

N11C5s (9063) Transducer



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The connector label on a BK Medical transducer contains information about the date of manufacture.

BK Medical Customer Satisfaction

Input from our customers helps us improve our products and services. Your opinions are important to us. You are always welcome to contact us via your BK Medical representative or by contacting us directly.

Hardcopy of this user guide can be requested free of charge.

Please go to

<https://www.bkmedical.com/support/bk/bk-ultrasound-user-guides-eu/>

N11C5s = Ref. Type 9063

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Introduction

This is the user guide for the N11C5s transducer, and it must be used together with the *Care and Cleaning* user guide which contains important safety information.


 Physicians only	Caution Rx-c1 United States Federal law restricts this device to sale by or on the order of a physician.
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Intended use

The transducer is intended for diagnostic ultrasound imaging or fluid flow analysis of the human body.

Indications for use

N11C5s is designed for intraoperative (neuro) and intraoperative imaging. Needle guide UA1346 provides guidance of a needle for biopsy and drainage.

	WARNING Cardio-w1 To avoid patient injury, do not use the transducer for applications where it may come in direct conductive contact with the patient's heart.
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Patient Population

The patient population is children (>2-12 years) and adults.




Figure 1. N11C5s transducer


Contraindications

	WARNING T-w6 To avoid causing injury to the eye, do not use this transducer for ophthalmic use, or any application that causes the acoustic beam to pass through the eye.
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General Information

Product specifications, acoustic output data and data about EMC (electromagnetic compatibility) for this transducer can be found in the *Product Data Sheet* and the *Technical Data (BZ2100)* that accompany this user guide.

	<p>WARNING GS-w2</p> <p>If at any time the system malfunctions, or the image is severely distorted or degraded, or you suspect in any way that the system is not functioning correctly:</p> <ol style="list-style-type: none">1 Remove all transducers from contact with the patient.2 Turn off the system. Unplug the system from the wall and make sure it cannot be used until it has been checked.3 Contact your BK service representative or hospital technician. Do not try to repair the system yourself.
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	<p>WARNING AO-w1</p> <p>To avoid tissue damage, always keep the exposure level (the acoustic output level and the exposure time) as low as possible.</p>
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Service and Repair

	<p>WARNING SR-w1</p> <p>Service and repair of BK electromedical equipment must be carried out only by the manufacturer or BK authorized service representatives. BK Medical reserves the right to disclaim all responsibility, including but not limited to responsibility for the operating safety, reliability and performance of equipment serviced or repaired by other parties. After service or repairs have been carried out, a qualified electrician or hospital technician should verify the safety of all equipment.</p>
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Caring for the Transducer

The transducer may be damaged during use or reprocessing, so it must be checked before use for cracks or irregularities in the surface, following the procedure in *Care and Cleaning*. It should also be checked thoroughly once a month following the same procedure.


Reprocessing

To ensure the best results when using BK Medical equipment, it is important to maintain a strict cleaning routine.

Complete details and procedures can be found in *Care and Cleaning* that accompanies this user guide.


A list of reprocessing methods that the transducer can withstand are listed in the *Product Data Sheet*.

Sterile covers are available. See the *Product Data Sheet* for more information.


	<p>WARNING Reproc-w2</p> <p>Users of this equipment have an obligation and responsibility to provide the highest possible degree of infection control to patients, co-workers and themselves. The instructions in this book are meant as a guide. To avoid cross-contamination, follow all infection control policies (including for reprocessing, packing and storage) for personnel and equipment that have been established for your office, department or hospital.</p>
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Starting Imaging

Before use, all equipment must be reprocessed according to expected use.

	<p>WARNING T-w5</p> <p>To prevent electrical shock and damage to the transducer, the connector pins in the transducer plug must always be completely dry before you connect to a system.</p>
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Connecting the Transducer

	<p>WARNING GS-w4a</p> <p>It is essential for the patient's safety that only the correct equipment is used.</p> <ul style="list-style-type: none"> • Do not use other manufacturers' transducers with BK ultrasound systems. • Do not use BK transducers with other manufacturers' systems. • Do not use unauthorized combinations of transducers and needle guides.
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The transducer is connected to the system using the array transducer socket on the system. To connect, flip the system's locking lever to the right. Align the transducer plug to the system socket and insert securely. Flip the system's locking lever to the left to lock it.

