User Guide

Kyma Medical Technologies Ltd.



Non-Invasive Fluid Status Monitor



Important

This User Guide is subject to periodic review, update and revision.

Do not use a defective product. Do not repair this product or any of its parts other than in accordance with written instructions provided by Kyma.

The user of this product has sole responsibility for any malfunction that results from improper use, faulty maintenance, improper repair, unauthorized service, damage, or alteration by anyone other than Kyma.

The safety, reliability, and performance of this device can only be assured under the following conditions:

- 1. The device has been used according to the accompanying operating instructions.
- 2. All fittings, extensions, readjustments, changes, or repairs have been carried out by Kyma's authorized representatives.

© Copyright 2012 Kyma Medical Technologies Ltd. All rights reserved.

No part of this publication may be reproduced, stored in a retrieval system or transmitted in any form by any means, electronic, mechanical, photo reproductive, recording or otherwise without the express prior written permission of Kyma Medical Technologies Ltd.

Kyma Medical Technologies Ltd. reserves the right to change or improve its products and accompanying technical literature without specific notice of changes or improvements.

This product is patent protected.

User Guide RA-72-002-008

Revision 3 · May 2013



Kyma Medical Technologies

Atir-Yeda Industry park 17th Atir-Yeda St. Kfar-Sava 44643, ISRAEL 2nd floor, East Entrance

Tel: +972.72.2119301 Fax: +972.72.2119304

http://www.kyma-



E-mail: info@Kyma-med.com med.com

CE Notice



The symbol CE 0344 indicates compliance of this device with the Medical Device Directives 93/42/ EEC, 2007/47/CE.



MedNet GmbH

Borkstrasse 10, 48163 Münster, Germany;

Tel.: 49-2506-8644-0 Fax: 49-2506-8644-22

Disclaimer

Information provided by Kyma Medical Technologies Ltd. is believed to be accurate and reliable. However, Kyma Medical Technologies Ltd. assumes no responsibility for the use of such information, nor for any infringements of patents or other rights of third parties, that may result from its use.

PLEASE READ THIS USER GUIDE BEFORE OPERATING THE SYSTEM

TABLE OF CONTENTS

Contents

1. Introduction	6
1.1. ABOUT THIS USER GUIDE	6
1.2. GLOSSARY AND ABBREVIATIONS	6
1.3. THE KYMA µCOR SYSTEM	6
2. Conditions for Use	7
2.1. INTENDED USE	7
2.2. INDICATIONS.	
2.3. Contraindications	7
3. Safety	8
3.1. Types of Warnings, Cautions and Notes	
3.2. General Safety Instructions	
3.3. ELECTRICAL SAFETY	g
3.4. EMC COMPLIANCE	9
4. Overview of System components	11
4.1. DEVICE DESCRIPTION	11
4.2. DIAGRAM OF SYSTEM MAIN COMPONENTS AND COMMUNICATION	11
4.3. CARTRIDGE	11
4.4. Charger	
4.5. MEDICAL PATCH	
4.6. COMPONENTS: SERVER	
5. Using the uCor Device	16
5.1. DETERMINING THE CORRECT LOCATION FOR THE MEDICAL PATCH	16
5.2. APPLYING THE MEDICAL PATCH	
5.3. REPLACING THE MEDICAL PATCH	
5.4. CONNECTING THE CARTRIDGE TO THE MEDICAL PATCH	
5.5. CHARGING THE CARTRIDGE	
5.6. REMOVING THE DEVICE CONNECTIONS FROM THE PATIENT	
5.7 CLEANING THE CARTRIDGE	
6. Troubleshooting	21
7. Cleaning and Maintenance	22
7.1. NOTES ON CLEANING AND MAINTENANCE	22
7.2. GENERAL CLEANING PROCEDURES	22
8. Repair policy	23
9. Storage	
10. System Labels and Symbols	
10.1. System Labels	
10.2. EXPLANATION OF SYMBOLS	
11. Specifications	28
11.1. System accuracy	
11.2. Environmental Information	
11.3. Electrical	
11.4. CARTRIDGE DIMENSIONS	28

12. Warranty	29
Appendix A: LED Indicator Lights on the Cartridge	30
Appendix B: Cartridge Battery Maintenance and Care	31
Appendix C: Hospital Protocol	31
DESCRIPTION:	31
Terms	32
Patient recruitment	32
PATIENT FOLLOW-UP	33
Patient release	32

1. INTRODUCTION

1.1. ABOUT THIS USER GUIDE

This User Guide provides the information necessary to operate the Kyma μ Cor System.

