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Medical Devices

# URGENT FIELD SAFETY NOTICE

**Affected Devices:** Rythmic Evolution product family

**Type of Action:** Field safety corrective action

**Ref.:** FSN2018-01

| | |
|---|---|
| **Date:** | 12 March 2018 |
| **Attention:** | Distributors, Biomedical Professionals, Homecare providers, Clinicians and other healthcare professionals involved with these devices |
| **Details on affected devices:** | **Rythmic Evolution** (all models, see Appendix 3)<br>**with serial number up to and including 174611237019**<br>(software version 1.4-A or earlier) |

Dear Valued Customer,

Micrel Medical Devices is issuing this field safety notice to notify you about a voluntary Field Safety Corrective Action for Rythmic Evolution ambulatory infusion pumps.

Micrel Medical Devices has identified an issue in the protocol library programming function of the affected devices. Under certain combination of events, the device may present to the operator for validation different infusion parameters and protocol name than those specified for the selected protocol. Micrel Medical Devices has not received any reports involving a serious injury or death related to this issue.

**Only Rythmic Evolution devices configured with a protocol library are affected by this issue.**

**Description of the problem**

The problem may appear after the installation of a protocol library that includes only one protocol and is replacing an existing protocol library in the device and furthermore, only if the last selected protocol of the replaced library was the second in the list. Under these conditions, when the operator selects the protocol to program a new infusion, the pump will present to the operator for validation different infusion parameters and protocol name than those specified for the selected protocol.

The infusion parameters and the protocol name are always presented to the operator for review and verification after the selection of a protocol and before the start of the infusion therapy. As described in the Instructions For Use, the operator should always validate the infusion protocol by checking all parameters before starting the infusion. Under the above mentioned conditions and sequence of events, if the operator mistakenly confirms the potentially inconsistent displayed parameters and name of the protocol and initiates the infusion, the patient may

receive incorrect infusion. The related risk is low, as the occurrence probability of the initiating conditions is low and the issue is likely to be noted during infusion programming if the Instructions For Use (IFU) are followed.

**Advise on action to be taken by the user:**
Subject to this Urgent Field Safety Notice, Micrel Medical Devices is requiring its customers to inspect the inventory and identify any affected devices.

If the affected devices of your inventory are configured with a protocol library, scroll over the protocol list of the pumps and select any protocol as detailed in the Appendix 1. This action eliminates the potential issue and the devices can continue to be used safely with the existing protocol library.

In case a new protocol library is wanted to be installed in the pumps, please contact an authorized customer service representative of Micrel to perform a software update before any new library installation. In all other cases the software update will be performed at the next scheduled preventive maintenance.

Micrel Medical Devices is requiring all its customers to complete and return the attached Acknowledgment Form (see Appendix 2) by email to regulatory@micrelmed.com or Fax to +30 210 6032335 within 10 days of receipt of this letter. Upon receipt of the completed form, if applicable, a customer service representative of Micrel will contact you.

**Transmission of this Field Safety Notice**
This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

**Contact reference**
For additional information please contact Micrel Medical Devices through email: regulatory@micrelmed.com or fax: +30 210 6032335

The appropriate Regulatory Agency has been duly informed of this field safety notice.

We are fully committed to providing high quality products to our customers and we sincerely apologize for any inconvenience this situation may cause you or your staff.

Sincerely,

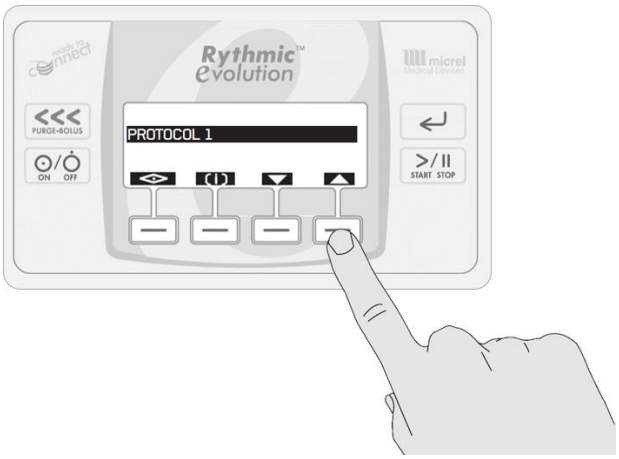
Sasa Karpeti
Quality Assurance Manager
Micrel Medical Devices S.A.
113 Geraka Str,
GR-15344 Gerakas, Greece

APPENDIX 1

## CORRECTION: STEPS TO FOLLOW ON AFFECTED DEVICES WITH PROTOCOL LIBRARY

Please follow the steps below for all affected devices configured with protocol library:

1. Turn the pump on
2. Enter the PROGRAMMING CODE and press ENTER
3. Select the NEW PATIENT-PROGRAM action from the menu
4. Press the SCROLL UP soft button in the protocol list, independently from the number of protocols (one or more), as shown in the picture below




5. Press the ENTER button to select any protocol from the list
6. Press ENTER button to navigate through the protocol review screen(s), till you reach the PUMP ON HOLD screen
7. Turn the pump off

**Note:** The above correction is required to be performed only one time per pump. There is no need to repeat the correction before every pump usage.

