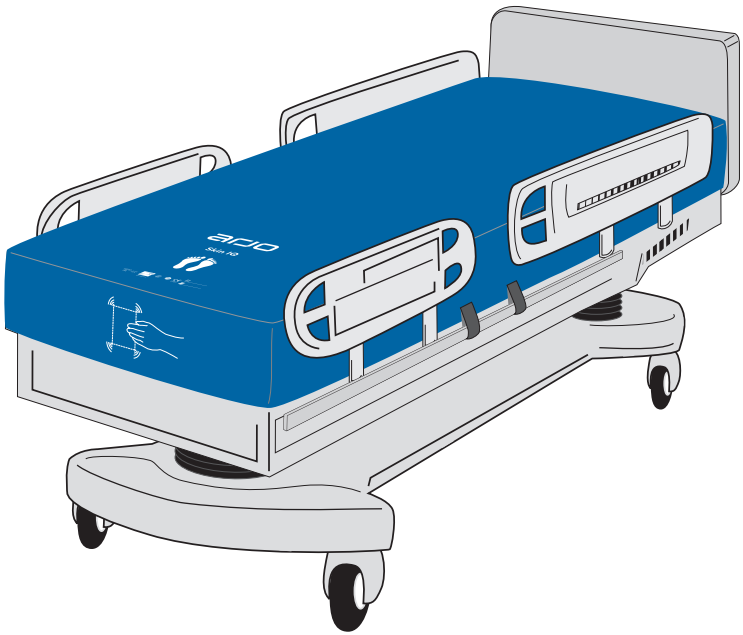
INSTRUCTIONS FOR USE

Skin IQ

Microclimate Manager



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EMPOWERING MOVEMENT

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Descriptions or specifications in Arjo printed matter, including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express warranties, except as set forth in the written limited warranty included with this product. Information in this publication may be subject to change at any time. Contact Arjo for updates.

IMPORTANT INFORMATION FOR USERS

In order for Arjo products to perform properly, Arjo recommends the following conditions. Failure to comply with these conditions will void any applicable warranties.

- Use this product only in accordance with these instructions and applicable product labeling.
- **WARNING:** Assembly, operations, adjustments, extensions, modifications, technical maintenance or repairs must be performed only by qualified personnel authorized by Arjo. Contact Arjo for information regarding maintenance and repair.
- Ensure the electrical installation of the room complies with the appropriate national electrical wiring standards. To avoid the risk of electric shock, this product must be connected to a grounded power receptacle.

Specific indications, contraindications, warnings, precautions and safety information exist for Arjo's therapeutic support systems. It is important for users to read and familiarize themselves with these instructions and to consult the treating physician prior to patient placement and product use. Individual patient conditions may vary.

NOTICE

This product has been configured from the manufacturer to meet specific voltage requirements. Refer to the power supply label for specific voltage.

