ApneaGraph® Spiro

Quick Guide Analysis Software Manual
0 Contents

0 Contents .................................................................................................................. 2
1 List of Tables ............................................................................................................. 4
2 List of Figures ........................................................................................................... 4
3 Intended Use ............................................................................................................. 7
4 The Software ............................................................................................................ 7
5 PC Requirements ..................................................................................................... 8
6 Get Started ............................................................................................................... 8
   6.1 Install the PC Software ....................................................................................... 8
   6.2 Install Android Apps ......................................................................................... 9
7 Spiro Analysis Activation ......................................................................................... 9
8 Data Import from the Torso Unit ............................................................................. 11
9 Data Analysis .......................................................................................................... 15
   9.1 The Ribbon ....................................................................................................... 15
      9.1.1 Tab “Overview” ......................................................................................... 16
         9.1.1.1 Group “Catheter” ................................................................................ 16
         9.1.1.2 Group “Envelope Curves” .................................................................... 16
         9.1.1.3 Group “Computed Data” ...................................................................... 16
         9.1.1.4 Group “Pulse Oximeter” ...................................................................... 18
         9.1.1.5 Group “Other Data” ............................................................................ 18
         9.1.1.6 Group “Time Axis” .............................................................................. 20
      9.1.2 Tab “Events” ................................................................................................ 20
         9.1.2.1 Respiratory event coding on the horizontal event bar ......................... 20
         9.1.2.2 Group “Apneic Events” ...................................................................... 21
         9.1.2.3 Group “Other Events” ........................................................................ 21
         9.1.2.4 Group “Time Axis” ............................................................................. 21
         9.1.2.5 Group “Level Colour Codes” ............................................................... 21
         9.1.2.6 Group “Event Edit” .............................................................................. 21
         9.1.2.7 Auto Range ......................................................................................... 24
      9.1.3 Tab “Edit” .................................................................................................... 24
         9.1.3.1 Group “Analysis Window” .................................................................... 24
         9.1.3.2 Group “Time Axis” .............................................................................. 25
         9.1.3.3 Group “Event Edit” .............................................................................. 25
1 List of Tables

Table 1 Curve manipulation using the mouse ............................................................. 31
Table 2 Curve manipulation using gestures .............................................................. 31

