BINDEX

Osteoporosis Diagnostics

User Manual

Bindex® LSC Software version 3.1
Bindex® model BI-2

CE
0537

Updated 15 July 2025 For distribution in the European Union and the United Kingdom only

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The Quality Management System of Bone Index Finland Ltd. complies with the United States Food and Drug Administration Code of Federal Regulations Title 21 Part 820 (Quality System Regulation), the European Medical Device Regulation 2017/745 (MDR) and the Quality Management Standard EN ISO 13485:2016. Bindex products comply with the Medical Device Directive MDD 93/42/EEC requirements.

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2. Warnings and precautions

Before using Bindex, the user must read and understand the following safety-related information. The user shall adhere to the warnings to ensure a safe and reliable performance of the system.

ELECTROMAGNETIC ENVIRONMENT HAZARD:
The Bindex system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in Appendix: Guidance and manufacturer's declaration - Electromagnetic Compatibility. If the use environment has specific requirements for EMC, the system setup should be assessed and inspected by qualified personnel. Incorrect installation could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.

ELECTROMAGNETIC ENVIRONMENT HAZARD:
Portable and mobile radio frequency (RF) communications equipment can affect the Bindex BI-2 device and result in improper operation. Do not use such equipment near the Bindex BI-2 device (See Appendix: Guidance and manufacturer's declaration - Electromagnetic Compatibility for additional information).

ELECTRICAL HAZARD:
Equipment used in the Bindex measuring system must comply with IEC 60601-1:2005+A1/2013 (medical electrical equipment), IEC 62368-1:2014 (non-medical IT equipment) or their general IEC/ISO variants. Electrical safety of the system can only be guaranteed on compliant equipment.

ELECTRICAL HAZARD:
Do not connect or use other devices in the Bindex measurement computer during patient measurements (excl. the mouse, keyboard and display). The electrical and electromagnetic compatibility of the system can only be guaranteed when Bindex device alone is connected.

ELECTRICAL HAZARD:
Non-medical equipment (including the PC) should be located outside the patient environment as described in IEC 60601-1 to guarantee the electrical safety of the system. If it is necessary for the non-IEC 60601-1 compliant equipment to be located within the patient environment, that equipment shall be powered by an internal battery or an EN 62368-1:2014 compliant isolation transformer or be connected to system ground via an additional protective earth terminal.

ELECTROMAGNETIC ENVIRONMENT HAZARD:
WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

HEALTH HAZARD:
Do not make Bindex measurements on the surface of skin with open sores or broken or irritated skin. There is an infection risk.

INCORRECT USE HAZARD:
Do not use the Bindex device in case of a fractured bone at measurement location. The result is only reliable when the measurement is made on an intact bone.

INCORRECT USE HAZARD:
Do not use the Bindex device in case of implants, plates or fixations at measurement location. If possible, conduct the measurement on the other leg. The result is only reliable when the measurement is made on an intact bone.

ENVIRONMENTAL HAZARD:
Do not use the Bindex device outdoors. The device is intended for indoor use only. See 6 Operating environment.

ELECTRICAL HAZARD:
Do not use the Bindex device near a heat source or an air conditioner. This may cause condensation of moisture inside the equipment. Moisture may cause improper operation or electrical safety hazards due to short circuiting. Let the device settle to operating room temperature before operation.

HEALTH HAZARD:
Use only gel intended for clinical ultrasound coupling for measurements with the Bindex device. Improper gel or other substances may cause symptoms such as skin irritation to the patient or operator.

INCORRECT USE HAZARD:
Do not apply ultrasound gel on the surface of the Bindex transducer before calibration. Conducting the calibration with an unclean transducer may cause the calibration or the initial device setup to fail. See 8.6 Bindex quality verification.

INCORRECT USE HAZARD:
Always use the Bindex BI-41 Measure for determination of the proper measurement location. The location is standardized for this measurement to produce reliable results. Failing to use the Bindex Measure in determining the location may lead to incorrect results.

MECHANICAL/ELECTRICAL HAZARD:
If you drop or bump the device on hard surfaces, conduct quality verification measurements. In case of any visible mechanical damage, please contact your local distributor or Bindex Support and Service (see for service. Store the device in its protective case between uses. Do not use a damaged device!

ENVIRONMENTAL/FIRE HAZARD:
The Bindex device is not intended to be used in oxygen rich environment. Using the device in an oxygen rich environment may lead to a fire or explosion.

ELECTRICAL HAZARD:
The patient shall be informed not to touch the connectors of the ME system (e.g. laptop connectors) during measurements. Touching the connectors of the system results in potential electrical safety hazard. Where possible, the computer should be kept away from the patient area.

ELECTROMAGNETIC ENVIRONMENT HAZARD:
WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

ELECTROMAGNETIC ENVIRONMENT HAZARD:
WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Bindex device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

HOME ENVIRONMENT HAZARD:
WARNING: Keep away from pets.

HOME ENVIRONMENT HAZARD:
WARNING: Keep out of reach of children.

3. Symbols and Abbreviations

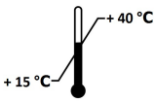
3.1. Abbreviations

US	Ultrasound
DI	Density Index
DXA	Dual Energy X-ray Absorptiometry
BMD	Bone Mineral Density
Cth.	Cortical thickness

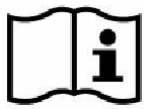
3.2. Symbols glossary

The symbols of this glossary can be found in Bindex product labels and this User Manual. If unsure about the meaning of a symbol, please contact Bindex Support and Service (see ch. 12 Contact information)

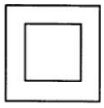
	DEVICE SYMBOLS
	Refer to instruction manual/booklet. To signify that the instruction manual/booklet must be read. (ISO 7010, Ref.No. M002)
	Serial number. Indicates the manufacturer's serial number so that a specific medical device can be identified. (EN ISO 15223-1:2016, Ref.No. 5.1.7)
	Manufacturer. Indicates the medical device manufacturer name and address. (EN ISO 15223-1:2016, Ref.No. 5.1.1)
	Type BF applied part. To identify a type BF applied part complying with IEC 60601-1. (IEC 60417, Ref.No. 5840)
	Caution. Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. (EN ISO 15223-1:2016, Ref.No. 5.4.4, symbol variant 0434B)
	The device is USB (Universal Serial Bus) compatible. The cable is equipped with a USB Type A connector. (Universal Serial Bus Specification rev.1.1, Fig. 6-5)



Temperature limit (for declared conditions). Indicates the temperature limits to which the medical device can be safely exposed.
(EN ISO 15223-1:2016, Ref.No. 5.3.7)



Consult instructions for use. Indicates the need for the user to consult the instructions for use. Includes the URL (web address) to the electronic User Manual.
(EN ISO 15223-1:2016, Ref.No. 5.4.3)



Class II device. To identify equipment meeting the safety requirements specified for Class II equipment according to IEC 61140. Referring to electrical equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions.
(IEC 60417, Ref.No. 5172)

IP22

IP rating. Indicates the protection level of the device against solid foreign objects and water. Bindex is rated as IP22, indicating protection against solid foreign objects of 12,5 mm and greater in diameter (e.g. fingers), and vertically falling water drops when the device is tilted up to 15°
(IEC 60529)

℞ Only

Symbol for the United States only, not applicable in the European Union or the United Kingdom.
(21 CFR 801.109 (b) (1))

PACKAGE SYMBOLS

EU only: Separate collection for electrical and electronic equipment waste required (see ch. 11.1 Disposal).
(EN 50419:2006)

Fragile, handle with care. Indicates a medical device that can be broken or damaged if not handled carefully.
(EN ISO 15223-1:2016, Ref.No. 5.3.1)

Keep dry. Indicates a medical device that needs to be protected from moisture.
(EN ISO 15223-1:2016, Ref.No. 5.3.4)

In this manual, software controls are indicated as follows: BUTTONS in capital letters, **Windows and Pages** in bolded capital and small letters and *Editable fields* in italic typeface.

4. Indications for use

Bindex measures apparent cortical bone thickness at the proximal tibia and can be used for assessment of probability of osteoporosis risk. Results can recommend that the patient consult with a physician for osteoporosis evaluation and diagnosis. When done by a healthcare professional, Bindex measurement can be used in conjunction with other clinical risk factors or patient characteristics as an aid to the physician in the diagnosis of osteoporosis and other medical conditions leading to reduced bone strength and in the determination of fracture risk.

4.1. Intended use

Bindex measures apparent cortical bone thickness at the upper shaft of tibia (See Figure 1) and reports the diagnostic parameter, Density Index (DI), an estimate of hip Bone Mineral Density measured with gold standard Axial DXA. Thresholds for osteoporosis for DI have been determined in comparison to DXA.

After the measurement, Bindex Software gives an estimation of the presence of osteoporosis marked in the color bar: Green (Low Probability of Osteoporosis), Yellow (Additional Investigations Needed) or Red area (High Probability of Osteoporosis). A total of 90% of osteoporotic patients diagnosed by hip BMD are in the yellow or red area (90% sensitivity) and 90% of non-osteoporotic patients are in the green or yellow area (90% specificity). Statistically at least 80% sensitivity and specificity for hip osteoporosis will be reached with 95% confidence. Patient classification is based on thresholds (separating red/yellow/green areas) published in a study by Karjalainen et al. “New method for point-of-care osteoporosis screening and diagnostics” in Osteoporosis International 2016.

A DI value below the upper threshold indicates for consultancy of a physician for osteoporosis evaluation and diagnosis. When done by a healthcare professional, the DI reported by Bindex can also be used as an aid to the physician in osteoporosis diagnostics and estimation of fracture risk.

Currently the use of Bindex DI thresholds is validated for Caucasian and Hispanic women at the age between 50 to 90 years. Bindex measurement takes about one

minute. Bindex device should be operated by a physician, nurse, pharmacist or trained person with a suitable background education and skills.

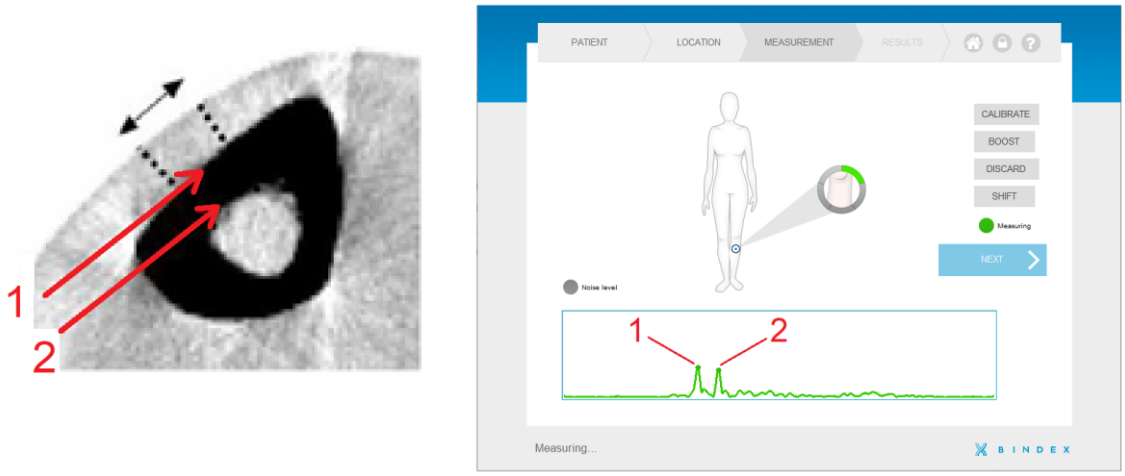


Figure 1: A Computed Tomography image of tibia shows the tubular structure of the bone (black area). When measuring the tibia with Bindex, the ultrasound echoes back from the front (1) and the back (2) surface of cortical bone layer. These echoes need to be clearly distinguishable. Bindex will automatically accept the echoes.

5. Bindex BI-2 overview and technical specification

Bindex BI-2 device

The Bindex BI-2 device consists of the handpiece including the measurement electronics and the USB cord (Figure 2). The device is connected to a free USB port of a personal computer. In the device, an electrical pulse is sent to the transducer which transforms the pulse into ultrasound waves that are transmitted into the bone. The transducer collects the sound waves reflected from the bone and transmits the signal via the electronics to the PC software for analysis.

Figure 2: Bindex BI-2 device shown together with the BI-41 Measure.

Bindex Software

Bindex utilizes software which is provided to customer as a web installer application which downloads the installation files for the latest version of the Bindex software. Computer hardware requirements are described in chapter 6 Operating environment. The Bindex device is operated using the software GUI (Graphical User Interface) to control the pulser and to collect the measured signals. Signals are analyzed to calculate the diagnostic/screening parameter DI. Results are saved in the Bindex database and can be exported in PDF format or as a text

file for easy transfer to e.g. a spreadsheet program.

Bindex BI-41 Measure

For determination of the standard location for Bindex measurement, device is supplied with a custom stick measure (Figure 3). The Bindex Measure is always used to determine the ultrasound measurement location at 1/3 length of the proximal tibia.

Figure 3: The Bindex Measure is used for determination of standard measurement location at the tibia.

Specifications

Mechanics	
Weight (incl. USB cord)	128g
Size (handpiece)	119 x 42 x 34mm (length x width x height)
USB cord length	2.0 m
IP Rating	IP22 (Protected against: - Solid foreign objects of 12,5 mm and greater in diameter; - Vertically falling water drops when the device is tilted up to 15°)

Electrical	
Power supply	Powered from PC USB port, 5V
Fuse	6V / 500 mA, resettable (not serviceable by user)

Environmental	
Operating Temperature	+15...+40 °C
Storage Temperature	+15...+40 °C
Transport Temperature	-25...+60 °C
Atmospheric Pressure	700hPa to 1060hPa (mbar)
Humidity	5…90%

Ultrasound	
Transducer centre frequency	3.0 MHz
Transducer type	Focused
Mechanical Index	0.220
Thermal Index ($TIB_{bs,ns}$)	0.011
Spatial-peak temporal-average intensity (I_{spta})	6.5 mW/cm^2

Safety standards compliance	
Medical electrical equipment safety	EN 60601-1:2006 + A1:2013 + A2:2021
Electromagnetic compatibility	EN 60601-1-2:2015 + A1:2021
Use in Home Healthcare Environment	EN 60601-1-11:2015 + A1:2021
Ultrasound safety	EN 60601-2-37:2008 + A11:2011 + A1:2015 EN 62359:2011 + A1:2018

Bindex and the connected PC are together considered a medical electrical system. The computer power source must comply with the IEC 62368-1:2014 standard, otherwise it is mandatory to connect the PC operated with Bindex to the mains supply with a medical isolation transformer. An isolation transformer or an additional protective earth connection from the computer is also required when the computer does not comply with IEC 60601-1:2005 and it is used within the patient environment.

Bindex can also be used with an IEC 62368-1:2014 compliant laptop computer operating on battery power without connecting to the supply mains. In this case, no additional precautions concerning electrical safety are required.

ELECTRICAL HAZARD:
The Bindex system, including the computer, must only be used with the electrical setup specified in this chapter. Operator and patient safety regarding electrical hazards can only be guaranteed with the specified conditions and devices.

ELECTRICAL HAZARD:
DO NOT plug the Bindex BI-2 device into supply mains!

6. Operating environment

See section 5 for operating and storing conditions.

- The basic principle is that you may use Bindex in the same environment as your computer.
- Bindex is intended to be operated indoors, in clinics, hospitals or home healthcare use environments (see Appendix: Guidance and manufacturer's declaration - Electromagnetic Compatibility for power supply requirements) by a trained operator
- Bindex is not recommended to be used near active high frequency surgical equipment or in an RF shielded room of an ME system for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.
- Bindex is powered from the USB port of your computer. Please make sure that your computer is connected to a power source (battery or a mains outlet).
- Do not use Bindex near heat source or air conditioner and do not expose device to excessive moisture, above or under specified limits in section 5.
- Do not store your Bindex in a place where it exposes to sunlight.
- Measurements can be done while patient is either sitting or lying on a bed.

Computer hardware requirements	
Operating System:	Windows 10 (64-bit) or Windows 11 (64-bit)
Processor:	2 GHz, x64
Memory:	2 GB
Hard Disk Drive:	installation: 72 MB Bindex Software 353 MB LabVIEW Run-Time Engine 2024 212 MB Microsoft Access Runtime (64-bit, 2016 or newer, see 7.2) 87.8 MB GPL Ghostscript (10.04.0) 2 MB FTDI device drivers (2.12.36.4) in use: 1.7 MB per patient NOTE: Bindex Software cannot be used if the remaining disk space is under 1 Gb.
Screen Resolution:	1024x768
Other:	USB port (type A) .NET framework v.4.7.2 or newer Internet connection

7. Setup

7.1. Unpacking Bindex

When you have received your Bindex BI-2 device package, remember to check that you have all components/parts which are listed in the packing list. Also remember to check that the packing list includes everything you have ordered. The package includes the Bindex BI-2 device and a Bindex BI-41 Measure. The electronic instructions for use (the User Manual) are downloadable from Bindex website (www.bindex.fi/en/manuals/) and accessible through Bindex software after installation.

The web installer application for downloading and installing latest version of Bindex Software can be downloaded at https://www.bindex.fi/en/sw_dwnld/ (link also provided by customer support).

7.2. Software installation

Installation of the Bindex Software should be done by a person with at least basic knowledge and experience about the Windows OS and installing new programs and hardware, e.g. a nurse with experience on the subject or an IT support technician. Software can also be installed by a Bindex representative as agreed.

PLEASE NOTE: Administrator rights are required for the installation.

To start the installation, start the web installer application for downloading the Bindex software installation files, press DOWNLOAD and wait for the download to finish and press INSTALL (Figure 4 & Figure 5). Alternatively, if the install files have been delivered separately double click on the “setup.exe” file. You need to confirm that the program is allowed to make changes to the computer. You may also need to enter the administrator password before the installation launches. You can stop the installation at any time by pressing the CANCEL button in the lower right corner of the installation window.

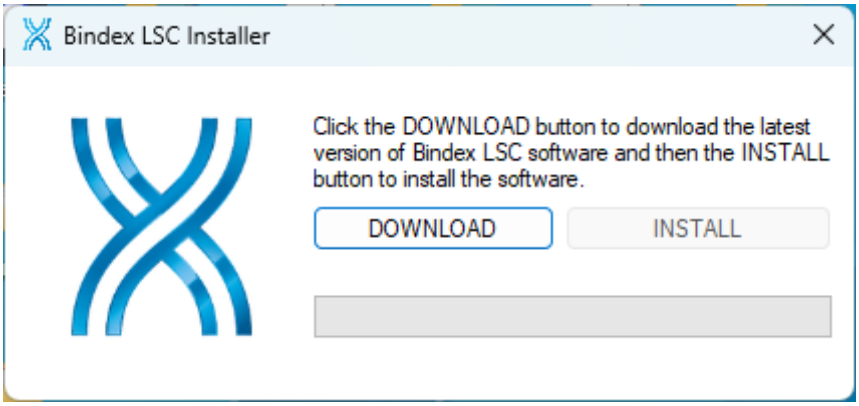


Figure 4. Bindex web installer used for downloading Bindex software installation files.

