

Thora-3Di™

Thoraco-Abdominal Dynamic Respiratory Imaging



Instruction Manual

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Declaration of conformity

The Declaration of Conformity for this medical device is in accordance with Annex VII of the Medical Device Directive 93/42/EEC.



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1 Installation

1.1 Safety

Read this section carefully. This manual describes the device, including software and accessories and it is important that the instructions are read thoroughly and understood before using the equipment.

Thora 3Di is classified as a Class IIa medical device in accordance with the European Medical Device Directive 93/42EEC as amended by 2007/47.

The following rules and regulations apply for the use of the device:

- BS EN 60601-1 Safety of electronic medical devices
- BS EN 60601-1-2 EMC
- EN 60950 Information Technology Equipment Safety
- All safety regulations and precautions of the appropriate countries remain in effect.

1.2 Warnings and Cautions

The European Medical Device Directive requires all manufacturers to include appropriate warnings and cautions.



A WARNING: is given when the personal safety of the patient or user may be affected and when disregarding this information could result in injury.



A CAUTION: is given when special instructions must be followed.

Disregarding this information could result in permanent damage being caused to the equipment.

Warnings and cautions are made throughout these instructions.

1.3 Electrical Safety



WARNING: Do not connect any other device to the Thora 3Di.

1.3.1 Protection Category - EN 60601-1

Thora-3Di electric shock protection is in accordance with class I requirements, touchable and maybe voltage-carrying metal parts are electrically conductively connected to each other and connected to earthing cable of the mains network.

1.3.2 Patient Safety - EN 60601-1



WARNING: To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth.

Only use PCs released by PneumaCare (in compliance with EN 60950).

Patient barrier:

- There must be a minimum distance of 1.5 m between patient and other electrical devices.
- During a measurement, the patient must not come into contact with the conducting parts of the device.
- The operator must not touch the patient and electrically operated devices at the same time.

1.4 Ambient Conditions



CAUTION: Do not use PneumaCare equipment in rooms with potential explosion hazards or in flammable atmospheres.

If not otherwise stated in the instruction manual, PneumaCare equipment must be used in normal environmental temperatures and conditions (EN 60601-1):

- Operating Temperature: +10° to +35° C

Transport and Storage Conditions:

- Temperature: -30°C to +50°C
- Relative Humidity: 10 to 95 %
- Barometric Pressure: 600 to 1200 hPa

1.5 Before Operation



WARNING: The device is not considered safe to use in the close proximity of electromagnetic imaging equipment. It is not MRI safe.

CAUTION:

- **Do not connect any USB devices to the instrument controller (All-in-one PC).**
- **Do not install any software on the instrument controller.**
- **Only use the USB port to back up the patient database on a portable USB stick.**

- Before connecting the unit to a power supply check the nameplate on the Thora 3Di system to ensure it complies with the local mains voltage and mains frequency power supply.
- Check the mains connection cable, plug, and receptacle for visible damage before making the connection.
- Replace damaged cables or plugs immediately.
- Assemble the device only according to the instructions found in the shipping documents.

1.5.1 Operating Safety

- Never open the housing of the Thora-3Di. This could lead to an electrical short-circuit or damage to the scanner.
- Do not cover the slots and openings in the scanner head, these openings are for ventilation and to prevent overheating.
- Never insert any objects through the slits and openings into the bottom of the scanner. This could lead to an electrical short circuit or damage to the scanner.
- Only operate this instrument from the type of power supply indicated on the marking label.
- Disconnect the instrument from the mains before you start any maintenance or installation procedures.
- Do not expose the instrument to liquid of any kind.
- Do not place objects filled with liquid on the apparatus.
- Disconnect the instrument from the wall outlet before cleaning.
- Do not use any unsupported attachments as these may be hazardous or cause damage to the instrument.
- Place the instrument away from direct sunlight.
- Do not place the instrument near a radiator or heat register.
- Do not place the instrument on an unstable cart, stand, tripod, bracket, or table where it can fall.

To terminate the operation of the Thora-3Di™, firstly close down the PneumaView™ software, then close down the Windows operating system, switch off the computer, switch off system cabinet LED panel.

- When replacement of parts is required, the service technician should only use replacement parts supplied by the manufacturer. Unauthorised substitution may result in additional damage to the unit.
- Do not use the instrument when it out of order. If you continue to use the instrument when defective, serious damage can be caused. Contact your distributor if the instrument is out of order.

- Refer all servicing to qualified service personnel. Servicing is required when the apparatus has been damaged in any way, such as damage to power-supply cord or plug or liquid spillage.
- Do not modify this equipment. Any unauthorised modification could result in a potential risk to the operator during use, or invalidate any measurements taken by the device.

1.5.2 General Safety Precautions

PneumaCare only guarantees the safety, reliability and function of the instrument if:

- Commissioning, extension, modifications, and repairs are exclusively carried out by PneumaCare authorised personnel.
- The unit is not connected to any other equipment or network/data couplings than otherwise specified by PneumaCare.
- The room where the equipment is used complies with the installation instructions.
- The instrument is plugged into a socket with protective conductor system.
- The ambient conditions at the place of installation are suitable for the instrument.
- The equipment is not used in an oxygen rich environment.
- The equipment is not used in the presence of flammable anaesthetic mixtures.
- The unit is used according to the training and instruction manual.

1.6 Warranty

PneumaCare Ltd guarantees the instrument for 12 months beginning from the date of purchase according to the terms of trade, delivery and payment.

1.7 Disclaimer

The right to claim under the guarantee expires if:

- Damage occurs as a result of operation by unqualified user personnel and by usage not in accordance to the intended use.
- Installations are not carried-out according to PneumaCare guidelines, or when the operation(s) are carried out by personnel who are not qualified, or if add-ons or spare parts used are not original parts supplied by PneumaCare.
- Alterations, add-ons, repairs or any other works are carried-out by personnel not authorised by PneumaCare.
- Electrical installations of the room where the device is planned to be installed do not meet the national requirements for electrical installations.
- Use of the device is not in compliance with the operating instructions.

When the period of guarantee has expired, use original PneumaCare spare parts and equipment to ensure that your device continues to run smoothly and without any problems for an extended period of time.

It is recommended that a Pneumacare distributor calibrate/service the instrument once a year.

1.8 Package Contents

- Parts list
- Quick Start Guide
- User manual
- Product Warranty
- Thora 3Di Scanner head
- Scanner Handle Set
- Touch screen all-in-one-computer (All in one PC)
- All in one PC mounting bracket
- Battery
- Battery charger unit
- Stand
- Articulating Arm
- Cable assembly
- Power cable
- Spare fuses
- Allen key set

1.9 Installation Procedures

The process for initial installation is as follows:

- 1.9.1 Inspect the crate for any damage or signs of tampering.
- 1.9.2 Ensure that the crate is the correct way up.
- 1.9.3 Undo all the catches around the front panel marked as Ramp.
- 1.9.4 Remove all packing materials to allow easy access to the Thora-3Di™ system.
- 1.9.5 Release the wheel brakes at the bottom of the stand.
- 1.9.6 Roll the Thora-3Di™ down the ramp and secure the brakes.
- 1.9.7 Remove all remaining packaging from the Thora-3Di™.
- 1.9.8 Inspect the Thora-3Di™ for any damage.
- 1.9.10 If any damage is identified then contact Pneumacare Limited and record and discrepancies.
- 1.9.11 Unlock the wheel brakes and move the Thora-3Di™ to the installation location. Position the system so that there is easy access to all four sides.
- 1.9.12 Ensure that the ON/OFF switch on the right hand side of the cabinet is in the OFF position.
- 1.9.13 Open the stand cabinet and locate the yellow battery connector and reconnect it.
- 1.9.14 Check all cables inside the cabinet are secure.
- 1.9.15 Close the cabinet door and lock it. (Put the keys in a safe location)

- 1.9.16 A 2 metre (6.5 feet) power cable is supplied with the Thora-3Di™ system, locate a suitable power outlet source and plug the cable into the wall socket. Connect the other end of the cable to the Thora-3Di™
- 1.9.17 Power input socket on the right-hand side of the stand. Put the ON/OFF switch to the ON position.
- 1.9.18 Go to the LED display panel on the front of the cabinet, the right hand LED should be flashing Green; this indicates that the battery is charging. (The system is not powered on)
- 1.9.19 Turn on the power to the system. Press the left button on the LED display panel for 2 seconds, you will hear a bleep. (The system is now powered on)
- 1.9.20 Turn on the scanner head. The scanner head ON/OFF switch is located on the back of the head. Put it to the ON position, the switch light will light up.
- 1.9.21 Power on the Scanner Head projector. The ON/OFF switch is located on the top of the head (colored Blue), press once to power on the projector press a second time to power on the light.
- 1.9.21 Turn on the All-in-one-PC (Computer). The power switch is located on the left hand side of the (top)
- 1.9.22 The All-in-one-PC will boot up to the windows logon screen.
- 1.9.23 Logon using the credentials: User *PneumaCare* and Password *12345*
- 1.9.24 Look at the computer screen and locate the PneumaView software icon and tap on it twice (or use the right hand mouse button).
- 1.9.25 The PneumaView software will start up and present you with a logon screen. Logon using the credentials: User *admin* and Password *administrator*
- 1.9.26 A message window will appear on the center of the All-in-one-PC screen informing the user that the software is communicating with the Scanner head.
- 1.9.27 The Thora-3Di system is now operational and ready to use.

Note: ***The Thora-3Di stand should not obstruct the power wall socket. The power inlet socket and wall plug must be easily accessible by the operator with no obstructions.***

2 Hardware

2.1 Introduction

2.1.1 About this manual

This manual is written for clinical professionals who have completed an approved Pneumacare training course.

Note: Maintain a full record of training for traceability according to local policy.

- Read these instructions before use and familiarise yourself with the handling of the instrument and its controls before you start working with it.
- Never allow the use of the instrument on anybody without their prior consent.
- Observe all signs on the instrument and renew all missing or damaged signs immediately.

These instructions are only a guide and should not be used as the only source of training material.

Note:

- Only qualified personnel should use the instrument.
- Follow the operating instructions.
- Comply with all the safety and maintenance information.
- Keep the operating instructions available for the staff at all times.
- Avoid installing the Thora-3Di in direct sunlight or in a location where it may be affected by significant changes in humidity, ventilation, or airborne particles containing dust, salt or sulphur.

2.2 Thora-3Di instrument

Thora-3Di provides accurate, fast and non-contact assessment to provide regional chest wall motion using structured light technologies and enhanced imaging processing. A grid pattern is projected onto a patient's chest wall and the movements made during breathing are measured and analysed.

This powerful unit meets all requirements in the field of modern Chest wall movement measurements. All units of the Thora-3Di series are designed to be compatible with most computer systems to allow a high storage capacity, display and printing of reports. The following is included in the delivery:

- Thora-3Di scanning head
- Adjustable/mobile stand
- System Controller (PC)
- Windows 7 compatible graphics user interface
- PneumaView-3D Application Software
- Database for storing patient- and test data

2.3 Intended Use

The PneumaCare™ Thora-3Di is used to measure and collect data of regional parameters from three dimensional reconstruction of the chest wall motion through imaging techniques. Indications for use include:

- Breathing difficulties
- Restricted breathing function

2.4 Contraindications

Contraindications for performing chest wall movement assessments:

- Recent eye surgery (e.g. cataract removal)

2.5 Safe Operation of the Thora-3Di instrument



WARNING: The device is not considered safe to use in the close proximity of electromagnetic imaging equipment. It is not MRI safe.

CAUTION:



- Do not connect any mains powered USB devices to the instrument controller (All-in-one PC).
- Do not install any software on the instrument controller.
- Only use the USB port to back up the patient database on a portable USB stick.

2.5.1 General

The Thora-3Di instrument is a non-invasive, non-contact medical device that measures Chest wall movement optically and records the measurements with Thora-3Di Application Software. These measurements are analysed with PneumaView-3D software, see PneumaView 3D Viewer for detailed software instructions.

It is an extremely safe device for both the user and patient.

2.5.2 Patient Safety



WARNING: Tell the patient not to stare directly into the projector. This may temporarily affect the eyes.

Note: The Thora-3Di captures and presents data reflecting a patient's physiological condition. The data should not be used as a means for determining a patient's diagnosis. To minimise the chances of a misdiagnosis it is the physician's responsibility to assure that tests are properly administered, evaluated and interpreted.

Do not perform a Chest wall movement test if the patient has recently had eye surgery (e.g. cataract removal).

Observe patients closely. If there are any reasons for concern, stop the test and take appropriate action.

2.6 To use the Thora-3Di Instrument

2.6.1 To get the best results

- Reduce all natural light entering the room by drawing all blinds and curtains. If any natural light enters the room, turn the patient to face away from the source of the light to create an artificial shadow.
- For mobile patients, use a chair with high-backed headrest and armrests. If a high-backed chair is not available, position a comfortable chair against a wall and ask the patient to put their head against the wall during the breathing measurement. If the seat has no armrests ask the patient to hold the seat of the chair during the measurement.
- Ensure that the patient's clothing is close fitting and crease free.
- For an ideal setup, line up the scanner head directly in front of the chair or bed in order to project the grid straight onto the patient's chest area. If the grid is projected at an angle the measurement may be inaccurate or fail completely. Centre the projected grid on the solar plexus and cover the entire patient's chest surface. This results in accurate and reproducible chest wall movement measurements.
- During each breath, ask the patient to keep as still as possible. Any movement affects the measurement quality and accuracy of the measurements.

2.6.2 Set up the equipment



CAUTION: Before turning on the device/system check that the mains cable, mains plug, outlet and power input of the instrument are free from defects.

1. Turn on the instrument controller. Log in to Windows using your usual password.
2. The PneumaView software opens. Enter the **User Credentials**, Username and Password provided by your administrator.
3. Turn on the power to the instrument:
 - a. Press the switch at back of scanner head
 - b. Press the switch on top of scanner head to turn on the projector

The status of scanning head unit displays: `Unavailable` or `Connected`.

NOTE: If the scanning head does not connect to the instrument controller turn the power to the head **OFF** and **ON**.

2.6.3 Position the patient



WARNING: Tell the patient not to stare directly into the projector. This may temporarily affect the eyes.

The Thora-3Di is simple to use, it offers a method of recording respiratory function from a wide age range of patients. Many patients will not have undertaken pulmonary function tests before. Some patients may be acutely or chronically unwell and may be very nervous. Take time to explain the procedure to the patient.

Note: During each breath, ask the patient to keep as still as possible. Any movement affects the measurement quality and accuracy of the measurements.

Supine Patient

1. Ensure the patient is lying straight on the bed.

Seated Patient

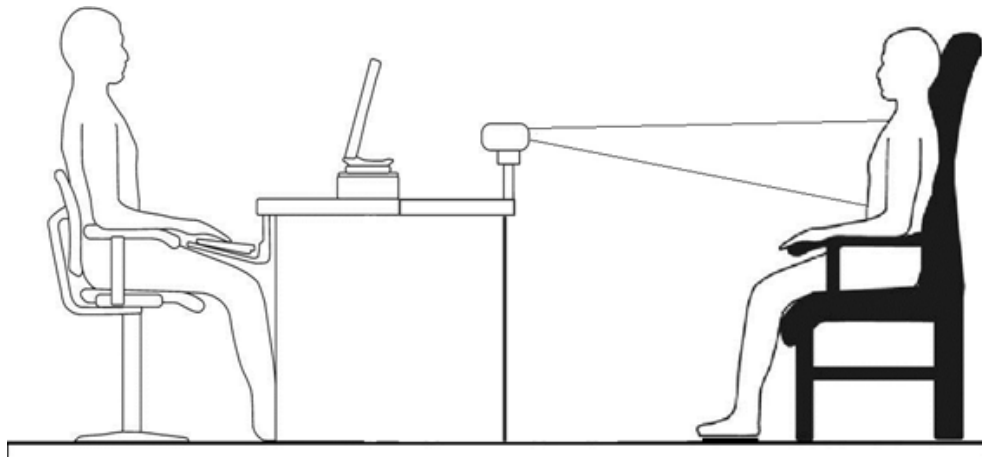
1. Ensure the patient:
 - a) Sits as far back in the chair as possible.
 - b) Sits correctly and comfortably between each measurement.



2.6.4 Align Equipment with Subject

Note: Ensure that no one enters the area between the patient and the instrument during use, as this will affect the results of the measurement.

The recommended position for the patient and operator is shown below.



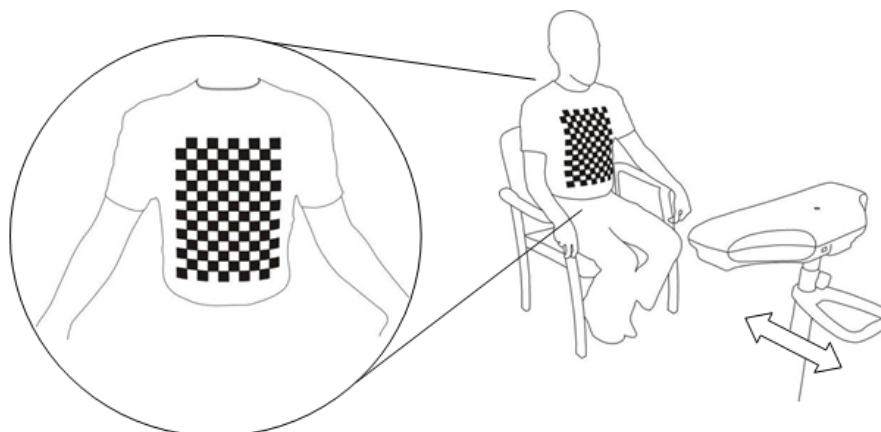
1. Scanner alignment: Standing / sitting patient

The scanner head is mounted on an articulating arm which can easily be re-positioned.

- Line up the scanner head directly in front of the chair or bed in order to project the grid straight onto the patient's chest area.
If the grid is projected at an angle the measurement may be inaccurate or fail completely.
- Adjust the height and angle of the scanning head to ensure the projected grid pattern is directed straight at the centre of the patient's chest.
- Adjust the position, height and tilt of the scanning head to ensure the projected grid pattern covers a majority of the patient's chest between the suprasternal notch and beltline.

Note: Do not project the grid past the edge of the patient's chest and onto the chair or bed.

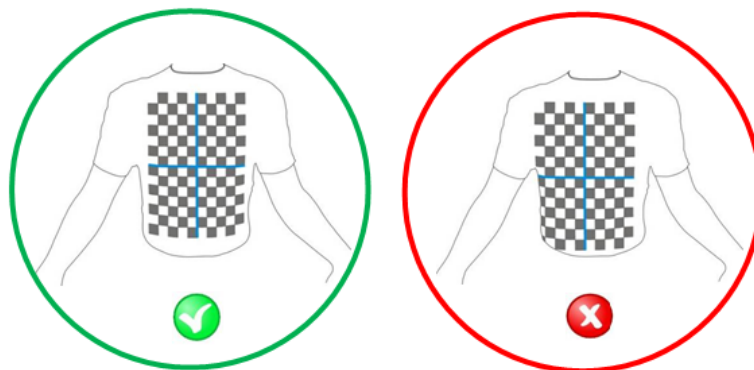
If the grid does not cover the entire chest the measurement may be inaccurate or fail completely.



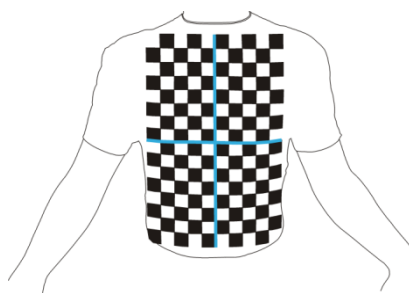
2. Grid positioning

- When the patient is comfortable, ask them to identify the bottom of their breastbone and clavicle.

- Position the target grid to intersect this point and the top edge of the grid across the clavicle.
- Centre the grid before each measurement.
Failure to correctly align the grid can result in inaccurate results or complete failure of the measurement.

