Instructions for Use

Re:Balans

Fluid Status Monitor

℞ only

PLEASE READ THIS ENTIRE INSTRUCTIONS FOR USE BEFORE OPERATING THE RE:BALANS® PATCH.

For assistance with the Re:Balans® patch, please contact Mode Sensors at:

support@modesensors.com

or;

Address:
Mode Sensors AS
Professor Brochs gate 2
Trondheim 7030 Norway

Trademark
Re:Balans is a US and EU- registered trademark of Mode Sensors AS.

Disclaimer
Information, operation, specifications, and product appearance may change without notice.

Symbols Glossary
The symbols glossary is in Section 2 of this Information for Use

Instructions for Use Identifier:
DOC0085A-IFU-A00
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Device Version ID:
PCT005A

About Mode Sensors AS
Mode Sensors AS develops and markets medical devices to support and improve healthcare and individual lives.
www.modesensors.com

Versions of this Instructions for Use

Versions	Changes	Status	Released
DOC0085A-IFU-A00	-	Effective	27th of January, 2023

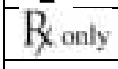
Table of Contents

1. Re:Balans Introduction

- Once activated, Re:Balans continuously collects bioimpedance data from the back of the patient for up to 7 days.
- Bioimpedance measurements are transmitted to a Re:Balans API installed device or system for measurement readout and validation by physician.
- The bioimpedance data facilitates the noninvasive monitoring and management of patients with fluid management problems in a variety of medically accepted clinical applications.
- Re:Balans is designed for use in hospital environments, outpatient clinic and home settings.
- Re:Balans is a medical electrical equipment, non-sterile and single-use for intact skin only.
- Data from the device should be considered in conjunction with other clinical data.

2. Symbol Glossary

The symbol glossary is useful for safe and effective use of Re:Balans. The symbols below are found on the Re:Balans pouch label, Re:Balans Instructions for Use and the Re:Balans patch.

Symbol	Title of Symbol	Symbol Reference
	Contact information of the manufacturer	Pouch Label – Quick Start
	UDI	Pouch Label – Quick Start
	A model or type reference	Pouch Label – Quick Start
	A serial number	Pouch Label – Quick Start
	Or lot or batch identifier	Pouch Label – Quick Start
	Use by date	Pouch Label – Quick Start
	The date of manufacture	Pouch Label – Quick Start
	Read Instructions for Use (Electronic)	Pouch Label – Quick Start
	Single use (do not re-use)	Pouch Label – Quick Start
	Safety Sign: Warning	Pouch Label and Section 4 in Instructions for Use
	An indication that the device is a medical device.	Pouch Label – Quick Start
	Recycling; To indicate the location of a recycling bin or container	Pouch Label – Quick Start
	Type BF (body floating): The equipment is considered one applied part	Pouch Label – Quick Start
	Atmospheric pressure limit	Pouch Label –Quick Start and Section 9.3 in Instructions for Use
	Humidity limit	Pouch Label –Quick Start and Section 9.3 in Instructions for Use
	Temperature limit: Storage temperature limits to which the device can be safely exposed.	Pouch Label –Quick Start and Section 9.3 in Instructions for Use
	Indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK	Pouch Label – Quick Start
	Waste stream disposal status	Pouch Label – Quick Start
IP54	No ingress of dust; complete protection against contact. Water splashing against the enclosure from any direction shall have no harmful effect.	Pouch Label – Quick Start
	MR unsafe, take off patch before undergoing MR	Pouch Label – Quick Start
	Non-ionizing radiation	Pouch Label – Quick Start
	Prescription only	Pouch Label – Quick Start
	Arrow indicating direction of patch; “this way up”	Re:Balans Patch
	Activation button	Re:Balans Patch
	LED indication	Re:Balans Patch

3. Indications for Use

The Re:Balans Fluid status Monitor is intended for adult patients:

With fluid management problems

- Taking diuretic medication
- Living with Heart Failure
- Living with End-stage Renal Disease
- Suffering from Recurrent Dehydration
- Recovering from Coronary Artery Disease related event.

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.

