INSTRUCTIONS FOR USE

Skin IQ 365

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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.

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.

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™ 365.

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* 365. 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* 365 is a multi-patient, reusable device that provides Negative Airflow Technology (NAT) to manage the microclimate when fitted over a customer-provided pressure redistribution surface.

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

The *Skin IQ* 365 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* 365 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* 365 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* 365.

Intended Care Setting

- Acute Care
- Post Acute Care

Compatibility

The *Skin IQ* 365 is designed to fit on a pressure redistribution surface that is 80 - 84 in (203.2 - 213.4 cm) long by 35 - 36 in (88.9 - 91.4 cm) wide by 7 - 8 in (17.8 - 20.3 cm) 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

Useful life of this product is one year or 35 laundry cycles, whichever comes first.

Patient specific duration of use may vary. 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* 365.

Height

The *Skin IQ* 365 will increase the height of the pressure redistribution surface it is applied to by approximately 0.375 in (9.53 mm).

Use With Other Devices

All *Skin IQ* 365 components are designed to be used as a single system device, in combination with a pressure redistribution surface.

The included power supply should only be used with the *Skin IQ* 365. The coverlet should only be powered by the *Skin IQ* 365 Power Supply part number MENB1010A1203B02 (Arjo P/N 44001211).

Any attempt to connect and use the power supply with any other device, or use any other brand or model of power supply will result in improper operation of equipment, possibly leading to increased risk of patient injury.

Patient Migration

Specialty surfaces have different friction 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

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* 365.

Power Supply

Only use the *Skin IQ* 365 Power Supply with attached power cord. The power supply cord should be positioned to avoid a tripping hazard and / or damage to the cord. The *Skin IQ* 365 should never be operated with a worn or damaged power supply cord. Routinely inspect the power supply and cord and should the power supply 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

Skin care monitoring should be conducted as per institutional guidelines. This product is not a replacement for proper skin care management and overall nursing care.

The *Skin IQ* 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 treatment if any signs of a reaction are observed.

For more information about the *Skin IQ* product family, contact Arjo at 1-800-343-0974.

Patient Weight

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

General Protocols

- Avoid contact of sharp instruments with the *Skin IQ* 365. Punctures, cuts and tears will prevent proper operation.
- Follow all applicable safety rules and institution protocols concerning patient and caregiver safety.
- The *Skin IQ* 365 can be removed or placed on a bed while the bed is occupied. This can be accomplished by clinical personnel using a common method usually referred to as the "Log Roll", in order to change soiled linens of immobile patients. At least two clinical attendants can roll the patient to one side of the bed and then placed, folded or rolled, directly behind the patient's back. The patient is then rolled over to the *Skin IQ* 365 applied side. The remainder of the *Skin IQ* 365 can now be applied to the newly unoccupied side of the bed. When finished, the patient can be rolled back on to the center of the bed.

Unpacking and Inspection

Unpack the *Skin IQ* 365 from the shipping box and locate items as listed.

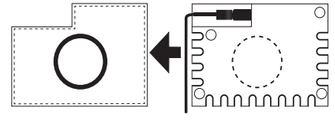
- Coverlet with instructions for use (included in complete kit or coverlet only)
- Power supply (included in complete kit or available as a separate item)
- Fan assembly (included in complete kit or available as a separate item)

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

Installation

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

1. Remove coverlet, fan assembly and power supply 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 tag on the coverlet is at the foot end of the bed. The blue colored layer is the patient contact surface and should be the visible outside layer when the coverlet is placed on the mattress.
4. The power supply should come connected to the fan assembly. If not, plug power supply into fan assembly.
5. The power supply comes with adapters specific to the type of plug used in the country. Identify the proper adapter and then insert adapter into the power supply and rotate clockwise until adapter clicks. To remove adapter, depress button on adapter and rotate counterclockwise.
6. Locate fan assembly port underneath the foot end of the coverlet. Snap fan assembly into round red fan port on coverlet. Rotate fan as necessary to achieve the correct final fan positioning as shown below. Vents should be aligned so that fan exhaust is vented down and to the sides of the coverlet.



7. Ensure the power supply cord is placed on the floor under the bed. Improper placement of the power supply cord could cause injury.
8. 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.
9. Smooth any wrinkles on the coverlet.
10. Secure the coverlet to the bed frame by using the hook-and-loop straps, located on the sides of the coverlet.
11. 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.
12. Confirm there are no sharp objects in the immediate area which may damage the coverlet.
13. Connect the power supply to an 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 cord is properly stored on the floor beneath bed.
14. Move hand along foot end of bed and feel for fan vibration. A low humming sound indicates the fan is operating.
15. To uninstall the *Skin IQ* 365 refer to the **Care and Cleaning** instructions.

Care and Cleaning

The *Skin IQ* 365 Coverlet should be cleaned regularly after each patient use. All staff members should wear appropriate protective clothing when cleaning mattress. It is recommended that the top cover (patient contact area) should be cleaned with a mild soap or organic solution and water prior to using standard disinfection solutions in order to remove gross contaminates. All disinfection solutions must be properly diluted according to manufacturer's instructions. This will be effective on most stains including blood, urine and perspiration. Please follow standard institutional cleaning and disinfection procedures.

