iSHEAR

shear genius.

USER MANUAL

iShear

ishear.com

Preface

Thank you for purchasing the iShear. This manual contains information necessary for the user to become familiar with the iShear. We kindly ask you to carefully read this information before using the iShear. Make yourself familiar with the potential dangers and risks of the iShear (see Chapter 2 Safety).

This document is product-specific and therefore only applies to the product as indicated in Paragraph 1.1 Product identification. In this manual, the iShear will be referred to as 'the iShear' or 'the product'.

Refer to the table of contents at the start of this manual to locate information relevant to you. Keep a downloaded version of this manual on the device with the iShear app and/or other devices in an accessible place near the product.

For more information, please contact:

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Revision 05/2017

Table of contents

1 Introduction to this manual

1.1 Product identification

The iShear is identified by the identification sticker on the product (see Figure 1).

Figure 1 - Location of the identification sticker with serial number

Table 1 - Product Identification	
Product / Model	iShear
Serial number (SN)	6 digits. For instance 100003. See Figure 1
Manufacturer	Vicair B.V.

1.2 Target groups

This document applies to different target groups, see Table 2.

Table 2 - Target groups	
Target group	Definition
Owner	The owner of the iShear
User	The operator of the iShear and iShear app. No special skills or training necessary.
Client	The person sitting in the wheelchair

1.3 Glossary of terms

Terms that are used in this document are defined in Table 3.

Table 3 – Glossary of terms	
(iShear) App	The iShear application for Apple iOS and Android devices, see Paragraph 3.3
Bluetooth	A Bluetooth Low Energy (BLE / Bluetooth Smart) connection between the iShear and the device with the iShear app is necessary.
Client	Person sitting in the wheelchair
File	A saved single measurement of TSF
Force Unit	The unit in which the TSF is measured: Kilograms (Kg), Newton (N) or Pounds (Lbs)
iShear	The physical product, see Paragraph 3.2 iShear
Lateral flaps	The left and right sides of the iShear mat
Log	A saved over-time measurement of TSF
Log session	Continuous measuring over a set time period
Menu symbol	
Seat plane	The horizontal plane between wheelchair seat base and the wheelchair cushion
Sensor bar	The aluminium bar of the iShear
Share	Share File(s) or Log(s)
Sync	Synchronise saved Logs between iShear and iShear app
TSF	Total shear force in the seat plane measured by the iShear (anterior – posterior force parallel to the seat plane)

1.4 Symbols used in this manual

The symbols below will be used on the product and throughout this manual to focus the attention of the user on important information

Table 4 – Used symbols	
Manufacturer	
Date of manufacture	
Serial number (on sensor bar – see Figure 1)	
Lot number (on mat label – for example 27.01.2017)	
Caution: Consult instructions for use for important cautionary information such as warnings and precautions	
CE	
Protected against tools, wires etc. greater than 2.5 millimeters. Protected against dripping water	IP31
Keep dry	
Do not dispose of with other waste products; contact the manufacturer for instructions Waste Electrical and Electronic Equipment recycling Directive: Battery	
Model or Type:	iSHEAR
FCC ID : ZAT26M1 IC : 451H-26M1	

⚠ DANGER	Danger! The signal word that indicates a hazard with a high level of risk which, if not avoided, will result in death or serious injury.
⚠ WARNING	Warning! The signal word that indicates a hazard with a medium level of risk which, if not avoided, could result in death or serious injury and/ or cause serious damage to the product.
⚠ CAUTION	Caution! The signal word that indicates a hazard with a low level of risk which, if not avoided, could result in minor or moderate injury and/or cause damage to the product.
NOTICE	Notice The signal word that indicates information considered important, but not hazard-related (e.g. messages relating to property damage).

1.5 Disclaimer

The product owner is responsible for ensuring that only the latest revision of this document is used, as supplied by Vicair. The latest revision of this manual can be found in the iShear app and at iShear.com/support. Make sure to install app-updates when provided. The user of the iShear should always have a downloaded offline version of the manual available for reference. Furthermore, the product owner is to ensure that the user is aware and in possession of this document and is familiar with its contents.

2 Safety instructions

This chapter informs the user of the iShear about safety. It is important to read and adhere to these instructions. Safety instructions are also mentioned in the chapters to which they apply.

⚠ WARNING

- Improper use and/or care of the iShear may lead to improper measurements, malfunction, failure or damage to the iShear.
- Do not use the iShear with clients weighing less than 45 kg / 99 lbs or more than 120 kg / 264 lbs.
- Do not use the iShear in temperatures below -10° C / 14 F or higher than 40° C / 104 F.
- Do not pivot on the iShear.
- Do not pull at the sides and/or the sensor bar of the iShear when the client is seated on the cushion.
- Do not remove the iShear when the client is seated on the cushion.
- Do not pull at the sensor bar and/or use excessive force when removing the iShear.
- Do not soak the iShear in fluids, keep away from water, (bodily) fluids and humidity.
- Do not continue to use the iShear when it is soiled with urine or soaked with any other kind of fluid. Contact Vicair.
- With incontinent clients, ensure incontinence material is being used when using the iShear.
- Before each session check the iShear for any visible damage to the sensor bar and/or mat (holes, tears, torn seams, dents etc.). In case of any visible damage, do not use the iShear. Contact Vicair.

⚠ CAUTION

- Do not remove the mat from the sensor strips of the iShear.
- Do not place the client directly on top of the iShear.
- Before starting a session with a new client, the iShear must be disinfected to avoid cross contamination.
- An iShear session may only be performed with the iShear placed underneath a seat cushion.
- Do not pinch or wrinkle the iShear.
- Do not fold the iShear in any other way than in the way it is originally placed in the storage case.
- Do not place any objects on top of a folded iShear.
- Do not use excessive force when placing the iShear in the chair.
- Be careful when using secondary positioning systems to transfer the client into the chair, as they may damage the iShear or alter its measurements.
- Check after transferring the client if the iShear and cushion are still in correct position.
- Always store the iShear in the original iShear carrying case after each session.

- If the iShear is not in use for an extended period, remove the batteries from the battery compartment of the sensor bar.
- Do not use undiluted bleach or Hydrogen Peroxide to clean the iShear.
- Cleaning products or disinfectants must be thoroughly wiped off the iShear mat after cleaning/disinfecting. Allow the iShear mat to dry thoroughly before use or storage.

