolution Rechargeable, Mini Rythmic™ Evolution Rechargeable, Rythmic™ Evolution Organiser 501/101.

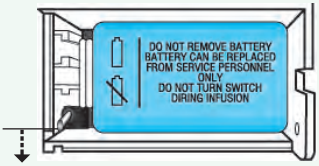
Warning

Ensure that the remaining battery power is enough for the infusion that is going to start. If the rechargeable battery is not likely to finish the infusion, charge it before infusion starts. Loss of power may result in non-delivery of medication which could result in death or serious injury to patient.

The pump has built in a Lithium Polymer rechargeable battery.

Caution

- Prior to using pump with rechargeable battery or IP Connect Pack accessory for the first time, use the power adaptor to fully charge the internal rechargeable battery for 3 hours.
- During charging of Rythmic™ Evolution while the pump is switched OFF, there is not any indication of charging progress.
- Do not turn the switch to position  while the pump is switched ON, as this may damage the pump.



- Do not store the pump with the rechargeable battery depleted. If the pump is to be stored for a long period of time, every three months recharge the battery by connecting the pump to a power adaptor connected to mains, for 1 hour to maintain battery's good condition and prolong battery's life time.

Pump can also be supplied with power using accessory external power supply and /or IP Connect Pack. In every case the presence of a battery (alkaline or rechargeable) is needed. Please refer to chapter 10, paragraph 10.2 and 10.4 for further details.

Charging the rechargeable battery

Warning

Do not use other external power adaptor than the one supplied by Micrel. In extreme cases of electromagnetic interference, Alarm C-05 may arise. There is no special problem with the pump, just follow the alarm handling instructions of this IFU.

Micrel power adaptor will charge the built in Lithium Polymer battery while powering the pump at the same time.
Charge the battery at least 3 hours, using the power adaptor, when Low or Dead battery signal is displayed on the screen.

When the battery is fully charged the battery sign on the top right corner on the screen will be full.

There is no danger of overcharging the battery. The charging cycle is an automatic function performed by special circuit inside the pump. The power adaptor can be used as frequently, and for as much time as needed for bedside use.

Care should be taken to fully charge the battery before portable use.
After full 3 hours charging, the pump has nominal autonomy for portable use.
Be aware that the nominal charging capacity of Lithium Polymer batteries decreases along with the time and the number of recharging cycles.
After 300 charge / discharge cycles, Lithium Polymer battery capacity is reduced by more than 30%.

2.4 Pre-Use checklist

Warning

Always inspect the Rythmic™ Evolution pump and its accessories for damaged plastic parts, wires and presence of liquids on its surface, prior to use. If the pump or accessories are dropped, hit, subjected to excessive moisture and/ or beyond temperature limits, immediately take it out of use and return it to authorized service department for inspection.

Before use the pump and it's accessories to carry out an infusion, run the following test for a complete alarm and safety features check for both pump and accessories.

Pump's Serial number (S/N): ..... Date: ..... / ..... / .....

Accessory information (description) : .....

Visual inspection for		Pass	Fail
Absence of impact marks / broken covers / damaged wires			
Sufficient legibility of all labels			
Absence of dust, dirt, particles or substances underneath the tubing cover			
Absence of liquid ingression / battery compartment			
Absence of debris, grime or damage of battery terminals			
Functional test			
Locking system operating properly			
Action	**Result**	**Pass**	**Fail**
Turn the pump ON and verify that buzzer functions properly.	An acoustic tone will sound twice.		
Check display during power ON.	No missing dots on dark display. Backlight turns ON.		
Check for correct date / time.	Actual date / time.		
Enter the new bag code, enter 1ml as volume to be infused and then press ↵ to reach "PUMP ON HOLD" screen. Press <<< PURGE•KEEP VTBI to prime (without administration set inside).	"DOOR IS OPEN" alarm should appear. Press ↵ to silent the acoustic tone.		
Press >/II START STOP to start infusion (without administration set inside).	"DOOR IS OPEN" alarm should appear. Press ↵ to silent the acoustic tone.		
Connect power adaptor to Mains and to Rythmic™ Evolution.	Mains indicator should appear.		
While power adaptor is connected to the Rythmic™ Evolution remove disposable alkaline battery and start infusion.	"BATTERY NEEDED AS BACK UP" message should appear and infusion should not start.		
Test result :			
Test performed by :			
Department:	Name:		

If the device fails to perform as described in one or more of the above tests, pump and its accessories should be immediately taken out of use and inspected by authorized service personnel to ensure their proper function prior to use.

2.5 Preparation of administration sets before the infusion

Warning

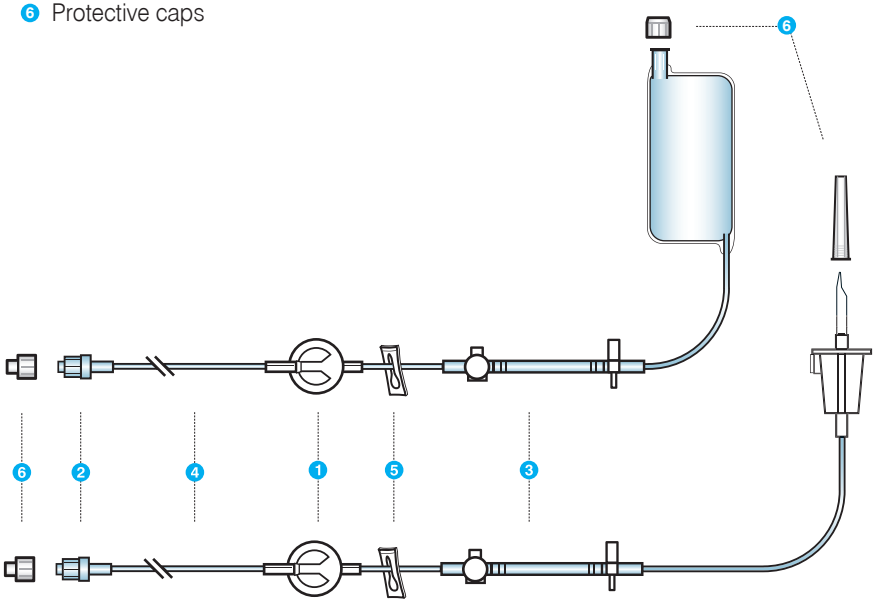
- Only Rythmic™ Administration sets shall be used with the pump. Use of other than Rythmic™ Administration sets may impair the operation of the pump and the accuracy of the infusion.
- Always inspect the integrity of the package and the administration set included. If package and / or the set are damaged, do not use it.
- Ensure that the slide clamp is closed before removing the administration set from the pump, to prevent free flow of medication.
- When using administration set with Y connector ensure a closed cap is used on the Y port when not in use. Air infusion could result in death or serious injury to the patient.
- Frozen medication must be thawed at room temperature only. Do not heat medication and administration set in an oven as this may damage the medication, the Rythmic™ administration set and, cause leakage.
- Ensure that the medication administered is indicated for the therapy / route and in accordance to healthcare provider drug / medication protocol and official drug prescribing information. Administration of medication other than those indicated for specific therapy / route may result in death or serious injury to the patient.
- Ensure that the administration set used to deliver medication is the appropriate one for the specific medication and for the therapy that will be used. Large molecule size medication when used with administration set with filter 0.2um pore size, could result in under or non- delivery of medication. Administration set used to deliver medication in epidural space shall not integrate other injection ports.
- Do not administer medications to the epidural space unless these medications are indicated for epidural space infusion.

Micrel offers a large variety of sets, the Full set range and the Spike set range, tailored for different medical applications.

Rythmic™ administration sets are considered as applied part of the pump and are made of biocompatible materials according to ISO 10993 series of standards. All sets are latex free and DEHP free.

All administration sets are single use products, sterile using ethylenoxide and are equipped with:

1. An in line air eliminating filter to ensure that any air trapped within the fluid is not delivered to the patient.
2. Anti-siphon valve to prevent free flow, if the set is removed unclamped from the pump while still connected to the patient.
3. Silicon pumping segment to achieve infusion accuracy
4. Anti-kinking extension line
5. Slide clamp
6. Protective caps



The Rythmic™ Administration Set is a single use product and shall be replaced according to the treatment protocol and the healthcare provider's policy for infection control. The Rythmic™ Administration Set shall be replaced earlier than 7 days of use.

Caution

When handling fluid-path connections always follow aseptic technique protocol.

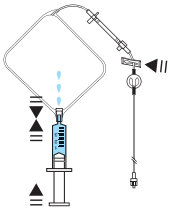
For administration sets with bag,

Prepare the medication for treatment. Prepare the infusion sets according to the instructions below and hospital protocols.

1. Unwrap the set.

2. Clamp the tube to inhibit flow.

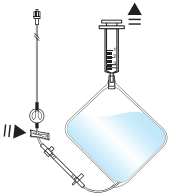
3. Ensure that the syringe is fully screwed into the valve.



4. Carefully fill the bag with fluid using the bag's injection port.

5. Continue until the bag has been filled with the prescribed volume.

6. Hold the bag vertically and remove any air using the syringe.



7. Remove the syringe.

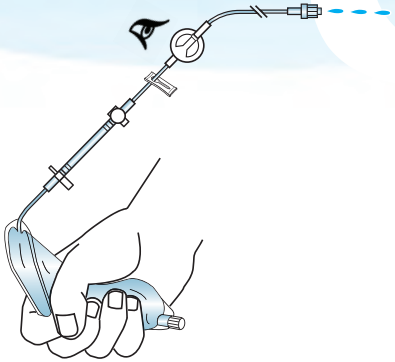
Warning

- Ensure that air has been purged from administration set before connecting it to a patient, to prevent air embolism.
- Extra care must be taken when using administration sets with Y connector. Ensure that air has been removed from Y connector. Air embolism could result in death or serious injury to the patient.

8. Unclamp the set.

9. Hold the bag in vertical position with the injection port facing downwards and gently squeeze the bag as shown, so as the air bubbles move to the top corner where it is connected to the tube. Continue to gently squeeze the bag to expel remaining air bubbles through the air eliminating filter. Ensure that the filter has

properly eliminated any air while priming the administration set. If the filter is not properly eliminating the air and air bubbles are observed in the line, then the administration set must be changed.



10. Continue to squeeze the bag gently until the liquid passes through the line and exits from the anti-siphon valve, in order to **fully prime the line manually**.

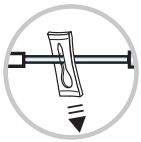
Note: *Alternatively, the administration set line can be primed through the pump (refer to Chapter 6, paragraph 6.1 "Priming the Administration set line")*

For sets with Spike and external medication container

Prepare the medication for treatment. Prepare the infusion sets according to their Directions for use and hospital protocols.

1. Unwrap the set.

2. Clamp the tube to inhibit flow.



3. Roll the external medication container to collect all the air bubbles into one single bubble.

4. Remove liquid from the external medication container set port. The external medication container should be port side up when the infusion set is attached.

5. Remove the protection of the port.

Warning

Ensure that the Spike connector is properly attached to the external medication container. Spike detachment from the external medication container could result in under or non-delivery of medication.

6. Insert the spike straight into the external medication container port. Twist and push the spike through the diaphragm. Do not spike external medication container while the external medication container is hanging on the IV pole.

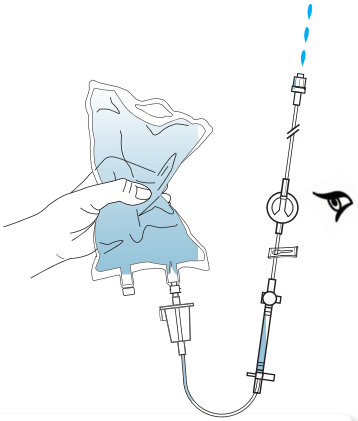
7. To remove air from the external medication container, lift the external medication container port side up, open the air vent located on the spike and gently squeeze the medication container until all air goes out, then close the air vent. Make sure no fluid will go into the air vent as this will make the priming of air very difficult.

Warning

- Ensure that air has been purged from administration set before connecting it to a patient, to prevent air embolism.
- Extra care must be taken when using administration sets with Y connector. Ensure that air has been removed from Y connector. Air embolism could result in death or serious injury to the patient.
- When rigid - non collapsible external medication containers (e.g. glass bottles, hard plastic bag) are used with a Rythmic™ spike set, then the air vent on the spike must be opened and the container must be suspended from a pole. If the air vent is closed it could result in under or non-delivery of medication. The air vent is fitted with an anti-bacterial filter.
- When collapsible external medication container are used with a Rythmic™ spike set, the air vent placed on the spike must be closed.

8. Unclamp the set.
9. Continue to squeeze the medication container gently until the liquid primes the line and exits from the anti-siphon valve, in order to fully prime the line manually. Ensure that the filter has properly eliminated any air while priming the administration set. If the filter is not properly eliminating the air and air bubbles are observed in the line, then the administration set must be changed.

Note: *Alternatively, the administration set line can be primed through the pump (refer to page Chapter 6, paragraph 6.1 "Priming the Administration set line")*



Warning

Ensure that the administration set has been properly installed and has not been trapped in transparent covers, as this may result in under or non-delivery of medication.

10. Hang the external medication container. For Rythmic™ Evolution Organisers: hang the external medication container from the bag hook placed in the transparent cover and secure it. When carrying bag is used, placed the external medication container inside the carrying bag. When IV pole is used, hang the external medication container from the IV pole.

2.6 Fitting the Administration set into the pump

Sets with reservoir, Rythmic™ Full Sets

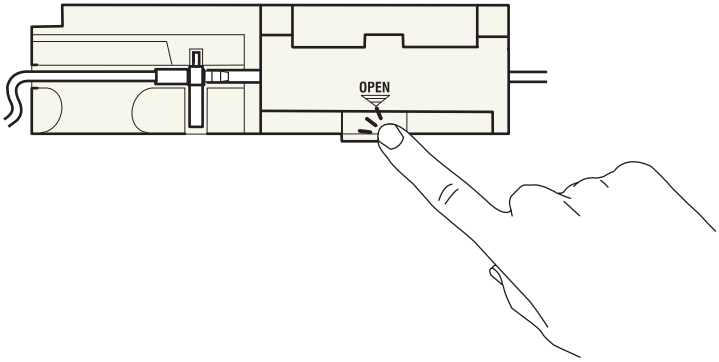
Rythmic™ Full Sets can only fit in Rythmic™ and Mini Rythmic™ Evolution models.

Warning

- Ensure that the slide clamp is closed before removing the administration set from the pump, to prevent free flow of medication.
- Always inspect for any marks, dust, dirt, particles or substance underneath the tubing cover or in the mechanical pumping area before use. Any of the above could result to under or non-delivery of medication. The pump should be immediately taken out of use and inspected by qualified service personnel to ensure its proper function prior to reuse.

1. Open the transparent cover.

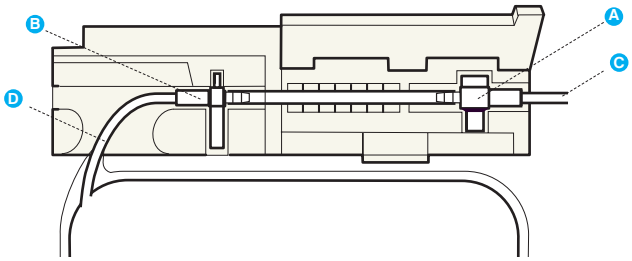
2. Press the tubing cover release lever to open the cover. This will expose the pumping mechanism.



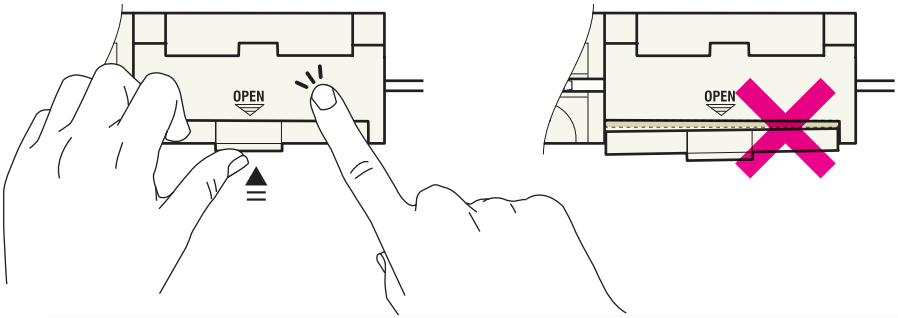
3. Remove empty administration set, if applicable.

4. Load the new bag into the pump with the filling port of the bag oriented nearby the key lock of the transparent cover.

5. Load the tubing into pumping mechanism. It can only be loaded one way round. Check that the pressure sensor Ⓐ is located under the door and positioned with the membrane facing downwards. The locating key Ⓑ should be correctly orientated. The tube Ⓒ shall exit the pump and connect to the patient side. Please make sure the tubing Ⓓ and the bag are placed properly inside the transparent covers.



6. Close the tubing cover firmly.



Warning

- Ensure that the transparent covers are securely closed, to prevent patient access to medication container.
- Ensure that the administration set has been properly installed and has not been trapped in transparent covers, as this may result in under or non-delivery of medication.
- Ensure that the release lever is locked in closed position and the tubing cover is closed firmly. If the release lever or the tubing cover become loose may result in under or non-delivery of medication.

7. Close the transparent covers. Ensure the transparent covers have been locked in position.

8. Unclamp the set, before priming through the pump or starting the infusion.

For sets with Spike and external medication container, Rythmic™ Spike Sets

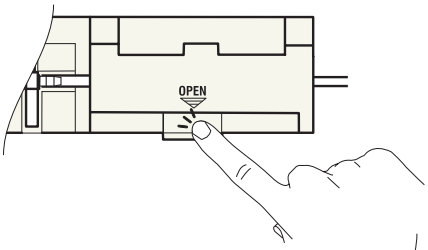
Rythmic™ Spike Sets can fit in all models of Rythmic™ Evolution range.

