BINDEX

Osteoporosis Diagnostics

User Manual

Bindex Standalone Software version 2.6
Bindex model BI-2

CE
0537

Updated 24 August 2018 U.S. law restricts this device to sale by or on the order of a physician.

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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 Quality Management Standard ISO-13485 and the products comply with the Medical Device Directive MDD 93/42/EEC requirements.

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2. Warnings and precautions

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

The Bindex® 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.

Portable and mobile radio frequency (RF) communications equipment can affect the Bindex® BI-2 device.

Equipment used with Bindex® measuring system must comply with IEC 60601-1 (medical equipment), IEC 60950 (non-medical equipment) or their general IEC/ISO variants.

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

Bindex® should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, Bindex® should be observed to verify normal operation in the configuration in which it will be used.

Do not make Bindex® measurements on the surface of skin with open sores. There is an inflammation risk.

Do not use the Bindex® device on broken or irritated skin or in case of a fractured bone at measurement location.

Do not use the Bindex® device in case of implants, plates or fixations at measurement location.

Do not use Bindex® outdoors. See 6 Operating environment.

Do not use Bindex® near a heat source or an air conditioner. This may cause condensation of moisture inside the equipment.

Use only approved ultrasound coupling gel for measurements with Bindex®.

Do not apply ultrasound gel on the surface of the Bindex® transducer before calibration. See 8.5 Bindex® quality verification.

Always use the Bindex® Measure for determination of the proper measurement location. The location is standardized for this measurement to produce reliable results.

If you drop or bump the device on hard surfaces, make quality verification measurements. In case of any mechanical or visible damage, please contact your local distributor or Bone Index Finland Ltd. for service. Do not use a damaged device!

Bindex® is not intended to be used in oxygen rich environment.

The patient shall be informed not to touch the connectors of the ME system (e.g. laptop connectors) during measurements.

Do not use a USB extension cord between the Bindex® device and the computer.

Caution: Federal law restricts this device to sale by or on the order of a physician.

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

Consulting accompanying documents before use is mandatory.

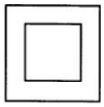
Device manufacturer contact information.

Type B applied part.

General warning.

Caution.

Operating Instructions.



Class II device, 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

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 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. The DI reported by Bindex is used as an aid in osteoporosis diagnostics by applying pre-determined thresholds. DI can help the clinician in estimation of fracture risk.

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.

Currently the use of Bindex® DI thresholds is validated for Caucasian women at the age between 50 to 90 years. Bindex® measurement takes about one minute. Bindex® device should be operated by a physician or under supervision of physician by a nurse, pharmacist or trained person with a suitable background education and skills.

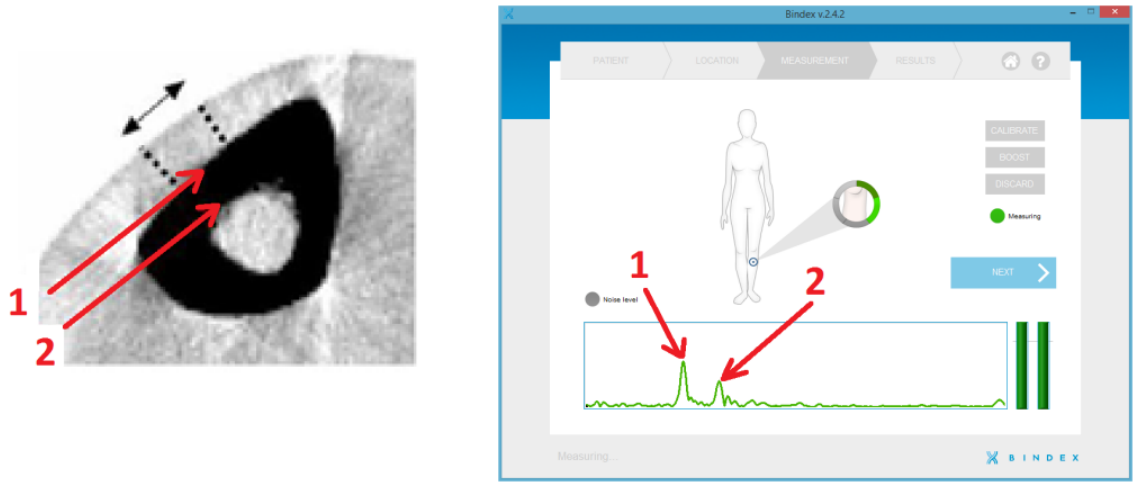


Figure 1: A Computed Tomography image of tibia shows the tubular structure of the bone (black area). When measuring the tibia with Bindex®, the ultrasound echoes back from the front (1) and the back (2) surface of cortical bone layer. These echoes need to be clearly distinguishable. Bindex® will automatically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

5. Bindex® BI-2 overview and technical specification

Device overview

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 on a USB drive or as a downloadable installation package. The software can be installed on Windows 7/8/10 operating systems on a PC. The Bindex® device is operated using the software GUI (Graphical User Interface) which controls the pulser and collects 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® - 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

Electrical	
Power supply	Powered from PC USB port, 5V

Environmental	
Operating Temperature	+15...+40 ° C
Storage Temperature	+15...+40 ° C
Atmospheric Pressure	600hPa to 1060hPa (mbar)
Humidity	5…85%

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	IEC 60601-1 ed. 3.0
Ultrasound safety	IEC 60601-2-37 ed. 2.0 and IEC 62359 ed. 2.0

Bindex® and the connected PC are together considered a medical electrical system. The computer power source must comply with the IEC 60950-1:2005 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 and it is used within the

patient environment.

Bindex® can also be used with an IEC 60950-1:2005 compliant laptop computer operating on battery power. In this case, no additional precautions concerning electrical safety are required.

The PC to which Bindex® is connected needs to comply with IEC 60950-1:2005 2.ed. or should be connected to power grid through a medical isolation transformer.

A medical isolation transformer is not needed when the PC is on battery use.

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 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 7, Windows 8 (8.1) or Windows 10
Processor:	2 GHz, 32-bit or 64-bit
Memory:	2 GB
Hard Disk Drive:	installation: 72 MB Bindex® Standalone Software 353 MB LabVIEW Run-Time Engine 2012 109 MB Microsoft Access database engine 2010 2 MB device drivers in use: 1.7 MB per patient
Screen Resolution:	1024x768
Other:	USB port .NET framework v.4.0.30319 or newer (upgrade with Windows Update, if necessary)

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 at least one Bindex® BI-2 device, one software installation disk, the User manual in electronic form and one Bindex® Measure.

7.2. Software installation

Installation of the Bindex® Standalone Software should be done by a person with adequate knowledge about computers. Administrator rights are required for the installation.

7.3. Running the installation program

To start the installation, 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.

Set the installation directories in the following window (Figure 4). Please verify the installation folder because you cannot move the software folder after installing.

The next step is accepting the license agreements (Figure 5). Carefully read the license terms before proceeding. Selecting "I accept the License Agreement" is required to use the Bindex® Standalone Software. Press NEXT to continue. The next window includes the license terms for the National Instruments software required for Bindex Standalone Software. Accept the terms and click on NEXT.

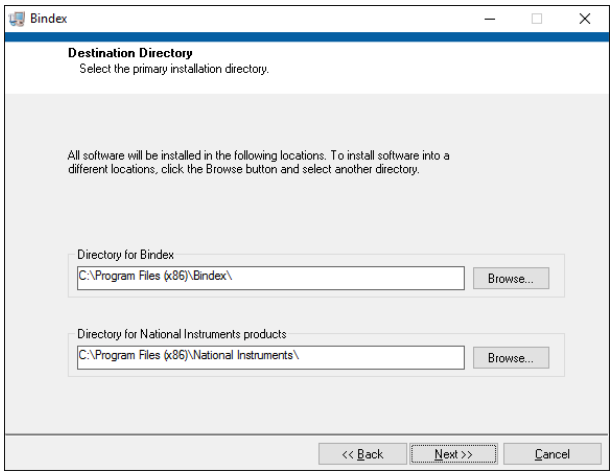


Figure 4: Setting the installation directories. The paths may be changed if needed.

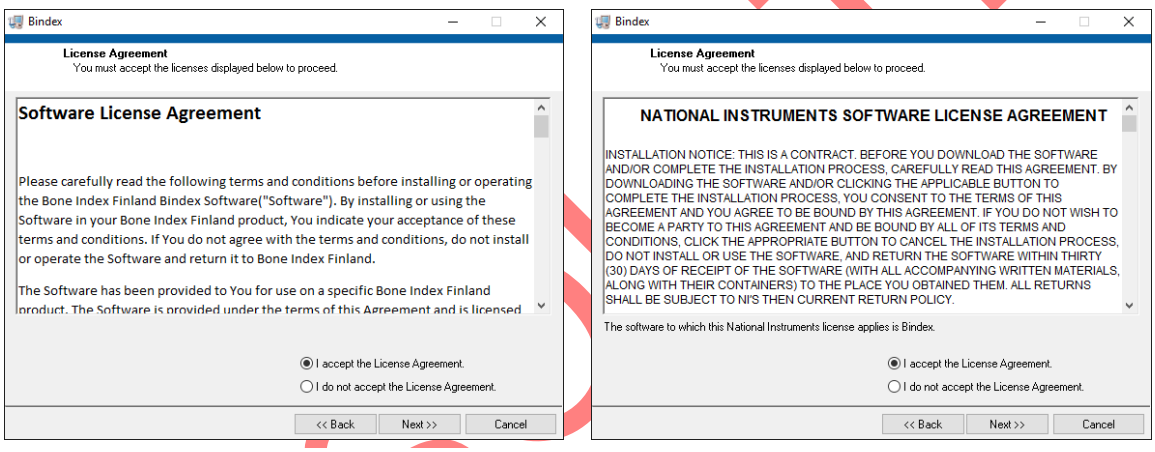


Figure 5: The license agreements. Carefully read the terms before proceeding. After accepting the licenses, continue with the installation by clicking on NEXT.

The following window (Figure 6) shows that you are about to install or change files related to Bindex Standalone Software. The installation starts by pressing NEXT.

After a successful installation a confirmation window is shown (Figure 7). Finish the setup by pressing NEXT. LabVIEW Run-time Engine 7.0 and Microsoft Access database engine 2010 are required to be installed to run Bindex Standalone Software. The installation of these programs is automatically launched after the Bindex installation. Please follow the instructions on the screen to complete the setup. A restart is required to before running Bindex

Standalone Software. You may do this at this point or later.

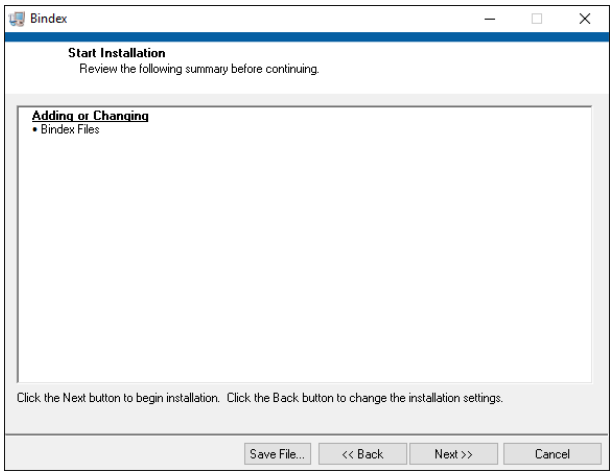


Figure 6: Starting the installation.