When connected, the transducer complies with Type BF requirements of EN60601-1 (IEC 60601-1).


Changing Frequency


The multifrequency imaging (MFI) control enables you to select the imaging frequency. See the applicable system user guide for instructions.


Using a Transducer Cover

BK recommends the use of a sterile transducer cover to reduce the risk of cross-contamination. See the **Product Data Sheet** for a list of available transducer covers. Follow local guidelines for the use of transducer covers in your area.

NOTE: *In the United States of America, it is recommended to use transducer covers that have been market cleared. In Canada, use only licensed transducer covers. In Europe, transducer covers must be CE-marked.*

	<p>WARNING TC-w1</p> <p>Some transducer covers can contain latex. Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), the FDA advises health-care professionals to identify their latex-sensitive patients and be prepared to treat allergic reactions promptly.</p>
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	<p>WARNING TC-w2</p> <p>For neurosurgical applications, use only approved non-pyrogenic, sterile transducer covers. This means that in the USA they must be market cleared by the FDA and in Europe they must be CE-marked. In Canada, they must be licensed by Health Canada.</p>
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	<p>WARNING TC-w7</p> <p>Use only approved non-pyrogenic, sterile transducer covers. This means that in the USA they must be market cleared by the FDA and in Europe they must be CE-marked. In Canada, they must be licensed by Health Canada.</p>
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Apply sterile gel to the tip of the transducer or fill the cover with 1 to 2 ml of sterile water. This improves screen imaging by preventing image artifacts caused by air bubbles.

Pull the transducer cover over the transducer. Check for air bubbles between the cover and the transducer and even out if necessary before proceeding.

Irrigate the organ to be imaged with 0.9% sterile physiological saline solution while imaging.

Follow these precautions when putting sterile covers on a transducer:

- Wear sterile gloves.
- When using a puncture attachment, place it gently over the cover and secure it, following the instructions for the puncture attachment.
- Verify that the cover has not been damaged in the process. If it has, repeat the procedure with a new transducer cover.

	<p>Caution T-c3</p> <p>Use only water-based gel (sterile if you are using a sterile transducer cover). Products containing parabens, petroleum, or mineral oils may harm the transducer or transducer cover.</p>
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Using the Transducer Control Button





The control button on the transducer controls the imaging.

Press the button to **Start** or **Stop** imaging (freeze frame). Press the button for more than one second to make a copy of the image.

Changing Orientation

To change the orientation of the image on the monitor, refer to the applicable system user guide for instructions.

Imaging with N11C5s



	<p>WARNING C-J-w1</p> <p>Do not use this transducer for neurosurgical applications if the patient is suspected of having Creutzfeldt-Jakob disease. If a neurosurgical transducer has been used on a patient suspected of or diagnosed as being Creutzfeldt-Jakob positive, the transducer must be destroyed, following approved procedures for your hospital.</p>
	<p>WARNING TC-w5</p> <p>If the transducer cover is damaged during interventional procedures, follow the policies of the hospital or clinic for treatment of the patient under such circumstances.</p>
	<p>WARNING TC-w10</p> <p>Avoid scraping the transducer against any raw bone edges along the drill hole. This could damage the transducer cover and increase the risk of contamination.</p>
	<p>WARNING Exam-w7</p> <p>To avoid patient injury, do not lean on, bend or apply excessive force when using the transducer. Remain aware of the location of the transducer tip at all times.</p>

Puncture and Biopsy Facilities


The N11C5s transducer can be used for puncture and biopsy. The appropriate puncture attachments are illustrated on the following pages with a brief description of their use and operating instructions.