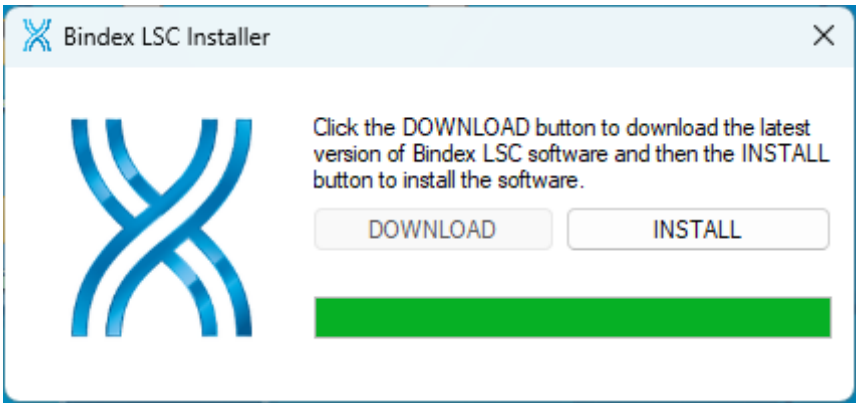


Figure 5. After the download, the Bindex software can be installed.

Set the installation directories in the following window (Figure 6). Please verify the installation folder because you cannot move the software folder after installing.

The next step is accepting the license agreements (Figure 7). Carefully read the license terms before proceeding. Selecting “I accept the License Agreement” is required to use the Bindex Software. Press NEXT to continue. The next window includes the license terms for the National Instruments software required for Bindex Software. Accept the terms and click on NEXT.

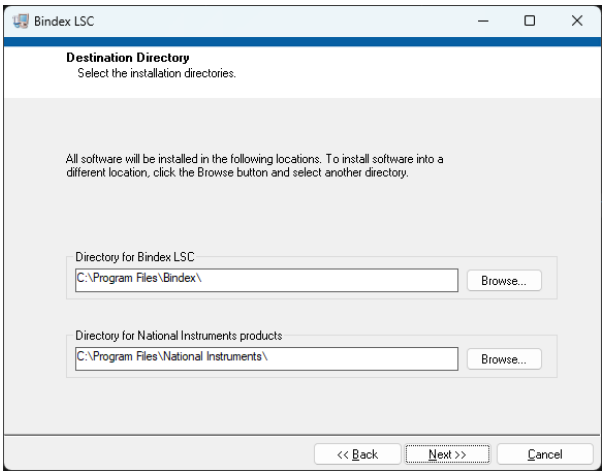


Figure 6: Setting the installation directories. The paths may be changed if needed.

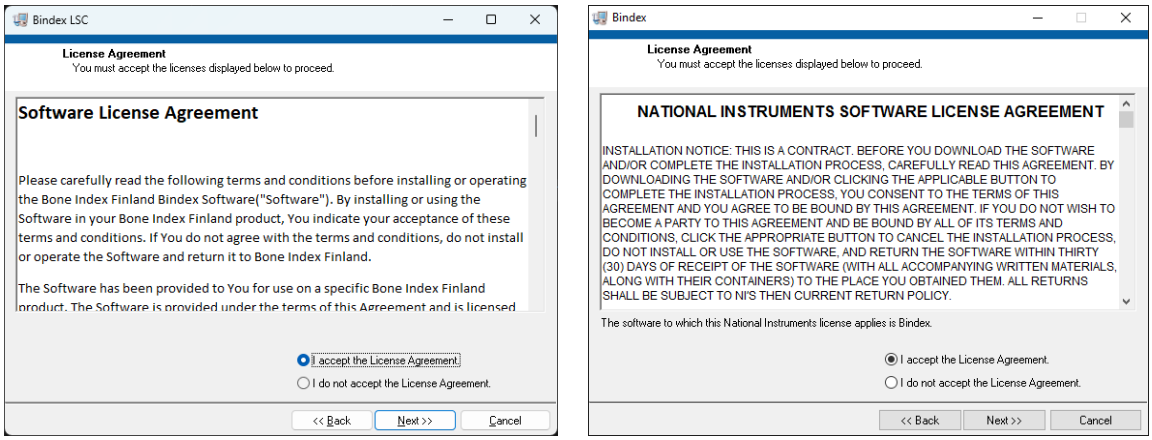


Figure 7: The license agreements. Carefully read the terms before proceeding. After accepting the licenses, continue with the installation by clicking on NEXT.

The following window (Figure 8) shows that you are about to install or change files related to Bindex Software. The installation starts by pressing NEXT.

After a successful installation, a confirmation window is shown (Figure 9). Finish the setup by pressing NEXT. LabVIEW Run-time Engine, FTDI CDM drivers, Microsoft Access Runtime and GPL Ghostscript are required to be installed to run Bindex Software. LabVIEW Run-time Engine is installed during Bindex Software installation and installers for FTDI CDM Drivers and GPL Ghostscript are launched after the Bindex installation. Microsoft Access Runtime is not included in the Bindex installation package and must be installed manually if required. Microsoft Access Runtime can be downloaded from Microsoft website (please

consult your IT support if required and see 6 Operating environment for computer requirements including software versions). Bindex Software will display a notification when attempting to use the software without compatible version of Microsoft Access Runtime installed on the computer. FTDI CDM Drivers installer is launched for installing required device driver (Figure 10). For more information on the device driver installation, see section 7.3 Device driver installation. Please follow the instructions on the screen to complete the setup. After installing the FTDI CDM Drivers, installer for GPL Ghostscript is launched (Figure 11). Please follow the instructions on the screen to complete the setup. A restart may be required before running Bindex Software. You may do this at this point or later, if required.

Please consult the Bindex Support and Service (see section 12 Contact information) for additional assistance.

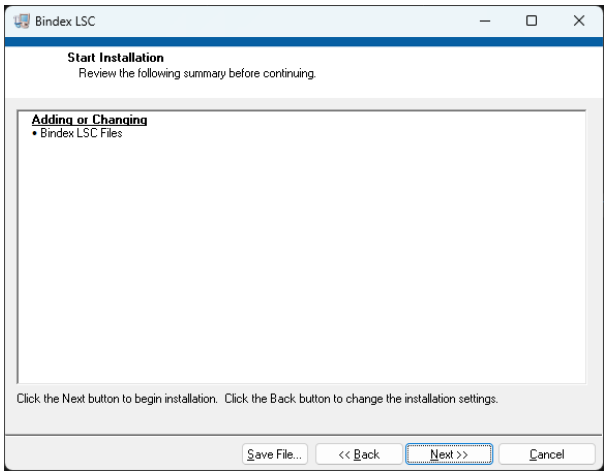


Figure 8: Starting the installation.

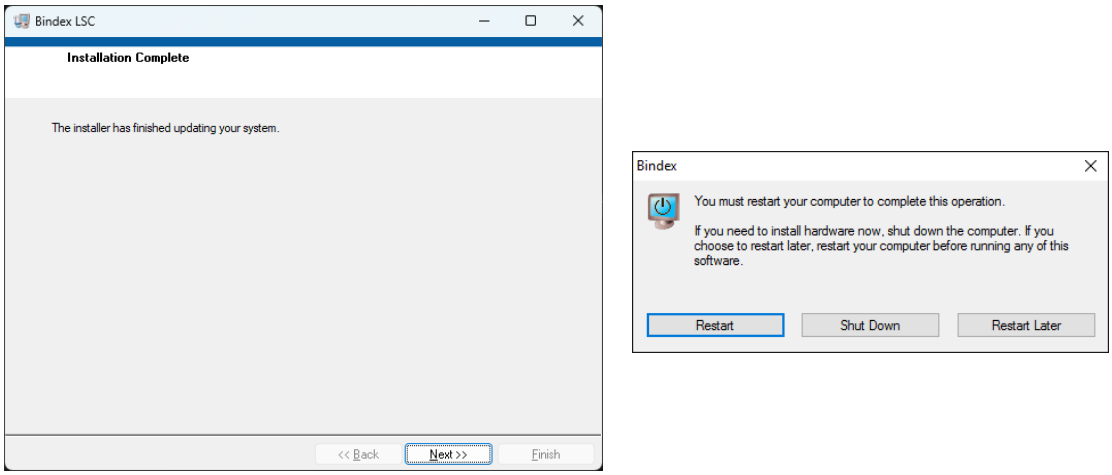


Figure 9: Installation completed successfully. Proceed by pressing NEXT, after which other required software are installed and device driver installer is launched. After installing all required components, a restart may be needed before using the software.

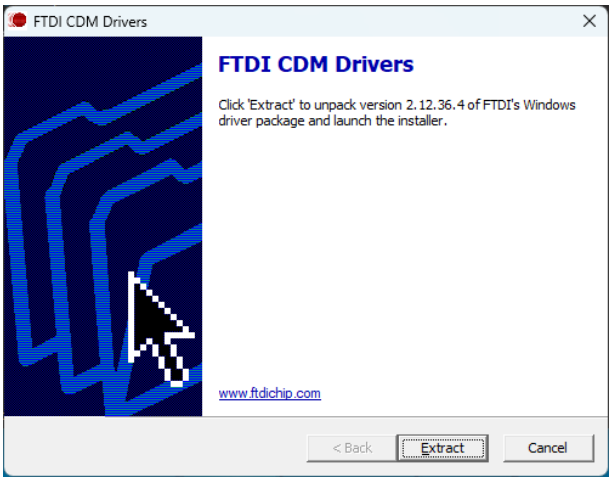


Figure 10: Starting FTDI CDM Driver installation.

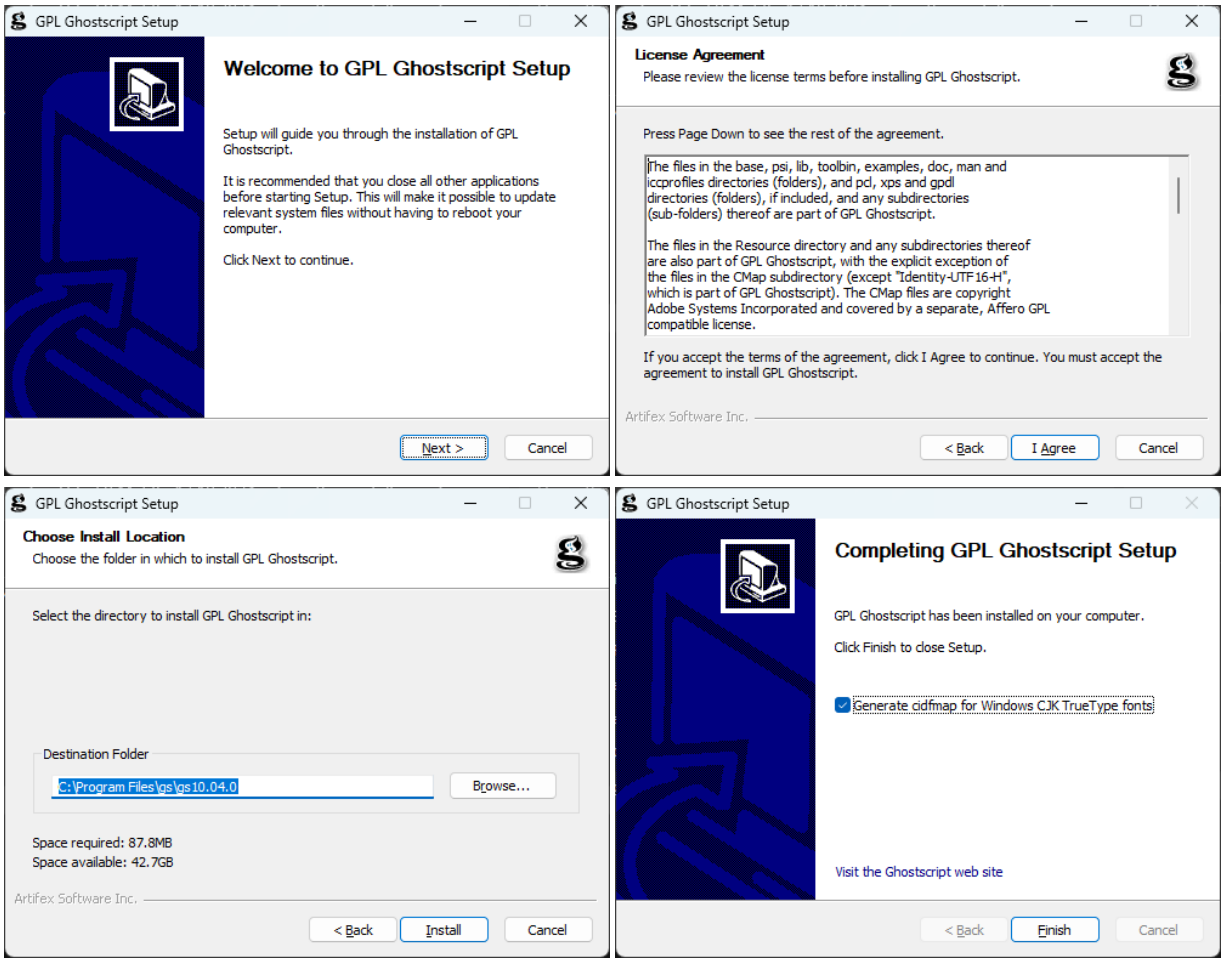


Figure 11: GPL Ghostscript installation. Continue with the installation by clicking on NEXT. After reading the license agreement click I agree. Select install location and click Install. After installation, the Generate cidfmap for Windows CJK TrueType fonts option is optional.

7.3. Device driver installation

Bindex BI-2 device driver can be installed during Bindex Software installation. Device driver is required for the computer to identify the Bindex device and to conduct the measurement correctly.

When the Bindex BI-2 device is plugged in and the computer is connected to the Internet, depending on the computer specific settings the operating system may automatically install the device driver. It is recommended to install the device driver as part of the Bindex Software installation and connect Bindex BI-2 device to the computer after installation. After installing the Bindex software, LabVIEW Run-time Engine, GPL Ghostscript, Microsoft Access Runtime and the device driver, the Bindex software is ready to be started.

Please consult the Bindex Support and Service (see section 12 Contact information) for additional assistance.

7.4. Software activation

Bindex software must be activated before it can be used. Activation of Bindex software requires internet connection for connecting to the Bindex License Server, which holds the license details of Bindex software activations of registered computers, and an organization key and a Bindex device, which are registered for your organization by Bone Index Finland. For more information on how to activate the software, see 7.4.1 Registration of computer. If you have already activated Bindex software and wish to transfer the activation to another computer, see 7.4.3 Transfer of activation.

There are two different license models that can be used for Bindex software, centralized and decentralized. In centralized license model the organization holds the amount of pre-paid analyses (PPA) available on the license server, and the PPAs are shared between all the activated computers of the organization. When using centralized license model, the amount of available PPAs is checked from the license server through internet connection before every measurement and updated

after every measurement. In decentralized license model the activated computers of the organization have individual amount of PPAs for use, which is tracked locally allowing offline operation of Bindex software for fixed number of days after which connection to the license server is required for updating license details and retrieving ordered additional PPA packets. For more information on how to order additional PPAs, see 7.4.2 Ordering additional analyses.

7.4.1. Registration of computer

To start using the Bindex software you need to register your computer to activate the software. Registration requires organization key that is registered for your organization, internet connection for connecting to the license server and a connected Bindex device belonging to your organization.

1) Launch Bindex Software (e.g. double-click on "Bindex.exe" in program folder or shortcut in your desktop). A dialog appears, asking you to enter name of the computer and organization key (Figure 12). Name of the computer can later be changed from **Settings** of Bindex software.
2) Check that you are connected to the internet and that a Bindex device is connected to the computer before trying to register the computer.
3) The software will inform you if the registration succeeds, after which the software is activated (Figure 13). If Bindex software users have not been managed in User Management Application (UMA) before, you will be directed to UMA. For more information on UMA, see section 7.5 User Management Application (UMA).

Please consult your Bindex representative or the Bindex Support and Service (see section 12 Contact information) for additional assistance.

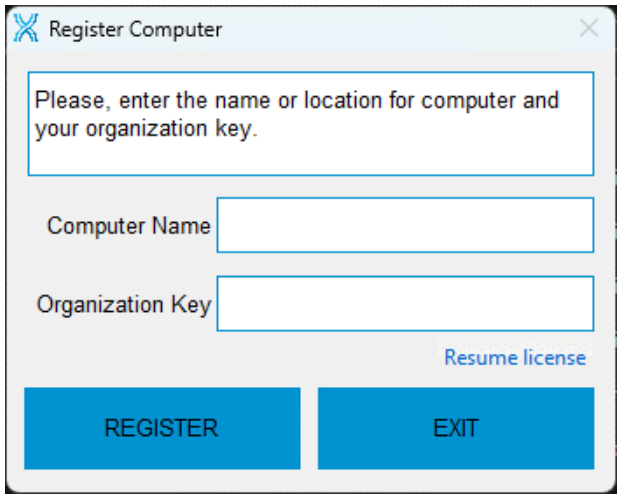


Figure 12. Software must be activated before use by registering the computer.

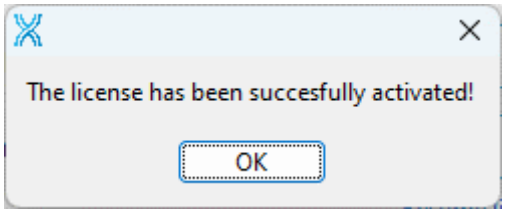


Figure 13. The notification when the activation succeeds.

7.4.2. Ordering additional analyses

After activating the software each new Density Index analysis consumes one pre-paid analysis (PPA). New measurements can be made until all PPAs have been used. After this, software can be started, and previous measurements viewed.

For centralized license model, the number of available PPAs for the organization is checked from the license server before every measurement and updated after every measurement. For decentralized license model Bindex software retrieves new ordered PPA packets for the computer from the license server at Bindex software startups automatically if connected to the internet and through **License management** window, which is accessible through LICENSE AND PPA in **Settings** page (Figure 14). A notification is displayed when new PPA packet have

been retrieved from the license server (Figure 15).

To order more analyses, please contact Bone Index Finland by sending email to Bindex Support and Service (see section 12 Contact information) with your contact details and number of PPAs to order. If using decentralized license model, please state name of the activated computer used in the Bindex software. Once the order for additional analyses has been processed, the Bindex Software will receive the updated PPA information upon next connection to the license server.

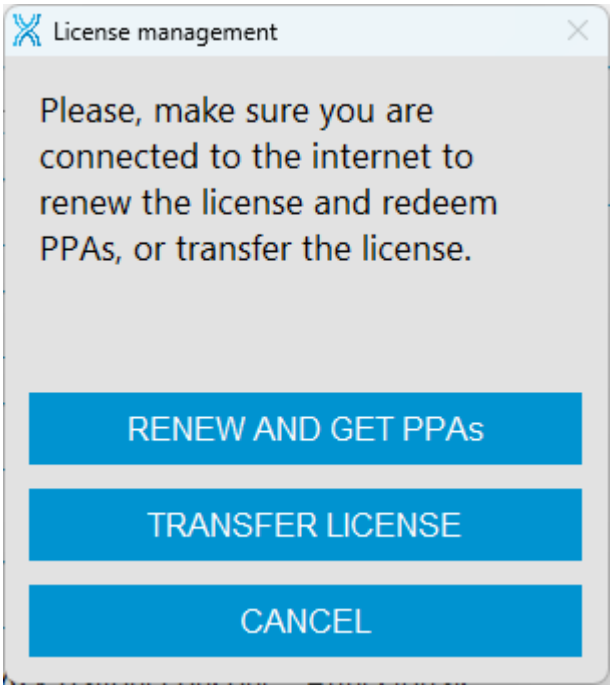


Figure 14. The license management window. License of the software can be transferred to another computer. For decentralized licensing model, available PPAs for the computer can be retrieved from the license server and license renewal expiration postponed.