NOTICE

- Make sure that the lateral parts of the cushion are in between the lateral flaps of the iShear.
- Make sure that the lateral flaps of the iShear are not covering the top of the cushion.
- Make sure there is no loss of seat depth when placing the iShear in the wheelchair.
- Measurement data and patient data are not in any way collected or stored by Vicair.
- Within the app you have the option to store patient information. It is the user's responsibility to safeguard this (sensitive) patient information.
- Measured values can be different with different client weight.
- The iShear is not a product selection tool.
- Friction in the back system could create a different TSF value.
- The values measured by the iShear do not provide an indication of the risk of tissue damage.
- Because of internal friction measured values between -2 kg and 2 kg are less accurate.
- A (re-)calibration of the sensors may only be performed after specific instructions from Vicair.
- For safe disposal of the iShear: please contact Vicair for instructions.

3 Product description

The iShear is a medical device that measures the sliding force in the seat plane of a client sitting in a wheelchair. The iShear app is the user interface of the product.

In this manual 'sliding force' will be referred to as 'TSF', as explained in 3.1.1.

By using the iShear and iShear app you can measure the TSF in different wheelchair set-ups and create a situation in which TSF is as low as possible. This decreases the negative effects of TSF on the client.

3.1 TSF

3.1.1 Explanation of TSF

The total shear force in the seat plane measured by the iShear is the anterior-posterior force parallel to the seat plane. It is measured between the cushion and the seat base interface. From now on we will refer to this as TSF. This paragraph further explains this definition.

In Figure 2 the client is sitting upright in the wheelchair. The forces shown in figure 2 are the vertical forces, perpendicular to the seat plane. The weight of the client pushes down on to the cushion (gravity – green arrows) and the cushion 'pushes back' with a force in the opposite direction (normal force – red arrows).

In Figure 3, the client is leaning against the back support. This situation introduces horizontal forces, parallel to the seat plane. Besides the vertical forces, the client exerts a horizontal force into the back support and the back support 'pushes back' with a horizontal force in the opposite direction (red arrow in back support).

In addition, there are horizontal forces in the seat plane. Because the client is pushing back in the back support his/her body consequently pushes forward in the seat plane (green arrow in seat plane). This horizontal force in the seat plane is the 'sliding force' and what is referred to as the TSF in this document. The red arrow in the seat plane is the friction force.

Figure 2 - Situation without sliding forces

Figure 3 - Situation with sliding forces

3.1.2 Wheelchair settings that influence TSF

In a clinical setting, the TSF can be influenced by setting up the wheelchair and its components. TSF variations can be expected with variations in (e.g.):

- Seat angle
- Back angle
- Tilt angles
- Foot supports
- Back support interventions
- Shell back supports
- Tension adjustable back supports
- Custom molded back supports
- Non-adjustable back supports
- Propulsion (hand and foot propulsion)
- Secondary support systems

3.2 iShear

The iShear consists of the following components (see Figure 4, 5 and 6):

- Sensor bar (see Figure 5)

The Sensor bar is made of aluminium. It holds:

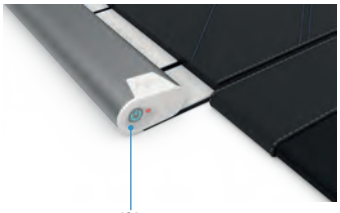
  - On/Off button
  - On/Off indicator light
  - Battery compartment
  - Button to unlock battery compartment
  - Bluetooth connection device
  - Log session indicator
  - U-shaped metal profile
  - Product identification sticker (see Figure 1)

- Sensor strips (see Figure 6)
- 4 AAA batteries
- Mat

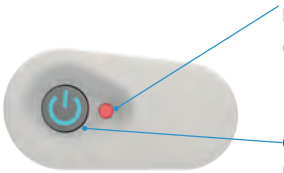
The iShear mat has a zero friction middle layer and a high friction top layer. The left and right sides of the mat are referred to as 'lateral flaps' (see Figure 4).

The iShear is equipped with a carrying case (see Figure 7)

Figure 4 - Components of the iShear



On/off button



Log session indicator light (flashing)

On/off indicator light (flashing)

Button to unlock battery compartment

Battery compartment for four AAA batteries

Figure 5 - Sensor bar components

Figure 6 - Sensor bar with sensor strips and U-shaped metal profile for stabilisation

Figure 7 - Carrying case

3.3 iShear app

Measurements of the iShear are registered by the iShear app. It is the user interface of the iShear and features the following functions:

- Single measurements of TSF
- Over-time measurement of TSF = 'Log session'
- View, share and compare measurements

For system requirements, refer to Paragraph 3.5 Technical Specifications and system requirements.

3.3.1 Login screen

The Login screen is the screen that appears when you open the app without being logged in.

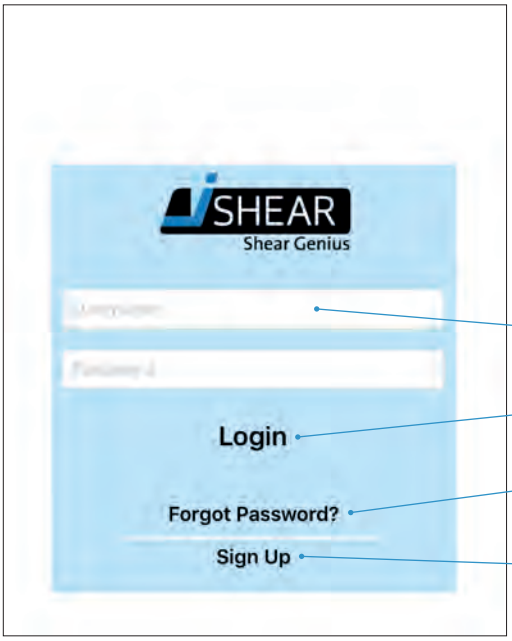


Figure 8 - Login screen

3.3.2 Connect screen

The Connect screen is the screen that appears when you open the app when you are logged in.

Figure 9 - Connect screen

3.3.3 Measurement screen

The Measurement screen is the screen from which you take measurements.

