bk ultrasound
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User Guide

bk3000 & bk5000 Ultrasound Systems

16-01249-EN-06
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CE 0543

For Professional Users Only

LEGAL MANUFACTURER

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The serial number label on a BK Medical product contains information about the year of manufacture.

BK Medical Customer Satisfaction

Input from our customers helps us improve our products and services. As part of our customer satisfaction program, we contact a sample of our customers a few months after they receive their orders. If you receive an email message from us asking for your feedback, we hope you will be willing to answer some questions about your experience buying and using our products. Your opinions are important to us. You are of course always welcome to contact us via your BK Medical representative or by contacting us directly.

If you have comments about the user documentation, please write to us at the email address above. We would like to hear from you.

System Software

- **NOT FAULT TOLERANT**. THE SOFTWARE IS NOT FAULT TOLERANT. BK Medical HAS INDEPENDENTLY DETERMINED HOW TO USE THE SOFTWARE IN THE DEVICE, AND MS HAS RELIED UPON BK Medical TO CONDUCT SUFFICIENT TESTING TO DETERMINE THAT THE SOFTWARE IS SUITABLE FOR USE.
- **EXPORT RESTRICTIONS**. You acknowledge that Windows 8 Embedded is of US-origin. You agree to comply with all applicable international and national laws that apply to Windows 8 Embedded, including the U.S. Export Administration Regulations, as well as end-user, end-use and country destination restrictions issued by U.S. and other governments. For additional information on exporting Windows 8 Embedded, see http://www.microsoft.com/exporting/
- The 2300 Ultrasound System is closed. Any modification of or installation of software to the system may compromise safety and function of the system. Any modification of or installation of software without written permission from BK Medical will immediately void any warranty supplied by BK Medical. Such changes will also void any service contract and result in charges to the customer for restoration of the original 2300 Ultrasound System.

Trademarks:

bk3000 & bk5000 = Ref. Type 2300

Contents

English source version
16-01249-EN-06

Chapter 1
General Information

This user guide is for all versions of the bk3000 and bk5000 ultrasound systems.

NOTE: *Some of the functionality and options described in this guide may not be available with your version of the system.*

Before using the equipment, please make yourself familiar with the information in the accompanying user information documents. Some documents are printed. Make sure that you also read the transducer user guide and specifications for each transducer that you use.

Document	Information
System User Guide	Introductory information, safety information, getting started.
Getting Started	User interface, basic operating instructions. Note: this book is part of the system user guide.
System Advanced User Guide	Information about advanced functions, glossary.
Product Data for system	Specifications for the system, including disinfection methods that can be used. Indications for use for each transducer that can be used with the system.
Technical Data (BZ2100)	Acoustic output data, clinical measurements (ranges and accuracies), factory default power levels and data about EMC (electromagnetic compatibility) for all transducers. Pro Package calculation formulas.
Care and Cleaning	Cleaning, disinfection, sterilization, checking, storing and disposing of BK Medical equipment. Includes environmental limits.
Transducer User Guide	Specific instructions for the transducer and puncture attachments.
Product Data for each transducer	Specifications for the transducer, including disinfection methods that can be used.

Table 1-1. User information documentation that accompanies the equipment.

Improper use

Failure to follow safety instructions or use for purposes other than those described in the user manuals constitutes improper use.

Essential Performance

The system can provide 2D and 3D ultrasound echo and flow imaging systems as an aid in diagnosis, data processing and -transfer, and guidance of puncture and biopsy.

The system can perform simple geometric measurements and calculations.

The system can guide biopsy- and puncture needles.

The system is free from artefacts or distortion in the image or error of a displayed value, which can be attributed to a physiological effect and which may alter the diagnosis.

The system displays correct numerical values associated with the diagnosis to be performed.

The ALARA (As Low as Reasonably Achievable) principle is used and safety related indications (MI, TIS, TIB, etc) are displayed as worst-case values.

The system does not generate unintended or excessive ultrasound output or transducer surface temperature.

There is no unintended or uncontrolled motion of transducer assemblies intended for intra-corporeal use.

Intended Use

The system is intended for diagnostic ultrasound imaging or fluid flow analysis of the human body, data processing and guidance of puncture and biopsy.

The system performs simple geometric measurements and calculations in the following areas:

- Urology
- Vascular
- Cardiology
- OB/GYN
- Emergency Medicine
- Surgery
- Anesthesia

Modes of Operation

- B-Mode (including Tissue Harmonic imaging)
- M-Mode
- PWD Mode
- CFM Mode
- Power Doppler
- Contrast Imaging[1]
- CW Doppler[2]
- Elastography[3]
- Fusion[4]

1. Contrast imaging on the bk3000/bk5000 has not been licensed by Health Canada.

2. CW Doppler on the bk3000/bk5000 has not been licensed by Health Canada.

3. Elastography on the bk5000 has not been licensed by Health Canada.

4. Fusion on the bk3000/bk5000 has not been licensed by Health Canada.

Indications for Use

The system is a diagnostic ultrasound imaging system used by qualified and trained healthcare professionals for ultrasound imaging, human body fluid flow analysis and puncture and biopsy guidance.

The clinical applications and exam types include:

- Fetal (including Obstetrics)
- Abdominal
- Pediatric
- Small Organ (also known as Small Parts)
- Adult Cephalic (also known as Adult Transcranial)
- Neonatal Cephalic
- Intra-operative[1]
- Intra-operative (Neuro)[1, 2]
- Trans rectal
- Trans-vaginal
- Trans-urethral
- Musculo-skeletal (Conventional and Superficial)
- Cardiac Adult
- Peripheral Vessel (also known as Peripheral Vascular)

Indications for use are different for different transducers. The Product Data sheet for the system contains a table listing the indicated uses for each transducer that can be used with the system.

Contraindications

- The bk3000 and bk5000 ultrasound systems are not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye.
- The Cardiac Adult application is not intended for direct use on the heart.

1. bk5000 only.

2. Intraoperative (Neuro) imaging has not been licensed by Health Canada.

Chapter 2
Safety Information

The system can be used for continuous operation, but imaging duration for individual patients must not exceed 60 minutes. We recommend, however, that you turn off the system at the end of each workday.

Safety Information

This user guide contains cautions, warnings and other information about what you must do to ensure the safe and proper performance of the ultrasound system. You must also follow local government rules and guidelines at all times.

⚠	**WARNING** Warnings contain information that is important for avoiding personal injury.

⚠	**Caution** Cautions contain information and instructions that must be followed to avoid damaging equipment, data, or software.

NOTE: *Notes contain information that you should be aware of.*

Safety Symbols and Information on the Equipment

Table 2-1 contains brief explanations of the symbols and information used to label the equipment. (Some labels in the table may appear on the transducer.)

BK Medical disclaims all responsibility for the operating safety, reliability and performance of the equipment if these symbols and warnings are disregarded in any way.

Symbol	Name	Description
⚠	Caution or Warning	Consult accompanying user guides when you encounter this sign on the instrument, to avoid reducing its safety.
	Consult instructions for use	Consult user guide or other instructions.
	Pushing prohibited	Do not use excessive force to push the system. Excessive force when pushing over uneven surfaces can cause the system to overbalance and tip.
	Keep hands clear	Show caution when you adjust the system monitor.

Table 2-1. Symbols and information on the equipment.

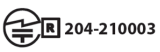
Symbol	Name	Description
	Manufacturer	Legal manufacturer.
	UL Classification for Canada and US	UL requirements are met for special conditions.
	UL Recognized Component for Canada and US	UL recognizes this as part of a UL-approved apparatus
	Rx only	United States Law restricts this device to sale or use by or on the order of a physician.
	Potential Equalization	Terminal connected to the chassis. Should be connected to corresponding terminals on other equipment to eliminate potential differences.
	Ground (earth)	Additional protective ground (earth).
	Type BF	BF: Isolated from ground. Maximum patient leakage current under • Normal condition ≤100 µA • Single-fault condition ≤ 500 µA
	Type BF	BF, defibrillator-proof.
	Type B	B: Maximum patient leakage current under • Normal condition ≤100µA • Single-fault condition ≤ 500µA
	No Pacemakers or Defibrillators	EM Transmitter may interfere with pacemakers and/or cardioverter defibrillators.
IP	Sealing	Dust- and immersion-protected according to EN 60529.
	Standby	Symbol on ON/Standby button on back of scanner unit – used to turn system on and off.
	ESD (electrostatic discharge)	Do not touch pins in connectors with this symbol unless you follow ESD precautionary procedures.
	Specified Radio Equipment	(On remote control UA2361) This equipment conforms to Japanese Radio Law regulations concerning frequency and power.
	WEEE waste	Within the EU, when you discard the equipment, you must send it to appropriate facilities for recovery and recycling.
	Battery waste	(On the battery.) Dispose of used batteries properly. When you dispose of the batteries you must follow national rules. Within the EU, you must send them to appropriate facilities for recovery and recycling.

Table 2-1. Symbols and information on the equipment. (continued)

Symbol	Name	Description
	Battery recycle	(On the battery.) Recycle used batteries properly.
	China ROHS 25 Years Lifetime	Environmentally Friendly Use Period for ROHS is 25 years.

Table 2-1. Symbols and information on the equipment. (continued)

General Safety Precautions

The ultrasound system is designed and tested in accordance with EN/IEC 60601-1 (2006) (Part 1: General requirements for basic safety and essential performance) and EN 60601–2–37 (2007) (Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment).