4. General Warnings and Precautions 

4.1. Contraindications

- Patients with known allergies or skin sensitivities to electrode hydrogel and/or acrylic based adhesives
- Patients with non-intact skin such as skin breakdown where the device is to be placed
- Patients with implantable pulse generators such as pacemakers and defibrillators
- Patients undergoing MRI
- Pregnant women

4.2. Precautions

- Remove the device from your body prior to an MRI scan, or any emergency medical procedure. Re:Balans system is not compatible for use with MRI machines.
- Re:Balans is an adjunct monitor device not intended to replace existing standard-of-care patient monitoring practices.
- Data from the device should be considered with other clinical data.
- Regardless of device status or output, consult physician if sensations of thirst, delirium, heartbeat, oedema, shortness of breath or other symptoms of fluid imbalance.
- Do not continue wearing if severe discomfort or irritation occurs.
- Re:Balans may damage the skin if removed carelessly
- Re:Balans has been clinically validated for use in adult patients only.
- Re:Balans may be used while showering. Minimize exposure directly under the shower head, use water proof protective cover, avoid excessive contact with soap, or scrubbing. Do not submerge the device in water or use in a sauna.
- Re:Balans is intended for up to 7 days wear. The sum of wear time should not exceed 30 days.
- Do not submerge the patch in water by swimming or sitting in a tub.
- Do not place on broken skin including wounds, sores, or abrasions.
- No creams or lotion should be applied to the skin prior to the application of the patch.
- Body hair should be trimmed, using only an electric trimmer, before application.
- If Re:Balans fails to operate, contact your healthcare provider or physician immediately.
- This device shall not be sterilized before use.
- Do not re-use the patch. The patch is designed for single use only.
- Do not modify the device in any way.
- Do not use the Re:Balans device if the package has been opened, or appears used, damaged, or expired.
- If patch loses contact with skin, terminate the monitoring.
- This device contains parts and assemblies that may be susceptible to damage by electrostatic discharge.
- Excessive adipose tissue and type of skin may affect the signal.
- The performance of the device may be degraded if one or more of the following occur: a) operation outside the manufacturer's stated temperature and humidity range; b) storage outside the manufacturer's stated temperature and humidity range; c) mechanical shock or impact.
- Do not excessively bend or twist the Re:Balans patch.
- Dispose of the Re:Balans device per local laws, care facility laws or hospital laws for routine/nonhazardous electronic waste.
- The Re:Balans radio signal may may affect other RF equipment.
- Recommended storage condition is 5-27 degrees Celsius. Storage outside these conditions may affect the device shelf-life and device performance.
- Re:Balans will not connect or transfer data to any devices that does not meet the Re:Balans radio specifications.

4.3. Residual Risks and Side Effects

Use of Re:Balans could potentially lead to skin irritations or allergies.

5. Descriptions of Re:Balans

5.1. Re:Balans Introduction

The Re:Balans is a non-invasive, battery powered impedance monitor designed to determine changes in the fluid status of patients with fluid management problems.

The device has a form-factor of an adhesive patch with four integrated electrodes to be applied on the back of the patient. The Re:Balans applies a low amplitude multi-frequent electrical current and measures the electrical impedance. The impedance signal is obtained by applying a small, safe battery-generated current and measuring the resulting electrical potential.

The impedance signal reflects the electrical resistance of the tissue and is modulated by the changes in fluid levels. The impedance signal is captured at multiple unique frequencies to enable the calculation of impedance values.

Once the patch is successfully placed and activated on the patient, the Re:Balans will collect impedance data periodically over a period of up to 7 days. The data facilitate the clinician's noninvasive monitoring and management of patients with fluid management problems.

The review and interpretation of impedance data are enabled through the integration with a third-party device or system.

Each Re:Balans patch has an intended weartime of up to 7 days.