Single-Use Sterile Needle Guide UA1346 for N11C5s

Needle guide UA1346 is supplied sterile in peel packs and is for single-use only. Contents are sterile only if the package is intact. The needle guide, inserts, and palettes must be discarded after use.

	<p>WARNING Sterile-w1</p> <p>Single-use components are packaged sterile and are intended for single-use only.</p> <p>Do not use if:</p> <ul style="list-style-type: none">• Integrity of packaging is violated• Expiration date has passed• Package label is missing
	<p>WARNING Sterile-w2</p> <p>Sterile-packed components must be stored in a safe environment and kept out of direct sunlight. Large temperature changes during storage may cause condensation and violate the integrity of the packaging.</p>

The sterile-packed needle guide must be stored at a temperature range from +5 °C (+41 °F) to +25 °C (+77 °F) and a storage humidity of 0% to 80%.

	<p>WARNING D-w1</p> <p>For disposal of contaminated items such as transducer covers or needle guides or other disposable items, follow disposal control policies established for your office, department, or hospital.</p>
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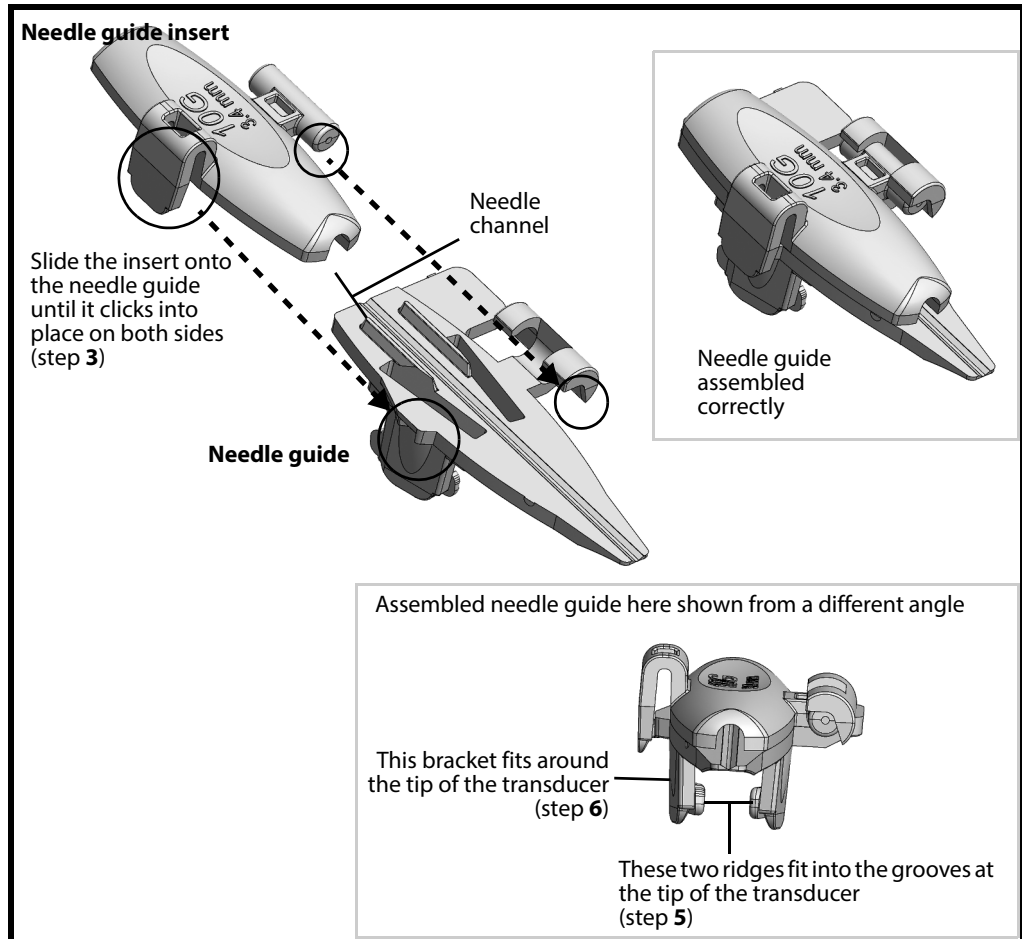


Figure 2. Needle guide UA1346 for the N11C5s; the numbered steps refer to the steps in the procedure describing how to mount the needle guide on the following pages.