2 List of Figures

Figure 1 The Spiro icon on the Desktop ...................................................................... 9
Figure 2 Software activation window ........................................................................ 9
Figure 3 Software activation alternatives ................................................................... 10
Figure 4 License ID and password page ..................................................................... 10
Figure 5 Entering the password ................................................................................ 11
Figure 6 The Spiro Analysis software prior to reading data ........................................ 11
Figure 7 Icon to click for import from Torso Unit ...................................................... 11
Figure 8 Import data welcome page ......................................................................... 11
Figure 9 Select folder page ....................................................................................... 12
Figure 10 Select recording page ................................................................................ 12
Figure 11 Read data page .......................................................................................... 13
Figure 12 Anthropologia page .................................................................................. 14
Figure 13 Password location ...................................................................................... 14
Figure 14 Save data page .......................................................................................... 14
Figure 15 Default filename ....................................................................................... 14
Figure 16 Erase SD card page ................................................................................... 14
Figure 17 File open .................................................................................................... 15
Figure 18 Catheter data checkboxes .......................................................................... 15
Figure 19 Tab "Overview" ........................................................................................ 16
Figure 20 PPH/POES ratio data .............................................................................. 17
Figure 21 Admittance data ....................................................................................... 17
Figure 22 Respiration frequency data ....................................................................... 18
Figure 23 Oximeter data ........................................................................................... 18
Figure 24 Body position data ................................................................................... 19
Figure 25 Tissue vibration and airborne sound data ................................................. 19
Figure 26 Airborne sound frequency window colour codes ..................................... 19
Figure 27 Actimeter data .......................................................................................... 20
Figure 28 Tab "Events" ............................................................................................. 20
Figure 29 Level colour codes ................................................................................... 21
Figure 30 Event edit activation buttons ..................................................................... 22
Figure 31 Event edit information .............................................................................. 22
Figure 32 Event edit warning message .................................................................... 22
Figure 33 Event edit dialogue .................................................................................. 23
Figure 34 The "Edited" symbol ................................................................................ 24
Figure 35 The level column ...................................................................................... 24
Figure 36 "Analysis Window" .................................................................................. 24
Figure 37 Group "Time axis" ................................................................. 25
Figure 38 Group "Editable Time Window" ........................................... 25
Figure 39 Statistics dialogue .............................................................. 26
Figure 40 Groups for range settings .................................................... 26
Figure 41 Tab "Output" .................................................................. 27
Figure 42 Enter clinic text dialogue..................................................... 27
Figure 43 Custom footer text example ............................................... 27
Figure 44 Custom icon example ......................................................... 28
Figure 45 Optional graphics to the report. Example............................. 28
Figure 46 Tab "Options" .................................................................. 29
Figure 47 Tab "Window" .................................................................. 29
Figure 48 Two recordings compared using tiled windows .................... 30
Figure 49 Tab "Graphs" ................................................................ 30
Figure 50 Tab "Anthropological".......................................................... 32
Figure 51 Tab "RDI" ..................................................................... 32
Figure 52 Tab "Level and Snoring" ...................................................... 33
Figure 53 Tab "RE" ..................................................................... 33
Figure 54 Tab "SpO2" .................................................................. 34
Figure 55 Tab "Pulse Rate" ................................................................ 34
Figure 56 Tab "Body Position" ............................................................ 35
Figure 57 Tab "Equipment" ................................................................. 35
Figure 58 Tab "Data Subfolder" ........................................................... 36
Figure 59 Detailed view of the "Data Subfolder" ................................. 36
Figure 60 The Bernoulli equation ....................................................... 38
Figure 61 Typical use of the Spiro Analysis software ............................ 39
Thank you for purchasing an ApneaGraph® Spiro equipment.

The ApneaGraph® Spiro is a sleep diagnostic tool providing information on your patients sleep and breathing.

The ApneaGraph® Spiro is unique in the sleep diagnostic market place in that it not only provides information on the type (obstructive or central), Severity and location of the nocturnal obstruction to better facilitate the clinician in choosing the correct form of treatment for the patient.

Manual version 4.5.1
Covers software versions 4.5.1
Date 07 December 2016
Copyright © 2015-2016
Spiro Medical AS All rights reserved

Made by
Spiro Medical AS
Nattlandsveien 8
NO-5093 Bergen
Norway
Website: www.spiromedical.com

Copyright Notice
This manual is copyright © by Spiro Medical AS.

Disclaimer
This document may contain typographical errors or technical inaccuracies. Spiro Medical does not accept any liability for the use or misuse whether direct or indirect of the products, or for damages arising out of the use of or inability to use the products. Users must accept all responsibility for any results obtained by or concluded from data obtained by the products including software from Spiro Medical. All clinical conclusions and decisions that are based on the use of this product are the responsibility of the user.
3 Intended Use

ApneaGraph® Spiro device is intended for recording of physiological signals during sleep. The ApneaGraph® Spiro® device is for continuous operation for a maximum of 8 hours of data acquisition, or one full night of sleep.

The software is intended used by a professional medical doctor who will review the data and decide on the diagnosis of the patient. The final diagnosis is entirely the responsibility of the doctor and not the Spiro Analysis software. The Doctor is responsible for assessment of the patient and his or her condition and should review the measured data carefully.

The intended equipment environments are hospitals, institutions, sleep centres, sleep clinics, or other test environments, including the patient’s home.

The device is to be used by a doctor, a nurse or specially trained personnel at a hospital or surgery. The software is to be used by a medical doctor.

The equipment must be installed and put into service in accordance with the information in the user manual, Spiro Medical document MAN 001.

The device or software does not require any operations or intervention by the patient.

All analysis based on current American Academy of Sleep Medicine (AASM) criteria 2007 & 2013.

4 The Software

The ApneaGraph® Spiro software comes in three separate downloads.

