THOR laboratories

HOME OF IDEGEN TECHNOLOGY

Otthon

IDEGEN™ Handheld Spirometer

User Manual

english
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Contents

1 Introduction

1.1 Intended use

User Category

The spirometer measures a series of parameters relating to human respiratory function. The product is therefore intended for use by a doctor or by a nurse practitioner under the supervision of a doctor.

The product is therefore intended for use by a doctor or by a nurse practitioner under the supervision of a doctor. Before first use please disinfect the device. The device may will not in disinfected status during the shipping.

Qualification and experience required

The correct use of the instrument, the interpretation of the test results plus the maintenance of the instrument,and in particular the avoidance of cross-infection, all requires qualified personnel.

Operating environment

The operation of the instrument is foreseen within a doctor's office or within a hospital.

The instrument is not intended for use in an operating theatre or in the presence of inflammable liquids or detergents, nor in the presence of inflammable anesthetic gases or oxygen or nitrogen gases.

The instrument is not designed to be used in direct air currents (e.g. wind), sources of heat or cold, direct sun rays or other sources or light or energy, dust, sand or any other chemical substances.

The user is responsible to check the suitability of the ambient conditions both for the storage and for the use of the instrument.

Patient effect on the use of the instrument

A spirometry test should only be carried out when the patient is at rest and seated in a suitable condition for the test. A spirometry test requires the collaboration of the patient; the patient must make a complete forced expiration in order to have a meaningful test result.

Do not use the spirometer in case of childrens above 4 years and mens over 99 years. The defined interval of usage for the spirometer related the patient age depends on the selected prediction algorithm.

1.2 Prediction algorithms age limits

	Age	Height	Weight
Reference	**Range [yr]**	**Range [cm]**	
	Male/Female	**Male/Female**	
Knudson	3…99 (3…99)	50…250 (50…250)	-
ERS 93/ Knudson	3…99 (3…99)	50…250 (50…250)	-
ERS 93/Zapletal	3…99 (3…99)	50…250 (50…250)	-
Barcelona / Zapletal	3…99 (3…99)	50…250 (50…250)	-
Crapo Bass / Knudson	3…99 (3…99)	50…250 (50…250)	-
Pneumobil/ Knudson	3…100	50…250 (50…250)	-
Austrian	3…99 (3…99)	50…250 (50…250)	+
Polgar	3…17 (3…17)	90…195 (90…195)	-
NHANES III	8…80 (8…80)	50…250 (50…250)	-
Crapo	3…100 (3…100)	145…180 (145…180)	-
Hsu	7…17 (7…17)	111…190 (111…180)	-
Chinese Adult HK 2006	18…80 (18…80)	50…250 (50…250)	-
Chinese Children HK 2006	7…19 (7…19)	116…186 (119…174)	-
Swiss Adult 1996	18…60 (18…60)	50…250 (50…250)	-
Chinese Hong Kong	7…80 (7…80)	50…250 (50…250)	-
Gore 1995 - Australia	18…78 (18…78)	158…195 (145…187)	-
Stanojevic 2009	3…80 (3…80)	50…250 (50…250)	-

Limitations of use - Contraindications

An analysis of the results of a spirometry test is not in itself sufficient to make a correct diagnosis of the patient's clinical condition. A detailed clinical history of the patient is also required together with any other tests suggested by a doctor.

Test comments, a test interpretation and suggested courses of treatment must be given by a doctor.

Any symptoms that the patient has at the time of the test must be carefully considered before a spirometry test is made. The user is responsible to assess both the mental and the physical capacity of the patient to make a correct test and the user must also assess the degree of collaboration for each test carried out.

Special attention should be given to testing elderly patients, children and handicapped people. The instrument should never be used when it is possible or probable that the validity of the results may be compromised due to any such external factors.

2 Important safety warnings

The safety and the correct performance of the instrument is warranted only when the warnings and the safety rules are correctly observed.

The manufacturer accepts no responsibility for problems or damage caused by the failure of the user to follow these instructions correctly.

The instrument must be used as described in the Users Manual with particular attention to section *1.1 Intended use* and only original spares and accessories as specified by the manufacturer may be used.

The maintenance operations detailed in this manual must be carried out precisely. If these instructions are not followed this can cause measurement errors and/or an incorrect interpretation of measured values.

Any modifications, adjustments, repairs or reconfiguration must be made by the manufacturer or by a qualified person authorized by the manufacturer. Never attempt to make a repair oneself.

