

N20P6 Transducer



LEGAL MANUFACTURER

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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.


N20P6= Ref. Type 9007

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Introduction

This is the user guide¹ for the N20P6² 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

N20P6 is designed for intraoperative (neuro).


	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 infants, children, adolescents and adults.




Figure 1. N20P6 transducer


	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.

1. This user guide is not for use in the EU.
2. N20P6 has not been licensed by Health Canada and is not CE-marked.

	<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> <ul style="list-style-type: none"> • Remove all transducers from contact with the patient. • Turn off the system. Unplug the system from the wall and make sure it cannot be used until it has been checked. • Do not try to repair the system yourself. • Contact your BK service representative or hospital technician.
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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 its authorized 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*.

**WARNING** Reproc-w2

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.

Starting Imaging

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

**WARNING** T-w5

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.

Connecting the Transducer

**WARNING** GS-w4a

It is essential for the patient's safety that only the correct equipment is used.

- Do not use other manufacturers' transducers with BK systems.
- Do not use BK transducers with other manufacturers' systems.
- Do not use unauthorized combinations of transducers and needle guides.

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).

NOTE: *Ensure that the transducer cable is secured so that it cannot move and pull the transducer out of position.*


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. 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.*

	<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 non-pyrogenic, sterile transducer covers that are approved for neurosurgical use. 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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Endoport

The N20P6 is compatible with NICO BrainPath® (diameters 11-13.5mm; lengths 50-95mm), Vycor ViewSite™ Brain Access System (widths: 12-28mm; heights: 8-20mm; lengths: 3-7cm), and Neuroendoport® (diameters greater than 13mm; lengths: 5.5-8.5cm). When used with cover please consider using an endoport with larger diameter.

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.

NOTE: It is possible to assign a different function to the transducer button when pressed more than one second. See the bk3000-bk5000 Advanced User Guide for instructions.


Changing Orientation


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

Imaging with N20P6


The N20P6 is for use in intraoperative (neuro) brain, spinal cord and transsphenoidal (during neurosurgical procedures).

For transsphenoidal use, make sure, that the hole drilled in the *sella turcica* is large enough to accommodate the tip of the transducer and any other instruments to be used for the operation.


	<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>
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	<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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This is an ultrasound transducer, and should never be used as a surgical instrument. It is specifically designed to image anatomy as described above. Using it as a surgical instrument can seriously damage the transducer and make it unfit for its purpose.

	<p>WARNING TC-w11</p> <p>Be careful during insertion. Avoid scraping the transducer against bone edges. This could damage the transducer and cover, increasing the risk of contamination.</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.

	<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 tip of the transducer at all times.</p>
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Always identify the orientation of the transducer by the image on the monitor before starting the exam.

The image on the monitor is oriented according to how you position the transducer. This likely depends on your position relative to the patient:

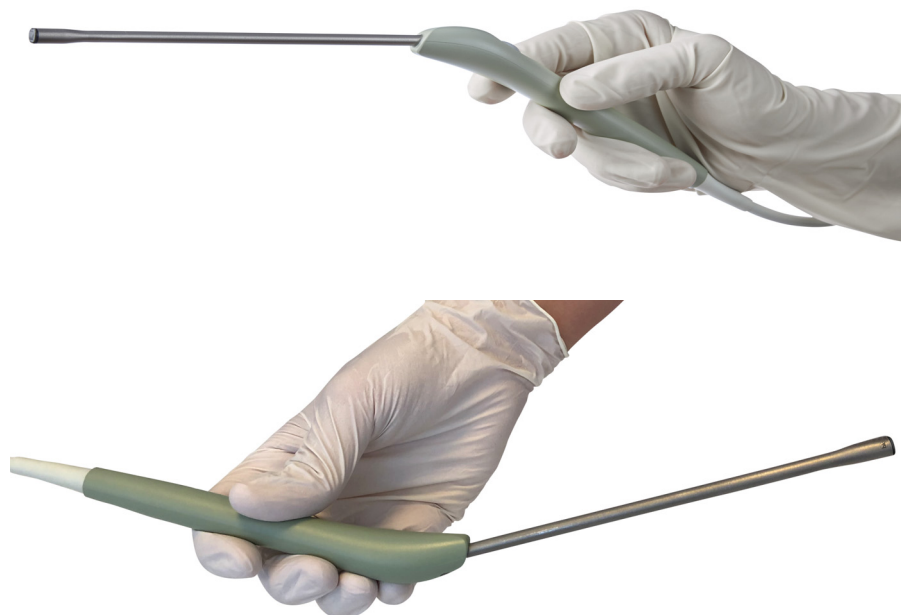


Figure 2. Transducer position.

The orientation marker on the transducer tip relates to the orientation marker icon on the monitor image:



Figure 3. The orientation marker on the transducer tip.

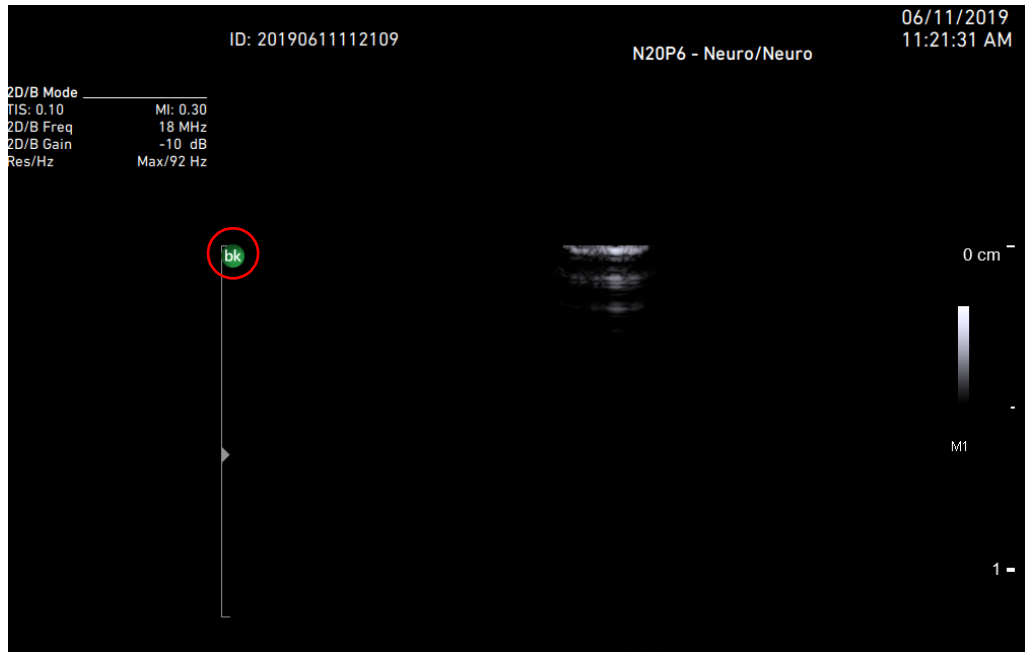



Figure 4. The bk orientation marker in the top left corner of the ultrasound image.


Cleaning after Use

	<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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