- App “AGS Clinical Setup”. This is Bluetooth® Low Energy Wireless software required to set up the ApneaGraph® for a patient study).
- App “AGS Monitor”. This is software required to monitor an ongoing data acquisition via the Bluetooth® Low Energy link (range 100 m free sight).
- PC Software “Spiro Analysis”. This is the desktop software required to analyse a completed recording.

Your Spiro Analysis is also used to upload a patient overnight recording from the ApneaGraph® Spiro Torso device.

At the time of writing, the Apps can be obtained from Spiro Medical.

The Spiro Analysis software can be obtained from www.spiromedical.com/Downloads. Sign up for a trial version and you will get a link for the download. You may get a warning that the software is not commonly downloaded, but this is because the software is relatively new. Both the installation file and the executable are signed – proving that the software comes from Spiro Medical AS.

The trial software can be used for 14 days. Activation codes can be obtained from Spiro Medical or purchased via the activation link.
To update the software, uninstall the old version and download a new trial package. Once installed on the same machine, the old credentials will be inherited and the full version will immediately be available.

5  PC Requirements

A Windows PC with Windows 7 (service pack 1) or higher. This is required in order for the graphics engine Direct2D to run. Note that some graphics adapters and know to crash on Direct2D (these are: Intel G35-1, Intel G35-2, Intel GL960-1, Intel GL960-2, Intel GM 965-1, Intel GM 965-2, Intel Mobile HD Graphics).

In order for the PDF report generation to work, Java Runtime Environment 1.5.x or higher is required (Version 8, update 60 is available for download from Sun).

6  Get Started

These are the files required:

- “Spiro Analysis 4.5.1 Setup.exe”
  - For acquisition and analysis of data from the ApneaGraph® Spiro Torso Unit.
  - The installation includes user manual and the executable file.
- «AGSMonitorV2.apk»
  - Monitor app for Android.
  - Can be obtained from support@spiromedical.com
- “AGSSetup V2.apk”
  - Clinical setup app for Android.
  - Can be obtained from support@spiromedical.com

6.1  Install the PC Software

- Download the Spiro Analysis software via the link on http://spiromedical.com/downloads/.
- Uninstall old versions of the Spiro Analysis software (via the Control Panel, Programs and Features. Name “Spiro Analysis”, Publisher “Spiro Medical AS”).
- Double click the file "Spiro Analysis 4.5.1 Setup.exe". (4.5.1 is the version number, this will change).
  - All users of the PC will be able to run the software.
- Software will be installed and shortcuts will be placed
  - on the Startup Menu under "Spiro Medical",
  - on the Desktop.
6.2 Install Android Apps

- Copy the apk files to the Android tablet or phone.
- Manage files on the Android device and tap the apk files. This will install the app.
- Note that security settings must be set to allow for installation of apps from other sources than Google Play.

7 Spiro Analysis Activation

1. Start the software by clicking on the desktop icon or by selecting Spiro Analysis under Spiro Medical (Apps by name listing or under the Start button if you have one).

   ![Figure 1 The Spiro icon on the Desktop](image)

2. If you choose to activate, the license window will appear. Click “Activate Spiro Analysis” or “Evaluate Spiro Analysis” to use the software for 14 days as a trial.

   ![Figure 2 Software activation window](image)
The Spiro Analysis Activation window will appear.

3. Click “Activate Spiro Analysis Online”.

The Licence ID and Password window will appear.

4. Fill in with License ID and Password that you received from Spiro Medical and click “Continue”. Note that you must be connected to the Internet.
If you do not have an Internet connection, you must click “Activate Manually” in step 4 above. This will take you to a page showing two codes (Code 1 and Code 2). These must be sent to Spiro Medical who can then return the activation codes (one or two) that you can then enter.

8 Data Import from the Torso Unit

Connect the ApneaGraph® device to the PC via the USB cable or by moving the SD card to a PC SD card slot. Open Spiro Analysis.

Click the Spiro logo button (“New”) in the top left corner.

Welcome page.