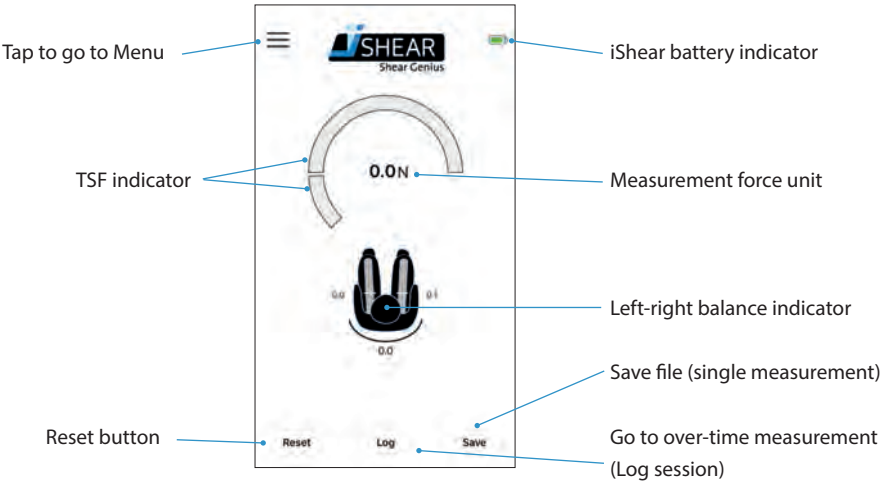


Figure 10 - Measurement screen

3.3.4 Menu screen

The Menu screen can be entered either by swiping to the right or tapping the Menu button.

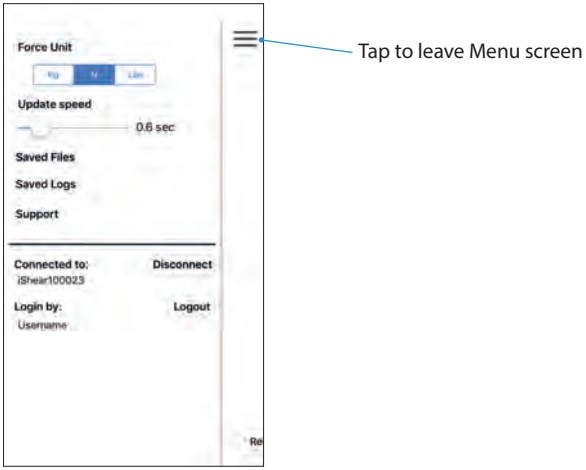


Figure 11 - Menu screen

Functions (see Figure 11):

- Force Unit: set the force unit to Kilograms (Kg), Newton (N) or Pounds (Lbs)
- Update speed: set the update interval for the measurement
- Saved Files: show saved single measurements
- Saved Logs: show saved Log sessions (over-time measurements)
- Support: go to Support screen
- Connected to: shows currently connected iShear
- Disconnect: disconnects the iShear from the app
- Login by: connected username
- Logout: Log out your user account

3.3.5 Support screen

NOTICE	• A (re-)calibration of the sensors may only be performed after specific instructions from Vicair.

The Support screen (Figure 12) can be entered via the Menu screen. There you can find the serial number of the connected iShear, its firmware version and the app version.

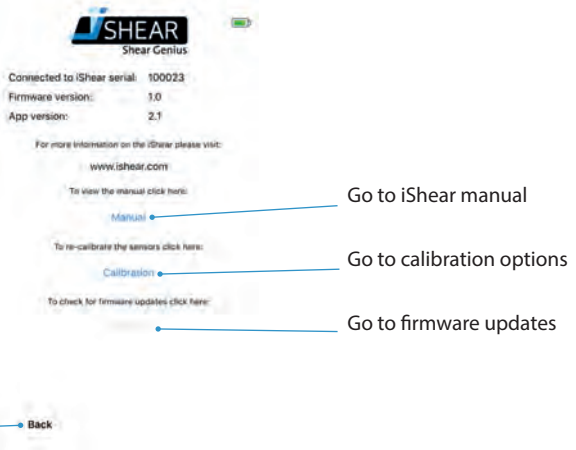


Figure 12 1- Support screen

3.4 Intended use and reasonably foreseeable misuse

⚠ WARNING	• Do not use the iShear in temperatures below -10° C / 14 F or higher than 40° C / 104 F. • Do not use the iShear with clients weighing less than 45 kg / 99 lbs or more than 120 kg / 264 lbs. • Improper use and/or care of the iShear may lead to improper measurements, malfunction, failure or damage to the iShear.
NOTICE	• Measurement data and patient data are not in any way collected or stored by Vicair. • Within the app you have the option to store patient information. It is the user's responsibility to safeguard this (sensitive) patient information. • The iShear is not a product selection tool • The values measured by the iShear do not provide an indication of the risk of tissue damage. • A (re-)calibration of the sensors may only be performed after specific instructions from Vicair.

The iShear is intended for measuring the total shear force in the seat plane of a client sitting in a wheelchair. It is intended to be used in combination with the iShear App, using a Bluetooth connection (Bluetooth Low Energy/BLE/Bluetooth Smart, see 3.5 Table 5).

Misuse can occur when the iShear is used beyond its capacity, capability or operational boundaries (see Paragraph 3.5 Technical Specifications and system requirements). Misuse can also occur if one does not keep to the safety precautions (see Chapter 2 Safety) or use the iShear for any other purposes than defined in this chapter.

Clinical applications include:

- Evaluate total setup of the wheelchair in combination with pressure mapping
- Measure the influence of seat and back angles on TSF
- Evaluate different seat and back solutions on TSF
- Evaluate effect of leg positioning on TSF
- Determine rotational forces in the seat plane
- Evaluation of a pelvic angle tilt/rotation on the TSF
- Measure TSF over time
- Evaluate the influence of secondary positioning aids on TSF
- Educational purposes (end users, care givers)

The iShear helps you to set up a wheelchair. The values measured do not provide an indication of the risk of tissue damage.

3.5 Technical Specifications and system requirements

Table 5 – Technical Specifications and system requirements

• Weight:	1,7 kg / 3.75 lbs
• Dimensions (HxWxD)	27 x 690 x 615 mm / 1.06 x 27.17 x 24.21 inches
• Material sensor bar:	aluminium
• Material top layer mat:	PU coated tricot and nylon fabric
• Batteries:	4 AAA 1,5V LR03 batteries
• Supported operating systems:	iOS 8.0 or newer, compatible with iPhone, iPad and iPod Touch Android 4.3 or newer
• Connection requirements:	Bluetooth Low Energy (BLE, also known as Bluetooth Smart). This Low Energy Bluetooth version is in general available on devices since 2011 (first BLE version was Bluetooth 4.0).