The system also complies with ANSI/AAMI ES60601-1 (2005) and CAN/CSA C22.2 No.601.1 (2008).

It fulfills the requirements for dust protection (IP20) for ordinary equipment specified in EN 60529.

⚠ Physicians only	**Caution** Rx-c1 United States law restricts this device to sale to, or on the order of, a physician.

⚠ Proper Training	**WARNING** GS-w1 To ensure safe and proper use of the equipment, before you attempt to use BK Medical equipment, you should be trained in ultrasonography or be under the supervision of someone who is trained in ultrasonography. You should also be thoroughly familiar with the safe operation of your ultrasound system: read all the user documentation that accompanies it. No further training is required, but BK offers training in how to use the system. Consult your BK representative for information.

⚠ Equipment failure	**WARNING** GS-w2 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: • 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 can be checked. • Do not try to repair the system yourself. • Contact your BK service representative or hospital technician.

⚠ Isolating the system	**WARNING** GS-w3 The power supply cord connects the equipment to the line voltage. To isolate the equipment, you must unplug the power supply cord from the power source. Do this before you try to make any repairs to the system.

⚠ Spilled liquids	**Caution** S-c2 The keyboard panel of the ultrasound system is **not** watertight. Be careful not to spill any liquids, gels or moist substances on the keyboard.

⚠ Conden-sation	**Caution** S-c3 Large variations in temperature or humidity may cause water to condense inside the system. If this happens, the system may fail to operate properly. Always let the system come to room temperature before you plug it in. • Wait at least 2 hours after the system has been subjected to major changes in temperature or humidity. • If there is visible evidence of condensation, wait at least 8 hours.

⚠	**Caution** S-c4 Never unplug the system from the wall while it is running. Turn off the system and wait for the light on the keyboard and the ON/Standby button to go out before unplugging.

Before you use the equipment, make sure that all the safety requirements described in this chapter have been satisfied.

Mechanical Safety

Mechanical failure or unintended use of ultrasound equipment can result in physical injury to patients or operators.

⚠ Mechanical injury	**WARNING** MS-w1 Be careful to avoid the following potential sources of injury: • Parts of the body can be pinched by moveable parts of the equipment, such as the control panel. • Tilting the system can cause it to be unstable and injure someone. • Do not lean or sit on the control panel or any other part of the system. The control panel or monitor can break if subjected to heavy weights or impact.

⚠ All parts must be stable	**WARNING** MS-w2 When parts of the equipment can be mounted individually (for example, for use in an operating room) each part must be securely mounted to a stable support so that it does not tip, fall or come loose and injure someone.

⚠	**WARNING** MS-w3 To avoid personal injury, be aware that the scan engine can become hot after prolonged use.

⚠ Don't push too hard	**WARNING** MS-w4 To avoid injury and equipment damage, do not push the system too hard, especially when you roll the system over an uneven surface. Applying excessive force near the top could cause the system to overbalance and tilt.

Explosion Hazards

⚠ Explosion hazards	**WARNING** EH-w1 The equipment is not designed to be used in potentially explosive environments. It should not be operated in the presence of flammable liquids or gases, or in oxygen-enriched atmospheres. There is a possible explosion hazard if the equipment is used in the presence of flammable anesthetic. The system should be placed at least 25 cm (10 inches) from the patient. The ultrasound system contains a lithium battery. Never remove or replace this battery. The lithium battery must not be removed except by a BK service representative.

Electrical Safety

⚠ Do not use a power strip	**WARNING** ES-w1 Do not plug the equipment into an ordinary power strip. If the ground connection fails, this is dangerous because • the total leakage current for all the connected equipment can exceed the limits specified in EN/IEC 60601-1 *(Part 1: General requirements for safety)*. • the impedance of the ground connection could exceed the limits specified in EN/IEC 60601-1.

⚠ Electrical shock	**WARNING** ES-w3 You risk electrical shock if you try to get inside the equipment (other than opening a cover to access connectors described in the user guide). Do not allow anyone but qualified service personnel to service the equipment.

⚠	**Caution** F-c1 With Fusion sensor mounted, the transducer only complies with type B requirements of IEC 60601-1

ESD Training

The ESD Symbol

Anyone using the equipment must be able to recognize the ESD symbol and understand how to take the necessary precautionary procedures, as described in the caution below.

⚠ ESD	**Caution** ESD-c1 Do not touch pins in connectors that have the ESD symbol . Do not connect anything to them unless you follow these ESD (electrostatic discharge) precautionary procedures: • Discharge your body to ground before you touch the pins with your hand or a tool. For example, touch an unpainted metal part of the system cover. • You can use a wrist strap connected to the additional protective ground or potential equalization terminal on the system if that is more convenient.

Interference

BK Ultrasound systems are suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Electrical Noise

⚠ Electrical noise	**WARNING** EN-w1 Electrical noise from nearby devices such as electrosurgical devices – or from devices that can transmit electrical noise to the AC line – may cause disturbances in ultrasound images. This could increase the risk during diagnostic or interventional procedures.

Electromagnetic Interference

Medical electrical equipment requires special precautions regarding EMC (electromagnetic compatibility). You must follow the instructions in this chapter when you install the system and put it into service.

If the image is distorted, it may be necessary to position the system further from sources of electromagnetic interference or to install magnetic shielding.

⚠ Other equipment nearby	**WARNING** EMC-w1 Do not use this equipment adjacent to other equipment. If you must place it next to or stacked with other equipment, verify that it operates normally there and neither causes nor is affected by electromagnetic interference.

EMC noise can reduce the usable image depth. Therefore, to avoid having to repeat an ultrasound examination, you must make sure beforehand that the ultrasound system can be used for the examination. Repeating an examination can be regarded as a potential risk that should be avoided, especially if the examination involves transducers used intracorporeally or transducers used for puncture.

RF (Radio Frequency) Interference

Portable and mobile RF (radio frequency) communication equipment can affect the system, but the system will remain safe and meet essential performance requirements.

An ultrasound system intentionally receives RF electromagnetic energy for the purpose of its operation. The transducers are very sensitive to frequencies within their signal frequency range (0.3 MHz to 80 MHz). Therefore RF equipment operating in this frequency range can affect the ultrasound image. However, if disturbances occur, they will appear as white lines in the ultrasound image and cannot be confused with physiological signals.

⚠ Possible interference sources	**Caution** Inter-c1 Other equipment may interfere with the system, even if that other equipment complies with CISPR (International Special Committee on Radio Interference) emission requirements.

⚠ Use specified equipment only	**Caution** Inter-c2 If you use accessories, transducers or cables with the system, other than those specified, increased emission or decreased immunity of the system may result.

Installation

⚠ Installation safety requirement	**WARNING** I-w1 To ensure safe performance, a qualified electrician or hospital safety personnel must verify that the equipment is correctly installed and that it complies with the following safety requirements: • Use only the original power supply cord. In the USA, this is fitted with a hospital grade three-prong grounded power plug. Never try to remove or change the plug on the power supply cord. • All equipment must only be connected to a grounded AC power supply (or wall outlet) that meets EN/IEC/NEC requirements or applicable local regulations. The examination room's grounding system should be checked regularly by a qualified electrician or hospital safety personnel. • Never use extension cords. The increased length of the cord will increase the resistance of the protective ground conductor and may increase the equipment's leakage current beyond an acceptable level. • Keep power cords, sockets and plugs clean and dry at all times. • Make sure that the power supply cord cannot be accidentally disconnected from the power source or the equipment.

Original power cords

If the original power cords are missing or damaged, you must order new ones from your local BK Medical representative.

Additional Protective Ground and Potential Equalization

An additional protective ground can be connected to the ⏚ terminal underneath the control panel, see Fig 2-1.

The potential equalization terminal ⏚ underneath the control panel is connected to the system chassis. It can be connected to corresponding terminals on other equipment to eliminate potential differences. Do NOT use it for additional protective grounding.

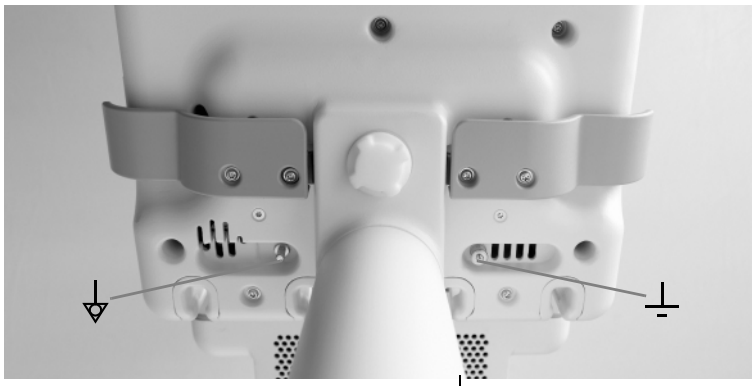


Figure 2-1. The terminals for potential equalization ⏚ and additional protective ground ⏚ are underneath the control panel.

Connecting Other Equipment

For connection to other equipment, BK systems have a communication protocol on top of TCP/IP.

⚠ Connection guidelines	**WARNING** C-w1 Follow the guidelines in EN/IEC60601-1 when you connect the system to other equipment.

