PowerCube+ Series

Pulmonary Function Testing

℞only

Art. no.: 01140070 2 Rev. 06

Instruction For Use

GANSHORN
SCHILLER GROUP

Sales and Service Information

The GANSHORN sales and service centre network is world-wide. For the address of your local distributor, contact your nearest subsidiary. In case of difficulty, you can find a list of distributors and subsidiaries on our Internet site:
http://www.ganshorn.de

Manufacturer

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CAUTION

Federal (USA) law restricts the sale of this device by or on the order of a physician.

If any serious incident occurs in relation with the PowerCube+ Series or LFX, such incident needs to be reported immediately to GANSHORN and to the competent national authority of the country which the user and/or patient is established.

CE 0123

The PowerCube+ Series bears the CE-0123 mark (Notified Body TÜV-SÜD Produkte Service GmbH, Ridlerstr. 65, 80339 Munich, Germany), indicating its compliance with the essential requirements of Annex I of the Medical Device Directive 93/42/EE regarding safety, functionality and labelling. The requirements apply to patients, users and third persons who come into contact with this device within the scope of its intended use.

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1 Safety Notes

- ▲ The safety notes detailed in your system instruction for use must be read and understood.
- ▲ Additional intended use and safety precautions applicable for the PowerCube+ Series are given here.

1.1 Intended Use

1.1.1 Intended Purpose

- ▲ A device used to measure the function of the respiratory system in adults and compliant children. It usually includes a spirometer with flow-sensing devices, a gas analyser for evaluation of absolute lung volumes and gas-diffusing capacity of the lungs, and computer capabilities for data processing and recording; a total-body plethysmograph to measure both lung volumes and airway resistance may be included. The device is mostly used for outpatient or presurgical screening, and may also be used in the diagnosis and evaluation of common diseases in children (e.g., asthma)
- ▲ The PowerCube+ series (Spiro / Body / Diffusion) is an PC based lung function diagnosis workstation.
- ▲ In combination with an lung function diagnosis software the PowerCube+ series is intended for measuring and analysing lung function parameters.
- ▲ The PowerCube+ series is intended for use in hospital, clinical settings and medical practices.

1.1.2 Indications

- ▲ Use of the PowerCube+ Series, in combination with a lung function diagnosis software, is indicated for detecting and screening/evaluating the current state or progression of respiratory disease, and for evaluating the effect of pulmonary treatment.

Indications for lung function testing:

Indications for Spirometry (lung function testing) - ATS/ERS Recommendation (2019)

- **Diagnosis**
  - to evaluate symptoms, signs, or abnormal laboratory test results
  - to measure the physiologic effect of disease or disorder
  - to screen individuals at risk of having pulmonary disease
  - to asses preoperative risks
  - to asses prognosis
- **Monitoring**
  - to asses response to therapeutic intervention
  - to monitor disease progression
  - to monitor patients for exacerbations of disease and recovery from exacerbations
  - to monitor people for adverse effects of exposuere to injurious agents
  - to watch for advers reactions to drugs with known pulmonary toxicity
- **Disability/Impairement evaluations**
  - to assess patients as part of a rehabilitation program
  - to assess risks as part of an insurance evaluation
  - to assess individuals for legal reasons

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- **Other**
  - research and clinical trials
  - epidemiological surveys
  - derivation of reference equations
  - preemployment and lung health monitoring for at-risk occupations
  - to assess health status before beginning at-risk physical activities

1.1.3 Contraindications

The use of the PowerCube+ Series is contraindicated if the patient is affected by the following health conditions, as recommended by the American Thoracic Society and the European Respiratory Society:

Contraindications for Spirometry - ATS/ERS Recommendation (2019

▲ Due to increases in myocardial demand or changes in blood pressure
  - acute myocardial infarction within 1 week
  - systemic hypertension or severe hypertension
  - significant atrial/ventricular arryhtmia
  - noncompensated heart failure
  - uncontrolled pulmonary hypertension
  - acute cor pulmonale
  - clinically unstable pulmonary embolism
  - history of syncope related to forced expiration/cough

▲ Due to increase in intracranial /intraocular pressure
  - cerebral aneurysma
  - brain surgery within 4 weeks
  - recent concussion with continuing symptoms
  - eye surgery within 1 week

▲ Due to increases in sinus and middle ear pressure
  - sinus surgery of middle ear surgery or infection within 1 week

▲ Due to increase of intrathoracic and intraabdominal pressure
  - presence of pneumothorax
  - thoracic surgery within 4 weeks
  - abdominal surgery within 4 weeks
  - late-term pregnancy

▲ Infection Control Issues

- active or suspected transmissible respiratory or systemic infection, including tuberculosis
- physical conditions predisposing to transmission of infections, such as:
  - hemoptysis
  - significant secretions
  - oral lesions
  - oral bleeding

1.1.4 Intended users

The PowerCube+ series is intended for use by healthcare professionals in hospitals, clinics and medical practices. These are adult users who have completed medical training of their respective field and a corresponding education. Acceptable impairments are small interferences of reading ability or visual capacity, if they are corrected.

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1.1.5 Patient Target Group

- The PowerCube+ is intended for measuring and analysing lung function parameters in adult and paediatric patients of all nationalities. No weight limitations apply, except in the use of the body option.
- The maximum load capacity of the bench in the cabin must be observed.
- The contraindications must be observed.
- The PowerCube+ is intended to be used for adults and paediatric patients from an age of 2.5 years on.

1.2 General Condition of the Patient

▲ Before starting a pulmonary function test, a preliminary check of the vital parameters as well as the medical history is recommended to ascertain that test can be carried out without any risk for the patient. This is especially important in case of forced breathing manoeuvres see para. 6.2 Preliminaries, page 70.

▲ The measurement shall not be performed in case the patient is affected by any of the circumstances listed in 1.1.3 Contraindications.

▲ After the test, it is recommended to check the patient's well-being and general medical condition.

Adverse side effect

▲ There is a residual risk of skin reaction from contact with the device if the skin is not intact.

▲ Protective measures must be applied if the skin is not intact.

1.3 Responsibility of the User

▲ The system must be calibrated at regular intervals as defined in this instruction for use.

▲ The numerical and graphical results and any interpretation given must be examined concerning the overall clinical condition of the patient and the general recorded data quality.

▲ The quality of the pulmonary function test results depends on the patient's cooperation. It is the user's responsibility to instruct and motivate the patient to perform tests of acceptable high quality.

▲ It is the owner's responsibility to observe valid regulations for the safety and prevention of accidents.

▲ All persons working with the system must read this instruction for use and any ancillary equipment operating instructions. In particular, the safety instructions of the system must be read and understood.

▲ Operating ancillary equipment with a defective casing or defective cables constitutes a danger to the patient or the user. Immediately replace a damaged unit, or damaged cables and connections.

▲ The device's safety, reliability and performance can only be guaranteed when the maintenance intervals, as stated in the maintenance section, are observed.

▲ The user has to observe the patient closely during the complete duration of the measurement. In case of breathing difficulties, dizziness or hyperventilation, the measurement must be interrupted.

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1.4 Organisational Measures

- ▲ Before using the PowerCube+ Series, ensure that an introduction regarding the functions and the safety precautions has been provided by a medical product representative.
- ▲ This instruction for use, and especially these safety notes, must be read and observed.
- ▲ These operating instructions do not override any statutory or local regulations for preventing accidents and environmental protection.
- ▲ Check that an operating instruction manual is always complete, legible and available at the point of use of the PowerCube+ Series.
- ▲ Portable communication equipment, HF two-way radios and devices marked with the  symbol can affect the system.
- ▲ Only use accessories and disposables recommended or supplied by GANSHORN. Using other than recommended or supplied parts may result in inaccurate information or damage the unit.
- ▲ If uncertain about the accuracy of any measurement or unexpected readings are obtained, check the patient by alternative means, make sure the equipment is functioning correctly, check the calibration, check the connections, change the bacterial filter.
- ▲ The device is used for lung function testing only.

Ambient Conditions

- ▲ The ambient conditions for storage and operation must be observed.
- ▲ The device is not designed for use in medical locations where an explosion hazard may occur. An explosion hazard may result from using flammable anaesthetics, skin cleansing agents and disinfectants. Furthermore, the device is not suitable for application in an oxygen-enriched atmosphere. The atmosphere is considered oxygen-enriched when the air in the room contains more than 25% oxygen or nitrous oxide.

Packaging

- ▲ Do not use the device and disposables if the packaging is damaged or has been unintentionally opened before.
- ▲ Do not use the device if the packaging is exposed to environmental conditions outside of those specified and contact your authorised GANSHORN partner.

1.5 Maintenance

- ▲ Do not open any part of the system. There are no serviceable parts inside. Refer servicing to qualified technicians authorised by GANSHORN only.
- ▲ The PowerCube+ Series must not be altered or modified in any way by non-authorised persons.
- ▲ The PowerCube+ Series must not be altered or modified by non-authorised persons.
- ▲ Inspection and calibration must be performed on a regularly basis, as detailed in the maintenance section (see para.15, Maintenance, page 156).

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1.6 Operation with other Devices

- If a GANSHORN device is combined into a system by the GANSHORN partner or the operator, the GANSHORN partner or operator becomes the system's producer of the system and, as such, is responsible for safety and compliance with all applicable standards.
- Equipment that is not part of the system delivered by GANSHORN must not be connected to the system.
- Accessory equipment must be certified according to the respective IEC standards (e.g. IEC 62386-1 for data processing equipment, IEC 60601-1 clause 16 for medical equipment. Furthermore all configurations shall comply with the current version of the system standard IEC 60601-1. Anyone who connects or modifies additional devices to the signal input section or connects signal output part configures a medical system and is therefore responsible for ensuring that the system complies with the requirements of the valid version of the system standard IEC 60601-1 standard. In case of doubt, contact authorised partner of GANSHORN.
- For devices of the **Eco variant** that are equipped with **ComIso**, the following must be taken into account:
  - To ensure the safety of the patient it must not be possible for the operator to touch the patient and the computer at the same time.
  - Therefore, the wheeled stand including the computer/monitor and printer (tested according to 62368-1) must be set up at a minimum distance of 1.5m from the medical device.
  - If not observed, the safety for the medical electrical equipment according to IEC 60601-1 is not guaranteed.
- Only use accessories recommended or supplied by GANSHORN. Use of other than recommended or supplied parts may result in injury, inaccurate information or damage. Additionally, using accessories, transducers and cables other than those specified or supplied by GANSHORN as replacement parts for internal components may result in increased emissions or decreased immunity of the ME equipment.
- Portable RF communication equipment, HF two-way radios and devices marked with the symbol  (non-ionic electromagnetic radiation) can affect the performance of this device (see para. 18.1 Preventing Electromagnetic interferences, page 168).

1.7 Cleaning

- Only use cleaning agents and disinfectants recommended by GANSHORN. Unsuitable agents can damage the device. Clean and disinfect the device in accordance with the instructions (see para. 14 Cleaning and Disinfection, page 148).
- For cleaning and disinfection observe the legal requirements applicable.
- Do not use solvent or abrasive cleaners on the either the unit, hoses or cable assemblies.
- Do not, under any circumstances, immerse the unit, cable assemblies, hoses, or transducers in liquid.

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1.8 Infection control/cross contamination

Infection control issues caused by cross contamination

▲ Transmissible respiratory infections, e.g. pneumonia, or systemic infection, e.g. tuberculosis, and physical health conditions predisposing to transmission of infections, such as hemoptysis, significant secretions or oral lesions and oral bleedings.
To avoid cross contamination from transmissible respiratory or systemic infections and above listed physical health conditions, the following infection control measures must be observed and implemented by the user:

▲ Do not reuse disposable accessories marked with the symbol  to prevent cross infection.

▲ Only use a Permanent Breathing Tube together with bacterial filters approved by GANSHORN.

– The PFT bacterial filter are single use disposables.

▲ Adhere to cleaning and disinfection measures recommended by GANSHORN as described in chapter:

– 14 Cleaning and Disinfection

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1.9 Electrical

- Equipment must only be connected to a mains supply with protective earth to avoid the risk of electric shock.
- For safety and EMC compliance reasons, only use power cables provided by the GANSHORN or authorised representative.
- The PowerCube+ Series unit must be connected to an approved power source, as shown on the specification label.
- The power cable must not be damaged. Applied pressure, heat, and stress can damage the power cable.
- The power cable must be routed correctly to help prevent people from stepping on the cable or the cable being run over by, e.g. the trolley.
- Do not overload the mains outlet or extension cable. Electrical shocks or fires may occur from overloading.
- Do not touch the power source during a thunderstorm.
- If your hands are wet, do not touch the plug.
- Do not pull the power cord to remove it from the mains socket because this can damage the cable. Use your thumb and index finger to grip the plug itself.
- Operating the device without the correctly rated fuse or with defective cables constitutes a danger to life, therefore:
  - Do not operate the unit if the earth connection is suspect or if the mains lead, the power supply unit or the device is damaged or suspected of being damaged.
  - Damaged cable connections and connectors must be replaced immediately.
  - Electrical safety devices, such as fuses, must not be modified.
  - Fuses must only be replaced with the same type and rating as the original.

Electric Circuit, Wall Sockets

- All system devices must be connected to the same electric circuit and powered via an isolation transformer (galvanic isolation) to avoid leakage currents. Do not connect any part of the system directly to a wall socket.

Portable Multiple Outlets

- Do not place multiple portable outlets on the floor to prevent liquid penetration and to protect them from mechanical damage.
- Using the multiple sockets provided by the system is not permitted to connect devices not defined as parts of this system.

AC Adapter

- Use only the original AC adapter provided with the equipment.

Opto-isolator

- An opto-isolator cable assembly provides 4 kV electrical insulation between the PowerCube+ Series and the PC. Do not replace this cable.

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1.10 Pressurised Gas

Measurement Gas Tube

- ▲ Only use the original gas, pressure gauge, and tubing provided with the equipment. If replacement is required, only replace with original equipment supplied or approved by GANSHORN. Failure to do so may cause inaccurate measurements and endanger the patient.
- ▲ Regularly check the measurement gas tube, gas valve and pressure gauge for any signs of damage or modification. If any damage or modifications are noticeable, immediately notify an authorised GANSHORN distributor or the GANSHORN service team.
- ▲ The measurement gas tube must not have gas pressure over 8 bar:
  - The normal pressure range is 6 to 8 bar (He/CO - for diffusion tests)
  - The normal pressure range is 5 to 7 bar (O_2 - for nitrogen washout tests)
- ▲ Before using the gas, check that the mixture certificates are available so that the values of the gas components for calibration can be checked.