High-frequency emissions may interfere with the correct operation of the instrument. For this reason, certain minimum clearances (a few meters) should be observed when high-frequency appliances such as a TV, radio, portable phone etc and other electronic units are operated at the same time in the same room.

If the instrument is connected to any other instrument, then in order to maintain the essential safety characteristics according to IEC 60601-1 only equipment which complies to the current safety regulations may be used.

For the recycling of the spirometer, accessories, plastic consumable materials (bacterial filter), use only the appropriate containers or better return all such parts to the seller of the instrument or to a recycling centre. All appropriate local regulations must be followed.

2.1 Danger of cross-contamination

A disposable bacterial filter is required to connect a patient to the spirometer to avoid cross-contamination. In order to avoid exposing the patient to the critical danger of cross contamination before each spirometry test a new single use bacterial filter must be used for each patient.

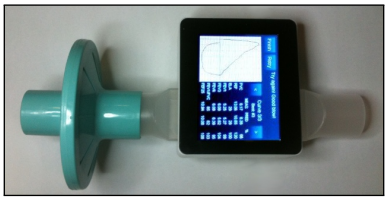
2.2 The Flowmeter

Do not allow dust or foreign bodies to enter the Flowmeter, to avoid incorrect functioning and possible damage.

The presence of any impurities such as hairs, sputum, threads etc within the body of the Flowmeter may seriously compromise the accuracy of the measurements.

2.3 The bacterial filter

We suggest you to use bacterial filter for every measurement preventing cross-contaminations. The intended use of the requires the bacterial filter. The bacterial filter should be placed on the end of the tube so that it is between the Flowmeter and the patient. The blue arrow on the device indicates the direction of the expiratory air flow in that case the bacterial filter needs to be placed .



FlowMeter with bacterial filter (illustration)

Any single use bacterial filter included with the instrument is supplied only as a guide to the correct type and dimensions of the bacterial

filter required for this instrument, and they are clean but not sterile. To purchase appropriate bacterial filter we suggest that you contact your local distributor who supplied the spirometer.

The use of a mouthpiece made from an inappropriate material could modify the bio-compatibility and could be the cause of an incorrect functioning of the instrument and of incorrect test results.

The user is responsible to obtain the correct type of bacterial filter for the instrument. Those required are standard type with an outside diameter of 30mm; they are commonly used and in general easily procured.

2.4 Unforeseen errors

Errors in measurement or in interpretation can also be caused by:

- use by non-qualified or non-trained personnel, lacking ability or experience
- user error
- use of the instrument outside the guidelines described in this Users Manual
- use of the instrument even when some operational anomalies may be encountered
- non-authorized servicing of the instrument

3 Description of the instrument

Otthon is a simple to operate, precise pocket spirometer (weight only 300g) able to measure the most important functional respiratory parameters with a quality control check on the test carried out.

3.1 General description

The instrument has the following user friendly features:

- Automatic internal calibration
- FVC, VC, MVV pulmonology measurements
- Patient database
- User friendly graphical interface, Quarter VGA (320X240 pixel), 256k colors
- No keyboard, the device is touchscreen euipped
- No moving parts
- Printing option

For a correct interpretation of the spirometry test results, the test results must always be compared with the so-called normal or predicted values which are calculated from the anthropometric data of the patient inserted in formulas of normal values published by the ERS (European Respiratory Society).

Otthon is intended for any doctor, from a family doctor to a specialist, requiring a small and compact instrument able to make a full spirometry test.

The instrument gives a simple summary of the test interpretation. This test interpretation is based on the ATS (American Thoracic Society) standards of 5 levels of obstruction, 5 levels of restriction and one of normal spirometry, the instrument thus gives a valid support to the doctor to make a diagnosis.

The sensor for flow and volume measurement is an Ultrasonic system based on the IDEGEN™ ultrasonic multiple-path principle. This prin-

ciple guarantees accuracy plus reproducibility of the measurement.

3.2 Technical specification

Here follows a complete description of the instrument and of the flow and volume measurement system.

Parameters measured:
FVC, PEF, FEV1, FEV1/FVC, FEF2575, FEF2550, FEF25, FEF50, FEF75, FEV3, FEV6, EV, ZeroTime, FET, PEFT, FIVC, PIF, FIV1, FIV1/FIVC, FIT, VC, EVC, IVC, IC, IRV, ERV, TV, MVV

Memory capacity:
The instrument is able to store more than 20 000 patients and/or measurements. The number is highly depends on the measurement type and the measurement length.