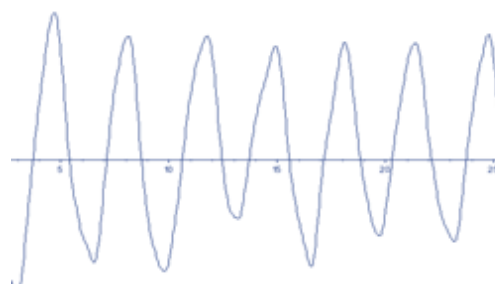


Ideal setup



Good data capture:

- Trace is blue
- Peaks and troughs are smooth



Extremely low contrast or very creased clothing

Typical output



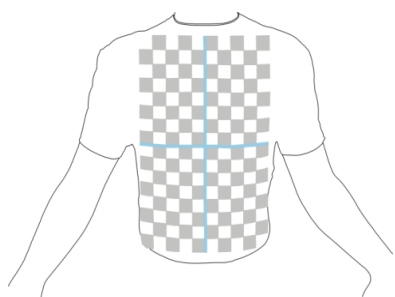
Bad data capture:

Trace is either:

- a flat red line
- mostly orange

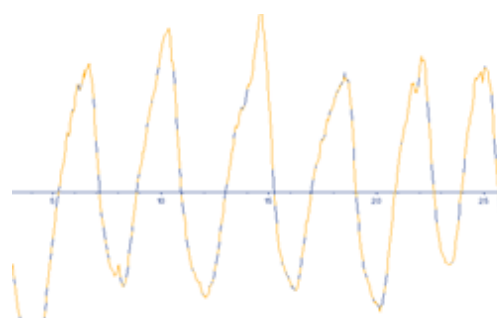


Low contrast or creased clothing



Poor data capture:

- Trace is a mixture of blue and orange
- Peaks and troughs are jagged



2.7 Control tests

To gain confidence in handling the unit and to become familiar with the measuring values obtained (Verification of multiple tests, reproducibility etc.); Pneumacare advise that the operator and department personnel volunteer as test subjects and take a complete set of measurements. Repeat the measurements at regular intervals (every few weeks) and record the results. You can compare new measurements with the information stored. If it appears that the measured values obtained from the patients are incorrect, this provides you with an effective check on the functional accuracy of the instrument.

2.8 Output

Thora-3Di is designed to give chest wall movement data. In the Pneumacare software program the graphical display shows the patient's breathing either as full body or regional parameters.

2.8.1 Full-body parameters

- Visual outputs:
 - Unscaled chest wall movement signal
 - Unscaled approximated Flow-Volume loop
- Respiratory Rate, in breaths/minute
- Inspiratory Time (Ti) of the full-body chest wall movement signal, in seconds
- Expiratory Time (Te) of the full-body chest wall movement signal, in seconds
- Total Breath Time (Ttot) of the full-body chest wall movement signal, in seconds
- Ratios derived from the full-body chest wall movement signal:
 - T_i/T_e
 - T_i/T_{tot}
- IE50

2.8.2 Regional parameters

Regional parameter properties are derived from two (or more) regional chest wall movement signals; for example, the movement of the Thorax signal versus the Abdomen signal or Left versus Right.

- Visual representations: Konno-Mead plot of two signals.
- Relative Expired Contribution of two or more signals, in %
- Overall Phase difference between two signals, in degrees
- Principal Angle between two signals, in degrees
- Spread Ratio of two signals
- Window Phase difference between two signals, in degrees
- Per-Breath Phase difference between two signals in degrees

2.8.3 Variation

A measure of variation is provided for the metrics Ti, Te and Per-Breath Phase difference.

2.9 Unusual Test Results

If your results are unusual, please check the following before reporting a fault with the instrument. Ensure:

- All cables are connected correctly.
- The project grid is displaying during the data capture procedure.
- The projected grid is correctly aligned with the patient before use.
- The patient does not have any creases in their clothing that interfere with the quality of the measurement.
- The device is not positioned directly below a light source, or that any natural light is entering the testing environment.
- The patient is not moving excessively during the breathing measurement.

2.10 Care and Maintenance



WARNING: Immediate maintenance is necessary if:

- The instrument has been extremely mechanically stressed (cables dragged, pulled or thrust)
- Any liquid is spilled inside the unit
- Defective cables
- Defective multiple connectors
- Housing displaced or missing
- Rubber connectors show cracks.

Immediately replace any damaged and frayed plugs and receptacles, conductors and pressure regulators.

Any work on the equipment should be carried out by an authorised PneumaCare specialist or engineer.



CAUTION: Before cleaning the equipment:

1. Turn the scanner head off.
2. Turn the All-in-one PC off.
3. Disconnect the power supply.

2.10.1 Daily Maintenance



CAUTION:

- Do not use a wet cloth.
- Do not steam-clean or jet wash any area.
- Do not use:
 - concentrated bleaching disinfectant solutions
 - organic solvents
 - abrasive powders
 - inflammable substance such as benzene or thinners
 - caustic cleaning agents
 - chlorine
- Do not expose any part of the device to excessive heat.
- Do not scratch the screen with fingernails or a sharp object.
- Only use LCD screen cleaning wipes on the system controller (all-in-one PC)

Stand and Articulating Arm

1. Wipe all surfaces using sterile wipes.
2. Check that the mains cable, mains plug, outlet and power input of the instrument are free from defects before turning on the system.
3. Check all fittings are secure.
4. Put system battery on charge when not in use.

Scanner head

1. Clean the surface and the lenses using sterile wipes.
 - A white stain may be generated on the surface of the projector if water gets on it.

All in one PC

1. Only use LCD screen cleaning wipes

2.10.2 Disinfection procedure

WARNING: Only use CE marked cleansers and disinfectants for medical devices to clean the unit.

Dilute all disinfectants in accordance with the manufacturer's guidelines.

**CAUTION:**

- Do not use a wet cloth.
- Do not steam-clean or jet wash any area.
- Do not use:
 - concentrated bleaching disinfectant solutions
 - organic solvents
 - abrasive powders
 - inflammable substance such as benzene or thinners
 - caustic cleaning agents
 - chlorine
- Do not expose any part of the device to excessive heat.

2.10.3 Cleaning inside the scanning head

- Contact an authorised PneumaCare specialist or engineer if dust or other substances are inside the scanning head.

2.10.4 Annual inspection

It is recommended that a Pneumacare distributor calibrates and services the instrument once a year.

3 PneumaView Software User Guide

The PneumaView software is the main program used to capture the patient data; a patient profile is created and Thora3Di is initiated to carry out the real-time data capture of the patient's chest movement.

3.1 To start PneumaView

CAUTION:

Do not connect any mains powered USB devices to the instrument controller (All-in-one PC).

Do not install any software on the instrument controller.

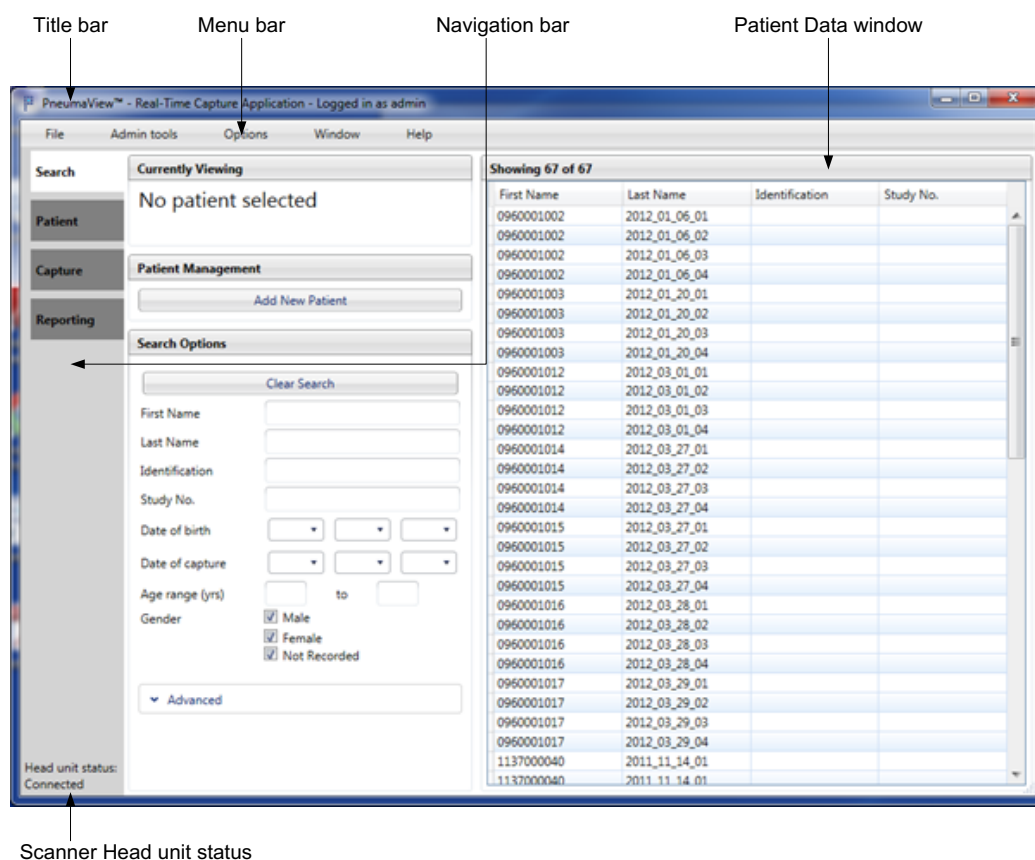
Only use the USB port to back up the patient database on a portable USB stick.

1. Turn on the instrument controller. The power switch is on the right side of the All-in-one PC.
2. Log in to Windows using your usual password. The PneumaView software opens.
3. Enter the **User Credentials**; Username and Password provided by your administrator. The PneumaView window opens.
4. Turn on the power to the instrument:
 - a) Press the switch at back of scanner head
 - b) Press the switch on top of scanner head to turn on the projector

The status of scanning head unit displays: `Unavailable` or `Connected`.

Note: If the scanning head does not connect to the instrument controller turn the power to the head OFF and ON.

3.2 Main PneumaView window



- The Title bar displays the software identification and the name of the person who is logged in.
- The navigation bar displays tabs for the program options and the status of the scanner head unit. The content of the two window panes changes according to which tab you select.

3.3 Menu bar

3.3.1 File

Menu	Description
Search Patients	To choose a patient who is already on the database and carried out a previous procedure
Add New Patient	To enter the personal details of a new patient
Save Changes	To save any changes made
Open PDF	Search to open a document in a pdf format. For example a doctor or surgeon's report
Logout <Current User>	To log off the current user (logon user displayed)
Exit	To close the program

3.3.2 Admin tools

Note: This is only displayed when an administrator is logged in to the program.

Menu	Submenu	Description
Synchronise		To synchronise the database with previous backups or data from another computer
Backup	Create backup	To back up the database to a new folder
	View backup	To view saved databases
Manage users		To manage: Users Login details Administrator privileges
Error logs	View error logs	To view or delete error logs (the logs contain details of test failures and software crashes)
	Save error logs	To save error logs
Configure	Grid image	To configure the processes used in data capture, set the projected grid size
View recycling bin	Restore Selected Patients	To restore deleted files
	Empty Recycle Bin	

3.3.3 Options

Menu	Submenu	Description
Settings	Spirogram change from zero	To set the displayed graph axis to zero
	Enable 2 stage capture	To start a real time measurement, then start a recording
Theme	Light	To set the display to a light theme
	Dark	To set the display to a dark theme
Search columns		To set the search columns displayed – a maximum of 5 can be displayed

3.3.4 Window

Menu	Description
Normal size	PneumaCare window is displayed full screen
Minimise	PneumaCare window is displayed as a reduced window

3.3.5 Help

Menu	Description
About	To open an information window displaying the software version and the scanner status

3.4 Navigation bar

There are four tabs in the navigation bar:

Search:	To search the patient database
Patient:	To enter patient data, including new patient
Capture:	To capture patient test movement
Reporting:	To create a report from captured measurements

3.5 To search for a patient

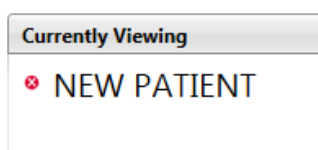
You can search for a patient using any of these fields:

- First Name
- Last Name
- Identification
- Date of Birth

The database automatically searches for all patients and displays the results in rows in the Patient Data window.

Tap on a row to expand the patient details.

Tap on **View** to open the details in the patient tab. To go back to the search screen tap the red X by the patient's name.



If there are no patients in the database the heading text in the Patient Data window displays:



For example: To search for a patient *David Brown*.

1. Tap the **Search** tab.
2. In the **Search Options** dialog box, tap the text box next to the Last Name field.
3. Type Br.

The database displays the results in the Patient Data window.

PneumaView™ - Real-Time Capture Application - Logged in as pneumacare

File Admin tools Window Theme Help

Search

Currently Viewing

No patient selected

Patient

Capture

Reporting

Patient Management

Add New Patient

Search Options

First Name

Last Name B

Identification

Date of birth

Age (yrs)

Gender

☒ Male

☒ Female

☒ Not Recorded

Advanced

Showing 1 of 1

First Name	Last Name	Date Of Birth	Gender	Is Smoker?
David	Brown	10/02/1958	Male	No

4. Tap on a row to open the column of patient data:

Showing 1 of 1

First Name	Last Name	Identification	Study No.
Mark			

Diagnosis History Height (cm) 0

Weight (kg) 0 Operator Ward / Clinic

Physician

View Remove

5. Tap **View**.

The main window tab changes to **Patient** and displays the patient details and the Results Preview pane.

PneumaView™ - Real-Time Capture Application - Logged in as admin

File Admin tools Options Window Help

Search

Currently Viewing

Mark

Patient

Capture

Reporting

Patient Details

First Name Mark

Last Name Everard

Identification

Study No.

Date of birth 10 09 1956

Gender

☒ Male

☐ Female

☐ Unknown

Height (cm) 0

Weight (kg) 0.000

Street

City

Phone

Profession

Diagnosis

Patient History

Is smoker

☐ Yes

☐ No

☒ Unknown

Insurance

Head unit status: Connected

Save Changes Remove patient

Results Preview

10/09/13 15:52

Time [s]

Measurement Started

Grid Size
14x10
14x10
14x10
14x10

3.6 To create a new patient entry

1. On the **Navigation** pane tap the **Search** tab.
2. Tap **Add New Patient**. The Patient tab opens with a blank new patient form.
3. Enter the patient details.
4. Either
 - a) Tap **Save Changes**. A confirmation window opens.
Tap **OK** to save the new patient details in the database.
 - b) Tap **Remove Patient**. The patient details are removed to the recycle bin.

Currently Viewing

NEW PATIENT

Patient Details

First Name

Last Name

Identification

Study No.

Date of birth

Gender ☒ Male ☐ Female ☐ Unknown

Height (cm)

Weight (kg)

Street

City

Phone

Profession

Diagnosis

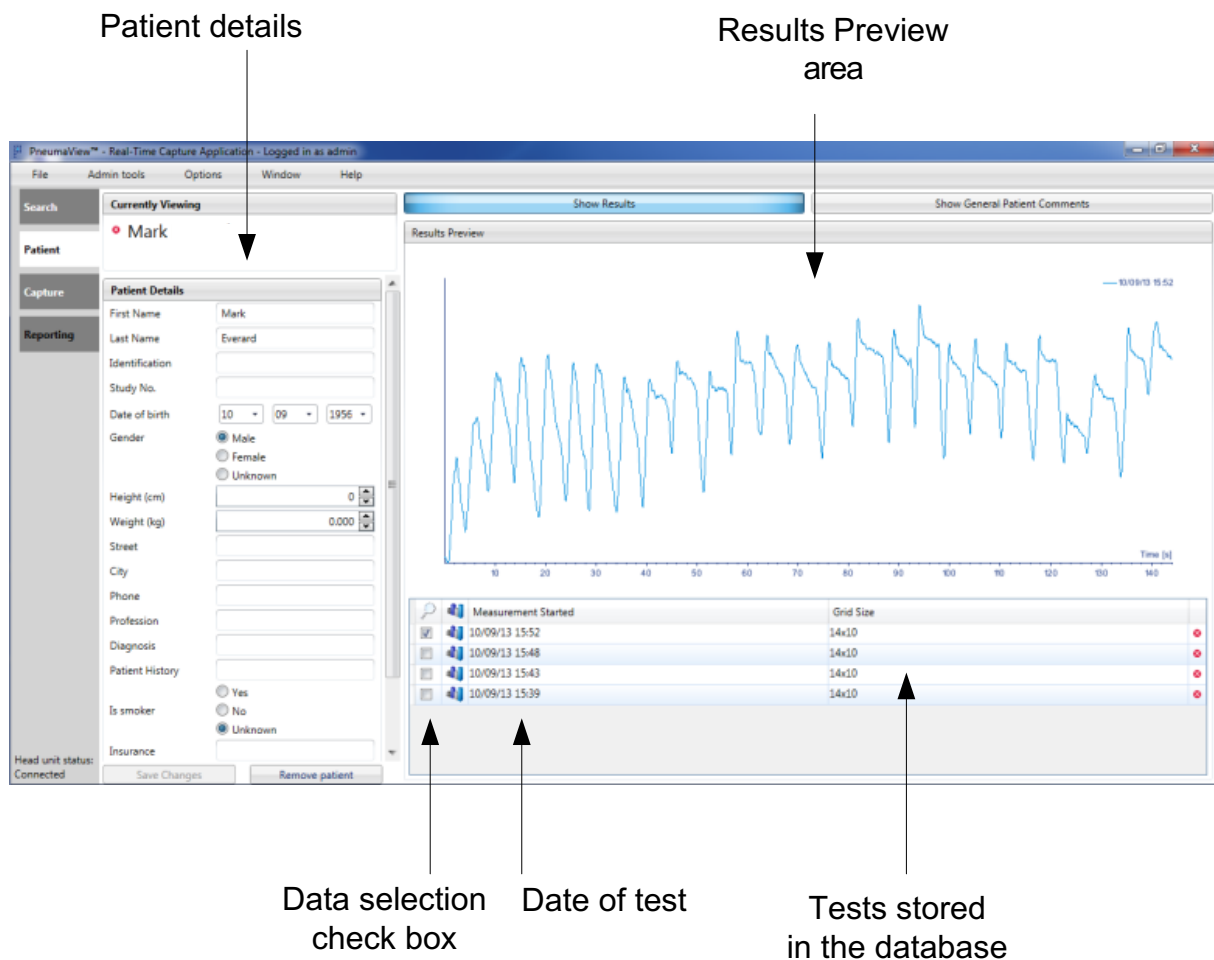
Patient History

Is smoker ☐ Yes ☐ No

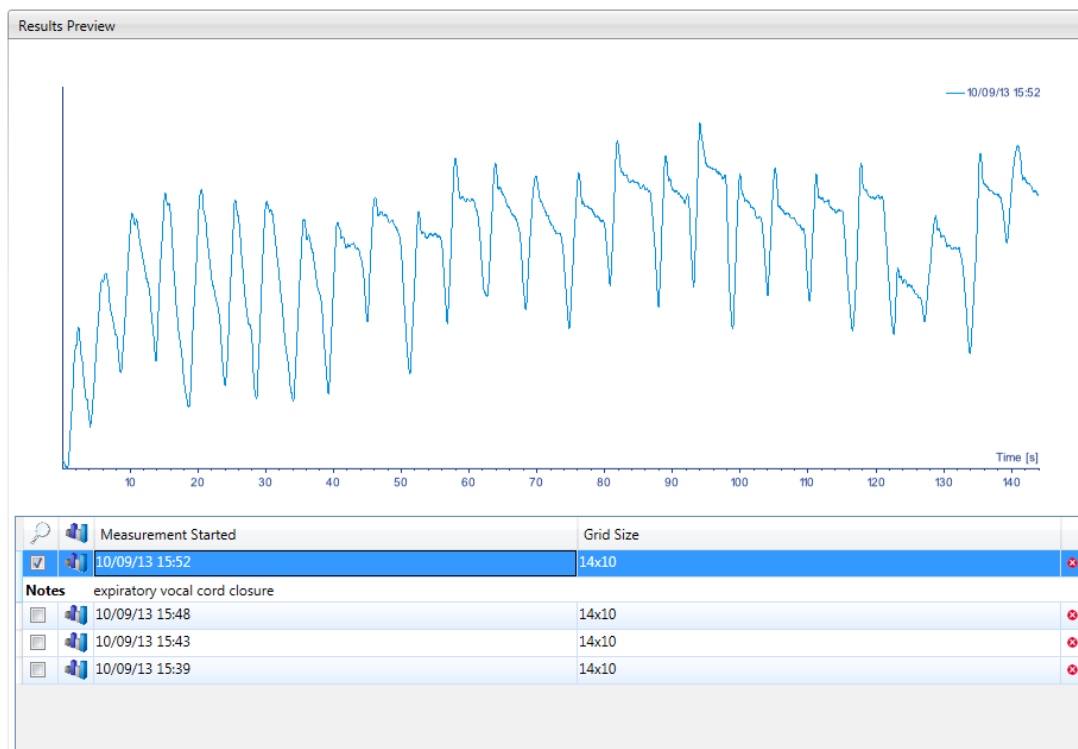
3.7 To preview patient data

1. Tap the **Search** tab.
2. In the **Search Options** dialog box, tap a text box and enter the patient name or identification in the search field. The database displays the results in the Patient Data window.
3. Tap on the row to open the column of patient data.
4. Tap **View**.