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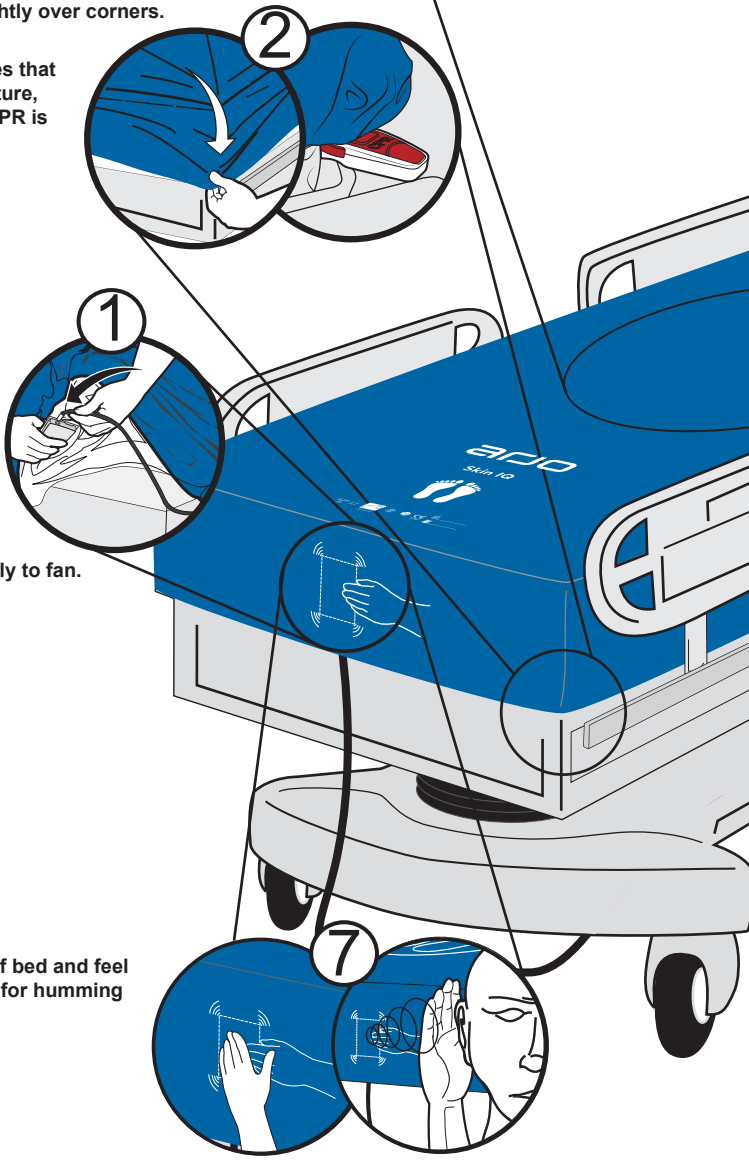
Quick Reference

Smooth out wrinkles.

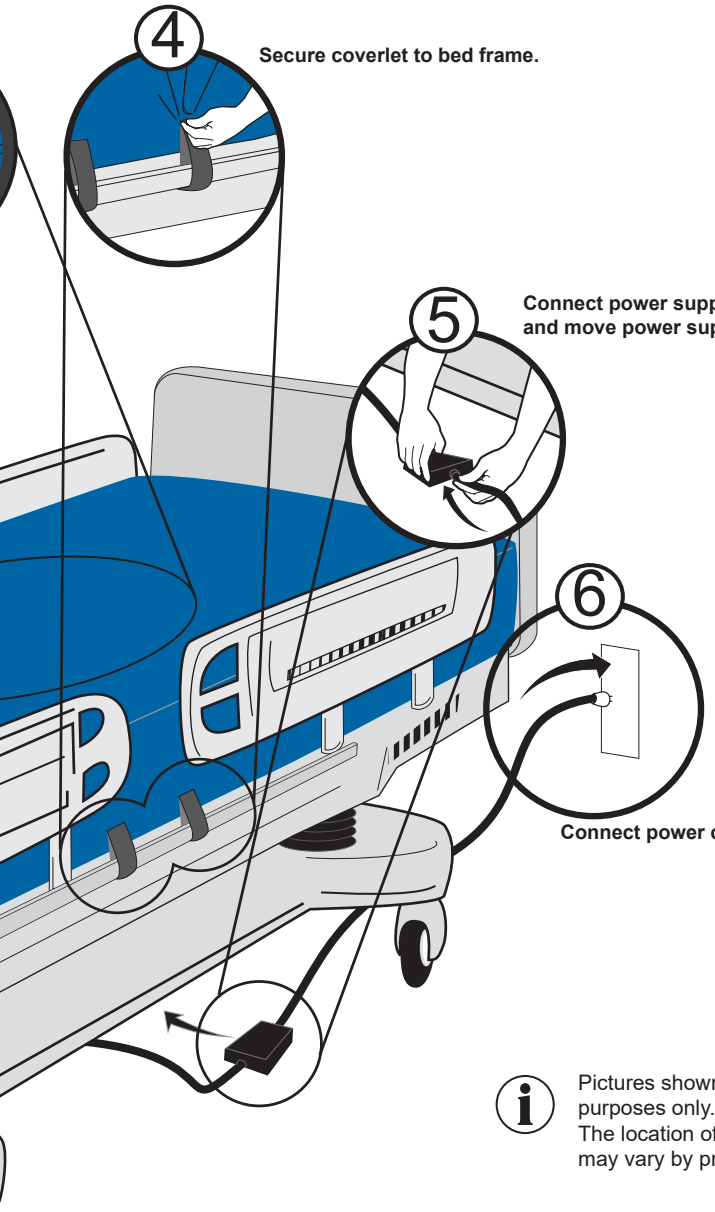
Pull coverlet tightly over corners.