Needle guide UA1346 is supplied together with one needle guide insert palette. The palette contains a needle guide and a set of 9 needle guide inserts.

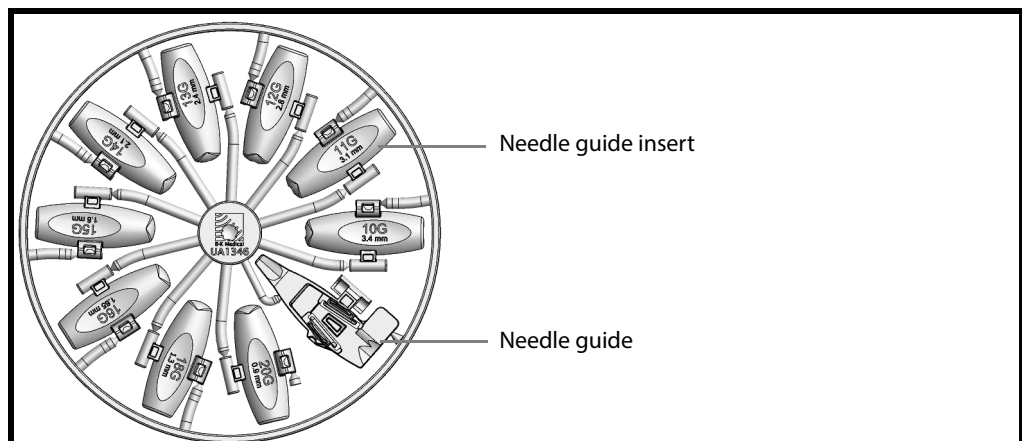


Figure 3. Palette with needle guide UA1346 and needle guide inserts.

The guide channel is angled at 8° to the transducer's image axis.

The distance from the guide channel entrance of the puncture attachment to the first dot on the scan image puncture line is approximately 7 mm (0.3 in). The distance between the dots is 5 mm (0.2 in).

Assembling and Mounting the Needle Guide

To assemble and mount a needle guide on N11C5s:

- 1 Apply a small amount of scanning gel to the tip of the transducer and carefully cover the transducer with a sterile cover.
- 2 Select the needle guide and the required needle guide insert by breaking them off the palette, see Fig. 3.
- 3 Slide the insert onto the needle guide until it clicks into place on both sides, see Fig. 2.
- 4 Hold the assembled needle guide with the bracket pointing down.
- 5 Align the two grooves on the transducer with the two ridges on the needle guide.
- 6 Carefully smooth and stretch the transducer cover along the face of the array while applying pressure until the needle guide clicks into place over the end of the transducer.
- 7 Fig. 4 shows the needle guide mounted on the transducer.

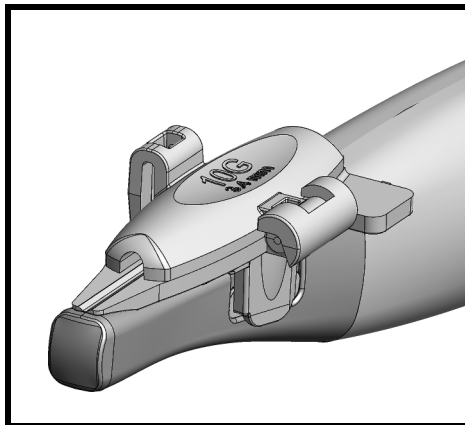


Figure 4. UA1346 mounted on transducer (shown here without transducer cover).

	WARNING P-w9 Ensure that the channel bracket and needle guide are correctly positioned. Never insert the needle guide while the transducer is inside the patient.
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- 8 Carefully insert the needle into the needle channel.