Handling of Pressure Gas Cylinders

- ▲ Improper handling of gas cylinders is a potential danger to human life and material objects. Pay attention to the warning notices.
- ▲ Secure the gas cylinders against falling over.
- ▲ Content and the current capacity level must be identifiable at all times.
- ▲ Seals, connections and cables must be free from oil and grease.
- ▲ The gas bottle must be checked regularly by an official testing centre.
- ▲ Close the main valve when the gas bottle is not being used.

1.11 Data Security

- ▲ If the computer is part of a network, e.g. a LAN, WLAN, HIS, transmitting over a telephone network or any other transmission/reception medium, or if it is exposed to the internet or other insecure networks, appropriate security measures must be provided to protect the patient data stored.
- ▲ Patient data security and security and network security are the user's sole responsibility.

Data Backup

- ▲ Check that adequate data backup facilities are in place and that backups are regularly performed to external storage media.

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1.12 Cybersecurity

- The LFX software is not password protected. Therefore it is essential that Windows® user management, including password protection, is activated to guard against unauthorised users gaining access to patient data and being unable to access, modify or damage data. GANSHORN or authorised GANSHORN partners configure/enable this during installation.
- Ensure that the minimum PC requirements are fulfilled so the system is used in its intended environment.
- It is recommended that the system is not connected to the internet. If the system is connected to the internet, check that adequate anti-malware software is installed and that this software is always up-to-date. Contact GANSHORN or authorised GANSHORN partners for information on approved anti-malware software. Contact information can be found on page 2.
- Contact GANSHORN or an authorised GANSHORN partner immediately in case of problems with IT security.

1.13 Implied Authorisation

Possession or purchase does not convey any express or implied license to use the device with replacement parts which would, alone or in combination with this device, fall within the scope of one or more patents relating to this device.

1.14 Additional Statement

FCC Rules

This equipment has been tested and found to comply with the limits for a class A digital device, pursuant to both Part 15 of the FCC (Federal Communications Commission) rules and the radio interference regulations of the Canadian Department of Communications. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with this instruction, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user must correct the interference at his own expense.

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1.15 Symbols and Pictograms

The following overview shows the safety symbols and pictograms used within this Instruction for Use on the unit and possibly found on accessories.

1.15.1 Symbols used in this instruction for use

⚠ DANGER Used to indicate direct danger, which could lead to severe personal injury or death.

⚠ WARNING Used to indicate possible dangerous situations which could lead to serious bodily injury or death.

⚠ CAUTION Used to indicate possible dangerous situations which could lead to personal injury.

Used for general safety notes.

Important or helpful user information or safety information.

Reference to other guidelines.

Attention: non-ionising electromagnetic radiation. Some devices contain an HF transmitter (GSM/Bluetooth).

The unit may radiate high-frequency electromagnetic energy and can disturb other devices if not installed and operated in accordance with the instruction for use. However, there is no guarantee that no interference can occur in certain installations. If the unit causes interferences, these can be determined by switching the device Off and On or transmitting/not transmitting data. The user can take the following measures to prevent electromagnetic interferences:

Increase the distance between the affected devices and the unit.

For more details (see para.18, Electromagnetic Disturbances, page 168).

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1.15.2 Symbols on the Device and Accessories

For general use symbols, see (see para.16, Appendix - Symbols and Pictograms, page 127)

Follow the instructions in the instruction for use and accompanying documentation.

Read the instruction for use or accompanying documents.

Attention: consult accompanying documents.

Type BF equipment, safe for external applications; not defibrillation-proof.

Potential equalization

IP20

PowerCube+ Series device classification. Splash-proof safety rating against dust and water ingression.

Indoor use only

Class of protection II.

Microphone Connector

Non-sterile

Do not use if the packaging is damaged

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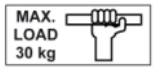
Use by (YYYY-MM-DD or YYYY-MM)

Disposable item, single-use, do not use twice.



Used to indicate the maximum load that can be applied to the grab rail (30 kg/65 lbs).

Maximum weight for the bench or seat (160 kg/325 lbs).

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Push point for securing the door.

This symbol indicates that electrical and electronic equipment waste must not be disposed of as unsorted municipal waste but must be collected separately. Contact your authorised GANSHORN partner for information concerning the disposal of your equipment.

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2 Introduction

The PowerCube+ Series is a lung function system that provides Spirometry parameters and is dependent on configuration, body plethysmography, and diffusion parameters. The PowerCube+ Series is based on flow measurement with an ultrasonic ScoutSensor mounted in the body cabin or on a diffusion arm.

2.1 Installation

Only GANSHORN or authorised GANSHORN partners are permitted to install the system.

⚠ WARNING

▲ If the medical equipment is modified, appropriate examinations and tests must be carried out to ensure patient and user safety.

2.2 Equipment Overview

The PowerCube+ Series configuration options are as follows:

PowerCube Body+ with Diffusion+	Spirometry, body plethysmography and Diffusion
PowerCube Body+	Spirometry and body plethysmography only
PowerCube Diffusion+	Spirometry and diffusion only

2.2.1 Options

- ROcc Shutter Resistance (option)
- PI/PE max and P0,1 (option)
- Bronchial challenge monitoring (option)
- Rhinomanometry (option)
- N_2 washout (option)

2.2.2 PowerCube Body+ (with Diffusion+)

The body cabin consists of an aluminium frame with safety glass panels. A handrail provides added safety when entering or leaving the cabin. The cabin door has an electromagnetic lock, i.e. locked/unlocked with the program. (For safety reasons, the door lock can also be released inside the cabin with an Open Door button).

The central control unit and the gas analyser are located below the baseplate of the cabin. An optional swivel chair (as shown) can be installed instead of the bench with a backrest.

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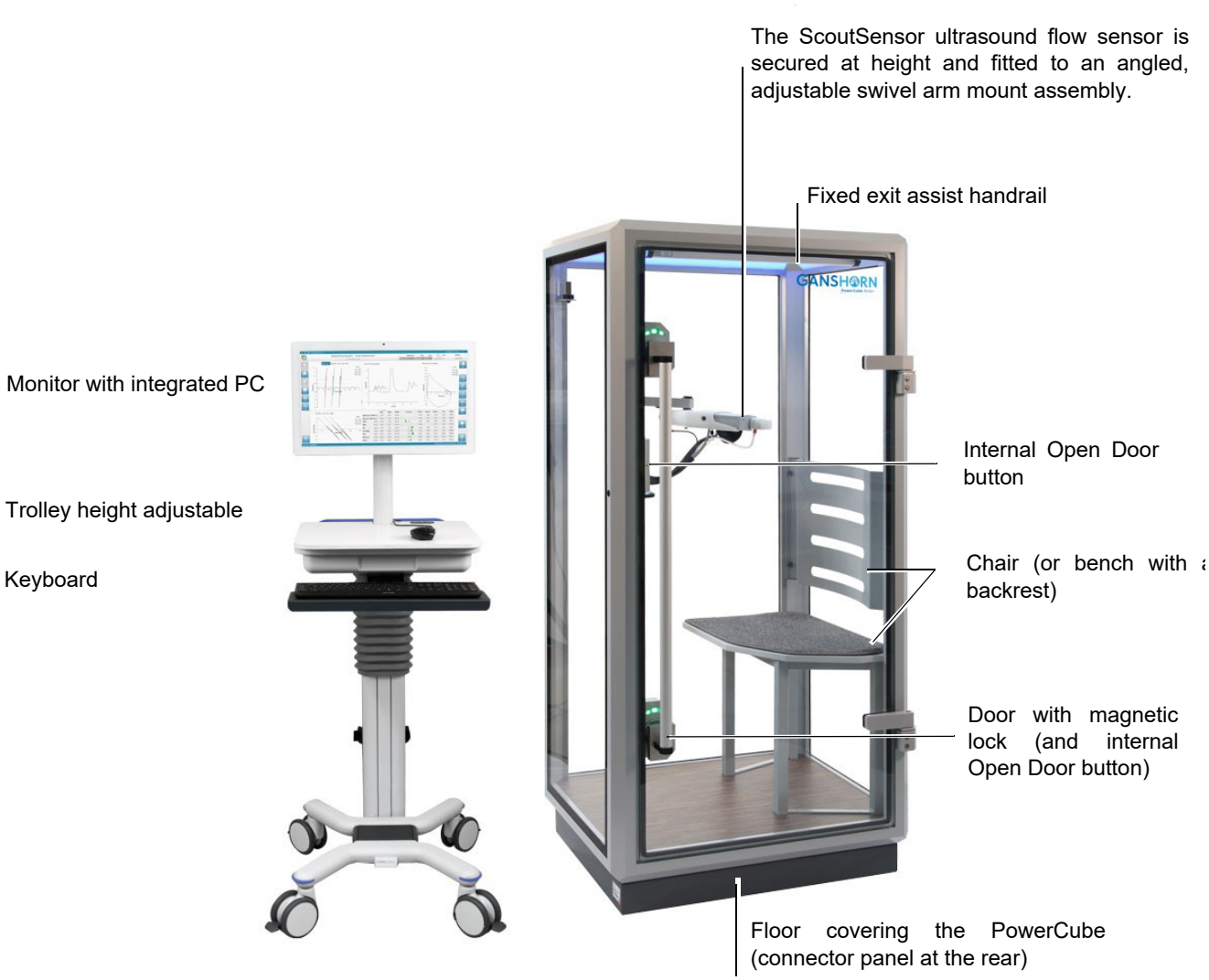

*The picture may differ from the original product and standard configuration

Note. When diffusion is included, the demand valve for gas inhalation and shutter unit is incorporated with the ScoutSensor.

Lighting Inside the Cabin (Option)

A remote control unit controls the lighting inside the cabin. The lighting can be switched on and off, and different colours can be selected.

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2.2.3 PowerCube Diffusion+

The shutter and ultrasonic transducer sensor unit are mounted on a swivel arm secured to the trolley.

The ultrasound flow sensor is secured at height and fitted to an angled, adjustable swivel arm assembly.
The assembly includes a demand valve for gas inhalation and an incorporated shutter unit.

Monitor with integrated PC

Trolley height adjustable

Keyboard

*The picture may differ from the original product and standard configuration

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2.3 Switching the System ON and OFF

Switching ON

➜ Press the **ON/OFF** button to switch ON the PC and all other System components.

Switching OFF

Important

LFX and MS-Windows® must be terminated before the system is switched off.

1. Close/check that the LFX program is closed.
2. Now shut down the PC via the Windows®, **Start > Power** icon.
3. After the PC has shut down, press the system master **ON/OFF** switch to the **OFF** position.

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2.4 Trolley

2.4.1 Adjust the Hight of the Trolley

➜ To adjust the hight, first pull the blue handle up, then use the large blue handle to lift the shelf up or down.

Height is adjustable between 885mm and 1150 mm.

2.4.2 Locking the Wheels of the Trolley

The unit wheels have spring-loaded braking mechanisms to lock the wheels and prevent the unit from moving during use. The unit wheels are locked by pressing the foot brake lever down until the wheel is locked. The lock is released by lifting the brake lever.

Wheel unlocked

Wheel locked

It is recommended that the wheels are always locked when the unit is stationary to prevent the unit from moving/rolling and causing possible injury.

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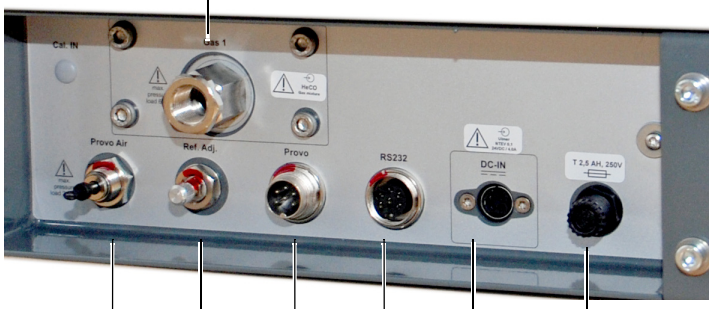
2.5 Connector Panel and Control Elements

2.5.1 Back Panel Connectors Outside the Body+ Cabin

The following connectors can be found in the base at the rear of the Body+ Cabin.



Gas inlet (He/CO gas) - connection for the gas cylinder used for diffusion and calibration

Fuse 2.5 AT

DC input from the AC adaptor

RS-232 - Opto-isolator, RS-232 connection for data transfer between PowerCube+ Series (located under cabin floor) and PC.

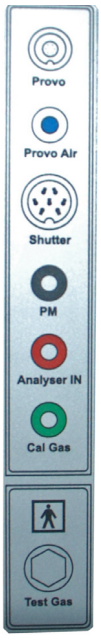
Provo - Connection for the provocation unit

Ref volume adjustment. For service engineers only!

Provo Air - Compressed air connection for the provocation unit (option)

2.5.2 Connectors and Control Buttons Inside the Body+ Cabin

The following connectors can be found inside the Body+ Cabin.



