SpiroTube

PC Spirometer

User Manual

English
r200
2016-12-13

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1 INTRODUCTION

1.1 Intended use

1.1.1 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.

Before first use please disinfect the device. The device may lose its disinfected status during the shipping.

1.1.2 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.

1.1.3 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.

1.1.4 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 children under 4 years and people over 99 years. The defined interval of usage for the spirometer related the patient age depends on the selected prediction algorithm.

1.1.5 Prediction algorithms age limits

Reference	Age	Height	Weight
	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)	-

1.1.6 Limitations of use - Contraindications

An analysis of the results of a spirometry test is not sufficient in itself 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, test interpretations 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 are 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 User 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 only 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 with 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

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

2.2 The flow tube

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

The presence of any impurities such as hairs, sputum, threads etc. within the body of the flow tube 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. For intended use bacterial filter is required. The bacterial filter should be placed on the end of the tube so that it is between the device and the patient. The blue arrow on the device label indicates the direction of the expiratory air flow in that case the bacterial filter needs to be placed. The USB cable is located on the patient side part, so it can be checked if the arrow shows the right direction.

SpiroTube with bacterial filter

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

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.

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 User 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 is a simple to operate, precise pocket spirometer (weight only 150g) 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,
- plug-and-play operation,
- no moving parts.

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).

SpiroTube 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 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:

Parameters measured
Evaluated by the ThorSoft Spirometry PC Software

Communication port/interface
Connection to PC via USB

USB connector type
Standard 5-pin mini-B

Dimensions of the device
30×65×95 mm

Dimensions of the flow tube
⌀30×165 mm

Weight
150 grams

Flow/volume measurement system
IDEGEN™ technology

Measurement principle
IDEGEN™ ultrasonic multiple-path

Maximum volume
± 20 L

Flow range
± 14 L/s

Volume accuracy
± 3% or 50 mL whichever is greater

Flow accuracy
± 3% or 50 mL/s whichever is greater

Sample rate
100 Hz

Expiratory impedance at 14 L/s flow
< 0,15 kPa/L/s

Level of electrical protection

BF

Protection against water ingress

IP44

Operating and storage conditions

Temperature: 10 - 40°C

Relative humidity: 5 - 95% without condensation

3.2.1 IEC 60601-1-2 relevant tables

Table 1

Guidance and manufacturer's declaration – electromagnetic emissions		
The SpiroTube is intended for use in the electromagnetic environment specified below. The customer or the user of the SpiroTube should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR11	Group 1	The SpiroTube 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.
RF emissions CISPR11	Class B	The SpiroTube is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity			
The SpiroTube is intended for use in the electromagnetic environment specified below. The customer or the user of the SpiroTube should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95% dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (3 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SpiroTube requires continued operation during power mains interruptions, it is recommended that SpiroTube be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 4

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The SpiroTube is intended for use in the electromagnetic environment specified below. The customer or the user of the SpiroTube should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 Test level</th><th>Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>3 Vrms
150 kHz to 80 MHz</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the SpiroTube, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance
$d = [\frac{3,5}{V1}]\sqrt{P}$

$d = [\frac{3,5}{E1}]\sqrt{P}$ 80 MHz to 800 MHz

$d = [\frac{7}{E1}]\sqrt{P}$ 800 MHz to 2,5 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b]
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2,5 GHz</td><td>3 V/m
80 MHz to 2,5 GHz</td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SpiroTube is used exceeds the applicable RF compliance level above, the SpiroTube should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SpiroTube.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.</td></tr>
</table>

Table 6

Recommended separation distances between portable and mobile RF communications equipment and the SpiroTube			
The SpiroTube is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SpiroTube can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SpiroTube as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = [\frac{3,5}{V1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3,5}{E1}]\sqrt{P}$	**800 MHz to 2,5 GHz** $d = [\frac{7}{E1}]\sqrt{P}$
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
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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,
- website of the manufacturer,
- additional symbols.

Flow direction label

The label on the flow tube shows the direction of the expiration.

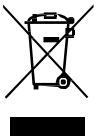
3.3.1 Description of symbols used on the label

CE mark for medical devices. The product is according 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 ”Attention, see instructions for use”.

Symbol for ”Caution, consult accompanying documents”.

4 OPERATION OF SPIROTUBE

The SpiroTube is a sensor device, which can be connected to laptops and PCs via USB (cable) connection.

Please read installation instructions below for the proper working.

4.1 Operation using USB connection

SpiroTube drivers are installed together with ThorSoft Spirometry Software. Please prepare your SpiroTube device.

IMPORTANT WARNING!

You must start ThorSoft Spirometry Software installer before you connect first the SpiroTube device. The installer sets up the system to be ready to accept the SpiroTube device. Please follow carefully the instructions of the installer and connect the device as described below when it is necessary.