PLEASE READ THIS USER GUIDE BEFORE OPERATING THE SYSTEM. If any part of this User Guide is not clear, contact Customer Support for assistance.

1.2. GLOSSARY AND ABBREVIATIONS

BT: Blue Tooth CHF: Congestive Heart Failure

ESS: Electronic Synchronization Signal GUI: Graphic User Interface

RF: Radio Frequency FS: Fluid Status

UCID: Identification number of the

Medical Cartridge

CLOUD: BT TO TCP/IP COMMUNICATION

1.3. THE KYMA µCOR SYSTEM

 μ Cor is a non-invasive, impedance-based device that assesses a patient's Fluid Status (FS) by measuring the electromagnetic properties of the thorax. The μ Cor system consists of the following main parts:

- **1. Disposable Medical Patch** An adhesive patch with a plastic anchoring frame and two ESS electrodes. The Cartridge clicks into the plastic frame.
- 2. Reusable Cartridge A plastic box which includes the RF bio-impedance sensor, communication unit, and two additional sensors: Electronic synchronization signal (ESS) leads and accelerometer. The Cartridge has also a green/amber LED light indicator.
- **3.** Charger A charging cradle for recharging the Cartridge battery.
- **4. Server** Data base application software, used to collect the data, analyze it and present the data to the user.

This device is intended for use under the direction of a physician, for the non-invasive monitoring and management of patients with fluid management problems in a variety of medically accepted clinical applications.

2. CONDITIONS FOR USE

2.1. INTENDED USE AND INDICATIONS FOR USE

The μ Cor System is indicated for patients:

- With fluid management problems
- Taking diuretic medication
- Living with heart failure
- Living with end-stage renal disease
- Recovering from an event related to coronary artery disease
- Suffering from recurrent dehydration
- With severe infection (such as sepsis)
- With hypertension.

2.2.CONTRAINDICATIONS

The system is not for use by patients:

- with allergies or skin sensitivities to electrode hydrogel and/or acrylic based adhesive
- with implanted Neurostimulators
- with skin breakdown in areas on the chest where electrode device placement is required.
- Pregnant women.

3. SAFETY

3.1. TYPES OF WARNINGS, CAUTIONS AND NOTES

Three types of special message appear in this User Guide:



Warning: A **warning** indicates precautions to avoid the possibility of personal injury or death.



Caution: A **caution** indicates a condition that may lead to damage to equipment, or a lower quality of treatment.



Note: A **note** provides other important information.

3.2. GENERAL SAFETY INSTRUCTIONS



Warnings:



DO NOT USE BEFORE READING THIS USER GUIDE.



Remove Cartridge and Medical Patch before external defibrillation or any emergency medical procedure.



Changes or modifications not expressly approved by Kyma Medical Technologies Ltd. can affect the safety and effectiveness of the system and will void the system's warranty.



The system contains no user-serviceable components.



Electrical shock and flammability hazard – Cleaning the device should be limited to the simple procedure discussed on page 22. For any additional cleaning or servicing, always consult Kyma Medical Technologies Ltd.



Electrical shock hazard – Do not remove the cover from any components of the system. An operator may only perform maintenance procedures specifically described in this User Guide. Refer servicing to qualified service personnel trained in the repair of this equipment.



Electrical shock hazard – Connect this equipment only to a hospital-grade AC electrical socket.



Electrical shock hazard –Keep any kind of liquid or food away from the charger



Cautions:



Disposal of this device should be performed in accordance with local regulations.



If the device is not working correctly, discontinue use and contact Customer Support for assistance.



Do not use this device in the presence of MRI or when entering extreme heat conditions. (over 50°C)



Do not disassemble any part of the system components. This system is not user-serviceable.

3.3. ELECTRICAL SAFETY

The device complies with IEC/EN 60601-1 for general requirements of medical electrical equipment safety:

- Type BF applied part
- Mode of operation: spot measurement
- Degree of mobility: portable
- Compatibility with implanted defibrillators
- Compatibility with pacemaker.

