

Instructions for Use

Revision: 7

Date: May 20th, 2022

aiSon™ FOCUS 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 can be used on any ultrasound probe with a sensor window 7.6cm x 2cm or smaller.

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 to be examined. 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-day multiuse 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).

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Choice of “adaptive” or “standoff” operating mode:

The aiSon™ FOCUS can be used in two different operating modes: “adaptive mode” and “standoff mode”. The most significant difference between the two modes is the level of tightness with which the aiSon™ FOCUS is adhered to the ultrasound probe, resulting in higher or lower ability of the pad to flexibly adapt its shape to the scanned surface. Depending on intended application and preference, the user must choose looser or tighter adherence.

The user should decide on an operating mode before adhering the aiSon™ FOCUS.

Adaptive mode

To achieve maximum adaptivity and flexibility of the aiSon™ FOCUS' surface, e.g., to scan irregular body surfaces, and decrease compression of the anatomy, the pad should be adhered to the ultrasound probe loosely. Due to lower tension on the pad's liquid repository the liquid can move around freely. This enables the overall shape of the aiSon™ FOCUS to flexibly adapt and mimic that of the scanned anatomy, maximizing surface contact with the patient. An example of the aiSon™ FOCUS in adaptive mode is depicted in the image below:



Standoff mode

To increase the distance between the ultrasound probe and the scanned anatomy, e.g., to create a fixed distance between the ultrasound probe and the patient, the pad should be adhered to the ultrasound probe more tightly. Due to the higher tension on the pad's liquid repository, the liquid will stay in front of the transducer, serving as a standoff that moves effortlessly with the probe. The standoff effect can be increased or decreased by compressing the pad with the probe, or releasing pressure. Overall, the liquid repository is stiffer to the touch. An example of the aiSon™ FOCUS in standoff mode is depicted in the image below:



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

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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 to the sensor, at least enough to fully cover it.



Without applying ultrasound gel to the sensor before adhering the pad, image artifacts can appear in some ultrasound systems.

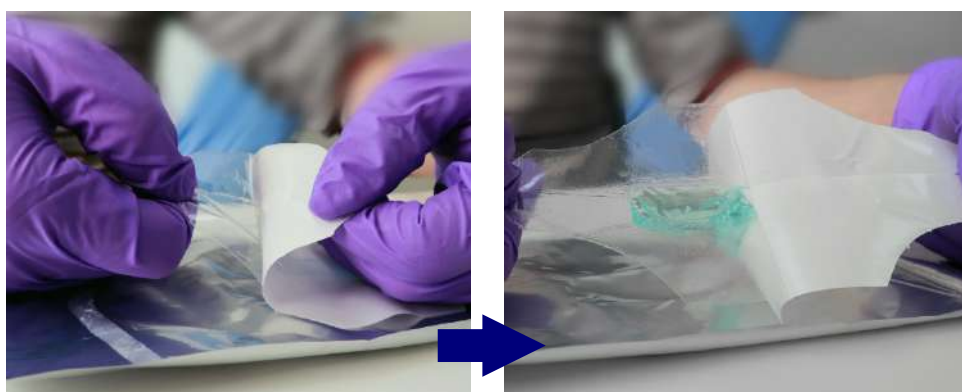
Step 3:

Verify that the aiSon™ FOCUS package is completely sealed and unopened before opening.
Next, fully peel open the aiSon™ FOCUS packaging.



Step 4:

Remove the liner (white paper) to expose the adhesive areas.



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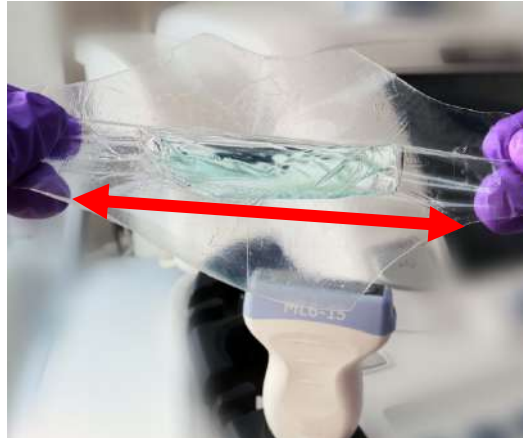
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Step 5:

Fully expand the pad to prevent the adhesive areas from adhering to one another. Should adhesive areas stick together, carefully try to release them without tearing the adhesive area.



Step 6:

Before adhering the pad, choose either "adaptive" or "standoff" operating mode (see descriptions on page 2) and follow the respective instructions below.

Option A: "adaptive mode" – loose adherence

For maximal adaptivity, adhere the pad loosely.

Step 6A.1:

Without adhering the pad, gently align its liquid repository with the probe's sensor and match the repository's margins with the sensor's using your thumbs.

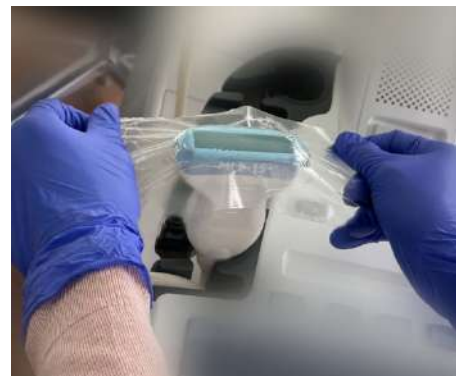


Option B: "standoff mode" – tight adherence

For faster scanning or use as a standoff, adhere the pad tightly.

Step 6B.1:

Stretch the pad and center the pad's liquid repository on the probe's sensor.