Click “Next” to continue.
“Select Folder” page. The folder should be “AGSPIRO (D:)” where D is the disk letter (it can vary from PC to PC). Note that the following text should appear: “Contains ApneaGraph® Spiro session folder(s)”. Click “Next” to continue. Note that it may take some time as all files and folders need to be checked.

Page “Select Recording”. This is a listing of all recordings on the Torso SD card, the most recent recording at the top.

- A selection check box to the left.
- Session number – this is the SD card folder where that data is located (a log file and an acquisition file).
- Date when the recording started.
- Start time of the recording.
- Length of the recording in hours and minutes (hh:mm).
- Recording ID (entered during clinical setup).
- Torso unit serial number.
- Catheter serial number.
- Wrist unit serial number.
- Neck unit serial number.

Select the recording by checking the selection check box – use the recording with the correct date and length.

Click “Next”. This may take some time as a huge data set must be read and processed.
Page “Read Data”. This is a listing of sensor channels including battery voltage and capacities.
For inspection of all data – for quality control.
The system may detect bad data, the percentage of bad data is listed in the table.
The figure to the right shows the contact microphone data.
The graph can be manipulated as follows:

- Radio button x-axis selected:
  - Left mouse button down, move sideways: moves graph horizontally (in time).
  - Right mouse button down: expands or contracts the time-axis (x-axis).
  - Mouse wheel: expands or contracts the time-axis (x-axis).

- Radio button y-axis selected:
  - Same as above with the exception that the right mouse button down now expands or contracts the gain axis (y-axis).
Page “Anthropologia”. Enter patient data here plus notes if required. Note that the password should be set, and it should be unique for the clinic. Check “Save password” if you want this password to be used again on the same PC.

Page “Save Data”. This is a listing of the AGS data files in the folder where you last saved data. Click the “Save data” button in the top right corner to save the data. The “Save As” dialog will open and allows you to select a folder for your data. The file name that appears – for example “ST 22.09.16 10016 Rec 29097ORD.AGS” contains the date of the start of the recording, the Torso serial number plus the recording ID. This should be sufficient to ensure a unique filename. But the filename can also be edited by the user.

Page “Erase SD Card”. This page contains an option to move the data to a recycler folder on the SD card. From there it can later be deleted.
Note that if the Torso Unit is left with the battery inserted, data acquisition will start at the preset time – the date is ignored. Hence one may experience that all channels are “dead” – if the Torso unit was on a desk.

Of particular importance is the ability to inspect the battery voltage, remaining capacity and full charge capacity. The latter indicates if the battery is near end-of-life or not. Note also that next to each data type is the result of an evaluation of data quality – showing percentage of “good” data.

9 Data Analysis

![File open](image1.png)

It is possible to use the designated short cut keys on the top left of the display.

Once you have opened the recorded file, choose the channels you want to display by using the check boxes.

![Catheter data checkboxes](image2.png)

Once checked the parameter signal will be displayed on the graphic below the menu tab.

9.1 The Ribbon

The Ribbon based layout allows you to choose displayed parameters
9.1.1 Tab “Overview”

![Figure 19 Tab "Overview"](image)

Note that if a data set is present in the recording, the check box for this data set is enabled. If a recording was done without a catheter for example, all the check boxes in the “Catheter” group will be disabled.

9.1.1.1 Group “Catheter”

These are the offset compensated and band pass filtered data from the catheter.

- POES. Oesophageal Pressure.
- PPH. Pharyngeal pressure sited retropalatal.
- T0. Temperature variation in the pharynx, represents pharyngeal flow.
- T1: Temperature variation in the nasopharynx, represents Nasal Flow.

9.1.1.2 Group “Envelope Curves”

These are the catheter data after detection of the envelopes – i.e. peak to peak values. These are therefore always positive.

Also the sum of T0 and T1 is represented.

9.1.1.3 Group “Computed Data”

These are data that are computed from the catheter data. PPH/POES represents the envelope of PPH divided by the envelope of POES and is used to indicate level of obstruction.