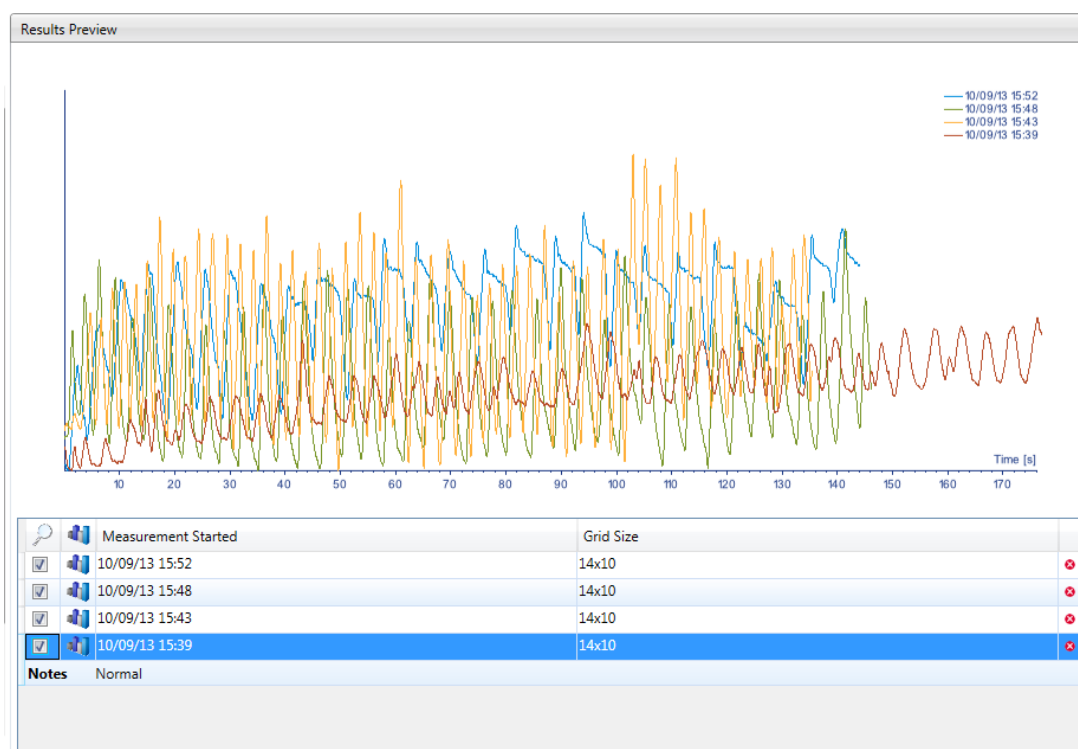
The main window tab changes to **Patient** and displays the patient details and the Results Preview pane.



5. Tap in a **Data selection** check box to view data in the Results Preview area.
Select one check box to preview an individual measurement:









Select multiple check boxes to compare measurements:



3.8 To clear the Results Preview

- In the **Data selection** check box, tap to cancel the selection.
The graphical data is removed from the Results Preview pane.

		Measurement Started
<input type="checkbox"/>		10/09/13 15:52
<input type="checkbox"/>		10/09/13 15:48
<input type="checkbox"/>		10/09/13 15:43
<input type="checkbox"/>		10/09/13 15:39
Notes		Normal

3.9 To view reports

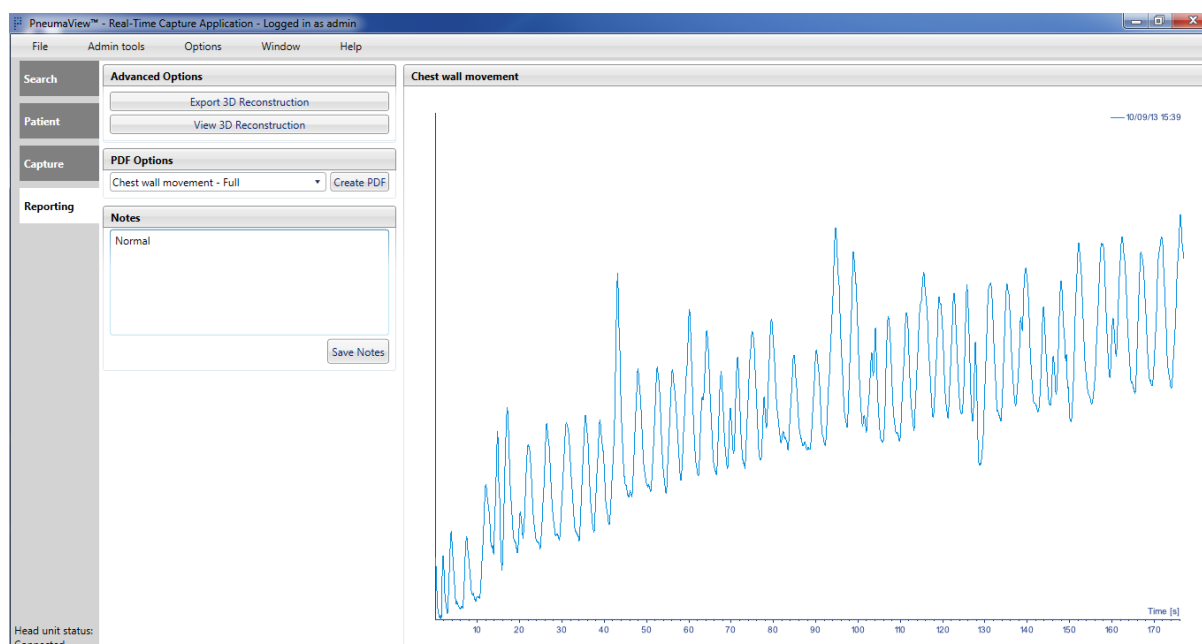
1. Select a patient; see To preview patient data.
2. In the **Results preview** pane, tap on a data row. The row is highlighted in blue.
3. To select more than one row tap the first row then drag across the additional rows.
4. Tap and hold the row(s). A dialog box opens.
5. Select:
 - **View 3D Reconstruction**, to open PneumaView 3D and display a reconstruction of the measurements, see PneumaView 3D Viewer
 - **Export 3D Reconstruction**, to export the measurements as a file, see To export reports
 - **Export data to CSV**, to export the measurements as a CSV file, see To export reports
 - **Batch Export Selection to PN3**, to export the selected files in PN3 format
 - **View Comparison Report**, to display the data and flow volume loop in the Reporting tab

3.10 To export reports

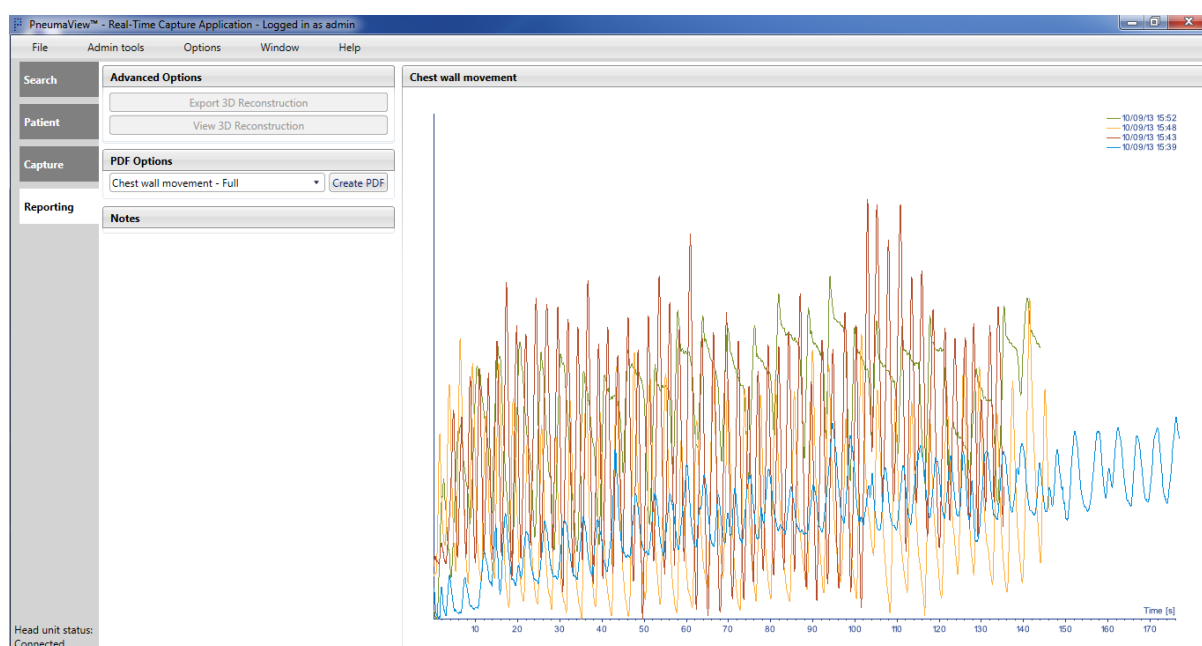
1. Tap **Export Selected**, a Save As dialog box opens with a default location and filename completed. You can change the default.
2. Tap **Save**. The dialog box closes.

3.11 To view a Comparison Report

1. Tap **View Comparison Report**. The Reporting tab opens and the screen displays the graphical data for the patient.



3.1 Single data file



3.2 Multiple reports

2. In **Advanced Options** select:
 - **View 3D Reconstruction**, to open PneumaView 3D and display a reconstruction of the measurements, see PneumaView 3D Viewer.
 - **Export 3D Reconstruction**, to export the measurements as a file, see To export reports.

3. In **PDF Options**, tap on the drop down arrow to select the type of pdf file you want to create.

- Chest wall movement – Full
- Chest wall movement – Anonymous

Note : Select anonymous to remove all patient data fields except gender, age, height and weight from the report.

4. Tap **Create PDF**. A Save As dialog box opens with a default location and filename completed. You can change the default.

5. Tap **Save**. A dialog box confirms that the report is saved.

6. Select **Yes** to view the report. The file opens in a pdf reader.

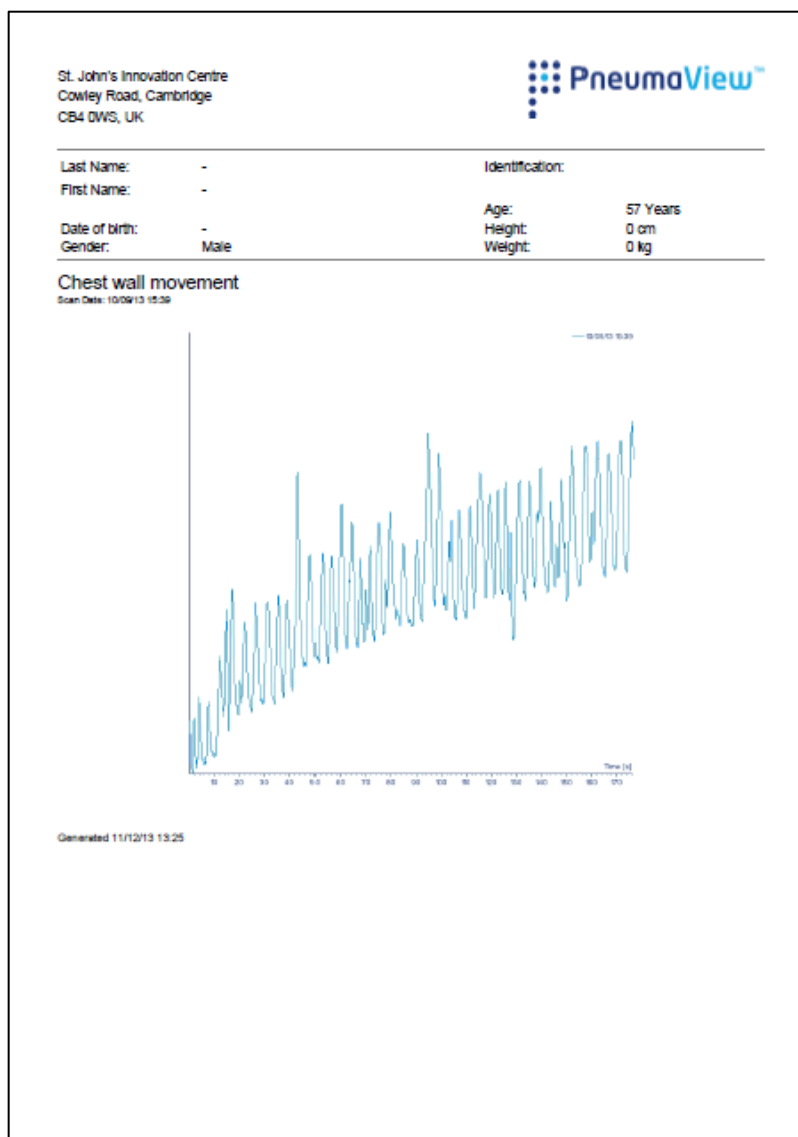


Figure 3.3 An anonymous report

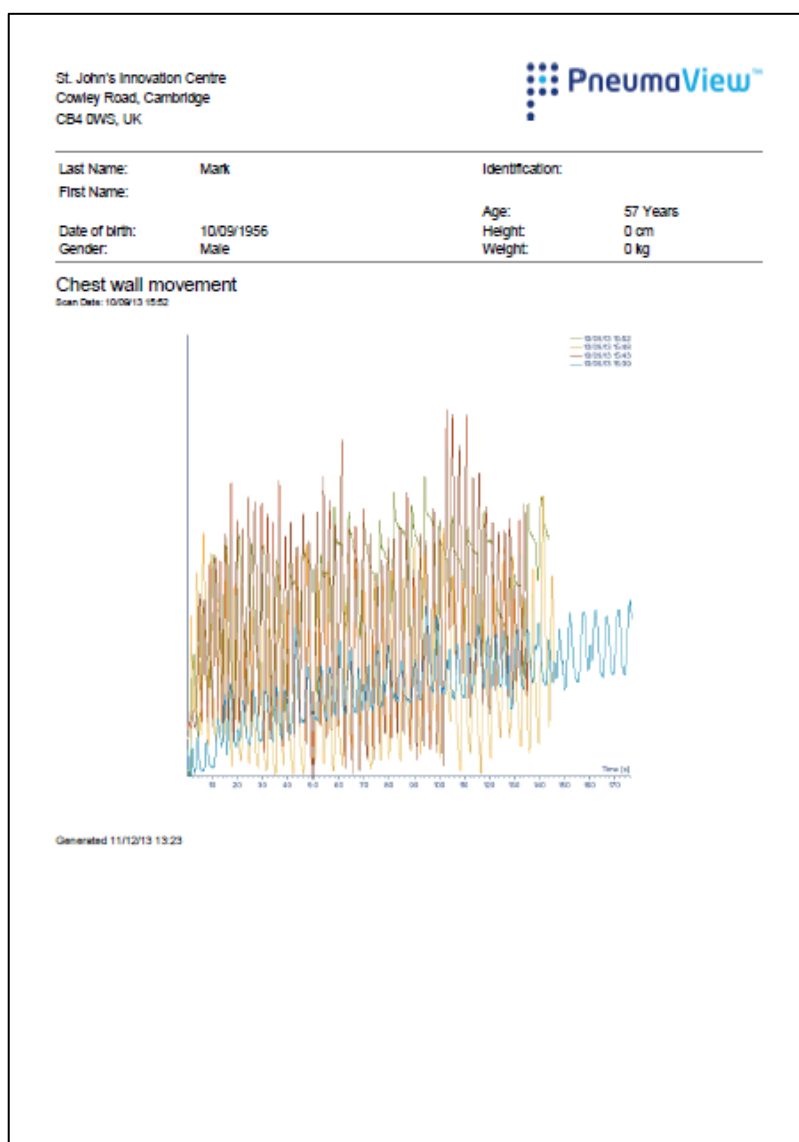


Figure 3.4 A complete report

3.12 To delete a measurement

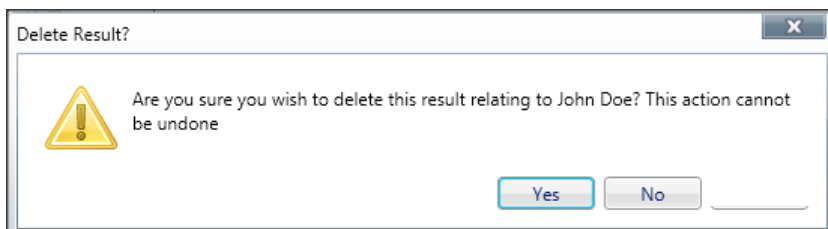
Note: This action cannot be undone and the data will be lost permanently.

If you want to delete a measurement:

1. Tap the red cross icon at the end of the data row. A dialog box opens.

	Measurement Started	Grid Size	
<input type="checkbox"/>	10/09/13 15:52	14x10	
<input type="checkbox"/>	10/09/13 15:48	14x10	
<input type="checkbox"/>	10/09/13 15:43	14x10	
<input type="checkbox"/>	10/09/13 15:39	14x10	

2. Tap **Yes**. The report is deleted.



3.13 To capture data

3.13.1 Position the patient and scanner

Make sure the patient is positioned correctly, for more information, see Position the patient.

Note: During each breath, ask the patient to keep as still as possible. Any movement affects the measurement quality and accuracy of the measurements.

Supine Patient

- Ensure that the patient is lying flat and straight on the bed.

Seated Patient

- Ensure that the patient:
 - Sits as far back in the chair as possible
 - Sits correctly and comfortably between each measurement



1. On the PneumaView program, tap the Patient tab.
2. Either:
 - a) Recover a saved patient record, using the Search tab, see To search for a patient; or
 - b) Enter a new patient; see To create a new patient entry.

Note: To go back to the search screen tap the red X by the patient's name.

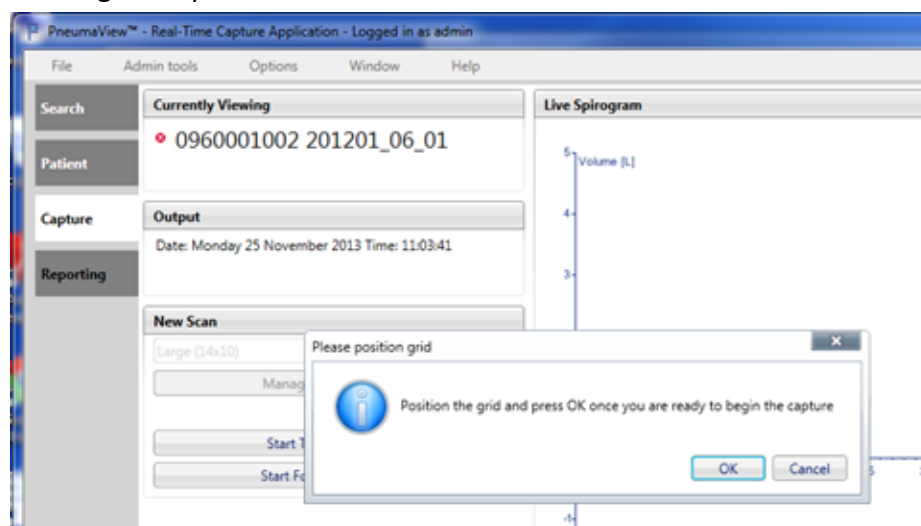
3. Tap the **Capture** tab.
4. In the New Scan box tap the grid size for the test. The default is Large.