3.4. EMC COMPLIANCE

The unit has IEC 60601-1-2 Class B compliance.

3.5. FCC COMPLIANCE STATEMENT

The FCC Wants You to Know

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- a) Reorient or relocate the receiving antenna.
- b) Increase the separation between the equipment and receiver.
- c) Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- d) Consult the dealer or an experienced radio/TV technician.



FCC Warning

Modifications not expressly approved by the manufacturer could void the user authority to operate the equipment under FCC Rules.

THE MANUFACTURER IS NOT RESPONSIBLE FOR ANY RADIO OR TV INTERFERENCE CAUSED BY UNAUTHORIZED MODIFICATIONS TO THIS EQUIPMENT. SUCH MODIFICATIONS COULD VOID THE USER'S AUTHORITY TO OPERATE THE EQUIPMENT.

4. OVERVIEW OF SYSTEM COMPONENTS

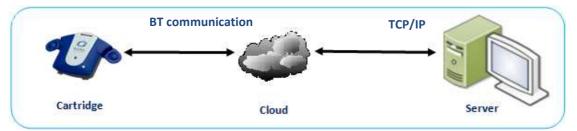
4.1. DEVICE DESCRIPTION

The Kyma μ Cor system is an RF-based non-invasive device that assesses and displays a patient's Fluid Status (FS) trends. The system is intended for use under the direction of a physician, for the non-invasive monitoring and management of patients with fluid management problems in a variety of medically accepted clinical applications.

The system can monitor heart rate, respiratory rate and motion level on top of FS.

4.2. DIAGRAM OF SYSTEM MAIN COMPONENTS AND COMMUNICATION

The main components of the Kyma μ Cor System and their connections are illustrated in the diagram below:



Communication between device main components

The description of system components is provided in the following sections.

4.3. CARTRIDGE

The Cartridge is a thin, waterproof, reusable plastic housing. It contains two ESS leads and a LED light. Note that while wearing the Cartridge the patient can do everyday activities such as walking or taking a shower. The Cartridge clicks into a disposable Medical Patch (page 13).



Cartridge

There is a wireless link between the Cartridge and the server.

The Cartridge transmits the data to the Cloud, where the data is sent to the server.

A Bi-Color LED (amber/green) is located close to the center of the Cartridge for status indications. See Appendix A for a description of the LED indicator light on the Cartridge and its meaning.



Note: The Cartridge contains a button for technician use only.

4.3.1. CARTRIDGE FRONT PANEL

The Cartridge front panel contains most of the components that are relevant for the user. The components are shown below.



Cartridge Front Panel Components

Number	Description	
1	ESS leads (Left and Right)	
2	LED light (Amber/Green)	
3	Technician button	
4	Upper snap in clip	
5	Lower snap in joints	

Cartridge front view



Caution: if you experience a problem with the Cartridge, do not use the device. Call customer support.



Caution: When not in use, the Cartridge must be stored in the Charger.

4.3.2. CARTRIDGE BACK PANEL

The Cartridge back panel contains the following:



Cartridge back panel

Cartridge Back Panel Components

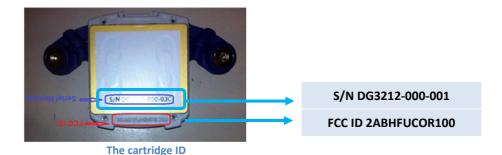
Number	Description	
1	ESS leads (Left and Right)	
2	Upper snap in clip Lower snap in joint	
3	Lower snap in joint	
4	Cartridge Serial Number	
	and FCC ID	



Caution: Avoid spilling food or liquids on the Cartridge.



Note: The Cartridge Serial Number (S/N) and FCC ID can be found on the back of the Cartridge:



4.4. CHARGER

A dedicated Charger is supplied along with the Cartridge. The Charger is a charging cradle for recharging the Cartridge battery.

The charger does not contain any LED lights, as battery status is shown on the Cartridge. The charger is supplied with an AC adapter.