PPH/POES indicates the site of obstruction - Upper, Mixed or Lower. A percentage well above 50, indicates upper obstruction (60%-100%). Multilevel obstructions are generally indicated by a percentage near 50 (40-60 %). Lower obstructions are indicated by a percentage below 40. If, during an event, the percentage is crossing several levels, the event is classified as multilevel.
Admittance is calculated as the T1 envelope divided by the POES envelope and indicates “ease of breathing”. It is used to detect arousals.

Respiration Effort Frequency is the number of attempted breaths per minute, the central Respiratory Drive via the Oesophageal (POES) pressure sensor.
9.1.1.4 Group “Pulse Oximeter”

These are data from the finger mounted pulse oximeter sensor.

9.1.1.5 Group “Other Data”

These include body position (left, right, prone, supine or upright), tissue vibration, airborne sound and actimetry.

Tissue vibration is detected by the patient mounted contact microphone and airborne sound is measured by the microphone in the neck unit.

High levels of tissue vibration and airborne sound indicates snoring. High levels of airborne sound with low levels of tissue vibration indicates external noise, for example bed partner. Note that the event “Snoring” is detected using the contact microphone signal alone.
The 4 airborne sound curves are listed with colours under tab Edit/Graph properties (expand the Airborne sound entry).

Actimetry is measured with a 3-axis accelerometer on the arm and is an indication of patient movement during the recording.

As a guide, the higher the Y axis recording on the graphical display, the greater the patient movement indicates probability of wake periods.
9.1.1.6 Group “Time Axis”

Entering the recording time (i.e. starts at zero, it is not the time of day) in the Centre field, centres the graphs at this point of recording time, entering a length value or selecting from the combo box, determines the time-axis (x-axis) scale.

Page arrow buttons shift the data a page at a time, Event arrow buttons shifts the data to the next or previous enabled (check to be displayed) event.

9.1.2 Tab “Events”

9.1.2.1 Respiratory event coding on the horizontal event bar

- Mixed Apnea: dark Green.
- Central Apnea: Red.

Figure 27 Actimeter data

Figure 28 Tab “Events”
- Obstructive Apnea: Blue.
- Obstructive Hypopnea: Olive Green.
- Central Hypopnea: Purple.
- SPO2 drops: Turquoise.
- Arousals Following Respiratory Events (RERA): Pink.
- Awake: Blue.
- Snoring: Light Green.

All analysis based on current American Academy of Sleep Medicine (AASA) criteria 2007 & 2013.

9.1.2.2 Group “Apneic Events”

These are the classic events plus Respiratory Effort Related Arousals (RERA). “Classic events” are mixed apnea, central apnea, obstructive apnea, hypopnea and oxygen desaturations.

9.1.2.3 Group “Other Events”

These are arousals that are not part of classic events, awake periods (from the actimeter), snoring periods (from the contact microphone).

9.1.2.4 Group “Time Axis”

The event arrows causes shift of the data to the previous or next enabled event.

9.1.2.5 Group “Level Colour Codes”

Events, when enabled, are indicated by transparent colour over the graphs. In case obstruction level is relevant, the colours are as shown below. Obstruction level is relevant for mixed apnea, obstructive apnea, obstructive hypopnea, RERA and snoring.

![Level colour codes](image)

9.1.2.6 Group “Event Edit”
If you click the upper button ("Editing"), the following warning will pop up:

![Event edit activation buttons](image)

You can tick “Do not show again” if you do not want reminded every time. Please continue with “ok”.

The “Reset” button will remove all previous changes, but you will be notified with a warning.

![Event edit warning message](image)

Next, the event edit dialogue will open:
The upper table contains the analysis window – this is the section of data that is being analysed. The body position sensor has been used to estimate time in bed. Start and length can be edited. The graph Window is the visible part of the time series on the graphics plot. If an editable time window is enabled, this is also specified in the table. Start and length can be edited.

The lower table has tabs for the different event listing key parameters for every event.

