



1012 Immittance Probe Cleaning Kit

Instructions for Use:



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Rx only



Associated Product Part Number:

8-69-28000 1012 Immittance Probe Tip Cleaning Kit (5 wires + 1 brush)

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Description:

The 1012 Immittance Probe Tip Cleaning Kit consists of a combination of a cleaning tool and a cleaning brush to remove any debris that clogs the probe tip and prevents it from functioning optimally.

Intended Use:

The intended use of the Probe Tip Cleaning Kit is to clean clogged probe tips.

Intended Users and Patient Target Group:

The product is for use only under the direction of trained medical professionals. This product does not come in contact with any patient.

Clinical Benefits:

The clinical benefits of the Cleaning Kit are to enable the user to remedy problems with clogged probe and probe tips so that the user can continue the examinations on the patients.

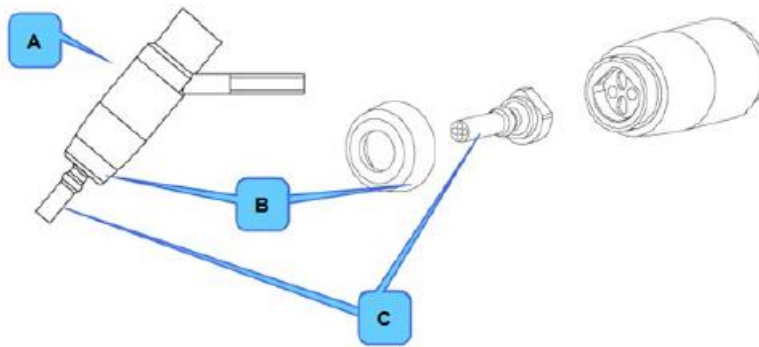
Contraindications and Side Effects:

There are no known contraindications or side effects for procedures performed with the Cleaning Kit. See Precautions below.

Operating Instructions:

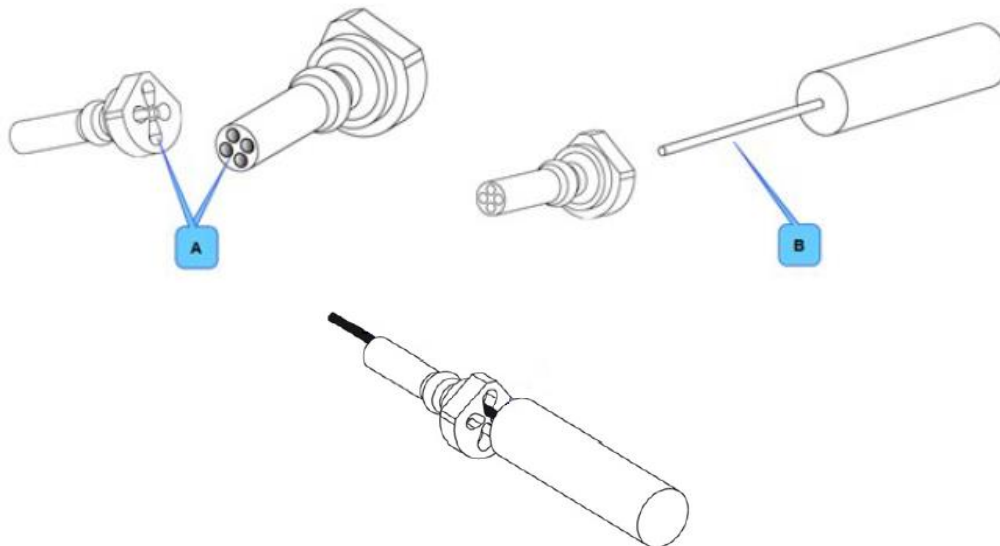
1. To remove the probe tip, hold the probe by the probe body and unscrew the threaded ring. Take off the probe tip.

- A – Probe Body
- B – Threaded Ring
- C – Probe Tip



2. Check if the sound channels of the probe tip are blocked. If they are blocked, use the cleaning wire to clean the sound channels. **Note:** Always clean from the rear.


- A – Sound Channels
- B – Cleaning Wire




3. If you are cleaning the probe tip during a session of testing a patient, use the cleaning brush to clean the cleaning wire, especially where it protrudes from the probe tip, before you pull it back through the hole.