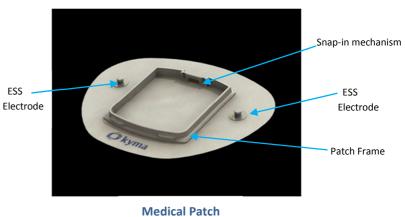


Caution: The Charger has its own AC adapter. Be sure to use only the adapter that is supplied with the charger.

4.5. MEDICAL PATCH

The adhesive Medical Patch is disposable and intended for one-time use. Although the Medical Patch is normally worn by the patient continuously, from patient admission to discharge, it may require replacement under certain circumstances (see page 17).

The Medical Patch consists of a plastic Frame for the Cartridge and two ESS electrodes embedded on each side of the Frame. Attachment of the Cartridge to the Medical Patch is performed using a snap-in mechanism, while attachment of the ESS leads is done by clicking in the ESS electrodes.



The Cartridge is connected to the Frame part of the Medical Patch when patient is admitted, and disconnected after the patient is released from hospitalization.



Cartridge and Patch, showing Patch Frame



Cartridge attached to the Medical Patch

Caution: If you suspect that the Medical Patch may be damaged, discontinue use and replace with a new Medical Patch. See page 17 for detailed Medical Patch replacement instructions.



Caution: If you are experiencing a problem with the Cartridge or components, contact Kyma Medical Technologies customer support.



Caution: Monitor the patch location for any irritation or inflammation.

4.6. COMPONENTS: SERVER

The server manages the data received from the Cartridge, using specialized database software. The server:

- Notes changes in the Cartridge status
- Downloads data from the Cartridge on a scheduled basis, and
- Processes the measured data.

5. USING THE UCOR DEVICE

Before using the Kyma μ Cor system, first read the system Contraindications on page 7. If the patient presents any of the Contraindications, do not use the system.

After you have verified that the Contraindications allow use of the system, prepare the patient by describing the system and procedure.

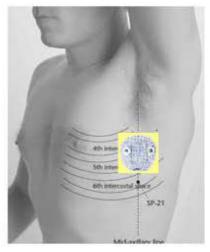
5.1. DETERMINING THE CORRECT LOCATION FOR THE MEDICAL PATCH

The Medical Patch should be located at or near the following desired anatomical location:

 Left (patient side) mid-axillar line at the fifth intercostal space.



Caution: The Medical Patch should be aligned with the mid-axillary line.



Location of the Medical Patch

5.2. APPLYING THE MEDICAL PATCH



Cartridge and Medical Patch



Proper attachment of the Patch to the left side of the patient's chest

Once the correct anatomical location for the Medical Patch is found, proceed as follows to attach the Medical Patch to the patient:

[1] Turn the Medical Patch so that the word "Kyma" that is printed on the bottom is pointing in the direction of the patient's legs:



- [2] Remove the Medical Patch's paper backing.
- [3] Attach the Medical Patch. The woven part of the Medical Patch should be flat and even.

Please note that the Medical Patch is normally worn by the patient from admission until discharge.



Note: When attaching the medical patch please ensure minimal air bubbles

5.3. REPLACING THE MEDICAL PATCH

After the initial attachment, the Medical Patch should remain in place on the left side of the patient's body, unless it requires replacement.

It is advised to use water to assist in removing the patch.

The patch should be removed gently. It is recommended to hold the skin with one hand while using the other hand to detach the patch from the patient's body.



Caution: Replace the old Medical Patch if one of the following conditions occurs:

- Medical Patch is causing discomfort to the patient.
- Medical Patch appears to be soiled.
- Medical Patch is not securely attached to the patient.
- Medical Patch is not smooth and even, or shows other signs of wear.
- The patch Frame part of the Medical Patch is worn, broken or otherwise unsuitable to providing a secure connection for the Cartridge.

It is recommended to replace the Medical Patch at least every 5 days.



Caution: In order to ensure accuracy in the measurements, the Cartridge (and therefore the Medical Patch) must be in the same location for all measurements. If the old Medical Patch requires replacement make sure to relocate the new Medical Patch at the same location as the old Medical Patch.



Warning: Be careful that removal of the Medical Patch does not harm the skin, especially for elderly patients.