APPENDIX 2

## URGENT FIELD SAFETY NOTICE ACKNOWLEDGMENT FORM

FSN2018-01

Please complete and return this form by email to regulatory@micrelmed.com
or Fax to +30 210 6032335.

| | | |
|---|---|---|
| ☐ | **I do not have any of the affected devices.** | |
| ☐ | **I have affected devices and I will follow the recommended actions.** | **Number of affected devices:** |
| ☐ | **I have not fully understood the recommended actions, I would like to be contacted.** | **Number of affected devices:** |

| | |
|---|---|
| **Name of department & facility:** | |
| **Facility address:** | |
| **Country:** | |
| **Telephone number:** | |
| **Name:** | |
| **Signature:** | |
| **Date:** | |

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## APPENDIX 3

List of Rythmic Evolution models:

| Reference | Description |
|---|---|
| KP5.04.125.x | RYTHMIC EVOLUTION BLUE |
| KP5.04.130.x | RYTHMIC EVOLUTION YELLOW |
| KP5.04.132.x | MINI RYTHMIC EVOLUTION BLUE |
| KP5.04.134.x | MINI RYTHMIC EVOLUTION (YELLOW) |
| KP5.04.136.4 | RYTHMIC EVOLUTION BLUE RECHARGEABLE |
| KP5.04.138.3 | MINI RYTHMIC EVOLUTION YELLOW RECHARGEABLE |
| KP5.04.141.x | RYTHMIC EVOLUTION ORGANIZER 500 BLUE |
| KP5.04.144.x | RYTHMIC EVOLUTION ORGANIZER 501 BLUE RECHARGEABLE |
| KP5.04.147.x | RYTHMIC EVOLUTION ORGANIZER 500 YELLOW |
| KP5.04.150.x | RYTHMIC EVOLUTION ORGANIZER 501 YELLOW RECHARGEABLE |
| KP5.04.151.x | RYTHMIC EVOLUTION ORGANISER 501 UK BLUE RECHARGEABLE |
| KP5.04.152.x | RYTHMIC EVOLUTION ORGANIZER 501 UK YELLOW RECHARGEABLE |
| KP5.04.154.x | RYTHMIC EVOLUTION ORGANIZER 100 BLUE |
| KP5.04.161.x | RYTHMIC EVOLUTION ORGANIZER 101 BLUE RECHARGEABLE |
| KP5.04.167.x | RYTHMIC EVOLUTION 501 & LOCKBOX GREEN PUMP |
| KP5.04.168.x | RYTHMIC EVOLUTION  501 GREEN UK |
| KP5.04.170.x | MINI RYTHMIC EVOLUTION BLUE RECHARGEABLE |
| KP5.04.173.x | RYTHMIC EVOLUTION YELLOW RECHARGEABLE |
| KP5.04.182.x | RYTHMIC EVOLUTION ORGANIZER 101 YELLOW RECHARGEABLE |
| KP5.04.184.x | RYTHMIC EVOLUTION ORGANIZER 100 YELLOW |
| KP5.04.186.x | RYTHMIC EVOLUTION BLUE RECHARGEABLE No key |
| KP5.04.190.x | RYTHMIC EVOLUTION BLUE RECHARGEABLE UK |
| KP5.04.249.x | RYTHMIC EVOLUTION YELLOW RECHARGEABLE UK |
| KP5.04.261.x | MINI RYTHMIC EVOLUTION LOCKABLE BLUE |
| KP5.04.263.x | MINI RYTHMIC EVOLUTION LOCKABLE YELLOW |
| KP5.04.265.x | MINI RYTHMIC EVOLUTION LOCKABLE RECHARGEABLE BLUE |
| KP5.04.266.x | MINI RYTHMIC EVOLUTION LOCKABLE RECHARGEABLE YELLOW PUMP |
| KP5.04.267.x | MINI RYTHMIC EVOLUTION LOCKABLE RECHARGEABLE YELLOW |
| KP5.04.268.x | MINI RYTHMIC EVOLUTION LOCKABLE RECHARGEABLE YELLOW UK |
| KP5.04.269.x | MINI RYTHMIC EVOLUTION LOCKABLE RECHARGEABLE BLUE UK |
| KP5.04.270.x | MINI RYTHMIC EVOLUTION LOCKABLE RECHARGEABLE BLUE w MINI BAG |