Warning

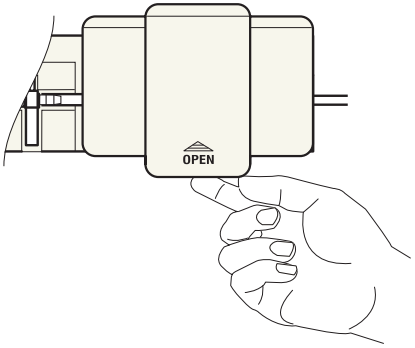
- Ensure that the slide clamp is closed before removing the administration set from the pump, to prevent free flow of medication.
- Always inspect for marks, dust, dirt, particles or substance that exist underneath the tubing cover or in the mechanical pumping area before use. Any of the above could result to under or non-delivery of medication. The pump should be immediately taken out of use and inspected by qualified service personnel to ensure its proper function prior to reuse.

1. Open the transparent cover.

2. Press the tubing cover release lever to open the cover. This will expose the pumping mechanism.

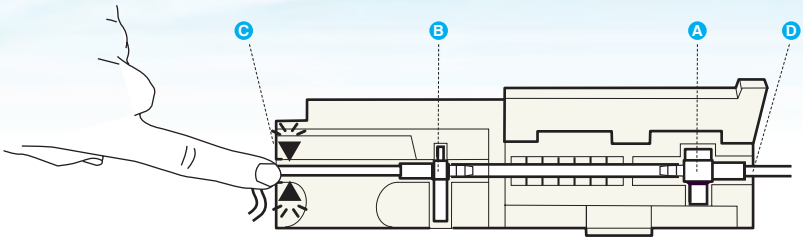


For Rythmic™ Organiser:
Lift the door hood to open. Press the tubing cover release lever to open the cover. This will expose the pumping mechanism.

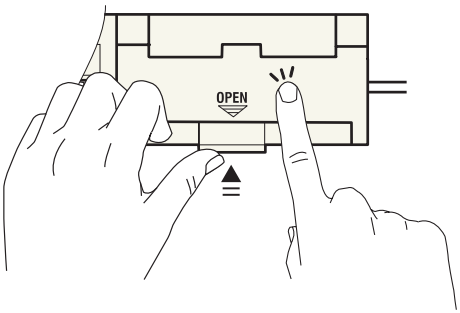


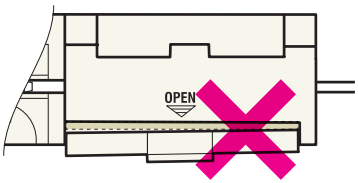
3. Remove empty administration set, if appropriate.

4. Load the tubing into pumping mechanism. It can only be loaded one way round. Check that the pressure sensor Ⓐ is located under the door and positioned with the membrane facing downwards. The locating key Ⓑ should be correctly orientated, inserted in the appropriate space in the battery door and pushed firmly until it **clicks** Ⓒ . The tube Ⓓ shall exit the pump and connect to the patient side.

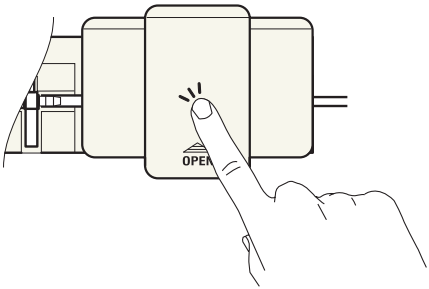


5. Close the tubing cover firmly.





For Rythmic™ Organiser:
Close the door hood firmly.



Warning

- Ensure that the administration set has been properly installed and has not been trapped in transparent covers, as this may result in under or non-delivery of medication.
- Ensure that the release lever is locked in closed position and the tubing cover is closed firmly. If the release lever or the tubing cover become loose may result in under or non-delivery of medication.

6. Close the transparent covers. Ensure the transparent covers have been locked in position.

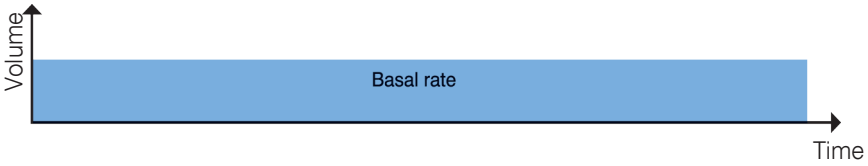
7. Unclamp the set before priming or starting the infusion.

3. Pump Functions and Terms

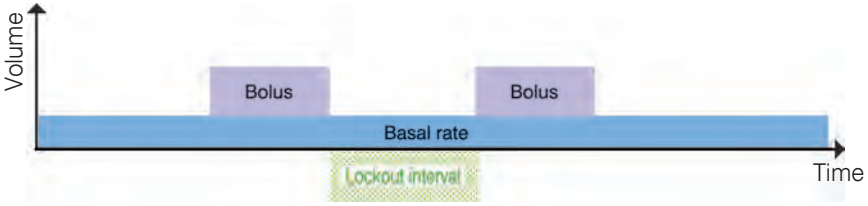
3.1 Delivery modes

The Rythmic™ Evolution pump offers 4 delivery modes.

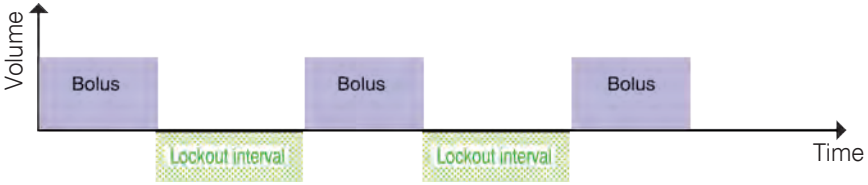
Continuous, this delivery mode gives the ability to infuse at a constant basal rate only. The infusion can be set in ml/hr or in mg or µg (mcg) entering a concentration (per ml). The basal rate and volume to be infused should be programmed.



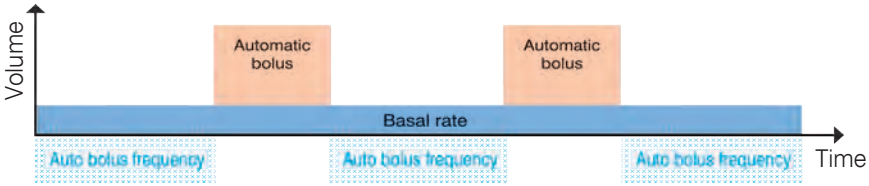
Contin + Bolus (standing for Continuous + Bolus), this delivery mode gives the ability to infuse patient bolus upon demand in addition to a constant basal rate.
This mode enables Basal rate, patient Bolus dose, Lockout interval, Dose limit or Bolus limit, Loading dose and Volume to be infused.
The minimum time between two patient bolus is defined by the lockout interval parameter. During bolus and lockout interval the basal rate will always be infused, if programmed.



Bolus only, this delivery mode gives the ability to infuse only patient bolus upon demand without basal rate.
This mode enables patient Bolus dose, Lockout interval, Dose limit or Bolus limit, Loading dose and Volume to be infused.
The minimum time between two patient boluses is defined by the Lockout interval parameter.

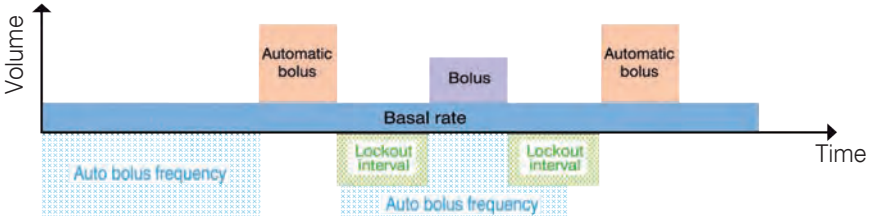


Auto Bolus (standing for Programmed Automatic Bolus – PAB), this delivery mode gives the ability to infuse automatically boluses with specified frequency in parallel to optional basal rate and patient bolus.
This mode enables Basal rate, Automatic Bolus dose, Automatic Bolus Frequency, patient Bolus dose, Lockout interval, Dose limit or Bolus limit, Loading dose and Volume to be infused.
The time between the automatic boluses is defined by the automatic bolus frequency parameter.

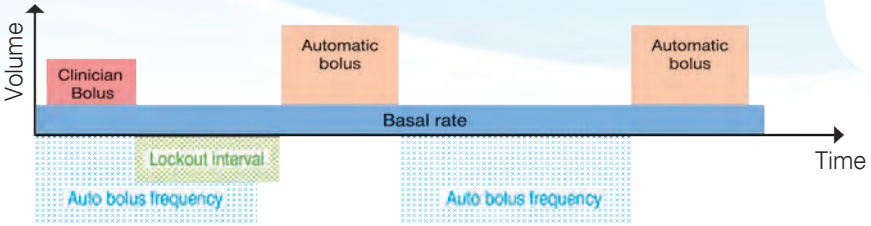


The automatic bolus delivery may be delayed by the lockout interval (defined for the patient bolus) as explained below.

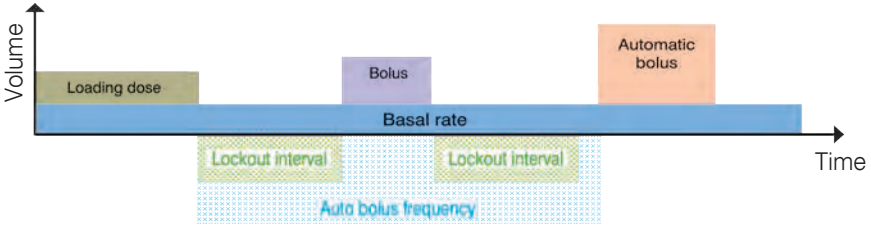
The time between an Automatic Bolus and a delivered patient bolus is at least equal to the lockout interval. This means that if a patient bolus has been delivered and the remaining time for the next Automatic bolus is less than the lockout interval, then the delivery of the Automatic Bolus will start after the lockout interval is over, as shown in the graph. A new lock out interval starts after a delivered patient bolus and after each delivered Automatic Bolus. Neither patient bolus nor Automatic Bolus can be delivered during a lockout interval. Only Clinician Bolus can be delivered during a lockout interval.



In case of a Clinician Bolus is delivered, the time to deliver the Automatic Bolus is at least equal to lockout interval time. This means that if a Clinician Bolus has been delivered and the remaining time for the next Automatic Bolus is less than the lockout interval, then the delivery of the Automatic Bolus will start after the lockout interval is over, as shown in the graph.



When the loading dose is used, the timer of the automatic bolus frequency and the timer of the lock out interval of the bolus are starting at the end of the delivery of the loading dose. If the loading dose is not used, the first automatic bolus will be delivered after the elapsed time of the automatic bolus frequency, which has begun after the start of the infusion.



3.2 Definitions of terms used

⊙ Basal rate

The basal rate is a continuous flow rate that can be programmed in ml/h, mg/h or µg/h. The infusion ends when the programmed Volume To Be Infused has been delivered.

⊙ Concentration

The drug concentration is required to calculate the basal rate while programming units mg or µg are used, with the following formula.

$$\text{RATE\_in\_ml/hr} = \frac{\text{Flowrate\_in\_mg/hr}}{\text{Concentration\_in\_mg/ml}}$$

or

$$\text{OR RATE\_in\_ml/hr} = \frac{\text{Flowrate\_in\_µg/hr}}{\text{Concentration\_in\_µg/ml}}$$

Output rate when calculated using the drug concentration is calculated with two decimals accuracy.
Programming units can be changed either from the basal rate programming screen after the start of programming or from the concentration programming screen.
When programming in ml/h the concentration is ignored.

⊙ Patient Bolus dose

The patient bolus (also called Bolus on the pump screen) is an amount of drug delivered at patient request, in addition to the basal rate and to the automatic bolus, if any.
The patient bolus delivery rate is the same as the automatic bolus delivery rate and is configurable through the Configuration menu and its default value is 100 ml/h. The patient bolus is delivered when the patient demand is valid (not within the lockout interval), the pump is not alarming the bolus limit or the dose limit has not been reached and the patient bolus dose will not increase the infused volume to reach the dose limit.

⊙ Lockout interval

The lockout interval is the period of time when the patient bolus demand cannot be delivered to the patient. This period starts after the delivery of a patient bolus or clinician override or an automatic bolus or loading dose.

⊙ Automatic Bolus dose

The automatic bolus (also called Auto Bolus on the pump screen) is an amount of drug delivered automatically and periodically in addition to the basal rate. The automatic bolus delivery rate is the same as the rate used to deliver the patient bolus. The automatic bolus is delivered when the pump is not alarming and the dose limit has not been reached.

⊙ Automatic Bolus Frequency

The automatic bolus frequency (also called Auto Bolus Frequency on the pump screen) defines the period of time between two automatic boluses.

⊙ Dose limit

The dose limit gives the capability to restrict the amount of drug that a patient can get within a period of time.

The entire drug volume infused by the pump, including loading dose, basal rate, clinician override boluses, patient boluses and automatic boluses are counted. A patient bolus will be infused if the total infused volume will not exceed the dose limit programmed. When the programmed limit is reached, the pump stops delivering drug. A warning is displayed. When the amount of drug within the pre-set period of time decreases bellow the dose limit, then the delivery restarts automatically.

The observation window is a shifting window during which all infused volume is totalized. Every 5 minutes a new totalizer is started creating a shifting observation window of the totalised infused volume.

If the dose limit alarm is triggered by a bolus, the bolus will not restart at the end of the dose limit alarm.

⊙ Bolus limit

The bolus limit gives the capability to restrict the number of patient bolus that a patient can get within a period of time.

Only the patient requested boluses given by the pump are counted. Clinician override boluses and automatic boluses are not counted. When the programmed limit is reached, no more patient bolus demand is delivered. A warning is displayed. If a basal rate and or automatic bolus has been set, the flow rate is maintained and automatic boluses will be infused. When the number of patient bolus within the pre-set period of time decreases bellow the bolus limit, then patient bolus are automatically authorised again.

The observation window is a shifting window during which all infused patient boluses are totalized. Every 5 minutes a new totalizer is started creating a shifting observation window of the totalised infused patient boluses.

⊙ Loading dose

The loading dose is an amount of drug delivered by the pump when initiating the infusion to a new patient.

The loading dose parameter is programmable during the programming phase, as long as it has been enabled through the pump configuration menu. The loading dose is delivered immediately after the start of the infusion. After the loading dose has been delivered, the pump infuses the basal rate if any.

If the loading dose is interrupted by stopping the infusion with the 

, then the pump will ask whether or not to finish it when resuming the infusion.

⊙ Volume to be infused

The volume to be infused parameter is used to trigger the near end of infusion alarm and then later to trigger the end of infusion alarm.
Usually the volume to be infused value is the bag volume minus the primed volume. The volume to be infused value, displayed on the pump screen, will decrease during the course of the infusion whilst the infused volume will increase accordingly.

⊙ Protocol library

The user can transfer customised protocol library from the PC application "Rythmic™ Evolution Therapy Manager" to the Rythmic™ Evolution pump. The protocol library contains preconfigured protocols, for which the values of the programmed parameters are pre-set, with or without limits in order to achieve programming errors prevention.
For detailed information regarding the operations and configuration for uploading a protocol library to the pump please refer to "Rythmic™ Manager Pack DFU".

4. Actions and codes

Warning

- We recommend the default codes of the pump to be changed (through the configuration menu) in order to secure the access to different actions related to each code.
- The supervisor of the infusion should decide to whom each code and its related actions should be distributed. Incorrect pump programming could result in death or serious injury to the patient.

Pump has different codes to secure access to certain programming and operations. Depending on the desired functionality, the appropriate code must be used. The table below lists the Actions possible and the corresponding code that must be entered to accomplish them.

Actions available after turning On the pump

After turning on the pump, a code must be entered by the user.

Actions \ Default codes	Programming Code	New bag code	Resume Code	Select mode code
Select delivery mode				x
Program an infusion	x			
New bag	x	x		
Resume an infusion	x		x	

Actions available after initiate infusion

Actions \ Default codes	Programming Code	New bag code	Resume Code	Select mode code
Titrate a running protocol	x			
Clinician bolus	x			
New bag		x		
Clear counters		x		
Stop infusion, if code protected stop of infusion is enable	x	x		

5. Programming procedure

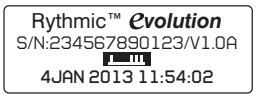
Warning

- We recommend the default codes of the pump to be changed (through the configuration menu) in order to secure the access to different actions related to each code.
- The supervisor of the infusion should decide to whom each code and its related actions should be distributed. Incorrect pump programming could result in death or serious injury to the patient.
- Always inspect the Rythmic™ Evolution pump and its accessories for damaged plastic parts, wires and presence of liquids on its surface, prior to use. If the pump or accessories are dropped, hit, subjected to excessive moisture and/ or beyond temperature limits, immediately take it out of use and return it to authorized service department for inspection.

5.1 Turn the pump ON/OFF

To turn the pump ON: Push and hold down the ON/OFF. Keep the ON/OFF held down and check that there are no missing dots on the dark display and hear that the buzzer sounds twice.

Keep the ON/OFF held down and check that date and time displayed are correct, if not refer to the chapter 9 "*Configuration*". Pump's serial number and Software revision number is also displayed on this screen. Release the ON/OFF.



To turn the pump OFF: The pump must be "ON HOLD" in order to turn off. To put pump "ON HOLD" during infusion press START STOP twice to stop infusion, in any other stage just keep pressing ↵ until you reach the "ON HOLD" screen.

Push and hold down the ON/OFF until the OFF screen appears.