5.4. CONNECTING THE CARTRIDGE TO THE MEDICAL PATCH

The Cartridge is attached to the Medical Patch during patient hospitalization for the TFC measurements. The Cartridge is attached to the patch **Frame** area of the Medical Patch, as shown below:



Cartridge and Medical Patch, showing the patch Frame area of the Medical Patch



Cartridge attached to the Medical Patch

Proceed as follows to connect the Cartridge to the Medical Patch:

- 1. Place the lower snap in joints of the Cartridge on the lower part of the patch Frame, pressing first on the bottom of the Cartridge. Make sure the lower snap-in joints are between the Frame and the woven part.
- 2. While pressing the upper snap in clip, press the rest of the Cartridge onto the Medical Patch.



Cartridge located at final position

- 3. The Cartridge should be firmly attached, and should stay connected to the Medical Patch without any effort on the part of the patient.
- 4. Attach the two ESS leads to the two ESS electrodes and make sure they are well attached.

It is preferable to charge the Cartridge when it is not assigned to a patient, unless it is assigned and the battery power is low.

Note: When applying the cartridge to a new patient, make sure the previous patient was released from the GUI application and that a flashing green LED light is on the Cartridge.

5.5. CHARGING THE CARTRIDGE

It is recommended that the Cartridge will be charged every two days for one hour in order to maintain adequate battery status.

In order to charge the Cartridge, remove the device and its connections from the patient. The Cartridge should be removed from the Medical Patch as follows:

- 1. Disconnect the two μCor ESS leads from the Medical Patch.
- 2. Tilt and remove the Cartridge from the Medical Patch while pressing the upper snap in clip.
- 3. Place the Cartridge in the charger and wait for a steady amber LED light.
- 4. The steady amber light should change to a steady green light within around one hour, indicating the device is fully charged.
- 5. Reconnect the Cartridge to the Medical Patch as described at page 23.





Steady green light

Steady amber light

5.6. REMOVING THE DEVICE CONNECTIONS FROM THE PATIENT

The Cartridge should be removed from the Medical Patch as follows:

1. Disconnect the two μ Cor ESS leads from the Medical Patch.

2. Tilt and remove the Cartridge from the Medical Patch while pressing the upper snap in clip.

- 3. Remove the Medical Patch from the patient.
- 4. Place the Cartridge in the charger and wait for a steady amber LED light. (If no

light appears after 1-2 seconds check troubleshooting table for required actions)



Flashing green light

Steady amber light

- 5. If patient is still active, the amber light will change to green after 1-2 hours, indicating the device is fully charged.
- 6. If the patient has been discharged, the steady amber light should change to a flashing green light within around two hours, indicating the device is charged and ready for a new patient.



Note: A steady (non-flashing) green light means the μ Cor is still referenced to the previous patient at the server.

The Cartridge is ready for a new patient only when there is a flashing green LED light- **DO NOT APPLY DEVICE TO A NEW PATIENT UNTIL THIS INDICATION OCCURS.**

The Cartridge should be cleaned and disinfected before using it for a new patient. Please see cleaning and disinfecting instructions on page 22.

5.7 CLEANING THE CARTRIDGE

After disconnecting the Cartridge from the patient:

- Clean and disinfect the Cartridge, as shown on page 22.
- Place the Cartridge in the charger and make sure the LED light is on.

When the green LED light is flashing, the system is ready for a new patient. (previous patient is released and the battery is fully charged)



Caution: If the green LED light is not flashing, the last active patient was not yet released from the server.

6. TROUBLESHOOTING

The following table lists the recommend actions that assist in μCor System troubleshooting.

Condition	Possible Cause	Recommended Action
Improper patch attachment to	Improper patch attachment	Replace the Patch and re-attach according to instructions(see page 22)
skin	Disposable patch reuse	Attach only new Medical Patch. Re – using patches may result in patient cross – contamination and inaccurate measurements
Low battery	Cartridge is not charged	place the Cartridge in the charger
	Charger is not connected to AC power	Make sure charger is connected to AC power and amber LED light is on
No LED light while in charger	Charger is not connected to AC power	Make sure charger is connected to AC power
	System fault	Contact customer support

7. CLEANING AND MAINTENANCE

7.1. NOTES ON CLEANING AND MAINTENANCE

The μ Cor System does not require maintenance or cleaning on a routine basis, except as suggested in this User Guide. Any other service should only be provided by an authorized Kyma Medical Technologies Ltd. representative. Failure to do so voids the warranty and may cause user injury.