IMPORTANT WARNING!

The fixed USB cable equipped device has a persistent USB cable, which cannot be detached from the sensor.

Fixed USB cable equipped sensor

For connecting the USB cable to your PC or laptop, please find the USB connector. It is typically located on the back of the desktop PCs or on the side of laptops. A USB symbol shall be somewhere close to the connector.

The USB symbol

USB connector on the back of the PC

Connect the larger end of the included USB cable to your computer, making sure the right direction.

Connecting the USB cable to laptop

5 MAINTENANCE

The flow tube used by SpiroTube 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 is an instrument which requires very little maintenance. The only regular maintenance operations required are:

- Cleaning and checking of the flow tube
- Recalibration of the spirometer

ATTENTION!

In order to understand the proper disinfection process please, observe section 5.1 Disinfection of the flow tube.

5.1 Disinfection of the flow 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.

5.1.1 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

5.1.2 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 flow tube 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 into the tube

Step 4: Carefully seal the other end of tube.

Step 5: Leave the solution in the tube for the specified time described above.

Step 6: Remove the upper cup and pour the solution out of the tube into a receptacle.

Step 7: After flushing of the fluid carefully wipe the outer perimeter of both ends of the flow tube with the disinfectant solution to prevent the patient from cross infection.

Wiping the outer perimeters with disinfectant

Step 8: Flush the tube with plenty of distilled water.

Step 9: Place a bacterial filter at the both ends of the flow tube and leave the tube to dry (e.g. for 30 minutes).

IMPORTANT SAFETY WARNINGS

- Only the flow tube 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!

5.1.3 INSTRUMED attentions

- 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)

5.2 Recalibration of the spirometer

Periodic Safety Checks are necessary to be carried out by recalibrating the spirometer every two years. For the recalibration process it is required to have a 3 liter syringe and the calibration software which can be purchased from THOR Laboratories Kft., if you wish to do it in-house.

There is also another opportunity requires the spirometer to be sent back to the manufacturer for an extra cost of maintenance.

6 PROBLEM SOLVING

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

6.1 Causes and solutions

- ThorSoft is not able to identify the SpiroTube

Pull out the USB cable from your laptop or PC, restart the ThorSoft Spirometry Software and then reconnect your SpiroTube device. If the software is still unable to recognize the spirometer, the wired USB cable may be damaged or broken. In this case call your technical service department or organization.

7 DECLARATION OF EC CONFORMITY

Manufacturer:

THOR Laboratories Kft.
1119 Budapest, Pajkos utca 50., Hungary

Description of the device:

PC Spirometer

Type:

SpiroTube PC

Classification

Class IIa
Council Directive 93/42/EEC of MDD as amended by Directive 2007/47/EC, Annex IX, rule 10

Declaration

We hereby declare that the above listed product complies with 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

MSZ EN 60601-1:2006/AC:2014	MSZ EN ISO 15223-1:2013
EN 60601-1-2:2007/AC:2010	MSZ EN 1041:2009
MSZ EN 60601-1-6:2010/A1:2015	MSZ EN ISO 14971:2013
MSZ EN 62366:2015	MSZ EN ISO 26782:2009
MSZ EN 62304:2006	MSZ EN ISO 10993-1:2010

Notified Body

CE Certiso Ltd., Organization for Certification and Testing on the Field of Medical and Hospital Engineering
H-2040 Budaörs, Gyár u. 2. BITEP, Gábor Dénes krt. 101.

EC Certificates

Directive 93/42/EEC	144571-15-07-28
MSZ EN ISO 13485:2012	144570-15-07-28
MSZ EN ISO 9001:2009	144569-15-07-28

CE 2409

Budapest, 2016-02-17

THOR Laboratories Kft.
8000 Székesfehérvár, Rádi u. 2.
Adószám: 24083559-2-07
Cégjegyzékszám: 07-09-022749

Nikolett Makovinszky
Executive Director

8 DECLARATION OF EXPECTED LIFETIME

Manufacturer:

THOR Laboratories Kft.
1119 Budapest, Pajkos utca 50., Hungary

Description of the device:

PC Spirometer

Type:

SpiroTube PC

Declaration

We hereby declare that the above listed product has an estimated working life of 5 years. This estimation is based on the MTFF (Meantime to First Failure) parameter of the components used in the production. The most critical component of SpiroTube spirometer is the wired USB cable, which needs special precautions during its lifetime. After their lifetime the products must be disposed of in an environmentally responsible manner.

9 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 User 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 a SpiroTube spirometer with the following serial number:

ST–

10 USER NOTES

Manufacturer:

THOR Laboratories Kft.

1119 Budapest, Pajkos utca 50., Hungary