5.2 Programming the pump

The user can program the pump by using the following options:

- By selecting and programming an existing (built-in) delivery mode
- By selecting a pre-configured protocol (through the protocol library)

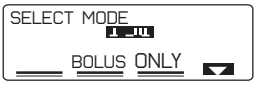
5.2.1 Selecting the delivery mode

After turning ON the pump, the delivery mode is displayed graphically on the upper right corner on screen.

Note: The default delivery mode is the "Continuous + Bolus" mode. After initial use, the mode displayed on the screen will be the one set at the previous infusion.

If the mode displayed on the screen after turning on the pump, is not the one desired by the user, then the process below needs to be followed in order to select a new mode:

Turn ON the pump, enter the selection mode code and press ↵.

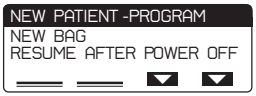


Select the desired mode using the key marked ▼. For each delivery mode a dedicated/ relevant symbol appears.
Press ↵ to confirm the selected mode. Then continue programming as described below. The selected mode will be automatically appear the next time the pump will be turned ON.

5.2.2 Programming with the last used delivery mode

If the mode displayed on the screen is the one desired by the user, then the process below needs to be followed:

Use  to enter the programming code.
Press ↵.

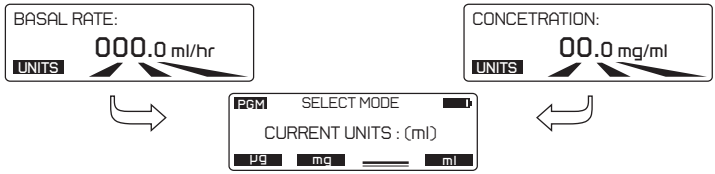


Use  to select "New patient – program".
Press ↵.

'New patient – program' allows the user to program the pump and start a new infusion. If a protocol library has been uploaded to the pump (via Rythmic™ Evolution Therapy Manager application), 'New patient – program' will provide access to all protocols of that library, please refer to Chapter 5 paragraph 5.3 *"Programming through protocol library."*
Moreover, the selection of "New patient-program" starts a new event log.
The user will have access to "New patient-program" only after turning on the pump and entering the programming code.

5.2.3 Select programming units

At the beginning of programming procedure, it is possible to select the programming unit from ml, mg and µg.
When mg and µg programming units are used, entering the drug concentration is required.
Press the UNITS soft key to select the programming unit from either the rate screen or the concentration screen.



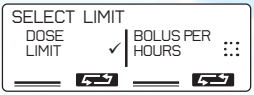
Use ◄ ► to select the desired programming unit.
The programming unit can't be changed over the course of an infusion.
The programming unit selected is stored and will be proposed for the next infusion.

5.2.4 Programming procedure for Continuous+Bolus mode

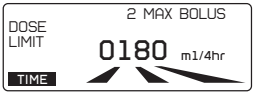
Enter the **BASAL RATE** and press ↵ .
You can change the programming units in this screen by using the UNITS *soft key, please refer to Chapter 5 paragraph 5.2.3 "Select programming units".*
If infusion was previously set in mg or µg, the drug concentration will be asked first.
If this parameter is not required, the value 000.0 should be entered.
Note: *If the basal rate value is higher than 49.9 ml/h then the Bolus dose and Lockout interval functions are disabled and will not appear on screen.*

Enter the patient **BOLUS** dose value and press ↵ .
If this parameter is not required, the value 000.0 should be entered.
Note: *If the patient Bolus parameter is set to 000.0 ml (or mg or µg) then the Lockout interval, bolus limit or dose limit functions are disabled and will not appear on screen.*

Enter the **LOCKOUT INTERNAL** value in minutes and press ↵ .
If this parameter is not required, the value 000 should be entered.

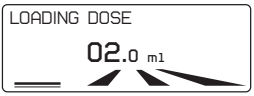


Select one of the two limits by pressing the appropriate key.

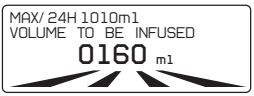


Enter the **DOSE LIMIT** value in minutes and press ↵.
DOSE LIMIT *observation window can be changed in this screen by pressing the* **TIME** *soft key.*
MAX BOLUS in the dose limit screen displays the maximum possible number of patient bolus that the patient can get within the preset period of time.
or

Enter the patient **BOLUS LIMIT** value in minutes and press ↵.
BOLUS LIMIT *observation window can be changed in this screen by pressing the* **TIME** *soft key.*
Note: *If dose limit or bolus limit is not required, the value 0000 should be entered.*



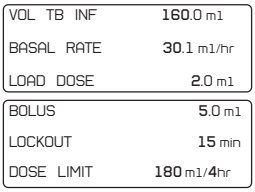
Enter the **LOADING DOSE** value, if required and press ↵.
Note: *If this parameter is not required, the value 000.0 should be entered.*



Enter the **VOLUME TO BE INFUSED** value and press ↵.
MAX/24H volume indication at the top of the screen indicate the maximum volume that a patient can receive within 24 hours, according to the above programmed values of each parameter.

Warning

Always validate infusion protocol values by checking all parameters, prior to start the infusion. If the **Protocol values are not correct**, please, restart the programming procedure by pressing ↵ when you are on the "PUMP ON HOLD" screen.



At the end of programming a summary of protocol appears on screen.
Press ↵ to scroll down the protocol.

If Protocol is correct, press >/II START STOP twice to start the infusion.

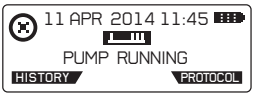
Warning

- Ensure that air has been purged from the administration set before connecting it to patient, to prevent air embolism. Air embolism could result in death or serious injury to the patient.
- Do not prime the administration set while it is connected to a patient, as this may result in air embolism or over- delivery of medication. Always disconnect the line from patient before priming.

Make sure that the administration set is fully primed. If not, press **NO** and prime the set using the pump, refer to Chapter 6, paragraph 6.1 "*Priming the Administration set line*". If the administration set is primed, press **YES** .

Warning

- Periodically inspect the fluid path for air. If air is seen stop infusion. Air infusion could result in under or non-delivery of medication. Air embolism could result in death or serious injury to the patient.
- Periodically inspect the fluid container for decreasing volume, inspect the fluid path for kinks, a closed clamp or other upstream obstruction. Upstream occlusions could result in under or non-delivery of medication.



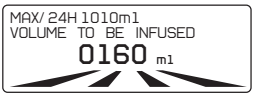
Infusion has started. The programmed parameters and their perspective values of the running protocol can be reviewed at once using the **PROTOCOL** key.

5.2.5 Programming procedure Continuous mode

Enter the **BASAL RATE** value and press ↵ .

You can change the programming units in this screen by using the **UNITS** *soft key, please refer to Chapter 5 paragraph 5.2.3 "Select programming units".*

If infusion was previously set in mg or µg, the drug concentration will be asked first.

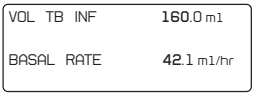


Enter the **VOLUME TO BE INFUSED** value and press ↵ .

MAX/24H volume indication at the top of the screen indicate the maximum volume that a patient can receive within 24 hours, according to the above programmed values of each parameter.

Warning

Always validate infusion protocol values by checking all parameters, prior to start the infusion. If the **Protocol values are not correct**, please, restart the programming procedure by pressing ↵ when you are on the "PUMP ON HOLD" screen.



At the end of programming a summary of the protocol appears on the screen, the programmed value of each parameter is displayed. Press ↵ to scroll down the protocol.

If Protocol is correct, press >/II START STOP twice to start the infusion.

Warning

- Ensure that air has been purged from the administration set before connecting it to patient, to prevent air embolism. Air embolism could result in death or serious injury to the patient.
- Do not prime the administration set while it is connected to a patient, as this may result in air embolism or over- delivery of medication. Always disconnect the line from patient before priming.

Make sure that the administration set is fully primed. If not, press **NO** and prime the set using the pump, refer to Chapter 6, paragraph 6.1 "*Priming the Administration set line*". If the administration set is primed, press **YES** .

Warning

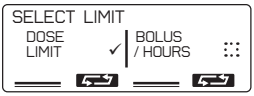
- Periodically inspect the fluid path for air. If air is seen stop infusion. Air infusion could result in under or non-delivery of medication. Air embolism could result in death or serious injury to the patient.
- Periodically inspect the fluid container for decreasing volume, inspect the fluid path for kinks, a closed clamp or other upstream obstruction. Upstream occlusions could result in under or non-delivery of medication.

Infusion has started. The programmed parameters and their perspective values of the running protocol can be reviewed at once using the **PROTOCOL** key.

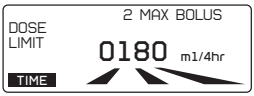
5.2.6 Programming procedure Bolus only mode

Enter the patient **BOLUS** dose value and press ↵ .

Enter the **LOCKOUT INTERVAL** value in minutes and press ↵ .
If this parameter is not required, the value 000 should be entered.

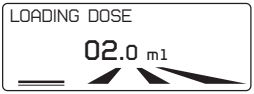


Select one of the two limits by pressing the appropriate key.



Enter the **DOSE LIMIT** value and press ↵ .
DOSE LIMIT *observation window can be changed in this screen by pressing the* TIME *soft key.*
MAX BOLUS in the dose limit screen displays the maximum possible number of patient bolus that the patient can get within the preset period of time.
or

Enter the patient **BOLUS LIMIT** value and press ↵ .
BOLUS LIMIT *observation window can be changed in this screen by pressing the* TIME *soft key.*
Note: *If dose limit or bolus limit is not required, the value 0000 should be entered.*

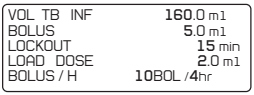


Enter the **LOADING DOSE** value if required and press ↵ .
Note: *If this parameter is not required, the value 000.0 should be entered.*

Enter the **VOLUME TO BE INFUSED** value and press ↵ .
MAX/24H volume indication at the top of the screen indicate the maximum volume that a patient can receive within 24 hours, according to the above programmed values of each parameter.

Warning

Always validate infusion protocol values by checking all parameters, prior to start the infusion. If the **Protocol values are not correct**, please, restart the programming procedure by pressing ↵ when you are on the "PUMP ON HOLD" screen.



At the end of programming a summary of the protocol appears on the screen, the programmed value of each parameter is displayed.
Press ↵ to scroll down the protocol.

If Protocol is correct, press >/II START STOP twice to start the infusion.

Warning

- Ensure that air has been purged from the administration set before connecting it to patient, to prevent air embolism. Air embolism could result in death or serious injury to the patient.
- Do not prime the administration set while it is connected to a patient, as this may result in air embolism or over- delivery of medication. Always disconnect the line from patient before priming.

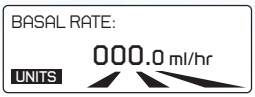
Make sure that the administration set is fully primed. If not, press NO and prime the set using the pump, refer to Chapter 6, paragraph 6.1 "*Priming the Administration set line*". If the administration set is primed, press YES.

Warning

- Periodically inspect the fluid path for air. If air is seen stop infusion. Air infusion could result in under or non-delivery of medication. Air embolism could result in death or serious injury to the patient.
- Periodically inspect the fluid container for decreasing volume, inspect the fluid path for kinks, a closed clamp or other upstream obstruction. Upstream occlusions could result in under or non-delivery of medication.

Infusion has started. The programmed parameters and their perspective values of the running protocol can be reviewed at once using the PROTOCOL key.

5.2.7 Programming procedure Automatic Bolus mode



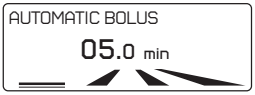
Enter the **BASAL RATE** value and press ↵.

You can change the programming units in this screen by using the **UNITS** *soft key, please refer to Chapter 5 paragraph 5.2.3 "Select programming units".*

If infusion was previously set in mg or µg, the drug concentration will be asked first.

If this parameter is not required, the value 000.0 should be entered.

Note: *If the basal rate value is higher than 49,9 ml/h then the Automatic Bolus dose, Auto Bolus Frequency, Bolus dose and Lockout interval functions are disabled and will not appear on screen.*



Enter the **AUTOMATIC BOLUS** dose value and press ↵.

If this parameter is not required, the value 000.0 should be entered.

Note: *If the Automatic Bolus dose value is 000.0 ml (or mg or µg) then the Auto Bolus Frequency is disabled and will not appear on screen.*

Enter the **AUTO BOLUS FREQUENCY** value in minutes and press ↵.

If this parameter is not required, the value 000 should be entered.

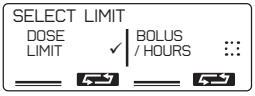
Enter the patient **BOLUS** dose value and press ↵.

If this parameter is not required, the value 000 should be entered.

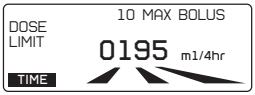
Note: *If the patient Bolus value is 000.0 ml (or mg or µg) then the Lockout interval, bolus limit or dose limit functions are disable and will not appear on screen.*

Enter the **LOCKOUT INTERVAL** value in minutes and press ↵.

If this parameter is not required, the value 000 should be entered.



Select one of the two limits by pressing the appropriate key.



Enter the **DOSE LIMIT** value and press ↵.

DOSE LIMIT *observation window can be changed in this screen by pressing the* **TIME** *soft key.*

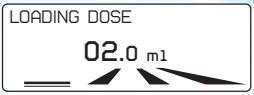
MAX BOLUS in the dose limit screen displays the maximum possible number of patient bolus that the patient can get within the preset period of time.

or

Enter the patient **BOLUS LIMIT** value and press ↵.

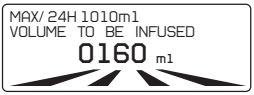
BOLUS LIMIT *observation window can be changed in this screen by pressing the* **TIME** *soft key.*

Note: *If dose limit or bolus limit is not required, the value 0000 should be entered.*



Enter the **LOADING DOSE** value if required and press ↵ .

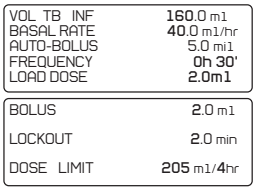
Note: *If this parameter is not required, the value 000.0 should be entered.*



Enter the **VOLUME TO BE INFUSED** value and press ↵ .
MAX/24H volume indication at the top of the screen indicate the maximum volume that a patient can receive within 24 hours, according to the above programmed values of each parameter.

Warning

Always validate infusion protocol values by checking all parameters, prior to start the infusion. If the **Protocol values are not correct**, please, restart the programming procedure by pressing ↵ when you are on the "PUMP ON HOLD" screen.



At the end of programming a summary of the protocol appears on the screen, the programmed value of each parameter is displayed.
Press ↵ to scroll down the protocol.

If Protocol is correct, press >/II START STOP twice to start the infusion.

Warning

- Ensure that air has been purged from the administration set before connecting it to patient, to prevent air embolism. Air embolism could result in death or serious injury to the patient.
- Do not prime the administration set while it is connected to a patient, as this may result in air embolism or over- delivery of medication. Always disconnect the line from patient before priming.

Make sure that the administration set is fully primed. If not, press NO and prime the set using the pump, refer to Chapter 6, paragraph 6.1 "*Priming the Administration set line*". If the administration set is primed, press YES key.

Warning

- Periodically inspect the fluid path for air. If air is seen stop infusion. Air infusion could result in under or non-delivery of medication. Air embolism could result in death or serious injury to the patient.
- Periodically inspect the fluid container for decreasing volume, inspect the fluid path for kinks, a closed clamp or other upstream obstruction. Upstream occlusions could result in under or non-delivery of medication.

Infusion has started. The programmed parameters and their perspective values of the running protocol can be reviewed at once using the PROTOCOL key.

5.2.8 Pre-programming the pump

It is possible to program the pump in advance and turn it Off after programming. The protocol is then stored in the pump. When the pump is ready and the set fitted, Turn the pump on and:

Enter resuming" code and press ↵ .

Warning

Always validate infusion protocol values by checking all parameters, prior to start the infusion. If the **Protocol values are not correct**, please, restart the programming procedure by pressing ↵ when you are on the "PUMP ON HOLD" screen.

If Protocol is correct, press >/II START STOP twice to start the infusion.

Warning

- Ensure that air has been purged from the administration set before connecting it to patient, to prevent air embolism. Air embolism could result in death or serious injury to the patient.
- Do not prime the administration set while it is connected to a patient, as this may result in air embolism or over- delivery of medication. Always disconnect the line from patient before priming.

Make sure that the administration set is fully primed. If not, press NO and prime the set using the pump, refer to Chapter 6, paragraph 6.1 "*Priming the Administration set line*". If the administration set is primed, press YES key.

Warning

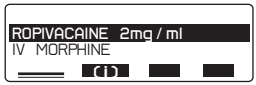
- Periodically inspect the fluid path for air. If air is seen stop infusion. Air infusion could result in under or non-delivery of medication. Air embolism could result in death or serious injury to the patient.
- Periodically inspect the fluid container for decreasing volume, inspect the fluid path for kinks, a closed clamp or other upstream obstruction. Upstream occlusions could result in under or non-delivery of medication.

Infusion has started. The programmed parameters and their perspective values of the running protocol can be reviewed at once using the PROTOCOL key.

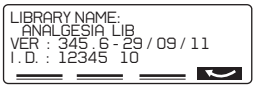
5.3 Programming through protocol library

If the pump has been configured with Protocol Libraries through the Rythmic™ Evolution Therapy Manager PC application, then the programming procedure below should be followed. Rythmic™ Evolution Therapy Manager is part of the Rythmic™ Manager Pack reference KP5.04.250.x.
Please, refer to Rythmic™ Manager Pack DFU for instructions about how to upload protocol library into the Rythmic™ Evolution pumps.

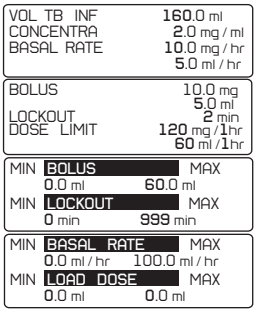
After “New patient-program” has been selected, protocols of the library appear in list.