Please see Appendix B on page 41 for Cartridge battery maintenance and care.

7.2. GENERAL CLEANING PROCEDURES



Note: The Medical Patch is normally worn by the patient from admission until discharge. However, see page 17 for conditions that require replacement of the Medical Patch.



Caution: The Medical Patch is for one-time use on one patient only. A Medical Patch that has been used once must be discarded. It cannot be reused. Re – using patches may result in patient cross – contamination and inaccurate measurements

If you replace the Medical Patch on a patient, please be sure to follow the directions on page 17.

Please observe the following cautions when cleaning the Cartridge:



Caution: Use cleaning solution sparingly. Excessive solution can cause damage to internal components.



Caution: Contact with solvents can cause severe deterioration of plastic parts and malfunctioning of the instrument and accessories.

7.2.1. CLEANING THE CARTRIDGE

The plastic and metal outer surface of the Cartridge may be cleaned with a soft, lint-free cloth dampened in a mild soap and water solution or ethyl alcohol (70-85%).

If disinfecting is required, wipe the surface with isopropyl alcohol (IPA), then wipe with a water-moistened soft cloth.

8. REPAIR POLICY

When under warranty, repair and service must be performed by Kyma Medical Technologies Ltd. When the Kyma warranty is not applicable, repairs may be made by Kyma or authorized representatives.



Warning: Do not remove the covers of the device components. Only perform procedures specifically described in this User Guide.

9. STORAGE

Environmental Conditions for Storage and Transportation		
Temperature -20°C to +60°C		
Relative Humidity	5% to 93%, non-condensing	

10. SYSTEM LABELS AND SYMBOLS

10.1. SYSTEM LABELS



System Label



Serial Label

FCC ID: 2ABHFUCOR100

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- 1) This device may not cause harmful interference and
- This device must accept any interference received, including interference that may cause undesired operation.

FCC Label





Patch Label

10.2. EXPLANATION OF SYMBOLS

The following symbols may appear on the device or shipping materials.

	Follow instructions for use
S/N DG3212-000-001	The serial number for this product
	Dispose of this product according to local environmental regulations
†	Type BF applied part
2012 - 07	Date of Manufacture
(2)	Do not re-use
****	Manufacturer
2014 - 06	Expiry date
===	Direct current

11. SPECIFICATIONS

11.1. SYSTEM ACCURACY

The overall system accuracy presents an error of less than 25cc fluid at a confidence level of 90%.

11.2. ENVIRONMENTAL INFORMATION

Operating room temperature	+10 to +35° C (+50 to +95° F)
Relative humidity	10% to 90% non-condensing

11.3. ELECTRICAL

11.3.1. POWER

Cartridge:

Max Power Consumption: 0.85W Nominal Power Consumption: 0.65W

Max Rating: 4.2V, 0.2A Nominal Rating: 3.7V, 0.18A

Battery Type: Li-Pol, 3.7V, 350mAh

Charger:

Consumption during charging: 1W

Input (plug): 5VDC, 0.4A

Adaptor:

Input: 100 to 240 VAC at 50/60Hz; 0.18A

Output: 5VDC; 0.6A

11.4. CARTRIDGE DIMENSIONS

• Height: 60.5 mm

• Width: 99 mm

• Depth: 15.9 mm

• Weight: maximum of 62 gram

12. WARRANTY

Service Support

Repairs of the μ Cor System under warranty must be made by authorized repair centers. If the device needs repair, contact Kyma Medical Technologies Ltd. service department or your local distributor.

If you need to ship the device, pack the device and its accessories carefully to prevent shipping damage.

Duration

Kyma Medical Technologies Ltd. will repair or replace, at its sole discretion, the product or any defective part, provided it is returned to Kyma service within 30 days.

APPENDIX A: LED INDICATOR LIGHTS ON THE CARTRIDGE

The table below describes the Cartridge LED lights indications. The LED is a two-color (green/amber), single element light.



Cartridge, showing amber LED Light

GENERAL LED LIGHT NOTES:

- When the Cartridge is out of the charger there is no light
- When the Cartridge is placed in the charger the light will be on (see table below for options)
- Green light means battery is fully charged
- Amber light means battery is being charged.