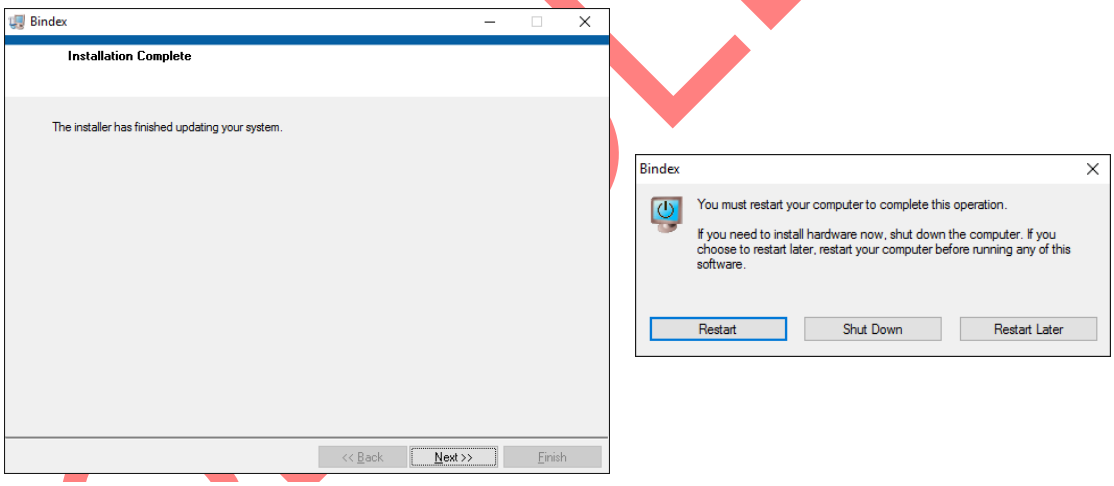


Figure 7: Installation completed successfully. Exit the installation program by pressing NEXT. After installing all required components a restart is needed before using the software.

7.4. Device driver installation

After completing procedures in section 7.3 the Bindex® BI-2 device may be plugged in for driver installation. Drivers are required for the computer to identify the Bindex® device and to conduct the measurement correctly.

If the computer is connected to the Internet, the operating system will automatically search for the correct drivers (shows up as FT240X USB FIFO) and install them (Figure 8). Please wait patiently until a message about USB Serial converter having been successfully installed is displayed. After this Bindex Standalone Software is ready to be started.

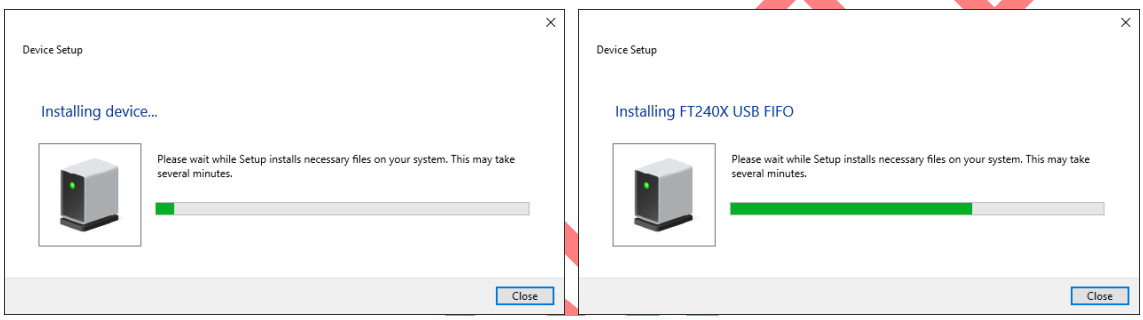


Figure 8: Device driver installation.

If the computer is not connected to the Internet or the automatic installation is unsuccessful for some reason, a driver installation package is supplied with the installation files for manual installation. Please consult your Bindex® representative or the Bindex Support and Service (see section 12) for additional assistance.

7.5. Software activation

First time activation

To start using the Bindex® device you need to activate the software using an activation file ("activation.key"). You will receive this key after sending a corresponding customer file ("customer.key") to Bone Index Finland. Run Bindex® Standalone Software (Bindex.exe in program folder or shortcut in your desktop) and enter your operator name. After pressing LOG IN you will see a dialog asking you to save the customer file (Figure 9). Save the file to a folder of your choice. Please send your customer.key file to Bone Index Finland Ltd. (info@boneindex.fi) together with your contact information and the number of pre-paid analyses (PPA) to include. The expiration date of PPAs will be set according to the currently valid agreement between the customer and the seller. You will then receive an activation file by email. Please, DO NOT edit the customer or the activation files or they will become void.

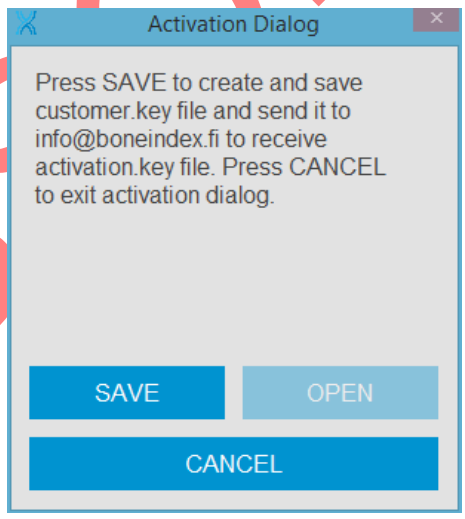


Figure 9: When you run the software for the first time a dialog appears.

Next time the Bindex® Standalone Software is run you will be asked for the activation.key file (Figure 10). After opening the correct activation file the software is ready for use (Figure 11).

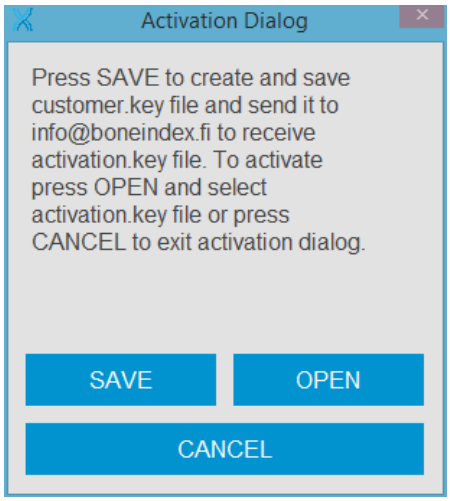


Figure 10: Before the software is activated a dialog showing your customer key and asking for the activation key appears.

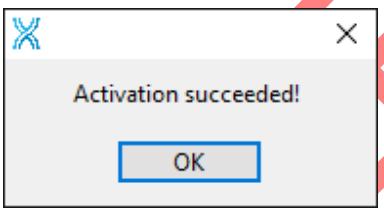


Figure 11: The software notification when the correct software activation file is opened.

PLEASE NOTE: The database MUST NOT BE COPIED or it will lock itself and require a new activation. In case of problems contact your local distributor or Bone Index Finland Ltd. for assistance.

Ordering additional analyses

After activating the software each new Density Index analysis reduces the pre-paid analysis counter by one. New measurements can be made until the PPA counter in the **Settings** page (Figure 19) reaches zero (all pre-paid measurements have been used). After this the software can be started and previous measurements viewed but no modifications can be made.

Additional PPAs can be ordered by going to the **Settings** page and clicking on LICENSE AND PPA (Figure 12). This opens the **Order Dialog**. Click SAVE to

create a new order file (“order.key”) and send it to Bone Index Finland Ltd. with your contact details and number of PPAs to order. Additional PPAs will then be provided by sending a PPA key file (“ppa.key”) in return.

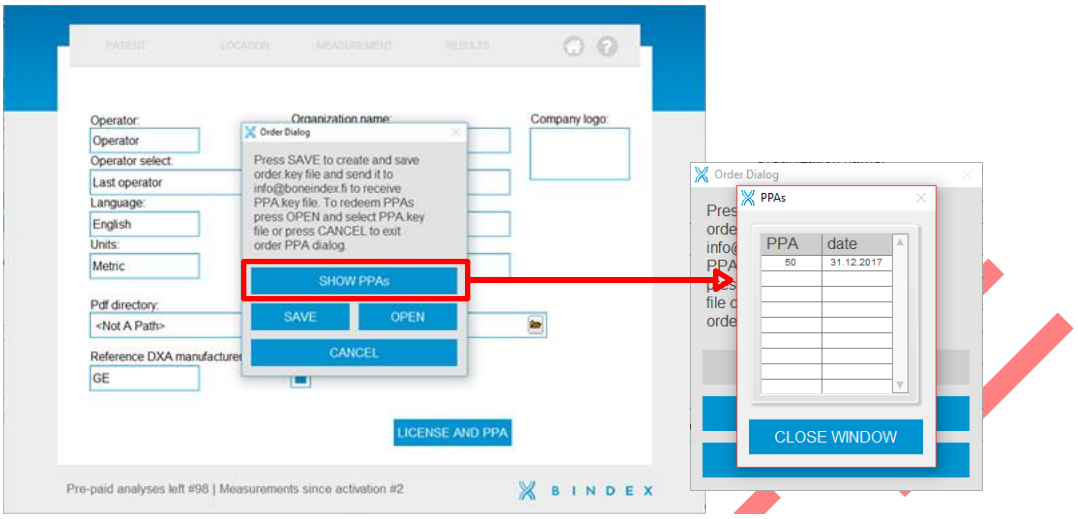


Figure 12: Licence and PPA window. You can create new order keys and add ordered PPAs from this menu. A list of activated PPA packages can be seen by clicking on SHOW PPAs.

To activate the additional analyses, please select OPEN in the **Order Dialog** and locate the PPA key file. After successfully opening the file, a notification will be shown with the amount of added PPAs shown.

Each activated PPA package can be viewed by clicking on SHOW PPAs in the **Order Dialog**. The PPA packages are depleted and listed in the order of their expiration date, starting from the first package to expire. Depleted and expired packages are removed from the list automatically.

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.

7.6. Bindex® device setup

Please install the Bindex® Standalone Software before connecting Bindex® equipment to the computer (see 7.3 Running the installation program). After the installation, plug the device connector into a USB port and launch the Bindex® Standalone Software.

The device is ready to be used. Once connected to a USB port, the device is in stand-by state. The ultrasound transmission is on only during a measurement in Bindex Standalone 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.

Do not modify this equipment without authorization of the manufacturer.

Do not use a multiple socket outlet to connect the system to the power grid.

Use a medical isolation transformer to connect your computer to power grid. (Not needed when the laptop computer is compliant with IEC 60950-1:2005 2.ed. or it is used with a battery!)

The ultrasound transducer is active only when measurement is turned on from Bindex Standalone Software.

8. Using Bindex®

8.1. Connecting and disconnecting the Bindex® device and launching the software

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 Standalone Software. If the device is disconnected from the computer while the software is running, the connection can be restored by 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.

Do not touch the connectors of the computer and the patient at the same time.

At startup the software first asks for your operator name (Figure 13) or alternately uses a name defined in your settings (see 8.1.4 Settings).

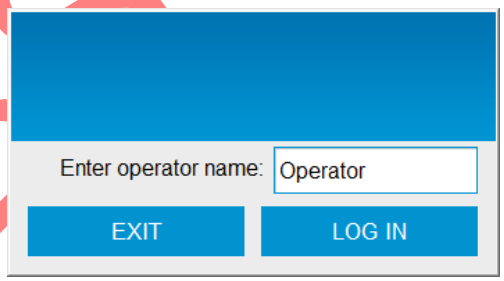


Figure 13: "Log In" view. When you press the LOG IN button you will continue to the front page of the software.