The scanner head projects a grid pattern with a blue cross defining the mid-point.

Note: Check that the patient's clothing is still free of creases.

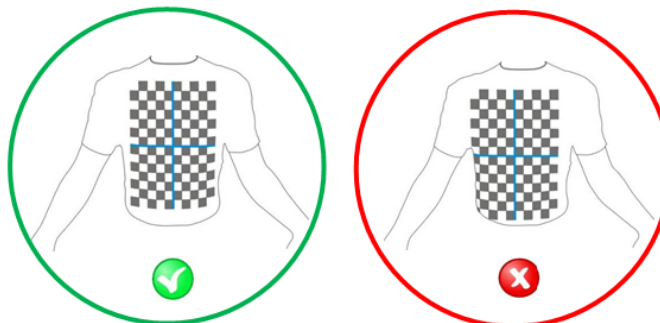
5. Tap **Start Tidal Manoeuvre**.

A dialog box opens:

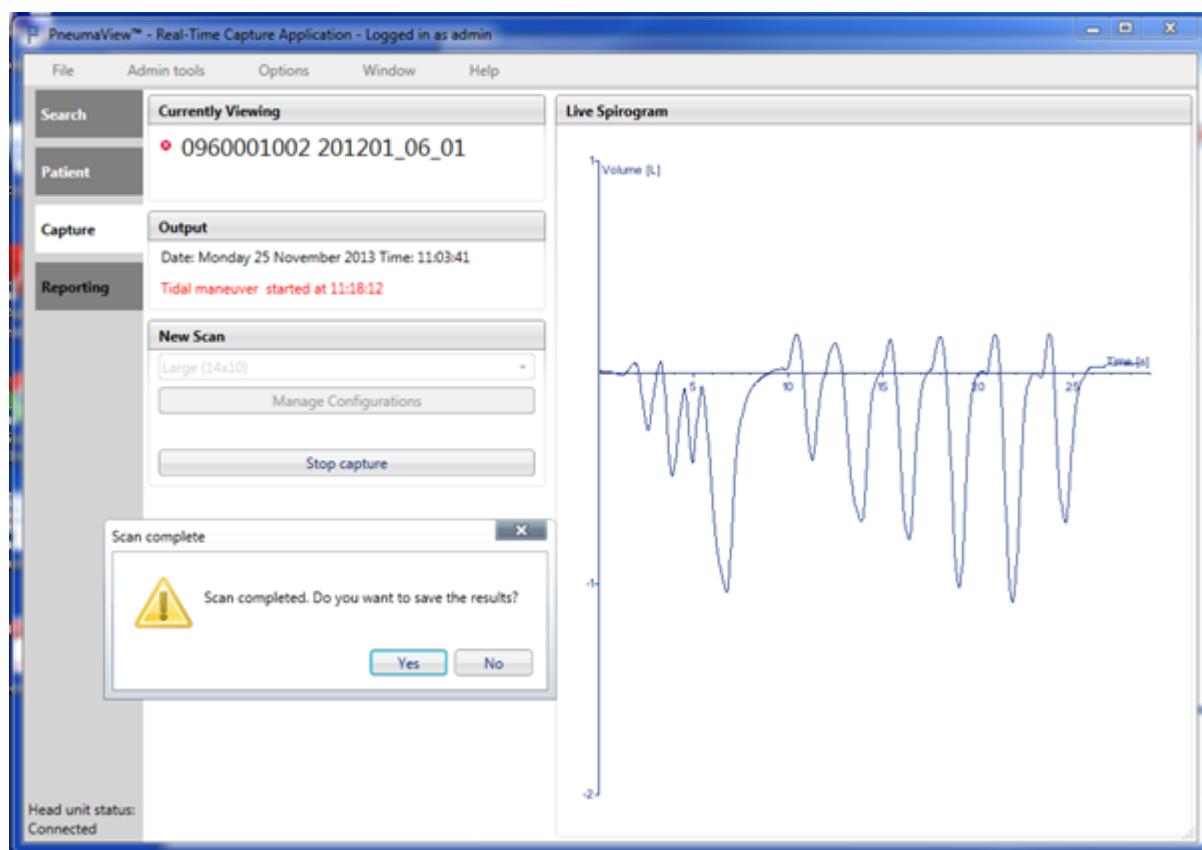


6. Position the grid, see Align Equipment with Subject:

Target the centre of the blue cross at the bottom of the patient's breast bone.



7. Tap **OK**. Recording begins and the trace appears on screen.
Recording continues for 5 minutes or until you tap **Stop Capture**. A dialog box opens.

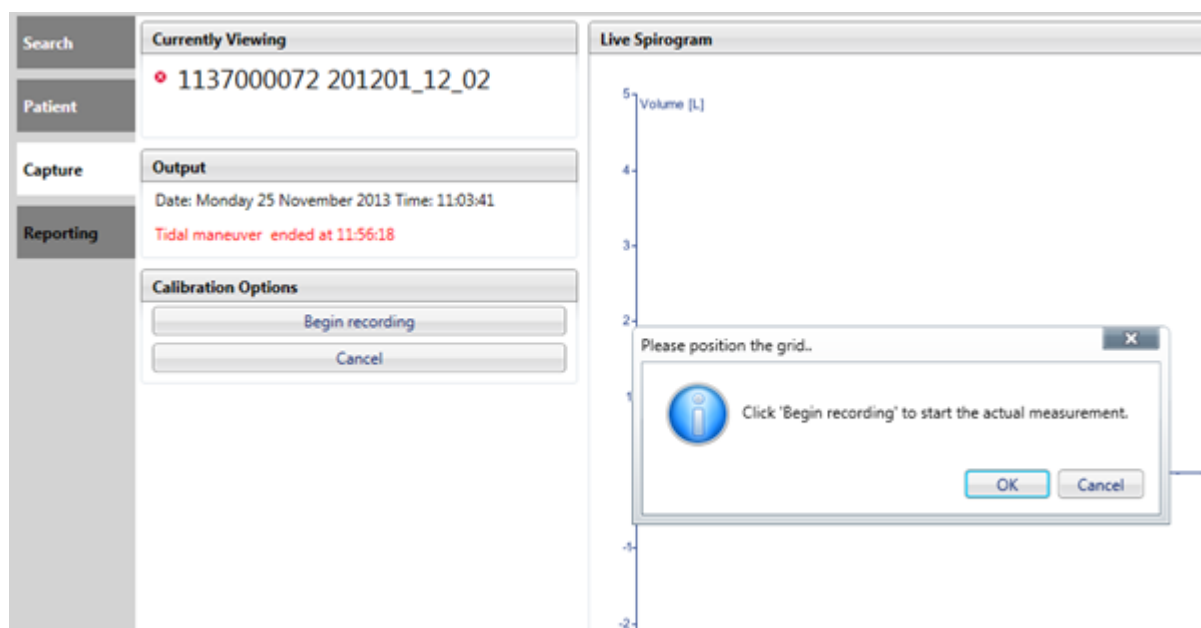


8. Tap **Yes** to save the results.

Two stage Capture

Select **Two Stage Capture** in the Options menu to delay the start of data recording. This allows you to make any final adjustments to the set-up of the instrument, and make sure you are receiving good data measurements before you start recording the data.

1. Tap **Start Tidal Manoeuvre**.
2. Position the grid. Tap **OK**. The measurement begins and the trace appears on the screen, but the recording does not start until you tap **Begin Recording**.



3.14 Administrator Tasks

Only the system administrator can:

- Synchronise the database
- Backup the database
- Manage users
- View and save Error logs
- Configure the grid image
- Manage the recycling bin

3.14.1 Synchronise the patient database

1. On the Admin tools menu, tap **Synchronise** to:
 - Import a patient database from another system
 - Merge your database with another database

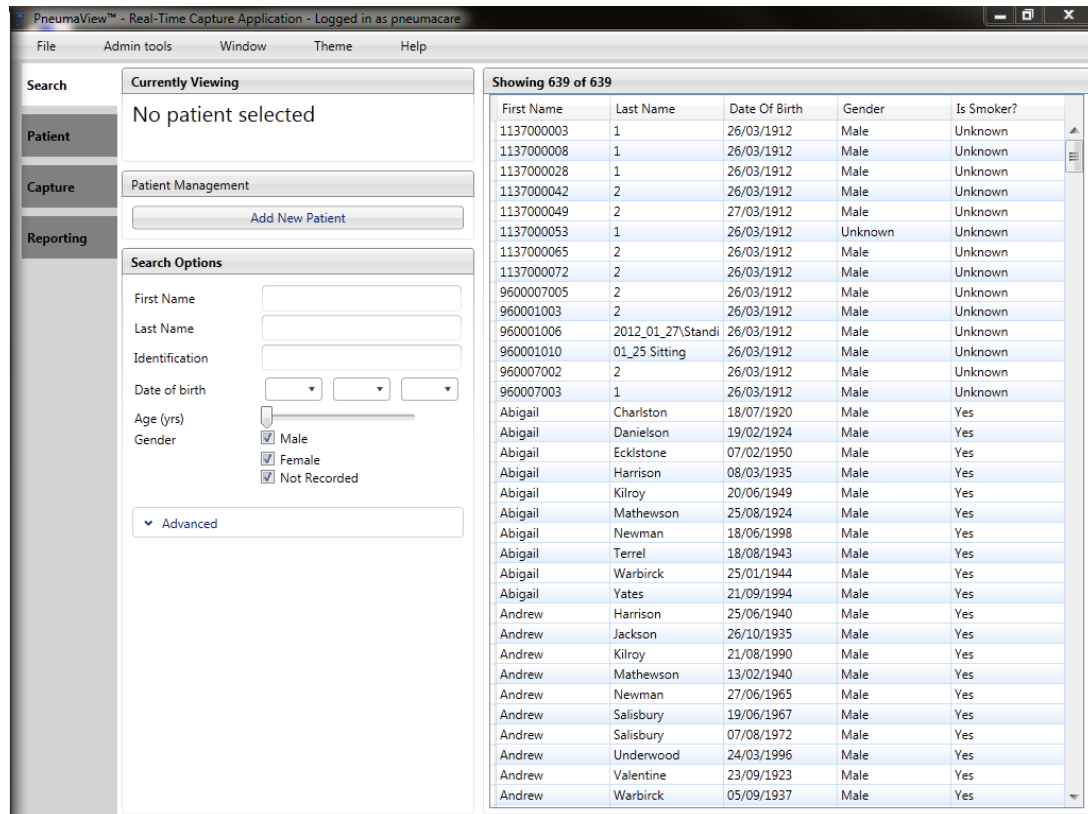
A dialog box opens.

2. Tap **OK**. A window opens displaying the default backup databases. You can browse to find databases stored in another location.
3. Tap on the database you want to use.

4. Tap **Open**. The database is unzipped and synchronised with the existing database. A dialog box opens when synchronisation is complete.

Note : This can take several minutes.

5. Tap **OK**. The patient data window is populated with the new data.



3.14.2 Backup and view a database

To back up a database to a new folder

1. In the **Admin tools** menu, tap **Backup** and then tap **Create backup**.

A window opens at the default location:

C:\Program Files\Pneumacare\Pneumaview\Database Backups

2. Tap **Save**. The database is saved as a compressed zip file.

To view a database

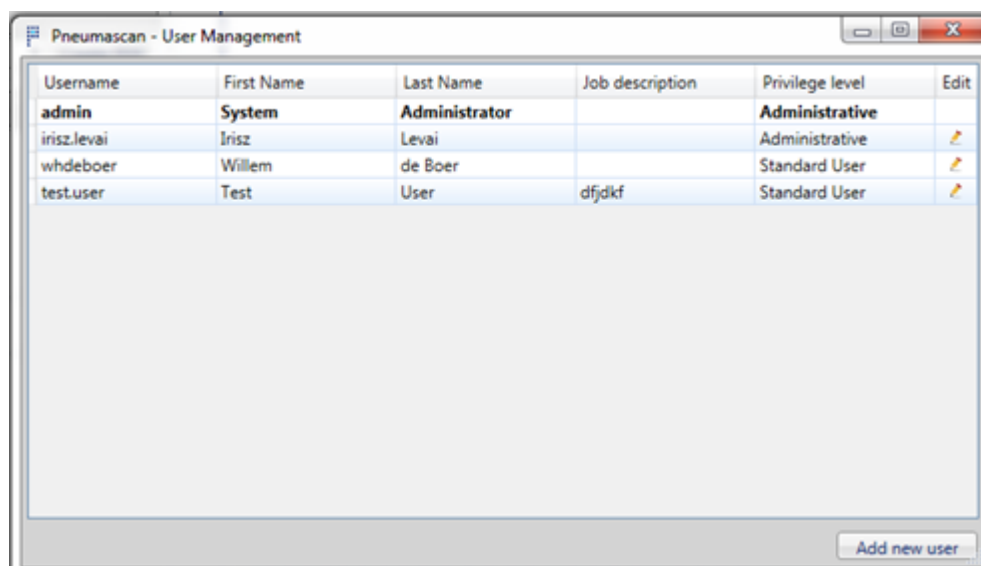
1. In the **Admin tools** menu, tap **Backup** and then tap **View Saved backup**.

A window opens at the default location

2. Tap on a file to select it.
3. Tap **Open**. The database is unzipped and opened in the patient data window.

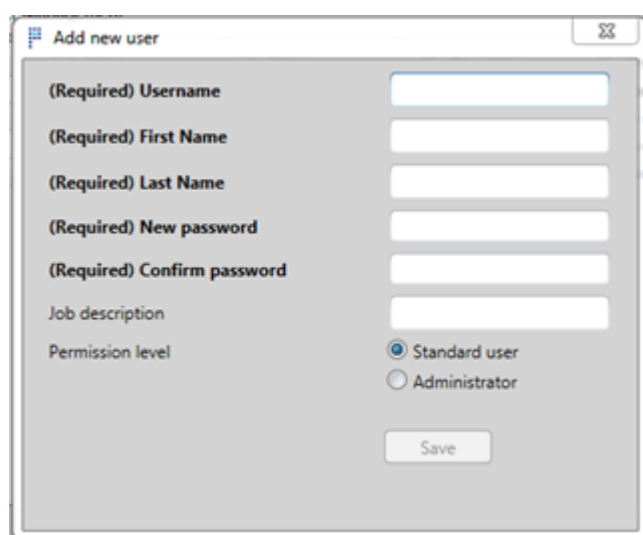
3.14.3 Manage Users

Use the Manage Users options to manage the Users, Log in details and Administrator privileges on the system:



Username	First Name	Last Name	Job description	Privilege level	Edit
admin	System	Administrator		Administrative	
irisz.levai	Irisz	Levai		Administrative	
whdeboer	Willem	de Boer		Standard User	
test.user	Test	User	dfjdkf	Standard User	

Add new user



Add new user

(Required) Username

(Required) First Name

(Required) Last Name

(Required) New password

(Required) Confirm password

Job description

Permission level
☒ Standard user
☐ Administrator

Save

3.14.4 Error logs

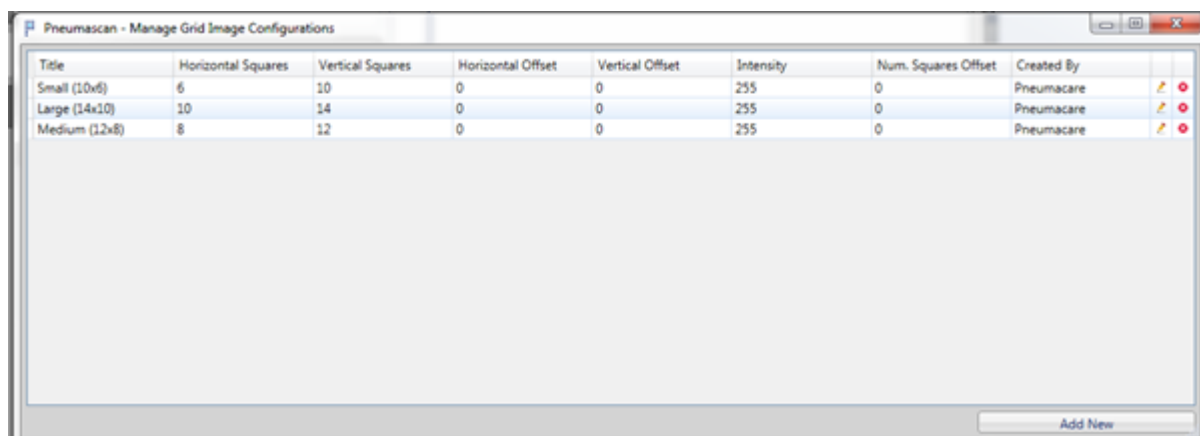
Error logs contain details of test failures and software crashes.

Use the View error logs option to:

- View
- Delete
- Save

3.14.5 Configure grid image

This menu option lets you configure the processes used in data capture and to set the projected grid size.



To define a custom grid size

1. Tap **Add New**. A window opens.
2. Enter a title for the custom grid.
3. Define the grid configuration.
4. Tap **OK** to save the custom grid.

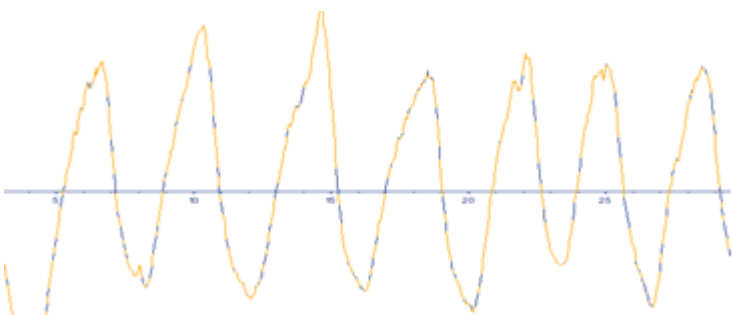

3.14.6 View recycling bin

Deleted files are stores in the recycling bin. You can select and restore files or delete the contents.

3.15 Errors

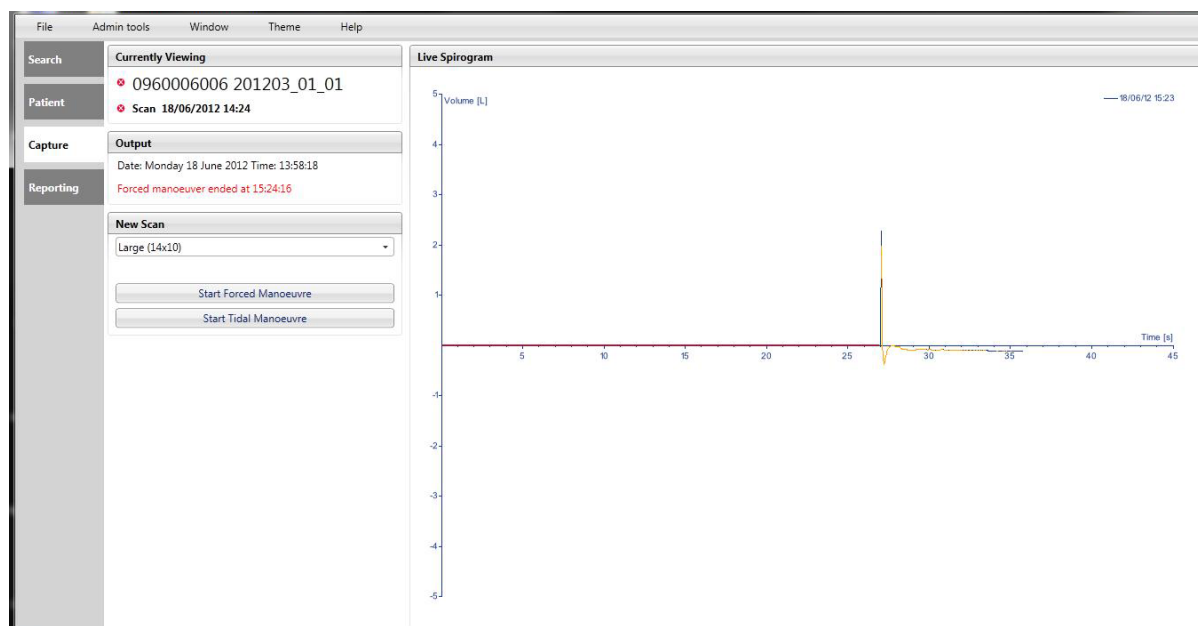
Bad data capture is displayed in the output:

Trace	Display	Reason
<ul style="list-style-type: none"> - a flat red line - mostly orange 		<p>The patient clothing is heavily wrinkled.</p>

Trace	Display	Reason
<ul style="list-style-type: none"> - a mixture of blue and orange - Peaks and troughs are jagged 		Low contrast lighting
<ul style="list-style-type: none"> - Red with no wave pattern 		<p>Grid is not in the correct position</p> <ul style="list-style-type: none"> - too high - too low - too far to the right - too far to the left <p>Grid is too large and is projected outside the patient's body</p>

For example:

This trace shows no recorded data and produces a flat red line, then a yellow spike as the patient moves. The grid reference is not set up properly and the projector records a distorted surface moving.