Display:
Quarter VGA (320X240 pixels), 262k colors with touch-screen

Communication port/interface:
Connection to PC via USB or BlueTooth(optional)
USB printer connection with USB cable

Printing
The instrument can print to any HP deskjet and officejet printers (via USB interface) that supports the PCL3 language.

Dimensions of the Device:
92x80x35 mm

Dimensions of the Flow tube:
⌀30 mm X 150 mm

Weight:
300 grams

Flow/volume measurement system:
IDEGEN™ technology

Measurement principle:
IDEGEN™ ultrasonic multiple-path

Maximum volume:
± 20 L

Flow range:
± 18 L/s

Volume accuracy:
± 3% or 50 mL

Flow accuracy:
± 3% or 50 mL/s

Sample rate:
100 Hz

Dynamic resistance at 14 L/s:
< 110 Pa/L/s

Battery:
Internal 3,7 V Li-Ion battery (Rechargeable via 5V 500mA miniUSB charger)

Electrical protection:
Internal battery power supply

Level of electrical protection:
BF

Protection against water ingress:
IP32

Operating and storage conditions:
Temperature: 10-40°C
Relative humidity: 5 - 95% without condensation

IEC 60601-1-2 relevant tables:

Guidance and Manufacturer's Declaration - Emissions		
The Otthon is intended for use in the electromagnetic environment specified below. The customer or user of the Otthon should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions, CISPR 11	Class B, Group 1	The Otthon uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonics IEC 61000-3-2	N/A	The Otthon is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Flicker IEC 61000-3-3	N/A	

Guidance and Manufacturer's Declaration - Immunity

The Otthon is intended for use in the electromagnetic environment specified below. The customer or user of the Otthon should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD IEC 61000-4-2	± 6kV Contact ± 8kV Air	± 6kV Contact ± 8kV Air	Floors should be wood, concrete, or ceramic tile. If floors are synthetic, the r/h should be at least 30%.
EFT IEC 61000-4-4	±2kV Mains ±1kV I/Os ±1kV Differential ±2kV Common	N/A N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycles 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Armband requires continued operation during power mains interruptions, it is recommended that Otthon be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration - Emissions

The Otthon is intended for use in the electromagnetic environment specified below. The customer or user of the Otthon should ensure that it is used in such an environment.

Emission Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile communications equipment should be separated from Armband by no less than the distances calculated/listed below:
Conducted RF, EC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	D=(3.5/V1)(Sqrt P) D=(3.5/E1)(Sqrt P) 80 to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	D=(7/EI)(Sqrt P) 800 MHz to 2.5 GHz Where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equip ment containing a transmitter.

Recommended Separation Distances for the Product

The Otthon is intended for use in the electromagnetic environment specified below. The customer or user of the Otthon can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the Otthon as recommended below, according to the maximum output power of the communications equipment.

Max Output Power (Watts)	Separation (m) 150kHz to 80MHz	Separation (m) 80 to 800MHz	Separation (m) 800MHz to 2.5GHz
0.01	0.1166	0.1166	0.2333
0.1	0.3689	0.3689	0.7378
1	1.1666	1.1666	2.3333
10	3.6893	3.6893	7.3786
100	11.6666	11.6666	23.3333

3.3 Labels and symbols

Product identification label

The identification label on the backside of the housing shows the product name, and additionally the following:

- Manufacturer's name and address
- Product conformity marking, in line with the CE 93/42 guidelines
- Serial number of the device
- Web site of the manufacturer

Description of symbols used on the label

CE 0120

CE mark for medical devices. The product is conform to the requirements of the 93/42/CEE medical devices directive.

Electrical safety symbol. In accordance with the EN 60601-1 the product and its component parts are of type BF and therefore protected against the dangers of direct and indirect contact with electricity.

Symbol for ”Manufacturer.” This symbol is adjacent to the name and address of the manufacturer.

Symbol indicating the ”date of manufacture.” The symbol is adjacent to the date that the product was manufactured, expressed as four digits for the year.

Symbol indicating ”Not for general waste.” This symbol marks devices that are reusable and not contaminated at the end of the device life.

Symbol for ”Caution, consult accompanying documents” and ”Attention, see instructions for use.”

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4 Operation of the Otthon

4.1 Starting the device

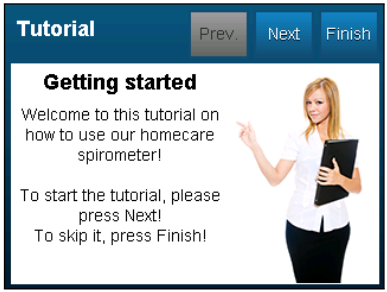
The power push button is located on the bottom left side of the device.