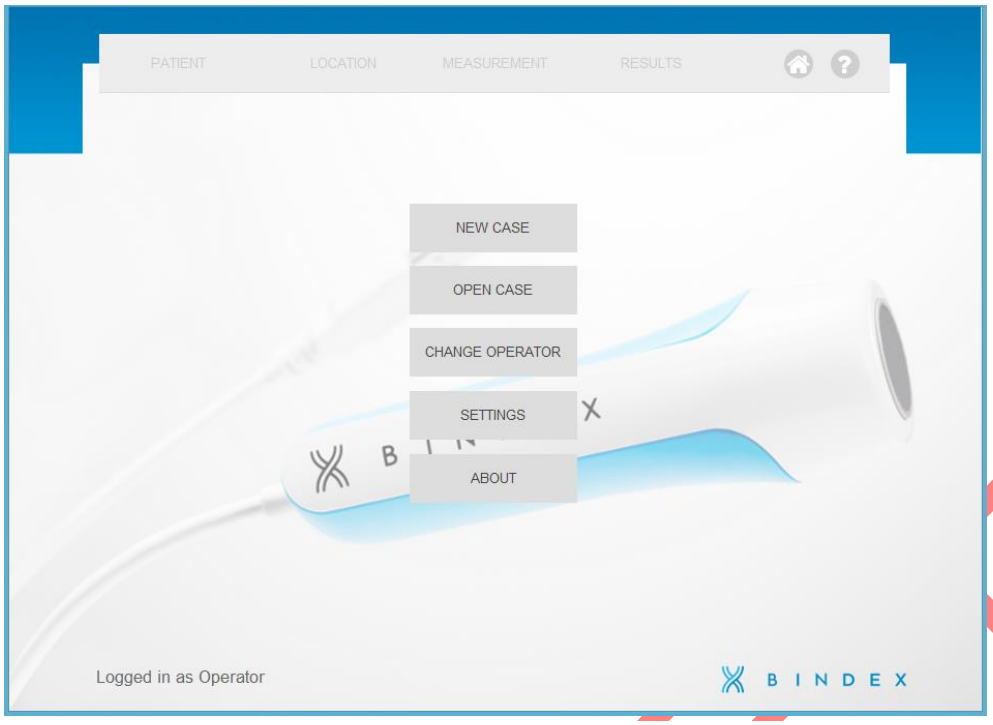


Figure 14: Front page of Bindex® software. You can always get back to this page by pressing the HOME button in the upper right corner. The "?" button will link to the Bindex web page for more information.

On the front page (Figure 14), you have five possibilities to continue: NEW CASE, OPEN CASE, CHANGE OPERATOR, SETTINGS or ABOUT.

8.1.1. New case

Press NEW CASE when you wish to start a measurement with a new patient (see 8.2 Patient). If you have an existing case open you will be asked a confirmation to proceed (Figure 15). Selecting OK starts a new empty patient case but all unsaved data from the current measurement is lost.

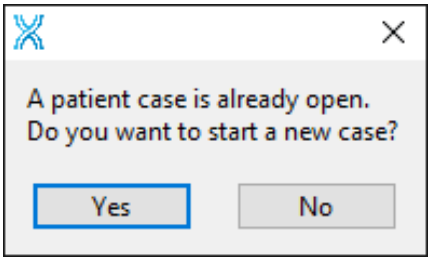


Figure 15: The software asks a confirmation before starting a new case over an existing case.

8.1.2. Open case

If you have measured a patient earlier and the patient exists in the database choose OPEN CASE (Figure 16). Patient can be searched by typing the first or last name or patient ID on the *Search term*. The software automatically suggests patients starting with the letter or phrase typed in this field. After selecting a patient, press OPEN to continue to the **Patient** page which shows the selected patient info.

By selecting a name from the list and pressing the RESULTS button you will continue to the **Results** sheet of a previous measurement.

By selecting the TIMELINE you will see all results of the selected patient if you have measured the patient more than once.

The DELETE button will delete either the selected patient or the selected measurement depending on what you choose in the following dialog (Figure 17). Deleting a measurement only deletes the selected measurement from the selected patient, but deleting a patient deletes the whole 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.

Always use NEW CASE for new database entries and OPEN CASE when a patient already exists in database.

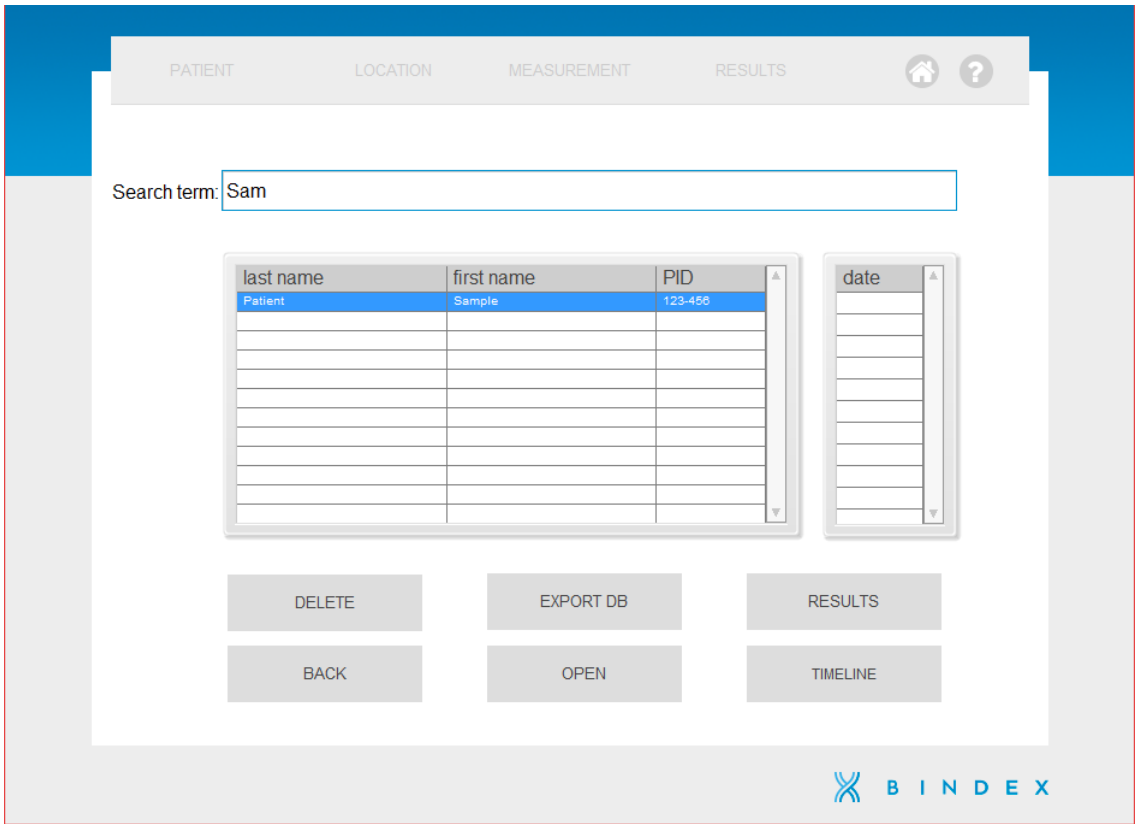


Figure 16: Open case view. By using the BACK button you will continue to front page of the software.

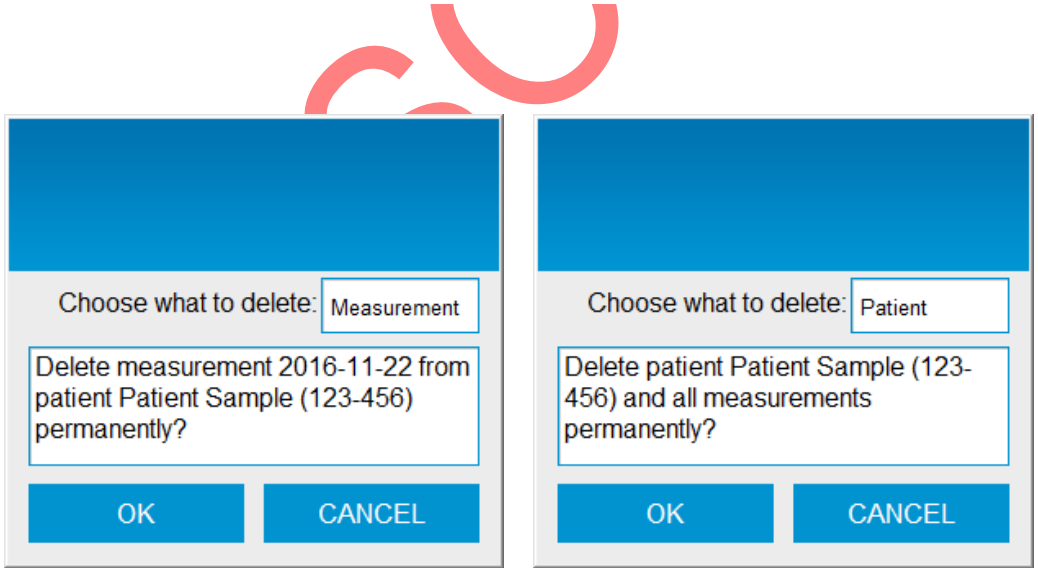


Figure 17: Delete a patient or measurement from the database.

8.1.3. Change operator

The CHANGE OPERATOR - button allows the user to change the name of the operator name (Figure 18). Operator name is stored together with measurement and can be seen in the exported PDF file.

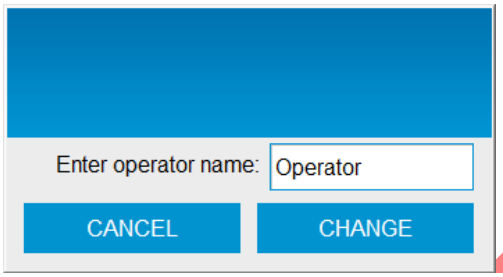


Figure 18: Change operator view. You can enter new operator name and press CHANGE.

8.1.4. Settings

By pressing the SETTINGS button, the operator naming method, software language and company information (contact details and logo) can be changed (Figure 19).

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).

From the info bar at the bottom of the page you can see the number of available PPAs. The measurement counter since the day of the software activation is also shown in info bar.

For more information about PPA ordering, please see 7.5 Software activation.

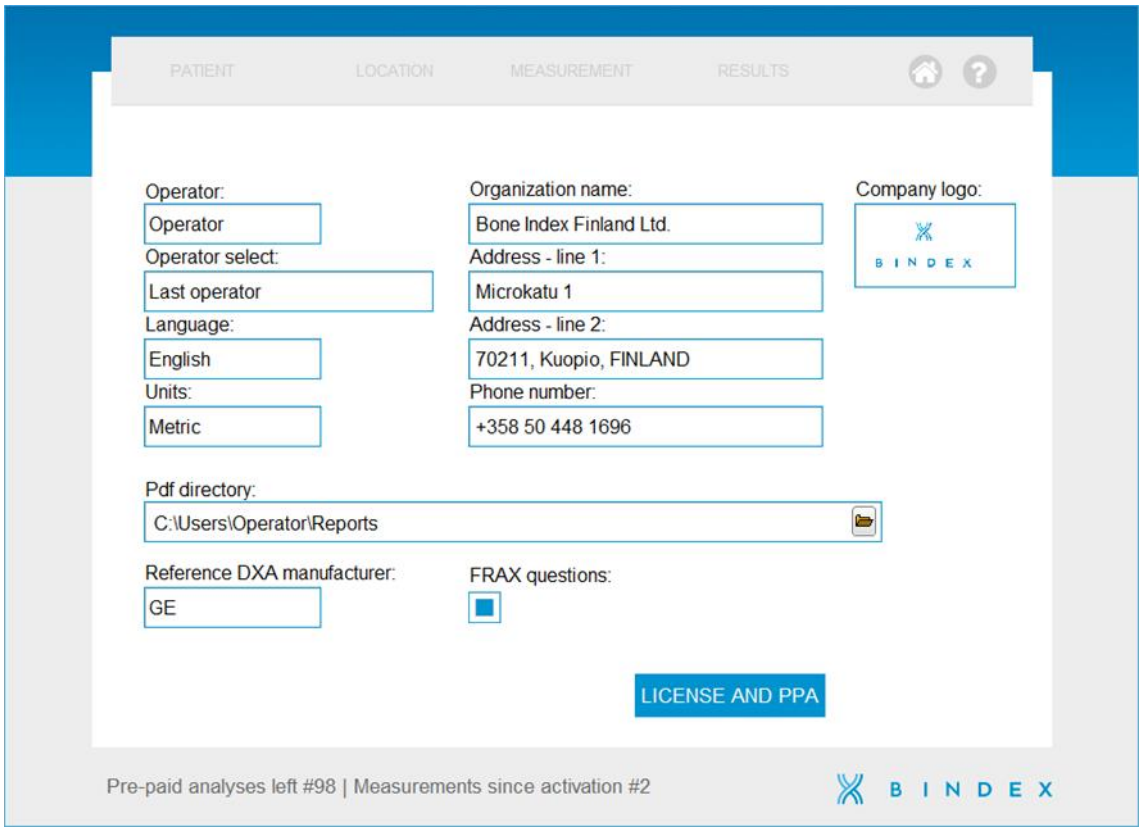


Figure 19: Change settings view. In this page you can change operator and company information settings, language and the default directory for saving the PDF reports.