Provocation - connection for the provocation unit (option)

Provocation Air - compressed air connection for the provocation unit

Shutter - socket for the connection cable to the shutter magnets

Connection for mouth pressure measurement tube

Analyse IN (Diffusion+ option) connection for mixed breathing gas after exhalation

Calibration Gas (Diffusion+ option)

Test Gas (Diffusion+ option)

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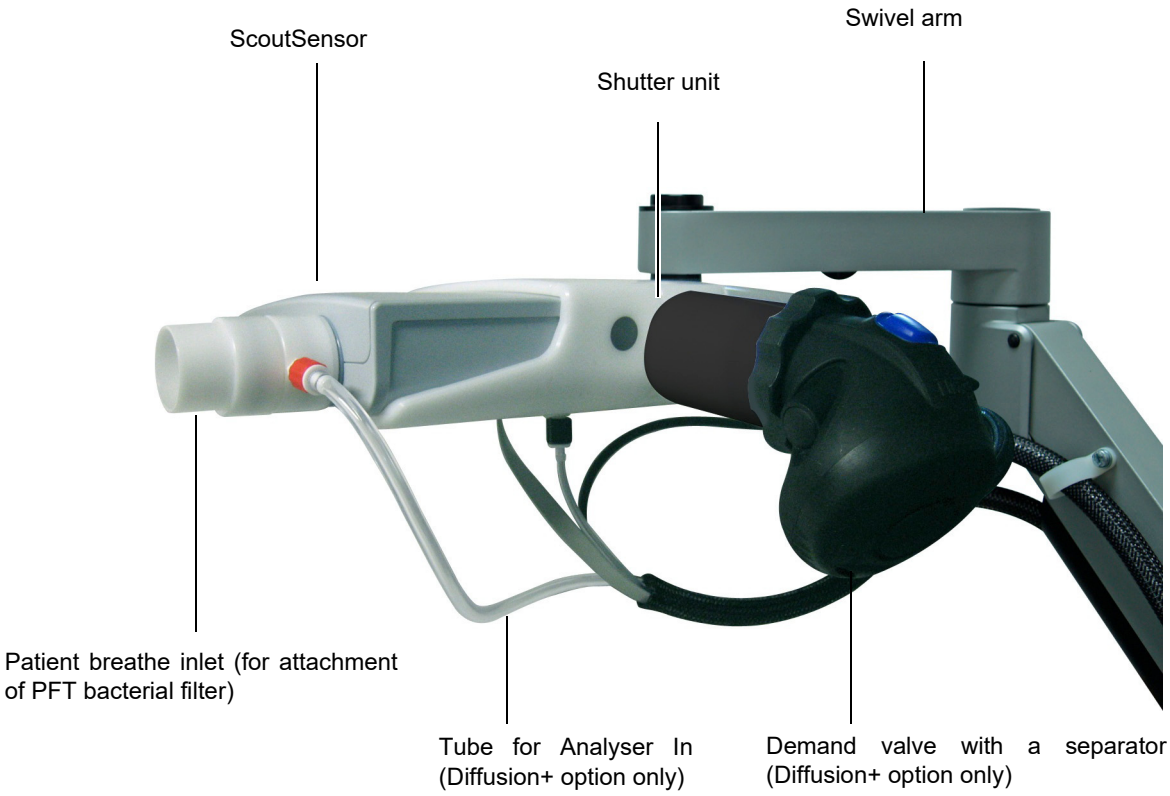
2.6 Swivel Arm and Shutter Unit

The swivel arm enables movement in all directions and positions, enabling the sensor to be positioned for different size patients and seating positions. It is designed so that it can be extended outside of the cabin when required.



*The picture may differ from the original product and standard configuration

⚠ CAUTION

▲ Always hold the ScoutSensor to move the swivel arm. Do not move the ScoutSensor by holding the swivel arm or arm joints; this will avoid pinching the fingers.

- When the PowerCube Diffusion+ is ordered alone without body plethysmography, the shutter and ultrasonic transducer sensor unit are mounted to the swivel arm and secured to the computer trolley.
- When a nitrogen washout is an option, an exhalation valve is added to the shutter unit.

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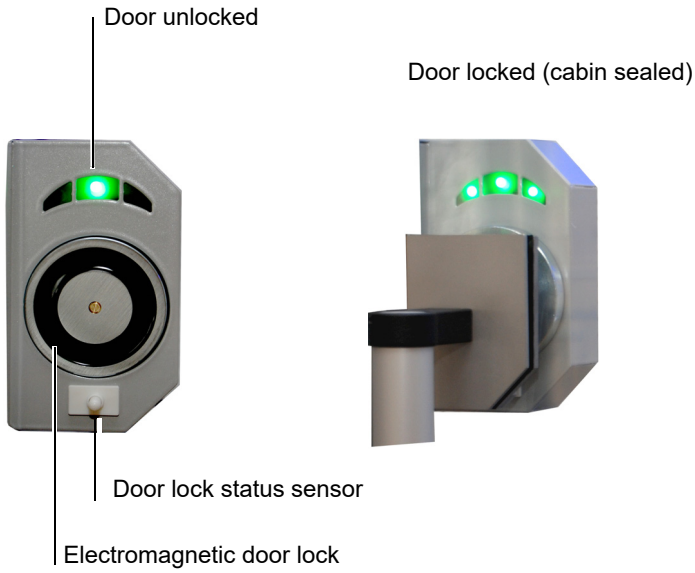
2.7 Door Mechanism

The door of the Body+ Cabin is closed by an electromagnetic system. The door lock can only be activated by the software when the body plethysmography program is activated, or calibration is being performed. A message, "**Please shut the cabin door"** is displayed on the screen when the door needs to be closed.



The door magnetic field is shielded, so there is no danger inside the cabin for patients with a pacemaker.

Three green LEDs indicate the status as follows:

LED	Meaning
No LEDs lit	The Body+ Cabin is switched OFF
Middle LED Lit	Door is unlocked
Right and left LED flashing	The magnet is active, but the door is not fully closed
All LEDs lit	The magnet is active, the door is closed, and the cabin is sealed.

Note that if attempting to close the door and the two side door indicators do not light, it may indicate that the open door button is activated inside the cabin (see the next page).

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2.7.1 Closing the door

To close the door take the door handle and firmly push it against the rubber door seal until you hear both door magnets close and all the LEDs light up continuously. If the door is not closed correctly, one or more LEDs flash.

- When closing the door, push the door evenly. Do push directly the upper or lower part of the door alone, as this causes the door to close unevenly.
- Never open the door by force or slam it shut, as this can damage the measuring system. Never swing the door fully open, straining the hinges: this can impair the door adjustment and may lead to leakage.
- When a body measurement is not taken, the door is adjusted, so it is always a little open. Never completely close the door, as this cuts off the necessary air circulation.

2.7.2 Opening the door

To open the door, only pull the door handle when the magnet is released. The release is activated in one of the following ways:

- Automatically when the measurement/calibration is completed.
- With the **Open Door** button inside the cabin.

To prevent the highly sensitive pressure transducers from being damaged, the door opens with a delay of approximately two seconds.

A malfunction or power failure opens the door automatically.

2.7.3 Opening the door from inside the cabin

The **Open Door** button deactivates the magnet and enables the patient to open the door inside the cabin.

Open Door indicator

The LED indicator is red when the **Open Door** button is pressed, and the open door is activated. When the red LED open door indicator is lit, it is impossible to activate the door magnets and secure the door closed. The side green LED door indicators are not lit (see the previous page).

Push the button again to enable the door lock mechanism. The door open indicator is extinguished, and the door can be locked.

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2.8 PFT Bacterial Filter

⚠ CAUTION

- ▲ Only use PFT bacterial filters approved by GANSHORN. Use of any other filters can cause incorrect measurements.
- ▲ **PFT Filters** are single-use:
  - – Do not use it for more than one patient.
  - – Do not attempt to clean.
  - – Dispose of after use.
- ▲ Before attaching a PFT filter, check that the PFT filter is undamaged and that there are no loose parts that the patient might inhale.
- ▲ To maintain hygiene:
  - – Wash hands (or use hand sanitiser) before fitting and after removing.
  - – When fitting, use the plastic packaging of the PFT Filter and paper tissues or wear protective gloves to prevent direct contact.
  - – When removing the PFT Filter after use, use disposable protective gloves. Dispose of the protective gloves after use.

The bacterial filter is a one-time-use bacteria filter designed to help minimise the danger of contamination and the risk of cross-infection when performing pulmonary function tests. It fits over the sensor adaptor to form an airtight seal.

The PFT bacterial filter can only be positioned in one direction. Attach the round end over the sensor adaptor as shown. The filter is tapered, so no force is needed to connect the filter to the sensor. Do not over-tighten.

At the End of the Test

- ▲ Observe all cross-contamination procedures when disposing of the PFT filter. Wear protective gloves, and do not let waste come into contact with any person.
- ▲ Wipe/clean the sensor with an approved cleaning solution or disinfectant (see para.14, Cleaning and Disinfection, page 148).

2.9 Cleaning and Disinfection

The ScoutSensor and surrounding areas can be wiped with a damp cloth to clean. Standard hospital disinfectant can be used to disinfect. The ultrasound sensor must be disinfected every week.

Cleaning procedures, approved cleaning materials, and disinfectants are detailed in the maintenance section (see para.14, Cleaning and Disinfection, page 148).

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3 Measurements Overview

3.1 Spirometry

3.1.1 Overview

The unit measures the patient's respiratory flow with the ScoutSensor and calculates volumes and flow speed. The ScoutSensor measures the airflow inside the mouthpiece using ultrasound measuring technology.

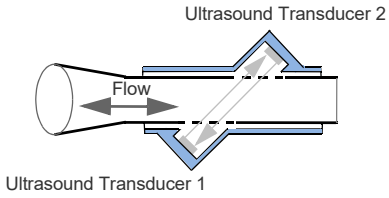
The PowerCube+ Series can perform the following measurements:

- Force Vital Capacity (FVC)
- Slow Vital Capacity (SVC)
- Maximum Voluntary Ventilation (MVV)

Several American and International authors can be selected for predicted value calculation and interpretation. Pre- and post-measurements can be taken for comparison.

3.1.2 Measurement Principle

Ultrasound Technology



The ScoutSensor measures flow based on ultrasound technology. Two diagonally opposed ultrasound transducers (piezo-elements) send and receive ultrasonic waves alternately. The difference in the sound transmission transit times between these two sensors is used to calculate flow direction, speed, and volume.

Without any air flow, the transit time of the ultrasound waves is the same in both directions, and no flow is registered. Any air flow inside the insert accelerates the waves in one direction and slows them down in the other, and the higher the difference between the transit times of the ultrasonic waves, the higher the air flow.

All other factors (gas properties, humidity and temperature) are the same for both directions and cancel each other out.

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3.2 Body Plethysmography

Body plethysmography determines the Thoracic Gas Volume (TGV) and specific airway resistance (sRaw) as primary measures. In combination with Spirometry, Total Lung Capacity (TLC) and Residual Volume (RV) can be determined.

Airway resistance (Raw) is calculated as the ratio of sRaw to TGV.

- Raw: sRaw/TGV

For determining sRAW and/or TGV, the movement of the chest, measured as a volume change in the closed box, is monitored against the flow for sRaw, and alveolar pressure (Palv.) for TGV.

- sRaw is calculated as a ratio of flow and delta volume box.
- TGV is calculated as a ratio of delta volume box and alveolar pressure (Palv).
  - TGV = d volume box/d alveolar pressure.

The volume change and thoracic volume shift during inspiration and expiration is the base for:

- Specific airway resistance [sRaw in kPa * sec]
- Thoracic gas volume [TGV in l]

The volume change is measured with a volume sensor inside the Body-Box. The Body-Box has a size of approximately 940 Litres. Typically, patients generate a chest-related volume change in the range of 50 ml.

In addition, a pressure sensor measures the alveolar pressure for TGV detection. To measure alveolar pressure at the mouth, you must occlude the breath for a short time, and a shutter occludes at the end of a breath inhalation. During the occlusion time, the pressure and volume shift for TGV calculation is recorded.

Boyles Law is used to calculate the volume within the lungs. The initial pressure of the cabin and its volume is compared to the pressure after expansion to calculate the volume, i.e. equivalent to the volume in the chest.

Combining the specific body plethysmography data (sRaw and TGV) with the Spirometry data, body plethysmography can calculate all relevant lung parameters such as:

- Residual volume [RV in l]
- Total lung capacity [TLC in l]

3.2.1 Taking a Body Plethysmography Recording

(see para.6.8, Maximum Voluntary Ventilation MVV, page 86).

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3.3 Single Breath Diffusion

Single breath diffusion is a non-invasive method to determine the following:

- Diffusion capacity [DLCO in mmol/min/kPa]
- Alveolar volume [VA in l]
- Total lung capacity, He [TLC He in l]

The subject inhales a mixed gas consisting of 18% He and 0.25% CO (the rest of the gas mixture contains typical air percentages of oxygen (19%) and nitrogen). The breath is held for 10 seconds. During the breath-hold time, He dilutes into the lung (for VA detection) while CO diffuses through the alveoli into the blood. After 10 seconds of breath-hold time, the subject exhales, and the exhaled gas is measured and analyzed. The diffusion capacity (DLCO) and the lung volumes (TLC, RV) are calculated based on the fraction of CO and He.

Single-breath diffusion determines the alveolar gas volume (VA) and the diffusion capacity (DLCO) as primary measures. Combined with the Spirometry measurements, total lung capacity (TLC) and residual volume (RV) can be determined.

3.3.1 Taking a Diffusion Recording

(see para.8, Single Breath Diffusion, page 97).

3.4 Options

3.4.1 ROcc

The measurement of airway resistance by the interrupter technique (ROcc) is an important determinant for assessing the respiratory system and is helpful in patients with acute asthma, geriatric patients, neonates, and preschool children because the required patient cooperation is less than in other methods.

The interrupter technique is based on the principle that the alveolar pressure (Pa) is closely linked to the pressure at the mouth (Pm) during a transient airflow interruption. Airway resistance (kPa/l/s) is thus the ratio between the pressure at the mouth (identical to the alveolar one) and the flow value before the interruption. This technique has been proven to be highly reproducible.

The patient breathes through a mouthpiece while an occlusion valve interrupts the airflow momentarily. The occlusion is virtually unnoticeable to the patient but long enough to allow the instantaneous measurement of the pressure at the mouth and back to extrapolate the alveolar pressure. Thus the airway resistance can be calculated.

3.4.2 Taking a ROcc Recording

(see para.10, ROcc, page 109).

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3.4.3 P0.1/Pmax

P0.1 and Pmax are parameters for investigating respiratory muscle strength. The examination ascertains the alveolar pressure which builds up through the activities of the respiratory muscles and allows conclusions to be drawn about the respiratory reserve of the respiratory muscles (respiratory pump).

3.4.4 Taking a P0.1/Pmax Recording

(see para.9, P0.1/Pmax, page 106)

3.4.5 Nitrogen Washout

The nitrogen washout measurement is used to determine the functional residual capacity of the lungs and the degree of heterogeneity of gas distribution in the lungs.

A patient takes a breath of 100% oxygen and exhales through a one-way valve measuring nitrogen content and volume. The patient performs an SVC manoeuvre. Then pure oxygen is inhaled, and the patient is asked to tidal breath as normally as possible over a few minutes. Nitrogen concentration is measured for each exhalation. Since nitrogen is not exchanged in the lungs, it sits there until exhalation. This is shown if the breath is too shallow due to respiratory inflammation. The washout manoeuvre can last between approximately three and more than 10 minutes; in healthy subjects, the time will be on the lower scale, and obstructive lung disease is indicated by a higher duration.

