THOR laboratories

HOME OF IDEGEN TECHNOLOGY

SpiroTube Mobile Edition

IDEGEN™ Bluetooth Spirometer

User Manual

english
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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

SpiroTube Mobile Edition is a simple to operate, precise pocket spirometer (weight only 150grams) 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:

- Plug-and-play operation
- Automatic internal calibration
- No moving parts

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

Communication port/interface:
Connection to PC via Bluetooth (SPP) or USB (optional)

Type of USB connector:
Standard 5-pin mini B

Dimensions of the Device:
27x60x170 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 SpiroTube Mobile Edition is intended for use in the electromagnetic environment specified below. The customer or user of the SpiroTube Mobile Edition 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 SpiroTube Mobile Edition 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 SpiroTube Mobile Edition 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 SpiroTube Mobile Edition is intended for use in the electromagnetic environment specified below. The customer or user of the SpiroTube Mobile Edition 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 SpiroTube Mobile Edition 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 SpiroTube Mobile Edition is intended for use in the electromagnetic environment specified below. The customer or user of the SpiroTube Mobile Edition should ensure that it is used in such an environment.

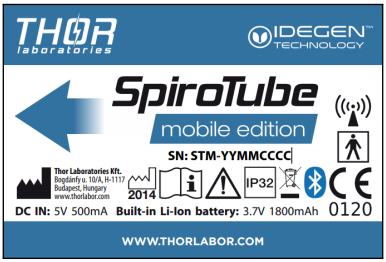
Emission Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile communications equipment should be separated from Armband by no less than the distances calculated/listed below:
Conducted RF, EC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	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 SpiroTube Mobile Edition is intended for use in the electromagnetic environment specified below. The customer or user of the SpiroTube Mobile Edition can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the SpiroTube Mobile Edition 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.”

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

Symbol for ”Radio frequeuncy radiation.”

4 Operation of SpiroTube Mobile Edition

The SpiroTube Mobile Edition is a sensor device, which can be connected to mobile devices, laptops and PCs via BlueTooth (wireless) or USB (cable).

Please read installation instructions below for the proper working.

SpiroTube Mobile Edition has internal Li-Ion battery to operate without any external power source. The device can be switched on by using the push button located on the side of the device. Due to power saving considerations the device will switch off automatically after a few minutes from the last button press. The device indicates a beep 30 seconds prior it switches off itself. The green LED symbol shows in the front of the device if there is an active wireless (Bluetooth) connection. The multi-function LED on the front indicates the device's power status and the level of the battery:

- **GREEN:** The battery is fully charged.
- **YELLOW:** The battery is half empty.
- **RED:** The battery is very low - empty.
- **BLINKING RED:** The battery is dead, the device will turn off soon.

The device can be turned off by using the Power button.

Controls of the device: (1-Power button; 2 - Wireless activity LED; 3-battery indicator LED; 4 - USB cable and charger

4.1 Operation using Bluetooth connection

After you switch on the device, it becomes discoverable and other devices can connect to it. Generally you should make a device discovery (find Bluetooth devices), choose the SpiroTube Mobile Edition device from the list and pair the device before the first use. The software will remember for the selection and the pairing. Please refer to the software manual for the discovery and pairing process. Please do not forget to switch on the SpiroTube Mobile Edition before you try to connect to it otherwise the connection will fail.

Note: Only one device can be connected to SpiroTube Mobile Edition. You cannot connect to the device if other device is already connected to it.

Note: Before the first connection the device must be paired. Generally it is an automatic process and the phone or the PDA will ask for a PIN if you try to connect to the device. The PIN is 1234 for SpiroTube Mobile Edition. There are some older phones which do not support the pairing this way. On these phones you must pair SpiroTube Mobile Edition manually at the Bluetooth settings of the phone. Please refer to the user manual of the phone.

If you use Bluetooth connection there is no need to use any outher

cable for the measurements. The device can be operated for 3-5 hours continously with one charge depending on the battery state. Three colour battery status indicating LED informs the User about the battery status. If the device does not switch on or it indicates with a short beep that the battery level is low, the device must be recharged.

5 Maintenance

The Flowmeter used by SpiroTube Mobile Edition 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.

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

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

ATTENTION

- **In order to understand the proper disinfection process please observe section *5.2 Disinfecting the tube*.**

5.1 Charging the battery

The device indicates with the battery status blinking red LED if the battery is empty or if the instrument will not switch on, then the battery must be recharged. For charging the device please use the USB cable, which was contained to the package. Plug the cable into the charger and to the device as well. The ON/OFF button LED next to the USB connector indicates whether the battery is being charged. The full charging may takes up to 4-5 hours. The charging time may vary on the battery level. The charging is done when the ON/OFF button blinking LED goes off.

ATTENTION

- **Do not charge during measurement.**

USB connector location on the device

Connecting the USB cable to the charger

The connected charger

5.2 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

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- **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 SpiroTube Mobile Edition.

6.1 Causes and solutions

- SpiroTube Mobile Edition 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 switches off
  May the battery is empty. Please charge up the battery. Try to switch it on again and follow the steps mentioned previously.
  Please note: The device switches on automatically after a few minutes for power saving after pressing the power on button. The device indicates with long beeps that it will switch off. Press the power on button any time to keep the device switched on.
- Following a test the measurement results are not reliable
  Check the tube for any kind of foreign body.

7 Declaration of EC conformity

Manufacturer

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

Product

Spirometer

Model number

SpiroTube Mobile Edition

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 SpiroTube Mobile Edition-spirometer serial number

STM-

Manufacturer:

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