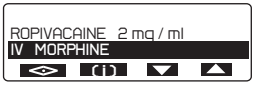
Use the  to scroll down the menu and choose the appropriate protocol. The last used protocol will be highlighted.



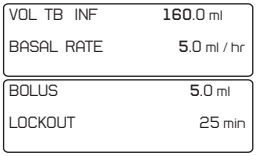
Pressing the  key will display library information.



Pressing the  key to preview the highlighted protocol and also the limits for each parameter.



Choose the appropriate protocol and press  .



Protocol’s parameters are shown in summary. Press  to scroll down the protocol.

Warning

Always validate infusion protocol values by checking all parameters, prior to start the infusion. If the **Protocol values are not correct**, please press "PROGRAM" when you are on the "PUMP ON HOLD" screen, to enter the programming procedure and modify the infusion parameters.

If Protocol is correct, press >/II START STOP twice to start the infusion.

Warning

- Ensure that air has been purged from the administration set before connecting it to patient, to prevent air embolism. Air embolism could result in death or serious injury to the patient.
- Do not prime the administration set while it is connected to a patient, as this may result in air embolism or over- delivery of medication. Always disconnect the line from patient before priming.

Make sure that the administration set is fully primed. If not, press NO and prime the set using the pump, refer to Chapter 6, paragraph 6.1 "*Priming the Administration set line*". If the administration set is primed, press YES key.

Warning

- Periodically inspect the fluid path for air. If air is seen stop infusion. Air infusion could result in under or non-delivery of medication. Air embolism could result in death or serious injury to the patient.
- Periodically inspect the fluid container for decreasing volume, inspect the fluid path for kinks, a closed clamp or other upstream obstruction. Upstream occlusions could result in under or non-delivery of medication.

Infusion has started. The programmed parameters and their perspective values of the running protocol can be reviewed at once using the PROTOCOL key.

6. Operation of pump

6.1 Priming the Administration set line

Warning

- Ensure that air has been purged from the administration set before connecting it to patient, to prevent air embolism. Air embolism could result in death or serious injury to the patient.
- Do not prime the administration set while it is connected to a patient, as this may result in air embolism or over- delivery of medication. Always disconnect the line from patient before priming.
- Ensure that the administration set is properly installed and has not been trapped in transparent covers, as this may result in under or non-delivery of medication.
- Ensure that the release lever is locked in closed position and the tubing cover is closed firmly. If the release lever or the tubing cover become loose may result in under or non-delivery of medication.
- When using administration set with Y connector ensure a closed cap is used on the Y port when not in use. Air embolism could result in death or serious injury to the patient.
- When rigid - non collapsible external medication containers (e.g. glass bottles, hard plastic bag) are used with a Rythmic™ spike set, then the air vent on the spike must be opened and the container must be suspended from a pole. If the air vent is closed it could result in under or non-delivery of medication. The air vent is fitted with an anti-bacterial filter.
- When collapsible external medication containers are used with Rythmic™ spike set, the air vent on the spike must be closed.

The prime function is accessible when the pump is on hold before initiating the infusion but also after the selection of an option just after the entry of the programming code (turn on) and/or after the entry of the change bag code. The Priming function is disabled once the infusion has been first started.

When external medication container is used with spike set, hang the external medication container prior to priming.

The administration set can be primed using two ways:

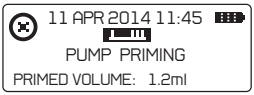
Manual priming of the administration line, as described in Chapter 2, paragraph 2.5 "*Preparing of Administration set before the infusion*"

Priming of the administration set through the pump, using the below procedure.

The same process is followed for both sets with bag and sets with spike and external medication container.

Ensure that the set is unclamped.

Press <<< PURGE-BOLUS for a few seconds until priming begins. Press again to stop priming.



Priming stops automatically at 3 ml priming volume. If the line is not fully primed, press once <<< PURGE-BOLUS.

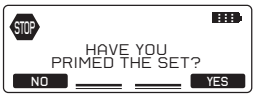
Press >/II START STOP twice to start the infusion.

The maximum primed volume is 9 ml.
The volume infused during the priming function is not subtracted from the volume to be infused.

Configurable option for safety priming process

Through configuration menu, please refer to Chapter 9, paragraph 9.2 "*Configuration menu*", there are three choices.

Warning



This screen always appear, when the >/II START STOP is pressed twice in order to start the infusion. The user selects to do the priming through the pump if the set has not been manually primed.

Mandatory

This screen will always appear, when the >/II START STOP is pressed twice in order to start the infusion.

The user will always have to press the <<< PURGE-BOLUS before the infusion is initiated.

No Warning: No relevant screen will appear, when the >/II START STOP is pressed twice in order to start the infusion. The infusion will start without reminding the user to prime the administration set line.

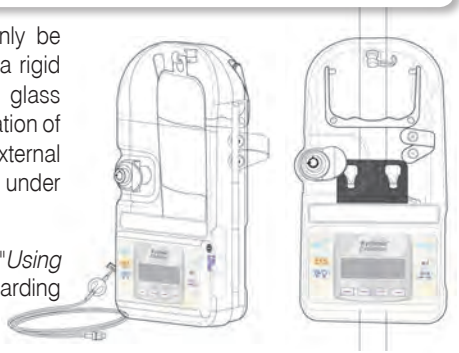
6.2 Placement of the pump

Warning

- Ensure that the spike connector is properly attached to the external medication container. Spike detachment from the external medication container could result in under or non-delivery of medication.
- When rigid - non collapsible external medication containers (e.g. glass bottles, hard plastic bag) are used with a Rythmic™ spike set, then the air vent on the spike must be opened and the container must be suspended from a pole. A closed air vent could result in under or non-delivery of medication. The air vent is fitted with an anti-bacterial filter.
- When rigid – non collapsible external medication containers (e.g. glass bottles, hard plastic bag) are used in ambulatory infusion (infusion during transportation), ensure that the external container is always placed vertical.
- In Rythmic™ Evolution Organiser pump range, the container must be suspended by the bag hook placed inside the pump's transparent cover.
- All Rythmic™ Evolution Organiser pumps should be placed in pole, during a non-ambulatory infusion.
- All Rythmic™ Evolution Organiser pumps can be transported using carrying belt, handle or carrying bag. Ensure that the container inside the Organiser remains always in vertical position.
- Only collapsible containers should be used when Mini Rythmic™ Evolution pump operates in waist-shoulder carrying bag.
- Ensure that the transparent covers are securely closed, to prevent patient access to medication container.
- Ensure that the administration set has been properly installed and has not been trapped in transparent covers or inside the carrying bag, as this may result in under or non-delivery of medication.
- Ensure that during infusion, the vertical distance between the pump and the injection site should be one meter height maximum.
- In all above cases, failure to follow the instructions may result in under or non-delivery of medication and air in line may occur, which could result in death or serious injury to the patient.

All Rythmic™ Organiser pumps should only be kept in a vertical position while using with a rigid container which could contain air (e.g. glass bottles, hard plastic bag). Non vertical operation of the Rythmic™ Organiser pump when rigid external medication container is used, could result in under or non-delivery of medications.

Please refer to Chapter 10, paragraph 10.5 "*Using carrying bag and carrying belt*" for details regarding the use of carrying bags for portable use.

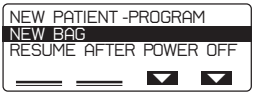


6.3 Changing the bag for the same patient (New bag)

This function allows repeating the same protocol and changing only the volume to be infused parameter. The rest of the protocol parameters will remain the same. It also allows reviewing infusion protocol, infused volume, patient bolus demanded / patient bolus delivered. Moreover, it allows resetting the counters which count infused volume, number of demanded patient bolus and number of delivered patient bolus if needed. The user can access this feature after turning the pump ON and during course of infusion. After turning the pump ON the user can either enter the new bag code or enter the new patient – program code and select New bag from selection menu.

Warning

- We recommend the default codes of the pump to be changed (through the configuration menu) in order to secure the access to different actions related to each code.
- The supervisor of the infusion should decide to whom each code and its related actions should be distributed. Incorrect pump programming could result in death or serious injury to the patient.



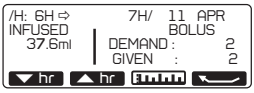
Use ▼ ▼ ▼ ▼ to select “New bag”. Press ↵.

The below sequence is the same when using programming code and new bag code.

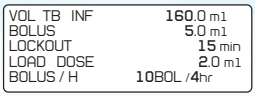
Enter the **VOLUME TO BE INFUSED** value and press ↵. MAX/24H volume indication at the top of the screen indicate the maximum volume that a patient can possibly get within 24 hours, according to the programmed values of each parameter.

The history data of infusion are displayed. Review infused volume, Patient bolus demand and given and Patient bolus infused volume. For infusion with Continuous mode only infused volume is displayed. Review bolus graph and pain level graph.

Press “CLEAR” to reset counters, if necessary. A message will appear, press YES to proceed with the reset of counters. Infused volume, patient bolus demanded, patient bolus given and volume infused due to patient bolus will be set to zero. Graphs, bolus list and pain list will remain.



Press hr/hr to review protocol per hour. Use ▼ hr ▲ hr soft keys to scroll up and down to review hour by hour the infused volume, patient bolus demand and patient bolus delivered down to the beginning of the infusion or down to the last time the counter has been cleared.



Protocol's parameters are shown in summary.
Press ↵ to scroll down the protocol.

Warning

Always validate infusion protocol values by checking all parameters, prior to start the infusion. If **the Volume to be infused value is not correct,** please, modify it by pressing ↵ to get on the relevant screen. Wrong infusion protocol could result in death or serious injury to the patient.

If the **Volume to be infused is correct**, press >/II START STOP twice to start the infusion.

Warning

- Ensure that air has been purged from the administration set before connecting it to patient, to prevent air embolism. Air embolism could result in death or serious injury to the patient.
- Do not prime the administration set while it is connected to a patient, as this may result in air embolism or over- delivery of medication. Always disconnect the line from patient before priming.

Make sure that the administration set is fully primed. If not, press NO and prime the set using the pump, refer to Chapter 6, paragraph 6.1 "*Priming the Administration set line*". If the administration set is primed, press YES .

Warning

- Periodically inspect the fluid path for air. If air is seen, stop infusion. Air infusion could result in under or non-delivery of medication. Air embolism could result in death or serious injury to the patient.
- Periodically inspect the fluid container for decreasing volume, inspect the fluid path for kinks, a closed clamp or other upstream obstruction. Upstream occlusions could result in under or non-delivery of medication.

Infusion has started. The programmed parameters and their perspective values of the running protocol can be reviewed at once using the PROTOCOL key.

During infusion, user can access "Change bag" following the below procedure:

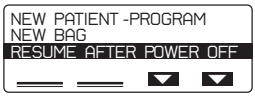
Put the pump on hold by pressing twice >/II START STOP and then press PROGRAM.

Enter new bag code and press ↵.

Repeat the procedure described above in order to enter the new Volume to be Infused and to start infusion.

6.4 Resuming the same infusion with the same patient after power off of the pump (Resume after power off)

This function allows continuing the infusion at the stage it was before power OFF, e.g. when 9V alkaline battery is replaced. There is no ability to change any infusion parameters. Since the infusion has already started before power OFF, there is no ability to prime the administration set using the pump.
The user can access this feature after turning the pump ON and either enter Resume after power off code or enter the New patient – program code and select "Resume after power off" from selection menu.



Use ⟵ ⟶ to select "Resume after power off".
Press ↵.

The below sequence is the same when using programming code and new bag code.

Warning

- Ensure that air has been purged from the administration set before connecting it to patient, to prevent air embolism. Air embolism could result in death or serious injury to the patient.
- Ensure that the administration set is properly installed and has not been trapped in transparent covers. An undetected upstream occlusion may result in under or non-delivery of medication. Depending upon medication under or non-delivery could result in death or serious injury to the patient.
- Ensure that the release lever is locked in closed position and the tubing cover is closed firmly. If the release lever or the tubing cover become loose, may result in under on non-delivery of medication.
- Periodically inspect the fluid container for decreasing volume, inspect the fluid path for kinks, a closed clamp or other upstream obstruction. Upstream occlusions could result in under or non-delivery of medication, which could result in death or serious injury to the patient.

Warning

- Periodically inspect the fluid path for air. If air is seen, stop infusion. Air infusion could result in under or non-delivery of medication. Air embolism could result in death or serious injury to the patient.
- Always validate infusion protocol values by checking all parameters, prior to start the infusion. Wrong infusion protocol could result in death or serious injury to the patient.

Press twice >/II START STOP to resume the infusion.
The programmed parameters and their perspective values of the running protocol can be reviewed at once using the PROTOCOL key. History can be reviewed using the HISTORY .

6.5 Changing the battery and continue the same infusion

Put the pump on hold by pressing >/II START STOP twice and enter the code to stop infusion, if code protected stop of infusion is enabled. Press ↵ .

Turn the pump OFF and change the battery, as explained in Chapter 2, paragraph 2.3. "Power Supply" section 2.3.1 "*For pumps with 9v alkaline battery*". Turn the pump ON and repeat the procedure as explained in Chapter 6, paragraph 6.4 "*Resuming the same infusion with the same patient after power off of the pump*" in order to resume the infusion after OFF.

6.6 Changing the Protocol

Warning

- We recommend the default codes of the pump to be changed (through the configuration menu) in order to secure the access to different actions related to each code.
- The supervisor of the infusion should decide to whom each code and its related actions should be distributed. Incorrect pump programming could result in death or serious injury to the patient.

Put the pump on hold by pressing >/II START STOP twice and enter the code to stop infusion, if code protected stop of infusion is enabled, please refer to Chapter 9 paragraph 9.2 "*Configuration Menu*". Press ↵ .

Press PROGRAM .

Enter your "programming" code and press ↵ .

Select PROGRAM .

Scroll down the screens by pressing ↵ until you reach the para-meter you need to change. Modify this parameter and press ↵.

Scroll down to the “PUMP ON HOLD” screen and Press >/II START STOP twice to resume the infusion.

6.7 Clinician Bolus override

Warning

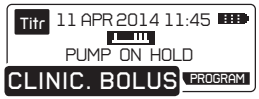
- Extra care when using the clinician bolus function. There is no limit, or frequency limit in the use of the override bolus function. Incorrect programming could result in death or serious injury to the patient.
- Do not leave the pump unattended while is on Clinician Bolus screen.
- We recommend the default codes of the pump to be changed (through the configu-ration menu) in order to secure the access to different actions related to each code.
- The supervisor of the infusion should decide to whom each code and its related actions should be distributed. Incorrect pump programming could result in death or serious injury to the patient.

The clinician bolus override function provides the medical staff with the capability to administer additional bolus doses to the patient, even during the lockout interval.
The clinician bolus dose is included in the dose limit counter totals.

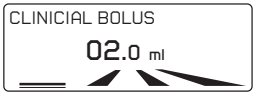
Put the pump on hold by pressing >/II START STOP twice and enter the code to stop infusion, if code protected stop of infusion is enabled. Press ↵.

Press PROGRAM.

Enter your “programming” code and press ↵.



Select CLINIC. BOLUS.



The Clinician bolus dose is pre-set to the value of the normal patient bolus dose. If needed adjust the dose and press ↵.

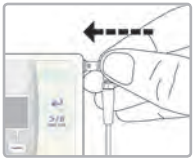
Pressing >/II START STOP twice will infuse the Clinician bolus dose and resume the infusion.

6.8 Bolus administration

Bolus administration can be achieved by using bolus handset or by using Purge-Bolus button placed on pump's panel. The patient bolus is delivered if the pump is not in alarm condition and if the lockout interval since the last bolus has elapsed. The bolus handset supplied is designed to be used in either hand and suitable for both adult and pediatric use.

Inserting bolus handset

Hold the bolus connector from the grip area and plug it into the socket labelled on the pump. Ensure that the handset is securely fitted.



Using the bolus button on pump's panel

Alternatively, bolus demand can be generated by pressing the button <<< PURGE-BOLUS placed on pump's panel for 2 seconds. A buzzer sound acknowledges the patient bolus demands. If a pain level question appears on the pump upon bolus request, please refer to Chapter 9, paragraph 9.2 "*Configuration menu*".

Using the bolus handset

Press the bolus handset to generate a patient bolus demand. A buzzer sound acknowledges the patient bolus demands.
If enabled through configuration menu, a pain level question appears on the pump upon bolus request, please refer to Chapter 9, paragraph 9.2 "*Configuration menu*".

Bolus interruption

Bolus delivery can be interrupted by pressing twice on button >/II START STOP. When resuming the infusion, the pump will ask whether or not to finish the interrupted bolus.

Removing bolus handset

Warning

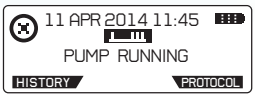
- Do not pull out the bolus handset at an angle, bolus may be damaged.
- Do not remove the bolus handset by pulling the cable, bolus may be damaged.
- Do not rotate the bolus connector while removing the bolus handset.

Bolus handset has incorporated a locking mechanism which prevents accidentaly bolus removal.

To remove the bolus handset from the pump, hold the bolus connector from the grip area and slowly pull it out without rotating the connector.

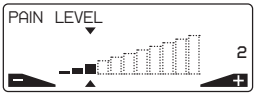
6.9 Answering to Pain level question

Pain level question can be manually accessible as described below:

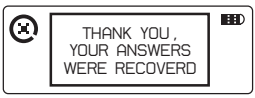


Press ↵ when the pump is on hold or during infusion.

Press YES to enter the questionnaire.



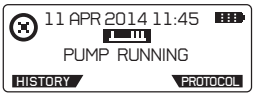
Press the – or + soft keys to select value in the 1-10 scale.
Press ↵ to answer.