3.4.6 Taking a Nitrogen Washout Recording

(see para.11, Nitrogen Washout, page 111)

3.4.7 Rhinomanometry

Rhinomanometry is a form of manometry used to help evaluate the nasal cavity and the respiratory function of the nose. It measures pressure and flows during regular inspiration and expiration through the nose. Increased pressure during respiration results from increased resistance to airflow through nasal passages, while the increased flow is related to better patency. Nasal obstruction leads to increased values of nasal resistance.

3.4.8 Taking a Rhinomanometry Recording

(see para.12, Rhinomanometry, page 119)

3.4.9 Bronchial Provocation

Bronchial Provocation/Challenge tests have phased airway irritants to monitor the effects on respiratory function using a pulmonary function test at each provocation level and by comparison of the results with those of the previous level.

Details of the provocation option are given in the instructions for use for Provocation Pulmonary Function Testing.

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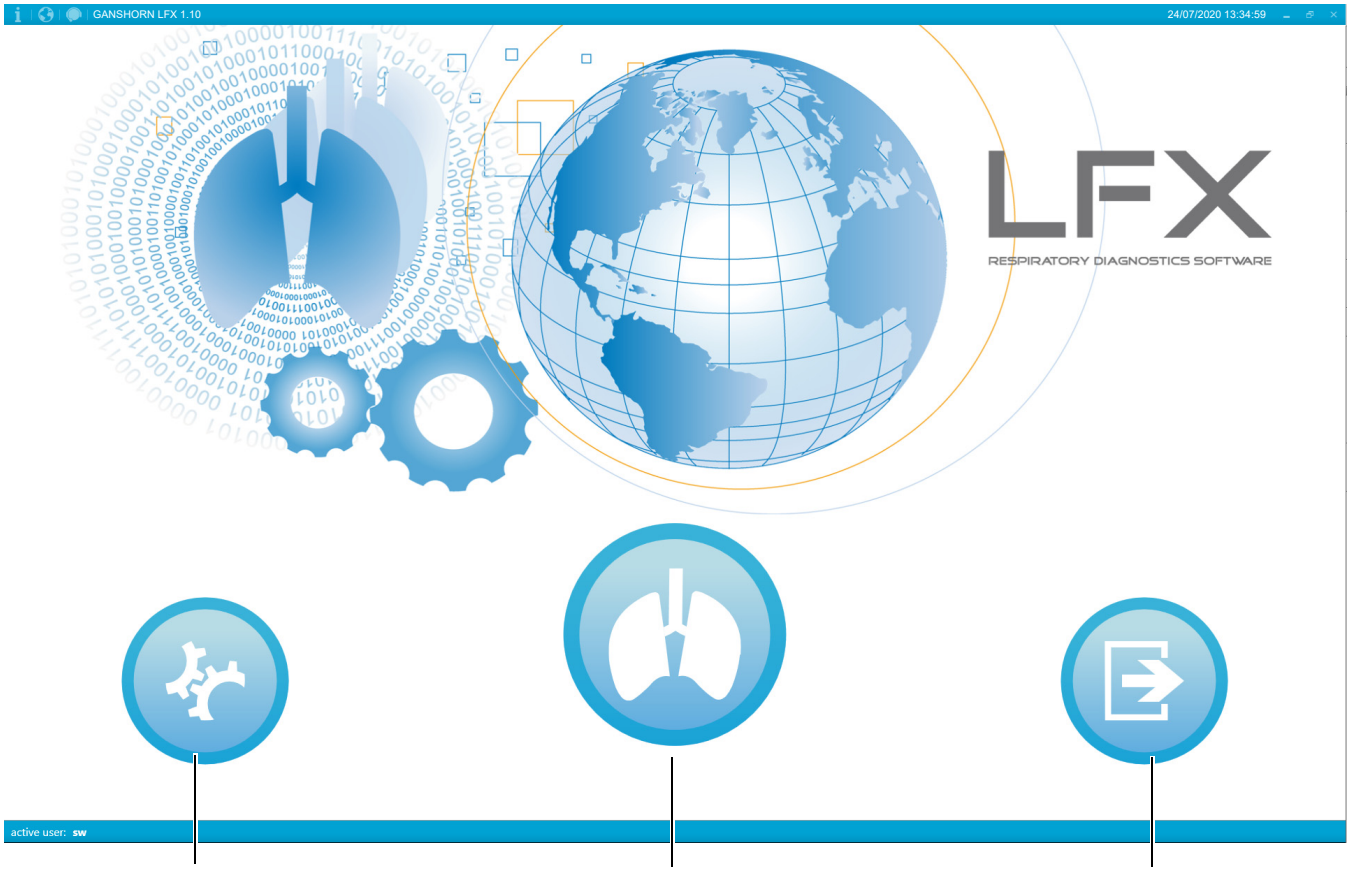
4 Program Overview

4.1 LFX Initial Screen

Start the LFX program from the Windows desktop by double-clicking on the **LFX** icon.

– The LFX start-up screen appears as shown below.

The initial screen is displayed after switching on and is the main screen from which all other settings, options and data screens are entered.



Enter Settings (see para.13, Settings Overview, page 129)

Select patient/define new patient/enter calibration and measurement screens

Exit Program

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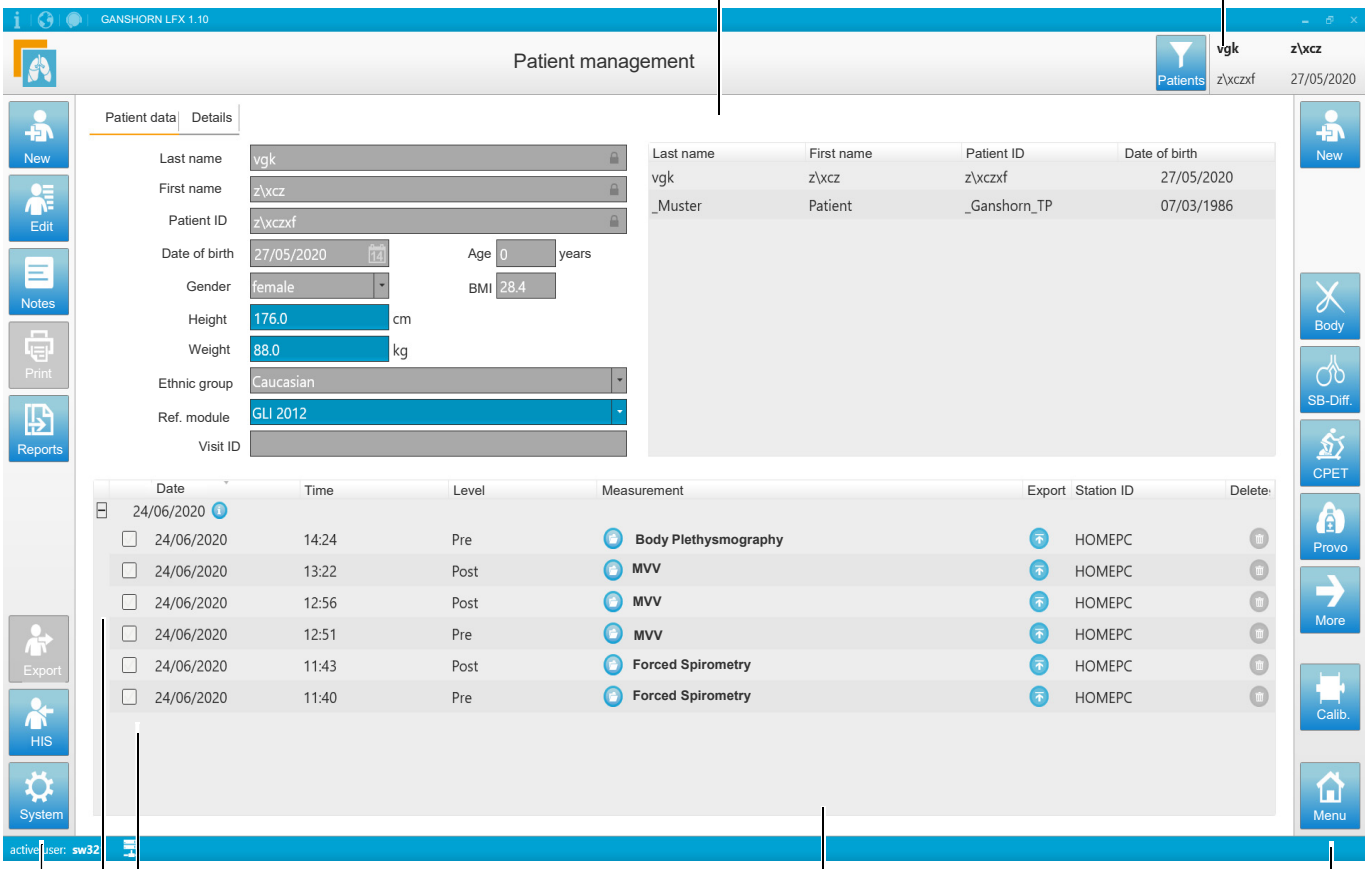
4.2 The Work/Patient Screen

Click the **Work** button. The first screen displayed is Patient management and function selection.

List of last 20 patients or list of patients found with search criteria. Click on a patient field to select.

Currently selected patient



Check recording(s) for report (print or PDF)

Hide/show recording detail

Recordings of the selected patient

Icons to:

- Edit existing/create a new patient.
- Enter notes (for specific recording and/or patient). Three note categories are available, general information, interpretation and technician notes. The general information is entered for the patient, and the interpretation and technician notes are for a specific recording and can only be entered when a recording is selected.
- Print (recording) - to the default printer.
- Generate report - select data and then print or PDF export.
- Import/Export - (see para. 4.7 Exporting/Importing, page 45)
- Enter system settings. The settings displayed depend on the screen; displayed on the patient screen, the network settings are given, and in a view or acquisition screen, the measurements for display can be defined (see para.13, Settings Overview, page 129).

Icons to:

- Create new patients (and search and select existing patients).
- Enter recording screens (see para.6, Recording Measurements, page 67).
- Validate/Calibrate the system (see para.4.9, Offline Parameters, page 47).
- Return to the initial screen.

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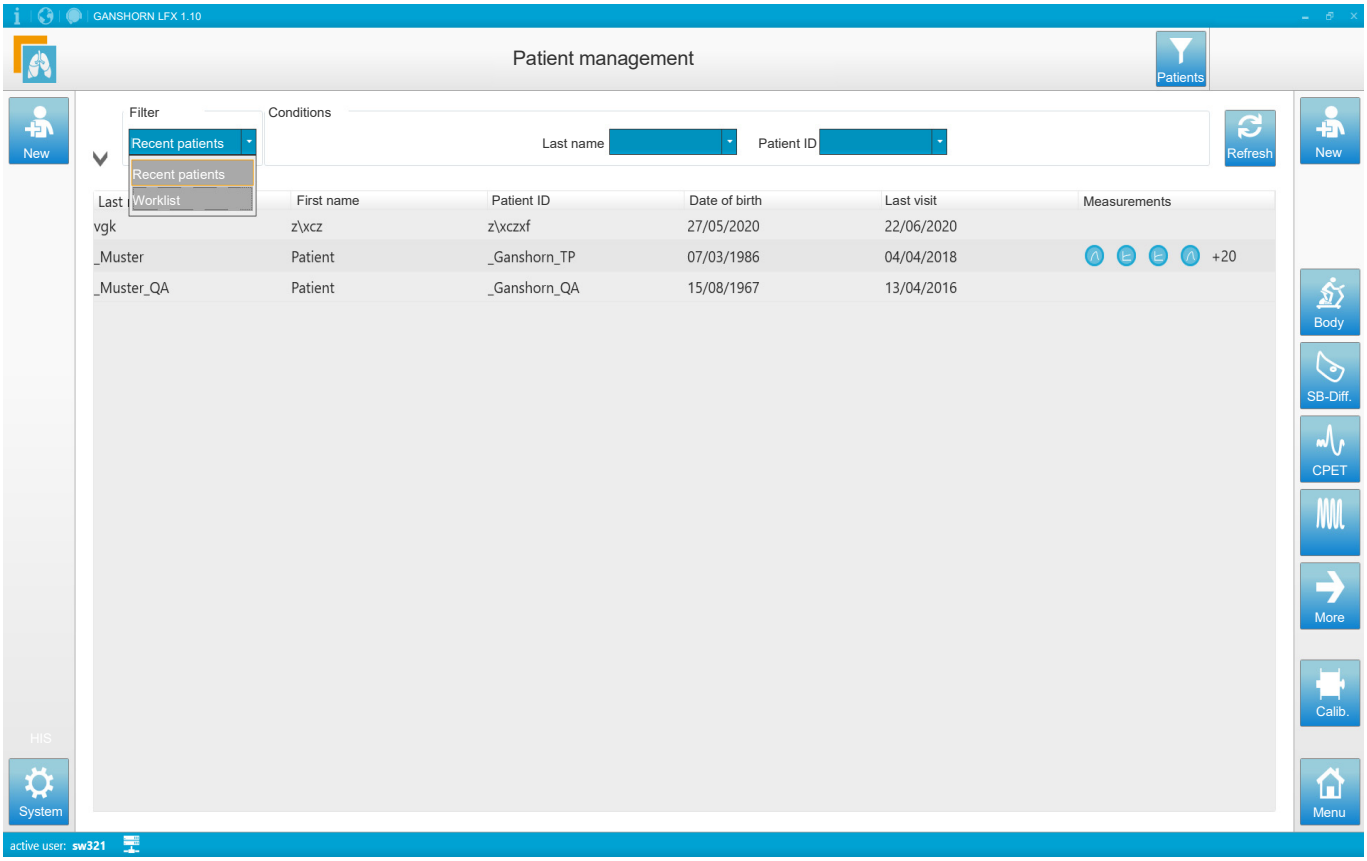
4.2.1 Patient and Worklist Search

Enter the patient's name (or part name) and/or patient ID. Patient data that match the entered characters are displayed as the characters are entered and refined as more characters are entered. When the searched patient is displayed, click the patient to select that patient. Any patient recordings are listed below the patient details, showing the type of recording and date.



4.2.2 Entering New Patient Data

Text boxes marked with an asterisk '*' cannot be left empty.