Network Connection

BK's range of ultrasound systems comply with the DICOM standard for handling, storing, printing and transmitting information in medical imaging.
DICOM includes a file format definition and a network communication protocol which facilitates the exchange of data between electronic medical systems.

For detailed information about:

- network requirements
- network configuration
- workflow between devices
- technical specifications
- safety specifications

see the DICOM conformance statement at
www.bkultrasound.com/support/bk/resources/DICOM

Network Security

It is the responsibility of the on-site personnel or technician to maintain the IT-network and identify, analyze, evaluate and control new risks caused by a change in the network configuration.

If the applicable network connection does not meet the required characteristics of the IT-network, the following hazardous situations may occur:

- Corrupt patient data due to network errors, see Warning Exam-w3 on page 27
- System is unable to use the network due to faulty or overloaded network, see Warning GS-w1 on page 11
- System overloads the network causing other equipment to fail.

Network guidelines

NOTE: *If your system interacts with other equipment directly or indirectly you must ensure that your network is properly dimensioned and that critical equipment is placed on a separate network. Otherwise you could risk overloading the network and your equipment failing.*

Network Printing

For printing on network printers, BK supports protocols PCL 5, PCL 6 and PS (Post Script).

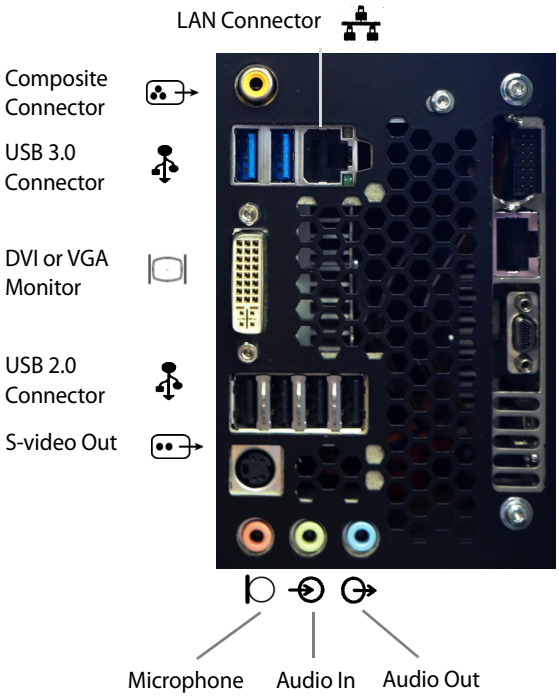
Connectors

As seen in Fig 2-2, the bk3000/bk5000 ultrasound system has four transducer sockets on the side of the system.

PC connectors for connecting the system to equipment such as approved printers and video equipment are located on the rear of the system. Do not use connectors that are not labeled.

Information about the correct cables to use is in Table 2-4.

Transducer Sockets



Wi-Fi Dongle

Figure 2-2. Transducer sockets and system connectors.

Symbol	Connector	Additional Information
	DVI-I	Connector for auxiliary DVI or VGA monitor
	Composite Out	RCA/Phono
	S-video Out	4-pin S-video connector
	Microphone	Microphone connector
	Audio In	
	Audio Out	
	4 USB 2.0 connectors and 2 USB 3.0 connectors (A-type)	500mA current limit on each
	10/100/1000 Ethernet	LAN: 10/100/1000 LAN connector, RJ45

Table 2-2. System connectors.

Video Output

Although 4 different video output signal formats are available, the image quality is not the same for all of them.

DVI gives best image quality

To get the best image quality possible, connect your monitor or other video equipment using the output signal that gives the highest quality image. See the list below.

Output signal types (in order of quality, with digital DVI highest)

1. DVI – digital output that gives the best image quality.
2. VGA – this analog output from the DVI connector gives slightly poorer image quality than the digital DVI output.
3. S-video – analog output
4. Composite – signal with the most loss of information

If you must use a cable that does not have a DVI connector, you may need to use an adapter. Table 2-3 shows you which adapters can be used.

Cable Connectors (in order of preference)	Adapter	bk3000/bk5000 Connector
HDMI 	Adapter needed 	DVI-I
DVI-D 	Not needed	DVI-I
15-pin (VGA) 	DVI to VGA adapter (2 views) 	DVI-I
S-video	Not needed	
BNC (Composite) 	BNC (female) to Phono (male) 	
Phono RCA (Composite) 	Not needed	

Table 2-3. Video connectors and adapters.

EMC Requirements

To fulfill EMC requirements, cables attached to the system must be shielded and no longer than 5 m.

Connector name	Cable type	Type and length
DVI-I	Dual link	Shielded, 5 m
Composite Out	Phono RCA	Shielded, 5m
S-video Out	S-video	Shielded, 5 m
Audio In	Stereo, 3.5 mm jack	Shielded, 5 m
Audio Out	Stereo, 3.5 mm jack	Shielded, 5 m
USB 1	USB, 2.0	Shielded, 5 m
USB 2	USB, 2.0	Shielded, 5 m
USB 3	USB, 2.0	Shielded, 5 m
USB 4	USB, 2.0	Shielded, 5 m
USB 5	USB, 3.0	Shielded, 5 m
USB 6	USB, 3.0	Shielded, 5 m
10/100/1000 Ethernet	Network, CAT6E	Shielded, 5 m

Table 2-4. List of cables used in testing for EMC compliance

Do not attach transducers and other accessories unless the user guide for the transducer or accessory states that it can be used with this system. Attaching other equipment may cause an increase in electromagnetic emissions or may cause the system to be more sensitive to electromagnetic interference.

Isolation of DICOM Network

The system must not be galvanically connected to a computer network (DICOM®) that has not been isolated. If the network is not isolated, the system must be connected via a network isolator DP0925 .

Wireless Networks

The system can be connected to a wireless network[1] for printing and archiving data. A Wi-Fi dongle and a 30 cm USB 3.0 extender cable are supplied with the system. Connect the dongle to the extender cable and insert into one of the USB 3.0 connectors (see Fig 2-2 on page 18).

Connecting to a Wireless Network

You must establish a secure wireless network at your hospital, clinic or institution, including a password for the network, before you can use the system's Wi-Fi for printing and archiving.

1. Wi-Fi on the bk3000/bk5000 has not been licensed by Health Canada.

Figure 2-3. Position of the Wi-Fi symbol on the screen.

To connect to a wireless network, click the Wi-Fi logo, choose the appropriate network, and type in the password.

Figure 2-4. Wi-Fi connection window.

You only have to type in a password the first time you connect to a specific network. When you turn on the system an attempt is made to reconnect to the network that the system was connected to before it was turned off.

Weak vs. strong signal

The bars in the Wi-Fi logo represents the signal strength. The more lit bars in the logo, the stronger the signal.

No wireless connection

When the system is not connected to a wireless network, the Wi-Fi logo has a red ‘X’ over it.

An advanced Wi-Fi setting option is available on the system using Windows configurations. Always follow the security procedures that have been established for your hospital, clinic or institution, as well as national guidelines. Contact your BK service representative for more information.

Additional characteristics	
Frequency band	2.412~2.4835 GHz
Data throughput	Max. 150 Mbps
Latency	Depends on network setup
Integrity	Full integrity of archiving operations
Security characteristics	Support for WEP, WPA and WPA2 encryption. Enterprise encryption (802.1x) requires assistance from an authorized BK Medical technician.
Spectrum management	None required

Table 2-5. Additional characteristics.

When you transmit data over a wireless network, some special considerations apply. In particular, the network connections must be set up correctly. See Warning GS-w1 on page 11.

NOTE: *The system only supports one network at a time.*

If the system loses connection with the network while transmitting (for example, because it is moved out of range of the network during a transmission), the pending data is stored temporarily and re-transmitted when the connection is re-established.

For information on saving and printing using the DICOM protocol, see the DICOM chapter in the *Advanced User Guide* for the relevant system.

⚠	**Caution:** Wifi-c1 The network must be set up correctly so that data is sent to the correct location. Otherwise data can be lost or accessed by unauthorized people.

⚠	**Caution:** Wifi-c2 A safe encrypted protocol for data transmission, approved by the hospital, must be used. This is to prevent unauthorized people from getting access to the data.

Medical Equipment

If any other electrical equipment/accessory is connected to the system, the system *including* this equipment and/or accessory will become a medical system. Medical systems must comply with EN/EIC 60601-1, ANSI/AAMI ES60601-1 or CAN/CSA C22.2 No. 60601-1.

⚠ Printers and auxiliary power outlet ⚠ ON/Standby button does not turn off outlet	**WARNING** ME-w2 An approved printer, specified in the Product Data sheet, can be connected to the internal auxiliary power outlet on the system. *Do not use the auxiliary power outlet on this BK system for any other equipment.* The auxiliary power outlet is still live even when the ON/standby button on the system is turned off. To remove voltage from this outlet, you must unplug the power supply cord from the power source.

Non-Medical Equipment

⚠	**WARNING** NME-w1 Follow the guidelines in EN/IEC 60601–1. If you connect non-medical equipment (instruments that do not comply with safety requirements for medical equipment, such as a video monitor, video recorder, endoscopic camera control unit or other documentation device), this equipment must be placed outside the patient environment (1.5 m from the bed, for example). The equipment must fulfill the relevant EN standard or other applicable national or international standard. One of the following conditions must be fulfilled: • The system and other equipment are plugged into an external common isolation transformer to control the leakage current during a ground connection fault. or • The system is grounded with an additional safety ground connection (see "Additional Protective Ground and Potential Equalization" on page 16). If in doubt, contact your BK representative.