4. If you are cleaning the probe tip between sessions, use alcohol wipes to clean the cleaning wire, and, if needed, the brush before you pull it back through the hole.
5. Make sure that the sound channels are completely dry before fitting the tip back into the probe body, or use a spare probe tip.
6. Fit the probe tip and screw the threaded ring firmly back onto the probe body. Tighten up to prevent leakage.

Understanding Caution Statements:

	CAUTION
Refers to a hazardous situation that could result in minor or moderate injury or material damage if not avoided.	
<ul style="list-style-type: none"> • Information on how the hazardous situation is avoided. 	

Precautions:

	CAUTION
Unauthorized modification, servicing, or use of supplies or components that are not approved by Natus could lead to loss of device function or performance.	
<ul style="list-style-type: none"> • Do not modify the device or use unauthorized accessories, supplies, or components. 	
Improper cleaning of the cleaning kit could lead to user or patient cross infection.	
<ul style="list-style-type: none"> • Ensure proper cleaning of the cleaning kit between the sessions. 	
Device damaged in transit or use could lead to loss of function or delayed diagnosis.	
<ul style="list-style-type: none"> • Inspect the device prior to each use and do not use if damaged. 	
Using or storing the device under extreme environmental conditions could lead to inconvenience and delay in procedure.	
<ul style="list-style-type: none"> • Do not store the device outside the prescribed storage conditions. • Do not use the device outside the prescribed operating conditions. 	

Environmental Specifications:

Operating Conditions:

- Temperature: +15°C to +35°C (+59°F to +95°F)
- Relative Humidity: 30% to 90%
- Atmospheric Pressure: 600 hPa to 1060 hPa

Storage Conditions:

- Temperature: -20°C to +60°C (-4°F to +140°F)
- Relative Humidity: Less than 90%
- Atmospheric Pressure: 500 hPa to 1060 hPa

Disposal Instructions:

Following use, dispose of Cleaning Kit with infectious waste.

Disclaimer:

Natus Medical Denmark ApS is not responsible for injury, infection or other damage resulting from the use of this product.

Any serious incident that has occurred in relation to the device should be reported to Natus Medical Denmark ApS and the competent authority of the Member State in which the user and/or patient is established.

Refer to the Natus website for an electronic copy of this document.

Instructions to Access the eIFU:









A copy of the Instructions for Use in PDF format is in the associated product area:




- Hearing and Balance: <https://hearing-balance.natus.com/manuals>

Search for "1012 Immittance Probe Cleaning Kit IFU" (refer to the Product Part Number) and choose the version for your local language for the instructions to use.

The files can be printed, saved, or searched using Adobe Reader. A copy of Adobe Reader can be downloaded directly from Adobe Systems (www.adobe.com).

Glossary of Symbols:

Symbol	Standard Reference	Standard Title	Symbol Title	Explanation
Medical Device	Not applicable	Not applicable	An indication of Medical Device	This product is a medical device.
Rx only	21 CFR Part 801.109(b)(1)	Labeling-Prescription devices	Prescription only	Indicates that the product is authorized for sale by or on the order of a licensed healthcare practitioner.
	ISO 15223-1 Symbol 5.4.5 (Reference Annex B for the general prohibition symbol)	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Not made with natural rubber latex	Indicates that the medical device is not made with natural rubber latex.
	ISO 15223-1 Symbol 5.1.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1 Symbol 5.1.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Date of manufacture	Indicates the date when the medical device was manufactured.
	ISO 15223-1 Symbol 5.1.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1 Symbol 5.1.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1 Symbol 5.4.3 Annex A #A.15	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Consult instructions for use	Indicates an instruction to consult an electronic instructions for use (eIFU).
	ISO 15223-1 Symbol 5.4.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	IEC 60601-1 Table D.1 #10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance		
	MDR 2017/745	EU Medical Device Regulation	CE marking	Signifies European technical conformity.

Symbol	Standard Reference	Standard Title	Symbol Title	Explanation
	ISO 15223-1 Symbol 5.3.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Temperature limit	Indicates the (storage) temperature limits to which the medical device can be safely exposed.
	ISO 15223-1 Symbol 5.3.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Humidity limitation	Indicates the range of (storage) humidity to which the medical device can be safely exposed.
	ISO 15223-1 Symbol 5.3.9	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Atmospheric pressure limitation	Indicates the acceptable upper and lower limits of atmospheric pressure for transport and storage.

033101_02 12/2020