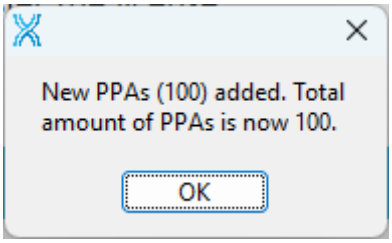


Figure 15. The notification when the computer has retrieved new PPA packet from the License Server when using decentralized licensing model.

7.4.3. Transfer of activation

You can transfer your Bindex software activation to another computer. Activation details, such as organization name, computer name, licensing model and number of available PPAs, can be transferred using the built-in activation transferring function accessible from activated Bindex software.

To transfer software activation to not activated software on another computer, internet connection, Bindex device, and organization and transfer keys are required. Transfer key is created when activated Bindex software is deactivated using TRANSFER LICENSE, which is accessible through **Settings** and LICENSE AND PPA in Bindex software.

To transfer the activation, follow the steps below:

1. Verify that the Bindex software version on both computers is the same and that both computers are connected to the internet.
2. Start the Bindex software on the activated computer, from which the activation shall be transferred.
3. Go to **Settings**, select LICENSE AND PPA and TRANSFER LICENSE in **License management** window (Figure 14).
4. A confirmation message will appear (Figure 16).
5. If the transfer license function succeeds, the software will be deactivated and **Transfer key** dialog (Figure 17) will appear. If the transfer license

function fails, please check the internet connection, restart the Bindex software and try again.

6. Save the transfer key. It will be required for activation.
7. Close the Bindex software.
8. Launch the Bindex software on the computer that shall be activated with the transfer key.
9. In **Register Computer** window (Figure 12), select RESUME LICENSE and type in transfer and organization keys (Figure 18).
10. Verify that you are connected to the internet and that Bindex device is connected to the computer before selecting RESUME to activate the software.
11. The software will inform you if the software activation succeeds (Figure 19). If the activation fails, follow the instructions in the **Register Computer** window, and if required, check the internet connection, restart the Bindex software, reconnect/switch Bindex device, if possible, and try again.

If the database contents on the deactivated computer are not manually deleted, the previously saved data by Bindex software on the computer will remain and will be usable after reactivation.

Please consult the Bindex Support and Service (see section 12 Contact information) for additional assistance.

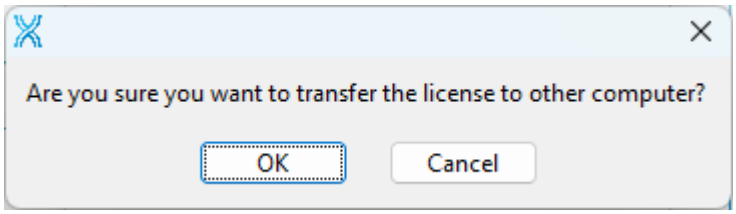


Figure 16. Confirmation after selecting Transfer License.

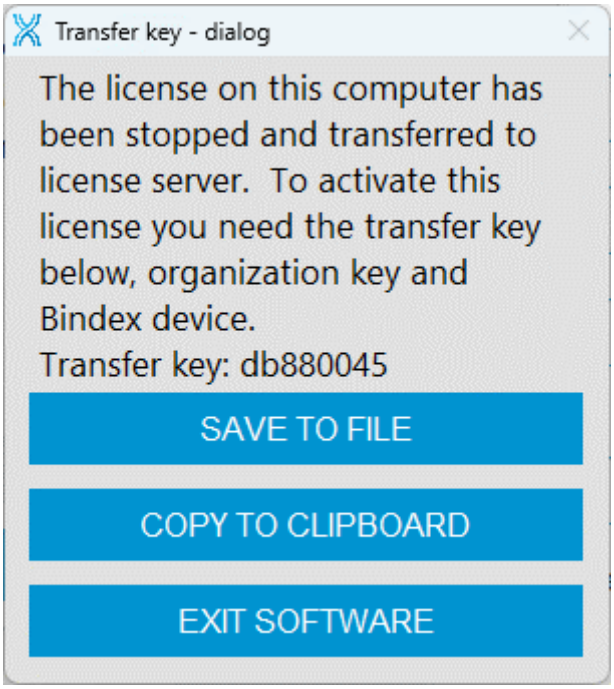


Figure 17. Transfer key dialog appears once the software has been deactivated and the license is ready to be transferred to another computer. The transfer key that is required for activation is displayed, and can be saved to file, or copied to clipboard.

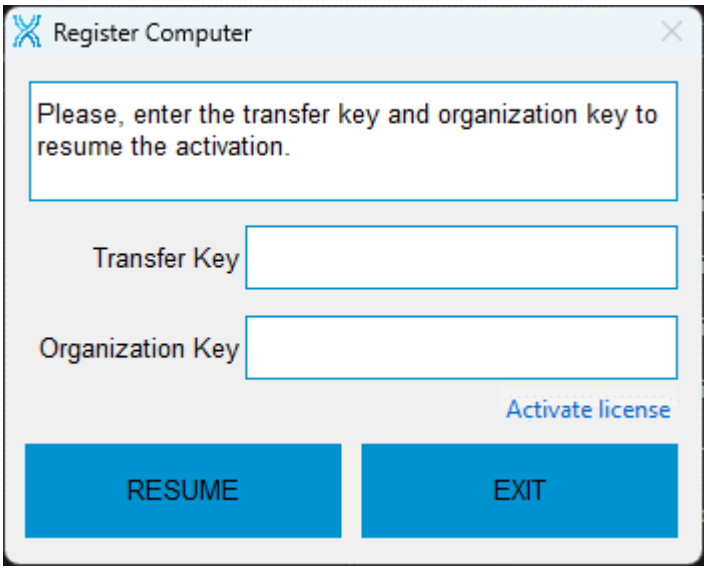


Figure 18. Register computer window when activating using transfer key.

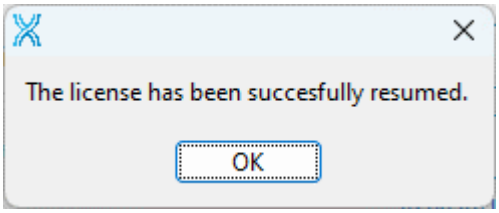


Figure 19. Activation transferred successfully.

7.4.4. Additional software

You can export the result sheets as PDF files. To be able to view them a PDF reader application (e.g. Adobe Reader) is required.

The User Management Application (UMA) is required for creating and managing Bindex users and setting the password protection for Bindex Software. UMA is automatically installed with the Bindex Software standard installation. For more information, see section 7.5 User Management Application (UMA).

7.4.5. Additional system setup

Adjust the computer screen brightness to a comfortable level from the

system/computer settings. Too low screen brightness may hinder the use experience and the measurement in Bindex Software.

Enable the system sounds of the computer to hear the audio signals for accepted signals during Bindex measurement.

For high resolution displays (above Full HD, e.g. 4K) it is recommended to use the Windows scaling function (Settings → Display → Scale and layout). Set the scaling to a level at which the Bindex Software window can be viewed with ease.

7.4.6. Information and system security

For ensuring data security it is highly recommended to use password-protected Windows user accounts or other authorization method for the computer Bindex Software is installed on. By default the password protection and user accounts for Bindex Software are on. Please see 7.5 User Management Application (UMA) for additional information.

Up-to-date antivirus, malware protection and a firewall (Windows Defender firewall) is also highly recommended for protecting the patient and operator data. It is recommended to enable automatic updates for the Windows operating system, firewall and virus/malware protection.

Bindex Software requires internet connection. It is vital to ensure the safety of the network environment when using Bindex Software. As a general rule connect only to secure local networks. Avoid using unsecure public networks.

In Bindex Software all patient and measurement data is stored in an encrypted format. Data exported from the program (database exports and PDF reports) is not encrypted by Bindex Software. The customer must ensure the exported data is stored in a secure manner to prevent unauthorized access.

Bindex Software does not use automated backups. Please make sure the Bindex database and measurement files (by default located in the folder C:\Program Files

\Bindex\database) as well as all other important files are backed up using e.g. Windows File History to a secure location regularly. Bone Index Finland is not responsible for any loss of data on a measurement computer.

Always follow your organization's IT guidelines and security practices. In case of questions, please contact Bindex Support and Service (see 12 Contact information).

7.5. User Management Application (UMA)

Bindex Software users are managed in a separate program, the User Management Application (UMA). UMA is installed in the Bindex main folder and is started automatically upon first startup of Bindex Software. It can later be used by double-clicking on “UMA.exe” file.

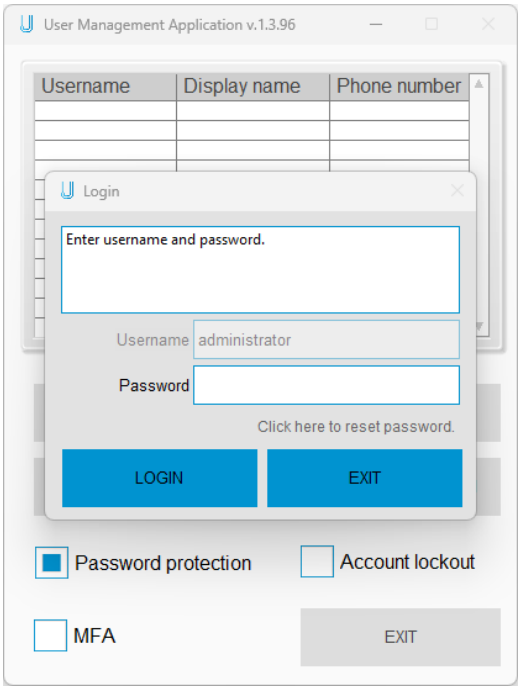


Figure 20: Only the Bindex administrator can login to the User Management Application.

Only the “administrator” account can login to UMA. The administrator can create a needed number of operator accounts for Bindex Software. At least one operator account needs to be created to access Bindex Software if password protected operator accounts are enabled, as the administrator account cannot be used in measurement software.

The first login is made using the password “changeme”. After entering the password, the administrator is required to change the password before continuing (Figure 21). The password is required by default to be at least six (6) characters in length and contain at least one uppercase and lowercase letter, a number and a special character from the following:

~ ! @ # $ % ^ & * _ - + = ' ´ ` | \ ( ) { } [ ] : ; . , " < > ? /

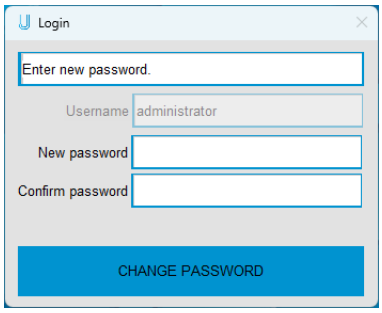


Figure 21: The administrator is required to change the password after the first login.

When logged in, the currently active users are shown in a list displaying their:

1) Username (used only for logging in to Bindex Software)
2) Display name (shown in PDF reports, e.g. full name or anonymous ID)
3) Phone number (used for multifactor authentication when logging in to Bindex Software)

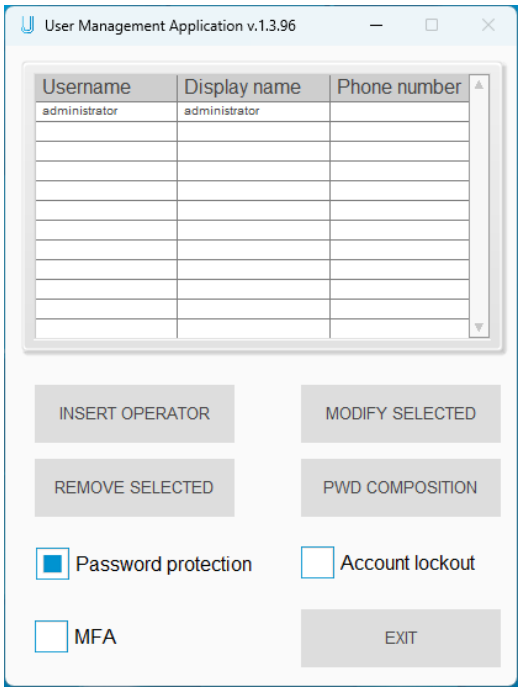


Figure 22: User Management Application main window.

When ready, click on EXIT to close UMA.

7.5.1. Password protection

Using operator accounts and password protection is on by default. The feature can be enabled or disabled by using the PASSWORD PROTECTION checkbox. When the option is disabled, any person with access to Windows and Bindex Software can conduct and view patient measurements. The automatic locking functionality is also disabled in Bindex Software. Locking of user account due multiple failed login attempts can be enabled using the ACCOUNT LOCKOUT checkbox. If enabled, user account will be locked for 15 minutes after 5 failed attempts in 5 minutes period. Multifactor authentication (MFA) can be enabled using the MFA checkbox. If enabled, a 5-digit passcode valid for 5 minutes is sent as SMS to phone number configured for the user account during login for verification. Internet connection is required during multifactor authentication.

The minimum password requirements and password ageing can be controlled from **Password composition** window (Figure 23) accessible through the PWD COMPOSITION button in UMA. *Expiration in months* option allows the administrator to enforce the users to change their password to Bindex Software every 1-24 months. When enabled, the operators are required to change their passwords upon login to Bindex Software after the selected number of months from the initialization of the current password. Password minimum length can be set between 6-64 characters. As for password composition requirements, minimum numbers of uppercase letters, numbers and special characters can be set between 0-4.

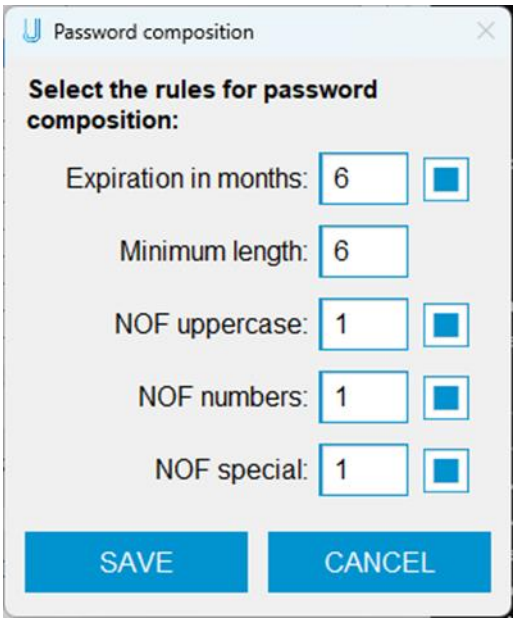


Figure 23: Password composition window.

7.5.2. Creating new operators

New operators are added to Bindex Software by clicking on INSERT OPERATOR. Enter the *Username*, initial *Password, Display name* and *Phone number* for the new operator (Figure 24). If phone number is not entered, the user will be required to enter phone number when logging in to Bindex Software with MFA enabled.

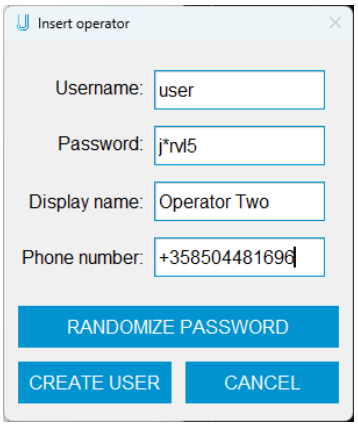


Figure 24: Creating a new operator account.

The *Password* is required to be according the minimum password requirement set by the administrator. The password can also be randomized by clicking on RANDOMIZE PASSWORD, suggesting a password according to password minimum requirements in use. The initial password must be changed by the operator after first login. The phone number must be in international format (+ followed by country code and possible area or city code).

When finished, click on CREATE USER to save the new operator to the Bindex database. Press CANCEL to stop the operator creation at any time.

7.5.3. Modifying operator details

Operator details (Password, Display name and phone number) can be edited by selecting an operator from the list and clicking on MODIFY SELECTED. The window showed in Figure 25 opens.

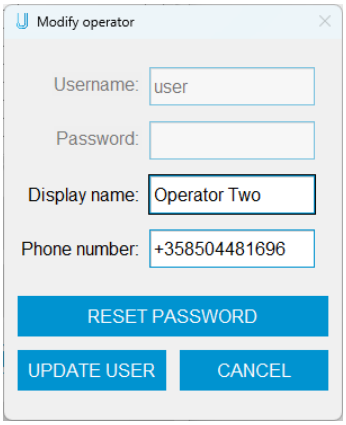


Figure 25: Modifying operator details. The administrator can change the Display name, phone number or e.g. reset a forgotten password of an operator.

Display name and *Phone number* can be edited. To modify the password (e.g. if forgotten by the operator), click on RESET PASSWORD and enter the new password. See section 7.5.2 for password strength requirements. The RANDOMIZE PASSWORD button becomes available after resetting the password. Click on UPDATE USER to save the changes. Click on CANCEL at any time to revert the changes and return to the main window.

7.5.4. Deleting operators

Operator accounts that are no longer needed can be removed from the database. After deleting them through UMA, the account holder can no longer login in Bindex Software. The operator data is still saved in previously made measurements.

To delete an operator account, select the operator from the list in the main window and click on REMOVE SELECTED. A confirmation window is displayed (Figure 26). Answer OK to confirm the deletion of the operator account. Select CANCEL to cancel the operation.

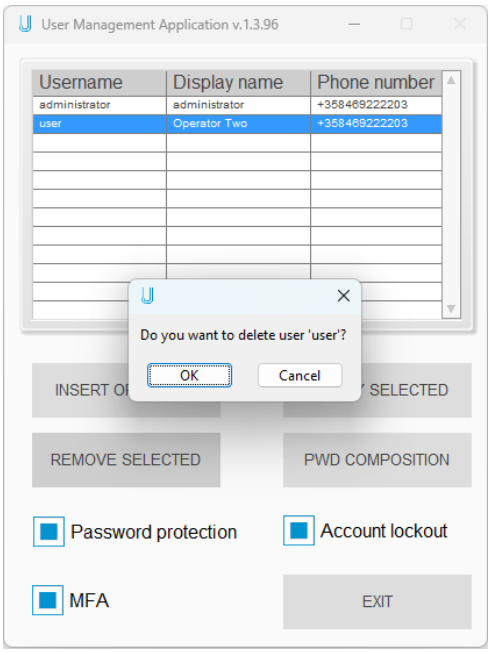


Figure 26: Confirmation for deleting an operator account.

PLEASE NOTE: After deleting an account, the username is still permanently reserved. Another operator account with the same username cannot be created.

PLEASE NOTE: The “administrator” account cannot be deleted.

7.5.5. Resetting the administrator password

If the administrator forgets the password, it can be changed by clicking on CLICK HERE TO RESET PASSWORD text in the login window (see Figure 20). A dialog

window opens, displaying a *Request Key* (Figure 27). To reset the password, follow these steps:

1) Copy the *Request Key* to an email message.
2) Send the key along with a request to change the administrator password.
3) The Reset Key will be sent by email.
4) Copy the *Reset Key* to the corresponding field in UMA and click RESET.
5) Multifactor authentication (MFA) is required, if MFA is enabled (see Figure 31).
6) The program informs about successfully resetting the password.
7) Enter the new administrator password twice and click on CHANGE PASSWORD to continue (see Figure 21).

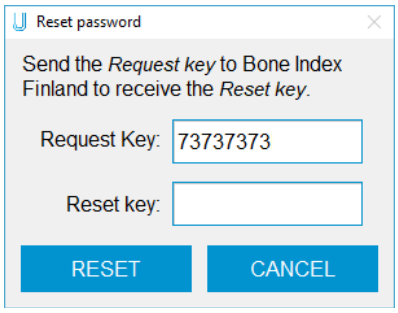


Figure 27: The dialog for resetting the administrator password.

In case of any issues with accounts or passwords, please contact Bindex Support and Service (see 12 Contact information).