Remote Control

Before you use a wireless remote control with the system, read the remote control chapter of this user guide.

The remote control uses short wave radio waves to communicate with the system.

⚠	**WARNING** RC-w2 The remote control is active at a distance of at least 10 meters from the system, even if the system is in a different room.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

⚠	**Caution:** RC-c1 The remote control can be disrupted by other equipment operating at the same frequency of 2.5 GHz.

1 This device may not cause harmful interference

2 This device must accept any interference received, including interference that may cause undesired operation

Battery Support System

If you use a battery[1] to supply power to the system, read the battery support chapter of this user guide.

Also observe the following warning for the battery:

⚠	**WARNING** BS-w6 To ensure proper ventilation and avoid overheating, keep both ends of the battery clear.

Battery disposal

When you dispose of the batteries, you must follow national rules. Within the EU, you must send them to appropriate facilities for recovery and recycling.

Computer Security

When BK Ultrasound systems are connected to a hospital network,
BK Medical does not take any responsibility for computer viruses from the network that may infect the system.

⚠ Check external media	**Caution:** CS-c1 You must perform a virus check on any external storage medium (USB device or DVD) to make sure that it is virus-free before you connect it to the system.

Printer

⚠	**Caution:** Print-c1 The quality of a printed ultrasound image may vary, depending on the printer.

Service and Repair

⚠ Authorized personnel	**WARNING** SR-w1 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.

1. The battery solution on the bk3000/bk5000 has not been licensed by Health Canada.

Transducers

⚠ Electrical shock	**WARNING** T-w1 The transducer sockets contain terminals with 3.3V. Do not touch the patient while you are touching an uncovered socket.

⚠ Type B transducers	**WARNING** T-w2 When using Type B (non-isolated) transducers, carefully check all electrical equipment within the patient area. Also, consider using additional protective grounding.

⚠ Electrical burns	**WARNING** T-w3 Do not leave transducers in contact with the patient when using HF electrosurgical equipment.

BK Medical transducers fulfill EMC requirements when they are outside as well as inside the patient's body.

⚠ Surface temperature on array	**WARNING** T-w4 Do not turn the transducer on and allow it to scan into mid-air without ultrasound gel applied to the surface of the array. Doing so may cause the surface temperature on the array to heat up to 27 °C above room temperature (measured according to EN 60601–2–37 [3] (*Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment*)). To avoid this, freeze the image when the transducer is not used for imaging.

⚠ Creutzfeldt-Jakob disease	**WARNING** C-J-w1 Do not use a 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.

During an Examination

Checking the Date

Before you start imaging, verify that the date and time displayed on the monitor are correct.

⚠ Date	**WARNING** Exam-w1 An incorrect date or time will make documentation of the image incorrect and may also cause some calculated values to be incorrect.

⚠ Patient ID required	**WARNING** Exam-w2 You must enter a new patient ID or check that the system has entered a timestamp before you image a new patient. Otherwise, the documentation will not contain the correct patient identification, and you will not be able to capture images and clips. We recommend that you enter the complete name of the patient.

⚠ Verify patient ID	**WARNING** Exam-w3 Verify that the patient name and ID are correct.

Verifying the Transducer Type

⚠ Type number displayed must match number on transducer	**WARNING** Exam-w4 Before you start to image, verify that the type number on the transducer matches the number displayed on the monitor. In case of any inconsistency, stop imaging, turn off the system, and contact your BK service representative.

Measurements

Pay careful attention when you position cursors to make measurements on a scanned image or on a Doppler curve.

⚠ Polygon measuring tool	**WARNING** M-w1 To prevent wrongful diagnosis, you must be aware that: • When you use the polygon measuring tool, if the sides of the polygon intersect (as in forming a curve like a figure eight, for example), the area calculation is incorrect. In this case, the calculated area of the polygon is the area of the bigger loop minus the area of the smaller loop.

⚠ Using Doppler curves	**WARNING** M-w2 Drawings of Doppler curves, manual and automatic, are meant as tools for positioning cursors so that measurements based on the curves can be calculated automatically. The system has no facilities for checking whether the automatic measurements are reasonable. Curves drawn on very noisy spectra may lead to misplacement of measurement cursors. Make sure that measurement cursors are positioned so that the results are reasonable. If they are not, you must adjust the position of the cursors manually.

Nuchal Translucency

⚠ Nuchal translucency	**Caution** NT-c1 You must be adequately trained before you attempt to make nuchal translucency measurements.

Contrast Imaging

⚠	**Caution** Exam-c6 When you turn on Bubble Burst, the acoustic output limits are increased to 1.9 (MI). This change overrides any limits you have set. During Bubble Burst, the acoustic output will exceed normal contrast imaging values and may approach the higher (Bubble Burst) limits.

VFI - Vector Flow Imaging[1]

⚠ Artifacts	**WARNING** VFI-w1 Before you turn on VFI, check the B-mode image to make sure there are no artifacts visible in the blood vessel. If there are strong artifacts in the B-mode image, the arrows in VFI may be pulled to point in a more axial direction (toward or away from the transducer), especially in low flow situations with correspondingly low PRF. These artifacts will not affect the color mode (CFM) image, so it is important to check in B-mode.

⚠ Arrow aliasing	**WARNING** VFI-w2 Check to make sure the VFI arrows are not aliasing before you activate the assisted Doppler gate placement. Otherwise, the Doppler gate will not be positioned correctly.

⚠ Diameter markers	**WARNING** VFI-w3 Check to make sure that the diameter markers correspond to the inner vessel wall and that the connecting line between the markers is perpendicular to the direction of the vessel. Otherwise, the real-time volume flow measurement may not be precise.

⚠ Doppler gate large enough	**WARNING** VFI-w4 Check to make sure that the Doppler gate covers the entire vessel. Otherwise, the real-time volume flow measurement may not be precise.

⚠ Doppler gate over only one vessel	**WARNING** VFI-w5 Check to make sure that the Doppler gate only covers one vessel. Otherwise, the real-time volume flow measurement may not be precise.

⚠ Doppler spectrum aliasing	**WARNING** VFI-w6 Check to make sure that the Doppler spectrum does not alias. Otherwise, the real-time volume flow measurement may not be precise.

1. VFI on the bk3000/bk5000 has not been licensed by Health Canada.

Puncture and Brachytherapy

⚠ Verify transducer type number	**WARNING** P-w1 Before you start imaging, verify that the type number or name of the transducer and the type number or description of the puncture attachment 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.

⚠ Verify puncture guide type number	**WARNING** P-w2 Verify that the type number of the puncture guide displayed on the monitor corresponds to the puncture guide that you are actually using. If the number is incorrect, the puncture line on the monitor may not correspond to the true puncture path in the tissue.

⚠ Watch the needle tip	**WARNING** P-w4 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.

NOTE: *If the image depth is set very low (to see tissue close to the transducer with high magnification), the needle tip echo can be outside the displayed image area. To see the needle tip in this case, zoom out so the full needle path is visible or pan the image to the side (to keep the high magnification).*

⚠ Offset changes	**WARNING** P-w3 Changes you make to the offset of a programmable puncture guide or brachy matrix will affect ALL programmable puncture guides and brachy matrixes. This could lead to incorrect puncture lines or matrix positions for a different guide than the one you wanted to change.

Brachytherapy and Prostate Transperineal Biopsy

⚠ Verify matrix type and coordinates	**WARNING** B-w1 Verify that the matrix type and coordinates displayed on the monitor agree with the actual matrix template you are using.

⚠ Verify user-defined matrix	**WARNING** B-w2 If you create a user-defined matrix, it is your responsibility to verify that the matrix that appears on the monitor corresponds to the physical matrix you are using.

⚠ Verify matrix alignment	**WARNING** B-w3 Before you use the matrix for seed implantation or biopsy, check the matrix offset value to verify that it corresponds with the chosen matrix. Then check the matrix alignment.

⚠	**WARNING** B-w4 To avoid harming the patient, check the needle alignment (and recalibrate if necessary) before each use.

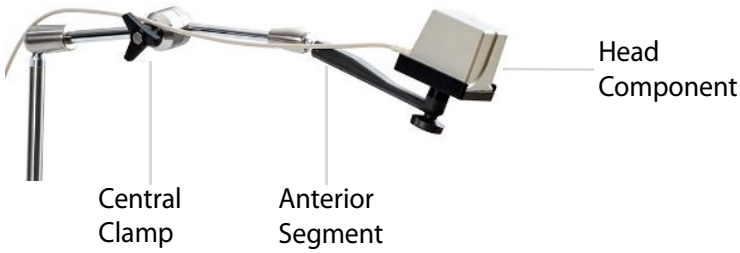
bkFusion[1]

⚠ High magnetic field	**WARNING** F-w1 Do not operate bkFusion hardware if you or the patient have an implanted pacemaker or cardioverter defibrillator. The high magnetic field generated by the EM Transmitter can cause implanted heart pacemakers and cardioverter defibrillators to cease operation.