4 PneumaView 3D Viewer

The PneumaView 3D Viewer software displays a reconstruction of the measurements recorded in PneumaView, allowing you to play back the recorded data and view a 3D reconstruction of the patient's chest movements.

4.1 To start PneumaView 3D Viewer

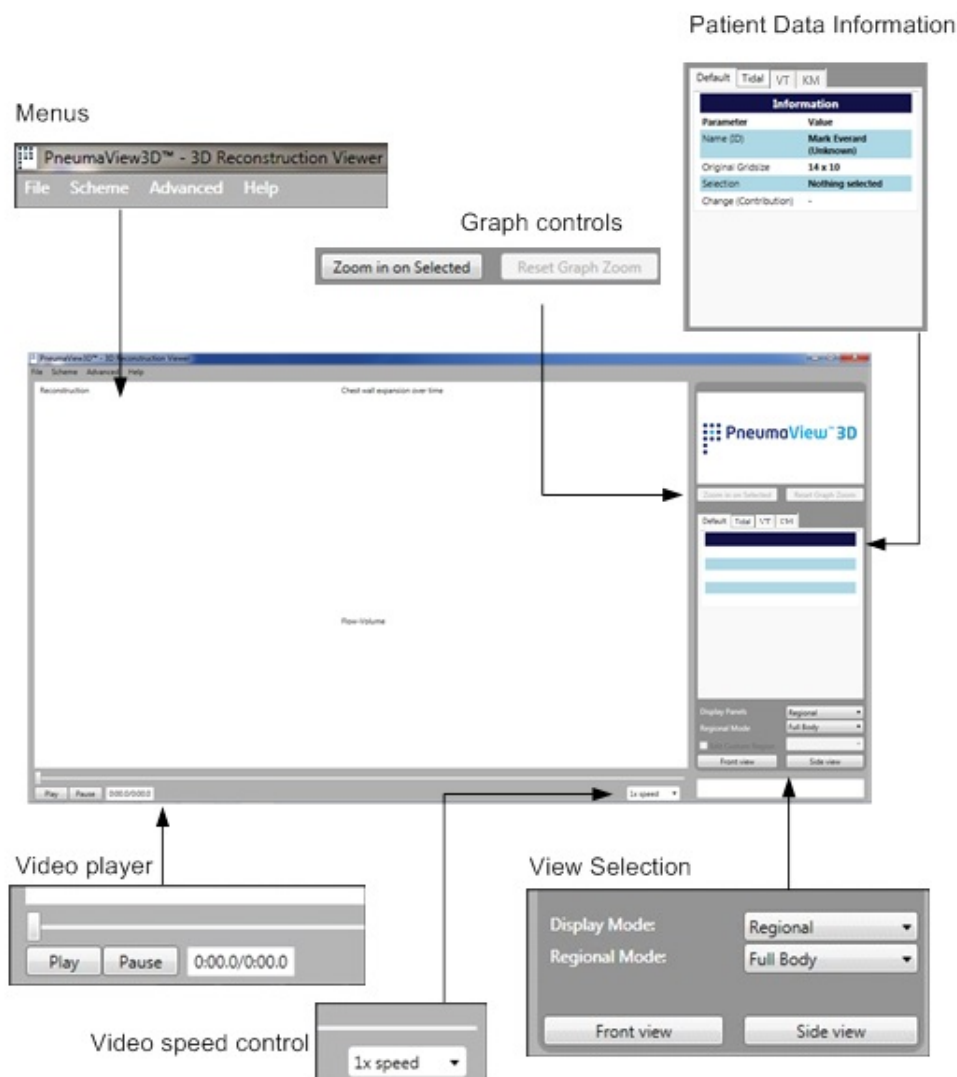
CAUTION:

Do not connect any USB devices to the instrument controller (All-in-one PC).
Do not install any software on the instrument controller.
Only use the USB port to back up the patient database on a portable USB stick.

Either:

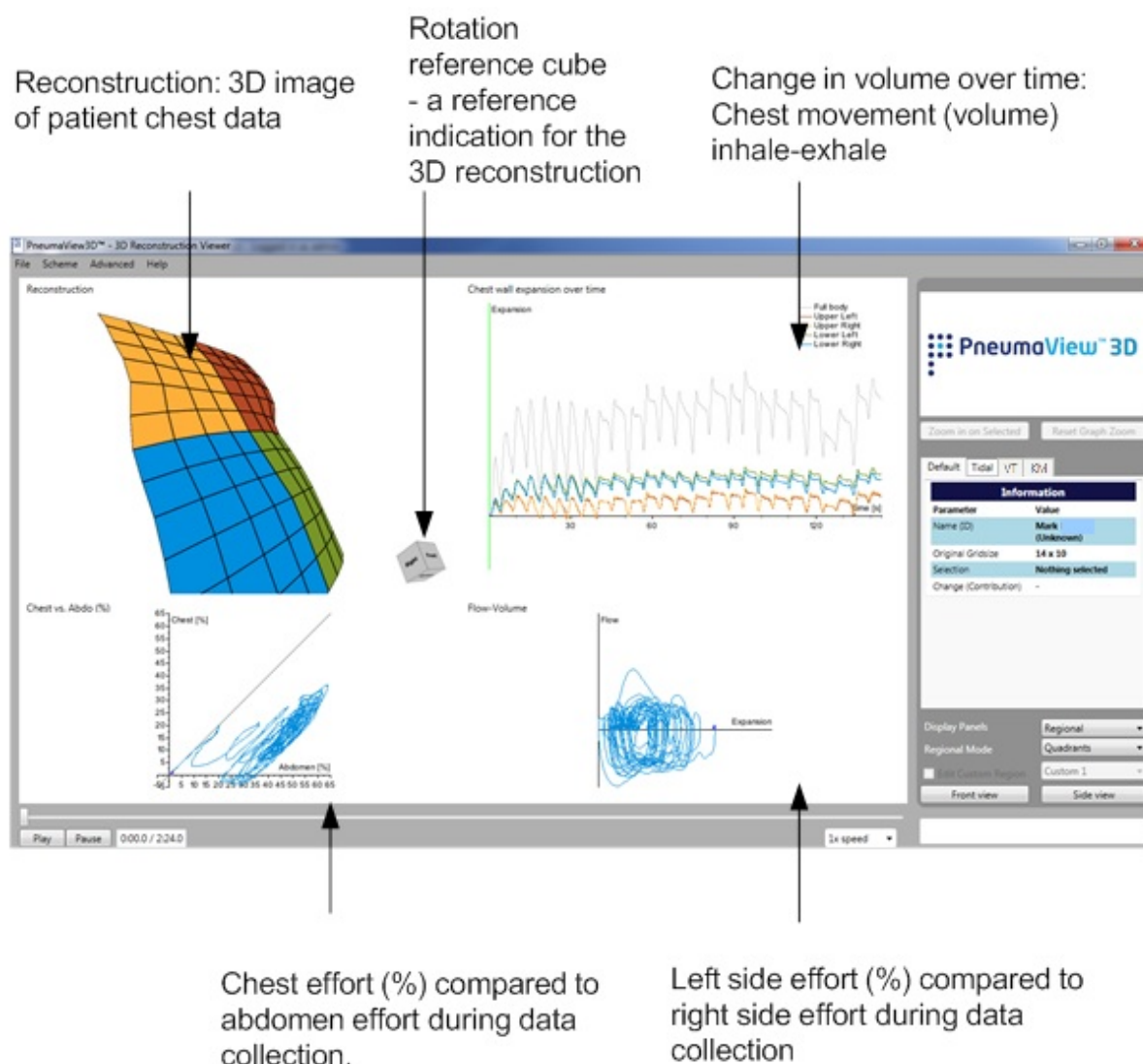
- Open the program from the computer Start menu or desktop icon. The program opens with empty fields and views.
- Select the **View 3D Reconstruction** option in the reports area of PneumaView, see To view reports. The program starts with the selected file open.

4.2 Main PneumaView 3D window



4.2.1 Data image areas

The images displayed on the screen can be altered using the view selection panel. For more information see View selection.



4.3 Menu Bar

4.3.1 File

Menu	Description
Open	To open a patient data file
Save As	To save the file
Save to Bitmap	To save the screen image as a picture file
Export to CSV	To export the measurements as a CSV file
Generate PDF	To generate a pdf file
Exit	To close the program

4.3.2 Scheme

Menu	Description
Light	To set the display to a light theme
Dark	To set the display to a dark theme

4.3.3 Advanced

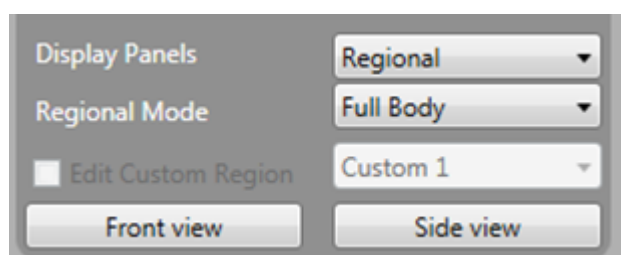
Menu	Sub menu	Description
Change from zero		To set the displayed graph axis to zero
Reverse Flow-Volume Loop		To reverse the loop to show inhalation above and exhalation below the x-axis
Additional Metrics	Show Flow-Volume Loop	To display the Flow-Volume loop in the main window
	Trend graph	To display a bar plot of the per-breath values of a parameter, and 1 minute average lines
Show Orientation Cube		To display the orientation cube
To enable Two Custom Regions		To enable a second custom region Note: The default is one custom region
Show raw frames		Select to show raw data in the video player (includes noise)

4.3.4 Help

Menu	Description
About	To open an information window displaying the software version

4.4 View selection

The View selection menu allows you to change the way the images are displayed on the screen.



4.4.1 Display Panels

Use the display panel options to change the display on the screen:

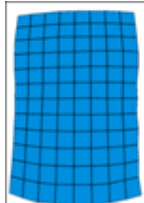
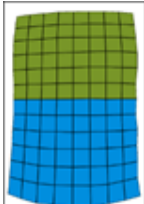
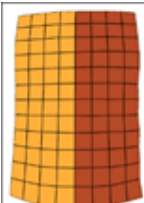
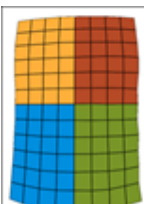
Recon. Only	3D reconstruction only
Recon. + Volume/time	3D reconstruction and tidal breathing trace
Regional	Chest versus Abdomen
	Left side versus Right side

4.4.2 Regional Mode

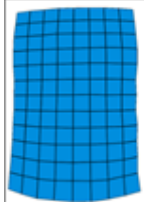
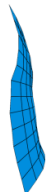
The graphical data recorded from the projected grid pattern in PneumaView is divided into quadrants.

Q1:	Right chest	Q3:	Upper right abdomen
Q2:	Left chest	Q4:	Upper left abdomen

Use Regional mode to select how you want to view the data.

Full Body	Full body displayed in blue Q1 + Q2 + Q3 + Q4	
Chest/Abdomen	Right and left chest (Q1+Q2) in green Upper right and Upper left abdomen (Q3+Q4) in blue	
Left/Right	Right chest and Upper right abdomen Q1+Q3 in orange Left chest and Upper left abdomen Q2+Q4 in brown	
Quadrants	Right chest(Q1) in orange Left chest (Q2) in brown Upper right abdomen (Q3) in blue Upper left abdomen (Q4) in green	

4.4.3 Front view and Side view buttons

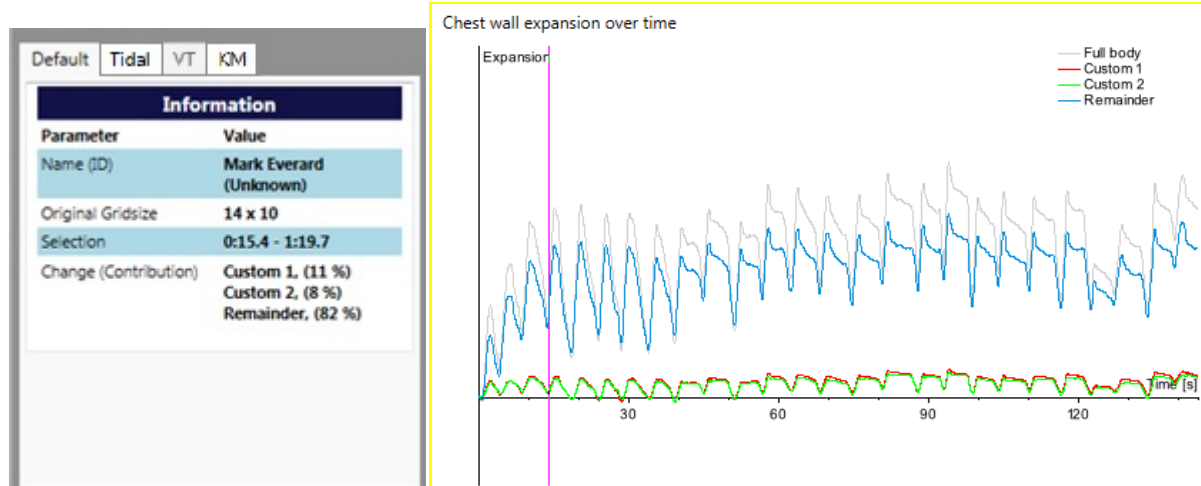
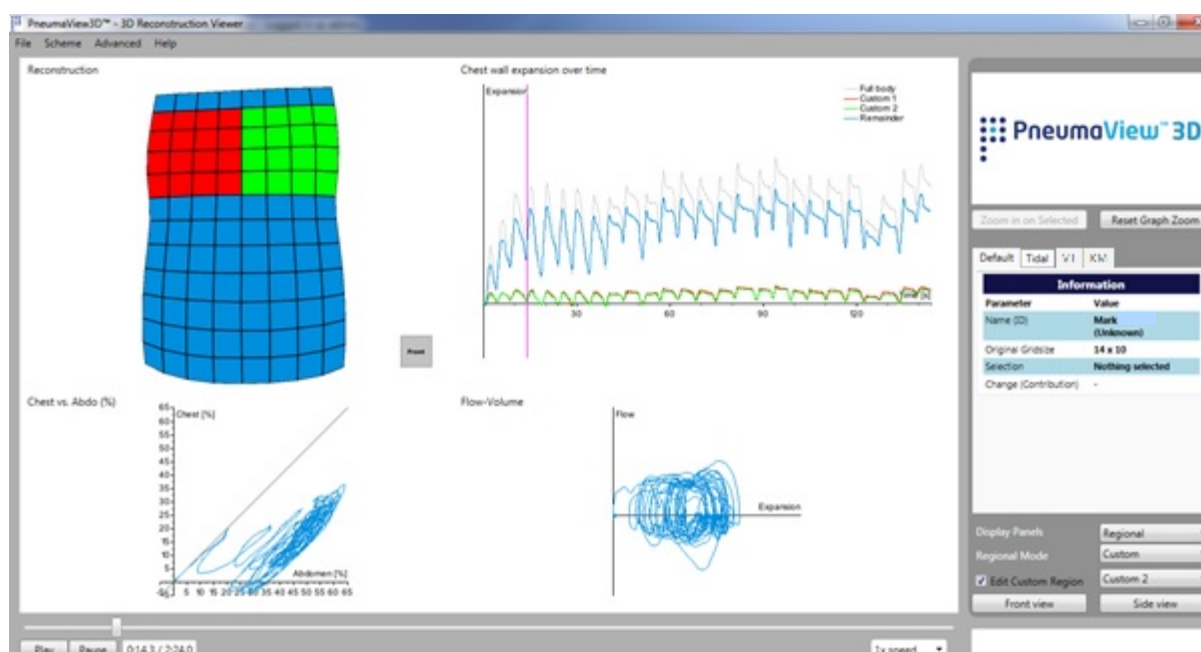
Front view	Displays the front view of the body	
Side view	Displays the right side view of the body	

4.4.4 Edit Custom Region

You can define two regions, **Custom 1** displayed in red and **Custom 2** displayed in green. Each custom view is saved in PneumaView 3D. To change the view, use the **Edit Custom Region** option.

To define a custom region

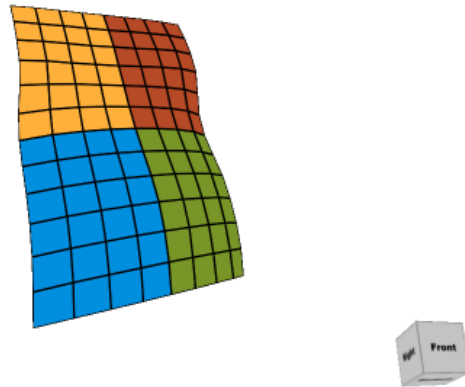
1. In the **Regional Mode** menu list, select **Custom**.
2. Tap the **Edit Custom Region** check box.
3. Tap the drop down arrow then select either **Custom 1** or **Custom 2**.
4. Tap and hold on the image of the chest wall, then drag the cursor to define your custom area. The colour of the image changes to show the area you define.
5. Release the cursor. The selected area is displayed in the Reconstruction area and its corresponding displacement over time trace is also displayed:



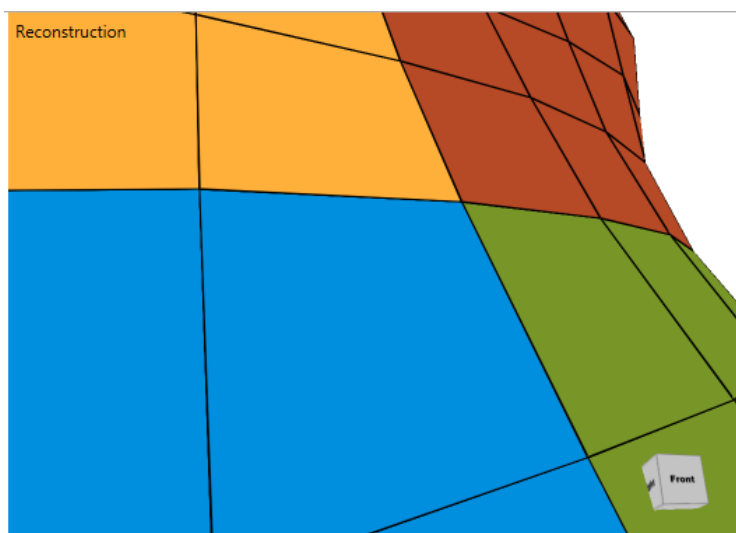
4.4.5 To change the size of the chest wall image

You can resize the chest wall image by tapping on the image with two fingers and then pinch in to zoom out, or pinch out to zoom in:

Reconstruction



4.1 Zoom out



4.2 Zoom in

4.4.6 Video player

Use the video player to view the patient's chest movements and breathing volume and effort of the recorded test.