	Caution P-c1 To avoid contamination, do not let the needle scrape the inside of the needle channel.
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Attaching N11C5s and UA1346 to a LEYLA Arm

Needle guide UA1346 has a tab that can be used to secure it to a LEYLA arm (see Fig. 5).

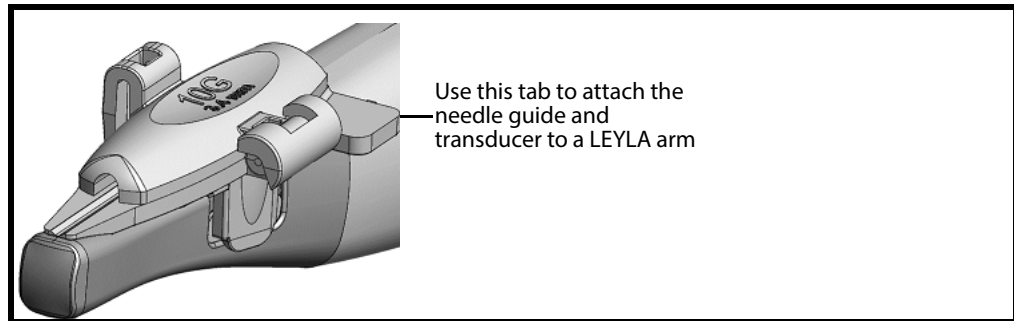



Figure 5. N11C5s with needle guide can be attached to a LEYLA arm.

	<p>Caution T-c4</p> <p>Ensure that the transducer and needle guide are attached firmly to the LEYLA arm so that they stay in position and do not fall off</p>
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NOTE: Ensure that the transducer cable is secured so that it cannot move and pull the transducer out of position.

Releasing the Needle During Biopsy

You can release the needle during biopsy so that the needle guide and transducer can be removed from the patient, leaving only the needle in place.

How to release the needle guide on N11C5s:

- 1 Hold the transducer with your left hand. With your right hand, carefully push the needle guide insert sideways until it opens up, see Fig. 6.

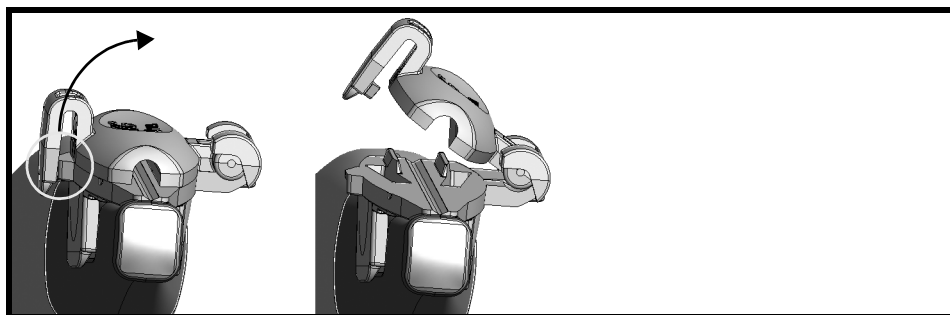






Figure 6. Push to release the needle guide on the N11C5s.

	<p>WARNING TC-w4</p> <p>If you detach the needle guide during interventional procedures, the transducer cover could be damaged. To avoid cross-contamination, cover the transducer with a new transducer cover before reattaching the needle guide.</p>
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	<p>WARNING Exam-w5</p> <p>Be careful not to lose any parts of the needle guide inside the patient.</p>
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Performing Puncture and Biopsy

	<p>WARNING P-w1</p> <p>Before you start imaging, verify that the type number or name of the transducer and the type number or description of the needle guide you are using match the number displayed on the monitor. Also make sure that the needle guide is positioned correctly. If the numbers do not match, or if the needle guide position is not correct, the puncture line on the monitor may not correspond to the true puncture path in the tissue. In case of any inconsistency, stop imaging, turn off the system, and contact your BK service representative.</p>
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	<p>WARNING P-w6</p> <p>The puncture line on the image is an indication of the expected needle path. To avoid harming the patient, the needle tip echo should be monitored at all times so any deviation from the desired path can be corrected. You must take extra care when taking a freeangle biopsy because the expected needle path is not shown.</p>
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If not sterilized, cover the transducer with a sterile transducer cover.