⚠ Patient distance from EM Transmitter	**WARNING** F-w2 Maintain a distance of at least 18cm between the patient and the EM transmitter for Fusion (International Commission on Non-Ionizing Radiation Protection guidelines). The Transmitter radiates a low-frequency magnetic field (modulated 80 Hz). Magnetic radiation at 18cm is <100 uT. The 50/60 Hz radiation from the mains power system is typically 10-100 uT.

⚠	**Caution** F-c1 With Fusion sensor mounted, the transducer only complies with type B requirements of IEC 60601-1

bkFusion Articulated Arm



NOTE: *The fixation of the articulated arm is based on the principle of friction. Changing the position without loosening the clamping mechanism can cause damage and will shorten the lifespan of the articulated arm. The articulated arm can be adjusted with little force. Turn the central clamp in a clockwise direction to tighten the arm and anti-clockwise to loosen the arm.*

1. bkFusion on the bk3000/bk5000 has not been licensed by Health Canada.

⚠ Accidental clamp release	**WARNING** MS-w5 The articulated arm can move unintentionally if the central clamp is released. Always hold the head component on the anterior segment with one hand and manipulate the central clamp with your other hand.

⚠ Do not use damaged equipment	**WARNING** Check-w1 To ensure safe operation, do not use the equipment if you find any signs of damage. Contact your BK service representative. If a transducer is dropped, and even if it shows no visible signs of damage, BK recommends that a High Voltage test is conducted before the transducer is used again.

⚠ All parts must be stable	**WARNING** MS-w2 When parts of the equipment can be mounted individually (for example, for use in an operating room) each part must be securely mounted to a stable support so that it does not tip, fall or come loose and injure someone.

3D

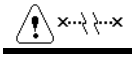
Pay particular care to the following safety issues when operating the 3D system.

⚠ 3D measure-ments	**WARNING** 3D-w1 Measurements obtained with the 3D system and used in diagnosis must be carefully and thoughtfully performed to ensure accurate quantitative assessment. Before you perform a calculation, make sure that all necessary calibrations and measurements are made. If you suspect that the 3D system's calibration is inaccurate (that is, the measurements are not as expected), contact your BK service representative to check and confirm the system's proper operation.

⚠ Untracked freehand	**WARNING** 3D-w2 You cannot make accurate measurements on a 3D data set acquired using the untracked freehand method.

If you start to make a measurement on a 3D data set acquired using the untracked freehand method, the following warning appears on the monitor:

Warning on monitor

Symbol	Description
	Measurement will not be accurate.

Picture in Picture

⚠ PiP must not cover important information	**WARNING** PIP-w1 When you use Picture in Picture, do not cover critical information (such as TI or MI) on the monitor. Make sure that all important information will appear if you print or save the ultrasound image.

Acoustic Output

General

Medical research has yet to prove whether or not ultrasound causes biological effects. Therefore, prudent use considerations require you to follow certain guidelines; see EN60601-2-37 *(Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment)*.

Prudent Use

⚠ Exposure level	**WARNING** AO-w1 To avoid tissue damage, always keep the exposure level (the acoustic output level and the exposure time) as low as possible.

- Image patients only when clinical reasons make it necessary.
- Keep exposure time as short as possible.
- Be careful to prepare the patient correctly so that you get the best possible image.
- Start imaging at a low acoustic output level (see "Thermal and Mechanical Indices" on page 33) and increase the level only as much as necessary to obtain a satisfactory image.
- If you switch from an application requiring high acoustic output levels (see "Functions Affecting Acoustic Output" on page 34), to one that requires lower levels (fetal imaging, for example), be sure to reset the levels before you image. (For example, start in B-mode.)
- Take into account all the types of tissue that may be affected. For example, when imaging a breast, it may be appropriate to monitor the TI in bone rather than in soft tissue because the ribs will be subjected to ultrasound.

⚠ Appropriate transducer	**WARNING** AO-w2 To avoid tissue damage, always use the transducer best suited to the examination.

Acoustic output data for transducers used with the system are given in the Technical Data (BZ2100) that accompanies this user guide. The uncertainty level for each parameter is also listed. For definitions of the parameters, refer to the Food and Drug

Administration (FDA) Guide as well as EN 60601-2-37 *(Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment)* and AIUM/NEMA standards.

The routes (or tracks) available for clearance by the FDA are well-defined. Track 3 is for diagnostic ultrasound systems that follow the Output Display Standard. Under Track 3, acoustic output will not be evaluated on an application-specific basis, but the maximum derated Spatial Peak–Temporal Average Intensity (I_{SPTA}) must be $\leq 720\,mW/cm^2$, the maximum Mechanical Index (MI) must be ≤ 1.9, and the maximum Thermal Index (TI) must be ≤ 6. All BK Medical transducers for use with bk3000 and bk5000 are Track 3.

Monitor Display

The Mechanical Index (MI) and Thermal Index (TI) can be viewed in all imaging modes.

Thermal and Mechanical Indices

The MI and TI indices are intended to allow users to implement the ALARA (As Low As Reasonably Achievable) principle using an indicator related to a potential bioeffect.

The full details of the indices are given in references EN60601-2-37 and AIUM/NEMA standard, but the formulas are given below.

MI Formula

$$MI = \frac{P_{r0,3}(z_{sp})}{\sqrt{f_c}}$$

where the variables are defined in the table below.

Variable	Definition
$P_{r0.3}(z_{sp})$	Peak Rarefactional Pressure (MPa), derated by 0.3 dB/cm·MHz, measured at z_{sp}, the point on the beam axis where pulse intensity integral ($PII_{0.3}$) is maximum
f_c	measured center frequency (in MHz)

TI Formula

$$TI = \frac{W_0}{W_{deg}}$$

where the variables are defined in the table below.

Variable	Definition
W_0	time-averaged acoustic power of the source or other power parameter (W)
W_{deg}	estimated power necessary to raise the temperature of the target tissue one degree Celsius (W/°C)

Blood perfusion and TI

As a rule of thumb, the Thermal Index (TI) indicates the highest expected temperature increase in degrees Celsius. It is based on an average level of blood perfusion. The displayed TI may underestimate the temperature rise in poorly perfused tissues; you must take this into account when deciding on the maximum TI you will allow. Conversely, in areas with a rich perfusion of blood the temperature increase will be less than the displayed TI indicates.

Fever

A temperature increase of one degree Celsius increase in a patient with fever may cause complications in certain circumstances; it may be safer to delay the investigation.

Acoustic Output Measurement

All values are measured in water according to the EN 60601-2-37 and AIUM/NEMA display standards. For some of the acoustic parameters, an estimated in situ derated value is given. This is derived assuming a tissue attenuation of 0.3 dB/(cm·MHz) when the estimated in situ derated value (I) is described by the following equation:

I formula

$$I = I_w \exp(-0{,}069 f z)$$

where the variables are defined in the table below.

Variable	Definition
I_w	Intensity in water at the position where I is maximum
f	transducer frequency (in MHz)
z	distance (in cm) from the transducer face to the position where I is maximum

It should be stressed that the in situ values given are only applicable when there is attenuating tissue between the transducer face and the focal point.

Possibility of Adverse Effects

Although it is believed that diagnostic ultrasound causes no significant biological effects in mammalian tissue, the user should be aware of the hypothetical possibilities of adverse effects.

Fetal imaging

Current scientific and clinical concern over possible adverse effects is particularly focused on fetal ultrasound imaging. It is due to the increased sensitivity of mammalian cells and organs at this phase of their development and the fact that such a risk could have profound implications on public health. If you use high acoustic output levels for some reason (see “Functions Affecting Acoustic Output”, below), be sure to return to B-mode alone and turn down the power level before you do any fetal imaging.

Functions Affecting Acoustic Output

The system has a control function that ensures that neither the I_{SPTA} nor MI nor TI value exceeds the maximum allowable value. When necessary, the system will reduce the output voltage and/or PRF (pulse repetition frequency) to the transducer to comply with requirements.

Some of the system functions can affect the acoustic output, as listed here. (Instructions for using these functions are given in the relevant sections of this user guide.)

- Sizing functions such as ROI (region of interest) – in general, smaller size results in higher acoustic intensity because the pulse repetition frequency (PRF) is higher or the ultrasound beam is more strongly focused.
- Focus – in general, strongly focusing the beam makes the acoustic intensity higher.
- Frame rate – higher frame rate results in higher acoustic intensity.
- Range – increasing the Doppler range increases the acoustic intensity by increasing the PRF.
- CFM Resolution – higher resolution increases the acoustic output.
- Color box size – narrowing the color box generally increases the acoustic output within it.

The user can set a Thermal Index limit. This will provide an upper limit for acoustic output.

Default Acoustic Output

After the system has been turned off, the transducers will start in the default setup when the system is turned on again. The default setup may be factory-defined or defined by the user.

The factory-defined default setup values of acoustic output for each transducer are listed in the Technical Data (BZ2100).

These setups have been optimized to give the best compromise between low acoustic output and enough power to obtain the image features as quickly as possible. The factory default setup for all transducers is B-Mode to ensure the lowest acoustic output when you start imaging.

When you enter a new patient ID, by default the transducer setup will be reset to the factory setup.

Fetal imaging

When you use transducers intended for fetal imaging, it is important to make sure that the default settings are appropriate and to reset to the default setting before imaging a new patient.

Clinical Measurements: Ranges and Accuracies

This section states the accuracies for measurements made using the BK Medical range of ultrasound systems. A table containing accuracies for specific transducers can be found in the Technical Data (BZ2100) that accompanies this user guide.