• Wheelchair requirements:	The iShear can be used in a seat plane of 35-50 cm / 13¾-20 inch width (X) and 35-50 cm / 13¾-20 inch depth (Y). (see Figure 12).The back-support canes must be at least 30 cm / 11.8 inch apart from each other
• Allowed user weight on the iShear:	Minimum: 45 kg / 99 lbs, Maximum: 120 kg / 264 lbs
• Ambient temperature	Minimum: -10 °C / 14 F, Maximum: 40 °C / 104 F
• Relative humidity	Operating: 30 to 75% RH (non-condensing) Storage: 10 to 100% RH (non-condensing)

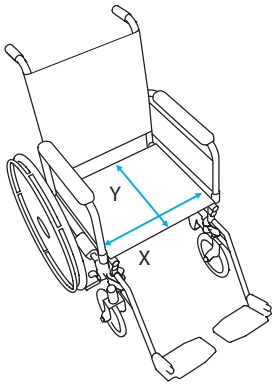


Figure 12-2 - Wheelchair requirements

4 Before using the iShear

4.1 Preparing the iShear

⚠ WARNING	• Before each session check the iShear for any visible damage to the sensor bar and/or mat (holes, tears, torn seams, dents etc.). In case of any visible damage, do not use the iShear. Contact Vicair.
⚠ CAUTION	• Do not fold the iShear in any other way than in the way it is originally placed in the storage case. • Do not place any objects on top of a folded iShear. • Do not pinch or wrinkle the iShear. • Do not remove the mat from the sensor strips of the iShear.

To make the iShear ready for use:

1. Take the iShear from its carrying case.
2. Unlock the battery compartment (see 3.2 Figure 5), take it out of the sensor bar and place 4 AAA batteries in the compartment.
3. Re-insert the battery compartment into the sensor bar.

4.2 Downloading the iShear app

The iShear app is currently only available for Apple iOS devices running on iOS 8.0 or newer and Android devices running on Android 4.3 or newer.

When you are going to use your own personal device (phone/tablet) with the iShear download the iShear app on that device.

When your company or institution uses one company-owned device (phone/tablet) that stays with the iShear, download the app on that shared device.

To download the iShear app:

1. Go to the app store / play store and search for 'iShear'.
2. Tap 'Download' and install the app.

4.3 Signing up and Login

1. Tap 'Sign Up' in the Login screen. (see Figure 13)
2. When you use your own personal device (phone/tablet) to download the iShear app on, you can choose to sign up with an individual account using your own email address. When your company or institution uses one company-owned device (phone/tablet) that stays with the iShear, download the app on that shared device. In this case it might be useful to create a shared company account with the company name as user name and a general company email address. (see Figure 14)
3. After filling in a username, email address and your password (the same password twice), check the 'I agree to the terms and conditions' box.
4. Tap 'Sign Up'.
5. You will receive a Sign Up confirmation via the email address that you have signed up with. This is to validate the used email address.
6. Confirm your email address through the link in the Sign Up confirmation email.
7. You can now go to the app and log in. The app offers to remember your account (see figure 15). If you prefer this then you can tap "Yes". Otherwise tap "No".

Figure 13 - Sign up

Figure 14 - Create an individual or group account

Figure 15 - Succesful Login- Remember account

If – at any time – it is necessary to login, you can do this by using the registered username and password.

4.4 Configuring your device

Configure your Apple or Android device so that the iShear app will work properly. Consult the user manual of your device for the following configurations:

- Bluetooth

Turn on the Bluetooth function. Bluetooth version 4 (Bluetooth Low Energy – BLE) is required to be able to connect. The iShear can now connect with your device.

- Free hard disk space

Make sure there is enough space available in order to install the iShear app and save measurements.

5 Using the iShear

5.1 Connecting the iShear with the iShear app

To establish a Bluetooth connection between the iShear and the iShear app:

1. Press the on/off button on the sensor bar (see 3.2 – Figure 5)
   A flashing blue light indicates that the iShear is turned on.
2. Open the iShear app on your device and log in with your username and password.
3. Tap 'Scan Done Press to rescan' (see Figure 16)
4. Tap the iShear you wish to connect to (see Figure 16). When the connection is successful, the Measurement screen (see Figure 10, chapter 3.3.3) will open automatically.

Figure 16 - Connect the iShear

5.2 Placing the iShear

⚠ WARNING

- Do not use the iShear with clients weighing less than 45 kg / 99 lbs or more than 120 kg / 264 lbs.
- Do not use the iShear in temperatures below -10° C / 14 F or higher than 40° C / 104 F.
- Before each session check the iShear for any visible damage to the sensor bar and/or mat (holes, tears, torn seams, dents etc.). In case of any visible damage, do not use the iShear. Contact Vicair.
- With incontinent clients, ensure incontinence material is being used when using the iShear.
- Do not pull at the sides and/or the sensor bar of the iShear when the client is seated on the cushion.

⚠ CAUTION

- Before starting a session with a new client, the iShear must be disinfected to avoid cross contamination.
- Cleaning products or disinfectants must be thoroughly wiped off the iShear mat after cleaning/disinfecting. Allow the iShear mat to dry thoroughly before use or storage.
- Do not use excessive force when placing the iShear in the chair.
- Do not pinch or wrinkle the iShear.
- Do not place any objects on top of a folded iShear.
- Do not place the client directly on top of the iShear.
- An iShear session may only be performed with the iShear placed underneath a seat cushion.
- Be careful when using secondary positioning systems to transfer the client into the chair, as they may damage the iShear or alter its measurements.
- Check after transferring the client if the iShear and cushion are still in correct position.

NOTICE

- Make sure there is no loss of seat depth when placing the iShear in the wheelchair.
- Make sure that the lateral parts of the cushion are in between the lateral flaps of the iShear.
- Make sure that the lateral flaps of the iShear are not covering the top of the cushion.

To place the iShear in the wheelchair. These steps correspond to image I-V of the Quick Guide provided with the iShear:

1. Transfer the client out of the wheelchair.
2. Remove the seat cushion from the wheelchair.
3. Place the iShear on the wheelchair seat base with the sensor bar placed horizontally between the back support canes. The lateral flaps should be folded upwards against the side guards/ armrests of the wheelchair. The space between the sensor bar and the wheelchair canes should be the same on both sides of the sensor bar (see Figure 17).