LED Constant/Flashing	LED Color	
	Green	Amber
Constant LED light	Active patient (the Cartridge placed in charger during patient admission and is fully charged)	Cartridge is being charged
Flashing LED light	Previous patient is released and Cartridge is ready for a new patient (the Cartridge placed in charger is fully charged)	Error, if repeats more than once contact Kyma



Note: Only when the flashing green LED light is on, the battery is full and the Cartridge is ready for a new patient.

APPENDIX B: CARTRIDGE BATTERY MAINTENANCE AND CARE

The Li-Pol battery used in the Cartridge will provide optimum life when the unit is fully charged every two days and after each patient release.

With the battery fully charged, the device can operate for about four days assuming measurement every two hours. Operation times may vary according to the measurement schedule and battery retention.

A depleted battery requires up to 120 minutes of continuous charge time to fully charge. Time between charging operations depends on measurement scheduling, for example:

- If scheduling 4 measurements per day of 1 minute each, device should be charged once a week.
- If scheduling a 1 minute measurement every 2 hours, device should be charged every 2-3 days.

Battery life varies depending on frequency of use and maintenance. For improved battery life, keep the Cartridge in the charger when not in use. If the battery has been fully charged and requires recharging after a few measurements, consider contacting customer service.

FOR OPTIMAL BATTERY PERFORMANCE:

- Always fully charge battery prior to assigning a new patient.
- Put the Cartridge in the charger when not in use.
- Connect the charger only to an AC power source that is supplied with the charger and wait for the amber LED light to change to green.
- Operate the Cartridge, charge batteries, and store at room temperature (25 °C / 77 °F).
- If the μ Cor system is not in use for more than a week, fully charge the battery prior to using the Cartridge.
- Repeated undercharging of the battery will damage the battery and reduce battery life.
- A fully charged Cartridge battery stored outside the charger will need to be recharged every six months. If the Cartridge battery is not charged every three months it will be damaged. A depleted battery will not perform as expected after a full recharge and will eventually require replacement.

APPENDIX C: STUDY PROTOCOL

DESCRIPTION:

uCor device is used supervised by Kyma field technician. Technician is responsible for all maintenance operations: charging, adhesive patch replacement, device removal & attachment. For each patient one uCor device is attached. Cellular Gateway (GW) is placed near patient bed. Server monitoring is performed by experiment supervisor at Kyma, on a daily basis.

Experiment duration: from admission until discharge and no longer than two month.

TERMS

- F.T Field Technician
- E.S. Experiment Supervisor

PATIENT RECRUITMENT

Step	Title	E.S Action	F.T Action
1	Device Attachment		Verify that LED is blinking green when device is in charger ("ready for new patient").
			Attach the device to the patch.
			Attach the Patch to the patient's chest; Inform E.S by e-mail that a new patient had been recruited (report: time of patch attachment, device Index).
2	Recruitment Form		Fill-in Form A. Send to E.S
3	Website patient recruitment.	Assign a patient ID at website. Fill in the patient details (uCor device Idxs, patient Idx, GW idx) at xls table (Use-at-hospital Device status.xls). Observe the first 2-3 measurements and verify ESS and RF signals are ok.	

PATIENT FOLLOW-UP

Step	Title	E.S Action	F.T Action
1	E.S follow-up (Performed twice a day)	Review error page and measurement results per patient twice a day and instruct the technician accordingly by mail. Fill in the relevant checks at experiment log.	-
2	F.T pre follow-up		Check your mail for instructions from E.S right before the visit. If any special instructions appear, act accordingly. If no special instructions, proceed according to next steps
3	Charging		Remove device from patient and place in the charger. Check patch condition- Replace if not satisfactory (starting to peel off) or 5 days from last replacement.
4	Back to work		After LED has turned green, place device back on patient (~1-2 hours charging time).

PATIENT RELEASE

Step	Title	E.S Action	F.T Action
1	Device Removal		Take off patch and Cartridge, collect the GW.
2	Server Release	Verify all measurement had been downloaded from uCor to server PRIOR to releasing the patient. Perform release procedure at server.	Place cartridge in charger and inform E.S of patient release by e-mail.
			Place device, charger & GW at storing room, connected to chargers.