5.2. Re:Balans Components

Re:Balans consists of the following components:

- Re:Balans wearable patch

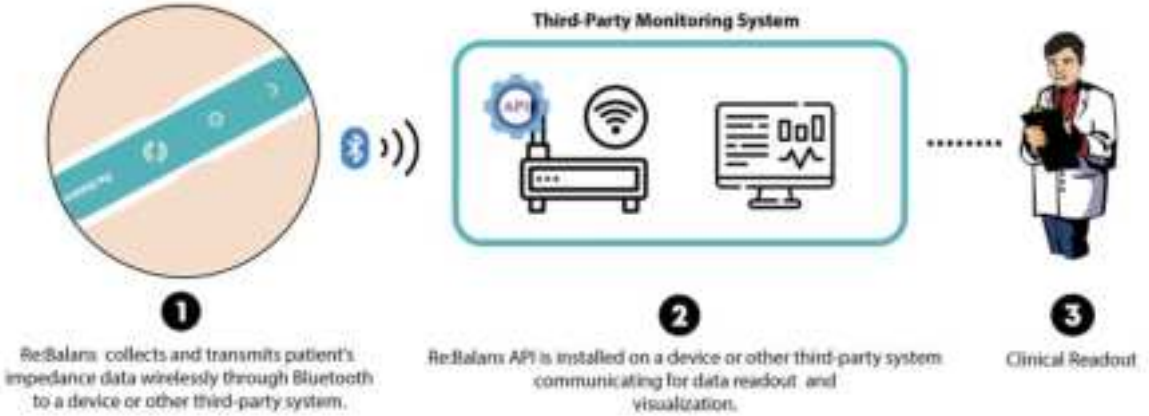
The Re:Balans device can be connected with third-party devices or system for data readout.

Please contact Mode Sensors AS to obtain implementation information, including Re:Balans Platform Integration Manual – Developer Guide.

5.3. Description of measurement technology

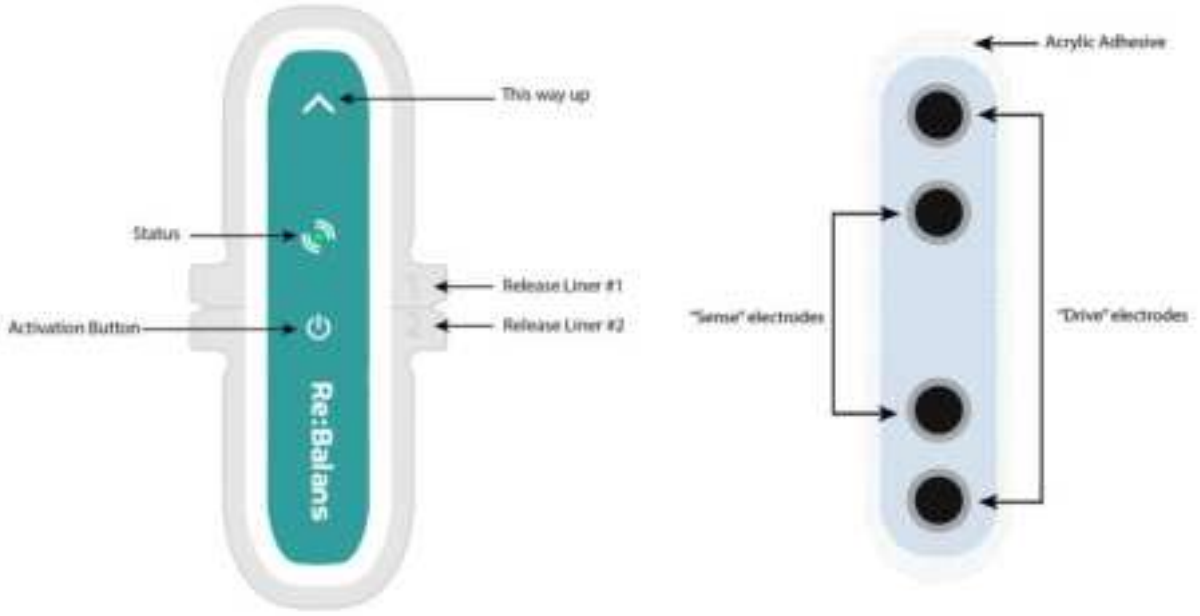
Re:Balans works by applying a measurement technique called "bioimpedance". Bioimpedance technology calculates opposition to the flow of an electric current by the tissue. The opposition of flow depends on the characteristics and properties of the tissue: The applied electrical current travels through the extracellular fluid of the tissue and through the lean muscle via the intracellular fluid. Impedance is low in lean tissue, extracellular fluid, and intracellular fluid, where electrolytes are primarily contained. Impedance is high in fat tissue because fat is primarily an insulator containing very few conducting elements. Therefore, impedance can be related to the fluid volume of the tissue because the impedance is a direct measure of both intracellular and extracellular fluid.