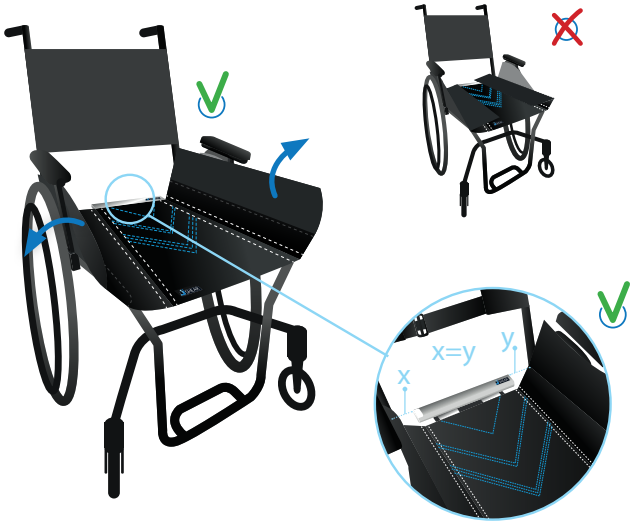


Figure 17

4. Place the seat cushion back in the wheelchair, on top of the iShear. Make sure the lateral flaps are positioned between the sides of the wheelchair cushion and the side guards of the wheelchair. The rear end of the wheelchair seat should be equal to the rear end of the iShear mat (see Figure 18).

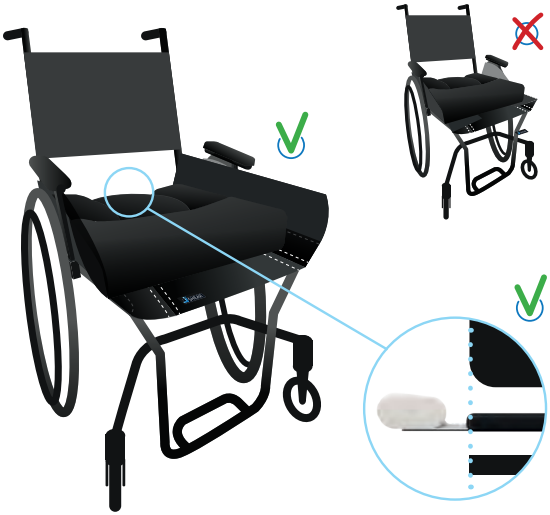


Figure 18

5. Transfer the client back into the wheelchair.

5.3 Measuring with the iShear

⚠ WARNING	• Do not pull at the sides and/or the sensor bar of the iShear when the client is seated on the cushion. • Do not pivot on the iShear. • Do not remove the iShear when the client is seated on the cushion. • Do not soak the iShear in fluids, keep away from water, (bodily) fluids and humidity. • Do not continue to use the iShear when it is soiled with urine or soaked with any other kind of fluid. Contact Vicair. • Improper use and/or care of the iShear may lead to improper measurements, malfunction, failure or damage to the iShear.
⚠ CAUTION	• An iShear session may only be performed with the iShear placed underneath a seat cushion. • Do not pinch or wrinkle the iShear.
NOTICE	• Measurement data and patient data are not in any way collected or stored by Vicair. • Within the app you have the option to store patient information. It is the user's responsibility to safeguard this (sensitive) patient information. • Measured values can be different with different client weight. • The iShear is not a product selection tool • Friction in the back system could create a different TSF value • The values measured by the iShear do not provide an indication of the risk of tissue damage. • Because of internal friction measured values between -2 kg and 2 kg are less accurate. • A (re-)calibration of the sensors may only be performed after specific instructions from Vicair.

5.3.1 Before measuring

Before measuring the TSF in different wheelchair setups, set the TSF to zero in a neutral sitting position:

1. Let the client sit upright in the wheelchair, without leaning against the back support (see Figure 19).
2. Tap 'Reset'. A popup with 'Reset value to 0' appears (see Figure 19).

Figure 19 - Sit upright and reset

Please note: Only reset before a measurement session. Do not reset once you have started measuring. This will alter the measurement data.

5.3.2 Single measurement

To take a single measurement of TSF:

1. Let the client lean against the back support (see Figure 20).
2. Wait until the real time measurement is stabilized.

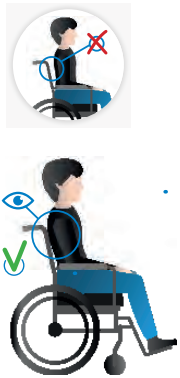


Figure 20 - Lean against back support

To save the measurement:

3. Tap 'Save' in the measurement screen (see Figure 21). The Save screen opens.
4. Tap the empty text field next to 'Patient ID' and fill in a patient ID (see Figure 22).
5. Tap the empty text field underneath 'comments' and fill in any relevant information about this measurement or wheelchair setup (see Figure 22) There is space for 200 characters max.
6. Tap 'Save' and then 'OK' in the popup screen (see Figure 23).
   The measurement is now saved.
7. Tap 'Back' to leave the Save screen.

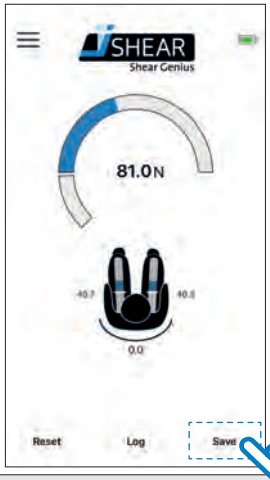


Figure 21 - Tap Save

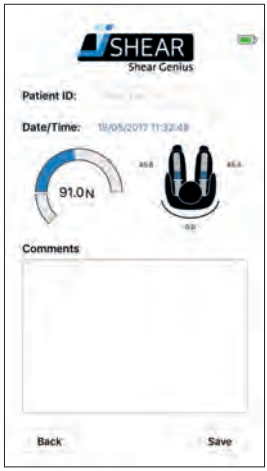


Figure 22 - Save screen

Figure 23 - Tap 'OK' to save

5.3.3 Over-time measuring (Log session)

To perform an over-time measurement of the TSF in a specific wheelchair setup over a set period of time:

1. Let the client lean against the back support (see Figure 24).
2. Tap the 'Log' button in the Measurement screen (see Figure 25). This takes you to the Log session screen (Figure 26).
3. Tap the empty text field next to 'Patient ID' and fill in a patient ID (see Figure 26).
4. Swipe up or down next to 'Duration' to set the desired duration of the measurement in hours and/or minutes (see Figure 26).
5. Tap the the desired log interval next to 'Type' to set the time interval of the measurement (see Figure 26).
   - 'Trend' = 1 measurement per 60 seconds.
   - 'Precise'= 1 measurement per 10 seconds.
   - 'Ultra'= 1 measurement per second.
   - 'Continuous'= 4 measurements per second.
6. Tap the empty text field underneath 'Comments' and fill in any relevant information about this measurement or wheelchair setup (see Figure 26). There is space for 200 characters max.
7. Tap 'Start' and then 'OK' in the popup screen with the Logging alert (see Figure 26a). Below in the Log session screen, next to 'Session Running', the left Log session time is counting down (see Figure 26).
8. Tap 'Back' to go to the measurement screen. The Log button will contain red lettering during a Log session (see Figure 27).
9. The red light of the Log session indicator on the side of the iShear Sensor bar is flashing (red) during the Log session.
10. You do not need to keep your device (phone/tablet) connected or close to the iShear that is performing the Log session. The Log session will go on for the set duration and stop automatically when the time is up.