7.6. Bindex device setup

After completing the software and driver installation (see 7.2 and 7.3), the device is ready to be used. Connect the Bindex device to a free USB port (type A) of your computer. To test that the device has been correctly installed:

1) Start Bindex Software and log in.
2) Click on OPEN CASE and search for “test patient”.
3) Select the test patient and click OPEN.
4) Conduct a calibration as instructed in 8.6 Bindex quality verification. If the calibration is successful, the device has been correctly installed.

Once connected to a USB port, the device is in stand-by state.
PLEASE NOTE: The ultrasound transmission is on only during a measurement in Bindex Software.

It is recommended to disconnect the Bindex when not in use to reduce the power consumption of the computer. If kept connected continuously, the Bindex device may feel slightly warm to the hand, but this is harmless. The device is not equipped with an external power switch or button.

GENERAL SAFETY HAZARD:
Do not modify this equipment without a specific authorization by the manufacturer. A modified device cannot be guaranteed to comply with the requirements of the applicable safety standards and regulations.

ELECTRICAL HAZARD:
Do not use a multiple socket outlet to connect the system to the power grid. The electrical safety of the system cannot be guaranteed for all required fault conditions if a multiple socket outlet is used.

ELECTRICAL HAZARD:
Use a IEC 62368-1:2014 compliant isolation transformer to connect the measurement computer to the power grid. (Not needed when the computer is used with a battery). The electrical safety of the system cannot be guaranteed in case a non-compliant power source is used.

8. Using Bindex

8.1. Connecting and disconnecting the Bindex device

Connect the Bindex device into the USB port of the computer before starting the pre-measurement calibration. This can be done before or after launching Bindex Software. If the device is disconnected from the computer while the software is running, the connection can be restored by reconnecting the device and pressing CALIBRATE in the **Measurement** window.

Operation can be safely terminated by shutting down the software by pressing the "X" at the upper right corner of the window and unplugging the pulser unit. If a patient case is open, a confirmation will be prompted before exiting. In case of an emergency, operation may be stopped by just unplugging the USB cord while the software is running, but data loss may occur.

ELECTRICAL HAZARD:
Do not touch the connectors of the computer and the patient at the same time. Touching the connectors of the system results in potential electrical safety hazard. Where possible, the computer should be kept away from the patient area.

8.2. Basics of Bindex Software

PLEASE NOTE: Bindex Software cannot be used with a Windows Guest account. Please use a Standard User or Administrator account.

Bindex Software is started by double-clicking on “Bindex.exe”, the Bindex shortcut created on the Desktop or by selecting “Bindex” in the Windows Start Menu.

Depending on the password protection setting in User Management Application (UMA), the login will be made as described in 8.2.1 or 8.2.2.

8.2.1. Logging in with password protection enabled

If password protection is enabled in UMA, at least one user must be created before logging in to Bindex Software is possible. The “administrator” user cannot be used for logging in.

At startup, a login screen will be displayed, asking for the *Username* and *Password* (Figure 28). Enter the username and password to their respective fields and click on LOGIN. If Multifactor authentication (MFA) is enabled in UMA, verification using 5-digit passcode sent as SMS to phone number configured for the user account is required (Figure 31). Passcode is valid for 5 minutes and can be resent if required. If phone number for the user account has not been configured, the user is required to enter phone number to be used for MFA (Figure 30). Internet connection is required during multifactor authentication. The operator is asked to change their password at first login (Figure 29). Enter the new password two times and press CHANGE to move on to the front page of Bindex Software.

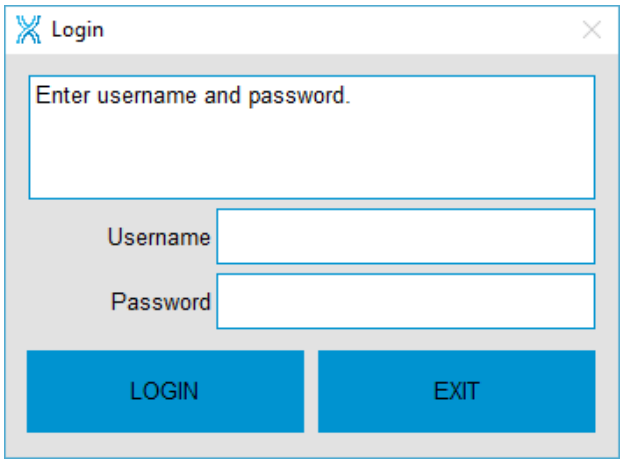


Figure 28: The Login window of Bindex Software, when password protection is enabled.

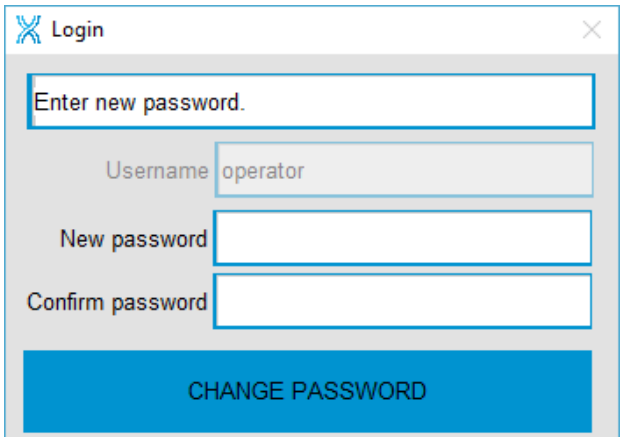


Figure 29: At first login, the user is required to change the password.

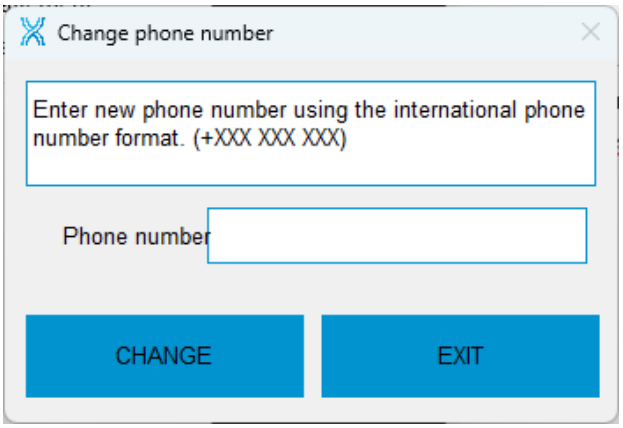


Figure 30: User is required to enter phone number to use MFA, if phone number has not been configured.

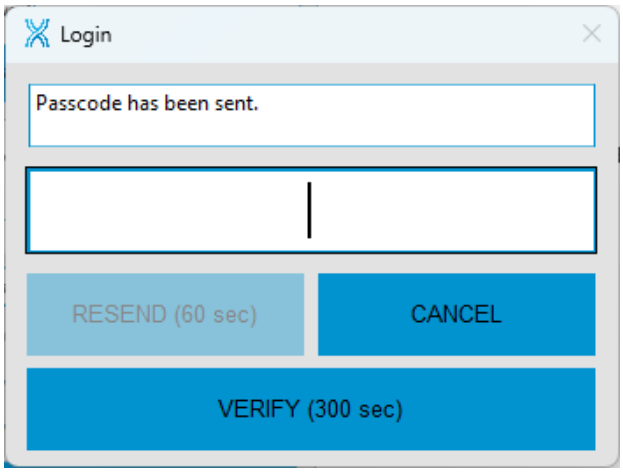


Figure 31: Multifactor authentication (MFA) using passcode is required, when MFA is enabled.

8.2.2. Logging in with password protection disabled

If password protection has been disabled in UMA, at startup the software asks for the operator name (Figure 32) or alternately uses a name defined in your settings (see 8.2.3.3 Settings). Enter the operator name to use and click on LOGIN to move on to the front page of Bindex Software.

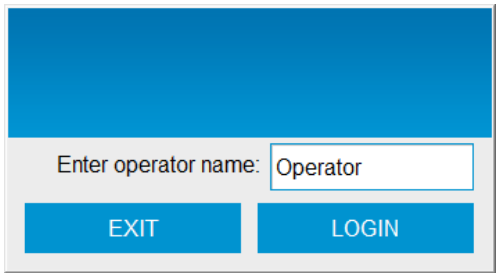


Figure 32: The Login view, when password protection is disabled. Press the LOGIN button to set the operator name and continue to the front page of the program.

8.2.3. Front page and functions

There are four buttons on the front page (Figure 33): NEW CASE, OPEN CASE, SETTINGS and ABOUT.

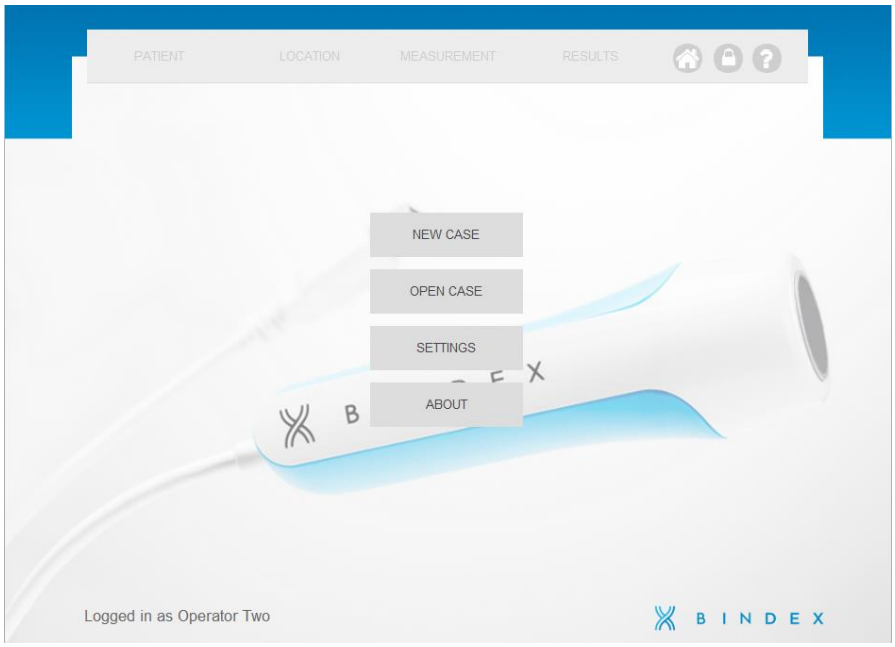


Figure 33: Front page of Bindex® software. You can always get back to this page by pressing the HOME button in the upper right corner.

When a patient case is open, the tabs **Patient**, **Location**, **Measurement**, and **Results** on the upper bar can be used to quickly navigate between measurement-related data. When no case is open, the **Patient** tab can be clicked for creating a new patient case.

Click on the HOME (symbol) button to return to the front page at any time.

The "?" (symbol) button opens the User Manual in a PDF reader in the language chosen in **Settings**. If there is no translation for the selected language, the English version is shown.

The LOCK (symbol) button is visible when password protection has been enabled in UMA. Pressing the button at any time locks Bindex Software and prevents its use until the current user logs in again or EXIT is pressed (Figure 34).

Bindex Software locks the program automatically after being idle for 30 minutes. The automatic locking is opened similarly to the manual locking (user logs in again or exits the program).

PLEASE NOTE: Exiting Bindex Software when the program is locked causes all unsaved data to be lost!

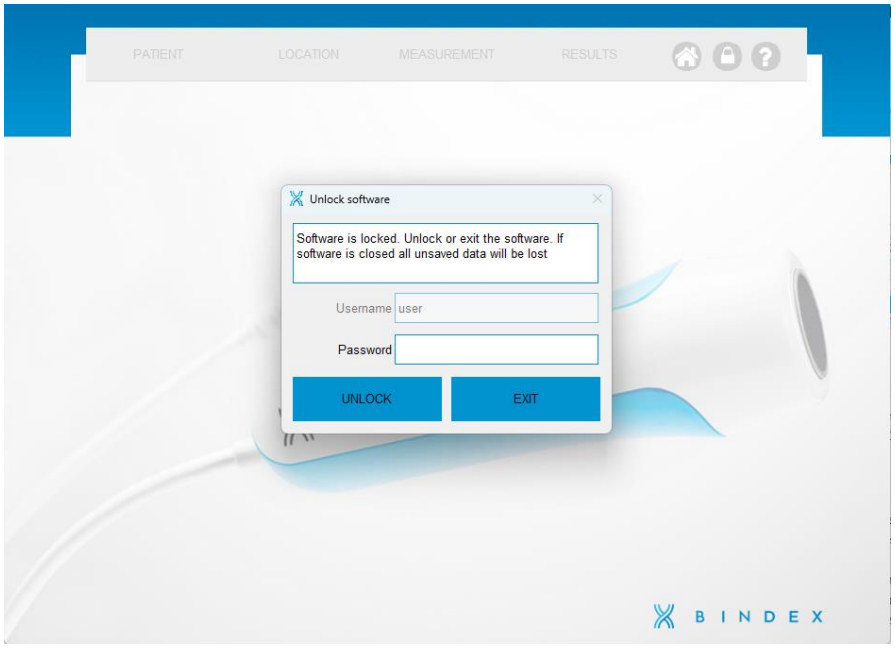


Figure 34: After 30 minutes of inactivity Bindex Software is locked. The program can also be locked at any time by pressing the LOCK (symbol) button.

8.2.3.1. New case

Press NEW CASE to start a measurement with a new patient (see 8.3 Patient information). To start measurement, you must have PPAs remaining, and depending on licensing model in use, internet connection may also be required. If you have a previous case open with unsaved data, you will be asked a confirmation to proceed (Figure 35). Selecting OK starts a new empty patient case but all unsaved data from the current measurement is lost.

If the patient's data has been saved previously, please use the OPEN CASE for a new measurement.

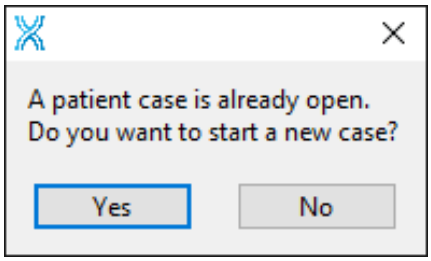


Figure 35: The software asks a confirmation before starting a new case over an existing case.

8.2.3.2. Open case

Use the OPEN CASE page (Figure 36) to:

1) Add another measurement to a previously measured patient.
2) View the results of a measured patient or make corrections to their details.
3) Delete patients or measurements.
4) View all the measurements of a single patient in timeline view.

A patient can be searched by typing the first or last name or patient ID on the *Search term*. Separate the used search terms (up to three) with spaces. Bindex Software automatically suggests patients starting with the letter or phrase typed in this field.

The patient list columns (last name, first name, PID) can be sorted in ascending order by double-clicking on the title. After selecting a column for sorting, the title appears as bolded.

Select a patient and press OPEN to start a new measurement and continue to the **Patient** page which shows the selected patient's previously saved details. You can also double-click on the patient list to start a new measurement for the selected patient.

To view previous results, select a name and measurement from the lists and press the RESULTS button. The **Results** sheet of the previous measurement opens. You can also double-click on the result list to view the results for the selected measurement.

Select TIMELINE to see all results of the selected patient in a timeline view if the patient has been measured more than once. The timeline can also be exported as a PDF file.

The DELETE button can be used to delete either the selected patient or the selected measurement (Figure 37). Select MEASUREMENT to delete only the selected measurement from the selected patient. Select PATIENT to delete the entire patient file including all the measurements.

The patient and measurement data can be exported to a text file by clicking on EXPORT DB. The exported content can be limited by filtering the patients by date of birth or measurement date. Press EXPORT ALL to export all measurement information currently saved in the database.

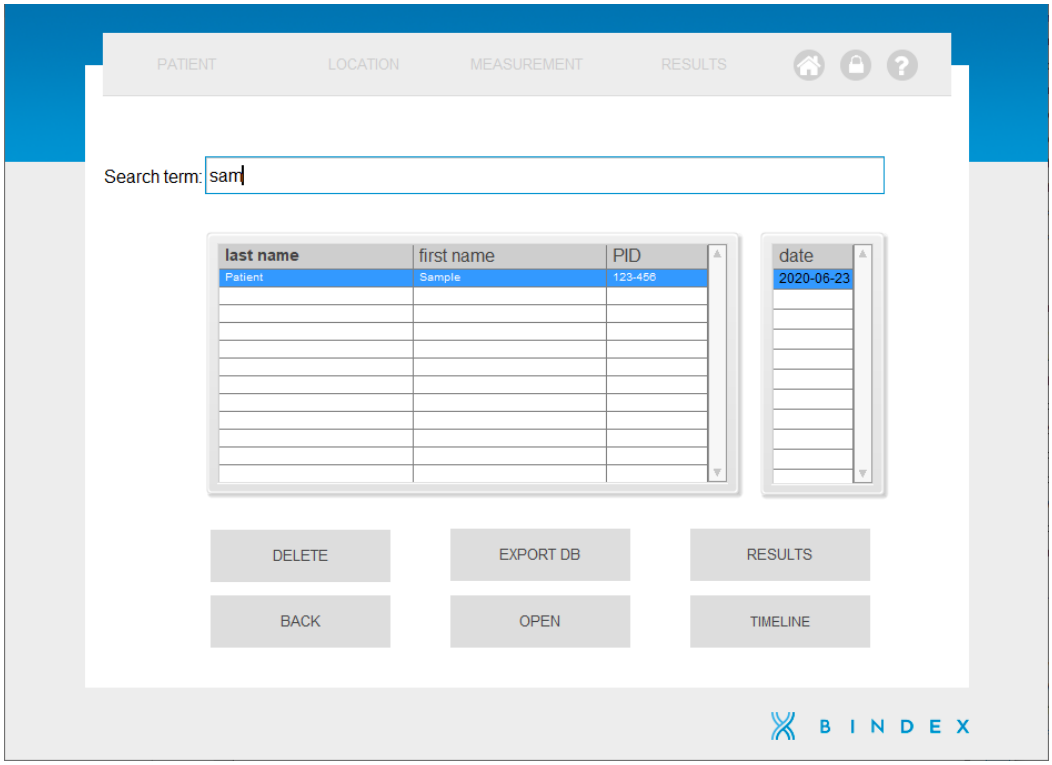


Figure 36: Open case view. By using the BACK button you will continue to front page of the software.

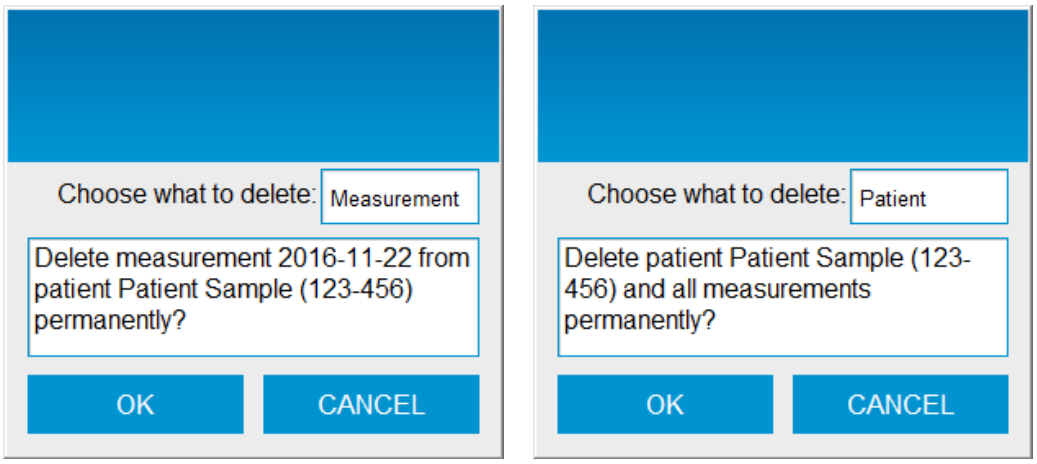


Figure 37: Delete a patient or measurement from the database.