Last name and First name — Enter the patient's name; lower-case and upper-case letters are allowed.

Patient ID — The patient ID is unique and can consist of digits, letters and special characters.

Date of birth — Enter the date of birth (date format can be defined in settings (see para.13, Settings Overview, page 129).

Gender — Select the gender of the patient using the arrow keys. The default gender is male.

Height — Enter the height of the patient in cm or inches.

Weight — Enter the weight of the patient in kg or lbs.

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Age and BMI

The age and BMI are calculated for the entered data. The BMI definition and formula are detailed later in this section (see para.4.2.4, Patient Calculated Values, page 41)

Ethnic group

Select the ethnic group of the patient:

- Caucasian
- Asian
- African American / African
- Latin American
- American Indian / Alaska Native
- South East Asian / Pacifc Islander
- Oriental
- Other

Ref. module

The following reference modules are available and pre-installed:

- GLI2017 & ECCS93
  - Combination of GLI2017, ECCS93 and GLI2012
- ECCS93
- ECCS93_GLI
- ATS94

The following reference modules are optional can be installed by the user:

- Chhabra 2014
  - Combination of Chhabra and ECCS93
- ECCS93 GLI Clausen
  - Combination of GLI2017, ECCS93, GLI2012 and Clausen (Pmax)
- Faisal ECCS
- Finnish (containing Viljanen, Koillinen & Kainu)
- Forche
- Forche ECCS93
- Gutíerrez
  - Combination of author Gutíerrez and ATS94 module.
- Hedenstrom / Solymar
- Kristufek
- NHANES III
- Perez Padilla
- Roca
- Roca ECCS93
  - Combination of Roca and ECCS93
- SEPAR
  - Combination of authors Casan, Garcia-Rio, Roca and ECCS93 module.
- Thai 2000
  - Combination of Thai 2000 and ECCS93

- The norms detailed here are examples only; other norms are available on request - (see para.13.13, Reference Modules, page 140).
- The default norm selected when the program is opened is defined as the last norm value.

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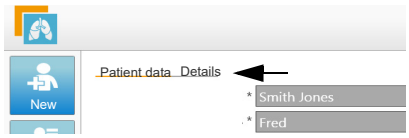
Further Patient Data Parameters



When **Patient Data Details** (top left) is clicked, further options are given. Note that these entries are not required for predicted values.

Arm Span

This option enables you to enter the arm span to estimate the patient's height when the patient's height cannot be determined, e.g. in a wheelchair. The arm span is measured by measuring the maximum distance between the tips of the middle fingers when the arms are fully outstretched. Enabling this option displays a text box where the arm span can be entered.

Middle name, Maiden name, Order ID, Insurance, Physician, Technician, Ward

Enter as required.

Smoker, History, Diagnosis

Enter as required.

Note for the pack years, when calculate is selected, a dialogue is entered where the user can enter cigarettes/day and number of years smoked for the program to calculate the pack years. The definition of pack years is given later in this section.

BSA, Ideal weight, Rel. weight and LBW

These are calculated for the data entered (see para.4.2.4, Patient Calculated Values, page 41).

4.2.3 Saving New Patient Data

The patient is automatically saved when the patient screen is exited, e.g. by entering the measurement screen or settings screen.

The basic information (Last name, First name, ID and Date of birth) is shown in the screen's current patient window in the upper right-hand area.

4.2.4 Patient Calculated Values

The following formulas used for calculation:

Calculated value	Explanation	Formula
BSA	Body surface area in m^2 according to Mosteller	• Formula for male and female: • BSA = ((height (cm) x weight (kg)) / 3600
BMI	Body Mass Index in kg/m^2 according to Adolphe Quetelet:	• Formula for male and female: • BMI = weight (kg) / height^2 (m)
Ideal weight	Ideal weight in kg according to Dr BJ Devine	• Male: Ideal weight = 50 + 2.3 kg per inch over 5 feet • Female: Ideal weight = 45.5 + 2.3 kg per inch over 5 feet
Rel. weight	Relative weight in %	• Formula for male and female: • Rel. weight = weight (kg) / (height (cm) - 100) * 100

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LBW	Lean Body Weight in kg according to James[a]	• Formula for male: LBW = (1.10 x weight (kg)) - 128 x (weight^2 / (100 x height (m))^2) • Formula for female: LBW = (1.07 x weight (kg)) - 148 x (weight^2 / (100 x height (m))^2)
Patient height from arm span	Formulas used to estimate the patient's height	• Age < 18 years (Hibbert, Torres): Height (cm) = arm span (cm) • Age > 18 years (Parker et al.): Height = 67.90+0.664182 * Arm span–2.816 * Gender–4.05 * Race–0.0709 * Age – where: Sex 1 = male, 2 = female, and Race 1 = white, 2 = black, height and arm span in cm, and age in years
Pack years (smoking)	Formula used for calculating the Pack years is as follows	• Pack years = $\frac{\text{Cigarettes per day}}{\text{Cigarettes per pack}}$ x Years smoked

a. James WPT. Research on obesity, London. Her Majesty's Stationery Office, Formula for a male.

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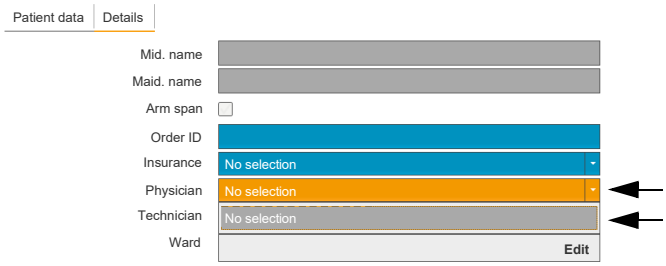
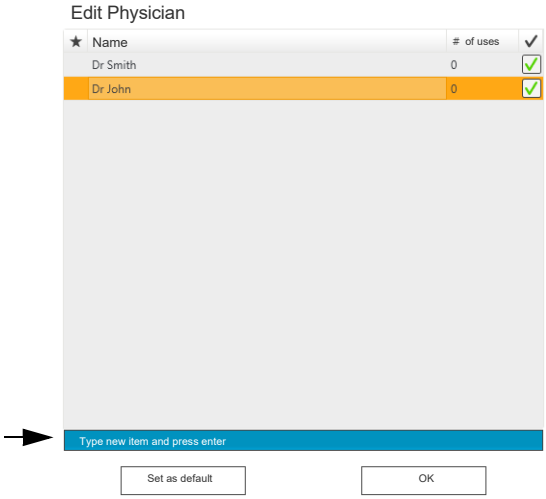
4.3 Editing User-Defined Drop-Down Lists

Some drop-down menus can be defined by the user. The procedure to edit a drop-down menu is the same for all drop-down menus that can be edited. The following procedure is an example of how to edit the physician menu.

1. Click the arrow in the Physician drop-down list.
   – A list of physicians already defined is shown.



2. Click **Edit** to open the window for editing the physician drop-down list. In this window, you can add, modify, show/hide and predefine the list of entries.



Add a new entry by positioning the cursor in the bottom line, entering the physician's name and pressing the **ENTER key** on the keyboard.

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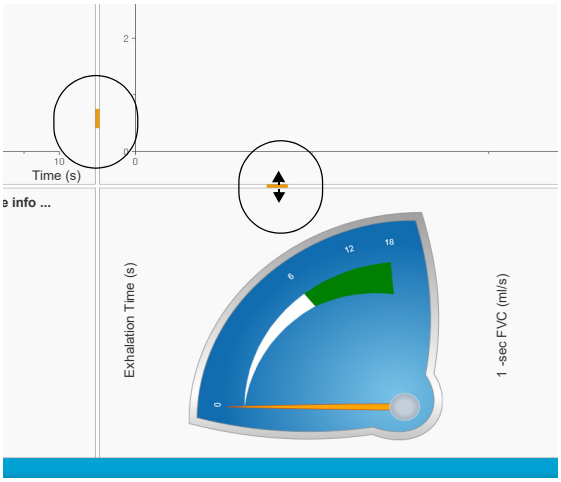
4.4 Changing the Size of the Graphs

In some measurement and view screens, the graphic size can be changed. In screens where this is possible, a marker is shown on the side of the graph. When the cursor is positioned on this marker, the cursor changes to a double arrow. Click and move the border as required.



4.5 Notes

In the notes screen, you can enter any general notes that may have influenced the recording or how a recording was performed. Enter any influences that may have affected a recording, e.g. cooperation, quality or interpretation or any general notes or findings associated with the recording or patient. Click the **Notes** button to open a window where the text (pictures or tables) can be entered.

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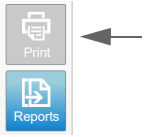
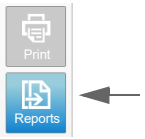
4.6 Printing or Generating a Report

4.6.1 Printing a Recording

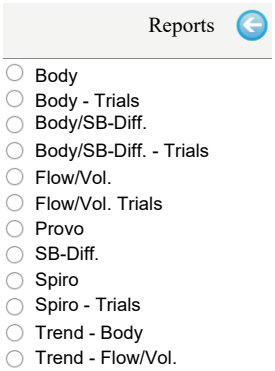


To print a recording from the patient screen, select recording(s) (see para.4.2, The Work/Patient Screen, page 38) and click the **Print** button.

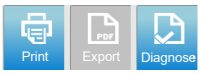
4.6.2 Generating a Report/Printing Specific Data



1. To generate a report/PDF file or other file formats for a recording from the patient screen, select recording(s) and click the **Reports** button.
   – A number of predefined reports are shown. Depending on the software configuration, additional programs are displayed on the screen.



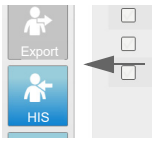
2. Select the data to be printed.
3. At the bottom of the data selection are icons to **Print, Export (PDF), or Diagnose.**



4. Select as required.
   – You can save and print the PDF and additionally save it as RTF.

4.7 Exporting/Importing

4.7.1 Exporting a Recording



To export a recording from the patient screen, select the recording(s) and click the **Export** button. The file is generated in the location specified in GDT settings.

4.7.2 Importing Patient Data

1. Define the GDT settings and the location where GDT has deposited the files.
2. Click the **HIS** button.

In the GDT settings, an option is available to import automatically. When selected, the import folder is regularly integrated, and new data is imported when available.

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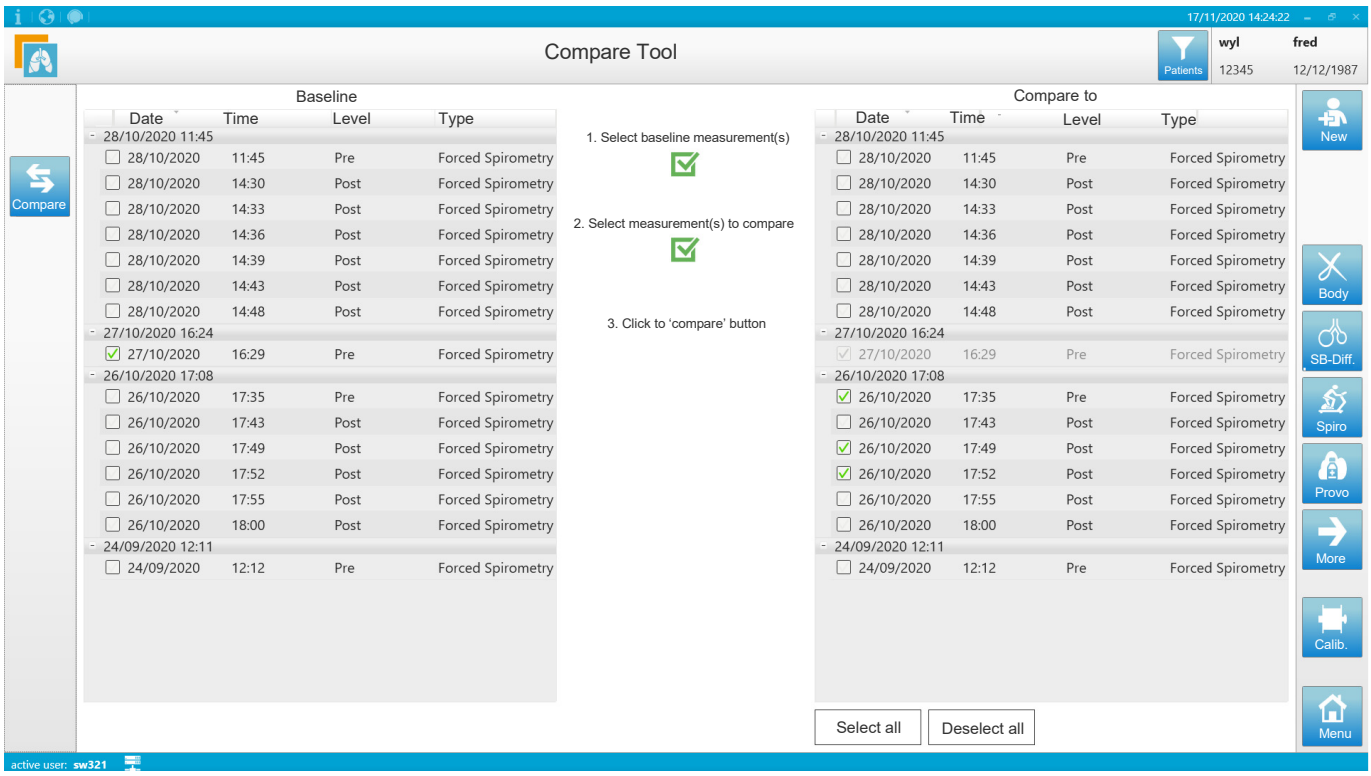
4.8 Comparing Recordings

Recordings of the same type and from the same patient can be compared. To compare recordings proceed as follows:

1. Select the patient.
2. In the right side panel, select the **Compare** button 

3. Select the recordings to compare, then select the **Compare** button on the left of the screen.



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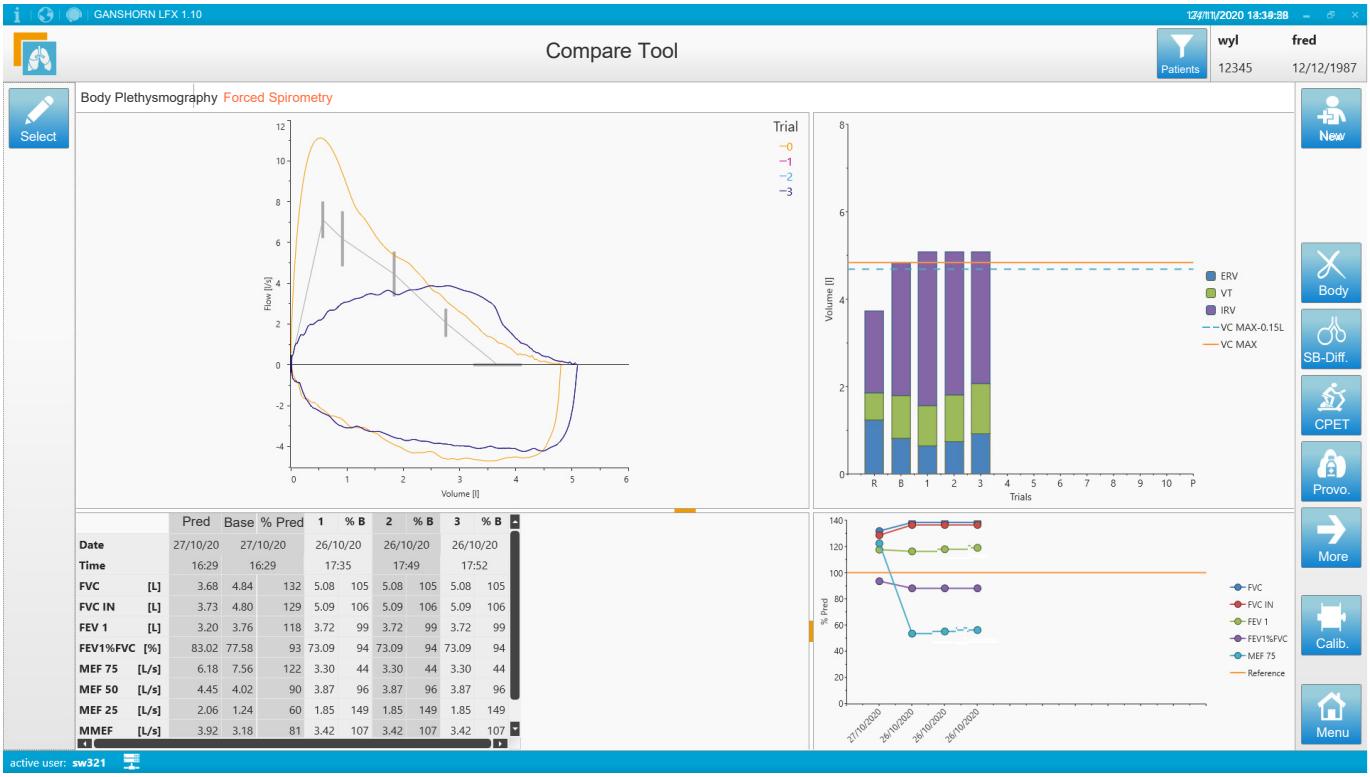
4. An overview of the recordings is given for comparison.

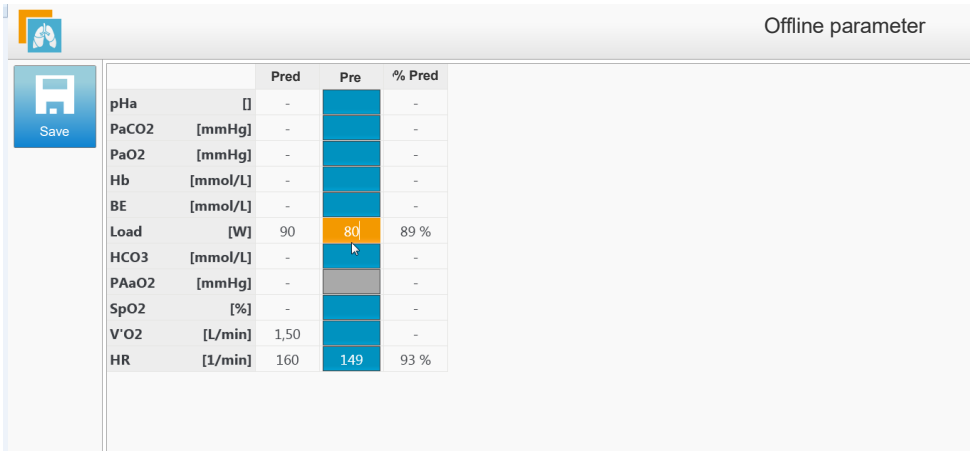


4.9 Offline Parameters

When a recording is displayed, the Offline parameters view provides a means of entering other parameters not measured by the program and storing them with the recording.

To enter the offline view, click the **Offline** button 

. The offline parameter screen is displayed:



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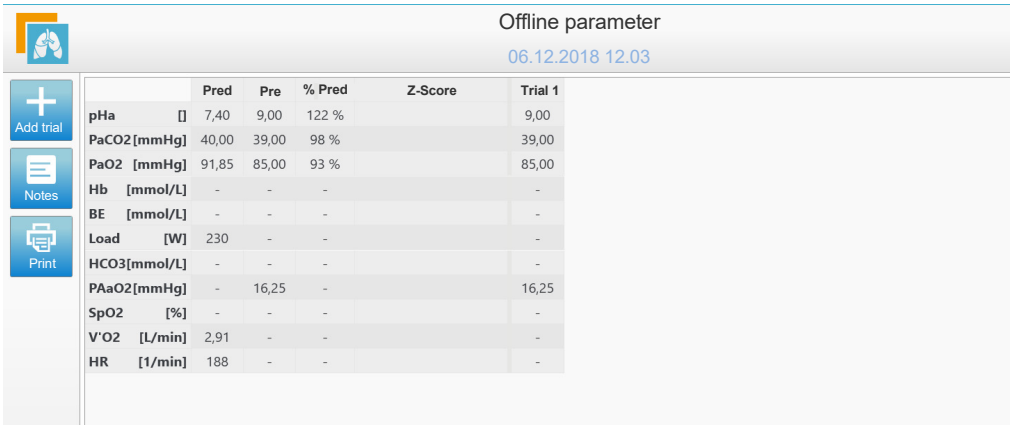
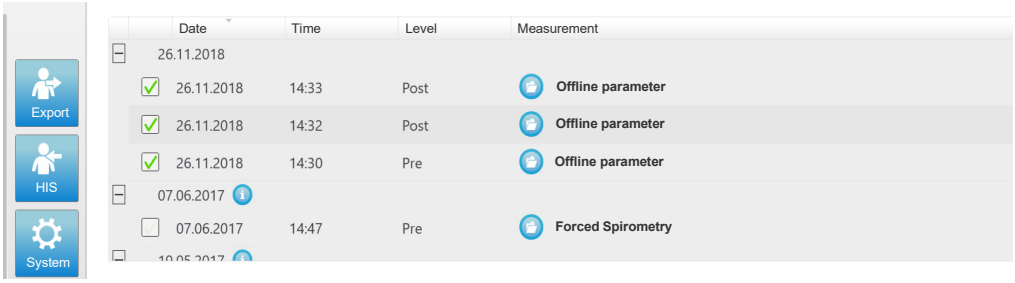
Enter the values of given parameters as required. If a predicted value has been given for a parameter, the percentage of prediction is calculated when an actual value is entered.

When saved, the recorded details are shown:



The offline parameters are referenced in the patient screen with the date they were entered (not the recording date).



The offline parameters displayed for data entry are defined in system settings (see para.13.11, Offline Parameters, page 138).

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5 Calibration

System calibration is required at regular intervals and is a prerequisite for precise measurement results. Different calibration intervals are necessary for the various components; some are automatic and controlled by the system, and some must be carried by the user. The calibration intervals are as follows:

5.1 Calibration Intervals

	Spiro	Body Plethysmography	Diffusion	ROcc	Rhinmanometry	Nitrogen Washout
Zero point[a]	Automatic	Automatic	Automatic	Automatic	Automatic	Automatic
Volume[b]	Not required (or according to local regulation or recommendation)	Not required (or according to local regulation or recommendation)	Not required (or according to local regulation or recommendation)	Not required (or according to local regulation or recommendation)	Not required (or according to local regulation or recommendation)	Not required (or according to local regulation or recommendation)
BodyLiveCal [c]	-	Weekly calibration	-	-	-	-
Gas	-	-	At the beginning of every day	-	-	At the beginning of every day
Ambient Conditions[d]	Annually (control)	Annually (control)	Annually (control)	Annually (control)	Annually (control)	Annually (control)

a. Zero point calibration is automatic and performed on start-up and then every 15 minutes when the program is open.
b. The ultrasound sensor technology and the in-built ambient sensors mean that the volume calibration is unnecessary. Calibration can be performed if required.
c. A combined calibration of mouth pressure and cabin pressure.
d. The system maintenance procedures and maintenance intervals are detailed in the maintenance section.

In addition to the specified or recommended intervals detailed above, Volume, BodyLiveCal, and Gas calibration can be performed at any time.

Article numbers for gas, calibration pump, and adaptors, e.g. are required to perform the calibration procedures as detailed in the accessories (see para.16, Accessories, page 160).

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5.2 Zero Point

5.2.1 Zero Point

Zero point calibration is performed automatically on switch-on and then every fifteen minutes. During zeroing, the zero point for the flow baseline for Spirometry is checked and set. During zeroing, please observe the following points:

- Do not move the sensor.
- Do not breathe into the sensor.
- Prevent drafts, i.e. keep all windows and doors closed in the room, and do not move any parts of the device.

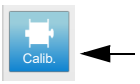
5.3 Ambient Parameters

The unit has sensors to measure ambient conditions, which are used by the program when taking a measurement. The accuracy of the sensors is checked during the control maintenance, and during normal use, it needs not be checked. Similarly, the height above sea level is set on installation. However, the height above sea level must be reset if the unit is moved.

The relative humidity must also be entered, but it does not affect volume measurement values (because the ultrasound measurement principle effectively cancels the effect of humidity) but does affect calculated correction factors; STPD and BTPS. Correction factors are calculated using the values measured directly by the system, temperature [°C] and ambient pressure [hPa], and the manually entered values, relative humidity [%] and altitude above sea level [m].

5.3.1 Checking/Verifying Ambient Conditions

- Calibration equipment is subject to verification regularly; check that the validation for all calibration equipment is in date. Failure to do so can result in inaccurate measurements.
- When values are entered, this sets the ambient values to this level and works as an offset for the ambient sensors. Therefore, the ambient parameters are entered accurately, and the reference values are taken from a calibrated measuring device.



1. From the Patient screen, click the **Calib** button.
2. The calibration settings are displayed on the right of the screen.
3. Click on **Ambient** to enter the ambient calibration screen.
4. Enter the values and confirm.

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5.4 Volume

- Because of the stable ultrasound technology, the ScoutSensor requires no volume calibration, even if used frequently. For confidence in the system, the volume can be calibrated/verified as required and described here.
- The American Thoracic Society (ATS) and European Respiratory Society (ERS) recommend that verification checks are completed regularly as follows:
  - At the beginning of every day
  - If there is any significant change in temperature, pressure, humidity
  - If the unit is moved to a different location (especially a different altitude)
- To perform a calibration check, you need a calibration syringe and a silicon adapter (for an airtight seal to the syringe), available from GANSHORN.

▲ Only use the original calibration syringe and silicon adaptor supplied or approved by GANSHORN. Calibration syringes are subject to verification regularly. Check that the syringe verification is in date. Failure to do so can result in inaccurate measurements.

Volume calibration is performed with a calibration syringe connected to the sensor and discharged/charged at a steady rate with a flow range between 0.5 and 12 L/s. The user is informed when sufficient discharge/charge cycles are made. A message is provided as to the success or state of the calibration.

The volumes measured should meet the accuracy requirement of ± 3.5% (including 0.5% accuracy of the syringe).

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5.4.1 Procedure

Attach a new filter to the (see para.2.8, PFT Bacterial Filter, page 32).

1. Connect the calibration syringe to the filter with a silicone adapter (019600835).
   – Check for good contact and that there are no leakages.

2. From the Patient screen, click the **Calib** button**.**
3. The calibration settings are displayed on the right of the screen.
4. Click on **Volume** to enter the volume calibration screen.
5. Enter the volume of the calibration syringe.
   – A 3-litre syringe is recommended.

6. Click the **Start** button.
   – A message is displayed:

Calibrating Offset. Please don't breathe or create any flow in front of the sensor.

7. After a few moments, the offset is calibrated, and the volume screen is displayed. Smoothly pull the piston completely back and forth with a constant flow.