The controls are:

- Play
- Pause
- Speed Control

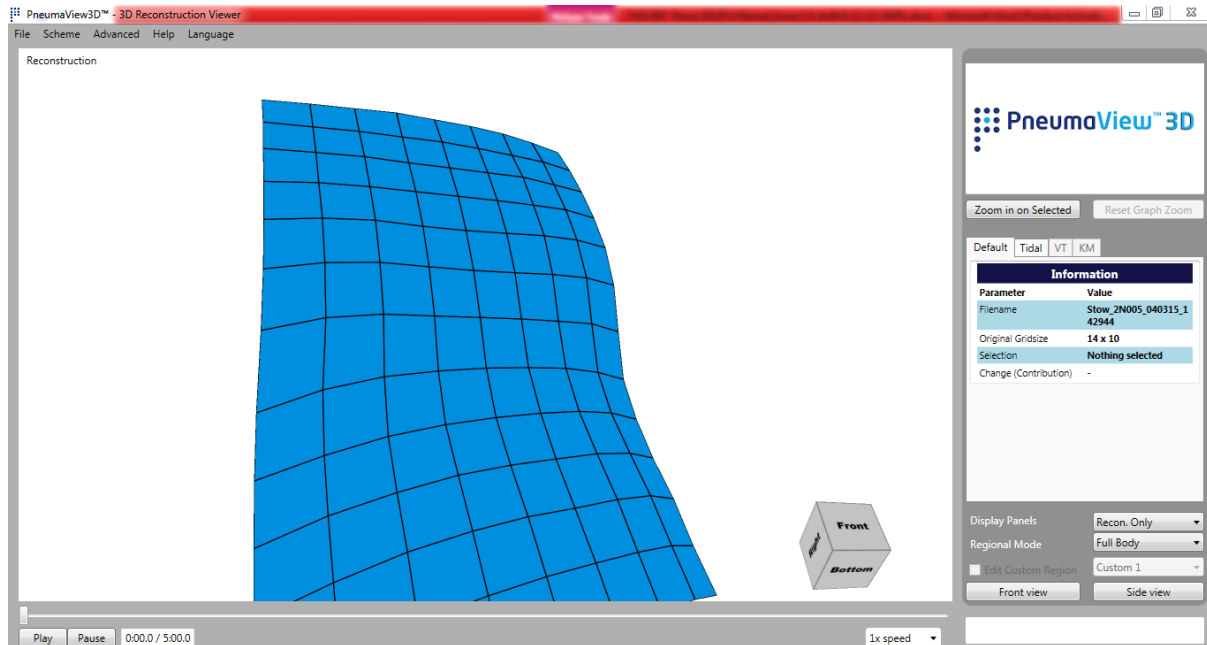
4.5 Display view

These examples show how you can change the views in the display.

4.5.1 Example 1

Select:

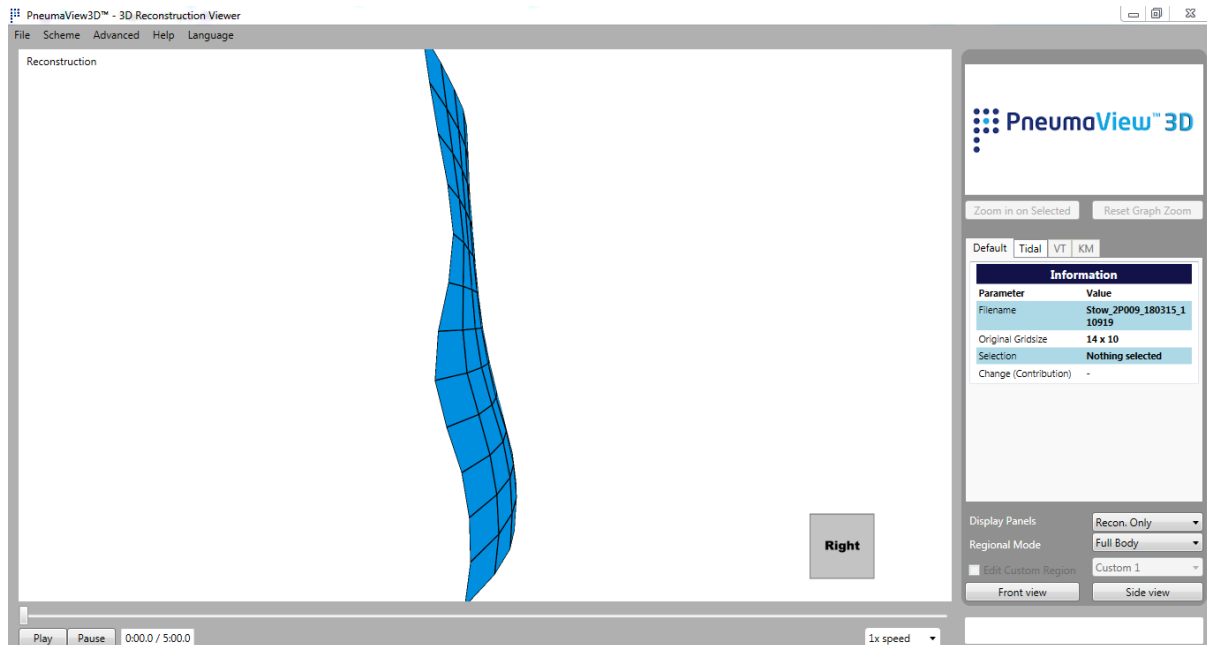
- Display Panels: Recon. Only
- Regional Mode: Full Body



4.5.2 Example 2

Select:

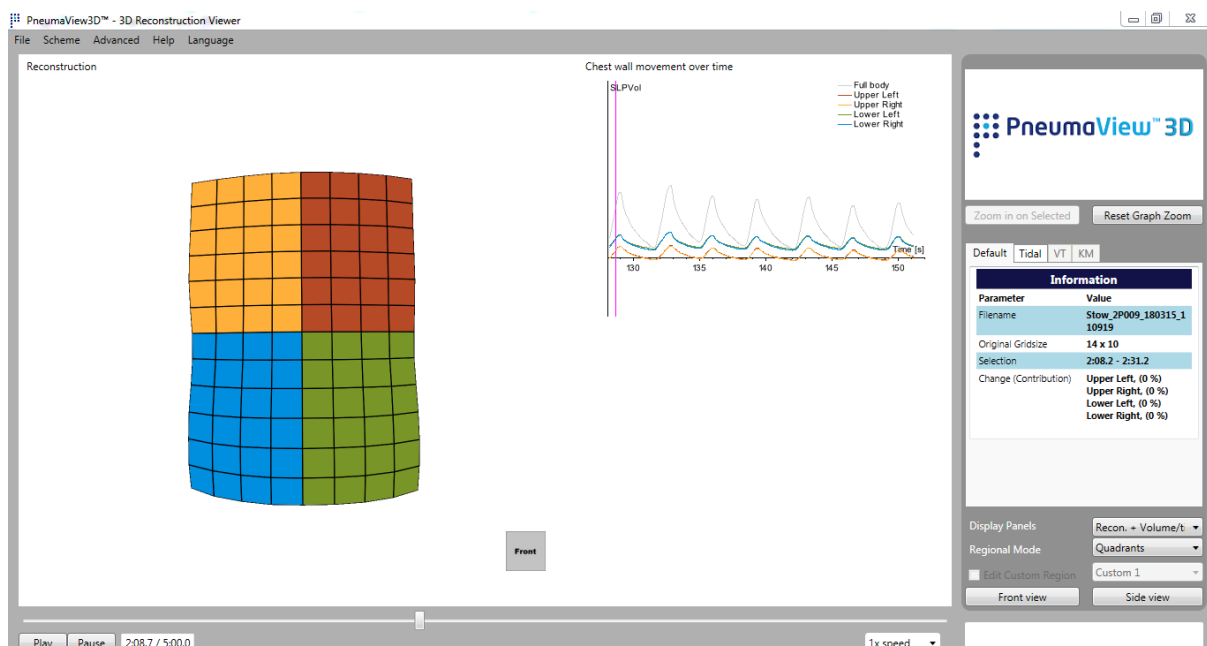
- Display Panels: Recon. only
- Regional Mode: Full Body



4.5.3 Example 3

Select:

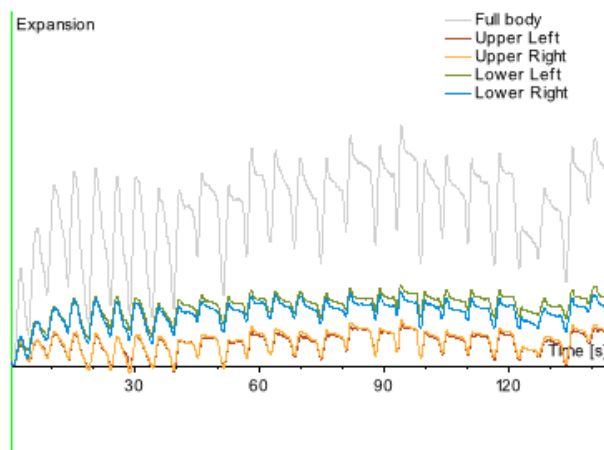
- Display Panels: Recon. Volume/Time
- Regional Mode: Quadrants



The graph area in detail shows the patient's chest movements over time. Change the options in Regional Mode

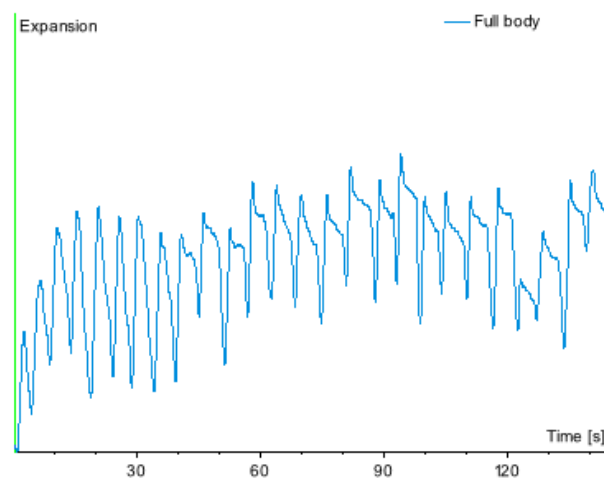
Quadrants: Each quadrant is represented in the graph as an individual input. A total displacement is shown in grey.

Chest wall expansion over time



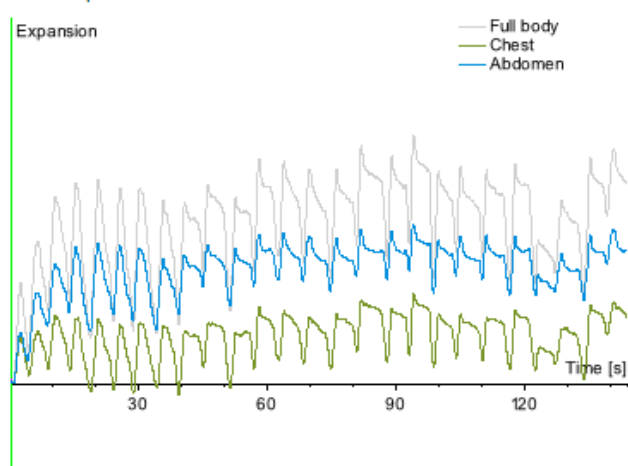
Full body: Full body single colour in blue

Chest wall expansion over time

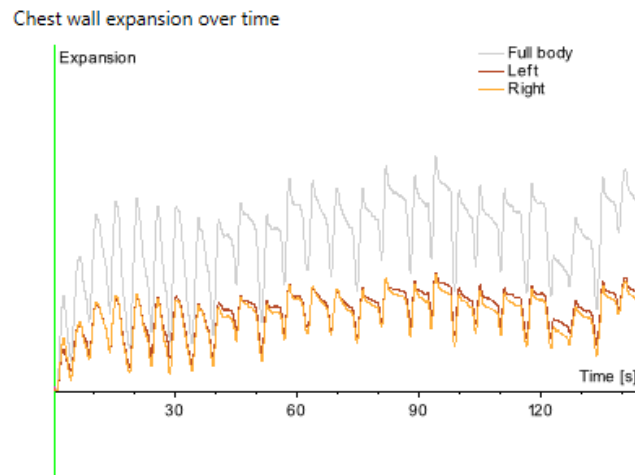


Chest/Abdomen: Blue and green
Plus total displacement in grey

Chest wall expansion over time



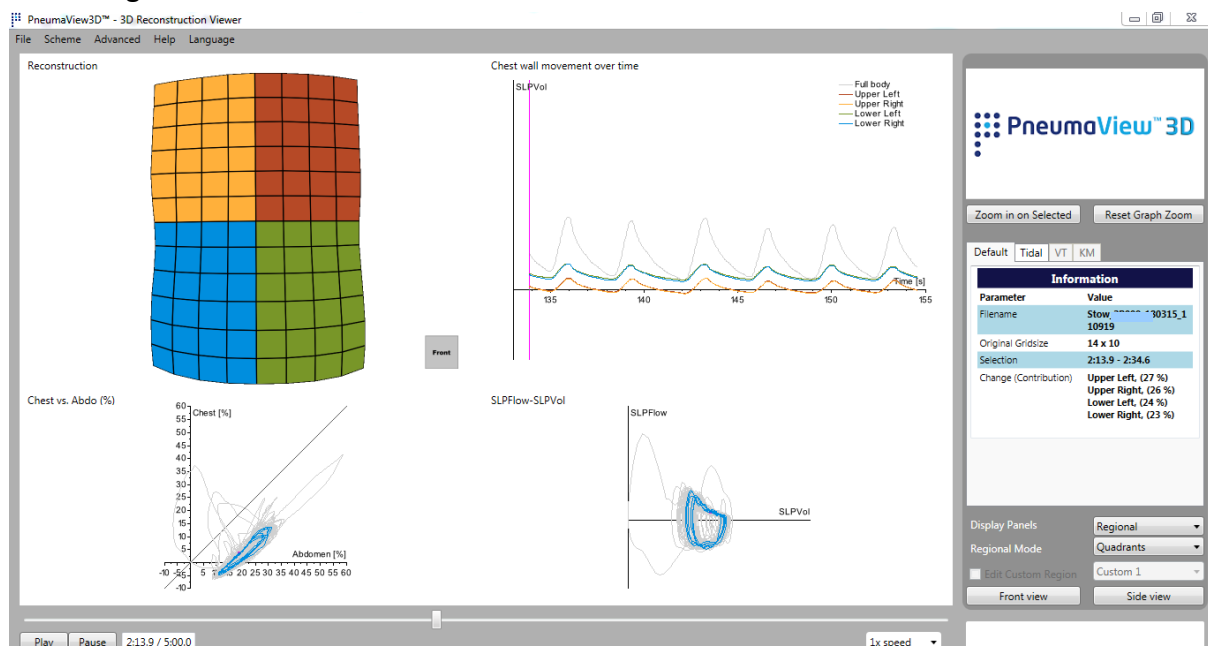
Left/Right: Yellow and Orange
Plus full body in grey



4.5.4 Example 4

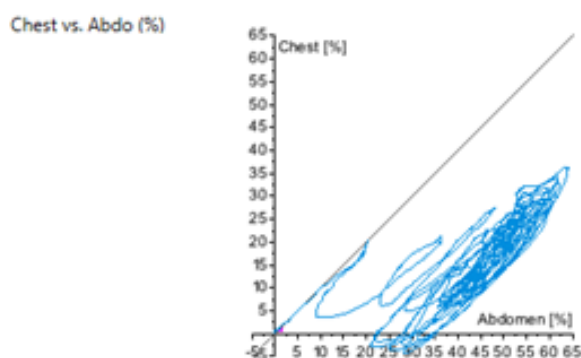
Select:

- Display Panels: Regional Rib Cage versus Abdomen and Left Side versus Right Side
- Regional Mode: Quadrants



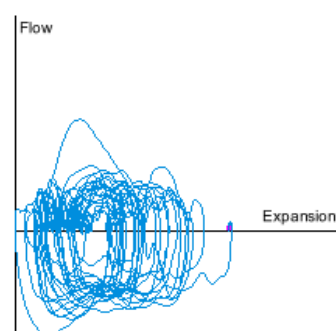
In detail:

Konno-Mead plot.



Flow –Volume Loop

Flow-Volume

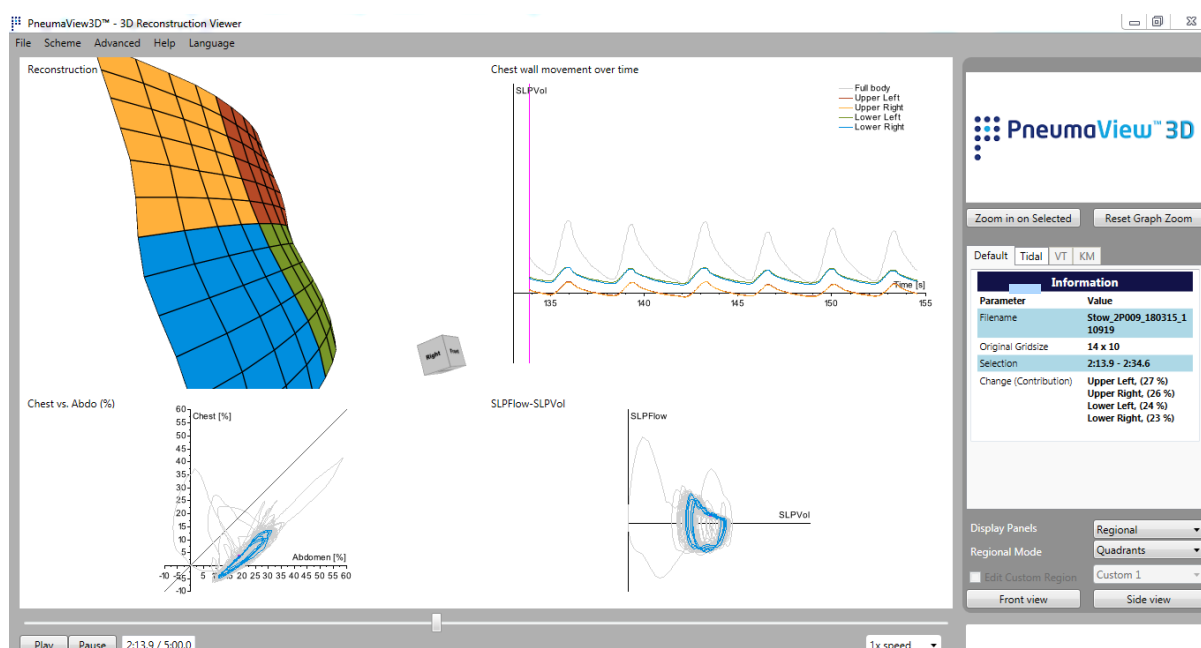


4.6 To display a 3D reconstruction of the recording

Use the video player to replay a test and view:

- chest movement

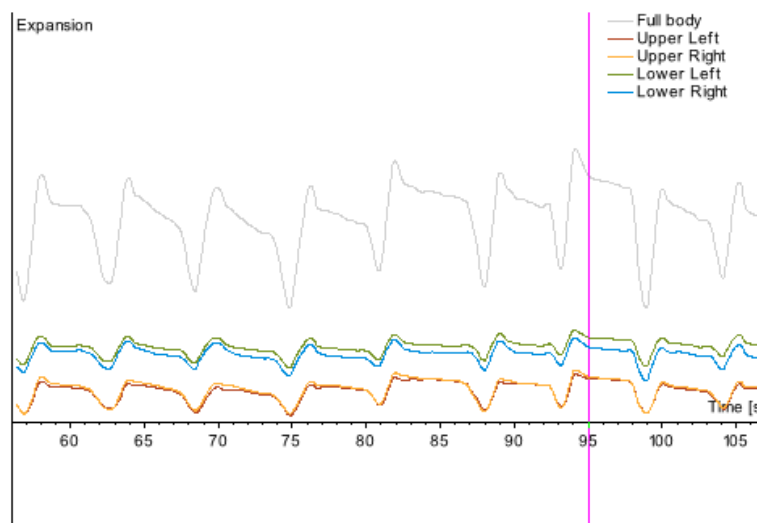
You can rotate the chest view using the orientation cube. Tap and hold the cube then move the cursor within the **Reconstruction** frame to rotate the image.