To start the device:

1. Press and hold the power button.
2. You will hear a beep. You can now release the power button. On the display of the device there will be appear a welcome screen.

3. A splash screen will appear on the display of the device.

4. After the splash screen, if enabled, the device usage tutorial will appear. This will guide you through the basics of using the device. You can navigate the tutorial using the on-screen Previous and Next buttons.



5. Exit the tutorial by tapping the Finish button. This will bring up the main menu.

4.2 Turning off the device

1. Finish all measurements and go back to the main menu.
2. Either
   a) tap the on-screen OFF icon, or
   b) press and hold the power button until the display turns black.

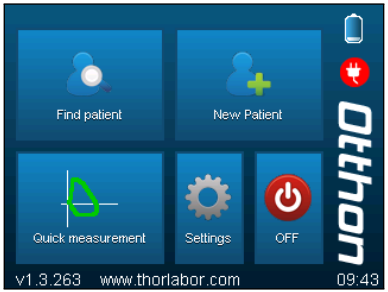
4.3 Touchscreen

The Otthon has a large and responsive color touchscreen. All manipulation of the device is done via the touching of on-screen elements, like buttons. The graphical user interface elements of the Otthon are designed to be big enough to facilitate operation of the device with a finger. Nevertheless, the touchscreen will respond to touching with objects made of any material.

4.4 Battery level

The battery symbol in the upper right corner of the main menu indicates the level of battery charge. The maximum charge is shown by five indicator bars on the icon. When the battery level becomes critically low (there are no indicator bars on the icon), the device will automatically turn off.

4.5 The Main Menu



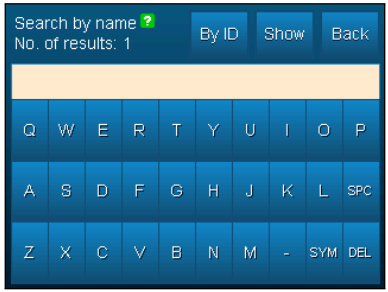
The main menu of the device is made up of two main parts:

- Buttons to access the different functions of the device:
  - Find patient
  - New patient
  - Quick measurement
  - Settings
  - OFF
- Status indicators:
  - Battery level
  - USB connection indicator
  - Firmware version
  - Current time

Find patient

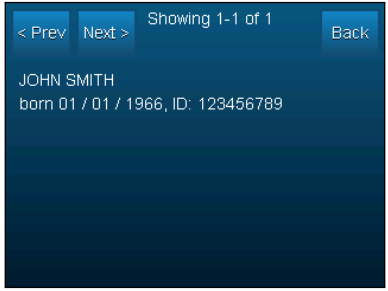
Before any measurement can be done, a patient must be selected. This is done using the Find patient dialog.

Search screen



Patients can be searched for either by name or ID. You can switch between the two modes by tapping the leftmost button at the top of the screen. To find a patient, enter a part of their name or ID, depending on which mode you have selected, using the on-screen keyboard. You can see the number of patients that match your search criteria even while you are typing in the top left corner of the screen. To list the patients whose name or ID includes the entered text, press Show. To see a list of all patients, leave the text entry empty then press Show.

Results screen



If the list of patients does not fit in one page then you can navigate between pages using the Previous and Next buttons. To go back to the search screen, press Back. To select a patient from the list of results, first highlight them by tapping on their name. Once you have highlighted a patient, you can confirm your selection by tapping on the highlighted entry a second time.

Patient profile screen

After a patient has been selected, their patient profile will appear. This screen shows the information about the patient that's kept in the database of the device, such as:

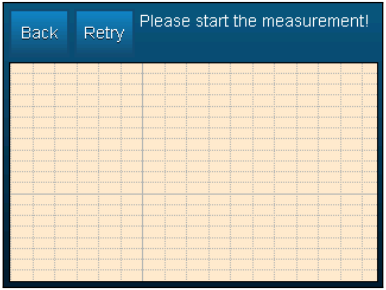
- Name
- ID
- Date of birth
- Gender
- Ethnicity
- Weight
- Height
- Prediction formula

To change a patient's name, ID, date of birth, gender or ethnicity, tap on the top pencil icon to the right of the patient information area. To change their weight, height or prediction formula, tap the bottom pencil icon.