By pressing OPERATOR SELECT - button the name of the operator and the manner in which the operator is selected can be changed. Option LAST OPERATOR will always ask for the operator name at startup but suggests using the name of last operator. When WINDOWS LOGON NAME is selected the software will suggest the Windows logon name at startup. When you select LOCKED the software will open without asking the name of operator. Software will use the name of last used operator name.

On this page the language of software interface may be chosen. 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.

When “FRAX questions” selection has been enabled, a FRAX questionnaire will be shown after the patient info has been entered (see 8.2 Patient). When the selection is disabled, only the basic information of the patient is entered before measuring.

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.

8.1.5. About

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

8.2. Patient

On the **Patient** page (Figure 20), the name, ID, date of birth (DOB), sex, ethnicity, 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**). If an existing case has been opened and patient information is changed, you will be asked (Figure 21) whether you want to update the data or discard the changes.

If you save or try to continue to the next page before you have filled patient information you will be notified to do this (Figure 22).

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

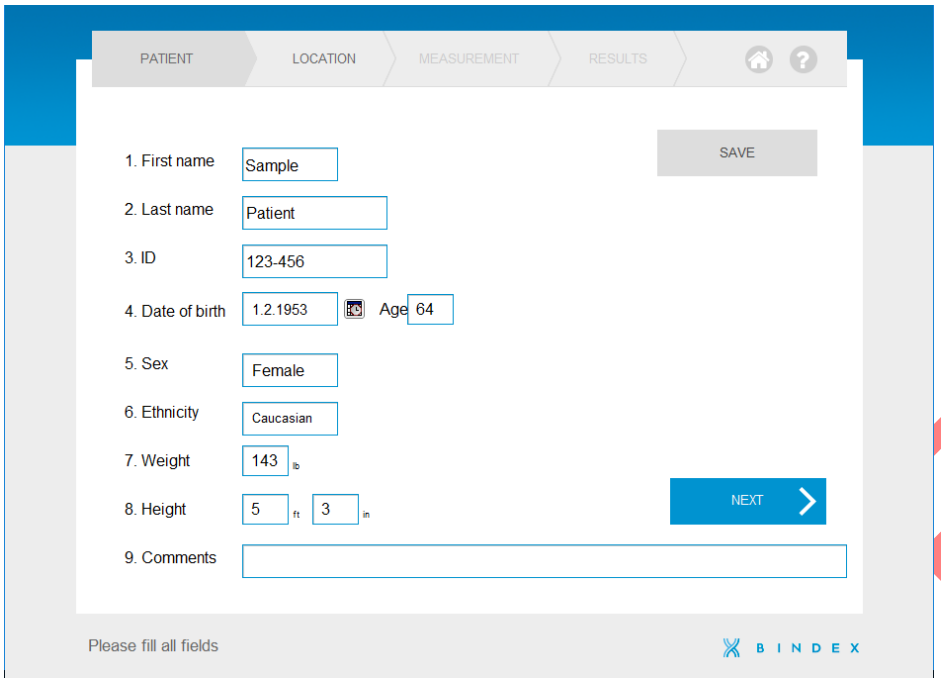


Figure 20: The Patient page. All information must be entered before you can continue by using the NEXT button. By saving the patient info you can find the info from OPEN CASE later.

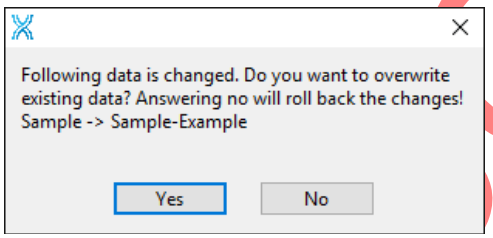


Figure 21: Software asks confirmation before writing over existing data.

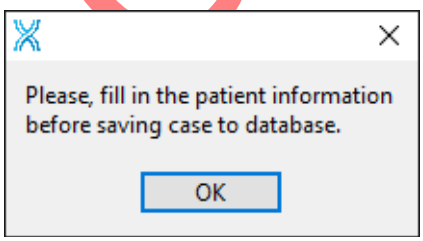


Figure 22: You will be asked to fill the necessary patient information before continuing to the measurement.

If enabled in Settings, the FRAX questionnaire will be shown after clicking NEXT in the Patient page (Figure 23). 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.

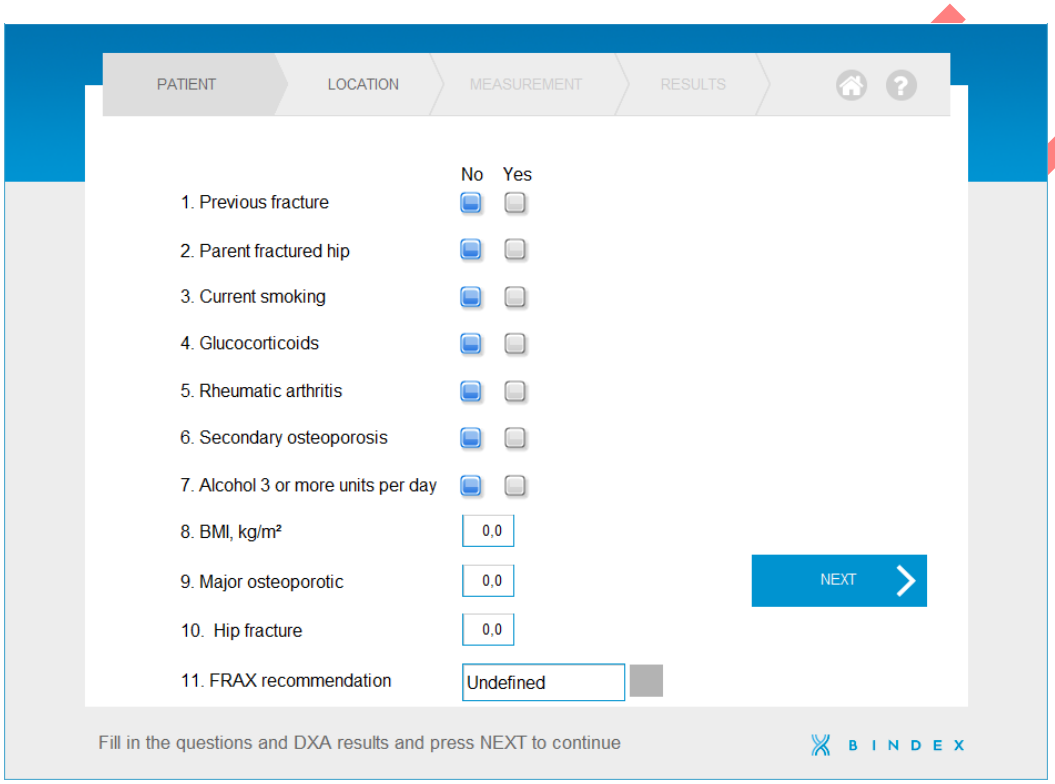


Figure 23: If enabled in settings, the FRAX questionnaire can be filled in after the basic information of the patient has been entered.

8.3. 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 24). Clothing must be removed below the knee up to over the ankle.

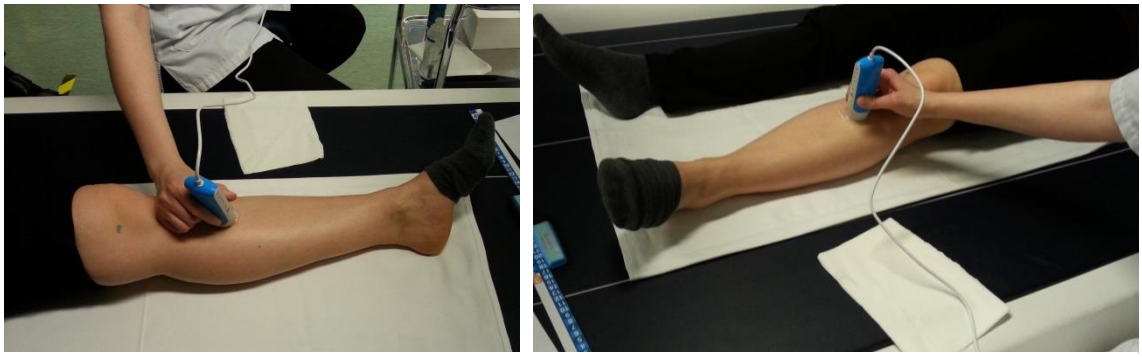


Figure 24: Patient positioning on a bed. Remember to keep an ergonomic position when you are measuring.

8.4. Measurement site location

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.

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 25). 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.

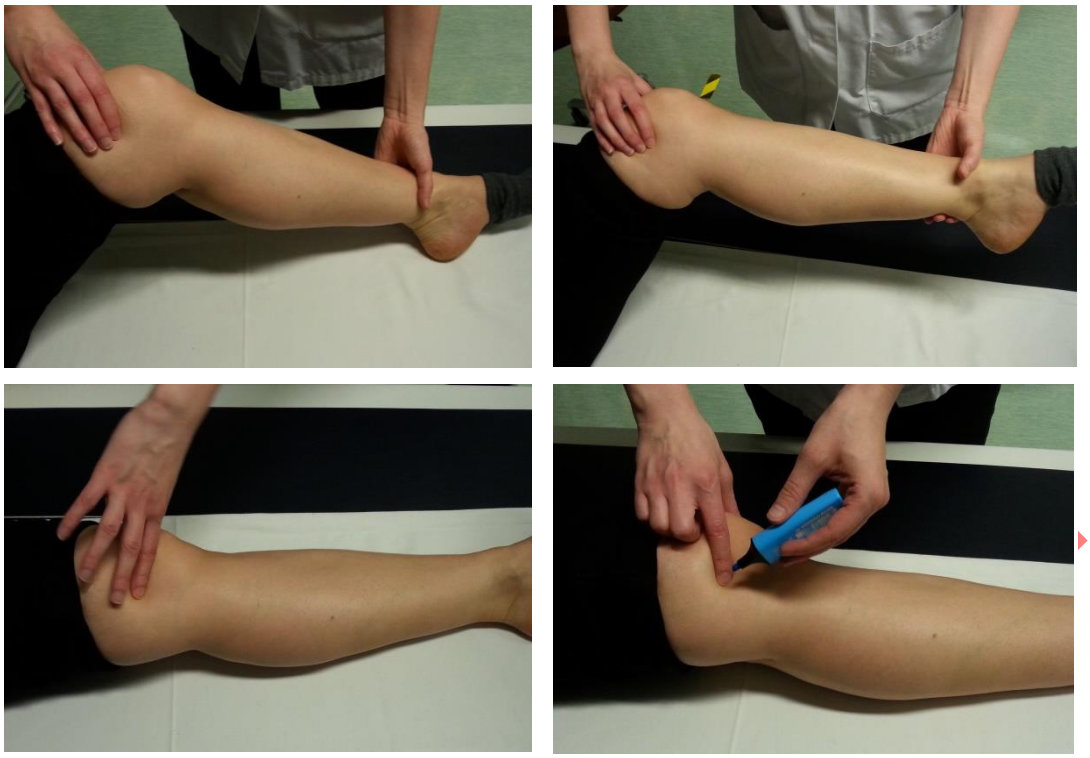


Figure 25: Locating and marking the knee joint. First you must locate the upper head of the tibia or the knee joint.