The zippered area must not be opened during normal use or during cleaning or disinfection procedures.

Disinfection

The *Skin IQ* 365 Coverlet, Fan and Power Supply can be disinfected using a wipe down approach with a 70% alcohol solution, bleach 1000 ppm, hydrogen peroxide 3%, or phenolic disinfectant 1%. Although bleach may be used for wipe-down disinfection, please be aware that if used extensively, discoloration and fading of the fabrics and labels used in the *Skin IQ* 365 may occur. Bleach should not be used when laundering the *Skin IQ* 365.

Disinfection solution efficacy data was based on microbiological studies using Staphylococcus aureus as a common clinically relevant aerobic skin infection organism.

Iodophor type disinfectants (e.g. Betadine, etc.) are not recommended and will stain fabric.

The zippered area must not be opened during normal use or during cleaning or disinfection procedures.

Laundering

Prior to laundering unplug the power supply from the fan assembly and remove the fan assembly from the red port on the *Skin IQ* 365 coverlet.

Do not bleach when laundering the *Skin IQ* 365.

Laundering of the *Skin IQ* 365 is permitted. Please follow standard institutional laundering procedures. It is recommended that wash temperatures do not exceed 140˚F (60˚C) and drying temperatures do not exceed 140˚F (60˚C). Be sure to unzip the *Skin IQ* 365 when washing and drying to allow the inside of the coverlet to be cleaned, disinfected and dried. When laundering process is complete, be sure to re-zip the *Skin IQ* 365 before it is returned to use. A tag located on the foot end of the *Skin IQ* 365 is used to track the number of times the coverlet is laundered.

Temperatures in excess of what is recommended will cause premature deterioration of the *Skin IQ* 365 coverlet.

The zippered area must be opened during laundering procedures, but closed during normal use.

End of Life Disposal

The coverlet itself is a multi-patient reusable product, but some of the items that come with it can be reused after the products expected service life, if they are handled properly when removed. The *Skin IQ* 365 power supply can be reused, but only on other *Skin IQ* 365 fans. Routinely inspect the power supply and cord and remove from service if damaged. Follow the steps below to remove the components of the *Skin IQ* 365.

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

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 protocols.

3. Remove fan from coverlet by pulling fan apart from the coverlet.
4. Dispose of coverlet and fan according to approved local institutional procedures.

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.

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.

Specifications

Specifications subject to change without notice.

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

Useful life of this product is one year or 35 laundry cycles, whichever comes first.

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

Electrical:

Voltage Input..... 230 VAC
Voltage Output..... 12 V
Frequency..... 60 Hz
Ampere Rating Input..... 0.3 A (0.3 A - 0.1 A)
Ampere Rating Output..... 1.0 A
Maximum Electrical Leakage..... 100 uA at 115 VAC 60 Hz and 200 uA at 230 VAC 50 Hz
Power Cord Length..... 20.0 ft (6.1 m)

Environmental Conditions:

Operating:

Temperature Range..... 32˚F (0˚C) to 104˚F (40˚C)
Humidity Range..... 5% - 90%

Transport / Storage:

Temperature Range..... -20.2˚F (-29˚C) to 167˚F (75˚C)
Humidity Range..... 5% - 95%

The *Skin IQ* 365 Coverlet is classified as a Type B applied part under IEC 60601-1.

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 manufacturer.

Portable and mobile Radio Frequency (RF) communications equipment can effect electrical equipment. Radios, cell phones and similar devices may affect this equipment and should be kept at least 6.5 ft (2 m) away from the equipment.
The *Skin IQ* 365 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 electrical equipment. The *Skin IQ* 365 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *Skin IQ* 365 can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communications equipment (transmitters) and the *Skin IQ* 365.

Symbols Used

Conforms to AAMI ES60601-1-6.
Certified to CSA Std. C22.2 No. IEC-60601-1 edition 3.1
IEC-60601-1-2:2014

Important Operational Information

Foot End

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

Consult Instructions for Use

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

Class II Device

Manufacturer

Temperature Limitations

Protected against ingress of liquids

Hospital name

Washable up to 60˚C

Do not iron

Date of first use

Do Not Open With Scissors

Tripping Hazard

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

Keep Dry

Warning of possible hazard to system, patient or staff

No Hooks

Do Not Shower

Type B Applied Part

Catalog Number

Humidity Limitations

Tumble dry at 60˚C

Customer Contact Information

For questions regarding this product, supplies, maintenance or additional information about Arjo products and services, please contact Arjo or an Arjo authorized representative or visit www.arjo.com. In the US call 1-800-343-0974. In the US call 1-800-343-0974.

At Arjo, we are committed to improving the everyday lives of people affected by reduced mobility and age-related health challenges. With products and solutions that ensure ergonomic patient handling, personal hygiene, disinfection, diagnostics, and the effective prevention of pressure ulcers and venous thromboembolism, we help professionals across care environments to continually raise the standard of safe and dignified care. Everything we do, we do with people in mind.

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