8.2.3.3. Settings

By pressing the SETTINGS button, the operator naming method, software language and company information (contact details and logo) can be changed (Figure 38).

Click on the white box under COMPANY LOGO to select the image file to use. The supported image formats are JPG, BMP and PNG. The image is automatically fitted to the measurement report. Best quality is achieved with a square-shaped image (side ratio 1:1).

For decentralized licensing model only, the numbers of available and used PPAs, and days until connection to the license server is required are shown at the bottom of the page in the info bar.

The computer name can be changed by typing maximum of 64 characters long name in the computer name text field, when connected to the internet. A confirmation message will be displayed after making changes. The computer name is used for identifying the computer by Bone Index Finland.

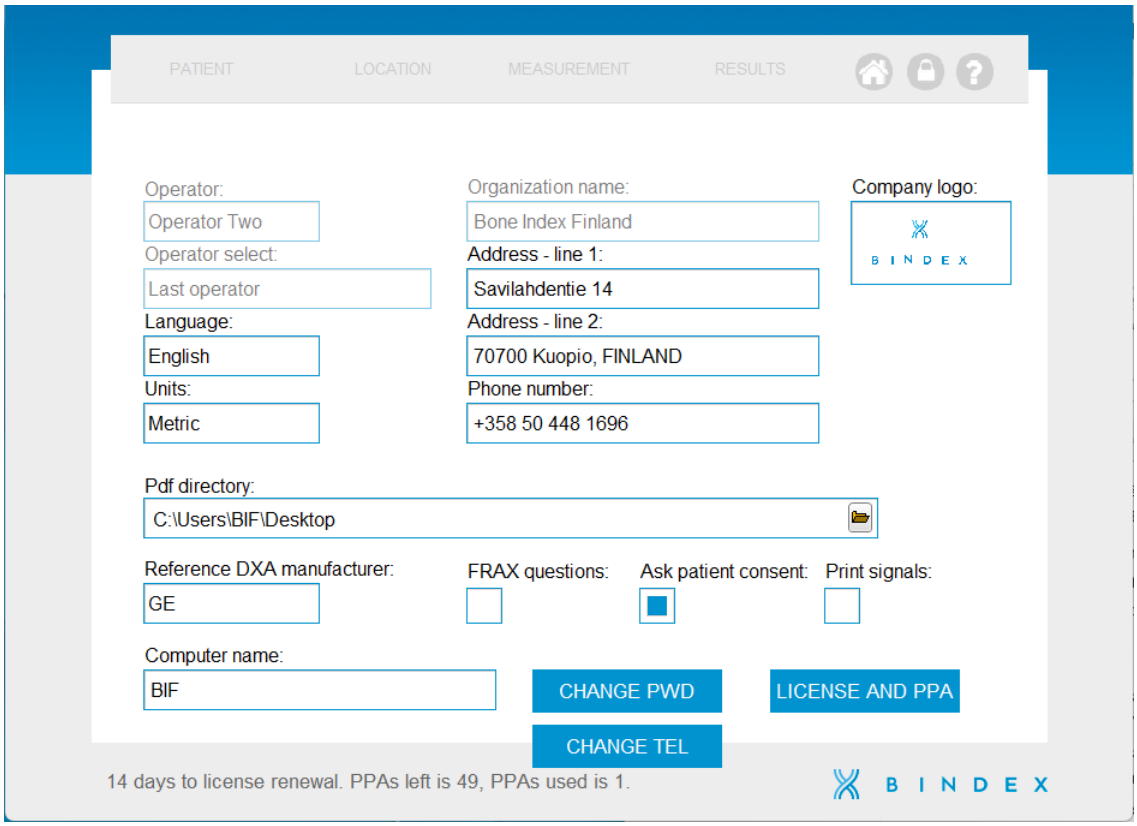


Figure 38: Change settings view. Language, operator and company settings and the default directory for saving the PDF reports can be changed.

When password protection is on, *Operator* and OPERATOR SELECT options are disabled. In this case the operator can be changed by closing the program and logging in with another user's details.

If password protection is disabled in the UMA, the operator name and the default operator name preset is selected (OPERATOR SELECT) can be changed.

1) LAST OPERATOR: the operator name is asked at startup, but the name of last operator is suggested.
2) WINDOWS LOGON NAME: software opens without asking the name of the operator. The Windows logon name is used.
3) LOCKED: software opens without asking the name of the operator. The last saved operator name is used.

The language of the software interface can be chosen in the **Settings** page. The measurement units (Metric, Imperial or U.S.) to be used with patient information can also be chosen.

The default location for saving the PDF reports can be set by using the PDF DIRECTORY control. The saving location can still be set separately for each report.

You can select which manufacturer's DXA device values to use as reference for calculating the BMD approximation by selecting a manufacturer from the drop-down menu REFERENCE DXA MANUFACTURER. This will slightly modify the BMD thresholds in accordance with the manufacturer in question.

When FRAX QUESTIONS option has been enabled, a FRAX questionnaire will be shown after the patient info has been entered (see 8.3 Patient information) When the selection is disabled, only the basic information of the patient is entered before measuring.

The ASK PATIENT CONSENT option adds a checkbox to the **Patient** tab, when enabled. The checkbox needs to be ticked before saving any patient information to the database. The checkbox acts as a reminder if local legislation or regulations require certain information to be provided to or permissions acquired from the patient before saving their personal information to the system.

The PRINT SIGNALS option allows the operator to include the measurement signals as images to the measurement PDF report. When enabled, the signals from the five repetitions are added to the report. The signal peak locations can also be seen in the images. When disabled, the signals and the peak locations can still be viewed in the Results tab of Bindex Software using the VIEW SIGNALS button.

CHANGE PWD button is visible, if password protection is enabled in UMA. Click on the button to open a dialog (see Figure 39). Enter the previous password once and the new password two times. Click on CHANGE to change the password. Please see section 7.5.2 for password strength requirements. A confirmation message is shown when successful.

CHANGE TEL button can be clicked to open a dialog (see Figure 40) for changing

the phone number of the operator related to multifactor authentication. Click on CHANGE to change the phone number. Phone number change must be confirmed by entering passcode sent to the new phone number (Figure 41).

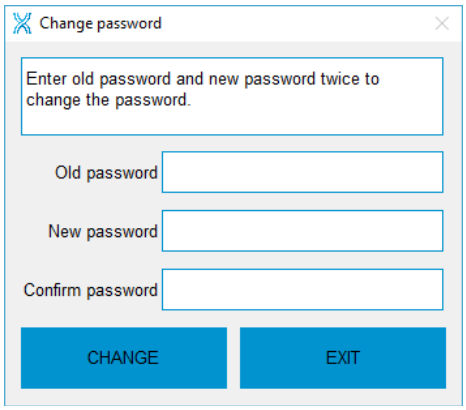


Figure 39: Changing the operator password. Enter the previous password once and the new password twice, then click on CHANGE.

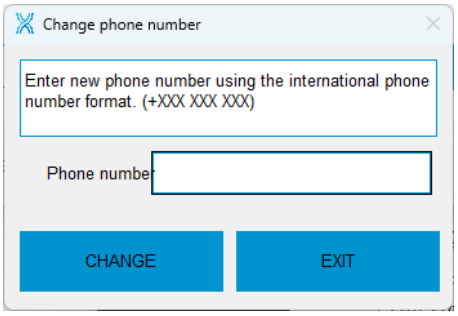


Figure 40: Changing the operator phone number. Enter the new phone number, then click on CHANGE.

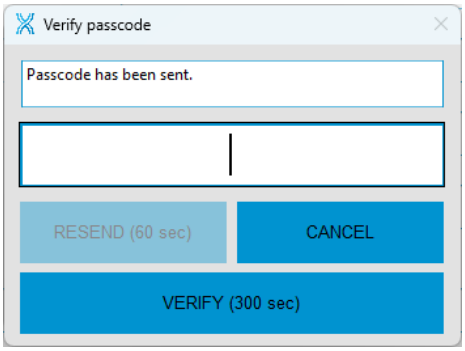


Figure 41: Confirmation using passcode is required after changing phone number.

The LICENSE AND PPA button opens the **License Management** window (Figure 14), from where it is possible to deactivate the software activation for transferring to other computer, and for decentralized license model only, it is possible to update license details and retrieve PPA packets from the license server, and post-pone the requirement for connecting to the license server without restarting the software. Please see 7.4.3 Transfer of activation and 7.4.2 Ordering additional analyses for more information

8.2.3.4. About

The ABOUT button will open the Bone Index Finland Ltd. web site (https://www.bindex.fi) in your default browser.

8.3. Patient information

On the **Patient** page (Figure 42), the name, ID, date of birth (DOB), sex, weight and height of the patient are entered. In addition, a comment field is located at the bottom of the page for entering any information that should be included in the results printout (e.g. risk factors for osteoporosis). The SAVE button saves the patient info to the database for later use. The NEXT button will lead to the next page (**Location**). Before saving or continuing, the "Consent obtained" checkbox needs to be ticked, if it has been enabled in the **Settings** (see 8.2.3.3 Settings).

If an existing case has been opened and patient information is changed, you will be asked (Figure 43) whether you want to update the data or discard the changes.

If you try to save or continue to the next page before you have filled patient information you will be notified to do this (Figure 44).

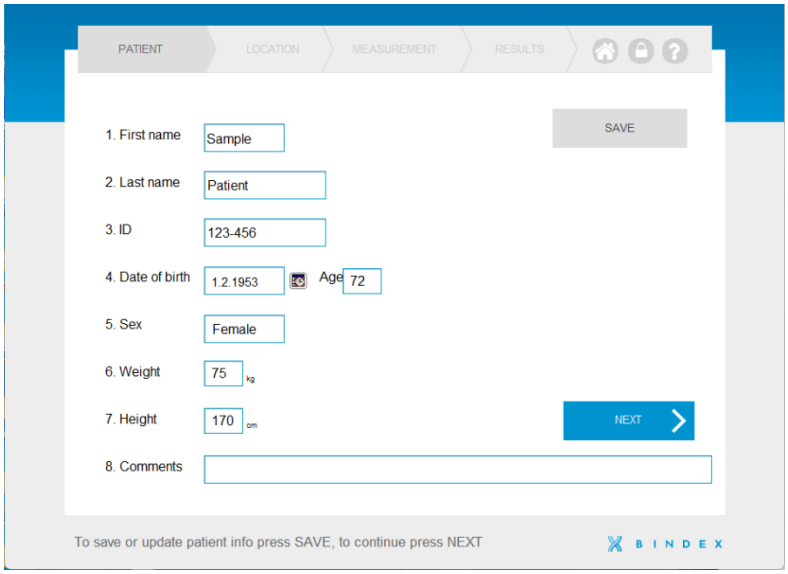


Figure 42: The Patient page. All information must be entered before you can continue by using the NEXT button. By saving the patient info you can find the info from OPEN CASE later.

PLEASE NOTE: The weight and height of the patient should be measured if possible! This way you will get the most reliable measurement result.

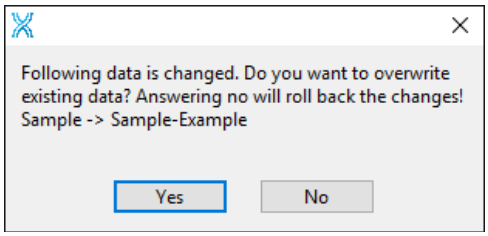


Figure 43: Software asks confirmation before writing over existing data.

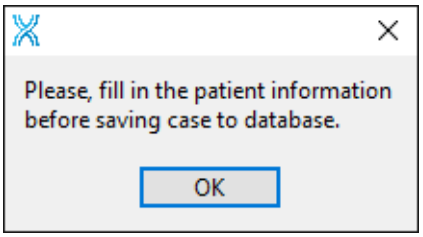


Figure 44: You will be asked to fill the necessary patient information before continuing to the measurement.

If enabled in Settings, the FRAX questionnaire will be shown after clicking NEXT in the Patient page (Figure 45). This questionnaire can be used to save the information of the (online) FRAX test. The information is also printed in the PDF report.

Bindex Software DOES NOT conduct the actual FRAX analysis or give out the recommendation but can only be used to save the input info and results.

The data entered in the FRAX questionnaire DOES NOT affect the Density Index calculation.

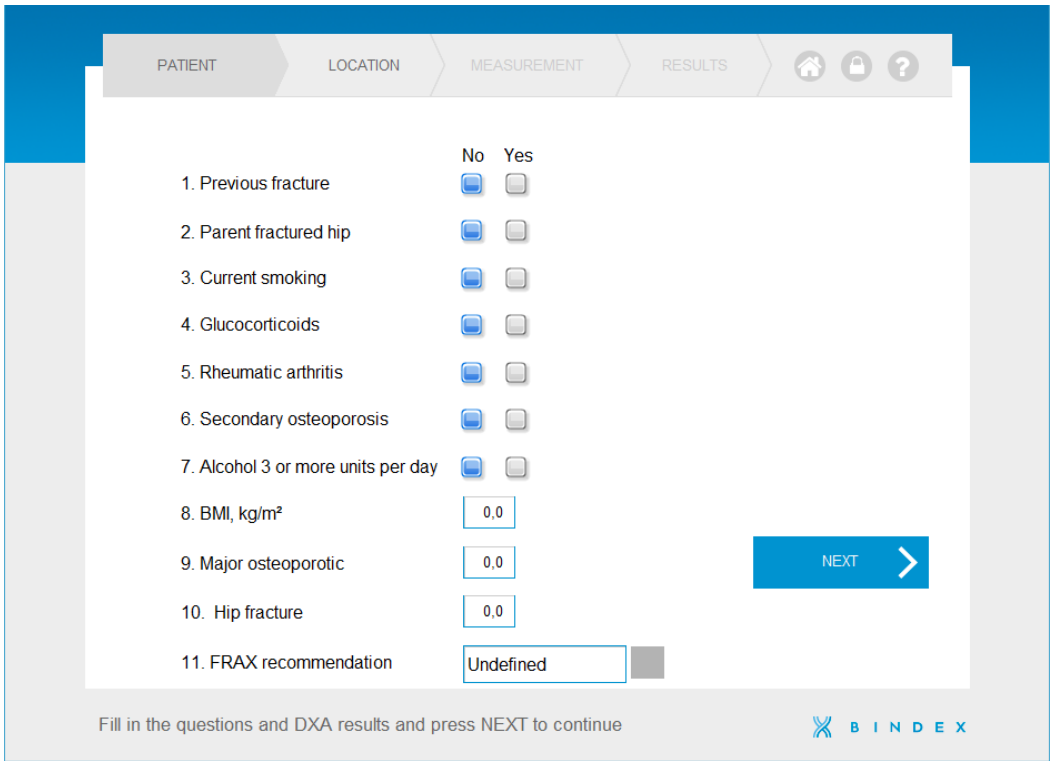


Figure 45: If enabled in settings, the FRAX questionnaire can be filled in after the basic information of the patient has been entered.

8.4. Patient positioning

For the duration of the measurement, the patient should be lying on e.g. a bed. Alternatively, the patient may be sitting and the examined leg is straightened and supported with e.g. a chair. Find a comfortable position for yourself and the patient (Figure 46). Clothing must be removed below the knee up to over the ankle.

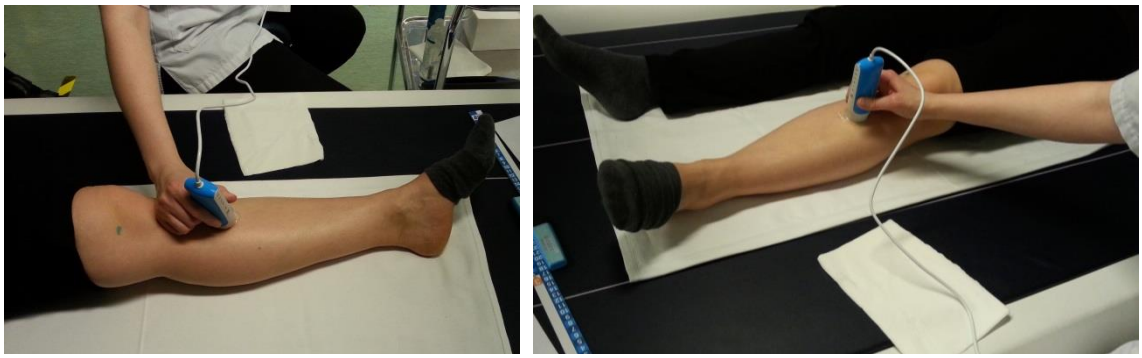


Figure 46: Patient positioning on a bed. Remember to keep an ergonomic position when you are measuring.

8.5. Measurement site location

By default, the measurement is conducted on the left tibia. When selecting the measurement location, remember that the Bindex measurement is contraindicated for locations with:

- broken or irritated skin;
- a fractured bone;
- implants, plates or fixations.

In case of contraindications on only the left tibia, conduct the measurement on the right tibia.

To determine the right measurement location, use the Bindex Measure. Before using the Measure you need to locate the upper head of tibial bone (the knee joint) (Figure 47). It may be helpful to move the patient's leg while palpating the knee joint. When you have located the knee joint, mark it on the skin.

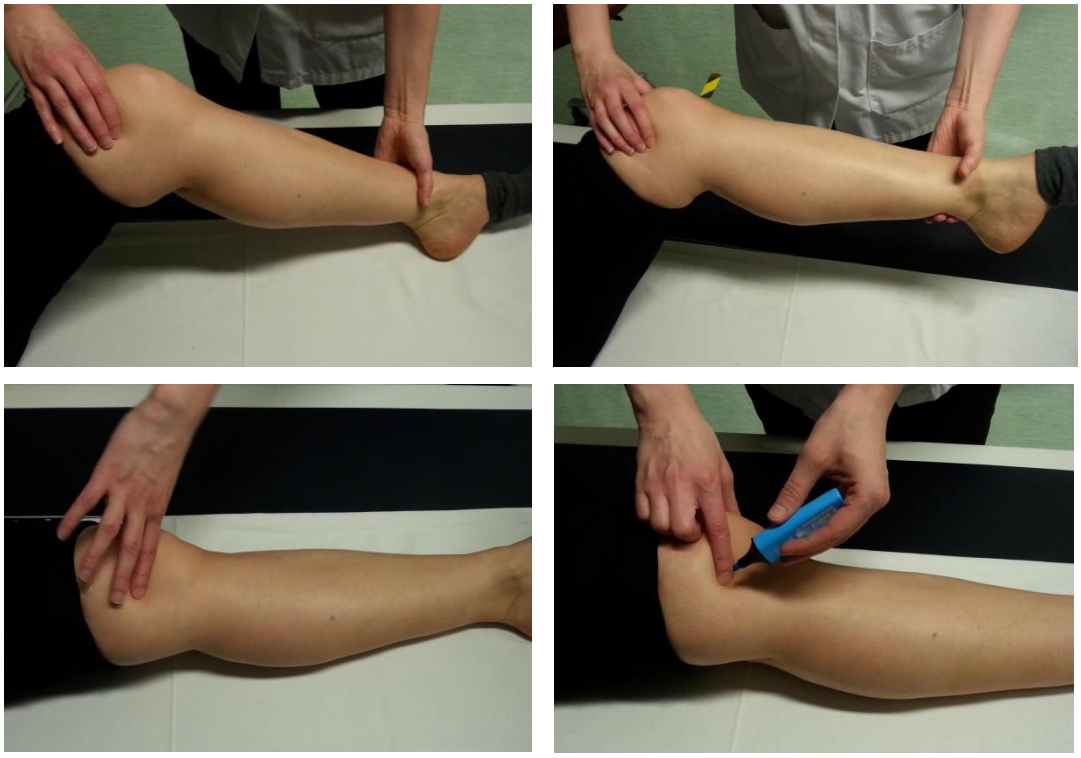


Figure 47: Locating and marking the knee joint. First you must locate the upper head of the tibia or the knee joint.

