

Instructions for Use

Revision: 10

Date: January 20th, 2023

aiSon™ Focus products Non-Sterile



Description and indications for use:

The aiSon™ Focus is intended to be used by sonographers and can be used on any patient independent of age, weight, or other health conditions.

It is intended to

- avoid misdiagnoses from compression of underlying structures (e.g., all pathological, superficial fluid collections),
- avoid painful examinations for the patient (e.g., acute trauma with open or closed fractures, nerve lesions),
- facilitate ultrasound-guided interventions that do not require sterile conditions,
- facilitate ultrasound-guided interventions using a sterile probe cover on top of the product when sterile conditions are required,
- increase patient comfort (e.g., babies, or if a patient shows resistance towards the generous usage of ultrasound coupling agent),
- enable diagnoses in hard-to-reach areas of the patient's body (e.g., Achilles tendon, anterior neck region, fingers, toes, pelvic floor, eyes, ears).

The aiSon™ Focus achieves its function by maximizing the contact area of the ultrasound probe with the patient's body. In addition, it is an adaptive ultrasound standoff pad, which allows for a dynamic shift of the ultrasound image focus (point of highest image resolution). The shift can be achieved by increasing or decreasing the distance of the ultrasound probe to the body to be imaged by manually compressing or releasing the pad.

It is intended for single use on intact skin. It is intended to be used as an accessory to an ultrasound device to specifically and directly assist the medical functionality of the ultrasound device in terms of its intended purpose (please refer to the Instructions For Use provided by the manufacturer of your ultrasound system).

Step-by-step setup guide:

Step 1:

Leave the ultrasound probe in its designated holder/storage on the ultrasound machine.



Step 2:

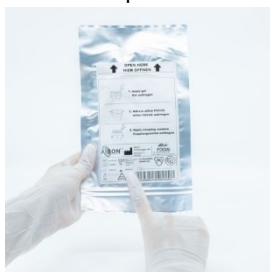
Apply regular ultrasound gel (or any coupling agent allowed by the manufacturer) to the sensor, at least enough to fully cover it.



Without applying ultrasound gel to the sensor before adhering the pad, image artifacts may appear.

Step 3:

Verify that the aiSon™ Focus package is completely sealed and unopened before opening. Verify that the product has not expired.



Step 4:

Next, fully peel open the aiSon™ Focus packaging.



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Step 5:

Pick up the aiSon™ Focus at the end with the integrated elastic opening.



Step 6:

Placing index and middle fingers on the inside of the integrated elastic opening, stretch it to enlarge the aiSon™ Focus' opening to approximately match that of ultrasound probe's widest point.



Step 7:

While keeping the integrated elastic opening stretched, gather the pad's material using the thumbs on the outside surface of the aiSon™ Focus, rolling it up to form a ring-like shape with the liquid repository in the center.



The product is packaged such that it does not have to be turned inside out. If you turn the pad inside out, the product may not function as efficiently as expected.

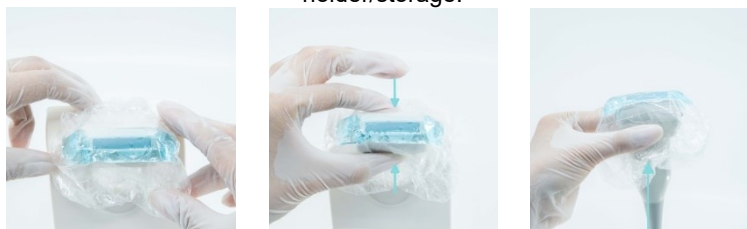
Step 8:

Maintaining the aiSon™ Focus stretched and in a ring shape, turn it upside down and place the liquid repository centered on the ultrasound probe's sensor. Once it is aligned with the probe's sensor, hold the pad in place by pressing it against the probe near the sensor with the thumbs while releasing the integrated elastic opening by retracting index and middle fingers.



Step 9:

Release the thumbs, then use one hand to fix the pad against the probe on the long sides of the probe while lifting it out of its holder/storage.



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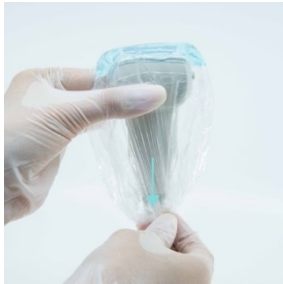
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Step 10:

While holding the pad in place with one hand, pull down on the aiSon™ Focus' bottom end with the integrated elastic opening with the other hand to fully extend the pad and cover the largest possible area of the ultrasound probe with its material.



Step 11:

Continue to hold the pad in place with one hand. With the other hand, carefully pick up the loose elastic band provided in the package with the pad and place it around the probe's neck, or below its widest point.