For powered air surfaces that have a CPR release feature, please make sure the CPR is visible.



Connect power supply to fan.

Move hand to end of bed and feel fan vibration, listen for humming sound.



Secure coverlet to bed frame.

Connect power supply to power cord and move power supply under bed.

Connect power cord to wall outlet.

Pictures shown are for illustration purposes only.
The location of the CPR feature may vary by product.

Skin IQ

Introduction

This document should be saved in an easily accessible place for quick reference.

It is recommended that all sections of these instructions be read prior to product use. Carefully review the **Indications, Contraindications, Risks and Precautions** and **Safety Information** prior to placing a patient on the Skin IQ® Microclimate Manager (MCM).

These instructions do not provide specific safety or operational information for the pressure redistribution surface and / or bed frame provided by the facility for use with the Skin IQ MCM. Consult product labeling for information.

Caregivers should discuss **Safety Information, Risks and Precautions** and **Contraindications** with the patient (or the patient's legal guardians) and the patient's family.

The Skin IQ MCM is a single patient use, disposable device that provides Negative Airflow Technology (NAT) to manage the microclimate of the skin at the patient surface when fitted over a customer-provided pressure redistribution surface.

It is also designed to reduce friction and improve patient comfort.

The Skin IQ MCM is suitable for use in acute and post acute facilities, is vapor permeable, and has a fluid-resistant nylon taffeta cover.

Indications

The Skin IQ MCM is indicated for use in conjunction with a pressure redistribution surface in order to aid in the prevention and treatment of skin breakdown and pressure ulcers (Stages I-IV) for patients who require microclimate management of the skin.

Contraindications

Although Skin IQ MCM has no associated direct contraindications the caregiver should refer to and follow any contraindications in the product labeling for the pressure redistribution surface and / or bed frame being used with the Skin IQ MCM.

Intended Care Setting

- Acute Care
- Post Acute Care

Compatibility

The Skin IQ MCM is designed to fit on a pressure redistribution surface that is 203.2 cm - 213.4 cm (80 - 84 in) long by 88.9 cm - 91.4 cm (35 - 36 in) wide by 17.8 cm (7 in) high.

Consult product labeling for the pressure redistribution surface and / or bed frame for compatibility.

Risks and Precautions

Transfer

This product is not intended for use as a transfer device.

Duration of Use

Recommended duration of use for single patient is not more than 60 days for patients < 172.37 kg (380 lb).

Duration of use for patients weighing 172.37 kg (380 lb) - 227 kg (500 lb) is not to exceed more than 30 days.

However, patient specific duration of use may vary. Clinical conditions such as, but not limited to, incontinence, skin condition, nutrition status, medications, mobility, weight, or etiology need to be considered when assessing duration of use for the Skin IQ MCM.

Height

The Skin IQ MCM will increase the height of the pressure redistribution surface it is applied to by approximately 6.35 mm (0.25 in).

Use With Other Devices

All Skin IQ MCM components are designed to be used as a single system device.

Skin IQ MCM should only be used with the included power supply (part number 4103832) or the coiled Skin IQ power cable for Arjo surfaces with Skin IQ integration (part number 636377).

Any attempt to connect and use the power supply with any other device, or use any other brand or model of power supply other than Arjo part numbers 4103832 or 636377 will result in improper operating of equipment, possibly leading to increase risk of patient injury.