5.4. System Overview



Once activated, Re:Balans patch transmits fluid data to a device or third party system for readout and validation by a physician, or under direction of a physician.

5.5. Symbols on Re:Balans



Front side of patch

Skin contacting side (Without release liner)

6. Directions for Use

IMPORTANT: The monitoring will be affected if these steps are not followed.

Ensure hands are clean and dry before handling the Re:Balans device. When handling the Re:Balans device, do not touch the adhesive. The steps below should minimize the chance of touching the adhesive. Contact with the adhesive prior to skin application may compromise the skin contacting materials.

Step 1: Remove from pouch

Tear open the pouch using the notch mark and remove the Re:Balans carefully.

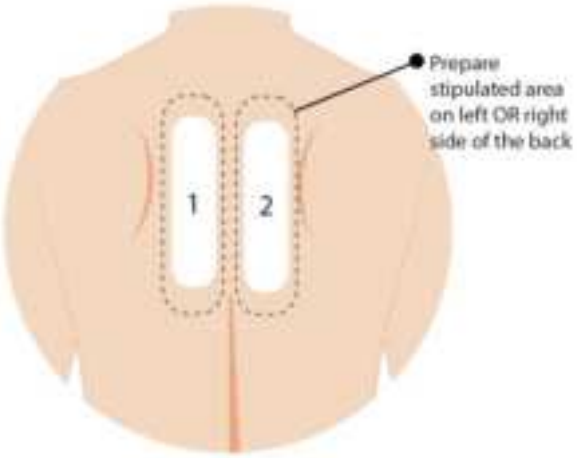
DO NOT remove the adhesive backings until instructed.

DO NOT use a scissor or other sharp objects to open the pouch.

Step 2: Prepare skin

The application site is located on the back of the patient; 2-4 cm left or right to spine.

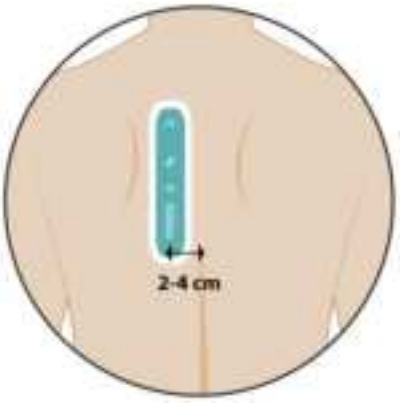
- Trim as much hair as possible by using an electric hair trimmer or similar. Trim an area slightly larger than Re:Balans® patch.
- DO NOT use razor or other equipment that will damage the skin surface before application. Device is for intact skin only.
- Clean the skin and allow the skin to dry. You may use a wet cloth with mild soap. Do not apply skin creams or lotions on the prepared area. The application site should be free of oils and lotions to maximize adhesion.



Step 3: Apply the patch to the body

a) Test the device prior to application by pressing and holding the button until blinking yellow light. This indicates that device is functional. Discard the device if green light or no light.

b) Remove first half #1 of the release liner.



c) Identify the prepared area from Step 2.
(2-4 cm from center patch to center spine)

d) Apply the first half of the patch with arrow up.

e) Remove release liner #2 and press patch gently.

f) Press and hold button until green light. If yellow light, read the Troubleshooting in Section 7.

Step 4: Connect Re:Balans with Software Application

After applying the Re:Balans to the skin, **retain the pouch with the device Patch ID**. You will need this information to connect to the Re:Balans to the preferred device or system.

Refer to your software application provider's user manual for more instructions on how to connect to the Re:Balans device.

Step 5: Remove and dispose the Re:Balans patch from the body

- Hold the skin in one hand while using the other to gently peel-off the patch. You may use a wet cloth to assist you in the process.
- Discard the patch immediately. Do not reuse.
- If required, replace the patch with a new according to the instructions in Step 1, Step 2 and Step 3.

Dispose of the Re:Balans patch per local laws, care facility laws or hospital laws for routine/nonhazardous battery-operated electronic products.

