



R_X ONLY

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

Acessa Pad Cable (Model Number 4300) Instructions for Use

Product Description:

The Acessa Pad Cable provides connectivity between the Acessa System Console and Acessa Pads.

Indications For Use:

The Acessa Pad Cable is an accessory to Acessa System Console (Model 7100) for use during the Acessa procedure.

Contraindication:

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

Warnings:

- The Acessa Pad Cable should be used only by physicians and medical staff who have been trained and have a thorough understanding of the Acessa System.
- The Acessa Pad Cable is shipped non-sterile. Cleaning and disinfection are required before each use.

Precautions:

- Do not use if the product is damaged in any way.
- Refer to the Acessa User's Guide (PL-01-0040) for additional information on the set-up and use of the Acessa System Console.
- The Pad cable has not been validated for more than 20 uses

Preparation and Operation:

1. Remove the Pad Cable from its packaging.
2. Inspect cable for damage. Do not use if it appears to be damaged.
3. Attach the Pad Cable (Model 4300) to the port on the Acessa Console labeled with the product graphic.
4. Connect one end of the cable to the Acessa System Console, ensure that there is a tactile feel when the connector latches or listen to the engaging click of the connector.
5. Connect the other end to the appropriate Left or Right Pad Cable connectors.
6. Follow any other instructions pertinent to the use of the Acessa System Console.
7. To disconnect the cable, pull straight back on the connector sleeve (see Arrow icon) and then disconnect. **DO NOT PULL ON CABLE.**



8. Store cable in a dry location.

Recommended Cleaning and Disinfection Procedure:

Hologic, Inc. recommends the following cleaning and disinfection steps as outlined below. All Acessa Pad Cables must be thoroughly cleaned; according to the process described in this section before proceeding with disinfection of the device. Thorough cleaning is the first and most important steps in reprocessing of any reusable medical device. Without thorough cleaning, it is not possible to achieve effective disinfection of the device.

Cleaning

The Pad Cable should be given reasonable care and be kept clean and sanitary. To clean the Pad Cable wipe down the device with a 70% isopropyl alcohol wipe. Clean surface until all visible soil is removed.

Disinfection





After cleaning as identified above to remove all visible, gross soil use a Super SaniCloth® 0.5%/55% (working solution) to wipe all surfaces. Make sure the surfaces remain visibly wet at room temperature for the minimum time specified by Super SaniCloth instructions. Remove any excess disinfectant solution using a soft lint-free cloth. Examine for damage. Discontinue use if the cable is damaged







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.

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.

Symbol	Standard Reference & Symbol Number	Title of Symbol	Description of Symbol
	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.
	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.

Symbol	Standard Reference & Symbol Number	Title of Symbol	Description of Symbol
	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

Technical Support and Product Return Information

Contact Hologic Technical Support if the Acesa Pad Cable 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 Acesa Pad Cable 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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<https://www.hologic.com/patent-information>

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