After finish answering to question, the following message will be displayed, informing that the answer is recorded.

6.10 Viewing the remaining volume to be infused and the infusion parameters.

When the pump is on hold or during infusion,



Press the PROTOCOL key to review the current infusion parameters.
Press ↵ to view the second screen.
Note: *when KVO is running the KVO rate is displayed instead of the basal rate value.*

e.g. Continuous mode

VOL TB INF	160.0 ml
BASAL RATE	5.0 ml / hr

e.g. Bolus only mode

VOL TB INF	160.0 ml
BOLUS	5.0 ml
LOCKOUT	15 min
LOAD DOSE	2.0 ml
BOLUS/H	10BOL /4HR

e.g. Auto Bolus mode

VOL TB INF	160.0 ml
BASAL RATE	40.0 ml / hr
AUTO - BOLUS	5.0 ml
FREQUENCY	0h30'
LOAD DOSE	2.0 ml

BOLUS	5.0 ml
LOCKOUT	20 min
DOSE LIMIT	195ml /4hr

Volume TB infused is the remaining volume to be infused. Press ↵ to return to the main screen.

PUMP ASSIGNED TO:
Mr PHIL. HIPPAIN
BIRTHDATE: 27 / 06 / 58

PROTOCOL: MORPHINE I.V. 10mg

Note: *when programmed or/and if the pump is connected to the web the patient name, birth date and protocol name are displayed.*
Press ↵ to return to the main screen.

7. Historical Data & event log

7.1 Overview

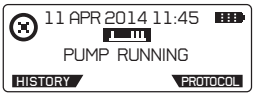
The pump keeps track of the following groups of information:

1. **Infusion protocol**
   Current active protocol (even after modification / titration from the user).
2. **Infusion progress and patient bolus counters total and per hour**
   Volume infused to patient & patient bolus information for the total infusion and also for each hour.
3. **Infusion graphs**
   Graphical display of infused volume, patient bolus demands / given, clinician override bolus and pain level.
4. **Infusion events log**
   Protocol prescriptions that have been programmed & detailed device operational information.

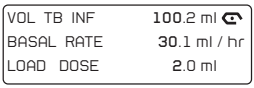
The above groups are accessible either during infusion or when the pump is on hold, or exclusively through the uploading to PC functionality. The following sections will outline how the user can access each group.

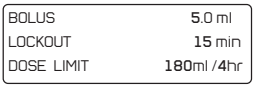
7.2 Viewing infusion protocol

During infusion or when the pump is on hold, the user has the ability to view the current infusion protocol.



Press the PROTOCOL key to review the parameters of the current infusion protocol.

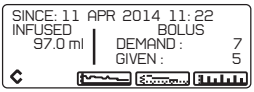




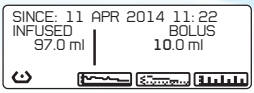
The parameters of the current protocol will be displayed.
Press ↵ to scroll pages.

7.3 Viewing infusion progress and counters

Press the HISTORY key to enter history and review the current infusion progress.



This screen displays the Infused Volume, the patient Bolus demand and patient Bolus given parameters, if any.
Press ↵ once to view the next screen.



This screen displays the Infused Volume and the volume infused due to patient bolus.

Bolus demand

This indicates the number of patient bolus demand, arising from either the patient handset or the bolus button. Clinician override boluses and automatic boluses are not counted as patient bolus demand.

Bolus given

This is a counter that totals the patient boluses delivered to the patient. Clinician override boluses and automatic boluses are not counted as patient bolus given. A patient bolus is counted as given, when it has been fully delivered.

Infused volume

This indicates the total volume infused from the beginning of infusion.

Note: *The total infused volume may appear higher than the sum of Currently Infused volumes due to the fact that the currently infused volumes have a single digit precision and thus can round off to a lower value.*

7.3.1 Viewing infusion progress and bolus counters per hour

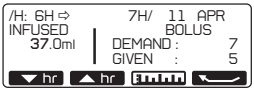
Total Infused per hour

This indicates the volume infused within each hour (actual time) and also the number of patient bolus demanded and given.

When the pump is on hold, the user can review infusion progress and bolus counters per hour :

Press the **HISTORY** key to enter history and review the current infusion progress.

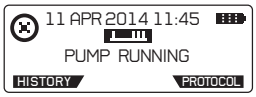
Press the **hr / hr** key.



Use **hr** **hr** keys to scroll up and down to review hour by hour the infused volume, patient bolus demand and patient bolus delivered down to the beginning of the infusion or down to the last time the counter has been cleared.

7.4 Viewing infusion graphs during running/pump on hold

Infusion graphs are accessible either during infusion or when the pump is on hold. Press HISTORY key at any time to review patient bolus demand, patient bolus given and infused volume.



Press the HISTORY key to review the current infusion progress.

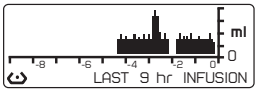
Press twice ↵ to return to the main screen.

Press to view the graph of the infusion.

Press to view the graph of the pain.

Press to view the graph of bolus.

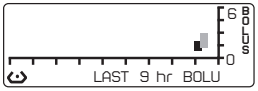
Infusion graph



The graph shows the infused volume curves over the last 9 hrs.

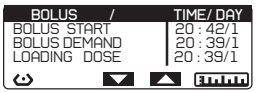
Press ↵ to return to the History screen.

Bolus graph and bolus list



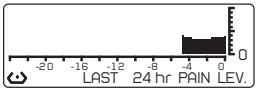
The graphs shows the patient bolus demanded/delivered and the clinician bolus over the last 9 hrs.

Press ↵ to see the bolus list.



In the bolus list patient bolus demanded/delivered, Auto-bolus started/given, loading dose and clinician bolus are included. Also, the date and the time of each event is displayed.

Pain level graph and pain list



The graph shows the pain level over the last 24 hrs.

Press ↵ to see the pain level list.

7.5 Infusion events log overview

Infusion events are only accessible through uploading event log to PC. These include:

User Interface warnings, User Interface Alarms, Pump On/Off events, Infusion Start/Stop, Priming Start/Stop, Loading Dose, Bolus Start/Given/Demanded, Titration, New Bag and Resume after power off.

7.6 Viewing infusion data even after turning off the pump

If the pump has been turned OFF, it is possible to review the above mentioned infusion data/graphs by turning ON the pump again and entering the “resume” code.

If however a “new patient-program” function has been selected after turning ON, the infusion data of the previous infusion will only be available through uploading functions.

7.7 Uploading event log to a computer

All the data can be uploaded to a PC for archiving purposes or custom statistical analysis. To upload event log to a computer, the “Rythmic™ Data Manager” software is required. Rythmic™ Data Manager is part of the Rythmic™ Manager Pack reference KP5.04.250.x. Data can be saved in a computer either in an excel format or in text format.

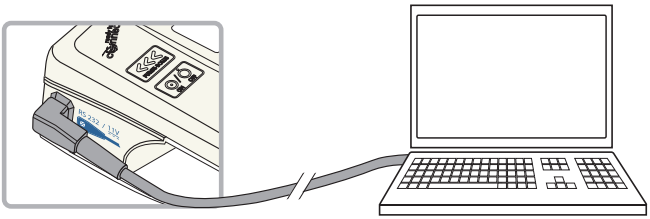
Warning

- The pump should be disconnected from the patient prior to being connected to a computer.
- Do not perform this operation in the presence of a patient.

In order to perform event log upload of the infusion data please follow the instructions shown below:

1. Connect the MicrelCom cord to the pump into the socket labelled on the pump.

2. Connect the other side of the MicrelCom cord to the PC.



3. Run the "Rythmic™ Data Manager" software at the PC. For detailed information regarding the operation of "Rythmic™ Data Manager", please refer to "Rythmic™ Manager Pack" DFU.

4. Turn the pump ON, enter the resume after power OFF code and confirm.

5. Or, if the pump is ON move to "**PUMP ON HOLD**" screen.

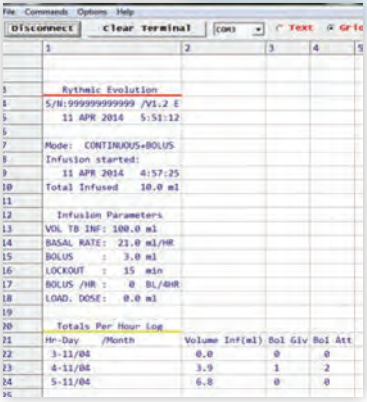
6. Press **HISTORY** key to enter history menu.
The data transfer key → should appear.

7. Press → to access the printing menu.

8. Use ▼ ▲ arrow to select the infusion period you wish to upload to the PC.

9. Press → to start the data transfer.

10. Data will be displayed on the computer screen as shown below:

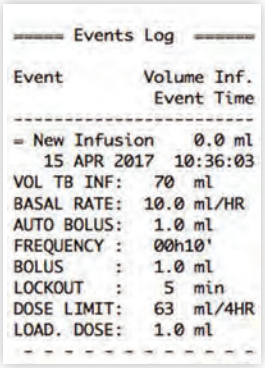


MicrelCom cords are available at Micrel.

7.7.1 Uploading detailed event log

After uploading the infusion data, there is the possibility to upload the detailed event log.

Press YES or NO to upload them or not and return to the selection screen.



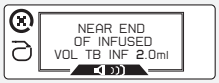
8. User Interface Alarms and Warnings

The Rythmic™ Evolution pump has means to make the user aware of any eventual equipment malfunction, and/or wrong operator equipment usage, and/or abnormal physiological conditions. There are three categories: User Interface Warnings, User Interface Alarms and Technical Alarms.

8.1 User Interface Warnings

Whenever user interface warnings are produced, the infusion continues and an identification message is displayed. Most of the user interface warnings have audible and visual signals. In case of audible warnings the pump sounds intermittently, press the key to silence the acoustic tone for one hour, but maintain the warning message on the display.

Near end of Infusion

Warning message	Type of signal	Cause	Action
	Audible YES Visual YES Acoustic tone: Intermittent	The remaining volume to be infused is low. Infusion will end soon.	Press to acknowledge the message. Anticipate on next action to be taken.

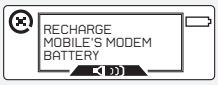
The sound alarm of the near end of infusion warning can be disabled on the pump to be forwarded by SMS messages when IP connect Pack is used. Refer to Chapter 10, paragraph 10.4 "*IP Connect Pack*". Press ↵ to acknowledge.

Low Battery

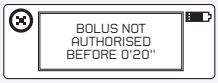
Warning message	Type of signal	Cause	Action
	Audible YES Visual YES Acoustic tone: Intermittent	Battery power is low but the infusion is still on going.	Change the battery when the infusion is finished.

The first time this warning is triggered, the remaining battery life is at least 12 hours.

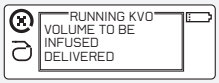
IP connect Low Battery

Warning message	Type of signal	Cause	Action
	Audible YES Visual YES Acoustic tone: Intermittent	The battery of accessory IP Connect Pack is low. Infusion will not stop but connection might be lost.	Charge the battery of IP Connect Pack, as instructed in Chapter 10 paragraph 10.4 *"IP Connect Pack."*

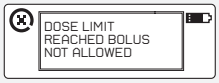
No patient bolus allowed

Warning message	Type of signal	Cause	Action
	Audible NO Visual YES	A patient bolus is demanded but not allowed eg: during bolus infusion, during lockout time or because dose or patient bolus limits have been reached.	Wait for the time limit to pass. Patient bolus will automatically be authorized after the limit elapsed.

Running KVO

Warning message	Type of signal	Cause	Action
	Audible YES Visual YES Acoustic tone: Continuous	The remaining volume to be infused has been delivered and pump started infusing at KVO rate.	If necessary, leave the pump to run with KVO rate. Or, turn the pump OFF. When the maximum KVO volume will be reached the infusion will stop and an alarm will be triggered.

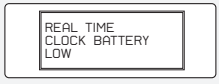
Dose limit reached. Bolus not allowed

Warning message	Type of signal	Cause	Action
	Audible NO Visual YES	The requested patient bolus exceeds the dose limit.	Wait for the limit to be elapsed, patient bolus will automatically be authorized.

Preventive maintenance date

Warning message	Type of signal	Cause	Action
	Audible NO Visual YES	There have been passed 3 years or 1000 days of infusion. The date for preventive inspection is approaching.	Press ↵ to acknowledge the message. Return the pump to a qualified technician for routine preventive inspection when the pump is available.

Low real time clock battery

Warning message	Type of signal	Cause	Action
	Audible NO Visual YES	A problem detected with the internal real time clock battery.	Return the pump to a qualified technician to change the battery.

Keyboard Continuously Pressed

Warning message	Type of signal	Cause	Action
	Audible YES Visual YES Acoustic tone: Continuous	A key on the keyboard or the bolus switch were continuously pressed.	Release the key or bolus switch and press ↵ to silence the alarm and to remove the message from the screen.

Value out of range

Warning message	Type of signal	Cause	Action
	Audible NO Visual NO	A value was set out of range during programming.	Pump proposes the nearest acceptable value. Confirm the proposed or change it.

8.2 User Interface Alarms

Whenever user inteface alarms are produced, the infusion stops and an alarm identification message is displayed. Most of the user interface alarms have audible and visual signals. In case of audible alarms, press key to silence the acoustic tone for one hour, but maintain the alarm message on the display. The buzzer is deactivated temporarily, should another audible alarm condition occur, the buzzer will sound again.

Occlusion

Alarm message	Type of signal	Cause	Action
	Audible YES Visual YES Acoustic tone: Continuous	High pressure, which may be a result of a closed clamp, a damaged filter, a downstream obstruction or a kink in the fluid path.	Press ↵ to put the pump “ON HOLD”. Remove the cause for occlusion. Check the administration line for kinks or closed clamp. After the remove of obstruction, infusion will resume automatically.

Depleted battery

Alarm message	Type of signal	Cause	Action
	Audible YES Visual YES Acoustic tone: Continuous	Battery power is too low to operate the pump.	Turn the pump OFF and change the disposable 9v alkaline battery. Turn the pump ON and enter your resuming code and press ↵. Press >/II START STOP twice to resume the infusion. **In case of a rechargeable battery**, connect the power adaptor to the mains and to the pump. Press ↵ and then press >/II START STOP twice to resume infusion.

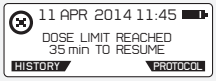
End of Infusion

Alarm message	Type of signal	Cause	Action
	Audible YES Visual YES Acoustic tone: Continuous	Infusion finished, the programmed volume to be infused has been delivered.	Press to acknowledge the alarm and press to put the "PUMP ON HOLD". Turn the pump OFF or change the bag and continue with infusion by pressing PROGRAM and entering the change bag code.

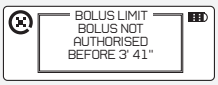
Door is open

Alarm message	Type of signal	Cause	Action
	Audible YES Visual YES Acoustic tone: Continuous	The tubing cover is not properly closed or the administration set has not been properly loaded into the pump.	Check the placement of the administration set and the tubing cover, it should be closed. Press START STOP twice to resume the infusion.

Dose limit alarm

Alarm message	Type of signal	Cause	Action
	Audible NO Visual YES	The delivered volume within the specific time has reached the limit.	Wait for the limit to be elapse, infusion will resume automatically. Or, stop infusion and enter the programming menu to modify this parameter.

Bolus limit alarm

Alarm message	Type of signal	Cause	Action
	Audible NO Visual YES	The number of delivered patient bolus within the specific time has reached the limit.	Wait for the limit to be elapsed, patient bolus will automatically be authorized. Or, stop infusion and enter the programming menu to modify this parameter.

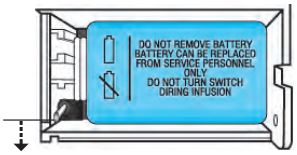
8.3 Technical Alarms

Whenever technical alarms are produced, the infusion stops and a coded alarm identification message is displayed. Press key to silence the acoustic tone for one hour, but maintain the alarm message on the display. The buzzer is deactivated temporarily, should another audible alarm condition occur, the buzzer will sound again.

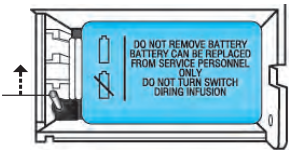
Alarm message	Type of signal	Cause	Action
⚠ ALARM ERROR : XX XX	Audible YES Visual YES Acoustic tone: Continuous	An internal error has been detected. An alarm may originate from temporary Electro-magnetic Interference or extreme vibration.	Note the error code. Turn pump OFF then ON again. If the alarm persists or the pump cannot turned OFF see below according to the pump type of power supply.

For pumps with rechargeable battery:

Ensure that the Micrel power adaptor is not connected to the Rythmic™ Evolution pump. Open the transparent covers and take the battery cover off. Turn the switch to , as shown in picture 1, the pump will turned OFF and the buzzer will stop. Wait for 3 seconds and then turn the switch to as shown in picture 2 and replace the battery cover. Turn the pump ON and continue.



pic.1



pic.2

Caution

Do not turn the switch to position while the pump is switched ON, as this may damage the pump.

Note: *If pump cannot be turned on, check that the switch inside the battery compartment is at position.*
If "battery needed as backup for infusion" warning message is displayed, check that the switch inside the battery compartment is at position.

For pumps with disposable 9V alkaline battery:

Ensure that the Micrel power adaptor is not connected to the Rythmic™ Evolution pump. Open the transparent covers and take the battery cover off. Take the battery out of the pump, wait for 3 seconds and then place the battery to the battery compartment. Turn the pump ON and continue.

If the alarm persists, return the pump and its accessories to service, note the error code and have the unit checked by a qualified engineer.

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

9. Configuration

Warning

The supervisor of the infusion must decide whether the Configuration chapter should be kept in the present IFU.

This chapter refers to pump configurations, which allows the pump to be customised to user and/ or patient specificities and must be manipulated by the clinician only.