The measurement accuracies are based on the assumption of "ideal" tissue, that is, a tissue characterized by a sound velocity of 1540 m/s. When making clinical measurements with ultrasound, errors may arise which are not taken into account in this section. For example,

- The sound velocity may vary from approximately 1450 m/s in fatty tissue to 1585 m/s in muscle. This can, in simple cases, give rise to errors of up to 6% for linear measurements. This inaccuracy may be further increased by refraction occurring at tissue boundaries.
- The user can introduce errors when using approximate formulas, when positioning the system's calipers with respect to the ultrasound image and when outlining structures in the image.
- The ellipsoid volume approximation, described in this user guide, is only applicable when the cross section of the structure being studied approximates an ellipse (the circle being a special ellipse), and when the structure is roughly symmetrical about the selected axis of rotation

NOTE: *The choice of the axis of rotation is important for the calculation of the volume. A vertical axis gives a different volume than a horizontal axis.*

The minimum requirement is that the cross section outlined by the user should be convex. If the user draws a non-convex outline, an inaccuracy is introduced which is not taken into account in this section. In this case, the system calculates and displays the convex hull of the figure, that is, the smallest convex figure containing the non-convex figure outlined by the user (see Fig 2-5). The system bases the calculation of the ellipsoid volume on the convex hull.

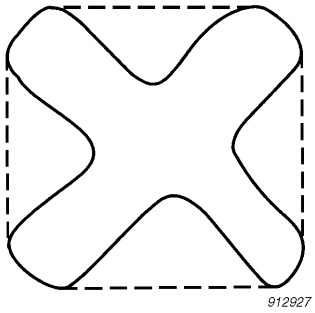


Figure 2-5. The dotted line indicates the convex hull of the non-convex figure.

Measuring volume using a stepping method produces an approximation caused by the finite number of steps in the measurement. The user must always try to assess how large an inaccuracy is introduced by the selected step size, that is, the distance between organ cross sections.

Geometric Measurements

2D Measurements

The geometric measurements performed by BK Medical ultrasound systems are distance, perimeter, area and ellipsoid volume. The accuracy of these measurements is influenced by the following factors:

- Transducer geometry
- Rounding of results
- Resolution of digital image memory

3D Measurements

The 3D volume is found by summing the marked area in the individual slices and multiplying by a factor that includes the distance between the slices and their relative orientation.

To obtain the accuracies listed in the table in the Technical Data (BZ2100), you must ensure that the calculation is based on contributions from at least 10 slices for very regular shapes and more for irregular shapes. It must also be possible to discriminate the boundary of the object from the surrounding tissue.

Volume accuracy

The volume accuracy in the table is given as a percentage of the captured 3D volume starting with the first slice and ending with the last slice that intersects the object of interest.

If the 2D ROI (region of interest) is set to be much larger than the object, the accuracy as a percentage of the object volume can be much worse (higher percent).

NOTE: *To ensure that the accuracy of your volume measurement is as high as possible, make sure that the object you are interested in fills the region of interest as much as possible.*

Distance and area accuracy

The accuracy of a distance measurement on a 3D image will never be better than 6%; the accuracy of an area measurement on a 3D image will never be better than 6%.

In the table in the Technical Data (BZ2100), the overall measurement accuracy for a full range measurement is given in the right-hand column for each measurement. The footnote below the table states the digital image resolution.

Time Measurements

In M-mode and spectral Doppler mode, data is displayed along a time axis. It is possible to measure time differences. The accuracy for a time difference measurement is

- Rounded to the nearest: 0.01 s
- Accuracy: 0.01 x t
  where t is the full time scale of the image field.

Doppler Measurements

In measuring blood flow velocity it is assumed that the measured power spectral distribution of the Doppler signal equals the blood cell velocity distribution.

The measurement accuracy of blood flow velocity is heavily dependent on the angle θ between the ultrasound beam and the velocity vector of the blood cells. The velocity accuracies given in the Technical Data (BZ2100) are valid for $\theta = 55°$. To find the percentage accuracy for other angles, multiply the stated accuracy by

$$\left(\frac{\cos\theta - \cos(\theta + 1{,}8)}{\cos\theta}\right) \times 100 + 0{,}5$$

If the blood velocity exceeds the selected velocity range, aliasing occurs, corresponding to an overload condition of the measurement system.

Chapter 3
Battery Support

This chapter is only relevant if your system has battery[1] support.

The battery enables you to operate the system while it is not connected to an external electrical supply.

Before You Start

Read the battery support warning in “Battery Support System” on page 25. Also read the rest of this chapter before you use the battery support system.

To setup and customize the battery operation, see the *Advanced User Guide* relevant for your system.

Imaging with Battery Support

This is an overview of the steps for using the battery support system to power the imaging system.

1. Make sure the battery is charged.

   (If not, plug in the imaging system to use it or to charge the battery.)
2. Turn on the system.
3. When the battery is empty, you do not have to turn off the imaging system. Plug it into a power outlet to recharge the battery while you run on power from the normal power supply.

Battery Location

The battery is located in the battery compartment on the wheel base of the system.

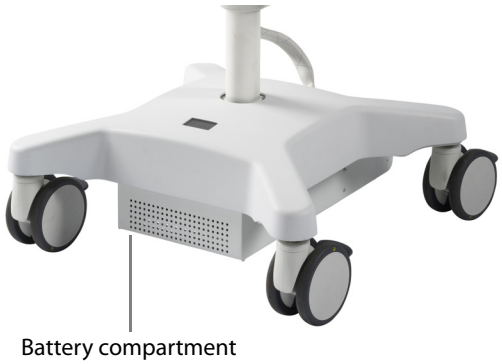


Figure 3-1. Battery in the wheel base.

1. The battery solution on the bk3000/bk5000 has not been licensed by Health Canada.

Power Supply

Plugging in the System

On systems with a battery, the power supply cord plugs into the battery compartment.

Charging the Battery

The battery automatically begins charging when the system is plugged into the power outlet.

There is a battery charge display on the battery compartment. The battery will be fully charged after approximately 4 hours.

May need to discharge and recharge fully

If the Battery Appears Not to Charge to 100%

After repeated use, the battery may require a full discharge, full charge, and full discharge in order to recalibrate the electronic fuel gauge so that the indication of how much charge is left in the battery is accurate.

Battery Status

While the system is operating, battery status is visible both on the monitor (in the bottom right-hand corner) and on the display on the battery compartment.

- When the system is plugged into a power outlet, battery status is shown as percent (%) of capacity remaining.

- When the system is running on the battery, battery status is shown as time remaining in “hours:minutes”.

NOTE: *The time displayed is an estimate based on typical use; for continuous imaging, the actual time available will be less than indicated on the display.*

Information Available on the Monitor

The battery status indicator appears in the bottom right-hand corner of the monitor.

Figure 3-2. Battery level shown as % or as time available.

A message appears on the monitor when a battery reaches the end of its lifespan and needs replacing. For information about the disposal of depleted batteries, see page 25.

Low Battery

When battery capacity is very low,

- A message appears on the monitor
- The on-screen battery indicator turns red
- The display on the battery compartment blinks regularly

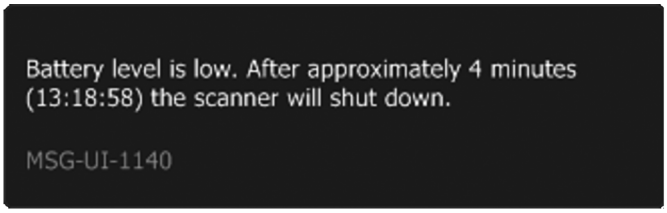


Figure 3-3. Low battery message.

The low-battery message informs you that the battery level is low and that the system will shut down when the system monitor clock matches the time stamp in the message (shown here as 13:18:58).

The display on the battery compartment begins to blink regularly when the low battery threshold is met, and it continues to blink even after the critical low battery threshold is met and the system has shut down.

⚠	**Caution** BS-c1 If the battery reaches the auto-shutdown level, plug in the system and keep it plugged in until the battery recharges to *at least* 10 %.

To set the level for the low battery message, see the **Battery Support Setup** section in the *Advanced User Guide* relevant for your system.

Critical Low Battery

The setting for critical low battery is set to 3 minutes by default. When the battery reaches the critical level, the system shuts down immediately.

To set the level for the critical low battery message, see the **Battery Support Setup** section in the *Advanced User Guide* relevant for your system.

When the system is plugged in, the display on the battery compartment is lit.

⚠	**Caution** BS-c2 Never shut down a system with a battery module simply by unplugging it from the wall. To preserve battery power, shut down the system properly.

Power Save Mode

Power save mode

With power save mode, you can conserve battery power and reduce energy consumption when the system is not in active use. A message appears on the monitor to notify you when the system is about to go into power save mode.

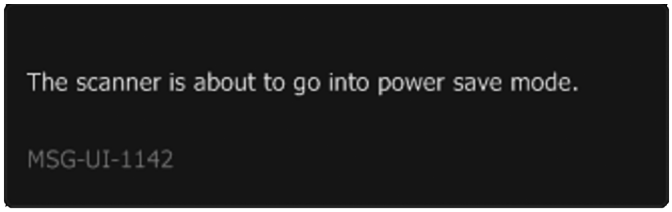


Figure 3-4. Power save message.