Figure 24 - Lean against back support

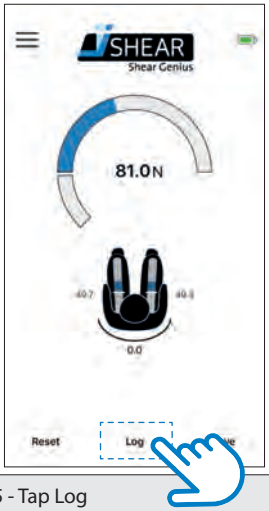


Figure 25 - Tap Log

Figure 26 - Log session screen

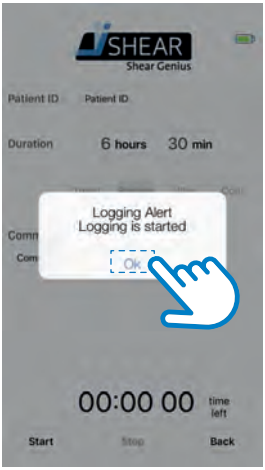


Figure 26a - Tap OK

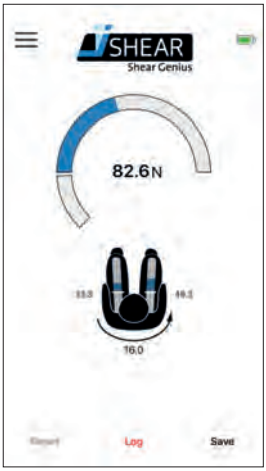


Figure 27 - Active Log session

To stop a Log session before the end of the set duration:

You do not need to keep your device (phone/tablet) connected or close to the iShear that is performing the Log session. Therefore it might be necessary to reconnect before you can stop the Log session before the end of the set duration. If your device and the iShear are still connected you can immediately perform step 4 and 5.

1. Log in (see chapter 5.1)
2. Tap 'Scan Done scan to rescan' (see chapter 5.1)
3. Connect with the iShear that is performing the Log session (see chapter 5.1)
4. Tap the 'Log' button in the Measurement screen (see Figure 25). This will take you to the Log session screen.
5. Tap 'Stop' in the Log session screen (see Figure 26). The Log session is now stopped.

5.4 Removing the iShear after measuring

⚠ WARNING	• Do not remove the iShear when the client is seated on the cushion. • Do not pull at the sensor bar and/or use excessive force when removing the iShear.
⚠ CAUTION	• Always store the iShear in the original iShear carrying case after each session. • Do not fold the iShear in any other way than in the way it is originally placed in the storage case. • Do not place any objects on top of a folded iShear.

Remove the iShear from the wheelchair:

1. Transfer the client out of the wheelchair.
2. Remove the seat cushion from the wheelchair.
3. Remove the iShear and press the on/off button on the sensor bar for 2 seconds to turn the iShear off. The blue light first flashes rapidly before it turns off.
4. Place the seat cushion back in the wheelchair.
   Make sure the cushion is used as described in the cushion operational manual
5. Transfer the client back into the wheelchair.
6. Place the iShear in the carrying case (see 6.3).

5.5 Working with saved measurements

NOTICE	• Measurement data and patient data are not in any way collected or stored by Vicair. • Within the app you have the option to store patient information. It is the user's responsibility to safeguard this (sensitive) patient information. • Measured values can be different with different client weight. • The iShear is not a product selection tool • Friction in the back system could create a different TSF value • The values measured by the iShear do not provide an indication of the risk of tissue damage. • Because of internal friction measured values between -2 kg and 2 kg are less accurate.

5.5.1 Viewing saved measurements

You can view saved measurements via the Menu screen.

5.5.1.1 Viewing saved single measurement files

1. Open the iShear app on your device.
2. Swipe to the right or tap the 'Menu' symbol in the top left corner of the screen to go to the Menu screen.
3. Choose 'Saved files' (see Figure 28). This takes you to the list of saved Files (see Figure 29).
4. Tap the File you wish to view and tap 'Open' (see Figure 29a)
5. If necessary you an add extra information to 'Comments' or edit the 'Patient ID'. Press 'Save' to save new information.

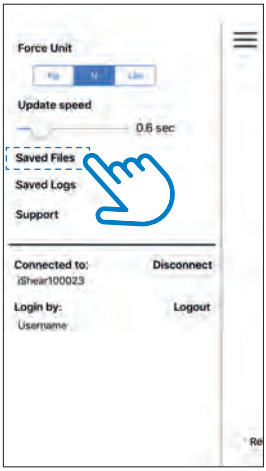


Figure 28 - Menu screen

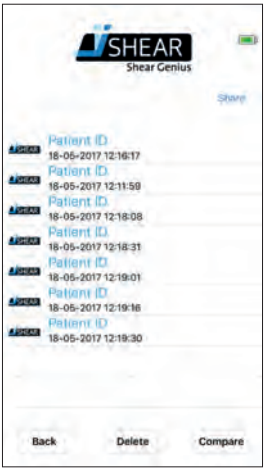


Figure 29 - Saved Files

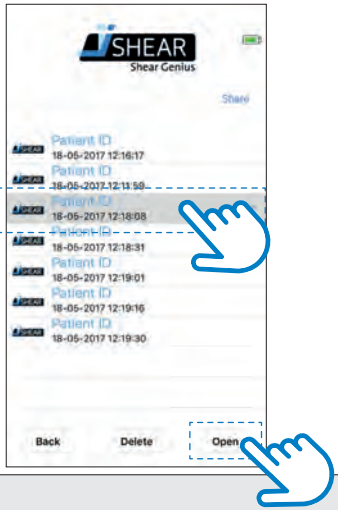


Figure 29a - Open selected File

5.5.1.2 Viewing saved over-time measurement Logs

Over-time measurements (Logs) are first saved locally on the iShear. Only the account that saved the Log can access the Log data to synchronise, view, share or delete.
A saved Log is a CSV file. You can only open (view) a Log by choosing to share it and then open in with a suitable app on your device.