9.1 Definitions

KVO

A Keep venous Open rate can be set to continue the infusion and maintain the venous access after the completion of the delivery of the programmed volume to be infused. The KVO rate can be preset in configuration menu. The actual KVO rate used will be the KVO rate or the basal rate whatever is the smallest. The KVO will last for 20 ml volume.

Note: *If this function is not required, it can be disabled. Refer to the Chapter 9, paragraph 9.2"Configuration Menu".*

Automatic restart of the infusion after occlusion release.

The infusion will be automatically resumed following an occlusion release, this happens when the pump has detected that the pressure is lower than the occlusion alarm level.

Note: *If this function is not required, it can be disabled. Refer to the Chapter 9, paragraph 9.2"Configuration Menu".*

Bolus rate

The rate to deliver bolus can be set in Configuration menu. The bolus rate can be set in a value between 50-100 ml/h.

Warning before end of infusion

The warning can be set either for remaining Volume or for remaining Time. If Volume is selected for warning, then it can be set from 1 to 10 ml inc. by 1 or it can be turned OFF. If Time is selected for warning, it can be set from 5-180 min or it can be turned OFF.

Note: *In Bolus Only mode the Time to warn before End Of Infusion cannot be used. In case pump is configured with Time to warn before End Of Infusion and a Bolus Only mode is selected then the pump will automatically enable the Volume to warn before End Of Infusion at the default value (3 ml).*

Note: *If this function is not required, it can be disabled. Refer to Chapter 9, paragraph 9.2 "Configuration Menu".*

Protection against infusing without priming (Prime)

There are two (2) levels of protection that can be configured. First level is Mandatory; infusion cannot start unless priming with the pump is done and a relevant message will be displayed on the screen. Second level is Warning, infusion can start without priming, a message appears on the screen, press Yes to continue with infusion.

Note: *If this function is not required, choose No warning. Refer to Chapter 9, paragraph 9.2 "Configuration Menu".*

Note: *If the set had been primed manually, choose Warning or No warning. Refer to Chapter 9, paragraph 9.2 "Configuration Menu".*
Detailed procedure for priming the line is displayed in Chapter 6, paragraph 6.1 "*Priming the Administration set line*".

Occlusion pressure level

The occlusion pressure level can be set in three levels: Low, Middle or High. Lowering the occlusion alarm level may generate unintended occlusion alarm. High viscosity medication, high delivery rate and catheter size increase the possibility of unintended occlusion alarms.

Request code to stop infusion

When this function is enabled from the configuration menu, infusion is protected from being stopped by using a code. This code is either the programming code or the new bag code.

Pain question

Pain level question is a numeric pain level scale that can be used to record patient pain level. Pain level question can be configured as Disabled, Enabled or On Bolus Request. When pain question is disabled, pain level question will not be accessible during infusion. When pain question is enabled, pain level question will be accessible only manually through during infusion or on hold. When pain question is set On Bolus Request, pain level question will appear on pump screen whenever a patient bolus is requested either through the bolus handset or through the purge/bolus button and also will be accessible manually as described above.

9.2 Configuration menu

Warning

- We recommend the default codes of the pump to be changed (through the configuration menu) in order to secure the access to different actions related to each code.
- The supervisor of the infusion should decide to whom each code and its related actions should be distributed. Incorrect pump programming could result in death or serious injury to the patient.

To access the configuration menu of the pump, make sure the pump is disconnected from the patient and it is turned OFF.

1. Turn the pump ON.
2. Enter the configuration code and press ↵.
3. Enter the "programming" code and press ↵.
4. Press ↵ to scroll along the parameters list to access to the values that need to be changed.

Description	How to select values	Your choice
Language selection	Use the ▼ key to select the language and press ↵.	
Time	Use the ▼ ▲ keys to adjust the time and press ↵.	
Date	Press ↵ to scroll down to the next parameter or use the ▼ ▲ soft keys to adjust the date and press ↵.	
Days of operation Service warning	Displays the number of full days of operation. Use the ⟳ key to select ✓ to activate the service warning or ☐ to disable it. Press ↵.	
Silent Keyboard	Use the ⟳ key to select ✓ to have no buzzer sound on key press or ☐ to have[1] each key press acknowledged by a buzzer sound tone. Bolus demands are always acknowledge by a buzzer sound tone. Press ↵.	
Backlight	Use the ⟳ key to select ✓ to enable[1] this function or ☐ to disable the backlight. Press ↵.	
Occlusion level	Use the ⟳ key to select High, Middle[1] or Low. Press ↵.	
Restart after occlusion release	Use the ⟳ key to select ✓ to enable[1] or ☐ to disable this function. Press ↵.	
Request code to stop infusion	Use the ⟳ key to select ✓ to enable[1] or ☐ to disable this function. Press ↵.	
Pain question	Use the ⟳ key to select Disabled, Enabled or On Bolus Request. Press ↵.	
Enable Clear totals	Use the ⟳ key to select ✓ to enable[1] this function in the History menu or ☐ to remove the function from the History menu. Press ↵.	
Dose limit / Bolus per hours	Use the ⟳ key to select ✓ to enable those functions in the programming menu or ☐ to remove those functions from the programming menu. Press ↵. *Both of the limits are enable by manufacturing default setting.*	
Time to lockout end	Use the ⟳ key to select ✓ to enable[1] or ☐ to disable this function. Press ↵.	
Enable Loading dose	Use the ⟳ key to select ✓ to enable[1] this function in the programming menu or ☐ to remove the function from the programming menu. Press ↵.	

[1] manufacturing default setting

Description	How to select values	Your choice
Bolus rate	Use the ▼ ▲ keys to set the bolus rate from 50.0 ml/h to 100 ml/h[1]. Press ↵.	
Keep Vein Open KVO rate	Use the ⟳ key to select ✓ to enable[1] or ☐ to disable this function. Use the ▼ ▲ key to set the KVO rate. KVO rate can't be activated if there is no basal rate. Press ↵.	
Time/Volume to warn before End Of Infusion	Use the left key to select which parameter you choose for the warning: Time or Volume[1]. If the warning is set to Volume: Press the ▼ ▲ keys to set from 1 to 10 ml. If the warning is set to Time: Press the ▼ ▲ keys to set from 5 to 180 min. Or you can choose OFF to disable this function. *Note: In Bolus Only mode the Time to warn before End Of Infusion cannot be used. In case pump is configured with Time to warn before End Of Infusion and a Bolus Only mode is selected then the pump will automatically enable the Volume to warn before End Of Infusion at the default value (3 ml).* Press ↵	
Prime	Use the ⟳ key to select No warning, Warning[1] or Mandatory. Press ↵.	
New patient – program code	Use the keys ⊟⊟⊟⊟ to enter your personal code. Press ↵.	
New bag code	Use the keys ⊟⊟⊟⊟ to enter your personal code. Press ↵.	
Resume after power off code	Use the keys ⊟⊟⊟⊟ to enter your personal code. Press ↵.	
Save and exit	Press Yes if your settings are correct.	

Press ⊙/O ON OFF to switch the pump OFF. Turn the pump ON and enter the programming code to review your settings.

Configured by: .....

according to the prescription of: .....

Date: ..... / ..... / .....

Pump SN: ..... to .....

10. Accessories and disposables

In this section you will find details for all Rythmic™ accessories dedicated to the Rythmic™ Evolution range.

Warning

Only accessories supplied from Micrel shall be used with the pump. Use of non-specified accessories may impair the operation of the pump and could result to patient death or serious injury.

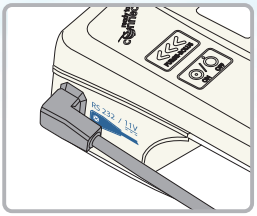
10.1 Alkaline Batteries Type for Rythmic™ Evolution

9V Alkaline IEC Type 6LR61			
Examples include			
Duracell	MN1604	Eveready	522
Rayovac	A1604	Kodak	K9V
Bright Star	7590	Panasonic	6AM6
Varta	4022	NEDA	1604A
Toshiba	6LF22		

10.2 External Power Adaptor

Warning

- Do not use other external power adaptor than the ones supplied by Micrel.
- External power adaptor should be used only indoors.
- The external power adaptor must no longer be used if the housing or cable becomes damaged.
- Ensure that the external power adaptor is not covered when in operation, is not in close proximity to a heating source and is not exposed to direct sunlight.
- The external power adaptor must not come into contact with liquids.



All Rythmic™ pumps can be powered using Micrel power adaptor in addition to the internal battery (9V alkaline or rechargeable). Please refer to Chapter 10 paragraph 10.7 *"Accessories"*. Micrel power adaptor is part of the Rythmic™ Evolution system.
Place the power supply to a mains socket and plug the cable end into the socket labelled RS 232 / 11V on the pump.

When the power adaptor is connected to the mains supply, the green LED indicator lights up.
When operating on mains, the mains symbol is displayed nearby the battery indication .
During operation, the housing of power adaptor may heat up.

In case of use the Micrel power adaptor with Rythmic™ Evolution with 9V Alkaline battery, Micrel power adaptor will not recharge the battery.
The alkaline battery must be in good condition as it assures continuation of infusion, in case of Mains power failure.
The use of the Micrel power adaptor does not inhibit the power of the alkaline battery and will not cancel any battery related warning or alarms. Micrel power adaptor is recommended to extend the life of internal battery and avoid battery alarms at night.
9V Alkaline battery may last for a year if Micrel power adaptor is always in use.
The unit does not require any maintenance and must not be opened or manipulated/ changed in any other way.

Caution

Always keep the internal battery (9V alkaline or rechargeable) inside the pump while the Micrel power adaptor is plugged to the pump.

10.3 Compatible administration set

Below is a list with the approved Administration sets and also their respective pump to be used with. The delivery accuracy of the below Rythmic™ Administration sets is less than ±5%.

Code	Description	Rythmic™ Evolution	Mini Rythmic™ Evolution	Rythmic™ Evolution Organiser	Not for IV use
Full set 160ml KM1.EE.100.x	Complete set with 160ml bag with filling port, air in line eliminating filter 0.22micron, antisiphon / back check valve and extension line.	X			
Full set 160ml 1.2u KM1.EE.135.x	Complete set with 160ml bag with filling port, air in line eliminating filter 1.22micron, antisi-phon /back check valve and extension line.	X			

Code	Description	Rythmic™ Evolution	Mini Rythmic™ Evolution	Rythmic™ Evolution Organiser	Not for IV use
Y full set 160ml KM1.EE.150.x	Complete set with Y connector. When the secondary line at administration sets with Y connection is not used, replace the cap present in Y connector with a closed cap.	X			
Full set 200ml KE1.EE.185.x	Complete set with 200ml bag with filling port, air in line eliminating filter 0.22micron, antisiphon /back check valve and extension line.	X			
Mini Full set 100ml KE1.EE.177.x	Complete set with 100ml bag with filling port, air in line eliminating filter 0.22micron, antisiphon /back check valve and extension line.	X	X		
Y Mini Full set 100ml KE1.EE.195.x	Complete Mini set with Y connector. When the secondary line at administration sets with Y connection is not used, replace the cap present in Y connector with a closed cap.	X	X		
Y Full set 200ml KE1.EE.196.x	Complete set with Y connector. When the secondary line at administration sets with Y connection is not used, replace the cap present in Y connector with a closed cap.	X			
Short set 160ml KM1.EE.140.x	To be used only with KM1.EE.141.x and not any other extension line.	X			
Short set 100ml KE1.EE.158.x	To be used only with KM1.EE.141.x and not any other extension line.	X	X		
Valve Extension set KM1.EE.141.x	It is exclusively used with Short set 160ml and Short set 100ml, NOT TO CONNECT WITH THE PUMP.	X	X		
Spike set KM1.EE.099.x	Set with vented spike connection, air in line eliminating filter 0,22micron, anti siphon/ back check valve and extension line. For use with external medication container.	X	X		
Spike set S KM1.EE.155.x	Set with vented spike connection, air in line eliminating filter 0,22micron, anti siphon/ back check valve and extension line. For use with external medication container.	X	X	X	
Spike set S.Y KM1.EE.187.x	Complete spike set with Y connector. When the secondary line at administration sets with Y connection is not used, replace the cap present in Y connector with a closed cap. For use with external medication containers.	X	X	X	
Green Spike set S KE1.EE.178.x	Complete spike set S with green tubing. For use with external medication containers.	X	X	X	
Green Spike set S with Surety connector KE1.EE.194.x	Complete spike set S with green tubing and SURETY NON LUER SAFE CONNECTOR. For use with external medication containers.	X	X	X	X

Code	Description	Rythmic™ Evolution	Mini Rythmic™ Evolution	Rythmic™ Evolution Organiser	Not for IV use
Yellow Full set 160ml KM1.EE.161.x	A Full set with yellow stripped tubing and 160ml bag.	x			x
Yellow Mini Full set 100ml KE1.EE.167.x	A Mini Full set with yellow stripped tubing.	x	x		x
Yellow Full set 200ml KE1.EE.190.x	A Full set with yellow stripped tubing and 200ml bag.	x			x
Yellow Spike set KM1.EE.160.x	A Spike set with yellow stripped tubing. For use with external medication container.	x	x		x
Yellow Spike set S KM1. EE.162.x	A Spike set S with yellow stripped tubing. For use with external medication container.	x	x	x	x
Yellow Spike set S with Surety connector KE1.EE.193.x	A Spike set S with yellow stripped tubing and SURETY NON LUER SAFE CONNECTOR. For use with external medication container.	x	x	x	x
Luer set KE1.EE.197.x	Set with male luer lock connection, air in line eliminating filter 0,22micron, anti siphon/ back check valve and extension line. For use with external medication container.	x	x		

10.4 IP connect Pack

Warning

Ensure that IP Connect Pack is ON to supply power to the pump.

All the pumps of Rythmic™ Evolution range can be equipped with IP Connect Pack accessory, a GPRS type of mobile phone to send or receive data. IP Connect Pack can be used to connect the pump to MicrelCare Server based on Internet and mobile communications. IP Connect Pack gives the ability to medical staff to monitor in real time the infusion from distance and receive information regarding:

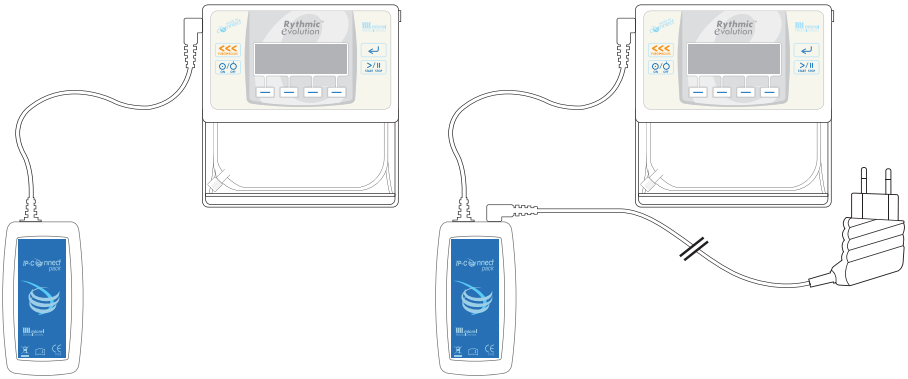
- progress of infusion
- alarms
- battery status
- pain level

IP-Connect Pack can operate as an external battery source, supplying power to the pump connected.

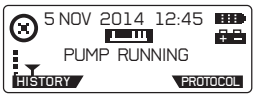
Connect the IP Connect Pack cord to the pump via the socket labelled 

on the pump. Refer to the IP Connect Pack Directions For Use for detailed operation and configuration of IP Connect Pack.
Access to Micrelcare is subject to a special procedure to open an account. Please, refer to your local contact for further details. For detailed information regarding the operation of MicrelCare, please refer to “MicrelCare” DFU.

Connection to pump and power adaptor



The operation of IP Connect Pack does not interfere with the pump.
Connection and operation of IP Connect Pack can be noticed in absence of any alarm or warning.



On the main screen two logos are displayed: a small antenna to mention the IP Connect Pack is connected to the pump and when sending data, waves comes out of the antenna 

When IP Connect Pack is ON and connected to the pump, the IP Connect Pack key appears in the History screen, providing some information on IP Connect Pack module.
When IP Connect Pack rechargeable battery is low, a message will be displayed on the pump advising to recharge the IP Connect Pack battery.

Caution

- Prior to using the IP Connect Pack accessory for the first time, use the Micrel power adaptor to fully charge the internal rechargeable battery.
- Always keep the internal battery (9V alkaline or rechargeable) inside the pump while the IP Connect Pack is plugged to the pump.