As the recording plays the instant in the recording shows as a:

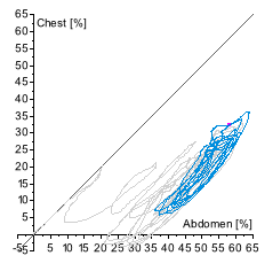
- Bar in Change in volume over time graph

Chest wall expansion over time

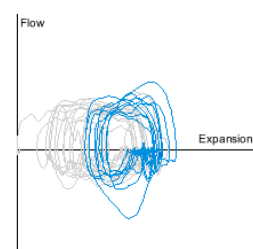


- Point in the Chest v Abdomen and Flow Volume loop graphs

Chest vs. Abdo (%)



Flow-Volume

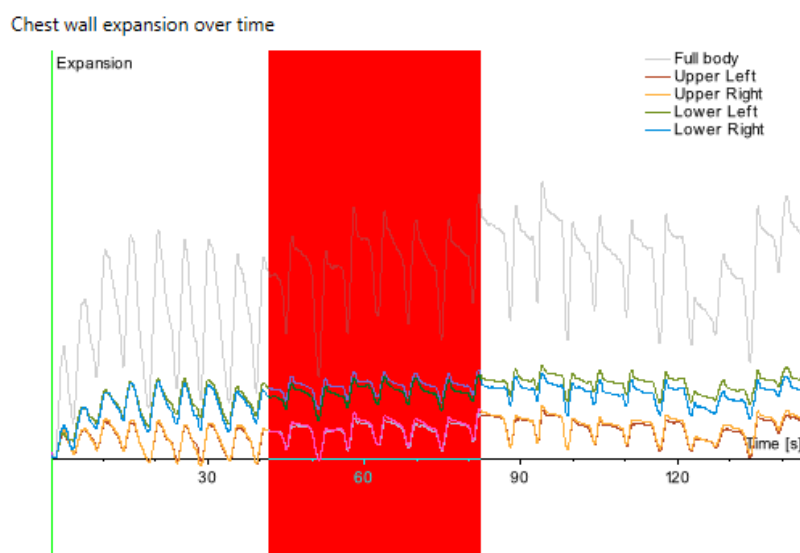


4.7 To select Information Data

You can populate the data in the Information Box.

1. In the **Chest wall expansion over time** graph, on the time axis tap and hold and drag the curser along to mark the data you want to view. This is the *current selection*.

The area you select is highlighted red.



In the Information box; the **Default** tab shows the Selection and Change(Contribution) populated with patient data and The **Tidal** tab displays the tidal parameters:

Default Tidal VT KM

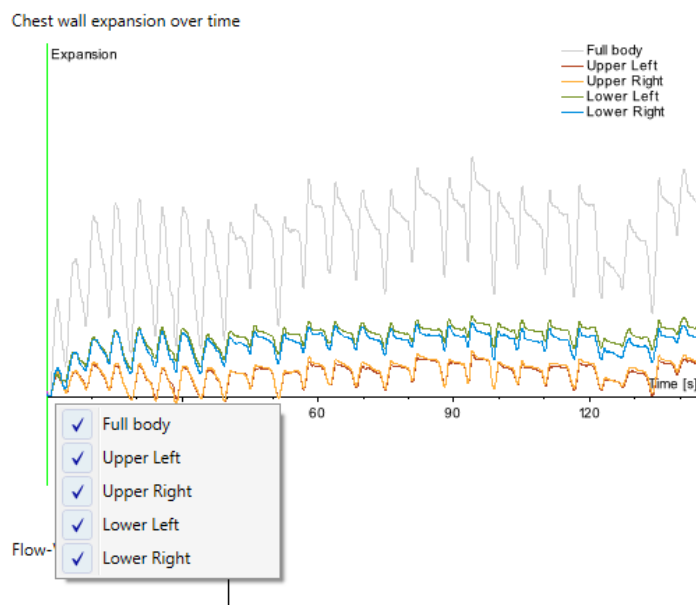
Information

Parameter	Value
Filename	Stow_80315_110919
Original Gridsize	14 x 10
Selection	0:54.0 - 2:18.8
Change (Contribution)	Upper Left, (17 %) Upper Right, (18 %) Lower Left, (31 %) Lower Right, (33 %)

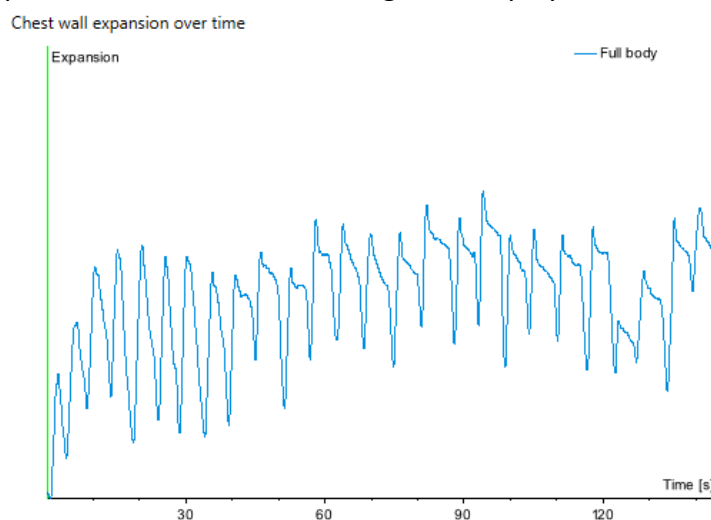
Default Tidal VT KM

Parameter	Average	Variation
Resp. Rate (/min)	17.4	
Ti / Te	0.48	
Ti (s)	1.14	-
Te (s)	2.37	-
Ti / Ttot	0.32	
Ttot (s)	3.50	
Relative expired (%)	Upper Left, 24 Upper Right, 24 Lower Left, 25 Lower Right, 26	

2. Tap and hold on the time axis, a drop down box appears showing the results displayed.



3. Tap on the check boxes to change the displayed results. For example Full body:



4.8 Numerical output explained

The *current selection* is that part of the measurement that is currently selected.

To make a selection, on the time axis of the chest wall movement graph tap and hold, and drag the cursor along to mark the data you want to view.

Respiratory Rate

The number of breaths per minute.

Change (Contribution)

A point-to-point relative contribution of the currently selected regions. This parameter denotes the ratio of the point-to-point change of a region to the total change.

Ti

The inspiratory time of a breath, from start of inhalation to end of exhalation, averaged over all breaths in the current selection.

Te

The expiratory time of a breath, from start of inhalation to end of exhalation, averaged over all breaths in the current selection.

Ttot

The total cycle time of a breath (from start of inhalation to end of exhalation); averaged over all breaths in the current selection.

Ti/Te

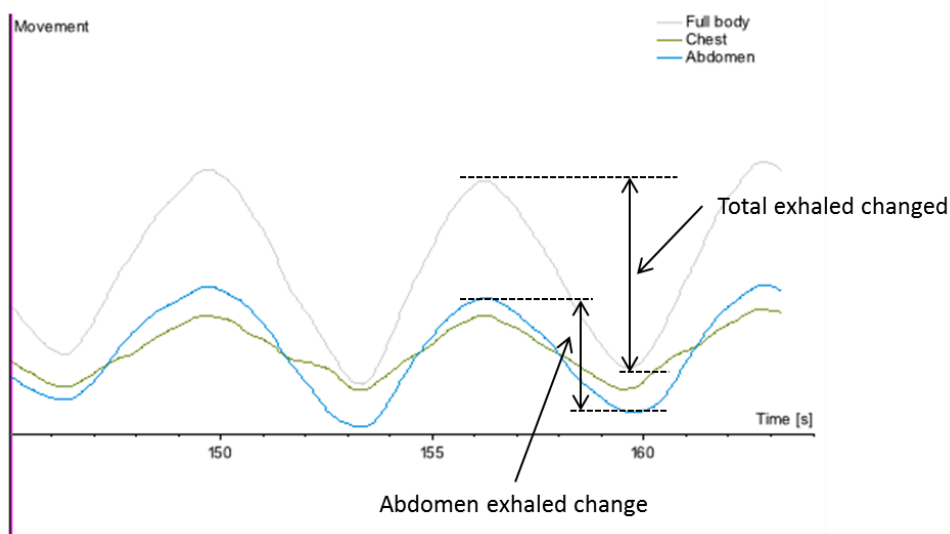
The ratio of Ti to Te, averaged over all breaths in the current selection.

Ti/Ttot

The ratio of Ti to Ttot, averaged over all breaths in the current selection.

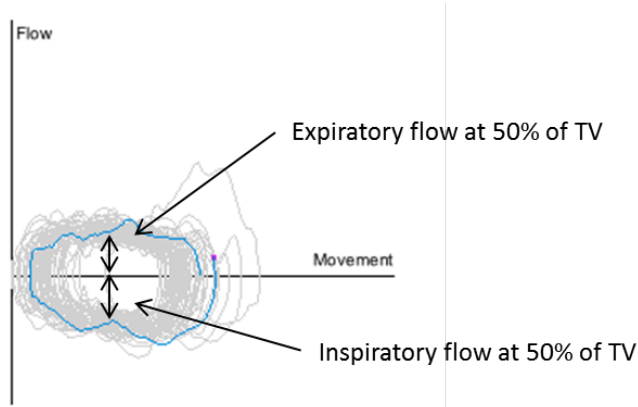
Relative Expired Contribution

The ratio of a region's expired chest wall movement (exhalation) to the total expired chest wall movement, averaged over all breaths in the current selection.



IE50

The ratio of inspiratory flow at 50% of tidal volume to expiratory flow at 50% of tidal volume (TV); where TV is the exhaled chest wall movement. IE50 is averaged over all breaths in the current selection.



Overall Phase

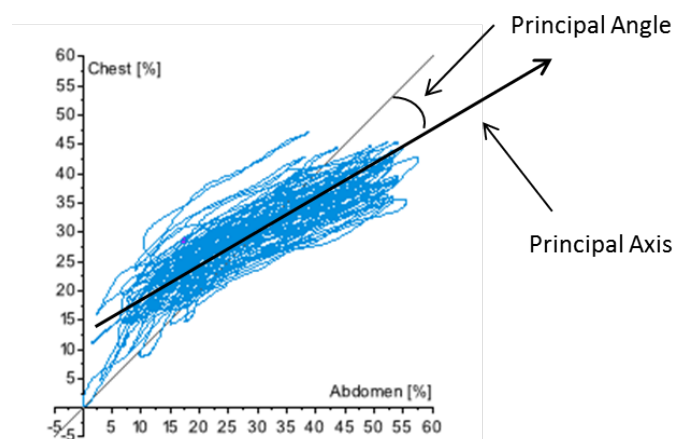
The phase difference between two regions calculated on the entire KM plot as a whole.

Principal Angle

The principal angle is the angle of the principal, *dominant*, axis of the KM plot relative to the 45 degree line.

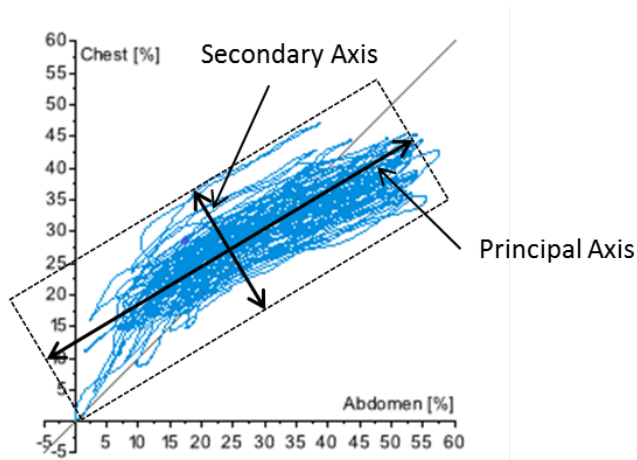
In this example, the angle is negative. This indicates abdominal dominant breathing, in terms of the abdomen's contribution to total chest wall movement.

A positive angle indicates chest dominant breathing.



Spread

Spread is the ratio of the length of the secondary axis to the length of the principal axis and denotes the overall *width* of the KM plot.



Window Phase

The phase difference between two regions; calculated for a 2-second window and then averaged over a sliding window for the current selection.

Breath Phase

The phase difference between two regions, averaged over all breaths in the current selection.

Variation

A variation metric is calculated for certain parameters. This metric tells you about the breath-by-breath variability of that parameter.

For example; if a parameter remains constant from breath to breath, then variation is 0. The more randomly the parameter varies between breaths, the higher the variation.

Note. Select a segment containing a minimum of 50 breaths to get a variation.

4.9 3D data quality appraisal

During 3D playback, indications of a high-quality dataset are:

- Chest wall movement are:
 - Stable
 - No high-frequency wobbles or ripples visible
- Breaths in the Chest wall movement graph are:
 - Smooth peaks and troughs
 - No high-frequency ripples visible

4.9.1 To select the best segment for data analysis

It is important that SLP data analysis is performed only on that part of a measurement that contains no patient movement.

Thora-3DI is intended to be used on patients who keep perfectly still during a measurement; the only movement that is registered should be from breathing. In practice, during longer measurements, some patient movement may still occur and patients tend to relax throughout a measurement which can have an effect on their breathing pattern. This can result in a noticeable drift in full-body Chest wall movement or one of the regions.

To perform a high quality analysis, it is important to know how to detect these types of events after a measurement, and to select only the best segment for the analysis. This section provides some guidelines on how to select the best segment.

What to look for when choosing a segment

The three main output graphs in PneumaView™3D; Chest Wall Movement, KM plot, and FV loop; can help you detect patient movement and choose the best segment.

Indications of movement are:

- An obvious shift in the baseline in the Chest wall movement graph, or a visible *drift* downwards or upwards of one of the regions, or the full body.
- The KM plot and/or FV loop consist of more than one part.
- The KM plot exhibits movement perpendicular to the breathing motion.

A well-chosen segment has the following characteristics:

- Chest wall movement is *stable*, with no drift or shift in baseline.
- The KM plot and FV loop both consist of one contiguous part.
- The KM plot does not contain significant movement perpendicular to the breathing motion.
- The FV loop is clear: it looks circular with a clear hole in the centre.
- The segment contains the maximum number of breaths possible while still exhibiting these properties.

Note Clinical output is averaged over all selected breaths; statistically the more breaths, the more stable the output.

4.9.2 Examples

Example 1

Some patients can be quite tense before a measurement, and then tend to relax during the measurement. This affects the output and can result in *drift*. This type of drift shows as movement of the Konno-Mead plot perpendicular to the movement of breathing, and the Flow Volume loop consists of two parts:

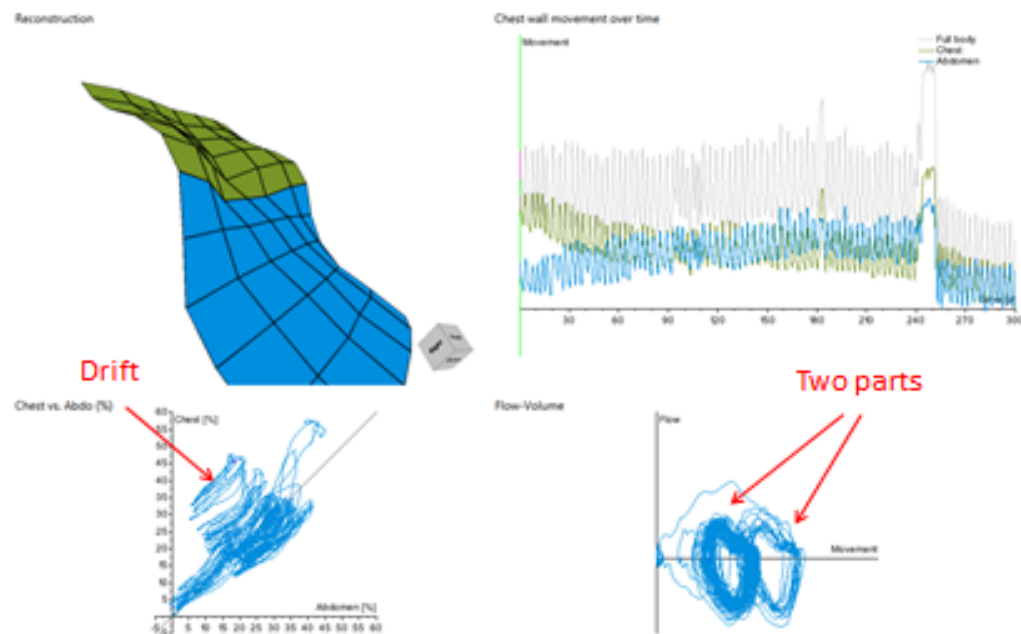


Figure 4.3: Movement manifested as drift in the KM plot, and the two parts FV loop

The best segment to select in this case is shown:

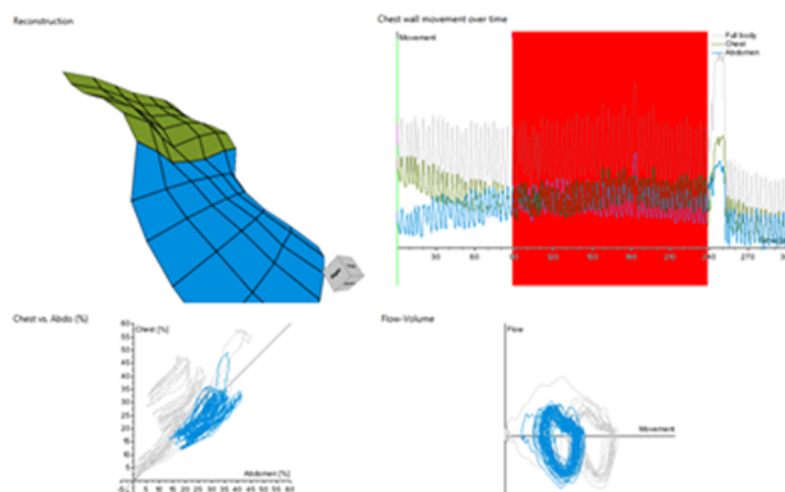


Figure 4.4: Good-quality segment that reduces drift

Example 2

This example shows the output of a patient who moved during measurement.

In the Chest wall movement graph; you can clearly see a shift in baseline when the patient moved. In the Konno-Mead plot there is a noticeable drift.