Patient Migration

Specialty surfaces have different shear and support characteristics than conventional surfaces and may increase the risk of patient movement, sinking and / or migration into hazardous positions of entrapment and / or inadvertent bed exit. Monitor patients frequently to guard against patient entrapment.

Safety Information

To avoid serious injury or death, the CPR rapid deflation unit must be visible and accessible at all times.

Please refer to and follow any safety information in the product labeling for the pressure redistribution surface and / or bed frame being used with the Skin IQ MCM.

Power Cord

Only use a grounded power outlet and the power cord supplied with the Skin IQ Power Supply. The power cord should be positioned to avoid a tripping hazard and / or damage to the cord. The Skin IQ MCM should never be operated with a worn or damaged power cord. Should the power cord become worn or damaged, contact Arjo or an Arjo authorized representative to order a replacement.

Coverlet

Use care when handling or transporting. Dropping or other sudden impacts may result in damage to the device.

Skin Care

Monitor skin conditions regularly and consider adjunct or alternative therapies for high acuity patients. Give extra attention to any possible pressure points and locations where moisture or incontinence may occur or collect. Early intervention may be essential to preventing skin breakdown.

The Skin IQ MCM Product Family has an antimicrobial agent formulated into the patient contact layer. Although rare, there is a potential that some patients may experience sensitivity or a reaction during use. Regularly monitor the patient's skin condition. Discontinue use and seek medical treatment if any signs of a reaction are observed.

If a serious incident occurs in relation to this medical device, affecting the user, or the patient then the user or patient should report the serious incident to the medical device manufacturer or the distributor. In the European Union, the user should also report the serious incident to the Competent Authority in the member state where they are located.

For more information about the Skin IQ MCM Product Family, please visit **www.arjo.com**

Patient Weight

The maximum patient weight for this device is 227 kg (500 lb). In addition, consult the specifications for the pressure redistribution surface and / or bed frame being used. Additional weight limitations may apply.

Disposal

The coverlet contains electrical components that may be removed and disposed of separately.

See Disposal on page 8 for removal.

General Protocols

- Avoid contact of sharp instruments with the Skin IQ MCM. Punctures, cuts and tears will prevent proper operation.
- Follow all applicable safety rules and institution protocols concerning patient and caregiver safety.

Unpacking and Inspection

Unpack the Skin IQ MCM from the shipping box and locate items as listed.

- coverlet with instructions for use booklet (included in complete kit or coverlet only)
- power supply (included in complete kit or available as a separate item)
- power cord (included in complete kit or power supply only)

Inspect all items carefully. If any items are damaged or missing, contact Arjo or an Arjo authorized representative.

Installation

See the Quick Reference on pages 2 and 3 for illustrations of the following procedures.

Failure to properly secure the coverlet to the existing surface may lead to patient or user injury or equipment damage.

1. Remove coverlet from shipping bag.
2. Remove all covers and sheets from the existing pressure redistribution surface.
3. Place the coverlet on top of the existing surface, ensuring the foot graphic on the coverlet is at the foot end of the bed.
4. Connect the power supply to the fan located underneath the foot end of the coverlet.
5. Ensure the cord that runs from the fan to the power supply is placed on the floor under the bed. Improper placement of the cord could cause injury.
6. Pull the coverlet over the pressure redistribution surface by stretching it over each corner securely. Do not trap the power cord between the coverlet and mattress.
7. Smooth any wrinkles on the coverlet.
8. Secure the coverlet to the bed by using the hook-and-loop straps, located on the underside of the coverlet.
9. Ensure strap placement does not interfere with the operation of the bed functions. Failure to do so could result in patient injury or equipment damage.
10. Write the therapy start date on the law tag at the foot end of the coverlet to track use. Failure to track duration of use may void warranty.
11. Confirm there are no sharp objects in the immediate area which may damage the coverlet.
12. Connect the power supply to the power cord.
13. Connect the power cord to a properly grounded electrical outlet and confirm outlet has power. Verify that the electrical outlet can be easily accessed when disconnecting the device from mains power. Ensure power supply and cord are properly stored on the floor beneath bed.
14. Move hand to the end of the bed and press the foot-end of coverlet to feel fan vibration. A low humming sound indicates the fan is working.