Put the arrow head of Bindex® Measure on the distal head of tibia (on the medial malleolus, see Figure 26). Check the number on the scale 1 (or A) at the mark on the knee joint (e.g. number 12 in the Figure 27). After this, find the same number on the scale 3 (or C) (mark this number as in Figure 27). This is the measurement site.

This site is 1/3 of the length of the tibia from the upper head (Figure 27 and Figure 28). Please enter this number to in the **Locations** page of Bindex Standalone Software (Figure 29). After this you can press the NEXT button and continue.

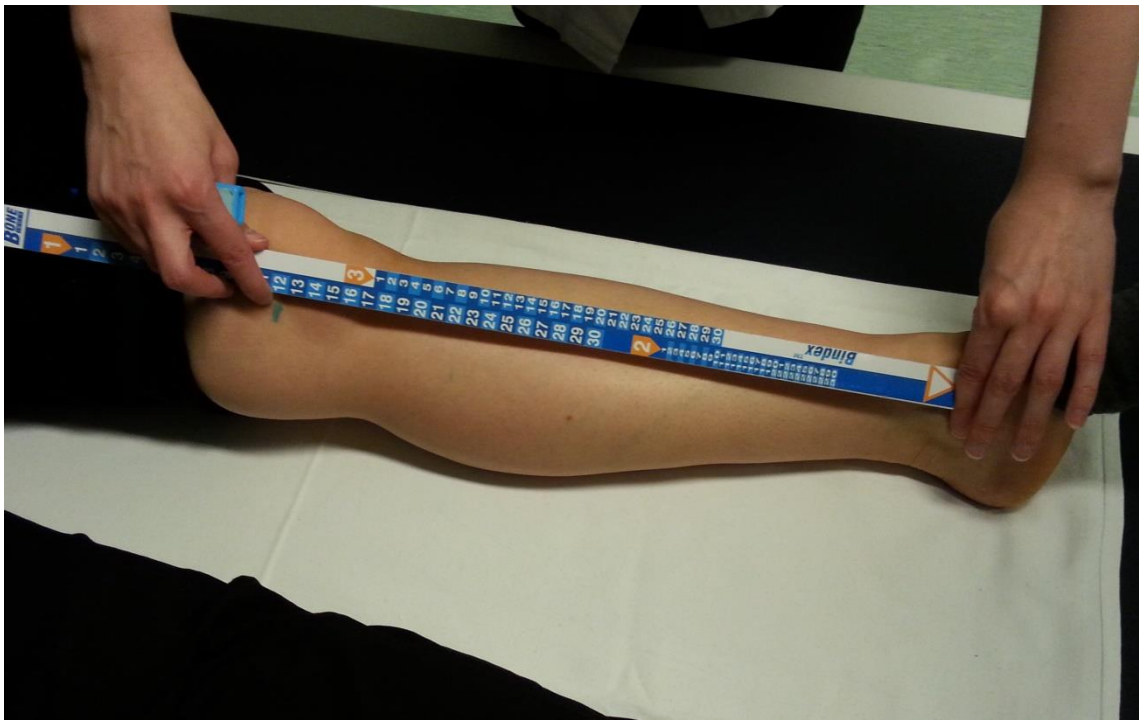


Figure 26: Locating the distal head of tibia. The arrow head of the stick is located on the medial malleolus. After this, check the number on the Bindex® Measure at the mark at the knee joint.

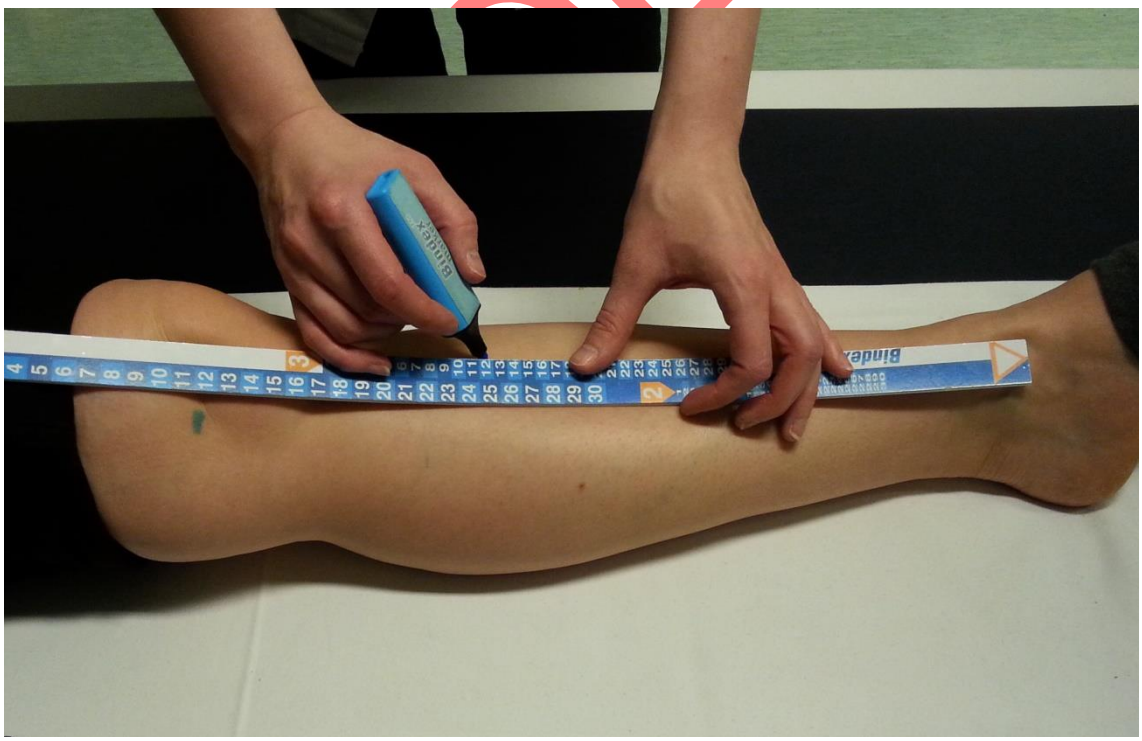


Figure 27: Locating the measurement location. The right measurement location can be found at the same number on scale 3 (or C), e.g. number 12 in this picture.

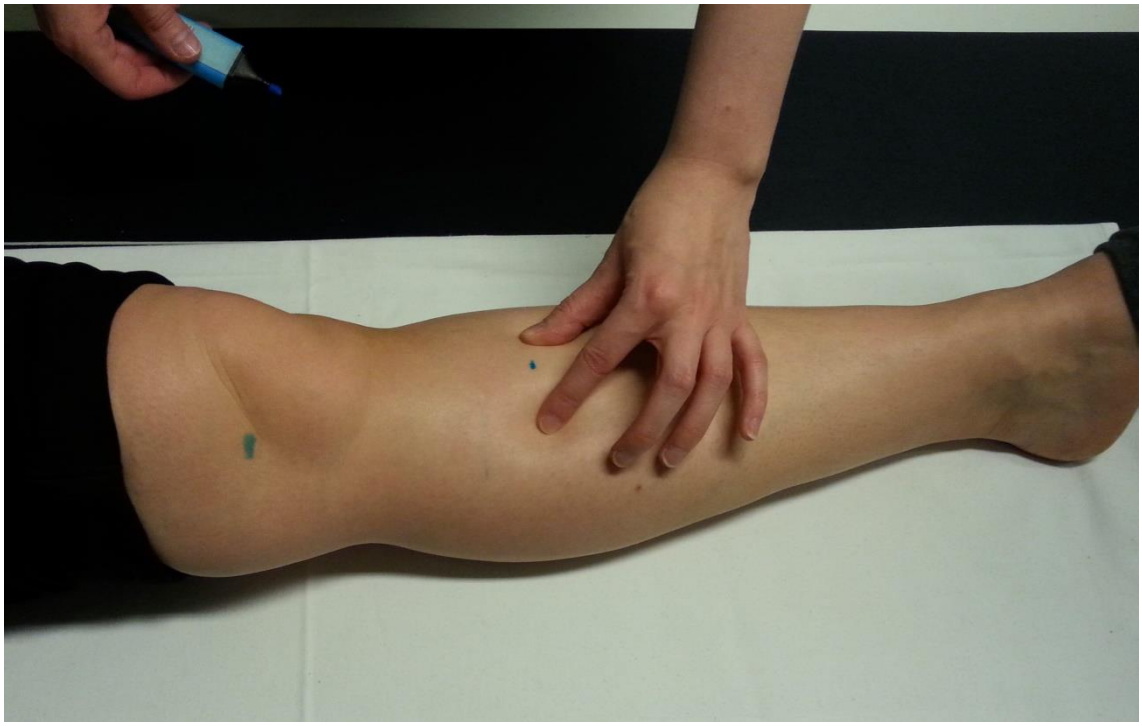


Figure 28: The tibia typically has a plate-like cortical surface at this site. The measurement should be made at the center of cortical bone plate.

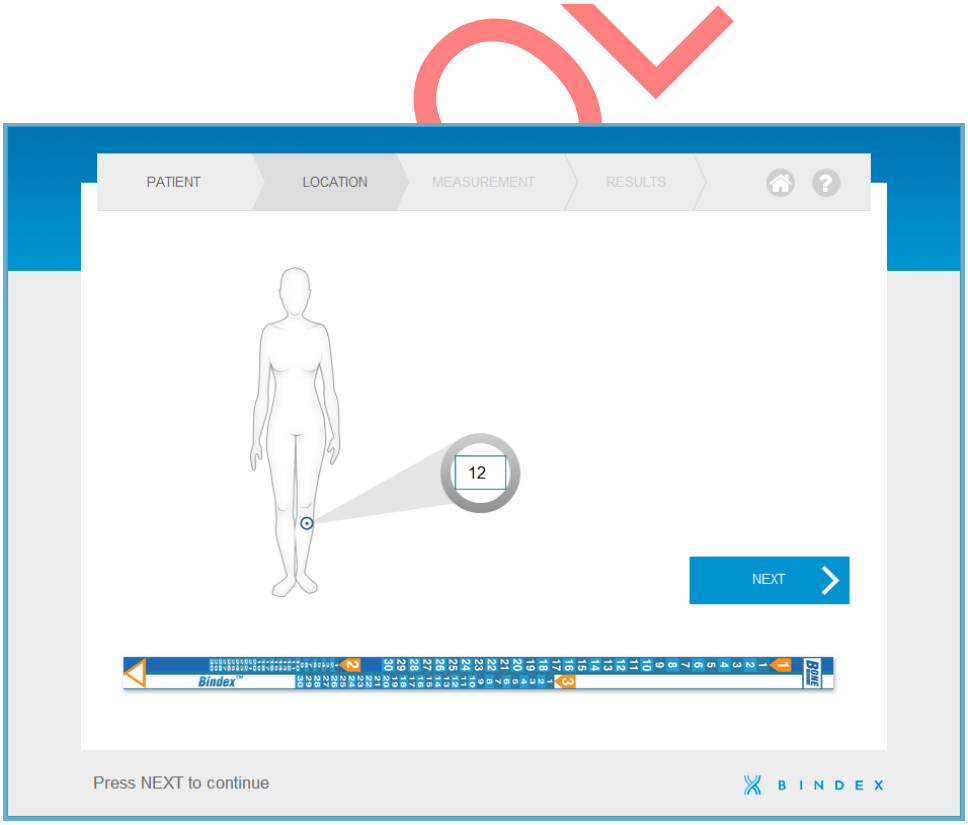


Figure 29: Enter the measurement location number from the Bindex® Measure to the software.