10.5 Using carrying bag and carrying belt.

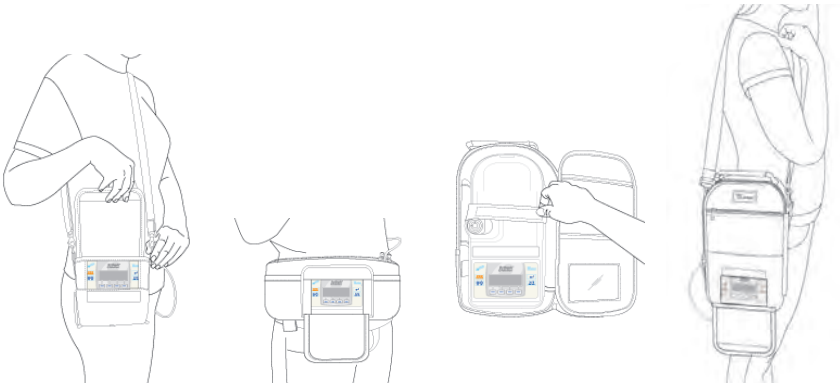
Warning

- Ensure that the spike connector is properly attached to the external medication container. Spike detachment from the external medication container could result in under or non-delivery of medication.
- When rigid - non collapsible external medication containers (e.g. glass bottles, hard plastic bag) are used with a Rythmic™ spike set, then the air vent on the spike must be opened and the container must be suspended from a pole.
- When rigid – non collapsible external medication containers (e.g. glass bottles, hard plastic bag) are used in ambulatory infusion (infusion during transportation), ensure that the external medication container is always placed vertical.
- In Rythmic™ Evolution Organiser pump range, the container must be suspended by the bag hook placed inside the pump's transparent cover.
- All Rythmic™ Evolution Organiser pumps should be placed in pole, in non-ambulatory infusion.
- All Rythmic™ Evolution Organiser pumps can be transported using carrying belt, handle or carrying bag. Ensure that the container inside the Organiser remains always in vertical position.
- Only collapsible containers should be used when the Mini Rythmic™ pump operates in waist-shoulder carrying bag.
- In all above cases, failure to follow the instructions may result in under or non-delivery of medication and air infusion may occur, which could result in death or serious injury to the patient.
- Ensure that the transparent covers are securely closed, to prevent patient access to medication container.
- Ensure that the administration set has been properly installed and has not been trapped in transparent covers or inside the carrying bag, as this may result in under or non-delivery of medication, which could result in death or serious injury to patient.
- Ensure that the release lever is locked in closed position and the tubing cover is closed firmly. If the release lever or the tubing cover become loose may result in under or non-delivery of medication.

A wide range of carrying bags suitable for each model are available, please refer to Chapter 10 paragraph 10.7 *"Accessories".*

The pump can be fitted into the carrying bag supplied; this will provide a convenient way of carrying the pump for portable use. The carrying bag can be fitted to a belt or suspended by the strap supplied.

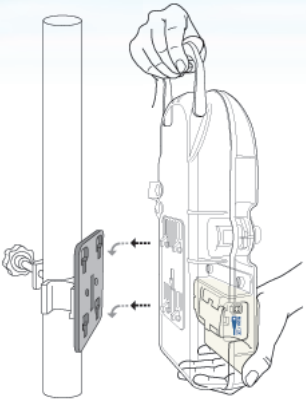
- Open the carrying bag.
- Fit the pump with the display visible through the clear display window.
- Align the set to the back of the pump as shown. Ensure that the extension lines are not trapped in the bag.
- Close the carrying bag.

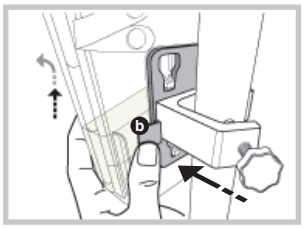


For Rythmic™ Evolution Organiser 500 and 501 except the carrying bag, can also be used the carrying belt for portable use.

- Insert the one clip of the belt in the hole placed on the carrying handle.
- Repeat the same for the other clip of the carrying belt with the other hole on the carrying handle.

10.6 Using IV pole clamp.

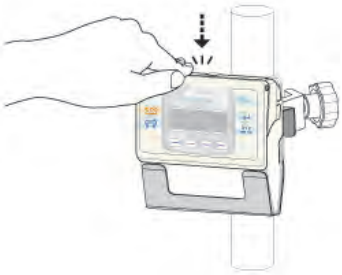


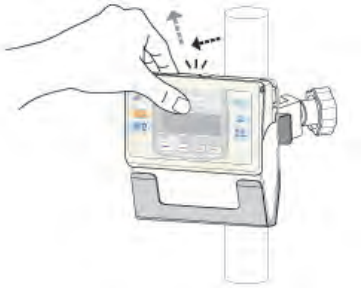


Rythmic™ Evolution Organiser

Ensure the pole clamp is secured to an IV pole able to sustain the pump and bag weight.

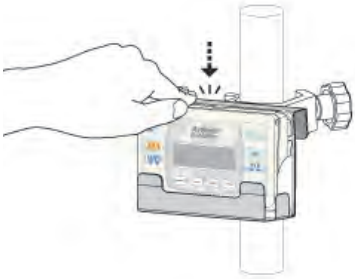
- Securely fix the pole clamp on the IV pole.
- Introduce the 4 inserts located at the rear side of the pump and slide down until a “click” is heard.
- Ensure the pump is fully secured in the pole clamp and that the extension lines are not trapped in pole clamp.
- The IV pole clamp provides a location to store the Micrel Power Adaptor when not in use.
  The pump can be securely lock to the pole clamp.
- To unlock the pump from the pole clamp push the black knob ⓑ located in the transparent cover and pull the pump outward and upward, as shown in the pictures below.





Rythmic™ Evolution and Mini Rythmic™ Evolution

Fit the pump with the display visible. Ensure the pump is fully secured in the pole clamp and that the extension lines are not trapped in pole clamp.



10.7 Accessories

A comprehensive list of accessories for the Rythmic™ Evolution pumps is included in the Product Catalogue. This can be ordered from Micrel Medical Devices, or authorized distributor.

Indicative list of accessories for Rythmic™ Evolution pumps

Code	Description
KP5.04.271.x	IP Connect Pack with power adaptor
KP5.04.250.x	Rythmic™ Manager Pack
KM1.YY.506.x	Waist/shoulder carrying bag
KM1.YY.417.x	Carrying bag for Rythmic™ + IP Connect Pack
KM1.YY.415.x	Carrying bag for Rythmic™
KM1.YY.547.x	Disposable Carrying bags for Rythmic™
KM1.YY.548.x	Disposable Carrying bags for Rythmic™ Organiser 500/501
KM1.YY.566.x	Disposable Carrying bags for Mini Rythmic™
KM1.YY.318.x	Carrying bag 200-500 ml with belt for Rythmic™
KM1.YY.365.x	Carrying bag 200-500 ml with belt for Mini Rythmic™
KM1.YY.317.x	Isothermal carrying bag for Rythmic™ (Flolan therapy)
KM1.YY.504.x	Carrying bag for Rythmic™ 500ml XL
KM1.YY.539.x	Carrying Bag for Two Rythmic™ Pumps
KM1.YY.418.x	Carrying Bag for Rythmic™ 500/501
KM1.YY.451.x	Carrying Bag for Rythmic™ 100/101
KS5.01.410.x	Patient demand switch V.x
KS5.01.430.x	Pole Clamp Rythmic™
KS5.01.524.x	Pole Clamp Rythmic™ 500/501
KS5.01.525.x	Pole Clamp Rythmic™ 100/101
KS5.01.615.x	Micrel Power Adaptor nc
KS5.04.021.x	Micrel Power Adaptor nc UK plug
KS5.04.046.x	MicrelCom system (RS232 & USB)

11. Precautions & Maintenance

11.1 Routine Maintenance Procedures

Warning

- Equipment can be modified as described in service manual by trained service personnel with valid certificate. Appropriate inspection and testing according to service manual, must be conducted to ensure safe use of the equipment.
- There are no user serviceable parts or user replaceable parts within the pump, except 9V alkaline disposable battery.
- Do not attempt to service the pump, only qualified service personnel can perform service / preventive maintenance.

Contact your healthcare professional regarding any required service.

All servicing should be performed by a qualified service engineer with reference to the MICREL Service Manual for this product. 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. Only trained technicians can perform service / preventive maintenance. In order to send the equipment for service / preventive maintenance, place the pump with its accessories in the original package, if available.

Preventive maintenance must be performed every 3 years or 1000 days of infusion and only by authorized service personnel.

11.2 Cleaning and disinfection

Warning

- Ensure that the pump is OFF and disconnected from any power supply before commencing the cleaning / disinfection procedure.
- In order to avoid cross-contamination, for each equipment use a new clean, lint- free cloth and pair of gloves and discard them after use, according to local protocols.
- During cleaning / disinfection procedure, pay attention that disinfectant solution does not go inside connectors.
- Always inspect the battery terminals for debris, grime and damages. If debris or grime exists, clean the terminals according to cleaning instructions. If the debris or grime persists or damage exists remove the device from service. Debris, grime or damage of the battery contacts could result in loss of power and non delivery of medication.

11.2.1 Cleaning procedure for pump

To insure that the equipment remains in good operating condition, it is important to keep it clean. Clean the pump periodically following the below described procedure.

1. Wear a new pair of protective sulphur free gloves and eye protection if splashing is likely to occur.
2. Slightly damp a clean, soft, lint -free cloth (microfiber) with solution of mild soap (pH 7-8) and warm water (up to 30˚C/86˚F) and wring thoroughly. Make sure that it is not dripping.
3. Wipe the pump using the damped cloth. Do not clean the area under the tubing cover. This area must be cleaned by special trained personnel.
4. Slide the battery door and remove the battery. Wipe the battery compartment.
5. Scrub and clean the surface of the battery terminals using a clean, soft, lint-free cloth (microfiber) with lightly damped with isopropyl alcohol. Do not use isopropyl alcohol to clean other parts of the device than the battery terminals
6. Wipe the surface to dry using a clean, soft, lint-free cloth damped with water.
7. Let air dry. Do not use compressed air to dry the pump.

11.2.2 Disinfection procedure for pump

In order to disinfect the pump, after cleaning procedure please follow the below described procedure. Disinfection must take place regularly and always when the user is changed.

8. Use one of the recommended disinfectant solutions listed below to spray 2 or 3 times on a clean, soft, lint-free cloth (microfiber). The cloth must be slightly damp with the sprayed disinfectant.
9. Wipe the pump using the damped cloth and repeat wiping for 5min.
10. Open the transparent covers and wipe the pump inside. Do not open the tubing cover to disinfect inside. This area must be cleaned by special trained personnel.
11. Wipe the surface to dry using a clean, soft, lint-free cloth damped with water.
12. 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. The disposable equipment must be discarded according to local regulations.

Wipe Information

material and weight: Non-woven PET (30%) / viscose (70%) blend, 50g/m2

size: 100 x 150 mm or
100 x 200 mm

Caution

- 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, ethylene oxide sterilise or immerse this Rythmic™ in any fluid.
- 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.
- **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.

Recommended Cleaning solutions and Disinfectants for Rythmic™ pumps' exterior surface

	Chemical type	Trade name / Manufacturer
1.1	Hydrogen Peroxide solution up to 10% w/w	Oxivir Spray E2n / JohnsonDiversey 0.1-1% w/w
		SteriMax Sporicide Wipes / Aseptix (1% w/w)
		Revital-Ox XL HLD / STERIS (2.3%)
1.2	Hydrogen Peroxide <1% w/w & Phosphoric Acid <1% w/w	Percept / Diversey diluted 1:16
1.3	Hydrogen Peroxide 2.5% w/w & Glycolic Acid 2.5% w/w	Indicin OxyWipe S / ECOLAB
2	Ethanol >95% aq. Solution (**no other ingredient**)	
3	Peracetic acid at 0.2-0.35% concentration	
4	Mild solution of soap water (PH:7-8)	

11.2.3 Cleaning and disinfection procedure for accessories

Warning

- Ensure that the IP Connect Pack is OFF and disconnected from the mains supply and from the pump before commencing the cleaning/disinfection procedure.
- Ensure that the bolus handset and the power adaptor are disconnected from the pump and from the mains supply (for power adaptor) before commencing the cleaning / disinfection procedure.

1. Bolus handset, IP connect Pack and power adaptor

1. Wear a new pair of protective sulphur free gloves and eye protection if splashing is likely to occur.
2. Slightly damp a clean, soft, lint -free cloth (microfiber) with solution of mild soap (pH 7-8) and warm water (up to 30˚C/86˚F) and wring thoroughly. Make sure that it is not dripping.
3. Do not clean the area under the battery cover for IP Connect Pack, inside of the connector at the end of the cable for both IP Connect Pack and Micrel Power adaptor and the metal parts of the plug.
4. Wipe the surface to dry using a clean, soft, lint-free cloth damped with water.
5. Let air dry. Do not use compressed air to dry the accessories.
6. Use one of the recommended disinfectant solutions listed in paragraph 11.2.2 to spray on a clean, soft, lint-free cloth (microfiber). The cloth must be slightly damp with the sprayed disinfectant.
7. Wipe the accessory using the damped cloth and repeat wiping for 5min.
8. Do not open the battery cover of the IP connect Pack to clean inside.
9. Be careful not to clean inside the connectors and the metal parts of the plug.
10. Wipe the surface using a clean, soft, lint-free cloth damped with water.
11. Let air dry. Do not use compressed air to dry the accessories.

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

2. Carrying bag (except disposable carrying bags, they are single use)

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 listed in paragraph 11.2.2 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 for 5min.
4. Be careful not to clean the metal parts of the carrying bag.
5. Wipe the surface 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.

Caution

- 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 equipment damage, cleaning solutions must be used according to the table displayed in paragraph 11.2.2 and manufacturer reccommendations.
- Do not use hard or pointed objects to clean accessories.
- Do not spray directly cleaning fluids on the accessories.
- Do not steam autoclave, ethylene oxide sterilise or immerse accessories in any fluid.
- Do not use UV radiation to disinfect the accessories.
- Do not use compressed air to dry the accessories.
- Do not mix the disinfectant with any other product or chemical.
- **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.

11.3 Storage

If the pump is to be stored for a long period of time (more than 3 months) it should be cleaned. Store the pump according to storage condition described in Chapter 12, paragraph 12.6 "*Enviromental Conditions*" and if available, employ the original packaging for protection.

For pumps with alkaline battery:
the alkaline battery should be removed.

For pumps with rechargeable battery:
Do not store the pump with the rechargeable battery depleted. If the pump is to be stored for a long period of time, every three months recharge the battery by connecting the pump to a power adaptor connected to mains, for 1 hour to maintain battery's good condition and prolong battery's life time.

11.4 Disposal

This symbol on the product indicates that collection of electrical and electronic equipment must not take place together with ordinary domestic waste and that it must be treated as WEEE, Waste Electrical and Electronic Equipment. This product contains electronic components and batteries that may be harmful to the enviromment, and should not be mixed with municipal waste. According to the directives for "Waste Electrical and Electronic Equipment 2012/19/EC" and "Material content, Labeling and Recycling of Batteries 2006/66/EC", the consumers within the European Union should properly dispose the product and the used batteries in an environmentally safe manner using the local collection and recycling points.
Contact Micrel's Authorised Distributor or Micrel Customer Support for specific instructions regarding disposal.
For consumers outside European Union the disposal or recycling of the used batteries and the product at the end of its useful life should be according to any goverment or local regulations that apply.
The correct dispose of the used batteries and the product at the end of its useful life will prevent any negative effects on the enviromment and human health which could arise from inappropriate waste handling.

12. Technical Description

Warning

- Equipment can be modified as described in service manual by trained service personnel with valid certificate. Appropriate inspection and testing according to service manual, must be conducted to ensure safe use of the equipment.
- There are no user serviceable parts or user replaceable parts within the pump, except 9V alkaline disposable battery.

All servicing / maintenance should be performed by a qualified service personnel with reference to the MICREL Service Manual for this product. A comprehensive service manual containing circuit descriptions, component part list, servicing and testing information is available on request. It can be ordered from Micrel Medical Devices or Micrel Medical Devices authorized distributor. Only trained technicians can perform service / preventive maintenance.

12.1 Regulatory Compliance

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**
Electrical safety classification for applied part, as per EN60601-1 and EN 6001-2-24	**CF**
Complies with EN60601-2-24.	

Declaration of Conformity can be available upon request.

12.2 Specifications

	Rythmic™ Evolution	Mini Rythmic™ Evolution	Rythmic™ Evolution Organiser 500 / 501	Rythmic™ Evolution Organiser 100 / 101
Weight with battery	335 g	300 g	740 g / 770 g	670 g / 700 g
Dimensions in mm: Width Height Depth	130x133x46 Including 160 ml/200 ml bag	130x75x46 Including 100 ml bag	157x299x82 Including 500 ml standard bag	148x249x69 Including 100 ml standard bag
Graphical display	65 X 31 mm, 132 X 40 pixels			
Class II device (double insulation on power adaptor)				
Degree of protection against fluid ingress IPX4				
Internal Battery Autonomy	9 days minimum at 2 ml/h 36 hours minimum at 25 ml/h 28 hours minimum at 100 ml/h			
External Battery input	6-9 Vdc 500 mA IP Connect Pack			
Micrel Power Adaptor	IN:100-240 v ~ 50-60 Hz 90 mA OUT: 11 Vdc 500 mA			

12.3 Performance & Protocol parameters

Volume to be infused	1 to 9999 ml 1 ml increment (inc)
Volume infused	0.1-9999.9 ml 0.1 ml inc. 0.1 mg to 9999.9 mg 0.1 mg inc. 0.1 µg to 9999.9 µg 0.1 inc.
Programming units	ml/h; mg/h; µg/h
Concentration	0.1-99.9 mg/ml 0.1 mg/ml inc. 0.1-999.9 µg/ml 0.1 µg/ml inc.
Basal Rate	From 0 to 100 ml/h 0.1 ml/h inc. (0 to 50 ml/hr when bolus is on), 0.1 to 999.9 mg/h 0.1 mg/h inc. 0.1 to 999.9 µg/h 0.1 µg/h inc.
Rate Accuracy	±5% nominal
KVO	0.1 to 2.0 ml/h KVO limited in volume to 20 ml.
Automatic Bolus Dose	0 or from 0.1 ml to 60.0 ml 0.1 ml inc. 0.1- 999.9 mg 0.1 mg inc. 0.1- 999.9 µg 0.1 µg inc.
Automatic Bolus Frequency	0 to 9 h 59 min 1min inc.
Bolus Dose	0 or from 0.1 ml to 60.0 ml 0.1 ml inc. 0.1- 999.9 mg 0.1 mg inc. 0.1- 999.9 µg 0.1 µg inc.
Bolus accuracy	±5% nominal according to IEC 60601-2-24
Bolus Lockout interval	0 to 9 h 59 min 1 min inc.
Priming Rate	Automatic adjustable, maximum 100 ml/hr
Bolus Rate	From 50 to 100 ml/h, 10 ml/h inc.
Dose Limit Volume	OFF or from 0 to 9999 ml 1ml inc. or 9999 mg 1 mg inc. or 9999 µg from 0.1-99.9 µg/ml 1µg inc. and 99990 µg from 100.0 - 999.9 µg/ml 10 µg inc.
Bolus limit	Off or from 0 to 999 boli 1 bol inc. limited to 100 ml/h
Dose Limit & bolus limit interval	1-9 HR 1 hr inc.