Connecting Skin IQ MCM to Arjo Surfaces with Skin IQ Integration

The Skin IQ MCM coverlet can connect directly to Arjo surfaces that have an integrated Skin IQ port located on the pump, removing the need to connect the Skin IQ MCM coverlet to the mains power.

To connect the Skin IQ MCM coverlet to Arjo surfaces with Skin IQ integration, a separate accessory is required: Product Code 636377

Skin IQ Integration Coiled Power Cable

1. Connect one end of the Coiled Skin IQ Power Cable to the fan located underneath the foot end of the coverlet
2. Connect the other end of the Coiled Skin IQ Power Cable to the Skin IQ port located on the pump.
3. The Skin IQ MCM coverlet will be in full operation at all times when the pump is switched on.
4. To confirm operation of the Skin IQ MCM coverlet move hand to the end of the bed and press the foot-end of the coverlet to feel fan vibration. A low humming sound indicates the fan is working.

Care and Cleaning

During patient use, clean Skin IQ Coverlet by wiping with a mild soap and water solution. Do not launder the Skin IQ Coverlet. The Skin IQ Coverlet is for single patient use only.

Avoid spilling fluids on any part of the Skin IQ power supply. If spills do occur:

- disconnect the power cord from the wall outlet
- clean fluids from the product

Ensure that there is no moisture in or near the power supply and power plug before reconnecting the power cord.

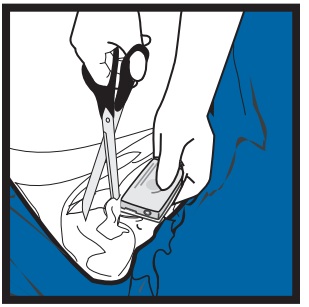
End of Life Disposal

The coverlet itself is a single patient use only product, but some of the items that come with it can be reused if they are handled properly when removed. Follow the steps below to remove the fan and dispose of all components of the Skin IQ MCM.

1. Disconnect power cord from wall outlet.
2. Disconnect power supply from fan.

Power supply and cord can be reused. Consider all facility policies and procedures with regard to cleaning, inspection and reuse of electronic equipment. If not reused, dispose of power supply per approved local institutional procedures.

3. Cut fan out of coverlet as shown.
4. Dispose of coverlet and fan according to approved local institutional procedures.



Fan assembly contains electronic components that may require alternate disposal than the soft goods of the coverlet.

Improper disposal of any component may result in regulatory non-compliance.

Fabric material used on the coverlet or any other textiles, polymers or plastic materials etc. should be sorted as combustible waste.

Units have electrical and electronic components that should be disassembled and recycled per Waste of Electrical and Electronic Equipment (WEEE) or in accordance with local or national regulation.

Specifications*

Maximum Weight Capacity..... 227 kg (500 lb)

Recommended duration of use for single patient is not more than 60 days for patients < 172.37 kg (380 lb).

Duration of use for patients weighing 172.37 kg (380 lb) - 227 kg (500 lb) is not to exceed more than 30 days.

Consult the specifications for the pressure redistribution surface being used. Additional weight limitations may apply.

Electrical:

Voltage.....100 - 240 VAC
Frequency.....50 / 60 Hz
Voltage (Saudi Arabia only) .....230 VAC
Frequency (Saudi Arabia only) .....60 Hz
Ampere Rating..... 0.5 A
Maximum Electrical Leakage..... 100 uA at 115 VAC 60 Hz and 200 uA at 230 VAC 50 Hz
Power Cord Length.....6 m (19.69 ft)

Environmental Conditions:

Operating:

Temperature Range..... 14˚C (57.2˚F) to 35˚C (95˚F)

Transport / Storage:

Temperature Range.....-29˚C (-20.2˚F) to 60˚C (140˚F)

The Skin IQ Coverlet is classified as a Type B applied part under IEC 60601-1:2005/A1:2012 (3.1 edition).