To permanently delete a patient along with all their previously recorded measurements, tap the red X icon. The device will ask you for confirmation before deleting the data.

At the bottom of the patient screen you can see three buttons. The FVC button will start a new FVC measurement. The Review button will take you to the list of previous trials. The Back button will take you back to the results screen.

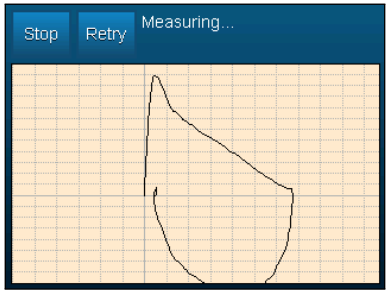
FVC Measurement screen



At first, most of the measurement screen is occupied by the real-time flow-volume curve plot. At the top of the screen there are two buttons: the Back button will take you back to the patient screen and the Retry button will start the measurement again.

Next to the buttons there is an informational area, where the instructional and interpretive messages of the device will appear. Whenever a message is too long to fit into this area, a small green arrow will appear indicating that there is more text to be displayed. To view the full message, tap anywhere inside the text area.

When the device is ready to start the measurement, it will indicate this in the informational area. Measurement is started automatically upon detection of air flow inside the tube.



After the measurement has started, a Stop button will appear that's used to end the current measurement. Measurement will also automatically end when no air flow is detected for 3 seconds.

Upon stopping the measurement, a panel will appear next to the plot containing the calculated lung function indices of the measurements in the on-going trial. You can navigate between the measurements using the arrow icons. Because all of the different indices would be too much to fit in one page, you can tap the table of indices to cycle between three pages.

By default the plot on the left of the screen shows the flow-volume

curve of the measurement. You can tap the plot cycle between the flow-volume, volume-time and flow-time curves.

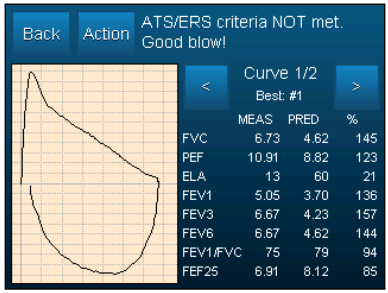
When multiple maneuvers have been performed, the best maneuver will always be plotted with green color over the latest maneuver, unless the best one is the latest.

To finish the trial, tap the Finish button at the top of the screen. This will automatically take you to the review screen of the current trial.

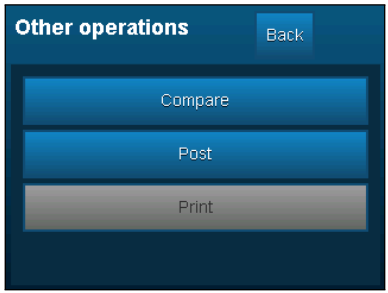
Review screen

First, a trial to be reviewed should be selected. The list of visits of the currently selected patient will appear on the left of the screen. You can scroll between pages of visits using the arrow icons beneath the list. Select a visit by double tapping the date.

The list of trials contained in this visit will appear on the right side of the screen. Select a trial by double tapping. You will be taken to the review screen of the selected trial.



The review screen of a trial is for the most part identical to the measurement screen as it appears after a measurement has been completed. The only difference is the Action button. Tapping this button will bring up the Other operations menu.



In this menu, the following options are available:

Compare Compare the best maneuver of the current trial to the best maneuver of a second trial. Selection of the second trial is identical to the trial selection detailed above.

Post Perform a post-bronchodilator test. The measurement is performed in the same way as a normal FVC measurement,

but after finishing the measurement, the Post measurement screen will open. This a comparison screen between the best maneuvers of the pre- and post-bronchodilator tests.

Print This option is only available when a compatible printer is connected to the normal-sized USB connector of the device. Selecting it will print out a report of the current trial. If you have bluetooth module in your instrument, don't forget to select the proper interface (USB or BT thermoprinter) on the "Options/Bluetooth settings" screen.