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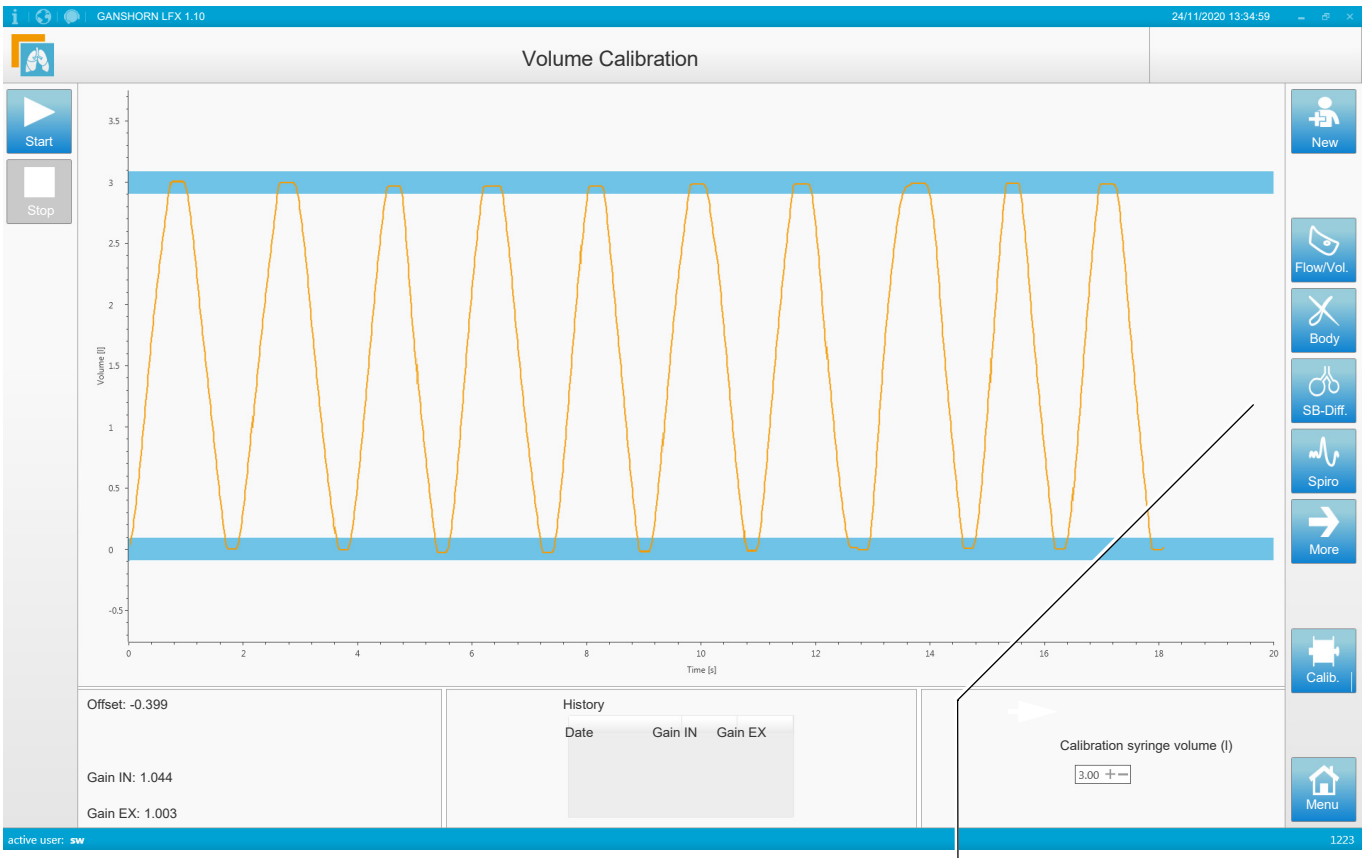
8. After several pumps, the program stops, and a success or failure message is displayed.



5.4.2 Tabular Results after Calibration

The volume, calibration, and measurements are displayed in the tabular results. The volume at each flow should meet the accuracy requirement of ± 3.5% (including 0.5% accuracy of the syringe). For a 3-litre syringe, the measured volumes at each flow should be between 2.895 and 3.105 litres.

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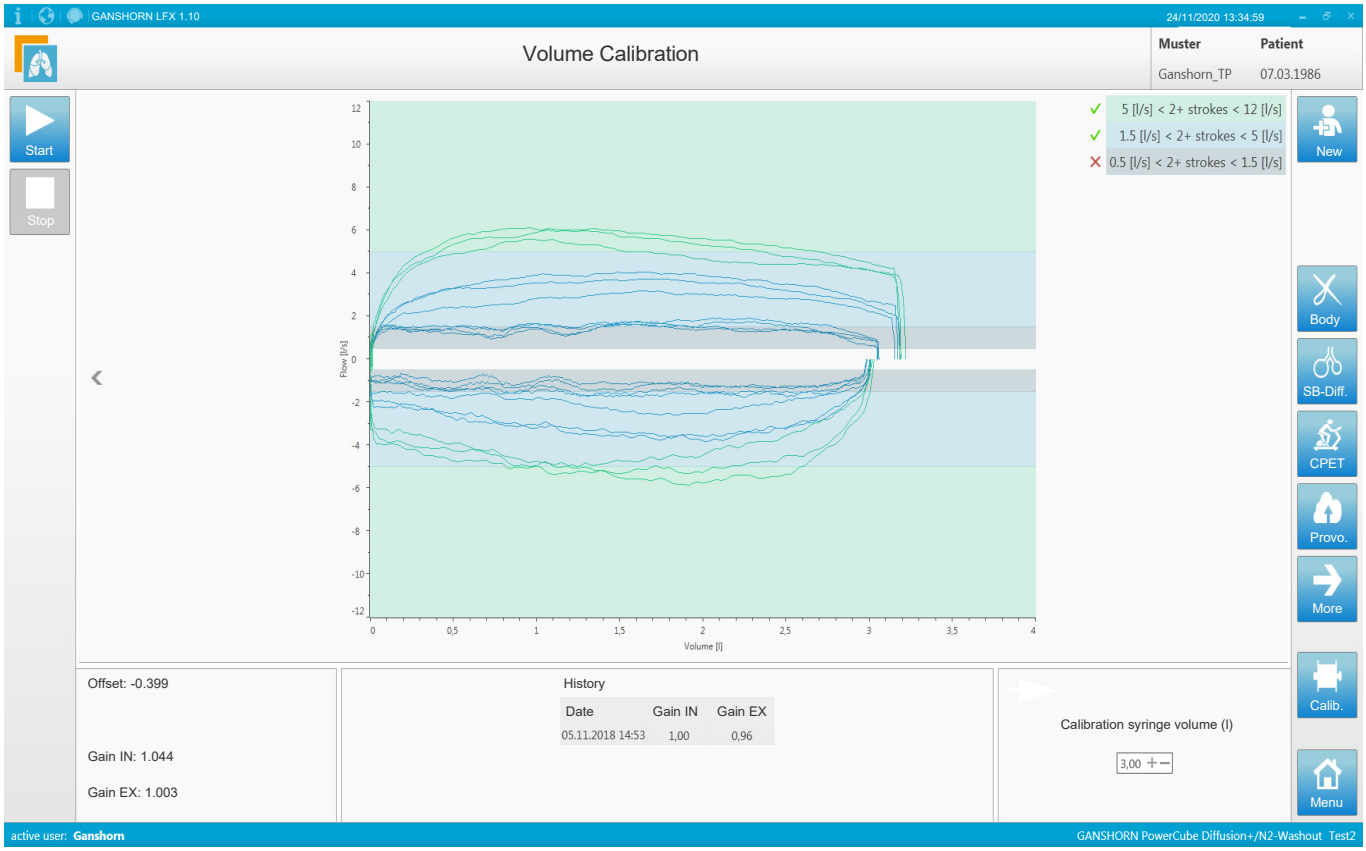
5.4.3 Flow Sensor Linearity Calibration Procedure

This procedure is optional to check that a linear measurement is made for all flow rates. To do this, perform the procedure as detailed for the Volume verification procedure at a low flow rate of approximately 0.5 L/s, repeat at approximately 6 L/s and then at 12 L/s flow rates.



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5.5 BodyLive

BodyLive calibration must be performed once a week. It can also be performed at any time for verification.

5.5.1 Overview

BodyLiveCal for body plethysmography is a fully automatic program. It includes measuring the cabin time constant and simultaneously calibrating the pressure transducers in a TGV simulation (thoracic gas volume).

Simultaneous Cabin Pressure and Mouth Pressure Calibration

After measuring the time constant waiting two minutes, a motor-driven syringe starts simultaneously applying a sinusoidal reference pressure to the cabin and the mouth pressure sensor with frequencies of 0.25 Hz, 0.5 Hz and 1 Hz. With this calibration step, the accuracy of cabin pressure and mouth pressure is verified at different respiration rates, from tidal breathing to panting. The mouth pressure calibration is part of the BodyLiveCal.

After a brief stabilisation period, the measurement curves appear on the screen, and the calibration process then automatically stops. A success message is given when the results meet the requirement, or an error message is displayed if the calibration is unsuccessful.

5.5.2 Environmental Conditions

Before calibrating the body, observe the following conditions:

- The PowerCube+ Series gas analyser system has warmed up for 30 minutes.
- The cabin must be at room temperature.
  - Check that there have been no quick temperature changes in the room where the cabin is causing a temperature differentiation.
- Avoid drafts.
  - Keep all windows and doors closed in the room.
  - Switch off the air conditioning in the room.

5.5.3 Calibration Requirement

For a successful calibration, the calibration values must be between 0.75 and 1.25.

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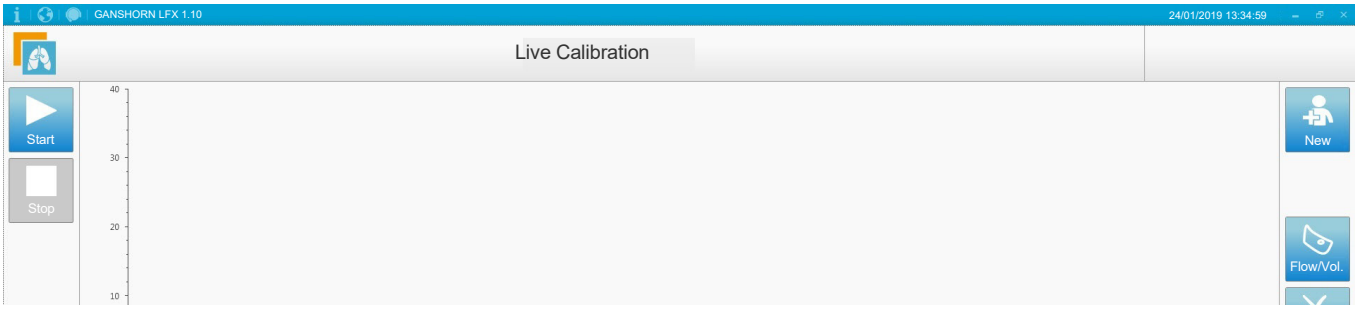
5.5.4 Procedure

1. From the Patient screen, click the **Calib** button.
2. The calibration settings are displayed on the right of the screen.
3. Click on **BodyCal** to enter the calibration screen.
4. The initial calibration screen is shown:



5. Click the **Start** button to begin the calibration process. The message **Please close cabin door** is displayed:

Please close cabin door

6. Gently shut the cabin door until you hear the door magnets close. Push the door handle top and bottom until both door seal indicators display the three green LEDs
   - The calibration starts automatically.
   - **T**he message **Measuring time constant of the cabin** is displayed, followed by **The time constant is within range.**
   - A system wait of two minutes is taken to allow the system to stabilise as the countdown is displayed on the screen.

Wait 63 seconds for the temperature to stabilise.

   - Calibration of the cabin pressure starts at the end of the stabilisation period. The diagram shows sinus curves for PB and PM against time.

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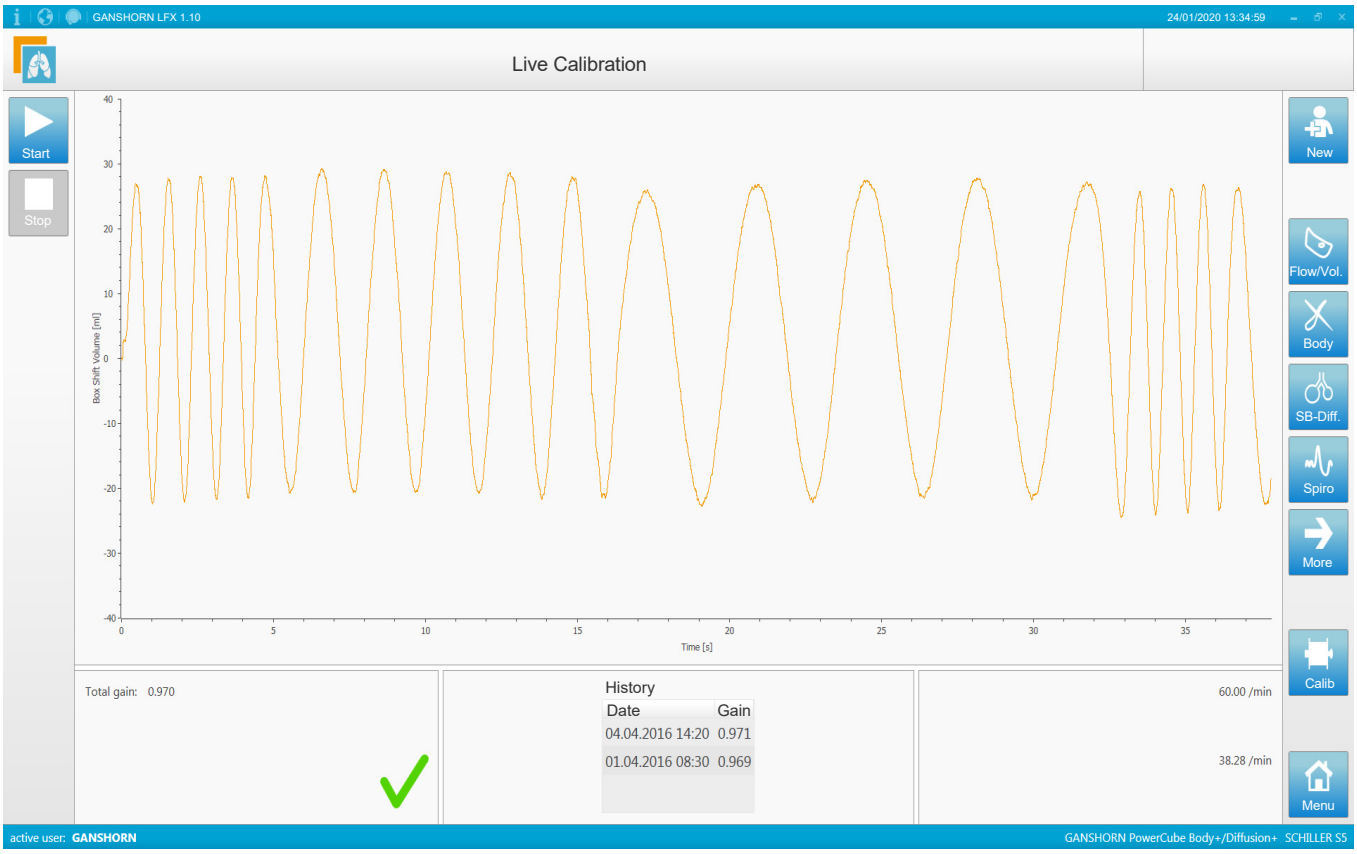
7. The BodyLiveCal ends automatically after the calibration of PB and PM for three frequencies. Calibration takes approximately 40 seconds.
   – A message appears to confirm that the calibration was successful.
   – The cabin door opens automatically.



The latest calibration factors are saved on successful calibration, and the program uses the latest calibration factors for future calculations.