If the transducer cover is damaged when attaching the puncture attachment, replace it with a new cover.


See the *Product Data Sheet* for a list of available transducer covers.

Superimpose
puncture line


Press the **Puncture** or **Biopsy** control on the system to superimpose a puncture line on the scan image.

If more than one puncture line is available, refer to the applicable system user guide for instructions on how to change which one appears.

Move the transducer until the puncture line transects the target. Insert the needle and monitor as it moves along the puncture line to the target. The needle tip echo will be seen as a bright dot on the screen.

	<p>WARNING TC-w5</p> <p>If the transducer cover is damaged during interventional procedures, follow the policies of the hospital or clinic for treatment of the patient under such circumstances.</p>
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To remove the puncture line from the scan image, refer to the applicable system user guide for instructions.

	<p>WARNING P-w5</p> <p>Avoid unnecessary tissue damage. When performing a biopsy, always make sure that the needle is fully drawn back inside the needle guide before moving the transducer.</p>
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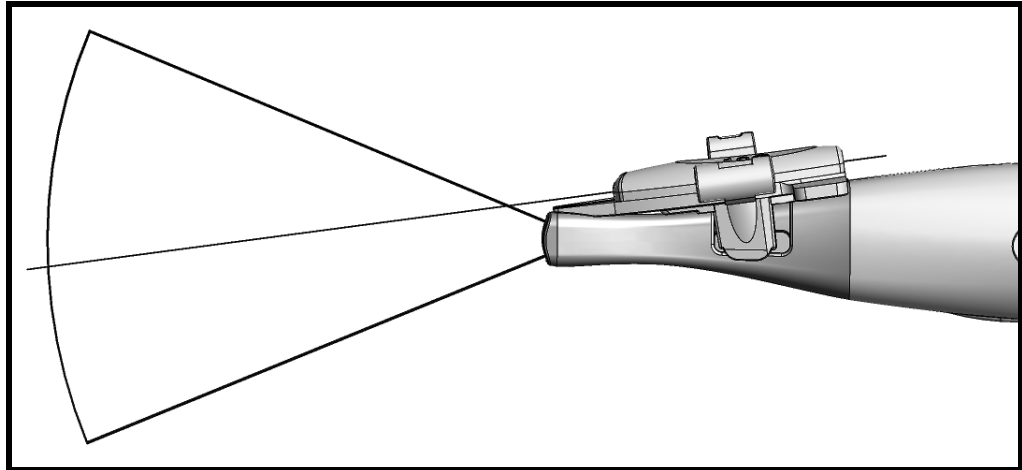



Figure 7. Illustration of the puncture line for single-use needle guide UA1346 when mounted on N11C5s.


Cleaning after Puncture and Biopsy

	<p>WARNING Reproc-w3</p> <p>Immediately after use, you must pre-clean the device until visually clean (including device lumens if existing). Conduct the thorough cleaning process as soon as possible after use in order to prevent bioburden drying on the surface. Dried bioburden can lead to inefficient cleaning, disinfection and sterilization, causing a risk of cross-contamination.</p>
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Use a suitable brush to make sure that biological material and gel are removed from all channels and grooves. See *Care and Cleaning* for cleaning instructions.

Disposal

When the transducer is scrapped at the end of its life, national rules for the relevant material in each individual land must be followed. Within the EU, when you discard the transducer, you must send it to appropriate facilities for recovery and recycling.

	<p>WARNING D-w1</p> <p>For disposal of contaminated items such as transducer covers or needle guides or other disposable items, follow disposal control policies established for your office, department, or hospital.</p>
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