7. Troubleshooting

Sensor light Status	**Status**	**Action**
	Blinking yellow ●	Measurement error: 1. Adhere the patch properly to the skin. Wait 15 minutes and try to activate again. 2. Remove patch and replace with a new patch.
	Green light blinking on body ●	Patch is functioning as intended.
Patch and monitoring	Patch is partly or completely lifted from the skin	If the patch has partially lifted from the skin but remains attached, press the patch down firmly against the skin to re-adhere. If one or both sides of the patch has completely lifted off the skin, replace the patch with a new.
	Termination: I want to remove the patch	Remove the patch according to step 5 in section 6.
	Possible Cause(s)	**Action(s)**
Unusual Data	1. This device might be damaged. 2. This device might not be worn correctly. 3. The operation temperature is too high or too low. 4. Improper or no skin preparation. 5. Incorrect attachment of adhesive.	1. Contact your device provider. 2. Recheck device's location or contact with skin. 3. Use this device under instructed operation temperature. 4. Prepare the skin before application. 5. Follow the instructions to attach the adhesive.
No data or intermittent data received by Re:Balans API installed device **No Bluetooth signal or data transmission latency**	1. Bluetooth turned off in the on third-party device. 2. Out of connection range. 3.Interference from other RF emitters, such as RFID, metal detectors, medical equipment etc., in the vicinity	1. Enable Bluetooth on the third-party device. 2. Move the Patch close to the third-party device 3. Move far away from any electronic equipment or change rooms or move to an open space. 4.Check if Re:Balans is activated. 5.Restart the third-party device. 6.The Re:Balans battery out of battery.

For issues related to the third-party user interface application or third-party device or other system and for additional troubleshooting guidance, refer to the separate Instructions for Use for the interface for the respective system.

8. Maintenance

Users are not required to perform any maintenance for the Re:Balans patch.

9. Technical Specifications

9.1. Wireless Communication

Wireless Data Transmission	
Bluetooth 5.3	10 meters (30 Feet Line of Sight)
Radio Modulation	FSK (Frequency Shift Keying)
Frequency range	2.4 GHz – 2.5 GHz
Transmit Power	≤ 10dbm
Security	AES – CCM 128 Bit Encryption (Advanced Encryption Standard CCM mode)

9.2. Re:Balans patch dimensions

Dimension	
Height	170 mm (6,7 inches)
Width	45 mm (1,8 inches)
Depth	3 mm (0,12 inches)
Weight	10g

9.3. Storage and Handling

Operating Conditions for Re:Balans Patch	
Temperature	5°C and 40°C (or 41°F and 104 °F)
Relative humidity	15% - 90% non-condensing
Pressure	700 hPa to 1060 hpa

Storage Conditions for Re:Balans Patch	
Temperature	5°C and 27°C (or 41°F and 81°F)
Relative humidity	5% - 93% non-condensing

Shipping and Transport Conditions for Re:Balans Patch	
Temperature	5°C and 40°C (or 41°F and 104 °F)
Relative humidity	5% - 93%
Pressure	700 hPa to 1060 hpa

Patch Shelf life	12 months in individually sealed pouch
Weartime	7 days per patch

10. Compliances

10.1. Electrical Safety

The device is tested according to IEC/EN 60601-1 edition 3.2 for general requirements of medical electrical equipment safety for

- IEC 60601-1:2005+A1:2012+A2:2020
- EN 60601-1:2006+A11:2011+A1:2013+A12:2014+A2:2021

Degree of mobility: body-worn

The device complies with:

- IEC 60601-1-2:2014+A1:2020
- IEC 60601-1-6:2010+A1:2013+A2:2020
- IEC 60601-1-11:2015+A1:2020

10.2. Electromagnetic Compatibility

The Re:Balans device is intended for use in the electromagnetic environment specified below. The end user of the device should assure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment
RF emissions CISPR 11	Group 1	The Re:Balans device uses RF energy only for its internal function. 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 Re:Balans device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

10.3. FCC Compliance

FCC ID: 2A6Z8-PCT005

FCC Interference Statement; 15.105(b) Class B Digital Device

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 of the following measures:

- Reorient or relocate the receiving antenna.

- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC Part 15 Clause 15.21:

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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 (2) this device must accept any interference received, including interference that may cause undesired operation.