New patient

Use this option to add a new patient to the database of the device. Using the on-screen keyboard, you have to provide the following data about the patient, in this order:

- First name
- Last name
- ID (you can use the Next ID button to automatically assign the next unused ID)
- Year of birth
- Month of birth
- Day of birth
- Gender
- Ethnical group
- Weight
- Height
- Prediction algorithm

The device supports the following prediction algorithms:

- NHANES III
- Knudson
- Crapo

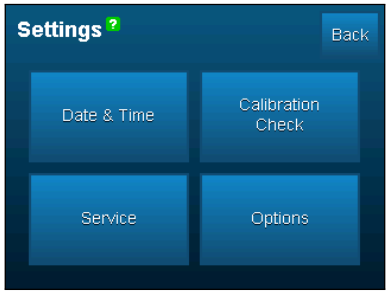
- Hsu
- Chinese Adult
- Chinese Child
- Austrian

After all the information has been provided, the new patient will be created, and you will be automatically taken to their profile screen.

Quick measurement

Choose this option to quickly perform an FVC measurement, when there is no need to archive the results. The measurement is performed in the same way as is detailed in FVC Measurement screen. If calculation of predicted values for the lung function indices is desired, the With prediction option should be enabled for Quick measurement in Settings. In this case, the device will ask for the following information before a quick measurement: gender, age, height and ethnicity.

Settings



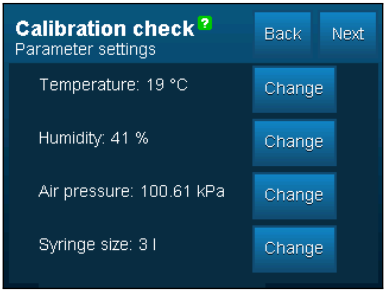
The Settings dialog is used for configuration and routine maintenance of the device. There are four buttons available:

- Date & Time
- Calibration Check
- Service
- Options

Date & Time

Use this dialog to set the internal clock of the device to the correct time for your time zone.

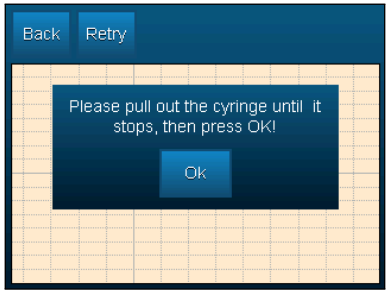
Calibration Check



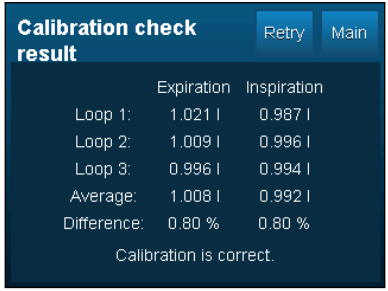
Calibration check is used to regularly validate the calibration of the device, as required by the ATS/ERS recommendations.

Before performing a calibration check, you need to enter the current environmental conditions into the device, such as: Temperature, Humidity, Air pressure. Additionally, the size of the syringe to be used should be specified. The device supports syringes of 1 and 3 Liters.

Press Next to proceed with the calibration check. A message will appear, asking you to pull out the syringe fully.



Follow the instruction then press Ok to start the calibration check. Fully empty then fill the syringe in quick succession three times. The calibration check will automatically stop after filling the syringe for the third time.



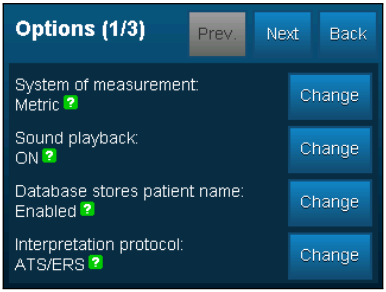
The results of the calibration check will appear. The individual expiratory and inspiratory volumes of the three measurement cycles are displayed as well as their average values. The percentage of difference from the expected volume is shown.

Service

Upon entering the Service option, the device will start sending flow sensor data over the mini-USB interface. This enables the use of the device with the ThorSoft desktop spirometry application for PC's.

Options

The Options dialog is used to configure the device. The available configuration options are:

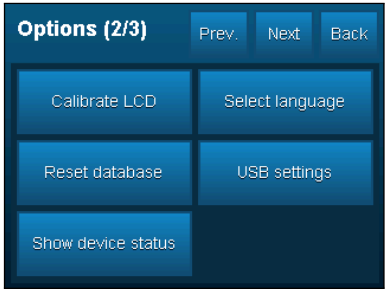


System of measurement Change the default units used for specifying height and weight. Available options are Metric and Imperial.

Sound playback When enabled, the device will read out loud the interpretive and quality control messages of the FVC measurement.

Database stores patient name When disabled, the device will no longer ask for and display patient names.

Interpretation protocol Used to toggle between interpretation protocols. Available options are ATS/ERS and NLHEP.