Put the arrowhead of Bindex Measure on the distal head of tibia (on the medial

malleolus, see Figure 48). Check the number on the scale 1 (or A) at the mark on the knee joint (e.g. number 12 in the Figure 49). After this, find the same number on the scale 3 (or C) (mark this number as in Figure 49). This is the measurement site.

This site is 1/3 of the length of the tibia from the upper head (Figure 49 and Figure 50). Please enter this number to in the **Location** page of Bindex Software (Figure 51). After this click on the NEXT button to continue.

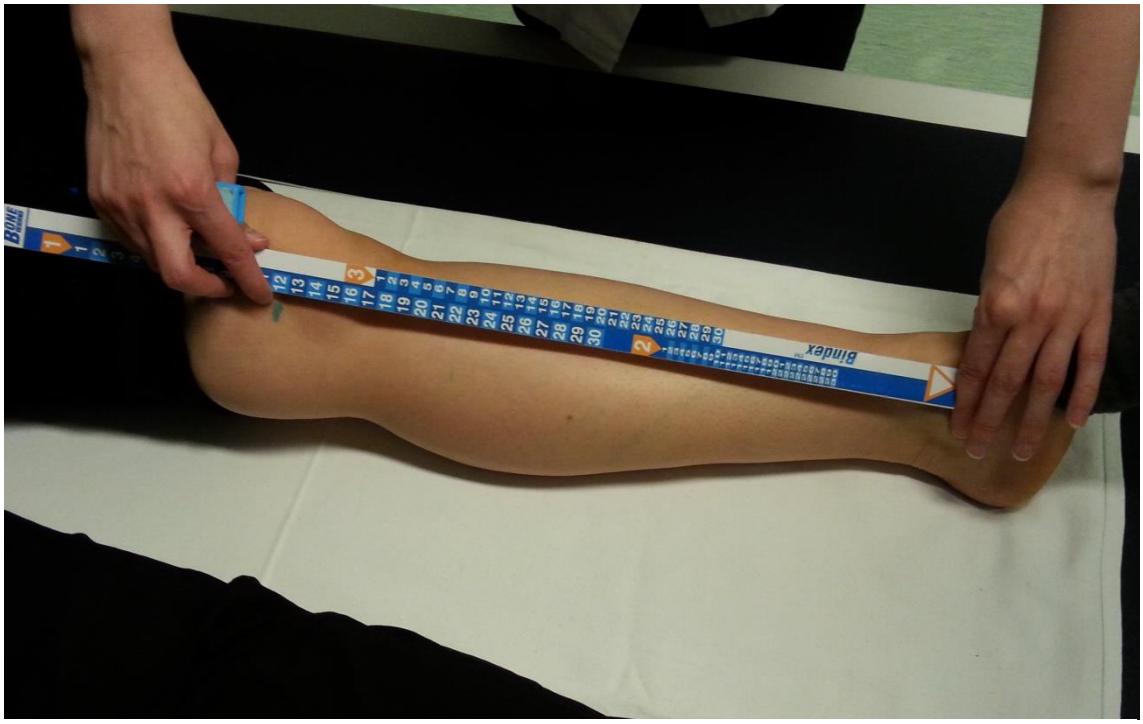


Figure 48: Locating the distal head of tibia. The arrowhead of the stick is located on the medial malleolus. After this, check the number on the Bindex Measure at the mark at the knee joint.

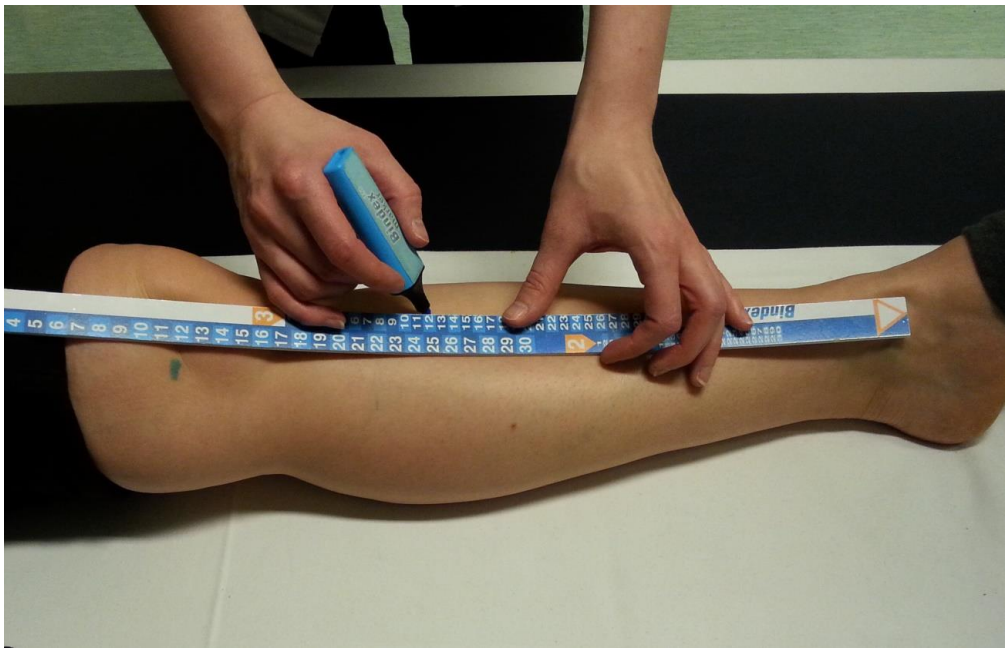


Figure 49: Locating the measurement location. The right measurement location can be found at the same number on scale 3 (or C), e.g. number 12 in this picture.

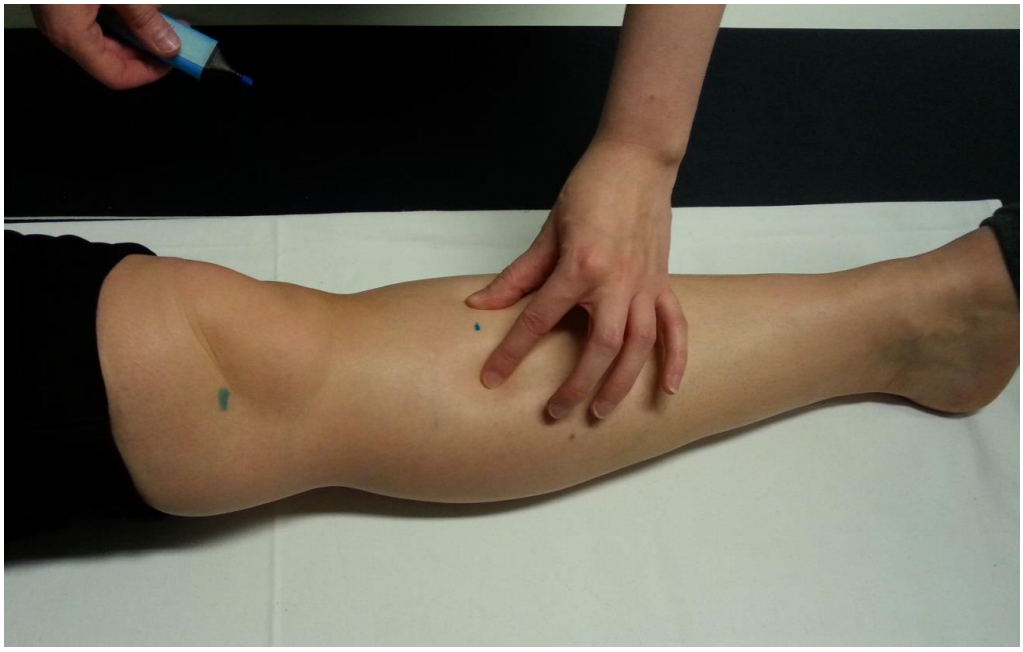


Figure 50: The tibia typically has a plate-like cortical surface at this site. The measurement should be made at the center of cortical bone plate.

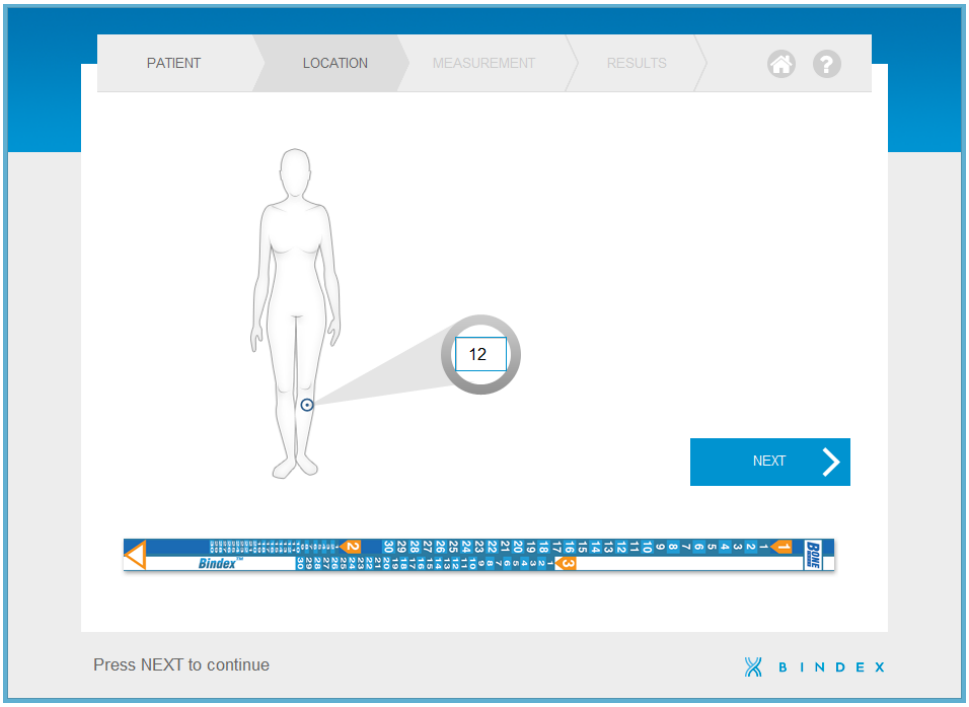


Figure 51: Enter the measurement location number from the Bindex Measure in the Location tab.

8.6. Bindex quality verification

Every time, the first thing to do on the measurement page is the quality verification check with Bindex. In the calibration the echo from the surface of the transducer is analyzed in order to verify that your Bindex is working properly.

Let the transducer head be freely in air (Figure 52) and press the CALIBRATE button (Figure 53). Make sure that the head of transducer is clean and there is no gel on it. The Bindex software shows a message if the calibration was not successful (Figure 54).

If the calibration fails, please check that the probe surface is clean and that the probe is properly connected to the computer before trying again. If the device has been kept in a hot or cold environment, the device may need to settle closer to room temperature (operating temperature 15-40°C) before the calibration succeeds. If the calibration fails consistently, please contact your local distributor or Bindex Support and Service for assistance (see section 12 Contact information).

Figure 52: The transducer head should be freely in air when you press the CALIBRATE button.

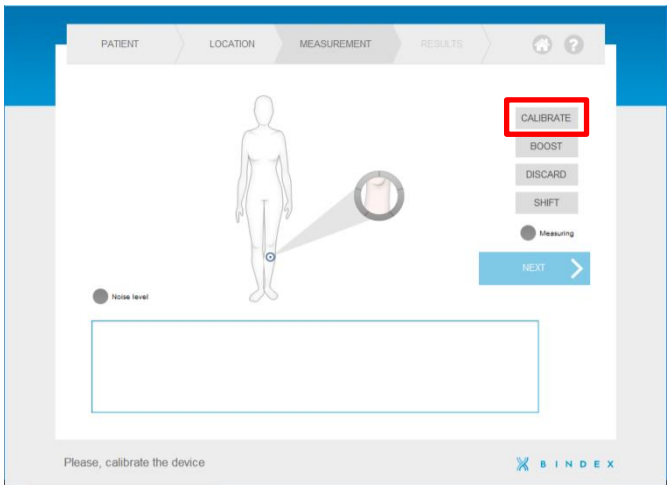


Figure 53: The CALIBRATE button. The button for calibration is located at the upper right corner. Measurement cannot be started before a successful calibration.

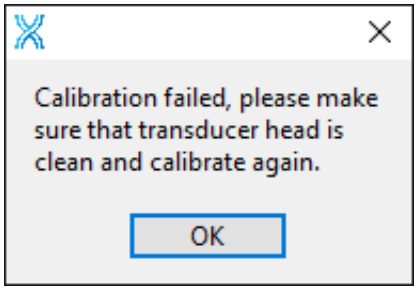


Figure 54: A failed calibration. Software notifies the user if the calibration was not successful.

8.7. Measurement with Bindex

To begin the measurement, first apply ultrasound gel on the skin over the measurement location. Turn on the measurement by pressing the circle button on the center of measurement page (Figure 55). The green segment on the circle lights and circular measure light turns to green under the buttons. Place the transducer on the skin beside the measurement location and move it slowly over your mark on the skin (Figure 55). When you clearly see two echo spikes in the signal window, you are at the right site. You may need to adjust the angle of the transducer to maximize the reflections.

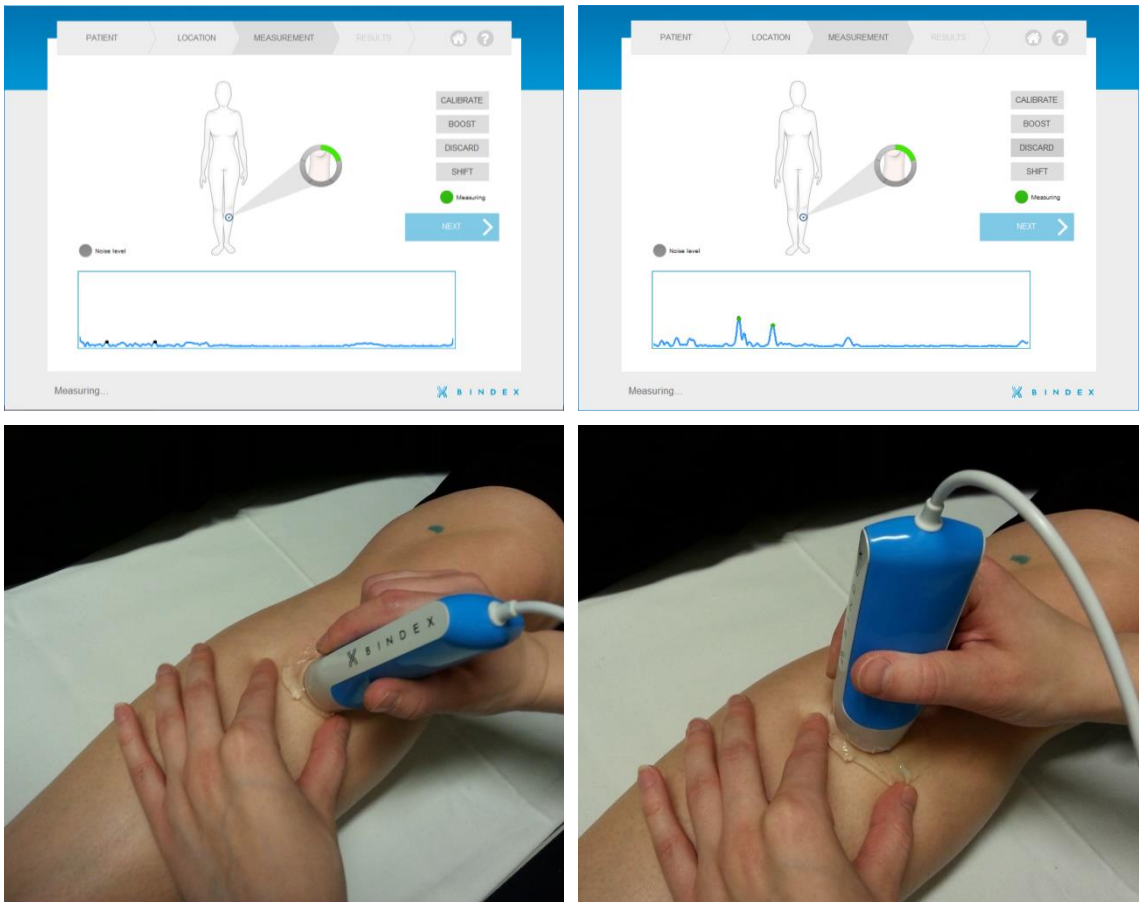


Figure 55: Conducting the measurement. First put the transducer next to bone and then move it over the bone. Keep an eye on the ultrasound signal on the signal window. When you see two echo spikes in the signal you are at the right location.

The software accepts the measurement automatically when the echoes are strong enough. The echo is strong enough when the dot marker on the echo peak turns from black to green. **Please note that observing the shape of the signal is also very important for a successful measurement!** For more information about signal acceptance please see 8.8 Signal Acceptance Window.

When a measurement is accepted an audio signal is played and the measurement stops for a short time (the signal is green at this time, the last accepted signal is shown). The transducer should be lifted off from the skin and the operator can proceed to make the next measurement similarly as explained above. If the signal is too noisy the indicator ”Noise level” is lit on the left side of the screen. Adjust the transducer location or angle to reduce the noise.

The circular measurement button has five segments which will light green upon a successful measurement. When five measurements are accepted the green circle is complete, the measurement stops and the user is directed to the **Signal Acceptance Window**. Information on accepting and discarding measured signals can be found in 8.8 Signal Acceptance Window

PLEASE NOTE: If the echo spikes are too weak for acceptance you can add gain to the signal by using the BOOST function.

The measured signal can be amplified by pressing the on-screen BOOST button or Spacebar on the keyboard of your computer (Figure 56). Additional boost is removed when the measurement is restarted. Press the measurement circle again to start measuring again without boost. The Boost functionality should only be used if the signal peaks can be located reliably, but the amplitude is not high enough for acceptance.

ELECTRICAL HAZARD:
Do not touch the connectors of the computer and the patient at the same time. The patient must be separated from the measurement computer connectors to preserve the electrical safety of the system.

INCORRECT USE HAZARD:
Do not use the BOOST function before detecting and attempting to capture the echo spikes! Adding amplification before setting the transducer to the correct location may cause incorrect reflections to be accepted upon conducting the measurement.

INCORRECT USE HAZARD:
Overusing the BOOST function may cause incorrect reflections or noise to be interpreted as the echoes from the bone surface. Only add amplification if the measurement location can be confirmed to be correct.