- To delete an event.
  - Use the check box to the left to tag one or more event.
  - Press “Delete Selected”.
- To centre an event on the graph.
  - Press the ‘>|<’ button next to the check box.
- To edit start and length of an event.
  - Click in the Start or Length column and change it. The “Edited” symbol will appear (see below) and the “Apply Changes” will be enabled.
  - Click “Apply Changes”.
- To change the level classification of an event (not available on all event types).
  - Click in the Level column and select a new level. The “Edited” symbol will appear (see below) and the “Apply Changes” will be enabled.
  - Click “Apply Changes”.
- To change the event type (not available on all event types).
  - Click in the “Alternative type” column and select a new type. The “Edited” symbol will appear (see below) and the “Apply Changes” will be enabled.
  - Click “Apply Changes”.

Figure 33 Event edit dialogue
9.1.2.7 Auto Range

Adjusts the screen display for the optimum display of chosen parameter. The time axis will always fill the screen.

9.1.3 Tab “Edit”

9.1.3.1 Group “Analysis Window”

This is used to set where the analysis should start and stop – i.e. leading or trailing excluded segments.

Note that after changing one of these, you must hit CR (Carriage Return) in order to make it effective – separately.
9.1.3.2 Group “Time Axis”

This is used to centre the data and set the time window length to a specific value. The “Page” arrows shifts the data one time window left or right and the “Event” arrows shifts the data to the next or the previous enabled event (i.e. that has been checked on the “Event” tab).

![Time Axis](image)

Figure 37 Group "Time axis"

9.1.3.3 Group “Event Edit”

This is explained in section 9.1.2.6.

9.1.3.4 Group “Editable Time Window”

This is enabled by checking “Enable”. A green section is then indicated on the graphs. “Include” or “Exclude” this to set this section as excluded from analysis or included with the analysis.

![Editable Time Window](image)

Figure 38 Group "Editable Time Window"

“Statistics” is used to obtain statistical parameters from the selected time window:

---

 Spiro Analysis Software Manual  
 Document MAN 005  
 SW Version 4.5.1  
 25
Check “Mouse Control” to manipulate the editable time window using the mouse. Left click to set the left margin and right click to set the right margin. If you left click to the right of the right margin, you move the entire time window to the right. If you right click to the left of the left margin, you move the entire time window to the left.

“Add Event” is used to add an event covering the editable time window.

The “Undo” and “Do” arrows allows you to undo a change that was done – or to do it again.

9.1.3.5 Groups “Pressure Range”, “Pulse Rate Range” and “SpO2 Range”

Range groups can be used to set specific limits on the pressure ranges, pulse rate range and the SpO2 range.

9.1.3.6 Group “Graphics”

This is used to edit the curve colours (“Graph properties”) or to autorange all curves (“Autorange”).
9.1.4  Tab “Output”

![Image of the Output tab](image)

*Figure 41 Tab “Output”*

9.1.4.1  Group “Report”

The standard report generates the Spiro Medical standard report and places the resulting PDF file in the Data subfolder (subfolder to the data file being worked on).

The custom report button is disabled unless specific custom reports have been designed – this is a future option.

Edit clinic text allows for custom footer on the report pages.

Enter clinic logo allows for adding a custom logo in the upper left corner of the PDF report.

![Image of the Enter clinic text dialogue](image)

*Figure 42 Enter clinic text dialogue*

![Image of the Custom footer text example](image)

*Figure 43 Custom footer text example*
9.1.4.2 Group “Graphs Output”

This group is only enabled if the “Graphs” view is selected (bottom tab to the left). Click “Add to report” to add a screenshot of the display to the end of the report. You will be asked to enter a caption to the image.
9.1.5 Tab “Options”

Allows for change the analysis detection settings.

Desaturations: Minimum 3% or minimum 4% drop in Oxygen saturation

Hypopnea: Reduction in Temperature sensor variation (flow) of 30%, 40% or 50% from baseline.

![Options Tab]

Figure 46 Tab “Options”

9.1.6 Tab “Window”

You can open several files and display them cascaded or tiled. It is especially useful to display a pre-treatment recording and a post-treatment recording from the same patient using “tiled” view.