8.5. 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 30) and press the CALIBRATE button (Figure 31). 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 32).

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.

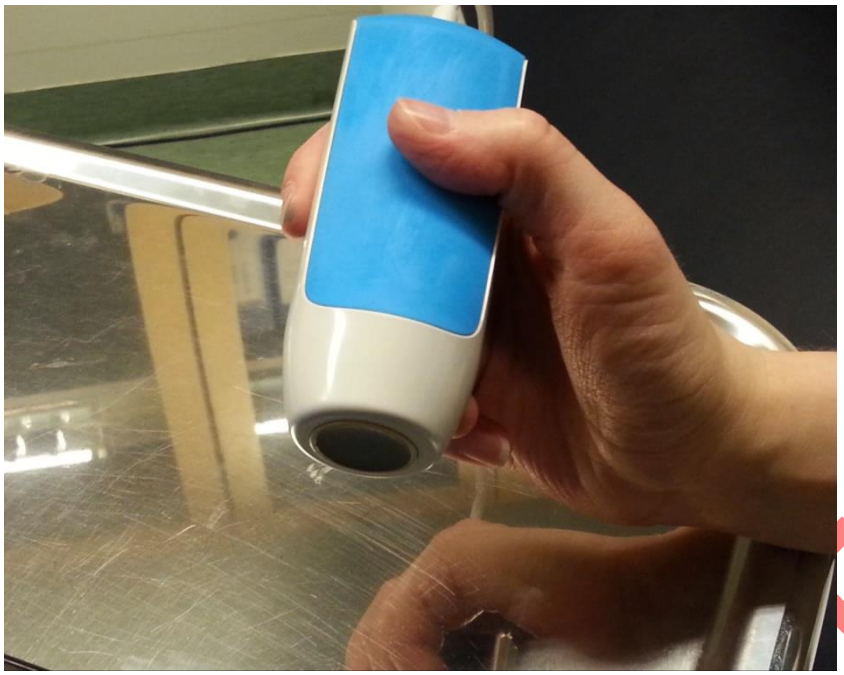


Figure 30: The transducer head should be freely in air when you press the CALIBRATE button.

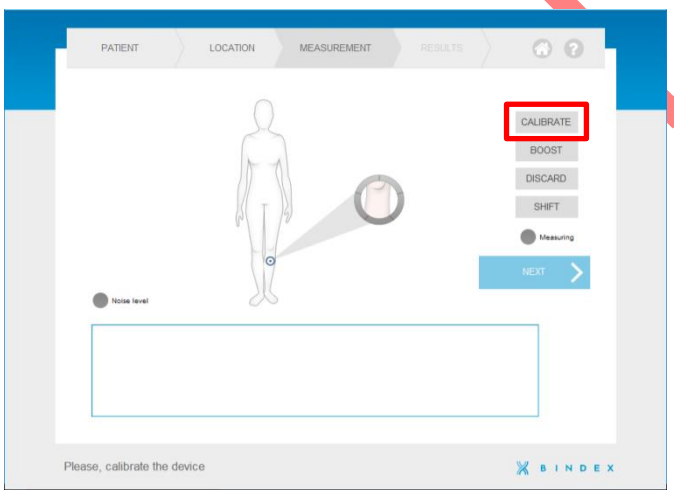


Figure 31: The CALIBRATE button. The button for calibration is located at the upper right corner. Measurement cannot be started before a successful calibration.

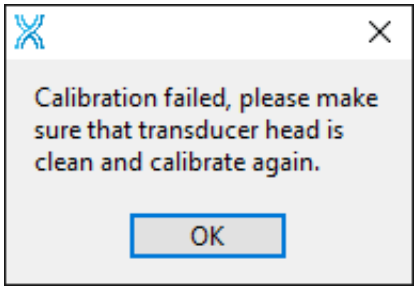


Figure 32: A failed calibration. Software notifies the user if the calibration was not successful.

8.6. Measurement with Bindex®

To begin the measurements, 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 33). 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 33). 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.

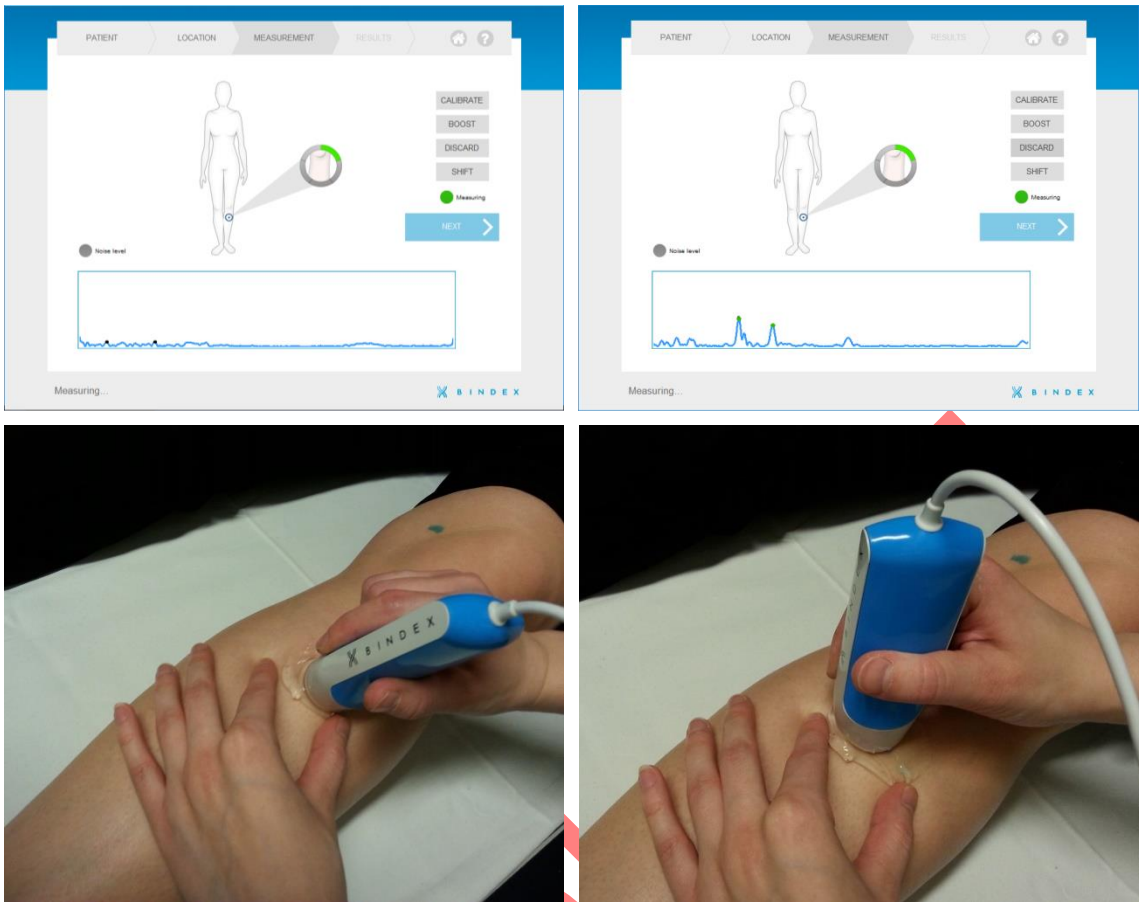


Figure 33: Conducting the measurement. First put the transducer next to bone and then move it over the bone. Keep an eye on the ultrasound signal on the signal window. When you see two echo spikes in the signal you are at the right location.

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 8.7 Signal Acceptance Window.

When a measurement is accepted the software makes a sound 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 8.7 Signal Acceptance Window

PLEASE NOTE: If you do not see two echo spikes or the spikes are too weak for acceptance you can add gain to the signal by pressing the on-screen "BOOST" button or spacebar on the keyboard of your computer. Boost will amplify the signal (Figure 34). Additional boost is removed when the measurement is restarted. Press the measurement circle again to start measuring again without boost.

Do not touch the connectors of the computer and the patient at the same time.

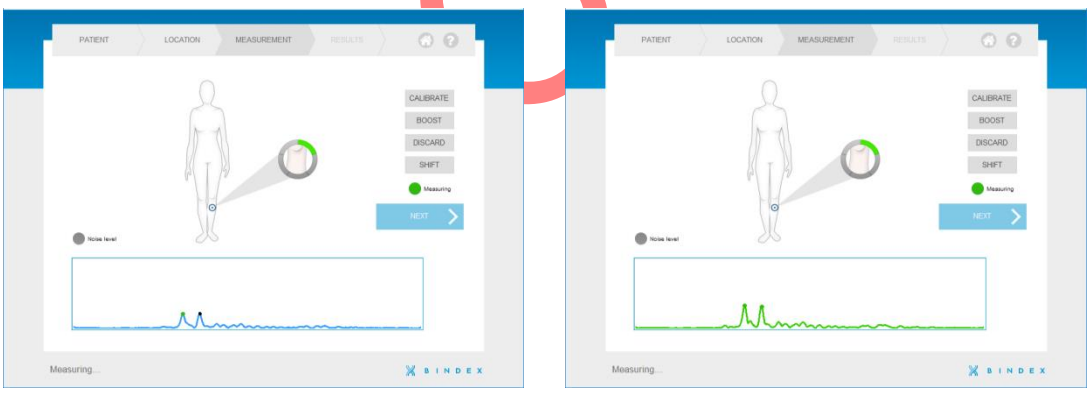


Figure 34: The use of the BOOST button. Measurement signal before (left) and after (right) boost effect.

If the software accepts a signal which is too noisy (Figure 35) 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 40).

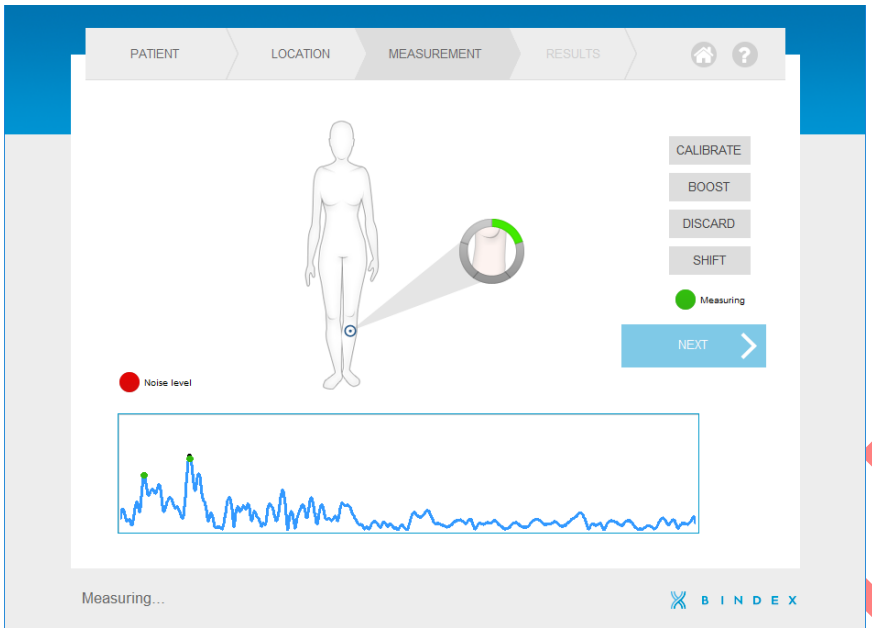


Figure 35: A noisy signal. If you use too much amplification you may see a very noisy signal. Now there are many strong echo spikes. An acceptable measurement only includes two strong spikes.