Loading dose	OFF or from 0.1 ml to 60.0 ml 0.1 ml inc. 0.1- 999.9 mg 0.1 mg inc. or 0.1- 999.9 µg 0.1 µg inc.
Clinician Override Bolus	OFF or from 0.1 ml to 60 ml 0.1 ml inc. 0.1- 999.9 mg 0.1 mg inc. or 0.1- 999.9 µg 0.1 µg inc.
Maximum infusion pressure	2 bar (1500 mm Hg, 29 psi, 200 kPa)
Occlusion alarm (3levels)	Low: $0.8^{+0,4}/_{-0.4}$ bar ($600\ mmHg^{+300}/_{-300}$, $11.6\ psi^{+5.80}/_{-5,80}$, $80\ kPa^{+40}/_{-40}$,) Middle: $1.2^{+0,4}/_{-0.4}$ bar ($900\ mmHg^{+300}/_{-300}$, $17.4\ psi^{+5.80}/_{-5.80}$, $120\ kPa^{+40}/_{-40}$,) High: $1.6^{+0,4}/_{-0.4}$ bar ($1200\ mmHg^{+300}/_{-300}$, $23.2\ psi^{+5.80}/_{-5.80}$, $160\ kPa^{+40}/_{-40}$)
Coded access	3 levels

12.4 Historic

Infusion monitoring	
	• Patient Bolus demand • Patient Bolus delivered • Total infused in ml and mg or µg • Volume to be infused • Hour by hour delivery analysis • Graphical infusion trend analysis
Event Log	
	• 6500 time stamped events • Protocols and protocol changes • Alarms • Patient bolus attempt and patient bolus delivered. • ON OFF, Loading dose, Clinician dose, set change
PC connection	
	• RS232 output • Data download • 9600 bds, 8 bit, no parity, one stop bit, Xon/X off flow control

12.5 Performances

Memory retention		10 years
Expected service life		10 years
Maximum over infusion volume under single fault condition		0.5 ml
Max Accuracy error (pump speed) under single fault condition		± 5%
Rate accuracy in all available range remains within acceptable limits when:		
temperature range		+ 5˚C to +40˚C
delivery rate range		0.1 ml/h – 100 ml/h 0.1 to 999.9 mg/h 0.1 to 999.9 µg/h
Max time to occlusion PL1	@ 1 ml/h @ 25.0 ml/h @ 100.0 ml/h	280 sec 10 sec 4 sec
Max time to occlusion at PL3	@ 1 ml/h @ 25.0 ml/h @ 100.0 ml/h	380 sec 17 sec 4 sec
Bolus at occlusion release at PL1 @ 25.0 ml/h Bolus at occlusion release at PL1 @ 25.0 ml/h		0.1 ml max

12.6 User Interface Alarms & Warnings

- Occlusion detection
- End of infusion / Programmed volume limit reached
- Depleted battery
- Open mechanism
- Program error
- Technical error
- Dose limit alarm
- Bolus limit alarm
- Near end Of infusion / Pre-end of programmed volume or time limit
- Low battery
- IP connect Pack low battery
- No patient bolus allowed
- Running KVO
- Dose limit reached. Bolus not allowed
- Preventive maintenance date
- Real time clock battery low
- Keyboard continuously pressed
- Value out of range
- Stand by audible buzzer sound every minute

12.7 Safety features

- Dual microprocessor based technology
- Lockable protective cover for drug container
- Differentiated access code for programming, set replacement and patient access
- Event log
- Anti-siphon valve and air eliminator integrated on consumables
- Code protected stop of infusion
- Protocol Library via Rythmic™ Evolution Therapy Manager

12.8 Miscellaneous

- Prime function
- Service date warning
- Pump configuration
- Programming via PC application
- Variable alarm tone
- With separate Micrel IP Connect Pack infusion can be monitored through internet

12.9 Environmental Conditions

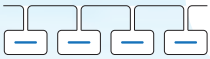
	Operating
Ambient Temperature	+5˚C - +40˚C
Relative Humidity	15% - 93%
Atmospheric Pressure	700 hPa – 1060 hPa
	Transport / Storage
Ambient Temperature	-25˚C - +70˚C
Relative Humidity	5% - 93%
Atmospheric Pressure	700 hPa – 1060 hPa

12.10 Symbol Definition

Consult instructions for use	
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 holster.	**IPX4**
Device complies with requirements of Medical Device Directive 93/42/EEC. Registered with the CE Mark.	
Manufacturer's address	
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.	
Class II device (double insulation on power adaptor)	
Do not use if package is damaged	
Do not re-use	
Do not resterilize	

Not for IV use	
Sterilized using ethylene oxide	
Non pyrogenic	
Non-pyrogenic fluid path	
Date of manufacture	
Batch code	
Expiry date	
Catalogue number	
Priming volume	
Temperature limitation for storage and handling	

Latex free	
DEHP free	
U.S. federal law restricts this pump to sale by or on the order of a physician.	
Aseptic technique required.	
Bio-hazardous waste. Dispose according to hospital's protocols.	
Storage volume	
Pressure	
Keep away from sunlight	
Keep away form rain	
ON / OFF button	
ENTER button	

Soft key function depends on the respective display symbol or label.	
Purge - Bolus button	
Start / Stop button	
Battery level indicator	
Rythmic™ Evolution supplied from the DC adaptor	
Rythmic™ Evolution supplied from IP Connect Pack	
External power adaptor inlet/ RS 232 output	
Battery type	IEC 6LR61
Battery polarity	
Bolus inlet	
Key inlet	

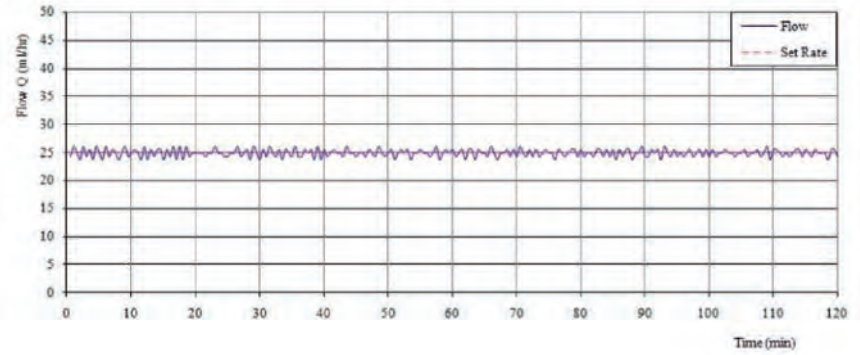
EAN number	
Do not use Dryer	
Do not iron	
Machine wash cold	
Do not use bleach	
Dry in the shade	
Do not wring	
Serial number with year code. The first 2 digits (YY) represents the production year of the pump.	YYXXWWAAABBB

12.11 Trumpet Curves

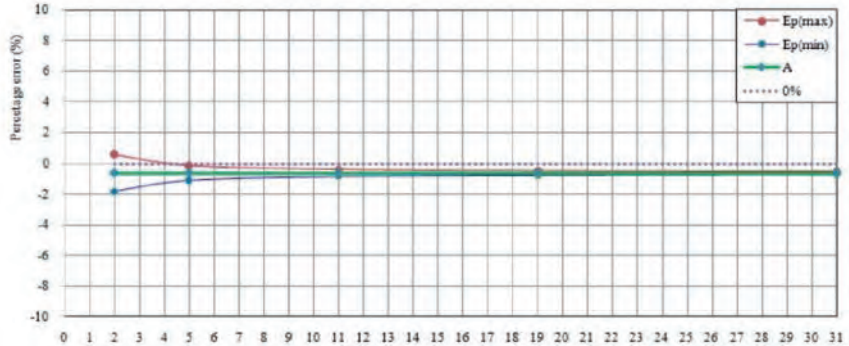
In this pump, as with all infusion systems, the action of the pumping mechanism and variations in individual sets cause short-term fluctuations in rate accuracy. The following curves show typical performance of the system in two ways:
1) the accuracy of fluid delivery over various time periods is measured (trumpet curves), and
2) the delay in onset of fluid flow when infusion commences (start-up curves).

The test protocol used to obtain these results is described in the EN 60601-2-24. For further information, please refer to this IFU.
This graph is therefore representative of pump and sets 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.

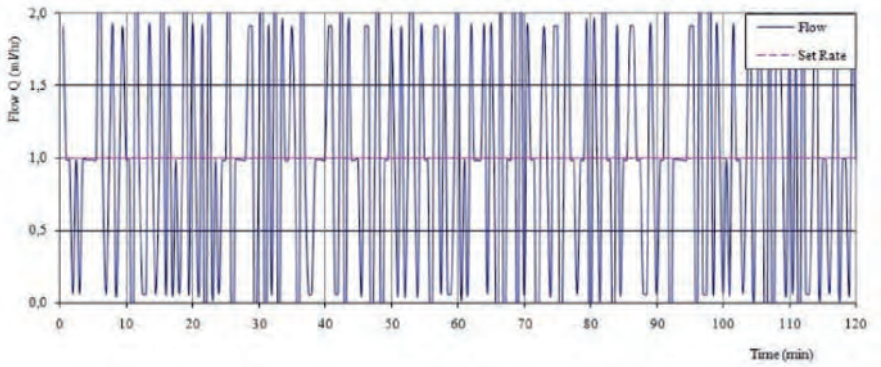
Start- up curve @ 25.0 ml/h



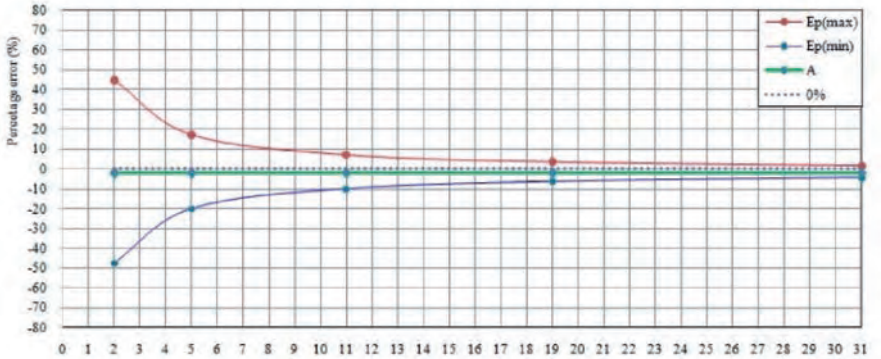
Trumpet Curve @ 25.0 ml/h



Start-up Curve @ 1.0 ml/h



Trumpet Curve @ 1.0 ml/h

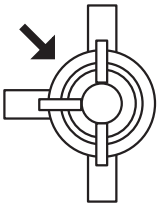


12.12 Operating Precautions

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 authorised distributor.

According to EN60601-2-24 , this pump 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 minimise the effects, for instance by repositioning or relocation.
An explosion hazard exists if the pump 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.

This equipment generates, uses, and can emit RF energy. If not installed and used in accordance with the instructions in this manual, electromagnetic interference may result. The equipment has been tested and found to comply with the limits set forth in EN60601-1-2 and EN 60601-2-24 for Medical Products. These limits provide reasonable protection against electromagnetic interference when operated in the intended use environments (e.g. hospitals) described in this manual.



MRI Notice
This equipment contains electromagnetic components whose operation can be affected by intense electromagnetic fields.
Do not operate the equipment in a MRI environment or in the vicinity of high-frequency surgical diathermy equipment, defibrillators, or short-wave therapy equipment. Electromagnetic interference could disrupt the operation of the pump.

The pump should not be directly irritation by therapeutic levels of ionizing radiation because the equipment may be permanent damaged. The best practice is to remove the equipment from the patient during therapeutic radiation or diagnostic levels of radiographic and fluoroscopic radiation. If the pump must remain in the vicinity during a diagnostic or therapy session

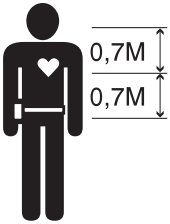
must be shielded and its ability to function properly must be confirmed following treatment.

Magnetic fields produced by magnetic resonance imaging (MRI) equipment may adversely affect the operation of the pump.
Remove the equipment from the patient and keep it away from the magnetic field.

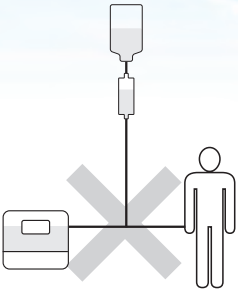
To ensure correct and accurate operation, only use Rythmic™ Administration sets. Use of non-specified reservoirs or administration sets may impair the operation of the pump and the accuracy of the infusion.

When combining several apparatus and/or pumps with administration sets and other tubing, for example via a 3-way stopcock 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 sets that can resist pressures of up to 2000 HPa.
The pump is designed to infuse any medical substance that can be injected. The physiological effects of medicine can be influenced by the characteristics of the pump and infusion sets used. 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 patient's heart.
Uncontrolled flow or siphoning may result if the administration line is removed from the pump before it is properly isolated from the patient. Isolation may include activating a flow stop clamp.

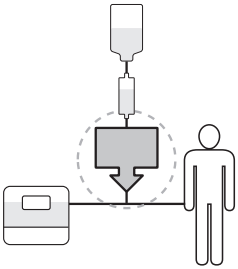


While in use, negative pressure variation may occur in the set, by the relative height from the device to the injection site or by combined infusion devices such as blood pump, alternative clamp, etc.
During infusion, the vertical distance between the pump and the injection site should be one meter height maximum.
When the device is placed higher than the injection site, please pay attention to correctly secure the set and manipulate it only when the infusion set is clamped or disconnected from patient side.



High vacuum or suction may create fluid siphoning. In this situation, you must check the integrity of the set used (possible leakage). In order to address those issues our sets are fitted with an anti-siphon valves or need to be used with an anti siphon valve inserted in the line.

Pressure variation may generate flow discontinuity mainly noticeable at low flow rates and depending upon the infusion system characteristics such as infusion set compliance, stickiness, compliance of syringes and mechanical back lash. Anti-siphon valves will also eliminate any risk of free flow during set changes. The vertical distance between the top level of fluid administered inside the container and the injection site should be one meter height maximum. An air leakage in a set with a line not equipped with an anti-siphon valve may generate an uncontrolled flow delivery.



Do not use in conjunction with positive pressure infusion devices that could generate back pressure higher than 2000 HPa susceptible to damage infusion administration set and the pump.

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 pump line as near to the patient side as possible in order to minimise the dead space and consequently the impact of any change in flow rate on the feeder line.

12.13 Technical Information

Electromagnetic Compatibility (EMC) Information

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC). Radio frequency (RF) communications equipment can affect devices such as Rythmic™ Evolution pump. As such, the pump should not be adjacent to these type of 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 Rythmic™ pump. Refer to Chapter 10, paragraph 10.7 "*Accessories*"

Guidance and manufacturer's declaration: electromagnetic emissions

Emissions test	Compliance	Electromagnetic environment/guidance
RF emissions CISPR 11	Group 1	The Rythmic™ Evolution 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 Rythmic™ Evolution pump is suitable for use in all establishments, including domestic surroundings.
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration: electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment/ guidance
Electrostatic discharge (ESD) IEC61000-4-2	± 6 kV contact ± 8 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode N.A.	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment/guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Rythmic™ Evolution pump, including cables, than the recommended separations distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=(3/3.5)\sqrt{P}$ $d=(3/3.5)\sqrt{P}$ 80 MHz to 800 MHz $d=(7/10)\sqrt{P}$ 800 MHz to 2.5 GHz 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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	

*Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic 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 above, 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 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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

The Rythmic™ Evolution 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 80 MHz and 800 MHz, 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.*

micrel
Medical Devices

WARRANTY

Micrel Medical Devices (here in after referred to as “Micrel”) warrants that:
(A) Each new Rythmic™ Evolution pump is free from defects in material and workmanship under normal use and service for a period of one year from the date of delivery by Micrel to the first purchaser.
(B) Each new accessory is free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by Micrel to the first purchaser.
If any product requires service during the applicable warranty period, the purchaser should communicate directly with the local Micrel service centre to determine appropriate repair facility. Repair or replacement will be carried out at Micrel’s expense, subject to the terms of this warranty. The product requiring service should be returned promptly, properly packed, and postage prepaid. Loss or damage in return shipment to Micrel shall be at purchaser’s risk.
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 repaired by anyone other than an authorised Micrel service representative or 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.
This warranty is in lieu of all other warranties, expressed or implied, and of all other obligations of liabilities on Micrel’s part, and Micrel neither assumes nor authorises any representative or other person to assume for it any other liability in connection with the sale of Micrel products. See packing inserts for international warranty.
Micrel disclaims all other warranties, express or implied, including any warranty of merchantability for function of fitness for a particular purpose or application.

Service Contacts

For service contact your local Micrel Medical Devices Office or Distributor:

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

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CE 1639

This pump is designed and manufactured in European Union-Greece, by Micrel Medical Devices S.A. Micrel Medical Devices reserves the right to alter product specifications without notice.

Pump patented under one or more of the following Micrel Medical Devices patents: EP0560270, EP0858812, US5980490

Published by Micrel Medical Devices.

All possible care has been taken in the preparation of this IFU, but Micrel reserves the right to make changes without notice both to this IFU and to the product which it describes. Micrel seeks to constantly improve its products; therefore, the specification for this device is subject to change.

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