![Window Tab]

Figure 47 Tab “Window”
9.2 Lower Edge Tabs (Views)

9.2.1 Tab “Graphs”

Shows Graphical selected data
The graphs will always have the same time axis (x-axis). Some curves can be manipulated wrt gain. Pressure, pulse rate and SpO2 can be set to fixed scales – see the section on tab “Edit”.

9.2.1.1 Curve manipulation using the mouse

Table 1 Curve manipulation using the mouse

<table>
<thead>
<tr>
<th>Action</th>
<th>Mouse movement</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hold cursor over curve</td>
<td>None</td>
<td>Tooltip window appears showing amplitudes, time and time of day, any events at this time.</td>
</tr>
<tr>
<td>Left mouse button down</td>
<td>Sideways</td>
<td>Shift the curves left or right</td>
</tr>
<tr>
<td>Right mouse button down</td>
<td>Vertical</td>
<td>Depending on the type of graph where the button is pressed, gain and/or offset will change.</td>
</tr>
<tr>
<td>Mouse wheel rotation</td>
<td>None</td>
<td>Expands or contracts the time axis (x-axis)</td>
</tr>
<tr>
<td>Double click</td>
<td>None</td>
<td>Centres the “double-clicked-point” in time</td>
</tr>
</tbody>
</table>

9.2.1.2 Curve manipulation using gestures

Table 2 Curve manipulation using gestures

<table>
<thead>
<tr>
<th>Action</th>
<th>Finger movement</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two-finger tap</td>
<td>None</td>
<td>Autorange time axis. Autorange</td>
</tr>
<tr>
<td>One finger press</td>
<td>Sideways</td>
<td>Shift the curves left or right</td>
</tr>
<tr>
<td>One finger press</td>
<td>Vertical</td>
<td>Offset will change on pulse rate graph, no change on others</td>
</tr>
</tbody>
</table>

9.2.2 Tab “Anthropological”
Allow to view and edit patient details.
Note if the encryption password is wrong, all data that can identify the patient is set to “****”. The encryption password is set when transferring data from the Torso unit – normally one would use the same password for all data handled by the clinic or doctor.

9.2.3 Tab “RDI”

Providing numbers and figures regarding respiratory events and effective sleep time

9.2.4 Tab “Level and Snoring”

Identifies the position of the airway obstructions by type of event.
Provides snoring time, localisation of snoring and snoring in relation to the sleep position.
9.2.5 Tab “RE” – Respiratory Effort

This page identifies the extent of respiratory effort in dependence of Level of Obstruction and Body position.

As a guide, a typical healthy patient’s respiration would be < 10 cm H₂O.

9.2.6 Tab “SpO₂”

Shows Oxygenation during the night and provides statistics about the oxygenation during the night.
9.2.7 Tab “Pulse Rate”

Provides statistics about the pulse rate distribution over the night.

9.2.8 Tab “Body Position”

Shows the patients sleeping position during the night and the type and number of patient events occurring in each sleep position.
9.2.9 Tab “Equipment”

Lists the equipment that was used — serial numbers and versions. For the catheter, the number of uses and remaining uses are listed also.

9.2.10 Tab “Data Subfolder”

Folder with each parameter graphical display available for print or copy to documents. The data sub folder offers you a selection of graphics and reports in PDF format for printing. Please note that the standard patient report (from option: Output) will be stored here.
This page can be manipulated as in the Windows file explorer – drag and drop of files or alternate views (like below showing “Detailed View” – right click on the page to achieve this).
10 Notes on POES vs PPH signals

Sometimes, the PPH signal is stronger than the POES signal. This may not be logical as the POES is the driving pressure.

PPH is in a channel where there is flow, POES is not.

The following physical phenomena are present:

A. Flow,
B. pressure variation,
C. tissue movement,
D. peristatic waves,
E. stretching of catheter (this effect has been virtually eliminated on the catheter).

A is present in PPH, not in POES
B is present in PPH and POES
C is present in both, but much more complicated in PPH.
D is present in both POES and PPH, as positive spikes.