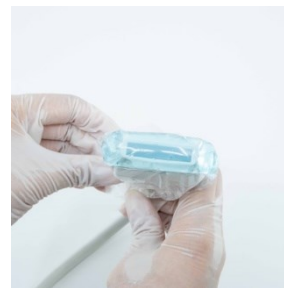
Step 12:

Carefully twist the elastic band with the free hand and wrap it around the probe as many times as necessary to tightly fasten the aiSon™ Focus on the ultrasound probe.



Step 13:

If the aiSon™ Focus' liquid repository is not centered on the ultrasound probe's sensor, pull on the pad's material to adjust without loosening the elastic band.



If the pad is fastened very tightly, image artifacts (e.g., reverberation artifacts) can appear in some ultrasound systems.

Step 14:

Remove any air pockets enclosed in the ultrasound gel between the pad and the probe's sensor by pressing down on the pad with a finger to avoid acoustic shadows or artifacts. Then apply ultrasound gel, or another coupling agent that is approved to be used on a patient's skin, such as disinfectant or water. Do not use disinfectants containing pyridine and pyridine derivatives as coupling agent. The aiSon™ Focus is ready for use.



Step 15:

While scanning, dynamically adjust the pressure exerted through the probe as to compress the pad and reduce the size of the standoff as required, or release pressure to increase the size of the standoff as needed (see horizontal arrow in the depiction below). The pad is designed to withstand pressure and the liquid will move by bulging on the sides (see vertical arrows in the depiction below), which is intentional, as shown in the depiction.



Without applying sufficient ultrasound gel, or another coupling agent, like water or disinfectant, between the pad and the patient's skin, there will be limited image visibility and image artifacts (e.g., reverberation artifacts).

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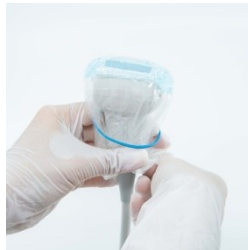
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Removal and disposal:

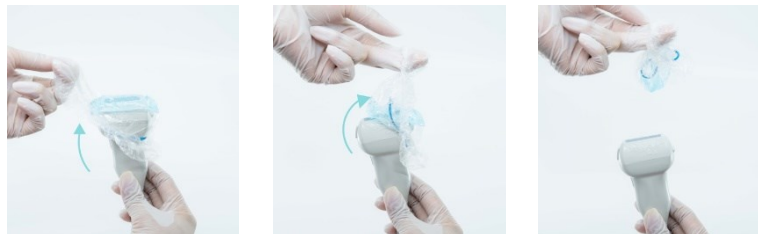
Step 1:

Unwind the elastic band around the ultrasound probe's neck. If the elastic band should be slippery due to excess ultrasound gel, first dry the elastic band and then unwind it.



Step 2:

Pull the aiSon™ Focus upwards at the integrated elastic opening and pull it off the ultrasound probe in one go. Dispose the aiSon™ Focus pad in a regular waste bin.



Step 3:

Remove the ultrasound gel on the sensor and clean the ultrasound probe in accordance with the manufacturer's cleaning instructions.



Safety Measures:

- The product does not contain any hazardous substances.
- The product does not contain latex.
- The product does not contain any endocrine-disrupting properties (e.g., bisphenol A or phthalates).
- Every aiSon™ Focus filling process has undergone quality checks.
- Does not contain animal or biological products.

Compatibility:

The aiSon™ Focus (UDI-DI 7649988699412) fits any ultrasound probe with a sensor area smaller or equal to 8.0cm x 2.0cm. The aiSon™ Focus Small (UDI-DI 7649988699429) fits any ultrasound probe with a sensor area smaller or equal to 4.5 cm x 1.5 cm.

Warnings and Precautions:

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Do not use if the package is damaged.



The product is provided as non-sterile.



Do not use the product after its expiration date.



Not made with natural rubber latex.



Do not reuse.

- If the product dropped on the ground or was otherwise contaminated with dirt, we recommend its disposal.
- Avoid applying excessive tension to the elastic band to prevent tearing. Tearing of elastic bands may result in injuries, e.g., to the eyes, resulting from uncontrolled recoil of a tensioned elastic band upon tearing.
- Keep the elastic band in the package until the time of application to mitigate contamination. Do not use the elastic band if it falls on the floor or comes in contact with any other unclean surfaces.
- Open the package only just before use.
- Not meant for intracorporeal use.
- Cannot be operated at temperatures below the freezing point.
- Do not leave a contaminated product unattended.
- Do not use disinfectants containing pyridine and pyridine derivatives as coupling medium.

Contraindications:

No known contraindications.

Any serious incident that has occurred in relation to the product should be reported to Aison Technologies and the competent authorities.

Storage and Disposal:

- The product can be used until the expiration date, which is indicated on the product label itself. The expiration date can be guaranteed if the product is stored at room temperature.
- After use, the aiSon™ Focus must be disposed of with the regular waste.
- Follow all local regulations for non-hazardous waste disposal.

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