To exit power save mode and restore the system to normal power, you can do one of the following:

- Press a key on the keyboard
- Press the transducer button
- Move the trackball

To enable and configure power save mode, see the **Battery Support Setup** section in the *Advanced User Guide* relevant for your system.

Battery Life

Typical vs. continuous use

With typical use (which includes imaging and freezing), a fully charged battery provides approximately 2 hours of operation. With a fully charged battery pack, you can scan continuously for approximately 1 hour 20 minutes.

Battery lifespan

When a battery reaches the end of its lifespan, the replace battery message appears on the monitor at start-up.

On average, a battery will need to be replaced after approximately 300 recharge and discharge cycles – the battery lifespan. Contact you BK Service technician for replacement of batteries.

For information about the disposal of depleted batteries, see page 25.

Battery Support Setup

To customize the operation of the battery, see the **Battery Support Setup** section in the *Advanced User Guide* relevant for your system.

Cleaning and Disinfection

The cleaning and disinfection instructions for the system in *Care and Cleaning* apply to the battery compartment.

Chapter 4
Remote Control

A wireless remote control is available for use with the bk5000 system. It uses Bluetooth to communicate with the system and control many of its functions.

The Remote Control and Its Functions

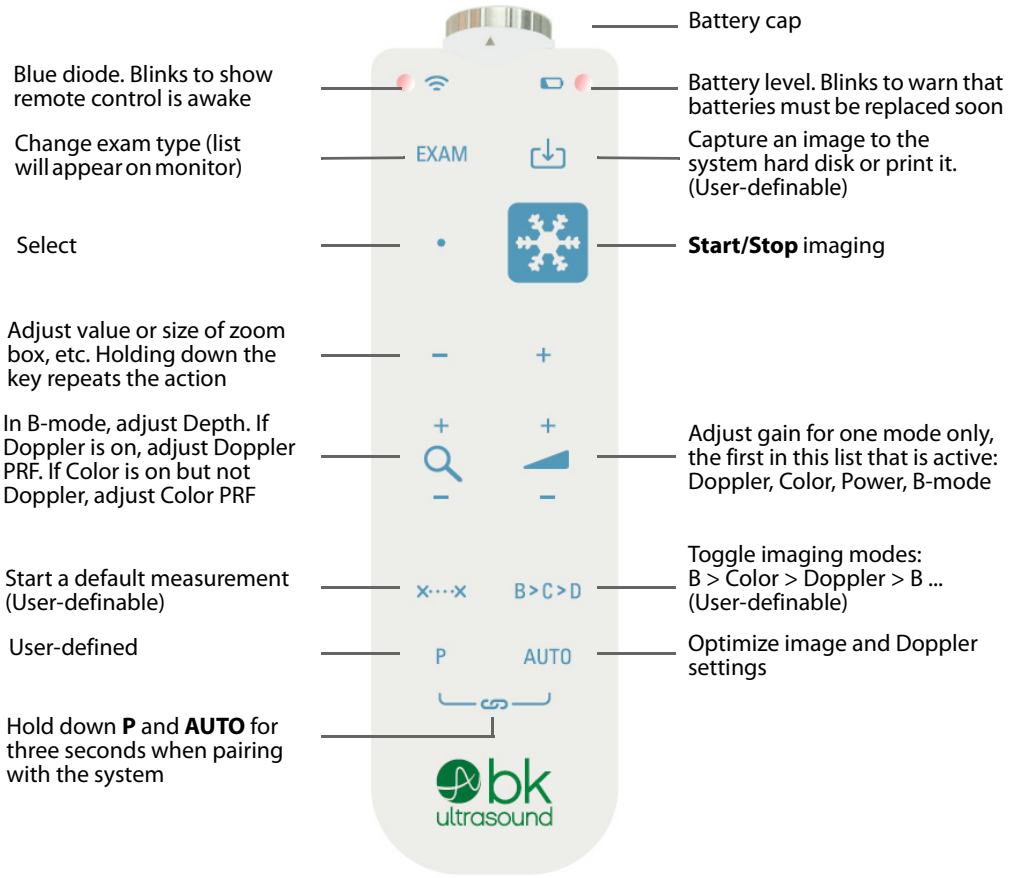


Figure 4-1. The remote control, with the location of its various functions.

Pairing the Remote Control with the System

1. Plug the Mini Bluetooth Adapter into a USB connector on the system (using the adapter that came with the remote control) and restart the system.
2. Press any key on the remote control to wake it up.
3. Hold down the **P** and **AUTO** keys on the remote control for three seconds.

   The remote control emits two beeps.
4. Release the keys after the second beep.

   The blue diode starts blinking rapidly.

   A dialog box appears on the monitor. This may take up to two minutes.

5 Click **Accept** to pair the system with the remote control (indicated by its serial no.).

The pairing process takes up to one minute.

When pairing is done, the remote control emits a beep and the blue diode blinks to show the remote control is awake.

NOTE: *The pairing process may time out. Try again if this happens.*

A remote control will remain paired to a specific system, even when the remote control is removed for disinfection/reprocessing. If you have more than one remote control, make sure you know the specific system the remote control is paired with. A remote control will remain paired to a system until it is paired with another, separate system.

Calibrating the Remote Control

When using the remote control for the first time, the cursor might start drifting on the monitor. To fix this issue, place the remote control on the tray in front of the transducer holders and leave it for two minutes to calibrate.

If the remote has been reprocessed or has been shaken so that the cursor starts drifting on the monitor, it needs recalibration. To recalibrate, repeat the process mentioned above.

Before use, verify that the remote control is working correctly.

Sleep

If the remote control is not used or moved for 5 minutes, it goes to sleep to save battery power. To wake it up, press any key.

Mouse Function

You can use the remote control as an air-tracking mouse to operate controls on the system monitor.

To move the cursor, tilt the remote control; move the front end up, down, or side-to-side. The mouse will not respond if you keep it level.

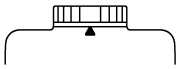
NOTE: *You do not need to point the remote control at the monitor. The cursor responds to changes in the position of the remote control.*

To select an object on the monitor, move the remote control so that the cursor is on the object, then press **Select**.

Replacing Batteries

1. Remove the battery cap.
2. Insert two LR6 size AA 1.5 volt batteries.
3. Screw the battery cap on tight until the arrow points to the area of the battery cap with a large gap between the ridges.

   When the battery cap is screwed on tight, the remote control is watertight and can be immersed.



Cleaning and Disinfection

For details of cleaning and disinfecting the remote control, see *Care, Cleaning & Safety*.

⚠ Remote Control	**WARNING** RC-w1 The remote control requires surface disinfection or sterilization as a minimum. The inside battery compartment cannot be classified as disinfected or sterile. Follow procedures established for your hospital, clinic or institution to avoid cross-contamination when inserting or removing batteries.

Chapter 5
Getting Started

Getting Started with bk3000 & bk5000 forms part of this user guide.

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Appendix A
Warnings and Cautions Displayed on the System

This appendix contains a list of warnings and cautions that may appear on the system if you perform an undesirable action or e.g. type in a wrong setting value. Contact a service technician if you encounter a persistent problem that can not be solved by the suggested action(s) below.

This list covers all warnings and cautions on systems bk3000, bk3500 and bk5000, so it may include warnings that are not relevant to your specific system.

The list also covers potential system and transducer malfunctions. Always contact a service technician if the system or the transducer malfunctions, see Warning GS-w2 on page 11.

Warning text	Action (if necessary)
Current date and time (%s) are before the scanner was last run (%s). Check your system clock.	
Failed to parse the prom received from the probe.	Try again.
Failed to read general settings from database.	Try again.
Failed to save bodymark catalog.	Try again.
Note that changing the time zone requires restarting the scanner.	Restart the system.
Probe prom read failed.	
Sensor data from probe is not received. Scanning is stopped.	
The probe could not be connected.	
The Probe FW is obsolete.	
The read probe prom has a wrong CRC.	
The read probe prom was empty.	
The system time is invalid and has been changed to %s %s. The system time can be set in the setup menu.	
The system time %s is invalid and setting it to %s failed. The system time can be set in the setup menu.	
Parking of the transducer %s failed.	Try again.

Caution text	Action (if necessary)
%d text(s) has been truncated to %d characters.	
"%s" is not a unique name.	Type in a unique name.
"%s" is not a valid number.	Type in a valid number.
A 3D volume was not acquired because no mover is connected. Please connect a mover.	
A 3D volume was not acquired because the connected mover does not match the selected mover. The connected mover is %s and the selected mover is %s. \n	Make sure that connected mover matches the selected mover.
A curve cannot have itself as parent curve.	
A formula in the measurement contains an invalid device attribute "%s.%s".	Use valid device attribute.
A formula in the measurement contains an invalid result name "%s".	Use valid result name.
A formula in the measurement contains an undefined measurement tool "%s".	Use a defined measurement tool.
A measurement cannot depend on itself.	
Adjusting the guide's height.	
Adjusting the guide's width.	
All available pro packs for %s has been hidden	
An error occurred while the patient archiving database was being copied.	Try again.
Another scanner is using this network drive for archiving. This can cause problems. For independent backups, each scanner must use a separate subdirectory.	
Changes not in effect until transducer(s) has been reconnected.	
Click Yes to clear the patient archive. All patients in the patient archive will be lost. Click No to cancel.	
Could not create temporary subdirectory for outgoing mail data.	Try again.
Curve name, x-axis and y-axis are required. Do not leave the fields empty.	Fill out required fields.
Default LCD backlight has not been adjusted.	Adjust default LCD backlight.