When there is a flow, pressure goes down according to the Bernoulli equation (this is why airplanes fly):
So during inhalation, pressure drops not only because P1 (figure above) changes, but also because of the speed of flow. The airflow reduces the pressure both during expiration and inspiration. Hence the peak-to-peak value is not so much affected.

When the pressure drops during inspiration, P1 is low and the flow goes from right to left. The PPH pressure will be influenced by both the reduction in P1 as well as the reduction due to the flow, hence soft tissue tends to collapse (obstruction) – and tissue directly compresses the volume around the PPH sensor. When the conditions are narrow this may be detected as a positive pressure (inverting). This may in theory cancel the “P1 component”, but only during flow – not if the flow is zero or low.

In case of an obstruction, PPH has no flow and the level detection is reliable. In case there is flow, level detection is not so reliable.

Figure 60 The Bernoulli equation
11 Typical use

11.1 Open file or Import Recording from the Torso Unit

Import from Torso Unit is covered above and opening an AGS file is done via standard Windows open file dialogue.

Note that in the folder where the AGS is, there is a subfolder with the same name as the AGS file. This subfolder contains results, image files and an XML-data file and this is where the PDF report will be saved. The subfolder also contains the “Events.dta” file. This file contains the entire analysis including any editing that was done when the AGS file was saved.

11.2 Inspect data
It is important to review the data – i.e. the graphs of all primary data. Primary data are the sensor data – POES, PPH, T0, T1, SpO2, Pulse Rate, Body Position, Actimeter, Tissue Vibration and Airborne Sound.

Typical issues to look for are signal dropouts that may be caused by sensor failures or loose equipment (finger sensor, contact mic, etc.).

We strongly recommend to display all the primary data and output this with the report as an overview as explained in section 9.1.4.2.

11.3 Edit events

It is important to review excluded parts of the recording. The software looks for the first time body position is horizontal for 5 minutes or more, and the data analysis starts at the beginning of this period. It ends at the beginning of the first period with upright position for 5 minutes or more. Therefore, if the patient has been up walking for 5 minutes or more, the excluded parts must be edited.

Also note that the awake detection is based on the arm actimeter alone. Some patients move the arm while having apnea and some patients are awake without moving the arm, the awake detection should therefore be reviewed and edited of necessary.

The editing technique is explained in section 9.1.2.6.

11.4 Add notes

Notes can be added to the “Anthropological” page as explained in section 9.2.2. Note that after expanding the “Notes” field, carriage return (CR) will close it again. Rather than using CR to provide a new line, use CTRL+CR.

The notes in the patients section will be added to the PDF report.

11.5 Generate report

Output the standard report as explained in section 9.1.4.1.
12 Shortcut keys

The following shortcut keys are available:

<table>
<thead>
<tr>
<th>Key combination</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTRL+N</td>
<td>New File – data import from Torso Unit</td>
</tr>
<tr>
<td>CTRL+O</td>
<td>Open AGS file</td>
</tr>
<tr>
<td>CTRL+S</td>
<td>Save AGS file</td>
</tr>
<tr>
<td>CTRL+Z</td>
<td>Undo edit action</td>
</tr>
<tr>
<td>CTRL+Y</td>
<td>Redo edit action</td>
</tr>
</tbody>
</table>

13 Encryption Policy

Data Recorded by the Torso unit are encrypted with AES 128 encryption. This is according to the Advanced Encryption Standard with 128 bit block size. The encryption key is hold by Spiro Medical and only Spiro Medical software can decrypt the data. Hence loss of a Torso SD card can not disclose patient information or patient data.

The AGS file format is proprietary to Spiro Medical and must be read with Spiro Medical Software.

Data that can identify the patient is encrypted, also with the AES 128 method, and saved with the data to the ags file. This key is defined by the user (doctor or clinic) and not know to Spiro Medical. As long as the file name contains no patient identifiable data, ags files can then be distributed.

14 Contact

In case of comments, need for support, bug reports, etc. – please contact:

support@spiromedical.com
15 References