***Specifications subject to change without notice.**

Electromagnetic Compatibility

Electromagnetic Interference - Although this equipment conforms with the intent of the directive 2014/30/EU in relation to Electromagnetic Compatibility (EMC), all electrical equipment may produce interference. If interference is suspected, move equipment away from sensitive devices or contact the manufacturer.

Portable and mobile RF communications equipment can effect medical electrical equipment.

Radios, cell phones and similar devices may affect this equipment and should be kept at least 2 m (6.5 ft) away from the equipment.

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information in the following tables.

The following tables document compliance levels and guidance from the IEC 60601-1-2:2014 (4th edition) Standard, for the electromagnetic environment in which the Skin IQ MCM should be used in a clinical environment.

<table>
<tr><th colspan="3">Guidance and manufacturer’s declaration - electromagnetic emissions</th></tr>
<tr><td colspan="3">The Skin IQ MCM is intended for use in the electromagnetic environment specified below. The customer or user of the Skin IQ MCM should assure that it is used in such an environment.</td></tr>
<tr><td>Emission Test</td><td>Compliance</td><td>Electromagnetic Environment</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The Skin IQ MCM 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">This equipment 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.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class B</td></tr>
<tr><td>Voltage fluctuations / flicker emissions
IEC 61000-3-3</td><td>yes</td></tr>
</table>

Guidance and manufacturer's declaration - electromagnetic immunity			
The Skin IQ MCM is intended for use in the electromagnetic environment specified below. The customer or user of the Skin IQ MCM should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV Contact ±15 kV Air	±8 kV Contact ±15 kV Air	In accordance with IEC 60601-1-2, if the floors are 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 ±1 kV for input/output lines	±1 kV lines to ±2 kV for power supply lines	
Surge IEC 61000-4-5	1 kV line(s) to Line(s) 2 kV line(s) to Earth	1 kV line(s) to Line(s) 2 kV line(s) to Earth	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	5% half cycle 40% for 5 cycle 70% for 25 cycle 5% for 5 seconds	5% half cycle 40% 5 cycles 70% 25 cycles 5% for 5 seconds	
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	30 A/M	30 A/M	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U, is the a.c. mains voltage prior to application of the test level.			

Recommended separation distances between portable and mobile RF communications equipment and the Skin IQ MCM			
The Skin IQ MCM is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Skin IQ MCM can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Skin IQ MCM as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter meters		
	150 kHz to 80 MHz not applicable	80 MHz to 800 MHz $d=[\frac{3.5}{E1}]\sqrt{P}$	800 MHz to 2.5 GHz $d=[\frac{7}{E1}]\sqrt{P}$
0.01	N/A	0.12	0.23
0.1	N/A	0.37	0.74
1	N/A	1.2	2.3
10	N/A	3.7	7.4
100	N/A	12	23
For transmitters rated at a maximum output power not listed above, the recommended separate distance d in metres (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 1, At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2, These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from surfaces, objects and people.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The Skin IQ MCM is intended for use in an electromagnetic environment specified below. The customer or user of the Skin IQ MCM should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Skin IQ MCM, including cables, than the recommended separation distance calculated from the equation application to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3Vrms 150K - 80 MHz	3 Vrms 150K - 80 MHz	Recommended Separation Distance Battery Operated Device
Radiated RF IEC 61000-4-3	3 Vrms 80 MHz - 2.5 GHz	3 Vrms 80 MHz - 2.5 GHz	$d=[\frac{3.5}{E1}]\sqrt{P}$ 80 MHz to 800 MHz $d=[\frac{7}{E1}]\sqrt{P}$ 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (see note a) should be less than the compliance level in each frequency range (see note b). Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1, At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2, These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) 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 environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Skin IQ MCM is used exceeds the applicable RF compliance level above, the Skin IQ MCM should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Skin IQ MCM.

b) Over the frequency range 150kHz, field strengths should be less than 3 V/m.