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.

8.7. Signal Acceptance Window

After the five measurements on a site the accepted signals from each repetition are shown in separate signal boxes (Figure 36). This enables you to monitor the quality of measurements and to remove faulty or inaccurate measurements from the series.

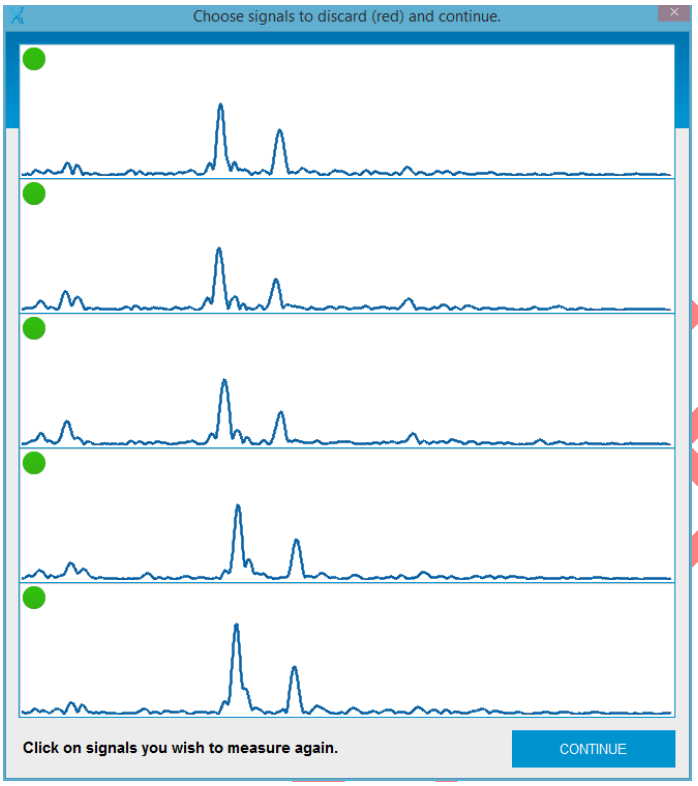


Figure 36: Window for accepting or discarding the measured signals. In this example the measurements are uniform and are therefore all accepted.

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 37). A green indicator is shown if the signal is close to the average. The signals marked with a red indicator are removed from the measurement series and are not used for result calculations.

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 38 and Figure 39.

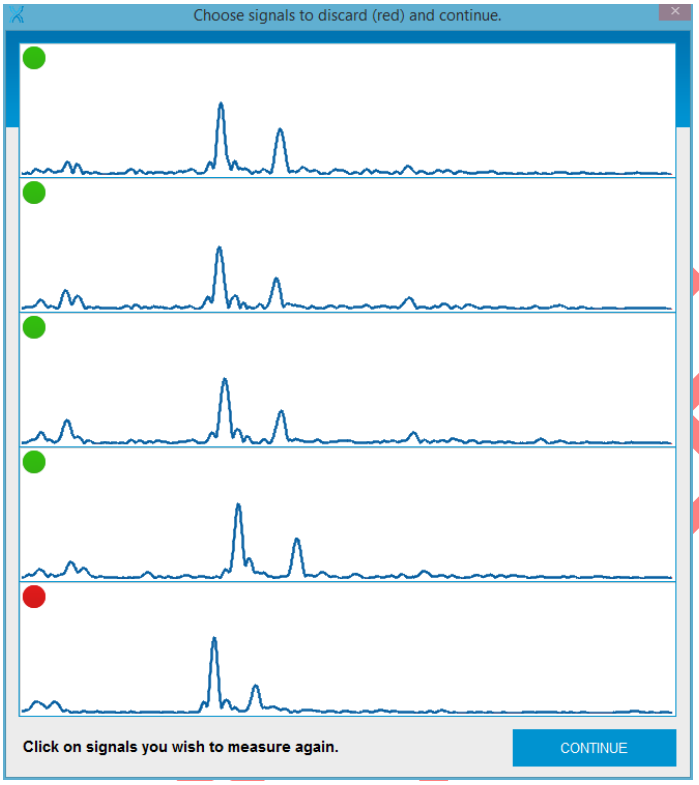


Figure 37: A signal deviating from the average. In this figure the bottom signal deviates significantly from the average of all measurements and is therefore suggested to be discarded by the software.

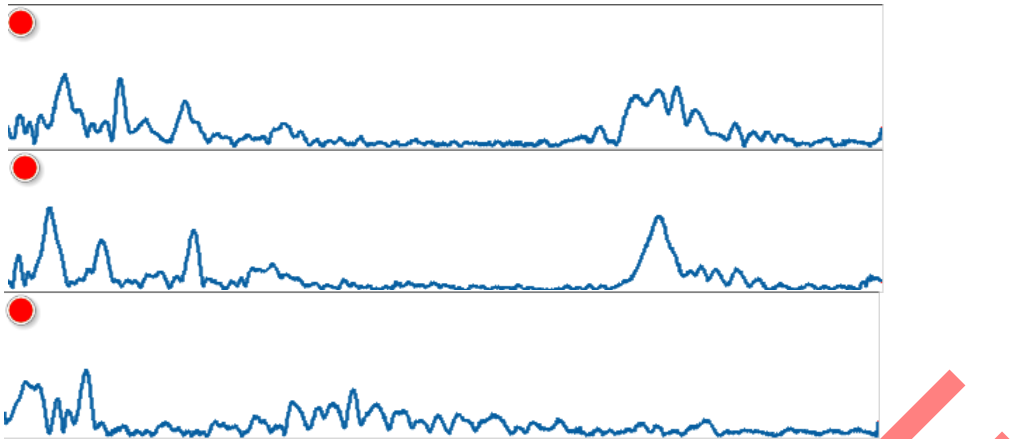


Figure 38: Excessive amplification. All signals shown in this figure should be discarded because they show too much noise and multiple high peaks due to the excessive use of the BOOST button.

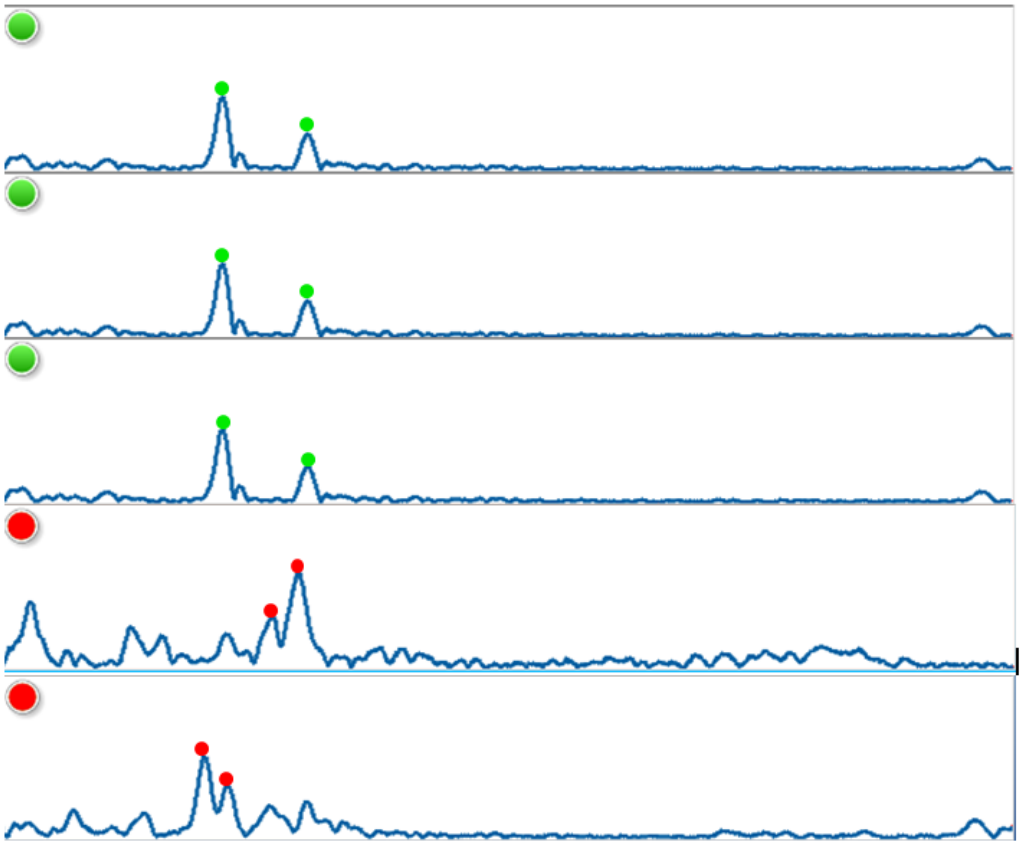


Figure 39: Incorrectly positioned probe. The lower signals marked as red deviate significantly from the average because the probe has been in a tilted position in comparison to the measurement location. The amount of noise generated in the signals is also high. The signal peaks accepted by the software 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.

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).

8.8. 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 40). 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.

Figure 40: 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 PDF report can then be printed 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 2015).

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 Density Index is calculated by using a linear model. The variables entered into the linear regression model are age, weight, height and apparent cortical thickness at proximal tibia.

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 determination of Density Index.

9. Cleaning, disinfecting and packing Bindex® BI-2

The surface of the transducer and the handpiece which comes into skin contact with the patient 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 on cleaning and disinfecting the device:

Do not allow sharp objects, such as scalpels or cauterizing knives, to touch the transducer or the cable.

Do not bump the device on hard surfaces while handling.

DO NOT immerse the device in water or cleaning liquids. The device can be sprayed lightly to moisten its surface.

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 of the solution before using it.

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.

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

To clean the Bindex® BI-2 device:

1. Wipe impurities, gel residues and other excess matter off the transducer, the handpiece and the cable 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 device and verify cleanliness.

To disinfect the Bindex® BI-2 device (after cleaning):

1. Use a soft cloth lightly dampened in disinfecting solution to wipe the surface of the transducer and the handpiece.

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

After use the Bindex® BI-2 device should be cleaned, disinfected and packed in its protective case to keep it in good condition for the entire lifetime of the device. 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

The Bindex® BI-2 device has a one (1) year warranty against defects arising from inadequate materials or craftsmanship (geographical terms and warranty periods may vary, please consult your local distributor for further information). During this time a defected device will be repaired or replaced by Bone Index Finland free of charge (delivery charges may apply). You can arrange a warranty service by contacting your local distributor or Bindex Support and Service (see section 12 for contact details). Do not try to service or repair the device by yourself, but please contact your local distributor or Bindex Support and Service. There are no self-serviceable or replaceable parts.

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 amount 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.** Should the label become illegible or break loose from the device, it needs to be replaced by Bone Index Finland. Please contact your local distributor Bindex Support and Service for further guidance.

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 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.

12. Contact information

Please use your local distributor as a primary contact. The contact details can be found in the information card provided in the pocket of the protective case. If no distributor has been declared, please contact Bindex Support and Service.