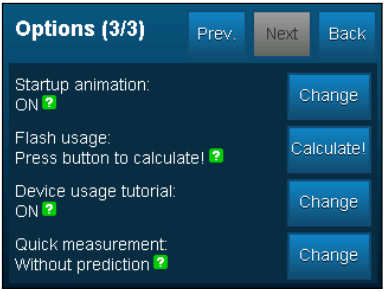
Calibrate LCD If you feel that the precision of the touchscreen has deteriorated to a point where it affects usability, you can recalibrate it using this option. An X will appear in each corner of the device, one at a time. Tap each X at the exact center five times in succession. The touchscreen is now recalibrated.

Reset database Wipe all recorded patient and visit data from the device. A confirmation will appear before the data is deleted. Please note that this operation is not reversible.

Device status Shows the following status information about the device:

- VUSB: USB power supply voltage.
- VBATT: Battery voltage.
- V19: Touchscreen backlight voltage.
- USB connection status.
- Percentage of remaining battery life.

Select language Select the language in which the on-screen text is displayed. Please note that this will not change the language of sound playback.



Startup animation Used to enable or disable the animated startup splash screen.

Flash usage To show how much of the storage space in the device is being used, press Calculate. The calculation process might take a long time (15-30 seconds).

Device usage tutorial Used to enable or disable the tutorial that appears after turning on the device.

Quick measurement Toggle between quick measurement with and without prediction. If prediction is enabled for quick measurement, the device will ask all the necessary information needed for a prediction before every quick measurement.

OFF

Tapping the OFF icon will cause the device to power off.

5 Maintenance

The Flowmeter used by Otthon guarantees the maximum measurement accuracy and has the great advantage of *not requiring everyday calibration*. To ensure the maximum accuracy of the respiratory sensor, it is recommended to make a simple cleaning operation in case of extensive use. It is a good practice from time to time to make a visual check inside the tube to ensure that no hairs, dust or foreign bodies of any kind have collected within the tube. Such an occurrence could undermine the accuracy of the measurements.

Otthon is an instrument which requires very little maintenance. The only regular maintenance operations required are:

- Cleaning and checking of the flow meter.
- Charging the battery.

ATTENTION

- **In order to understand the proper disinfection process please observe section *5.1 Disinfecting the tube*.**

Charging the battery

If the battery is empty or if the instrument will not switch on, then the battery must be recharged. The proper charging method of the Otthon in case of empty battery the device needs to be charged till the flashing LED light turns off on the power button. If the LED flashing ended the Otthon can be used in normal function. The charging process may not suggested to suspend because the incorrect charging time will cause the battery lifetime drop. **ATTENTION**

- **Do not charge during measurement.**

5.1 Disinfecting the tube

The disinfection process was tested and validated using INSTRUMED as disinfection liquid. *If you intend to use disinfection liquid other than*

INSTRUMED please consult your local sales representative.
INSTRUMED is a cleansing instrument disinfectant concentrate which uses the latest in active agents, adjuvants and corrosion protection compounds, with a wide anti-microbial spectrum of application. INSTRUMED is a yellow colored, mildly viscous product with a distinctive aroma, which allows it to be distinguished from other medical instrument disinfectants.

Preparation of the disinfectant solution

Using an appropriately large container, fill with 10 liters of tap water at a temperature not warmer than 40 °C. To this add the disinfectant to the appropriate cubic volume, for example in the case of a 2% solution add 2dl, for a 1% solution add 1dl, and so on.

The working solution must always be prepared fresh before being used.

Appropriate concentrations and exposure time

- 3% solution effective within 15 minutes
- 2% solution effective within 30 minutes
- 1% solution effective within 60 minutes

In the solution sterilization occurs with

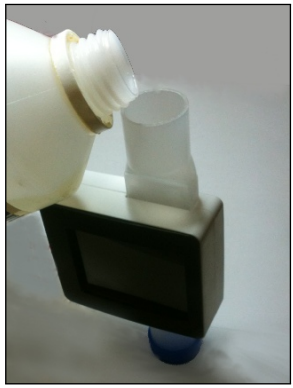
- 5% solution effective within 3 hours

Disinfection steps

Step 1: Prepare 1%, 2% or 3% solution from the INSTRUMED as described above

Step 2: Cover hermetically one of the end of the flowtube with the shipped cup.