Warranty

In connection with your purchase of a Skin IQ MCM, Arjo, Inc. and its affiliates, (collectively referred to herein as “Arjo”) warrants, to the original purchaser, its Skin IQ MCM against manufacturer’s defects in material and / or workmanship for a period of sixty (60) days from first date of product placement on patient surface; or one year from date of product purchase, whichever comes first under normal usage and so long as all applicable procedures are followed per the instructions for use (IFU).

This Limited Warranty is non-transferable. THIS LIMITED WARRANTY SHALL BE IN LIEU OF ANY AND ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ALL OF WHICH ARE EXPRESSLY DISCLAIMED BY ARJO. REPAIR OR REPLACEMENT AS PROVIDED UNDER THIS WARRANTY IS THE CUSTOMER’S SOLE REMEDY. ARJO SHALL NOT BE LIABLE FOR ANY INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES AND EXPENSES, INCLUDING DAMAGES OR INJURY TO PERSON OR PROPERTY, FOR THE BREACH OF ANY WARRANTY ON THIS PRODUCT. SOME STATES AND JURISDICTIONS MAY NOT ALLOW THESE LIMITATIONS ON WARRANTIES. THIS WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS, AND YOU MAY ALSO HAVE OTHER RIGHTS, WHICH VARY FROM STATE TO STATE OR JURISDICTION TO JURISDICTION.

Conditions and Limitations:

Under this warranty, upon reasonable notice, Arjo will replace defective parts or whole units covered under this warranty at its sole option. No returns or replacements will be allowed without authorization from Arjo. This warranty applies to material / parts replacement costs and labor costs only and does not include shipping and handling costs or disposal fees.

This warranty does not extend to, nor cover:

- Patient wearables, such as, but not limited to, non-integrated cover sheets(s) and disposables used in conjunction with the Skin IQ MCM product; or
- Normal wear and tear; or
- Damage, or product failure due to causes beyond Arjo’s control such as, but not limited to, abuse, theft, fire, flood, wind, lightning, freezing, power failure, power reduction, clogging of coverlet pores due to tobacco smoke, unusual atmospheric conditions, or force majeure.

This warranty is VOID if:

- Proof of purchase cannot be made by the original purchaser;
- Adjustment, modification, and / or repair beyond that described in the Skin IQ IFU is carried out by entities not authorized by Arjo;
- The electrical installation of the room does not comply with the appropriate national electrical wiring standards;
- The product is not installed or used in accordance with the instructions and warnings enumerated in the Skin IQ IFU.

This warranty is in no way to be construed as an extension of any other agreement entered into by the parties.

Arjo reserves the right to make material changes to the product predicated upon the availability of raw materials of like quality.

SYMBOLS USED

ETL CLASSIFIED
Intertek
4008071

Conforms to AAMI ES60601-1, IEC 60601-1-6 Certified to CSA Std. C22.2 NO. 60601-1

No Hooks

Important Operational Information

Foot End

CE
2797

CE marking indicating conformity with European Community harmonised legislation.
Figures indicate Notified Body supervision.

Direct Current

Consult Instructions for Use

REF

Catalog Number

Manufacturer

Temperature Limitations

IPX1

Protected against ingress of liquids

Protective Earth Class 1 Device

Hospital name

Maximum patient weight

Do Not Open With Scissors

Content Information

Tripping Hazard

This product or its parts are designated for separate collection at an appropriate collection point. At the end of useful life, dispose of all waste according to local requirements, or contact your local Arjo representative for advice.

Alternating Current

Keep Dry

Warning of possible hazard to system, patient or staff

Date of Manufacture

Do Not Shower

Type B Applied Part

Single Patient Use

MD

Indicates the product is a Medical Device according to EU Medical Device Regulation 2017/745

Date of first use

Wipe surfaces with cleaning solution, then wipe with a cloth moistened with water and dry thoroughly

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