Acessa Pad

(Model Number 3000)

℞ONLY **Instructions for Use**

Caution: Federal law (U.S.) restricts this device to sale by or on the order of a physician.

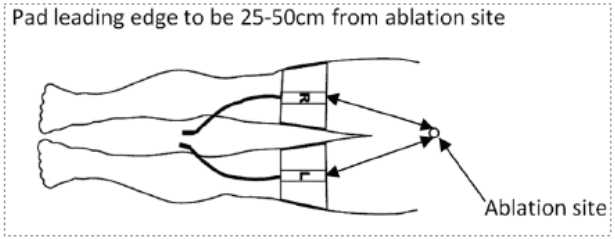
Product Description:
A set of two (2) disposable Pads that provide a return path for applied RF energy.

Indications for Use:
The Acessa Pad is an accessory to the Acessa System Console (Model 7100) for use during the Acessa procedure.
Intended for use with Pad cable (Model 4300) as return path for applied RF energy.

Contraindication:
The Acessa Pad is contraindicated for any time use of the Acessa System Console is contraindicated.

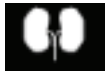
Instructions:

1. The Pads should be used only by physicians and medical staff who have been trained and have a thorough understanding of the Ablation system.
2. Prep patient where pads will be placed. Prep per user facilities SOP and/or AORN or AAMI Standards in the placement of the pads.
3. Ensure intended site is clean and dry.
4. Remove the pads from their packaging.
5. Carefully peel back release liner from the pads and discard release liner.
6. Inspect cables and pads for damage. Do not use if they appear to be damaged.
7. Place pads exactly on the patient according to the illustration below.



8. Avoid placement over scars, bony prominences, metal prostheses, or EEG electrodes.
9. Avoid placement where fluids may pool.
10. It is also recommended to avoid skin- to- skin or pad- to- pad contact, such as between the legs or between the torso and arms, by insulating with sheets or other dry material.
11. Verify entire pad surface conforms to patient applied surface (no bubbles or lifted surface).
12. Connect the pad cable on the patient's right leg to the "R" on the pad cable per the illustration below.
13. Connect the pad cable on the patient's left leg to the "L" on the pad cable per the illustration below.

14. Attach the Pad Cable (Model 4300) to the port on the Acessa Console labeled with the product graphic below.



15. The Pads may be externally cooled at the discretion of the physician.

Warnings:

- Unintended skin burns may occur if Acessa Pads are not placed as instructed!
- DO NOT cut or modify the electrode in any manner. This will adversely affect the performance of the device and could cause unintended burns.
- For single patient use! Re-use of Pads may result in patient burn and/or infection.

Precautions:

- Store in a dry place.
- For monopolar use only!
- The Pads are shipped non-sterile.
- DO NOT use product after its expiration date (see packaging label).
- All packaging should be inspected prior to use.
- DO NOT use if the packaging or product is damaged in any way (including Hydrogel delamination or exposed metal contact).
- After use, this product is potentially a biohazard. Handle and dispose of, in accordance with accepted medical practice and with applicable laws and regulations.

Symbols Glossary

Symbol	Standard Reference & Symbol Number	Title of Symbol	Description of Symbol
	EN ISO 15223-1, 5.1.5 ISO 7000, 2492	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	EN ISO 15223-1, 5.1.6 ISO 7000, 2493	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	EN ISO 15223-1, 5.4.4 ISO 7000, 0434A IEC 60601-1, Table D.1, 10	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	EN ISO 15223-1, 5.4.3 ISO 7000, 1641 IEC 60601-1, Table D.1, 11	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	EN ISO 15223-1, 5.4.2 ISO 7000, 1051 IEC 60601-1, Table D.1, 28	Do not re-use	Indicates a medical device that is intended for one single use only.
	EN ISO 15223-1, 5.2.8 ISO 7000, 2606	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
	EN ISO 15223-1, 5.3.4 ISO 7000, 0626 ISO 780	Keep dry	Indicates a medical device that needs to be protected from moisture.

Symbol	Standard Reference & Symbol Number	Title of Symbol	Description of Symbol
	EN ISO 15223-1, 5.1.1 ISO 7000, 3082	Manufacturer	Indicates the medical device manufacturer.
	ISO/DIS 15223-1, 5.7.11 ISO 7000, 6049	Country of manufacture	To identify the country of manufacture of products.
	EN ISO 15223-1, 5.2.7 ISO 7000, 2609	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	ISO 7000, 2794	Packaging unit	To indicate the number of pieces in the package.
	FDA 21 CFR 801.109	Prescription use only	Caution: Federal law restricts this device to sale by or on the order of a physician.
	IEC 60601-1, Table D.1, 20 IEC 60417, 5333	Type BF applied part	To identify a Type BF applied part complying with IEC 60601-1
	EN ISO 15223-1, 5.1.4 ISO 7000, 2607	Use-by date	Indicates the date after which the medical device is not to be used.

Warranty

Except as otherwise expressly stated in an agreement between Hologic and its original customer ("Customer), Hologic equipment ("Equipment") is warranted to the original Customer to perform substantially in accordance with published product specifications for one (1) year starting from the date of shipment ("Warranty Period"). Replacement parts and remanufactured items are warranted for the remainder of the Warranty Period or 90 days from shipment, whichever is longer. Consumable supplies are warranted to conform to published specifications for a period ending on the expiration date shown on their respective packages. Licensed software is warranted to operate in accordance with published specifications. Services are warranted to be supplied in a workman-like manner. Hologic does not warrant that use of Products will be uninterrupted or error-free, or that Products will operate with non-Hologic authorized third-party products.

These warranties do not apply to any item that is: (a) repaired, moved, or altered other than by Hologic authorized service personnel; (b) subjected to physical (including thermal or electrical) abuse, stress, or misuse; (c) stored, maintained, or operated in any manner inconsistent with applicable Hologic specifications or instructions, including Customer's refusal to allow Hologic recommended Software upgrades; or (d) designated as supplied subject to a non-Hologic warranty or on a pre-release or "as-is" basis.

Technical Support and Product Return Information

Contact Hologic Technical Support if the Acessa Pad fails to operate as intended. If product is to be returned to Hologic for any reason, Technical Support will issue a Returned Materials Authorization (RMA) number and a biohazard kit if applicable. Return the Acessa Pad according to the instructions provided by Technical Support.

If applicable, return used or opened product according to the instructions provided with the Hologic-supplied biohazard kit.

Disposal:

Consult your local regulations for disposal and/or electronics recycling as applicable. Do not place into a municipal waste system unless authorized to do so by local authorities.

FOR MORE INFORMATION

For Technical Support or reorder information in the United States, please contact:

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Marlborough, MA 01752 USA
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Telephone : 800-442-9892

https://www.hologic.com/patent-information