While placing the pad, make sure no air pockets are between the ultrasound probe and the pad. Also make sure that no adhesive area gets in contact with the ultrasound probe sensor.

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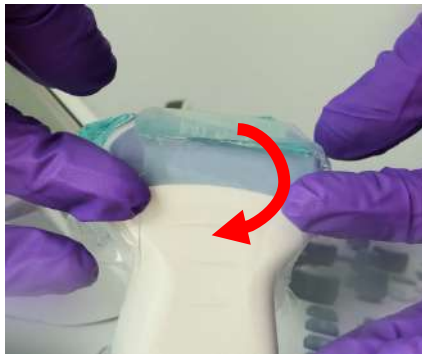
Step 6A.2:

Gently fold down the adhesive flaps on the short sides without pulling down.



Step 6A.3:

Gently fold down the adhesive flaps on the long sides without pulling down (only one side depicted).



Step 6A.4:

This is how the loosely adhered pad would appear.



Step 6B.2:

Pull down and adhere the short sides of the pad to the probe.



Step 6B.3:

Pull down and adhere the long sides of the pad to the probe.
(not depicted)

Step 6B.4:

This is how the tightly adhered pad would appear.



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Step 7:

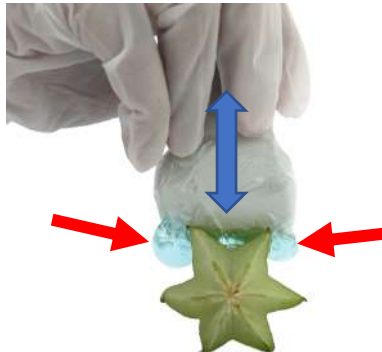
Remove any air bubbles enclosed in the ultrasound gel between the pad and the probe's sensor by pressing down on the pad with a finger to avoid acoustic shadows. Then apply ultrasound gel, or another coupling agent, such as disinfectant or water. The probe is ready to use.



Without applying ultrasound gel, or another coupling agent, like water or disinfectant, between the pad and the patient's skin, there will be limited visibility. Potentially image artifacts (e.g., reverberation artifacts) can appear in some ultrasound systems without a coupling agent.

Step 8:

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. The pad is designed to withstand pressure and the liquid will move by bulging on the sides, which is intentional as depicted below.



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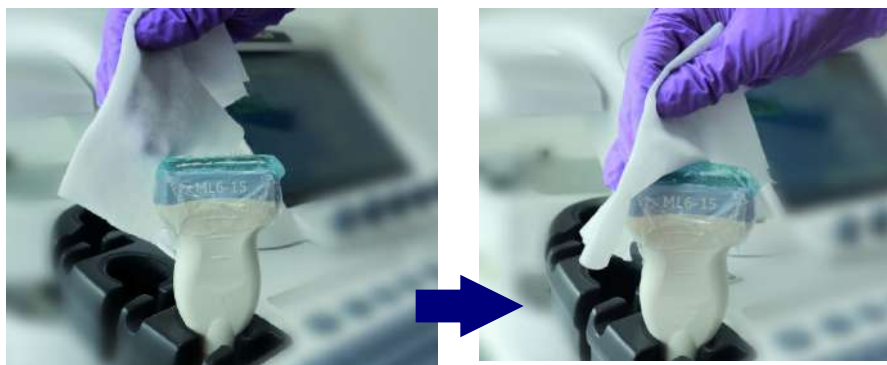
Step 9:

To safely reuse the aiSon™ FOCUS pad, leave it on the ultrasound probe. Next, clean and/or disinfect the top and all four sides of the aiSon™ FOCUS as follows:

1. Remove visible contaminants from the aiSon™ FOCUS pad's surface using a non-linting cloth soaked in clean water, and detergent (soap) where necessary.
2. Disinfect the aiSon™ FOCUS pad's surface soaking a non-linting wipe with a disinfectant, e.g. alcohol (70-90%) for a medium-level disinfection.

Do not use disinfectants that contain pyridine or pyridine derivatives. These can cause the product to dissolve.

For any detergent or disinfectant, follow manufacturer's instructions and recommendations for concentration, time of contact, and post-process procedure.

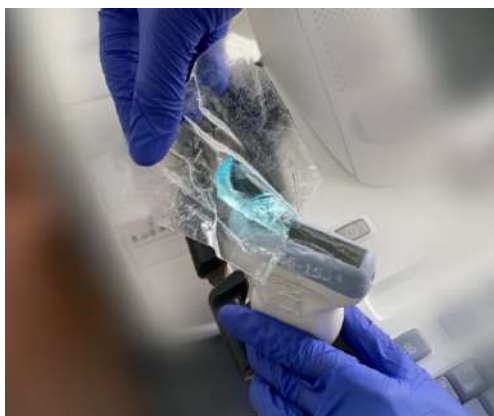


Use the product only up to 12 hours after opening the package.

Reuse product only after cleaning and disinfection.

Removal and disposal:

Carefully peel off the aiSon™ FOCUS pad to avoid tearing. This is the easiest when pulling off the corner side-adhesive flaps. Remove the ultrasound gel on the sensor and clean the ultrasound probe in accordance with the manufacturer's cleaning instructions. Dispose the aiSon™ FOCUS pad in a regular waste bin.



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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 fits any ultrasound probe with a sensor area smaller or equal to 73.20 mm x 20.20 mm.

Warnings and Precautions:



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.

- If the product dropped on the ground or was otherwise contaminated with dirt, we recommend you to dispose it instead of reprocessing it with a disinfectant.
 - Should two adhesive areas glue together, carefully pull them apart.
 - 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 with the product.
-

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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Article number: 001.002.001