1. Open the iShear app on your device.
2. Make sure you are connected to the iShear (see chapter 5.1).
3. Swipe to the right or tap the 'Menu' symbol to go to the Menu screen.
4. Choose 'Saved Logs' (see Figure 30). This takes you to the list of saved Logs (see Figure 31).
5. To make sure you see all the Logs created by your User account, you first have to synchronise the Log data. 'Sync' will be blue if you need to synchronise. Tap 'Sync' (see Figure 31). Your saved Logs are then synchronised (see Figure 32).
6. Tap the Log you wish to view and tap 'share' (see Figure 33). You can now choose the app in which you would like to open and view the Log (see Figure 33a).

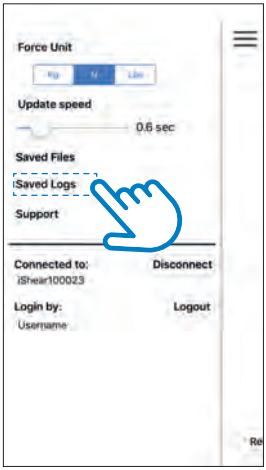


Figure 30 - Tap Saved Logs

Figure 31 - Saved Logs

Figure 32 - Syncing Logs

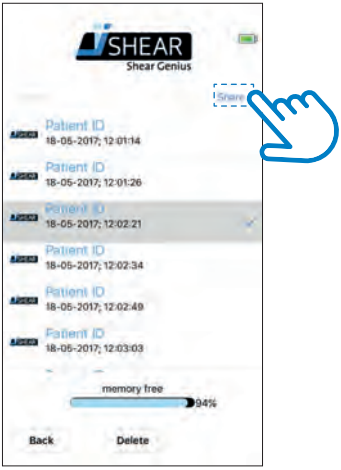


Figure 33 - Tap Share

Figure 33a - Choose app to open or share

5.5.2 Deleting saved Logs to create free memory space

Over-time measurements (Logs) are first saved locally on the iShear. Only the account that saved the Log can access the Log data to synchronise, share or delete. The 'free memory indicator' in your Saved Logs screen will show you when you need to delete saved Logs to create free memory space.

Please Note: Share your Logs before deleting!

If you wish to save created Logs for your own administration, make sure you store your saved Logs locally on your device (phone/tablet) by sharing them with yourself via email or another suitable app on your device. Otherwise this data will be lost. See 5.5.3 'Sharing saved measurements' for instructions.

To delete a Saved Log:

1. Open the iShear app on your device.
2. Make sure you are connected to the iShear (see chapter 5.1).
3. Swipe to the right or tap 'Menu' to go to the Menu screen.
4. Choose 'Saved Logs' (see chapter 5.5.1.2 – Figure 30). This takes you to the list of saved Logs (see chapter 5.5.1.2 – Figure 31).
5. To make sure you see all the Logs created by your User account, you first have to synchronise the Log data. Tap the 'Sync' button (see chapter 5.5.1.2 – Figure 32). Your saved Logs are then synchronised.
6. Tap the Log(s) you wish to delete and tap 'Delete' (see Figure 34).
7. Tap 'OK' in the pop-up screen to permanently delete the Log(s) from you device (phone/tablet) and from the iShear and the iShear app(see Figure 34a).

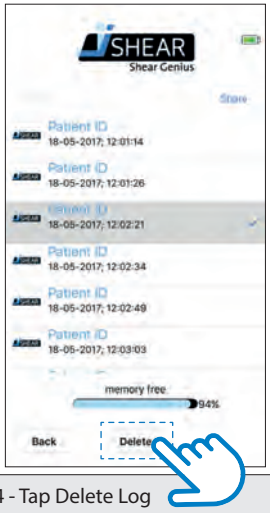


Figure 34 - Tap Delete Log

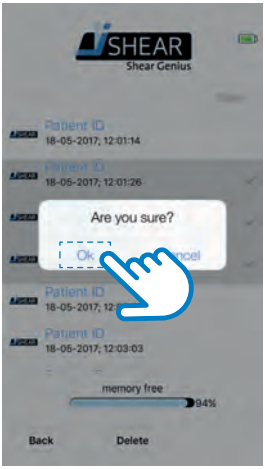


Figure 34a - Tap OK

5.5.3 Sharing saved measurements

Please note: When you choose to share multiple Files/Logs, the data will be combined in one CSV file. If you wish to receive a separate file per File/Log, then you will have to share them one at a time.

To share a saved File or Log via email or another suitable app on your device (phone/tablet):

1. Go to your list of Files or Logs (as explained in 5.5.1 'Viewing saved measurements').
2. Tap the File(s) or Log(s) that you want to share. For multiple selection simply tap more than one saved measurement (for Files there is a maximum of 5 that you can share at once).
3. Tap 'Share' (see Figure 35).You can now choose the app with which you would like to share your File(s) or Log(s) (see Figure 35a).

Figure 35 - Share File(s) or Log(s)

Figure 35a - Choose app to share

5.5.4 Comparing single measurements

You can only compare saved single measurements (Files). It is not possible to compare Logs.

To compare Files:

1. Swipe to the right or tap the 'Menu' symbol
2. Tap 'Saved Files'
3. Tap the Files that you want to compare (see Figure 36). There is a maximum selection of 5 Files.
4. Tap 'Compare' (see Figure 36).

You can now compare the selected Files (see Figure 37).
The wide light-blue graphs show the TSF of the Files that you are comparing. The two narrow dark-blue graphs (placed inside the light-blue graphs) show the left-right balance of the measurements. You can tap one of the graphs for the specific File details.

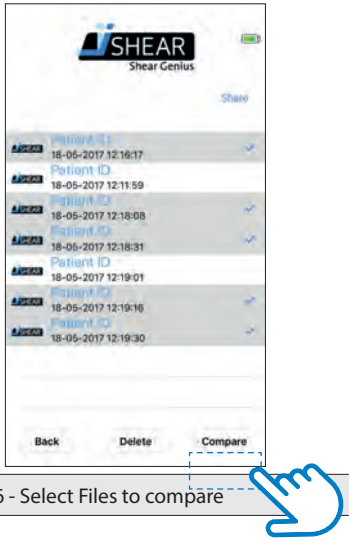


Figure 36 - Select Files to compare

Figure 37 - Compare Files screen

6 Maintenance, cleaning and storage

6.1 Maintenance and cleaning

⚠WARNING	• Before each session check the iShear for any visible damage to the sensor bar and/or mat (holes, tears, torn seams, dents etc.). In case of any visible damage, do not use the iShear. Contact Vicair. • Do not soak the iShear in fluids, keep away from water, (bodily) fluids and humidity • Do not continue to use the iShear when it is soiled with urine or soaked with any other kind of fluid. Contact Vicair.
⚠CAUTION	• Do not remove the mat from the sensor strips of the iShear. • Do not pinch or wrinkle the iShear. • Do not fold the iShear in any other way than in the way it is originally placed in the storage case. • Do not place any objects on top of a folded iShear.Do not remove the mat from the sensor strips of the iShear. • Do not use undiluted bleach or Hydrogen Peroxide to clean the iShear. • Cleaning products or disinfectants must be thoroughly wiped off the iShear mat after cleaning/disinfecting. Allow the iShear mat to dry thoroughly before use or storage.