General contact address:

UNITED STATES:
Bone Index Finland Ltd.
3710 Rawlins St., Suite 1420,
Dallas, TX 75219,
USA

tel. 469.805.5419
info@boneindex.fi

INTERNATIONAL:
Bone Index Finland Oy
Microkatu 1,
70211 Kuopio,
FINLAND

tel. +358 50 448 1696
info@boneindex.fi

Bindex Support and Service:

Email: info@boneindex.fi
Phone: + 358 50 448 1696

13. Troubleshooting

In case of errors or other issues with Bindex Standalone Software, see if there are 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.

13.1. Installing the software

Question: I opened the activation file but the software tells me that the activation has failed (Figure 41).

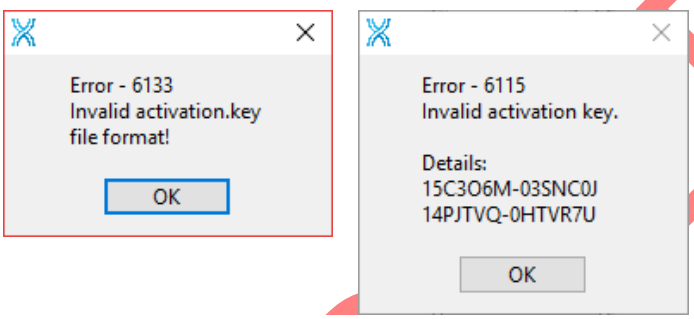


Figure 41: Failed activation notifications.

Answer: This usually occurs when trying to open an incorrect activation file. Please try opening the activation.key file again. If you have renewed your activation due to an expired license, please check that you are trying to open the latest activation.key file sent to you. If the problem persists, contact Bone Index Finland Ltd. and explain your situation.

Question: I tried to run the Bindex® Standalone Software but it showed me an error message (6122 or 6123). What does it mean and how should I proceed?

Answer: This error and notification may come up if you have changed your system time and date after installation. After receiving this error you need to restart the software and contact Bone Index Finland Ltd. to receive a new

activation.key file.

Question: I activated Bindex® Standalone Software successfully, but now I received a message saying "Failed to load FTD2XX.DLL. Are the FTDI drivers installed?" (Figure 42). What does this mean?

Answer: The error indicates that the Bindex device has not yet been connected to the computer before running and activating the program. The device drivers are installed after connecting it for the first time. For additional information please see 7.4 Device driver installation.

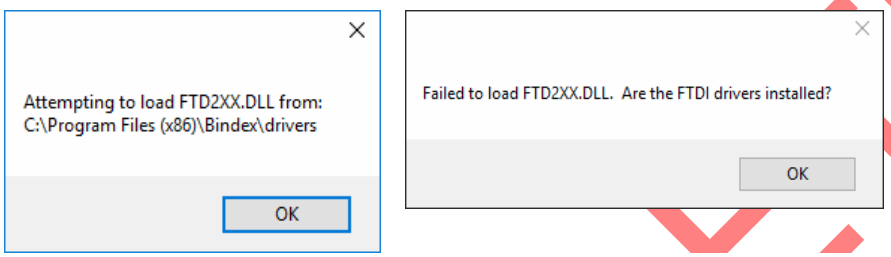


Figure 42: Bindex device not connected before running the program after activation.

13.2. Using the software

Question: I would like to measure the same patient again. When I go back to the measurement sheet it tells me that the measurement is locked. How can I measure the patient again?

Answer: Bindex® Standalone Software counts the number of analyses used and therefore the measurement is locked after visiting result sheet. You can go back to the measurement sheet but you cannot measure the locked measurement location again. To measure the patient again go to the front page, select OPEN CASE, select the patient and click OPEN. Proceed with the measurement as usual.

Question: I got an unexplained error message (Figure 43) while using the Bindex® Standalone Software. What should I do?

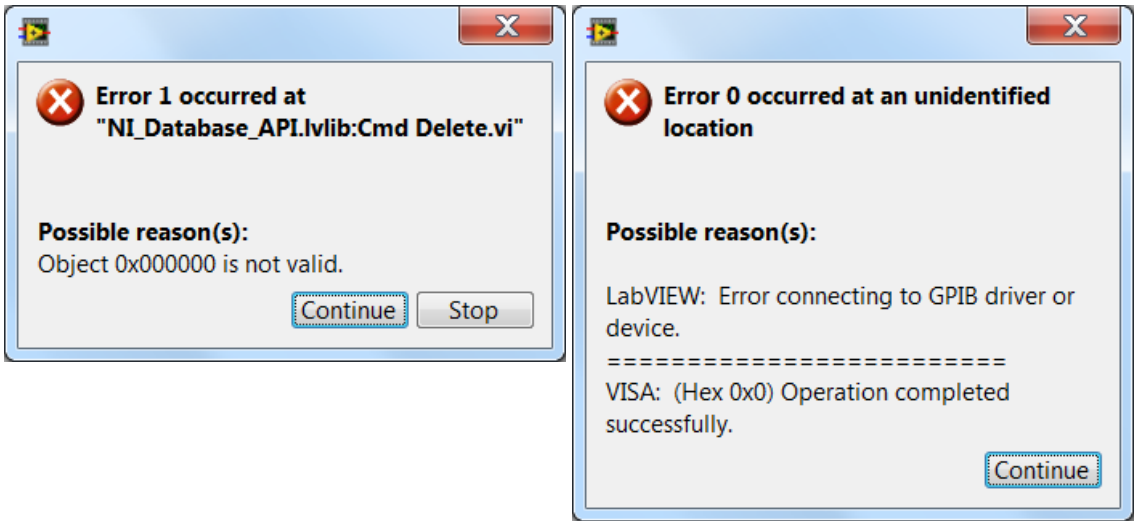


Figure 43: Example of a general error message.

Answer: In case of a general error situation you should write down the error number, location and possible reason(s) (Figure 44) and send them to Bone Index Finland Ltd. Alternatively you can take a screen capture of the error message and send it. Please explain the situation, at least where and how this problem occurred. After an error message you should not continue using the software as it cannot be guaranteed that the software works correctly. Before continuing please close the software and start again.

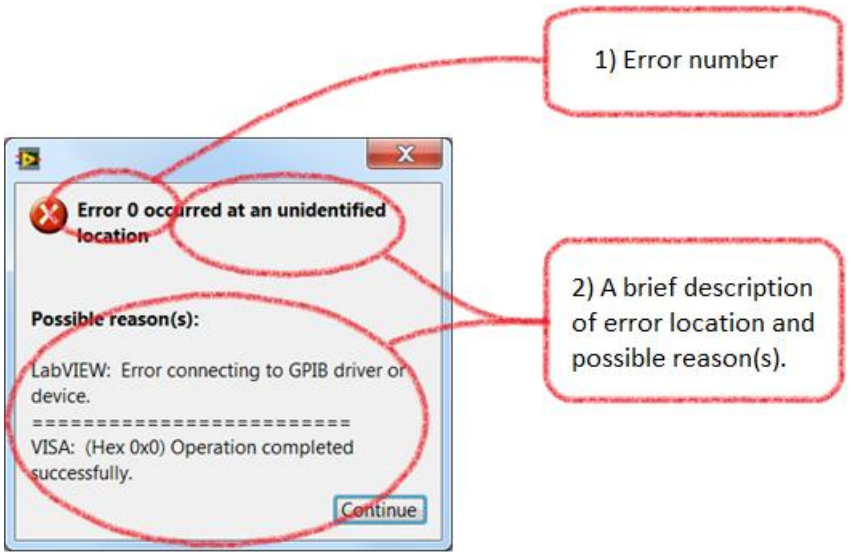


Figure 44: The information that should be sent to Bone Index Finland Ltd. after receiving an unknown error message.

Question: I receive the following error message when trying to start the program (Error – 214767259).

Answer: Bindex® Standalone Software is currently running on another user profile on the computer. Currently the database cannot be used simultaneously by multiple users. Please ask the other user or the system administrator to close Bindex® Standalone Software before trying to run it again.

Question: I receive this error message when trying to start the program about "Error 7" saying that a file is not found.

Answer: This message is displayed when the database file is not found or its location is incorrectly defined. In this case the file may have been deleted, moved or renamed so that the program cannot find it. It is also possible that the database path has been incorrectly set in the **Settings** page or "settings.ini" file.

Users with sufficient understanding of file editing may try the following: Please open "settings.ini" in Notepad and check the line "database_directory". Then check that "database.accdb" file can be found in the folder defined on the line. The "database_directory" points to another location, please correct the path. If unsure or the issue cannot be clearly identified, please contact Bindex Support and Service for assistance.

Question: I got this error message (Figure 45) while changing settings?

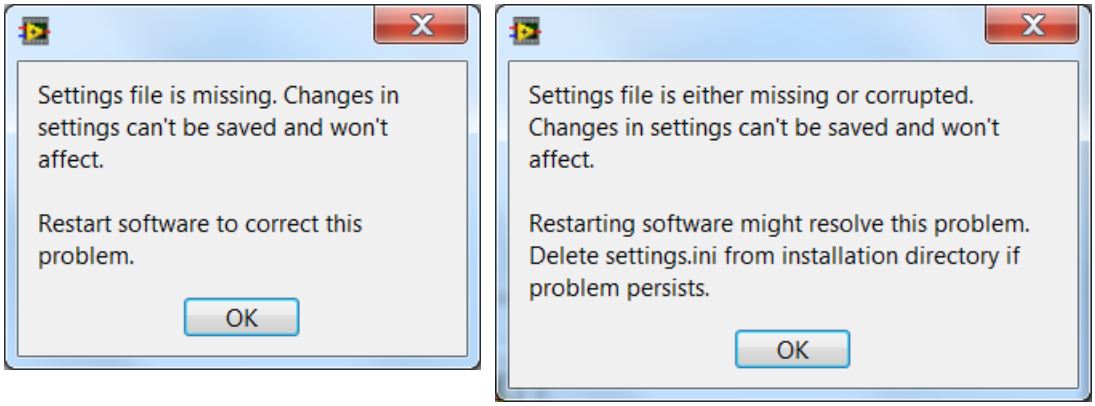


Figure 45: Error when changing software settings or at software startup.

Answer: For some reason the software either cannot locate the settings.ini file or the settings.ini file has been corrupted. Try closing the software and then running it again. If this does not help, locate the settings.ini file in the Bindex® Standalone Software directory and delete it. Then try running the software again. After deleting the settings file, you have to re-enter your user and organizational data in the **Settings** view. If the problem persists please contact your distributor or Bone Index Finland Ltd.

13.3. Measuring with Bindex®

Question: I have pressed CALIBRATE but the software says the calibration fails. What is wrong?

Answer: Remember to clean the front surface of the transducer. The software measures the echo signal from the surface of the transducer and therefore it has to be clean. If this does not work, contact your distributor or Bone Index Finland Ltd. Please write down or take a screenshot of the entire error message for more accurate pinpointing of the problem.

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Appendix: Guidance and manufacturer's declaration - Electromagnetic Compatibility

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.

Essential performance is defined as maintaining the manufacturer defined accuracy for the apparent thickness measurement even during tested electromagnetic disturbances.

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® is not suitable for use in all establishments, other than domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC6100-3-3	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	±6kV contact ±8kV air	±6kV contact ±8kV 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 for power supply lines ± 1kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T)for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Not applicable	Mains power quality should be that of a typical 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.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical 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 – Not life supporting

ELECTROMAGNETIC IMMUNITY			
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 RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of Bindex® including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800MHz $d = 2{,}3\sqrt{P}$ 80MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2,5GHz	3 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®.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4: Recommended separation distances between portable and mobile RF communications equipment and Bindex®.

Recommended separation distances between portable and mobile RF communications equipment and Bindex®			
Bindex® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Bindex® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Bindex® as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** **m**		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,3
10	3,7	3,7	7,4
100	11,7	11,7	23,3