Step 3: Pour the prepared solution in the tube to leaving space only for covering the other side the tube



Pouring the solution in the tube

Step 4: Leave the solution in the tube for the specified time described above

Step 5: Remove the upper cup and pour the solution out of the tube

Step 6: After flushing of the fluid carefully wipe the outer perimeter of both ends of the flowtube with the disinfectant solution to prevent the patient from cross infection

Wiping the outer perimeters with disinfectant

Step 7: Flush the tube with plenty of distilled water

Step 8: Wait for the tube to dry or dry the tube with a ventilator.

IMPORTANT WARNINGS

- **Only the flowtube can be disinfected. Never put the device itself under a running tap (or other liquid) as irreparable damage may be caused.**
- **If you intend to use disinfection liquid other than INSTRUMED please consult your local sales representative.**

ATTENTIONS using INSTRUMED

⚠

- **It is forbidden to mix with other cleansers or disinfectants!**
- **R22: Harmful if swallowed**
- **R34: Causes burns**
- **S2: Keep out of the reach of children**
- **S13: Keep away from food, drink and animal feeding stuffs**
- **S25: Avoid contact with eyes**
- **S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice**
- **S28: After contact with skin, wash immediately with plenty of water**
- **S36/37/39: Wear suitable protective clothing, gloves, goggles and facemasks**
- **S45: In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)**

6 Problem solving

Here follow some of the possible problems which can occur when using Otthon.

6.1 Causes and solutions

- Otthon does not switch on: the device doesn't start when the button is pressed, try the followings:
  May the battery is discharged completely. In that case, connect the device to its charger. Please let the device to be charged about 4-5 hours. If the device is still not switching on call your technical service department or organization.
- During operation of the machine it switches off
  May the battery is empty. Please charge up the battery. Try to switch it on again and follow the steps mentioned previously.
- Data in memory lost
  The test data in memory have been lost. Call your technical service department/organization.

7 Declaration of EC conformity

Manufacturer

THOR Laboratories Kft.
Bogdánfy u. 10/a., Budapest, 1117, Hungary

Product

Spirometer

Model number

Otthon

Classification

Class IIa, Council Directive 93/42/EEC of MDD, Annex IX, rule 10

Declaration

We hereby declare that the above listed products comply to the provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Applied standards

EN 60601-1:2006/AC:2010
EN 60601-1-2:2007/AC:2010
EN 60601-1-6:2010
EN 62366:2008
EN 62304:2006
ISO 15223-1:2012
EN 1041:2008
EN ISO 14971:2012
EN ISO 26782:2009

Notified Body

SGS United Kingdom Ltd. Systems & Services Certification;
202B World Parkway Weston super Mare, BS22 6WA UK

EC Certificates

Directive 93/42/EEC
EN ISO 13485:2012
ISO 9001:2008
HU09/6306
HU09/6307
HU09/6308

CE 0120

8 Limited Warranty Conditions

This product together with its standard accessories is guaranteed for a period of ONE YEAR from the date of purchase. In the case of any warranty claims the relevant sales invoice (or another proof of purchase document) must be submitted.

The instrument must be checked at the time of purchase and any claims must be made immediately in writing.

This warranty covers the repair or the replacement (at the discretion of the manufacturer) of the product or of the defective parts without charge for the parts or for the labor.

All consumable parts are specifically excluded from the terms of this guarantee.

The warranty is not valid, and the judgment of the manufacturer's technicians is final, in the following cases:

- If the fault is due to an improper operation of the machine, or if the installation does not conform to the current safety norms in the country of installation.
- If the product is utilized differently from the use described in the Users Manual.
- If any alteration, adjustment, modification or repair has been carried out by personnel not authorized.
- If the fault is caused by lack of or incorrect routine maintenance of the machine.
- If the machine has been dropped, damaged or subjected to physical or electrical stress.
- If the fault is caused by the mains or by another product to which the instrument has been connected.
- If the serial number of the instrument is missing, tampered with and/or not clearly legible.

The repair or replacement described in this warranty is supplied for goods returned at the customer's expense to our certified service centre. For details of these centers please contact your supplier of

the spirometer or contact the manufacturer directly.

The customer is responsible for the transportation and for all transport and customs charges for the delivery of the goods both to and from the service centre.

Any instrument or accessory returned must be accompanied by a clear and detailed explanation of the defect or problem found.

The manufacturer reserves the right to modify the instrument if required, and a description of any modification made will be sent along with the returned goods.

This manual is attached to the following Otthonspirometer serial number

OTH-

Manufacturer:

THOR Laboratories Kft.
Bogdánfy u. 10/a., Budapest, 1117, Hungary