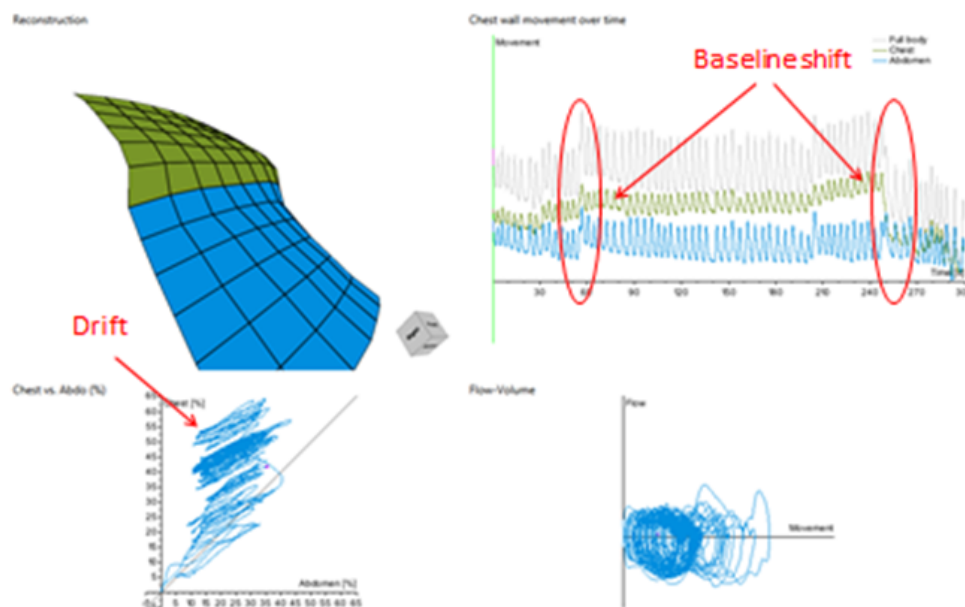


Figure 4.5: Significant baseline shift in Chest Wall Movement, and drift in KM plot

The best segment to select in this case is shown; note the minimal Konno-Mead plot drift and a clear Flow Volume loop:

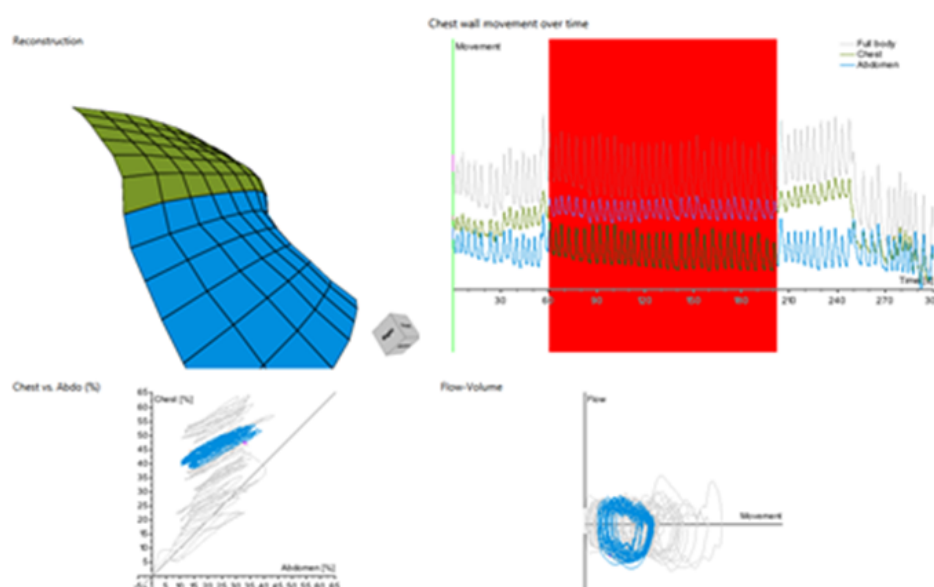


Figure 4.6: High-quality segment.

Example 3

A Konno-Mead plot that consists of more than one part indicates gross movement.

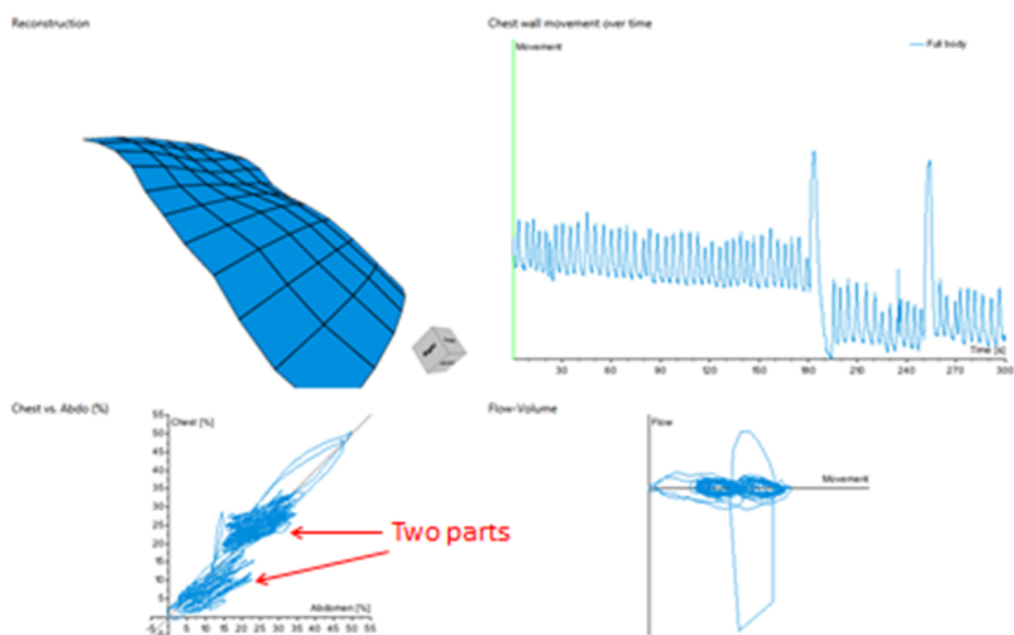


Figure 4.7: KM plot consists of two parts, indicating movement

The best segment to select in this case is shown:

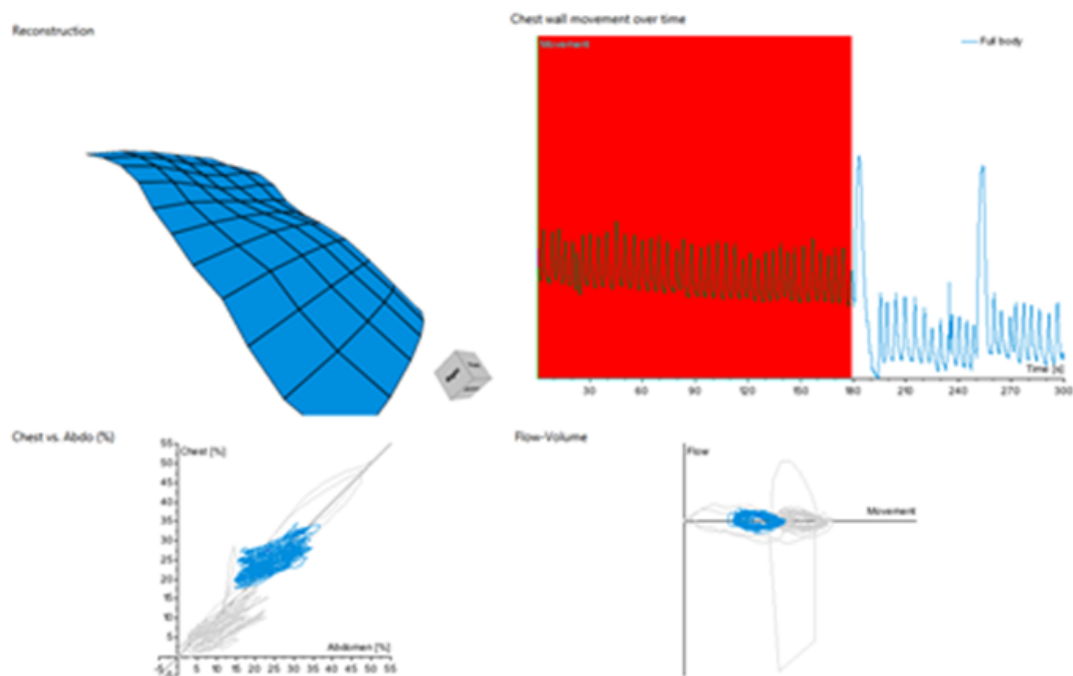


Figure 4.8: Good quality segment selection

Example 4

A Flow-Volume loop that consists of more than one part indicates gross movement.

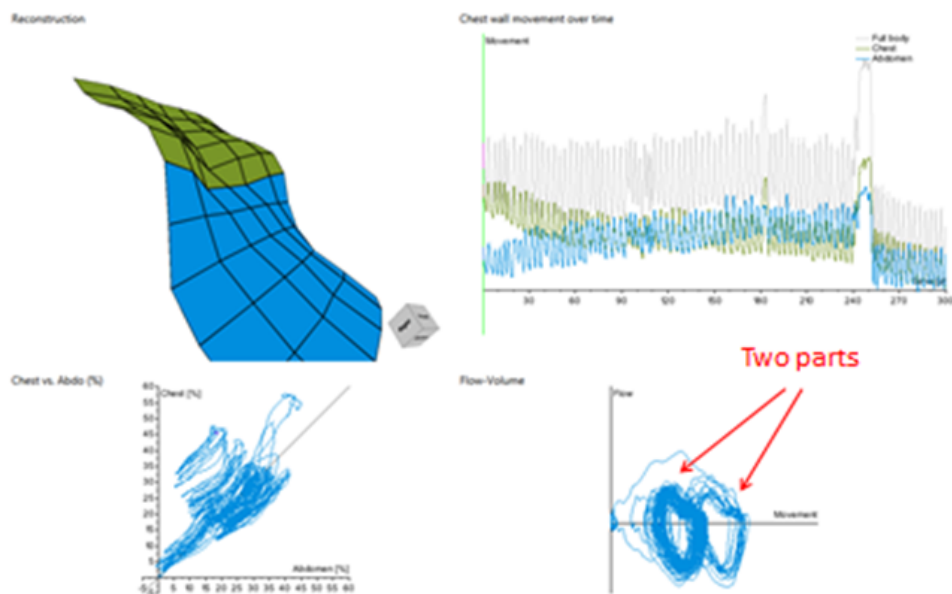


Figure 4.9: The FV loop consists of two distinct parts

The best segment to select in this case is shown:

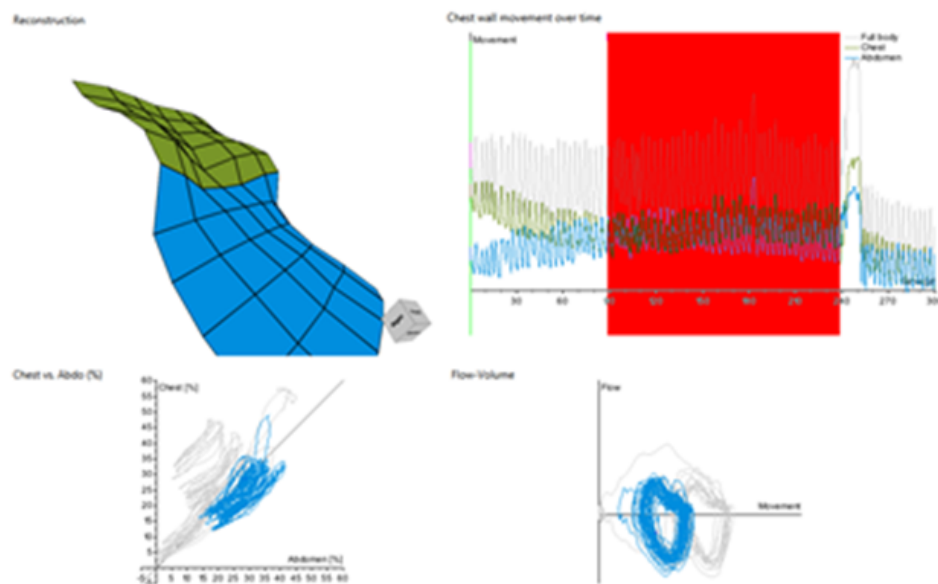


Figure 4.10: Good quality segment

4.10 To open a patient data file

If you start the PneumaView 3D Viewer from the computer desktop, you need to open a patient data file.

1. On the main menu tap **File** and then tap **Open**. A window opens in the default PneumaView data file location.
2. Tap on the file name of your patient and then tap **Open**. The patient data **Information** fields are completed and the main screen is populated.

5 Technical Data

No unauthorised modification of this equipment is allowed. Any unauthorised modification could result in a potential risk to the operator during use, or invalidate any measurements taken by the device.

Full body parameters		Accuracy	Range
Respiratory Rate (breaths/min)		+/- 2	4 - 50
Inspiratory Time, Ti (seconds)	Full-body chest wall movement signal	+/- 0.1 s	0.5 – 10
Expiratory Time, Te (seconds)	Full-body chest wall movement signal	+/- 0.1 s	0.5 – 10
Total Breath Time, Ttot (seconds)	Full-body chest wall movement signal	+/- 0.1 s	0.5 – 20
Ti/Te		+/- 0.1	0.5 – 2.0
Ti/Ttot		+/- 0.01	0.25 – 0.80
IE50		+/- 0.01	0.25 – 4.00

Regional parameters

Relative Expired Contribution of two or more signals in %	+/- 1%	0 – 100
Overall Phase difference between two signals (in degrees)	+/- 1 deg	0 – 80, 100 – 179
Principal Angle between two signals (in degrees)	+/- 1 deg	-90 - +90
Spread Ratio of two signals	+/- 0.02	0 – 1
Window Phase difference between two signals (in degrees)	+/- 1 deg	0 – 80, 100 – 179
Per-Breath Phase difference between two signals (in degrees)	+/- 1 deg	0 – 80, 100 – 179

Variation

Inspiratory Time (Ti), Expiratory Time (Te) and Per-Breath Phase difference

Accuracy:	+ / - 0.1
Range:	0 to 1

Scanning Head

Dimensions:	610 x 400 x 160 (w x d x h)
-------------	-----------------------------

Weight: 4kg

Handle set

Weight: 2.6kg

Stand

Manoeuvrable wheeled metal stand with cabinet for housing the battery and charger unit.
Fixed height column for mounting All-in-one computer and articulating arm holding the scanner unit.

Weight: 95kg

Articulating Arm

Variable Height: 48 cm

Variable reach: 86 cm

Thora-3Di Power supply

The power supply is part of the equipment and must only be replaced with the same part; XP Power model 90 PS18.

Power input: 120 V AC or 230 V AC

47 to 63Hz

1.06-0.45A

Power output: 90W max

Battery

Sealed Lead Acid 55Vah

Battery pack

230V 300W 90Ah medical grade charger
IEC60601-1

Fuse - Scanner Head

20mm 2amp quick blow

Fuse - Stand

20mm 10amp 250vac

Fuse - Battery

20 amp 12v car type fuse (Blade automotive)

Ambient Operating Conditions

Temperature: +10°C to +35°C

Rel. Humidity: 30 to 75% RH

Ambient pressure: 700 to 1060 hPa

Transport and storage conditions

Temperature: -30°C to +50°C

Rel. Humidity: 20 to 95% RH
Ambient pressure: 600 to 1200 hPa

Recommended All-in-one PC hardware requirements:

Processor: Intel PENTIUM G860 3.0GHz
Hard drive space: 500GB 2.5inch SATA II (5.400 Rpm) Hard Drive
Memory: 4GB SODIMM 204-pin DDR3 SDRAM 1066MHz
Drive: 500GB 2.5inch SATA II (5.400 Rpm) Hard Drive

Electrical Safety Classification according to EN 60601-1

Thora-3Di Protection class I

Category according to MDD 93/42/EEC

Complete system: Class IIa medical product

Note: On request the manufacturer can provide circuit diagrams, component part list, descriptions, calibration instructions to assist trained Service personnel to repair parts of the Thora-3Di.

5.1 Electromagnetic compliance

Guidance and Manufacturer's Declaration – Electromagnetic emissions			
The Thora-3Di is intended for use in the electromagnetic environment specified below. The customer or user of the Thora-3Di should assure that it is used in such an environment.			
Emission tests	Compliance	Electromagnetic environment – guidance	
RF emissions CISPR 11	Group 1	The Thora-3Di uses only energy for its internal function. Therefore, its RF emissions are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class A	The Thora-3Di is suitable for use in all establishments other than domestic 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	Class A		
Voltage fluctuation/flicker emissions IEC 61000-3-3	Complies		
Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Thora-3Di is intended for use in the electromagnetic environment specified below. The customer or the user of the Thora-3Di should assure that it is used in such an environment			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	6 kV contact 8 kV air	6 kV contact 8 kV 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	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV differential mode 2 kV common mode	1 kV differential mode 2 kV common mode	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 % UT (> 95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 s	< 5 % UT (> 95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Thora-3Di requires continued operation during power mains interruptions, it is recommended that the Thora-3Di be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE UT is the A.C. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Thora-3Di is intended for the use in the electromagnetic environment specified below. The customer or the user of the Thora-3Di should assure that it is used in such an environment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Thora-3Di, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter: Recommended protection distance:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.17 \sqrt{1/V} \cdot \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.17 \sqrt{m/V} \cdot \sqrt{P}$ for 80 MHz to 800 MHz
			$d = 2,33 \sqrt{m/V} \cdot \sqrt{P}$ for 800 MHz to 2.5 GHz
			where P is the maximum output power rating of the transmitter in watts (W) acc. To the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:



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 reflections 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 the Thora-3Di is used exceeds the applicable RF compliance level above, the Thora-3Di should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Thora-3Di.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distance between portable and mobile RF Communications Equipment and the Thora-3Di			
The Thora-3Di is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Thora-3Di can help prevent electromagnetic interference by maintaining minimum distance between portable and mobile RF communications equipment (transmitters) and the Thora-3Di as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Protection distance depending on the transmit frequency (m)		
	150 kHz to 80 MHz $d = 1.17 \sqrt{1/V * \sqrt{P}}$	80 MHz to 800 MHz $d = 1.17 \sqrt{m/V * \sqrt{P}}$	800 MHz to 2,5 GHz $d = 2.33 \sqrt{m/V * \sqrt{P}}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.7	7.37
100	11.7	11.7	23.2
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watt (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.			

NOTE: The device is not considered safe to use in the close proximity of electromagnetic imaging equipment. The device is considered “not MRI safe”.

Appendix

For all of the PneumaCare devices:

The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the equipment or system as replacements for internal components, may result in increased emissions or decreased immunity of the system.

The system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

Connection of Devices in Medically Used Locations

According to EN 60601-1, all electrical devices have to be connected via an additional protective ground conductor or an isolating transformer becomes necessary if several devices are connected in order to get a medical system in a medically used location.

All configurations shall comply with the valid version of the system standard EN 60601-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard EN 60601-1. If in doubt, consult the technical service department or your local representative.

Connection of Devices Installed Outside Medically Used Locations

If devices/systems (for example external printer, host computer etc.) installed outside medically used locations are connected to a Thora-3Di device installed in a medically used location, the EN 60601-1 regulations must be observed.

Such a connection should only be done in co-operation with the PneumaCare Customer Care Division! Patient safety must be checked and documented again.

Ambient Conditions

PneumaCare units have not been constructed for operation in rooms with potential explosion hazards or in flammable atmospheres.

If not otherwise stated in the instruction manual, PneumaCare equipment has been conceived for operation under normal environmental temperatures and conditions (EN 60601-1):

Temperature: +10° to +35° C

Thus, the units should be effectively protected against moisture. Ventilation slots should be kept unobstructed in order to enable circulation of air.

Transport and Storage Conditions:

Temperature: -30°C to +50°C

Relative Humidity: 10 to 95 %

Barometric Pressure: 600 to 1200 hPa

Putting the Unit into Operation

Always consult the nameplate on the device/system for compliance of the unit's own data with those of the local power supply system (mains voltage and mains frequency) before actually connecting the unit.

Inspect the mains connection cable, plug, and receptacle for visible damages prior to establishing the connection. Damaged cables or plugs must be replaced immediately. Assemble the device only according to the assembly instructions which can be found in the shipping documents.

Class 1 LED Product

The DMD Panel used in DLP Projectors consists of several hundred thousand micro mirrors. The DMD Panel may include a few bad pixels. PneumaCare and the DMD Panel manufacturer have a rigid bad pixel identification and limitation procedure in place and products will not exceed the maximum number of bad pixels set by our standards. Rarely, non- displayable pixels may exist, however it does not affect the picture quality nor the lifespan of the product.














Correct Disposal – Europe only

Correct disposal of this product (Waste electrical & electronic equipment) – Europe only
(Applicable in the European Union and other European countries with separate collection systems)

This marking on the product, accessories or literature indicates that the product and its electronic accessories (e.g. charger, VGA cable) should not be disposed of with other household waste at the end of their working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate these items from other types of waste and recycle them responsibly to promote the sustainable reuse of material resources.

Users should contact their supplier and check the terms and conditions of the purchase contract. This product and its electronic accessories should not be mixed with other commercial wastes for disposal.

Graphical symbols

	Alternating current
	Protective earth (ground)
	Earth (ground)
	Caution
	Operating instructions
	OFF (power)
	ON (power)
	Year of Production
	Manufacturer
	CE sign with code number of the examining authority. The certified assurance system of PneumaCare corresponds to the international standards of ISO 13485 and EN 9001
	Disposal in compliance with WEEE

Training Records

Topic	Trainer	Trainee	Date	Signed
Overview				
Environment				
Patient Position				
Taking a measurement				
Grid alignment				
Data Capture				
T=0				
Common Faults				
General Safety Precautions				
Care and maintenance				

Version History

Issue	Date	Brief description of change
1	Dec 2015	Minor updates to document and re issued under new document number
2.0	March 2016	Update name and address



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