Clean the iShear mat daily with a damp (not wet) cloth using a mild detergent and water solution.

For institutional cleaning use a general disinfectant cleaner. Mild alcohol based cleaners and cleaners containing no more than 10% bleach may also be used.

Do not use undiluted bleach or Hydrogen Peroxide to clean the iShear.

Cleaning products or disinfectants must be thoroughly wiped off the iShear mat after cleaning/disinfecting. Allow the iShear mat to dry thoroughly before use or storage.

6.2 Disinfecting

⚠WARNING	• Do not soak the iShear in fluids, keep away from water, (bodily) fluids and humidity • Do not continue to use the iShear when it is soiled with urine or soaked with any other kind of fluid. Contact Vicair.
⚠CAUTION	• Do not remove the mat from the sensor strips of the iShear. • Do not use undiluted bleach or Hydrogen Peroxide to clean the iShear. • Cleaning products or disinfectants must be thoroughly wiped off the iShear mat after cleaning/disinfecting. Allow the iShear mat to dry thoroughly before use or storage.

Before starting a session with a new client, the iShear must be disinfected to avoid cross contamination. Clean the iShear as instructed above. Preferably use an antibacterial detergent. After cleaning spray the iShear mat with a disinfectant. Cleaning products or disinfectants must be thoroughly wiped off the iShear mat after cleaning/disinfecting. Allow the iShear cover to dry thoroughly before use or storage.

6.3 Storage

⚠CAUTION	• Always store the iShear in the original iShear carrying case after each session. • Cleaning products or disinfectants must be thoroughly wiped off the iShear mat after cleaning/disinfecting. Allow the iShear mat to dry thoroughly before use or storage. • Do not fold the iShear in any other way than in the way it is originally placed in the storage case. • Do not place any objects on top of a folded iShear. • If the iShear is not in use for an extended period, remove the batteries from the battery compartment of the sensor bar.

For temporarily storing the iShear after each session, make sure the iShear is turned off and place it in the provided carrying case. Store in a dry place.

Store the iShear by gently folding the two lateral flaps downwards underneath the section of the iShear with the sensor strips. Place the iShear in the carrying case with the top of the iShear facing up (See Figure 18)

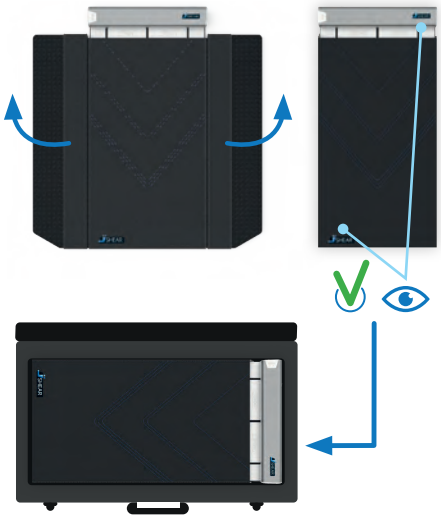


Figure 18 - Store the iShear correctly in its case

Remove the batteries before you store the iShear for a longer period of time. This will prevent battery leakage and consequential damage to the product.

Storage and transport conditions

Ambient temperature	Minimum: -10 °C / 14 F - Maximum: 40 °C / 104 F
Relative humidity	Storage: 10 to 100% RH (noncondensing)

Store the iShear folded as described in this paragraph. Do not place any objects on top of a folded iShear.

7 Troubleshooting

In case the iShear or iShear App is not working as expected, please try one of the following solutions:

- Close down all running apps, except the iShear app.
- Re-start the iShear app.
- Check for app-updates (updates will be available in your app store / play store)
- Disconnect the iShear and reconnect.
- Try new batteries.

If this does not solve the problem, call technical support for assistance:

Vicair B.V.
Bruynvisweg 5
1531 AX, Wormer
The Netherlands

Worldwide Technical Support
+31 (0)75 642 9999
Monday to Friday

e-mail: support@ishear.com

Visit our website at:
www.ishear.com

8 Disposing of the iShear

NOTICE

- For safe disposal of the iShear: please contact Vicair for instructions

The meaning of the symbol on the product, its accessory or packaging indicates that this product shall not be treated as household waste. Please dispose of this product and/or accessory by returning it to the manufacturer. Contact Vicair for information. See 7.2 for contact details.

Do not dispose of batteries as household waste. Take them to a battery recycling facility.

9 Warranty

Vicair offers a limited warranty against defects in workmanship and materials for a period of two (2) years from the original date of purchase, provided the product has been used normally. Please retain your receipt as proof of purchase. Before using the iShear, the user must ensure that it is functional and in proper working conditions. The user must know how to operate the iShear.

These operating instructions are part of the iShear. Compliance with these operating instructions is mandatory in order to ensure the correct function and operation of the iShear.

Any damage arising from abnormal use, or caused by improper handling, cleaning or negligence is excluded from this warranty. No responsibility shall be accepted for damage caused by any of the following: unsuitable or improper storage or use, incorrect installation or putting into operation by the owner or third parties, natural wear and tear, changes or modifications, incorrect or negligent handling, overuses, chemical, electrochemical or electrical interference or humidity, unless this is attributable to negligence on the part of Vicair. If operating, climatic or any other influences lead to a major change in conditions or material quality, the warranty for perfect functioning of the iShear shall be rendered null and void.

This warranty is void if failure of the software and/or hardware has resulted from accident, abuse, or misapplication. Any modifications by a third party to the software and/or hardware will void the manufacturer's warranty and any obligations to provide maintenance services.

Should a defect in materials or workmanship occur within two (2) years from the original date of purchase, Vicair will, at its own choice, repair or replace the product free of charge.

Remedies for breach of express warranties herein are limited to repair or replacement of the product. In no event shall damages for breach of any warranty include any consequential damages or exceed the cost of non-conforming goods sold.

For additional product information, see our website: www.ishear.com.

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