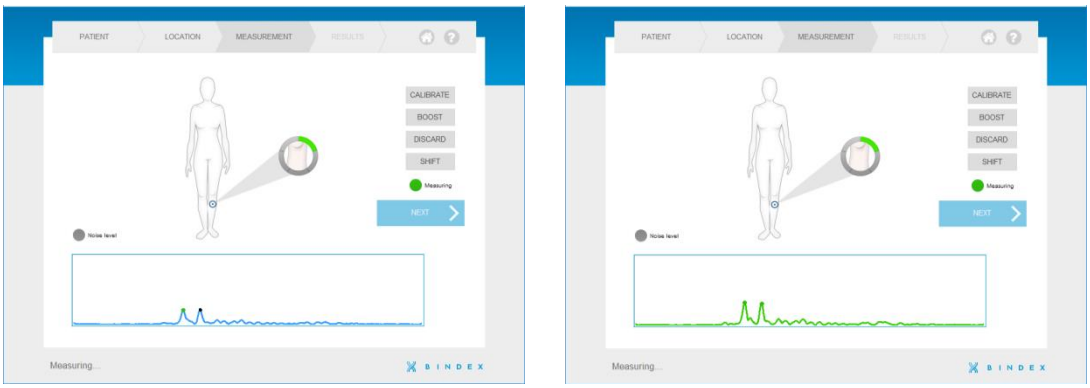


Figure 56: The use of the BOOST button. Measurement signal before (left) and after (right) boost effect.

If the software accepts a signal which is too noisy (Figure 57) e.g. due to excessive amplification, you can delete the measurement by pressing the DISCARD button. The last accepted measurement is removed. Signals can also be discarded from the **Signal Acceptance Window**, as described in the next section. You can see the accepted signals later in the Results page by pressing VIEW SIGNALS (Figure 62).

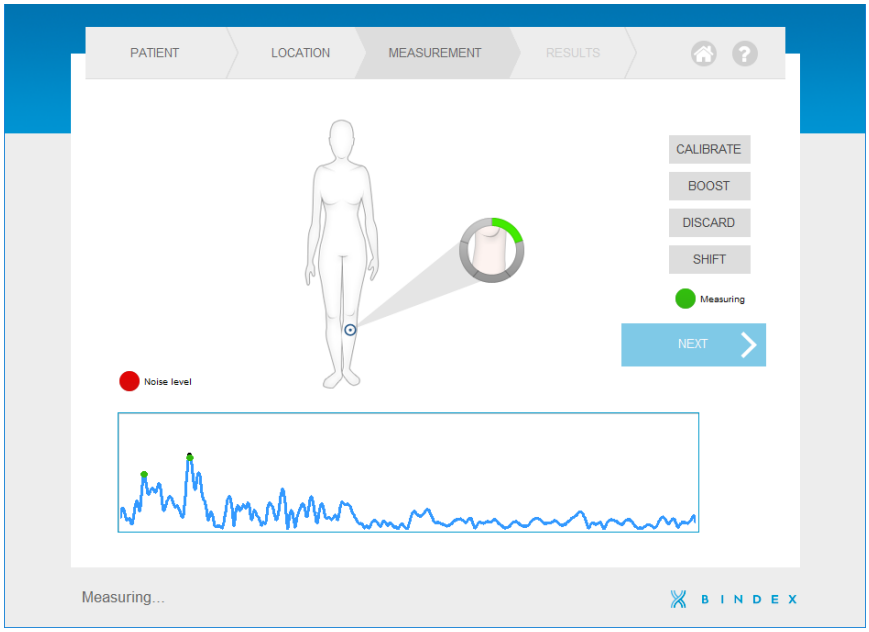


Figure 57: A noisy signal. If too much amplification is used, you may see a very noisy signal with multiple strong echo spikes. An acceptable measurement only includes two strong spikes.

Sometimes plenty of soft tissue or swelling at the measured limb may cause the

echo peaks to be cropped out of the default signal window. By clicking on the on-screen SHIFT button the signal window is set to show a later time frame, i.e. echoes deeper from the tissue can be viewed. To the operator this appears as the signal plot being moved towards the left side of the window. The SHIFT button turns blue when activated.

8.8. Signal Acceptance Window

After the five measurements on a site the accepted signals from each repetition are shown in separate signal boxes (Figure 58). This enables you to monitor the quality of measurements and to remove faulty or inaccurate measurements from the series.

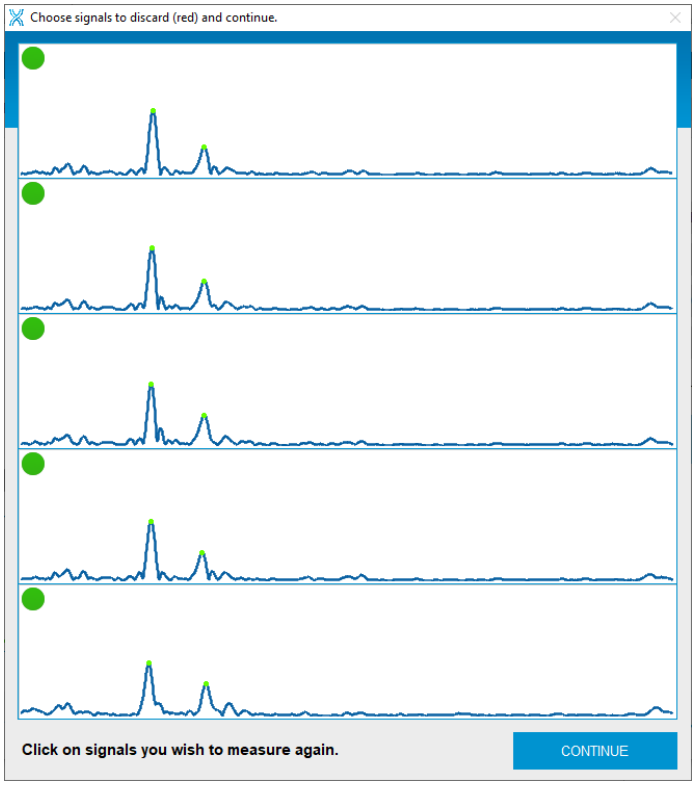


Figure 58: Window for accepting or discarding the measured signals. In this example the measurements are uniform and are therefore all accepted.

Signals that deviate significantly from the average of all measurements are marked with a red indicator at the top left corner of each signal box (Figure 59). A green indicator is shown at the upper left corner of the signal window if the signal is close to the average. The signals marked with a red indicator at the upper left corner are removed from the measurement series. If any signals are removed, software will return to the Measurement window.

The signal peaks used for thickness measurement are marked with green indicators.

You may select any number of signals to be discarded or accepted, even the deviating signals automatically marked by the software. The status of the signal box can be changed between discarded/accepted by clicking on the signal window. The color of the indicator changes along with the status of the signal. Examples of discarded signals and their possible causes are given in Figure 60 and Figure 61.

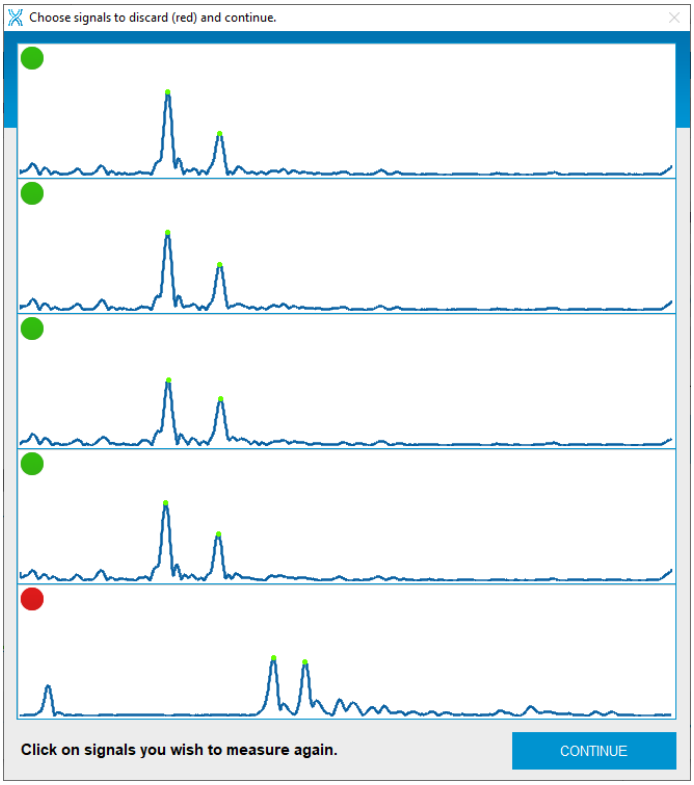


Figure 59: A signal deviating from the average. In this figure the bottom signal deviates significantly from the average of all measurements and is therefore suggested to be discarded by the software.

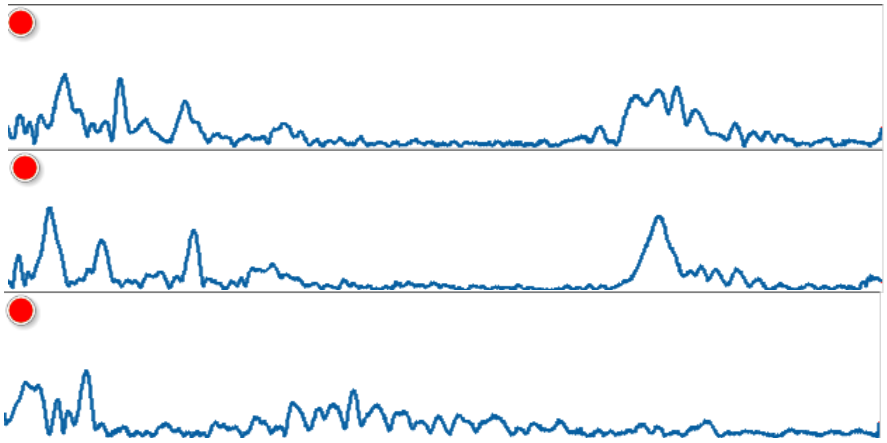


Figure 60: Excessive amplification. All signals shown in this figure should be discarded because they show too much noise and multiple high peaks due to the excessive use of the BOOST button.

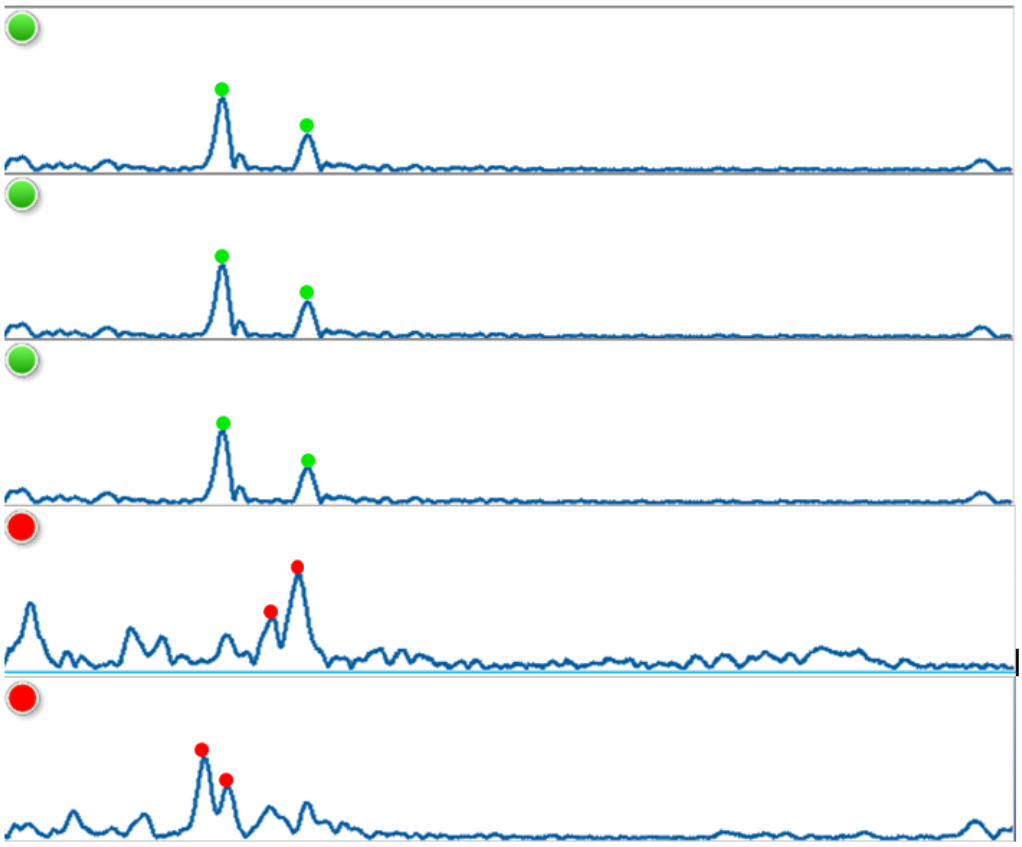


Figure 61: Incorrectly positioned probe. The lower signals marked as red deviate significantly from the average because the probe has been in a tilted position in comparison to the measurement location. The amount of noise generated in the signals is also high. The signal peaks accepted by the software have been marked to the figure with dots.

If one or more measurements are selected to be discarded, new measurements need

to be made to replace the removed ones. In this case, after pressing CONTINUE the user will be guided back to the **Measurement** page. New measurements can be made after pressing the measurement circle. New calibration of the Bindex device is not required after returning from the signal selection window. When all five repetitions are accepted, the user is guided directly to the **Results** page. Depending on the license model in use, internet connection may be required before the user is guided to the **Results** page.

It is important to check the uniformity of the measured signals always before accepting them. The most important factors to monitor in the signal acceptance window are:
1) the distance between the signal peaks
2) the location of the signal peaks
3) the shape of the signal.

If any of these factors deviates significantly from the others in one or two measurements, the deviating signals should be removed from the measurement series and new measurements should be conducted. At least three signals should be similar to each other. Otherwise, the series should be re-measured (turn all status indicators red and press CONTINUE).

8.9. Interpretation of the Bindex results

On the results page you will find the Density Index value which is an estimation of total hip bone mineral density measured with DXA (Figure 62). The value is also presented as a marker (blue arrow) on a three-color scale (green, yellow and red). The marker on the green zone indicates a “Low Probability of Osteoporosis”. The marker on the red zone indicates a “High Probability of Osteoporosis”. If the marker is in the yellow zone, the patient needs additional investigation for the determination of osteoporosis status.

If the marker is off the visible scale (under 0.6 or over 1.2 g/cm^2), a notification is displayed. The user is prompted to check the patient details for possible typographical errors, which may cause atypical results.

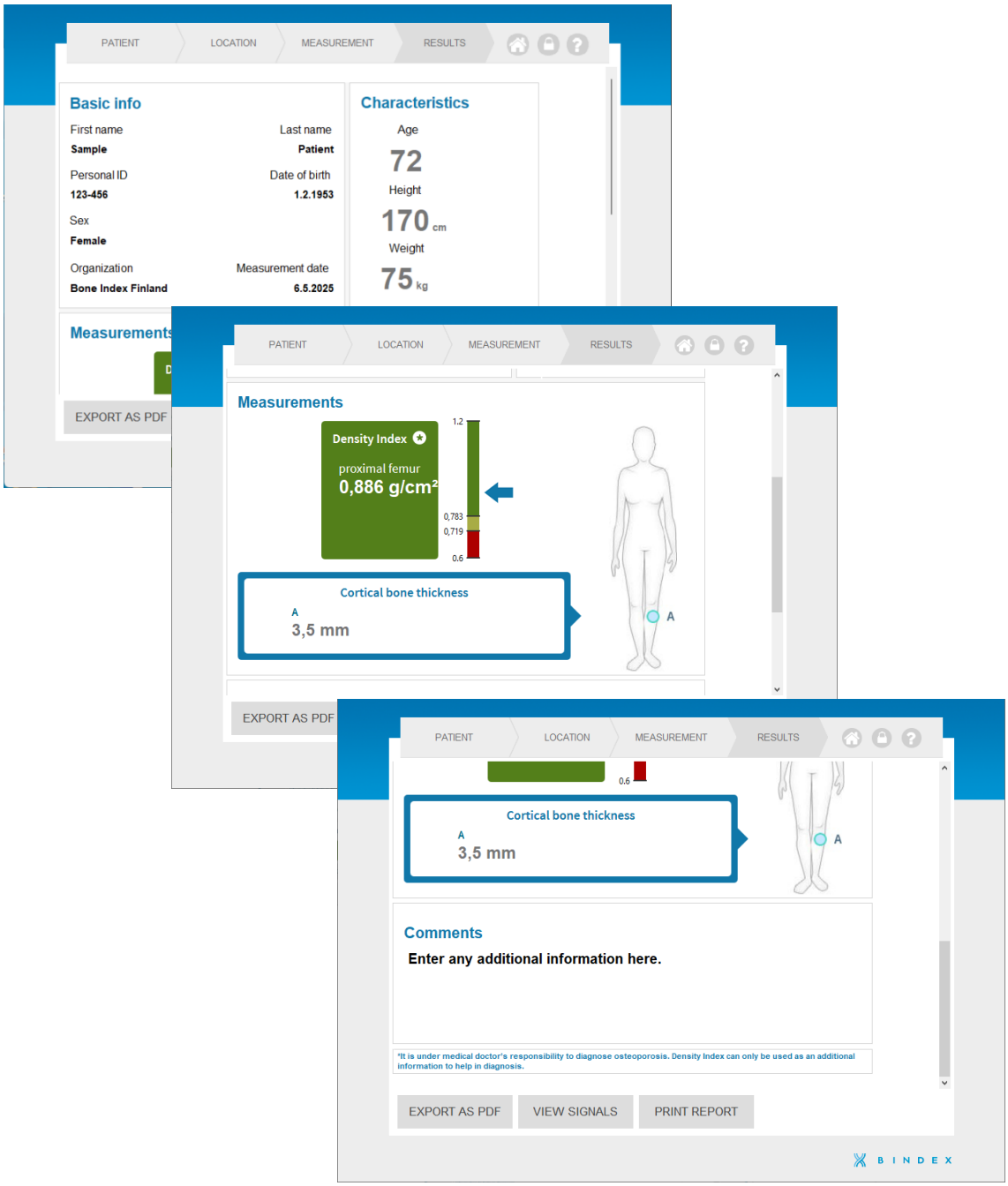


Figure 62: The result page includes patient information, Density Index and apparent cortical bone thickness values. In addition, the Density Index value is also presented on a three-color scale (green, yellow and red).

The results can be exported to PDF format by clicking EXPORT AS PDF and choosing the location for saving the file. The report can also be printed by clicking PRINT REPORT and given to the patient. Please go through the information shown in the report together with the patient first.

PLEASE NOTE: It is under the Medical Doctor's responsibility to diagnose osteoporosis. Density Index can only be used as additional information to help in diagnosis.

The color scale is based on a 90% sensitivity and specificity threshold analysis which has been determined in the clinical trials. The threshold value 0.84 between the green and yellow zone presents the sensitivity threshold and value 0.78 between the yellow and red zone present the specificity threshold. For Bindex the thresholds for osteoporosis with 90% sensitivity and specificity have been determined in population with 75 osteoporotic and 373 healthy patients (Karjalainen et al. Osteoporos Int 2016).

Originally the use of thresholds was proposed by Blake et al. Osteoporos Int Issue:16; 2005. It was suggested that the thresholds should be determined with at least 70 osteoporotic and 70 healthy subjects. Thereby, it is ensured with 95% confidence that the true sensitivity and specificity of a method will not fall below 80%.

The Density Index is a predictive index of proximal femur bone mineral density and thus intended for detection of hip osteoporosis. The apparent cortical bone thickness reported by Bindex has been assessed from measurement of the time difference between the echoes from periosteum and endosteum and using estimated constant speed of sound. The speed of sound in bone may vary due to the biological changes in bone tissue and structure. Therefore, the reported cortical bone thickness is an estimate. The apparent cortical bone thickness is an important input parameter into the Bindex for the determination of Density Index.