Caution text	Action (if necessary)
Empty volume name is not allowed.	Type in volume name.
Engine configuration validation failed. One or more Engine item versions are not valid.	
Error opening database %s. %s	
Error. The file did not contain a user-defined puncture guide.	Include user-defined puncture guide.
Failed to acquire 3D volume. %s	
Failed to calculate expression "%s": %s.	Try again.
Failed to calculate measurement. Syntax error in formula.	Check formula.
Failed to clear patient archive. Please contact a service technician.	
Failed to clear the patient dialog cache.\n%s	
Failed to configure the server.	Try again.
Failed to connect to SMTP server "%s". (%s)	Try again.
Failed to copy file: "%s" To: "%s" %s	Try again.
Failed to copy.	Try again.
Failed to create Diagnostic Setup ID: %s.	Try again.
Failed to create new Pro Package %s.	Try again.
Failed to delete catalog in database.	Try again.
Failed to delete curve in database.	Try again.
Failed to delete measurement in database.	Try again.
Failed to delete the server.	Try again.
Failed to export table "%s". %s	Try again.
Failed to import license keys from ""%s"". It is not a valid license file.	
Failed to import table "%s".\n%s	Try again.
Failed to open file "%s". \n%s	Try again.
Failed to process 3D volume.	
Failed to read catalog from database.	Try again.
Failed to read deleted Presets.	Try again.
Failed to read key action definitions from database.	Try again.

Caution text	Action (if necessary)
Failed to read key assignments from database.	Try again.
Failed to read key definitions from database.	Try again.
Failed to read measurement list from database.	Try again.
Failed to restore factory default catalogs in database.	Try again.
Failed to restore factory default general settings.	Try again.
Failed to restore factory default measurement groups.	Try again.
Failed to save 3D volume.	
Failed to save configuration "%s" in database.	Try again.
Failed to save measurement in database.	Try again.
Failed to send SMTP message (%s).	Try again.
Failed to store catalog in database.	Try again.
Failed to store clip in file.	Try again.
Failed to store curve in database.	Try again.
Failed to store general settings in the database.	Try again.
Failed to store key assignments in database.	Try again.
Failed to store the curve "%s". Two curves cannot have the same Reference Name, and the imported curve's Reference Name "%s" is already used for the curve "%s".	Use a different reference name to store the curve.
Failed to update Pro Package: %s.	Try again.
Failed to update the ICM file.	
Failed to validate database %s. Reverting to the latest backup from %s.	
Hard disk space on %s is critically low. Please clear some space on the hard disk or contact a service technician before proceeding.	
Hard disk space on %s is getting low.	Free up hard disk space.
Import of license keys from "%s" completed. The following license keys could not be imported: %s	Try again.

Caution text	Action (if necessary)
Incorrect settings for HistoScanning acquisition. Data will be rejected by HistoScanning. Please adjust the scanner settings.	
Invalid %s. Empty names are not allowed. Names must be shorter than %d characters. Names must not contain any of the following characters: %s	Fill out the required fields according to the on screen instructions.
License already in use.	
License key ""%s"" is invalid.	
Licenses missing: No available pro packs for %s has valid licenses	
Login error. Please try again.	
Name and description are required. Do not leave the fields empty.	Fill in name and description.
Name and formula are required. Do not leave the fields empty.	Fill in name and formula.
No available pro packages in database for transducer %s	
No catalogs available. Assign catalogs in setup window.	
No default propackage available for the %s transducer choose a default propackage	
No Preset name was specified.\nNothing will be saved.	Specify a preset name.
One or more batteries are wearing out. Consider replacing the following batteries: %s (where 1 is the top battery).	
Only %d fields can be selected for the Patient window. Deselect some of the fields.	
Please disconnect all transducers, restart the scanner, and start the import again.	
Please enter a number	
Please enter an SMTP Server Address. It must be entered as a name or an IP address.	
Please insert the archive disc labeled "%s" and try again.	
Pro Package %s could not be deleted because it would leave some transducers without a Pro Package.	

Caution text	Action (if necessary)
Staging area is not ready. Try again later.	
System restarts now.	
The '%s' curve could not be found in the database.	Try again.
The 3D volume is too big for the scanner memory. Please reduce the capture area or extent and try again.	
The AE title is invalid.	
The alias "%s" for the measurement "%s" is invalid. 1: Aliases cannot be empty. 2: Aliases must not contain any of the following characters: %s . 3: Aliases in each measurement must be unique.	Fill out the required fields according to the on screen instructions.
The archived document (%s) was not found on the network drive.	
The connected transducer cannot be used because there is a problem with its PROM. Please remove the transducer and contact a service technician.	
The curve definition is not compatible with this software version.	Upgrade software.
The curve definition must contain x and y values.	
The Display Controller Board has no ICM file.	
The document cannot be displayed because document data is corrupted	Contact BK service technician.
The document cannot be displayed.	Try again.
The document cannot be displayed. Currently there is no viewer available.	Install a viewer.
The entered license key has expired: %s.	
The entered license key is invalid.	Type in valid license key.
The field must not be empty.	
The file \\"%s\\" is too large to open. Max size is %d bytes.	If possible, reduce the file size.
The file does not contain a valid curve.	Use valid curve.
The file does not contain a valid measurement.	Use valid measurement.
The file size is too large to display on scanner	

Caution text	Action (if necessary)
The following licenses have expired:\n%s.	Install new license.
The formula exceeds the maximum length of %d characters.	Reduce length.
The guide's height is invalid.	Use valid height setting.
The guide's horizontal holes/cm is invalid.	Use valid horizontal holes/cm setting
The guide's horizontal offset is invalid.	Use valid horizontal offset setting.
The guide's name is invalid.	Use valid guide name.
The guide's vertical holes/cm is invalid.	Use valid vertical holes/cm setting.
The guide's vertical offset is invalid.	Use valid vertical offset setting.
The guide's width is invalid.	Use valid guide width setting.
The host name is invalid.	
The license could not be removed.	
The measurement cannot be edited. The template contains errors.	Contact service technician.
The measurement contains an invalid procedure name "%s".	Use valid procedure name.
The measurement could not be found in the database.	Try again.
The measurement definition is not compatible with this software version.	Upgrade software.
The measurement requires an unsupported measurement device type "%s".	Install supported measurement device type.
The measurement type is invalid.	Use valid measurement type.
The media was not burned: %s	
The name ""%s"" is already used.	
The name is invalid.	
The port number is invalid	
The procedure "%s" takes %d parameters.	
The report cannot be saved before a patient ID is entered.	
The report file cannot be generated: "%s"	Try again.
The same CD cannot contain both archived and non-archived documents.	

Caution text	Action (if necessary)
The scanner cannot communicate with the battery system. If you want to run the scanner using battery power, we recommend that you contact a service technician.	
The scanner is ready to enter service mode. The next time it starts, the PC will start in Windows mode. Please press the standby switch to turn off the scanner.	
The scanner is unable to communicate with other equipment through a COM port. %s	Use appropriate communication port(s). See *System User Guides* or contact service technician.
The scanner's hardware does not support %s.	
The selected curve is invalid.	Use valid curve.
The system has not finished sending the last mail. Please try again later.	
The system must be restarted for changes to take effect.	
The system must be restarted to fully implement the language change.	
The tool attribute %s is invalid.	Use valid tool attribute.
The transducer button %d is stuck on the transducer connected to connector %s.	
The two passwords you have typed are not identical.	
The USB Device cannot be safely removed. Try again.	
The user already exists. Enter a different username.	
The value "%s" (%s) contains the invalid character(s) "%s".	Type in valid characters.
The value "%s" (%s) is outside the legal range (%.2f - %.2f).	Keep value (s) within legal range.
The volume name is already used in the patient archiving system. Please enter another name.	
The volume name is not valid. It contains only illegal character(s). Please enter the new volume name.	
The volume name is too long. The name must be no longer than %d characters.	

Caution text	Action (if necessary)
The width and height must be numbers between %d and %d.	
There are no files to be burned to a CD.	
There is no mail receiver (SMTP To-address) configured.\nTechnical service must configure this service before it can be used.	
There is no USB Device connected to the scanner.	
There was a problem saving the Diagnostic Setup %s.	Try again.
This scanner does not support CW Doppler. (This may be because of the power supply version.)	Try again or contact BK service technician.
Transducer "%s" cannot be used with this scanner.	Connect a compatible transducer. See *Product Data Sheet* for more details.
Transducer "%s" cannot be used with this scanner. A hardware upgrade may solve the problem.	Connect a compatible transducer. See *Product Data Sheet* for more details.
Transducer ""%s"" is disabled for this scanner.	
Unable to capture image.	Try again.
Unable to connect remote control.	
Unable to connect to the network drive. Check server (UNC path), username and password.	
Unable to connect to the network drive. %s	
Unable to create backup of database because of %s. If the error persists, contact a service technician.	
Unable to launch application ("%s")	Try again.
You must end the on-going exam before you can clear the patient archive.	
You must restart the scanner after you enable or disable the OEM interface.	
Your old password is not valid.	Create new password.

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