9. Cleaning, disinfecting and packing

The parts of the Bindex system that come into skin contact with the patient (i.e. the surface of the transducer, the handpiece and the BI-41 Measure) should be **cleaned (or checked for cleanliness) and disinfected before each patient measurement**. This is to minimize the risk of cross-infection between patients.

It is recommended to use isopropanol disinfective solutions (up to 70%) designed to be used on ultrasound transducers (for instance Transeptic, Parker Laboratories Ltd.). Ethanol solutions must not be used. Protective gloves are recommended during the cleaning and disinfection to minimize skin irritation.

Precautions for preventing damage to the Bindex device upon cleaning and disinfection:

MECHANICAL HAZARD:
DO NOT allow sharp or hot objects to touch the transducer or the cable.

MECHANICAL HAZARD:
DO NOT bump the device on hard surfaces while handling.

ELECTRICAL HAZARD:
DO NOT immerse the device in water or cleaning liquids to prevent the accumulation of liquid inside the device. Bindex is not intended to be immersed. The device can be sprayed lightly to moisten its surface.

MECHANICAL AND ELECTRICAL HAZARD:
DO NOT USE cleaning solutions that can damage the plastic of the device, such as ammonia, acetone or strong acids. If unsure, please check the suitability from the manufacturer of the solution before using it.

MECHANICAL HAZARD:
The device MUST NOT BE disinfected or sterilized using heat or steam, e.g. in an autoclave. The device does not need to be sterilized; regular disinfective solutions are sufficient to guarantee patient safety.

MECHANICAL HAZARD:
DO NOT USE regular rough tissues to wipe the transducer delay line, as they may scratch and damage its surface.

MECHANICAL HAZARD:
Ethanol solutions MUST NOT BE USED to disinfect the Bindex device. Ethanol may weaken the plastic cover over time, resulting in loss of mechanical integrity.

In case of visible damage, please contact your local distributor or Bindex Support and Service before attempting to use the Bindex device.

To clean the Bindex BI-2 device and the BI-41 Measure:

1. Wipe impurities, gel residues and other excess matter off the surface of the transducer, the handpiece and the cable as well as the BI-41 Measure with a dry soft cloth or a soft tissue.

2. A moistened cloth or tissue can be used in case of stains that are harder to remove.

3. Visually inspect the surface of the Bindex BI-2 device and the BI-41 Measure and verify cleanliness.

To disinfect the Bindex BI-2 device and the BI-41 Measure (after cleaning):

1. Use a soft cloth lightly dampened in disinfecting solution to wipe the surface of the transducer and the handpiece as well as the BI-41 Measure.

2. Allow the disinfected parts to dry before using the system again.

After use the Bindex BI-2 device and the BI-41 Measure should be cleaned, disinfected and packed in its protective case to keep them in good condition for the entire lifetime of the system. The packing needs to be done so that no excessive stress accumulates on the device or the USB cord. Make sure that the cord is not sharply twisted or bent and that it is not caught between the edges of the case while closing it.

10. Bindex service

Do not try to service or repair the Bindex device by yourself. There are no self-serviceable or replaceable parts. The Bindex BI-2 device does not require regular servicing by Bone Index Finland. If the device is in need of service or repair (e.g. visible mechanical damage or continuously failing calibration without an apparent reason), please contact your local distributor or Bindex Support and Service (see section 12 Contact information). The expected service life for the Bindex BI-2 device and the BI-41 Measure is three years or 7200 measurements (2400 measurements a year with an average of 10 patient measurements per day, 20 days in month and 12 months).

It is recommended to regularly inspect the condition of you Bindex device, including the casing, the USB cord and the surface of the transducer delay line. The condition of the device should be visually checked every week or at least monthly, depending on the frequency and number of measurements. If the device suffers significant mechanical stress (e.g. falls off a table), its use must be stopped immediately and the condition of the device must be checked. If you notice any changes in the integrity of the device or loss of functionality, please contact your local distributor or Bindex Support and Service before using the device.

The label by the USB connector needs to be legible at all times. The condition of the label should be regularly (recommended monthly) checked to ensure its good condition and legibility. The label is designed to withstand the same disinfection procedures as the device itself so it does not required special care during the cleaning phase. **The label MUST NOT BE REMOVED from the device or any accessories.** Should the label become illegible or break loose from the device, it needs to be replaced by Bone Index Finland. Please consult your Bindex representative or the Bindex Support and Service for additional assistance.

If any serious patient/operator incident (death or serious injury) occurs in relation to use of the Bindex device or Bindex Software, the incident must be reported to Bone Index Finland and the competent supervising authority for medical devices in your country without delay.

In case of lost or stolen Bindex device or computer with Bindex software, please contact Bindex Support and Service (see section 12 Contact information) without any delay.

11. Storing of Bindex

Do not store your Bindex BI-2 in direct sunlight. Sunlight may damage the material properties of the transducer. Store your Bindex in its own case in a dry location and in room temperature.

A quality phantom measurement conducted by Bone Index Finland Ltd. is recommended after one year of continuous storage time before patient measurements.

See section 5 Bindex BI-2 overview and technical specification for operating and storing conditions.

11.1. Disposal

Dispose the Bindex BI-2 device according to national or local laws and regulations or according to your disposal policy of your facility regarding Waste Electrical and Electronic Equipment (WEEE).

12. Contact information

Please use your local distributor as a primary contact. If no distributor has been declared, please contact Bindex Support and Service.

General contact address:

Bone Index Finland Oy		Tel.	+358 50 448 1696
Savilahdentie 14,		Email:	info@boneindex.fi
70700 Kuopio,			
FINLAND			

Bindex Support and Service:

Email: info@boneindex.fi

Phone: + 358 50 448 1696

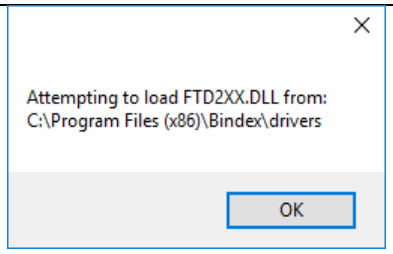
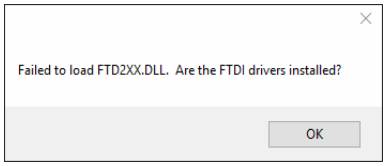
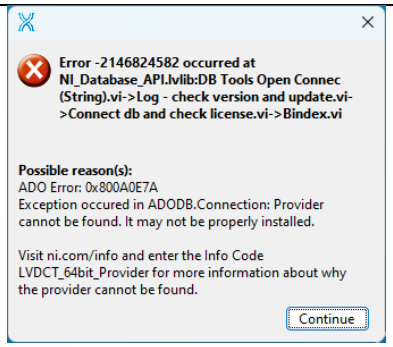
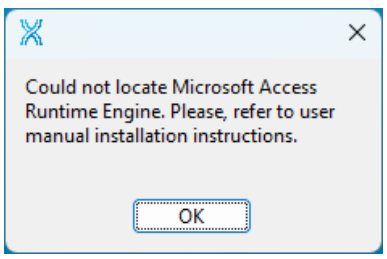
INFORMATION SECURITY HAZARD:
WARNING: Do not send sensitive information, such as patient health information through email.

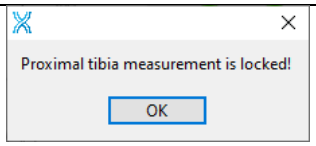
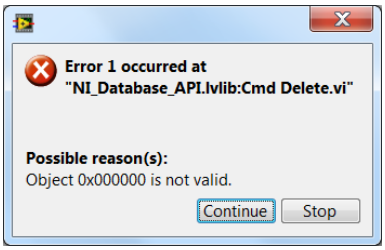
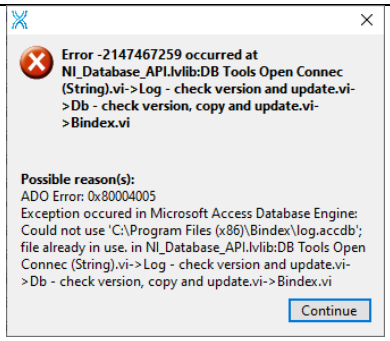
INFORMATION SECURITY HAZARD:
WARNING: Verify the email recipient carefully before sending any information.

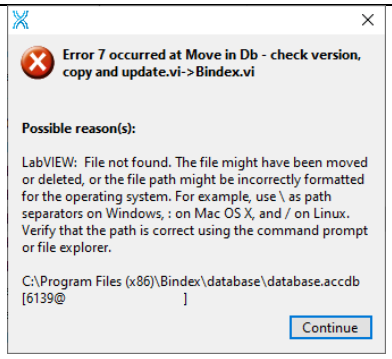
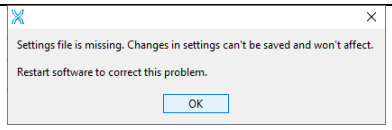
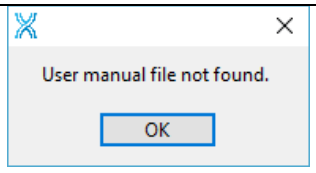
13. Troubleshooting

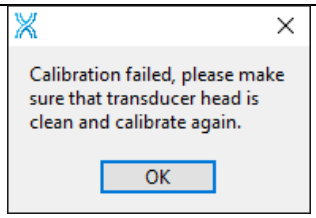
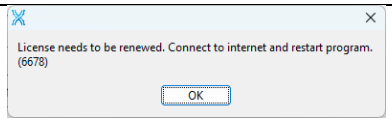
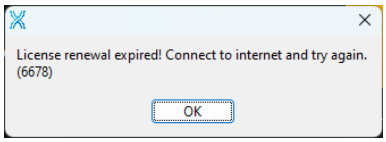
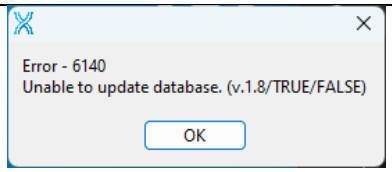
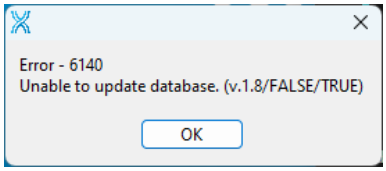
In case of errors or other issues with Bindex Software, look for any error messages or notifications. Write down or take a screenshot of any messages and error codes with their details. This will help in resolving possible issues if you need to contact Bindex Support and Service.

Please do not reinstall or delete/modify any files related to the Bindex installation yourself, as this may lead in the activation, patient data and/or activated PPAs being lost.

Installing Bindex Software			
Symptom / Issue	**Notification(s)**	**Possible cause(s)**	**Solution**
Error messages on software startup. Bindex device connection not established.	 	The Bindex device drivers have not been installed. The Bindex device has not been connected to the computer before activating the program.	Drivers are installed after connecting the Bindex device for the first time. Complete device driver installation by the instructions in 7.3 Device driver installation.
Software fails to start. Error messages on software startup. Bindex Software not able to locate Microsoft Access Runtime Engine.	 	Compatible version of Microsoft Access Runtime have not been installed.	See 7.2 Software installation for instructions on how to install Microsoft Access Runtime.

Using Bindex Software			
Symptom / Issue	**Notification(s)**	**Possible cause(s)**	**Solution**
The measurement cannot be restarted after going to the Results tab.		The measurement is locked after visiting the Results tab. You can go back to the Measurement tab but the measurement cannot be restarted.	To measure the same patient again go to the Main Menu, select OPEN CASE, search and select the patient and click OPEN. Proceed with the measurement as usual.
Unexplained error message(s) when using Bindex Software.	Examples:  	General error message, may be caused by a number of reasons, e.g. unsuccessful install, insufficient user rights, changes in program files. Always needs to be investigated separately.	In case of a general error situation, write down the: - error number, - location, and - possible reason(s) and send them to Bindex Support and Service. Alternatively, a screen capture of the error message can be taken and sent. Explain where and how the problem occurred. After an error message restart Bindex Software to prevent incorrect functionality.
Software fails to start. Error message 214767259 on software startup.		Bindex Software is currently running on another user profile on the computer. The database cannot be used simultaneously by multiple users.	Ask the other user or the system administrator to close Bindex Software on the other user profile. After this, restart the program.

Symptom / Issue	Notification(s)	Possible cause(s)	Solution
Software fails to start. Error message 7 on startup.		The database file is not found, possible reasons: The database location is incorrectly defined in "settings.ini". The database file has been deleted, moved or renamed so that the program cannot find it.	Users with sufficient understanding of file editing: open "settings.ini" in Notepad and check the line "database_directory". Then verify that "database.accdb" file is found in the folder defined on the line. Correct the path, if needed. If unsure or the issue cannot be clearly identified, contact Bindex Support and Service for assistance.
Error message when editing software Settings.		The Bindex settings file is not found. The "settings.ini" file has been deleted, moved or renamed during program use.	Relocate or rename the "settings.ini" file, if possible. If the original file has been lost, restart software. A new settings file is generated. The user and organizational data must be re-entered in the Settings page. If the problem persists, contact your distributor or Bindex Support and Service.
User Manual cannot be opened in software.		The User Manual file has been moved, renamed or deleted from its original location. The User Manual files are installed in the "user manual" folder of the Bindex install.	At least the default manual in English should be found in the folder with the name "user manual_EN.pdf". Relocate or rename the User Manual file, if possible If the file is missing, please contact Bindex Support and Service for assistance.

Symptom / Issue	Notification(s)	Possible cause(s)	Solution
Calibration of the Bindex device fails.	 	The transducer surface is not clean. The storing or operating temperature of the Bindex device is or has been outside of set limits (see the product labels). The transducer is damaged.	Clean the front surface of the transducer. Software measures the echo signal from the surface of the transducer, which must be clean from any gel or other impurities. Check that the ambient temperature is suitable for the Bindex device. If the device has been stored in a cool or a hot place, the temperature inside the device needs to settle. This usually takes about 15 minutes. If the problem persists, contact your distributor or Bindex Support and Service. Please write down or take a screenshot of the entire error message.
Software does not launch, or new case cannot be created.	 	Decentralized license model in use and too much time from last connection to license server.	Connect the computer to the internet and restart the software. When using decentralized license model, the software must be periodically in connection to the license server, for more information see 7.4.
Software does not launch.	 	Software was updated from earlier software version without valid activation. Database has been modified.	Please contact Bindex Support and Service for assistance. Please write down or take a screenshot of the entire error message.

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DATA CONFIDENTIALITY
During mutually agreed technical support the staff of Bone Index Finland may need to process confidential customer or patient information. The data may be in the form of individual files, logs, databases or measurement reports. All such data is considered strictly confidential and shall only be used to the extent least required.

The support personnel is responsible for handling customer data only as necessary for the purpose of troubleshooting. Customer data, including patient details, shall be deleted from Bone Index Finland workstations and any storage media as soon as possible after the support case. If certain details are needed for further quality assurance, regulatory or product development purposes, the customer shall be asked for a permission to use the information for such purposes.

TITLE

Title, ownership rights, and intellectual property rights in the Software shall remain with Bone Index Finland. This Software is protected by the copyright laws and international treaties.

Appendix: Guidance and manufacturer's declaration - Electromagnetic Compatibility

Bindex is intended for use in an electromagnetic environment as specified in section 6 Operating environment. The customer or the user of the Bindex should assure that it is used in such an environment.

Essential performance is defined as maintaining the manufacturer defined accuracy for the apparent thickness measurement even during tested electromagnetic disturbances. Possible degradation or loss of performance due to electromagnetic disturbances can appear as one or more of the following:

1) inability to establish or maintain connection to the measurement PC,
2) unusual, possibly regular or repeating disturbances or patterns in the signal,
3) Bindex software unable to accept the measured signal due to disturbances,
4) incorrectly accepted signals with disturbances.

Electromagnetic compatibility along EN 60601-1-2:2015 applies only for an unmodified Bindex BI-2 device with its original cable 9355 installed by Bone Index Finland Ltd. There are no user-replaceable parts or components.

Table 1: Guidance and manufacturer's declaration – Electromagnetic Emissions.

ELECTROMAGNETIC EMISSIONS		
Emission test	**Compliance**	**Environment guidance**
RF emissions CISPR 11	Group 1	Bindex uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Bindex should be operated indoors, in clinics, hospitals or home healthcare use environments.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Table 2: Guidance and manufacturer's declaration – Electromagnetic Immunity

ELECTROMAGNETIC IMMUNITY			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Environment guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±15kV air	±8kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2kV 100 kHz repetition frequency	Not applicable	Mains power quality should be that of a typical home healthcare use, commercial or hospital environment.
Surge IEC 61000-4-5	±0,5 kV, ±1 kV Line-to-line ±0,5 kV, ±1 kV, ±2 kV Line-to-ground	Not applicable	Mains power quality should be that of a typical home healthcare use, commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°	Not applicable	Mains power quality should be that of a typical home healthcare use, commercial or hospital environment. If the user of Bindex requires continued operation during power mains interruptions, it is recommended that Bindex is powered from an uninterruptible power supply or a battery.
RATED power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz and 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare use, commercial or hospital environment.
NOTE U_T is the AC mains voltage prior to application of the test level.			

Table 3: Guidance and manufacturer's declaration – Electromagnetic Immunity

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Bindex is intended for use in the electromagnetic environment specified below. The customer or the user of the Bindex should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Environment guidance**
Conducted disturbances induced by RF fields IEC 61000-4-6	3 Vrms 0,15 MHz - 80 MHz 6 Vrms in ISM and amateur bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 0,15 MHz - 80 MHz 6 Vrms in ISM and amateur bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are: 6,765 to 6,795 MHz 13,553 to 13,567 MHz 26,957 to 27,283 MHz 40,66 to 40,70 MHz The amateur radio bands between 0,15 MHz and 80 MHz are: 1,8 to 2,0 MHz 3,5 to 4,0 MHz 5,3 to 5,4 MHz 7 to 7,3 MHz 10,1 to 10,15 MHz 14 to 14,2 MHz 18,07 to 18,17 MHz 21,0 to 21,4 MHz 24,89 to 24,99 MHz 28,0 to 29,7 MHz 50,0 to 54,0 MHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:  The minimum separation distance for portable RF communications devices and the Bindex device can be calculated as follows. **Minimum separation distance** $d = \frac{6}{E}\sqrt{P}$ where d is the minimum

Radiated RF EM fields IEC 61000-4-3 + A1:2008 + IS1:2009 + A2:2010	10 V/m 80MHz to 2,7GHz	10 V/m 80MHz to 2,7GHz	separation distance in metres (m); *E* is the immunity test level in V/m; and *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Proximity fields from RF wireless communications equipment EN 61000-4-3 + A1:2008 + IS1:2009 + A2:2010	9 V/m, 27 V/m, 28 V/m 80 MHz to 5800 MHz 380 MHz to 390 MHz: 27 V/m 430 MHz to 470 MHz: 28 V/m 704 MHz to 787 MHz: 9 V/m 800 MHz to 960 MHz: 28 V/m 1700 MHz to 1990 MHz: 28 V/m 2400 MHz to 2570 MHz: 28 V/m 5100 MHz to 5800 MHz: 9 V/m	9 V/m, 27 V/m, 28 V/m 80 MHz to 5800 MHz 380 MHz to 390 MHz: 27 V/m 430 MHz to 470 MHz: 28 V/m 704 MHz to 787 MHz: 9 V/m 800 MHz to 960 MHz: 28 V/m 1700 MHz to 1990 MHz: 28 V/m 2400 MHz to 2570 MHz: 28 V/m 5100 MHz to 5800 MHz: 9 V/m	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Bindex is used exceeds the applicable RF compliance level above, Bindex should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Bindex.			