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5.5.5 Calibration Errors

If it is not possible to measure the time constant correctly, the message **The time constant is out of range** is displayed. Wait for the completion of BodyLiveCal or interrupt by clicking **End**. If it is not possible to perform the leakage calibration correctly, the message **Calibration not possible/calibration not valid** is displayed. Check for potential sources of error (also refer to the error messages) and repeat. Possible causes of error are as follows:

Error	Possible Cause	Remedy
Small time constant	• Cabin is considerably colder than the room air. • Fluctuations of the cabin pressure PB (lower curve) indicate pressure fluctuations in the room. Drafts from open doors and windows could cause this.	➜ Allow at least 30 minutes of warm-up time. ➜ Check that the room is draft free. ➜ Check that the air conditioning is switched off in the room.
High time constant:	• Ventilation valve not adjusted correctly. • The cabin door was closed too slowly.	➜ Contact GANSHORN. ➜ The overpressure necessary to measure the time constant was not generated. Recalibrate, closing the door more quickly.
Cabin leakage	• The cabin door is not closed correctly. • Door seal is not intact.	➜ Check the door magnets. ➜ Check that the three green door closed LED indicators on the top and bottom door magnets are lit. ➜ Check the rubber door seal. If the seal has perished, cracked, or nicked, contact GANSHORN for replacement.

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5.6 Diffusion Gas (He/CO)

- Gas calibration must be performed before the first test every day. It can also be performed at any time for verification.
- Confirm a minimum pressure of 6 bar.
- Only use the original gas, pressure gauge, and tubing provided with the equipment. If replacement is required, only replace with original equipment supplied or approved by GANSHORN. Failure to do so can result in danger to the patient and inaccurate measurements.

5.6.1 Procedure

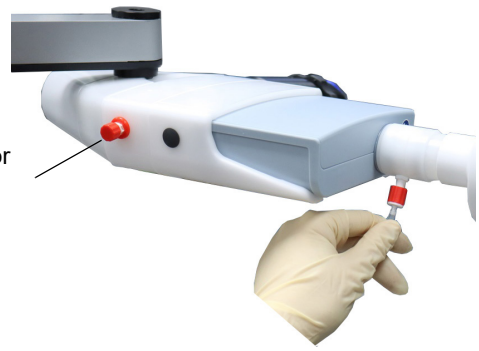
1. On the gas bottle, open the gas valve fully.
   – The open valve rotation is anti-clockwise. The open-close direction is printed on the valve.
2. From the Patient screen, click the **Calib** button 

3. The calibration settings are displayed on the right of the screen
4. Click on **He/CO** (Helium/Carbon monoxide) to enter the calibration screen.
5. The initial calibration screen and the message to connect the gas tube to the test input are shown.

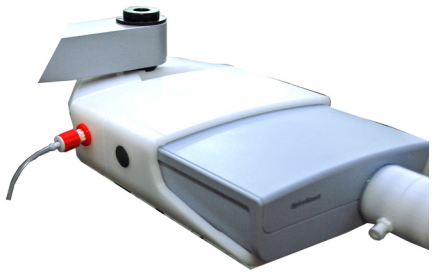
Check that the gas tube has been connected to the test input.

6. Remove the gas connector from the patient part of the sensor to the gas test connector in the sensor.

Gas calibration connector with protective cap



Remove from the patient part



Calibration position

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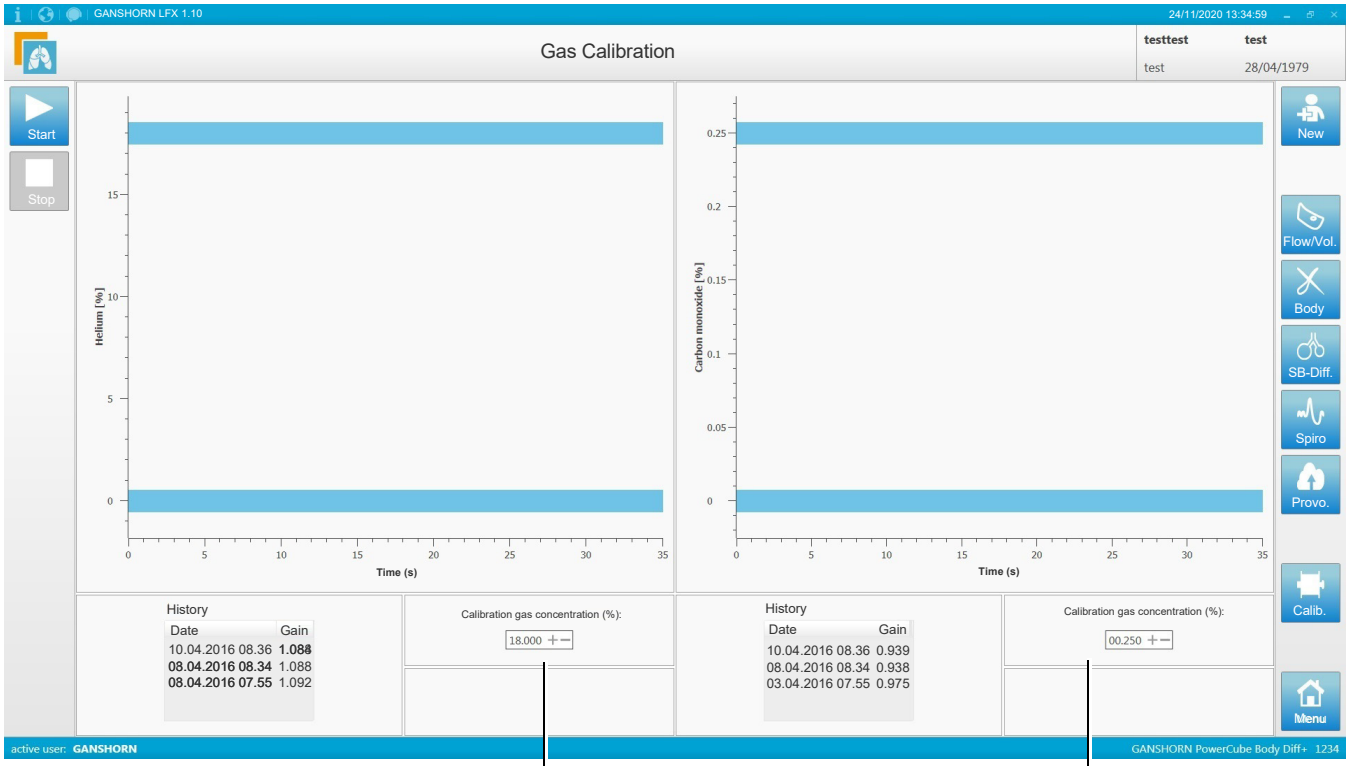
7. Check, and enter the gas percentage of the helium and carbon monoxide.



Enter/check **He** gas percentage (written on gas bottle)

Enter/check **CO** gas percentage (written on gas bottle)

8. Click the **Start** button
   – A message appears, reporting that the gas calibration has started.

Preparing gas calibration. Please wait . .

   – The gas calibration starts, and the percentage of the helium (left graph) and CO (right graph) are displayed.
   – A success message is displayed when the gas calibration has been successfully completed.

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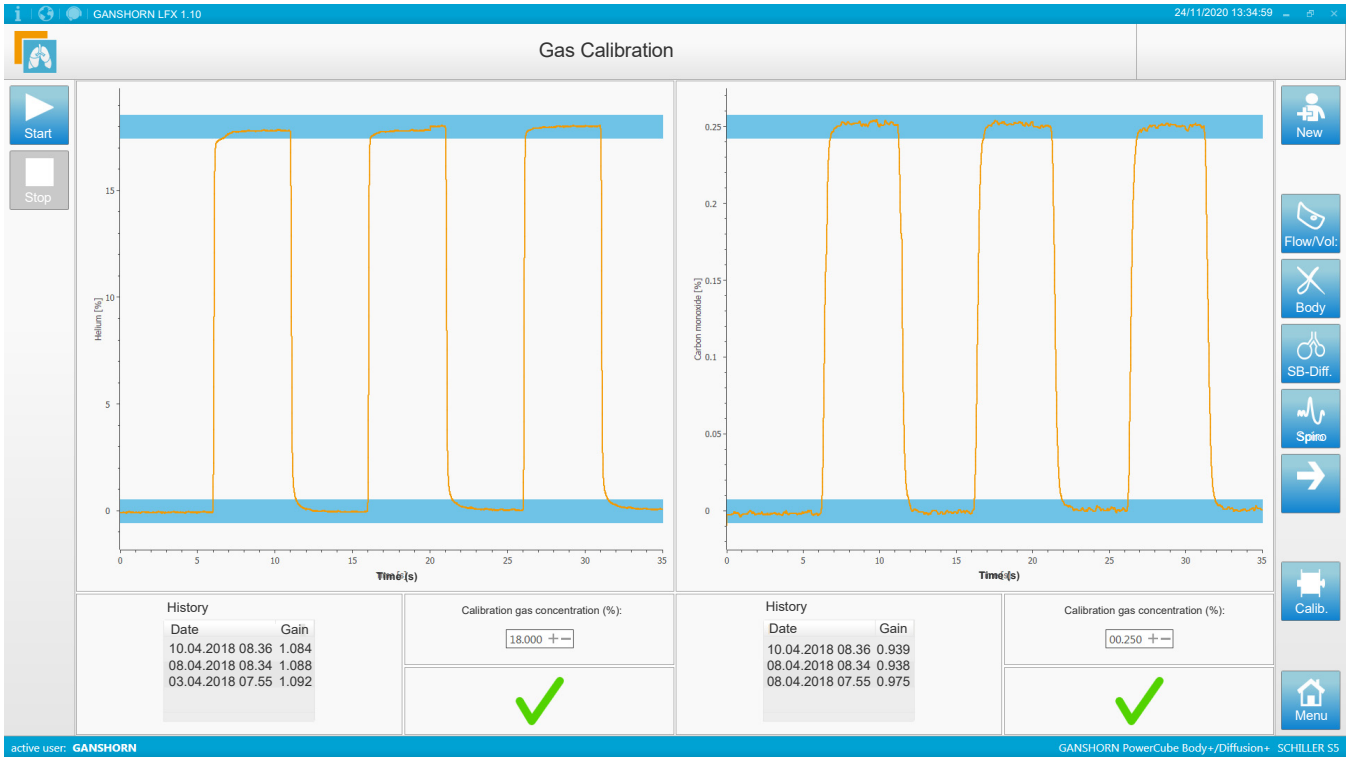
9. Upon completion, you are prompted to remove the gas tube from the test inlet and replace it on the patient sensor inlet. Replace the safety cover on the test gas inlet (see step 6).

Check that the gas tube has been reconnected to the flow tube of the patient interface.



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5.6.2 Calibration Factors

Based on the ATS/ERS guidelines, a maximum calibration factor of ± 3% is allowed.

The LFX gas calibration does not show the actual gain value immediately when the calibration has been completed. Exit and re-enter the calibration screen to see the past gas-calibration gain values and trends.

5.6.3 Calibration Errors

If it is impossible to correctly calibrate the gas, repeat the calibration. If the calibration still fails, the possible causes of the error are as follows:

Possible Cause	Remedy
• The gas valve is not On	➜ Open the gas valve fully.
• The gas bottle is empty	➜ Check the pressure on the gas bottle (minimum of 6 bar). ➜ Replace the gas bottle.
• Incorrect Gas concentration entered	➜ Check the He and CO percentage concentrations (found on a label on the gas bottle), and check that the exact concentration has been entered in the calibration program.
• Gas leakage	➜ Visually check the gas tubes for signs of any damage or leaks.
• Hardware malfunction (PowerCube+ Series module (under the cabin)	➜ Contact GANSHORN.

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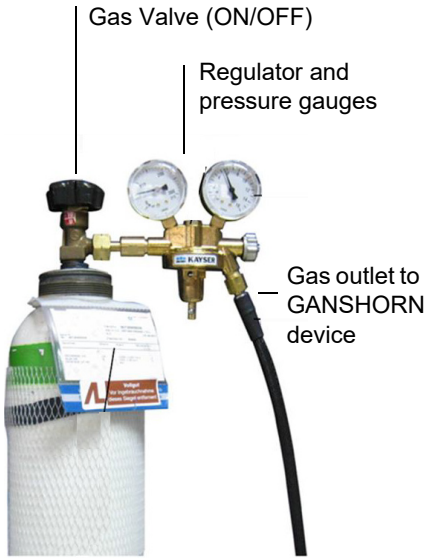
5.7 Nitrogen Washout Gas (O_2)

The O_2 required for this test can be provided by a bottle or directly to the hospital O_2 port. The gas, pressure gauge and tubing must be of approved hospital quality, and GANSHORN can advise if required. Failure to use non-approved equipment can result in danger to the patient and inaccurate measurements.

5.7.1 Procedure

- Gas calibration must be performed before the first test every day. It can also be performed at any time for verification.
- Check for a minimum pressure of 5 bar.

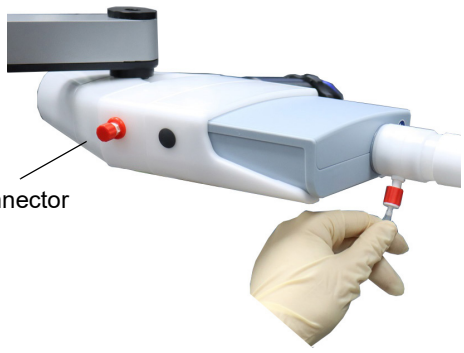


1. Remove the rubber cap from the valve on the top of the shutter assembly (see para.11, Nitrogen Washout, page 111).
2. On the gas bottle, open the gas valve fully.
   – The open valve rotation is anti-clockwise. The open-close direction is printed on the valve.
3. From the Patient screen, click the **Calib** button 

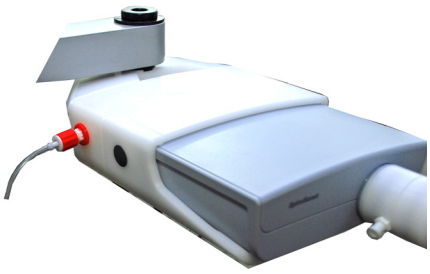
4. The calibration settings are displayed on the right of the screen.
5. Click on **N2 Washout** (O_2) to enter the calibration screen.
6. The initial calibration screen and the message to connect the gas tube to the test input are shown.

Check that the gas tube has been connected to the test input.

7. Remove the gas connector from the patient part of the sensor to the gas test connector in the sensor.



Remove from the patient part



Calibration position

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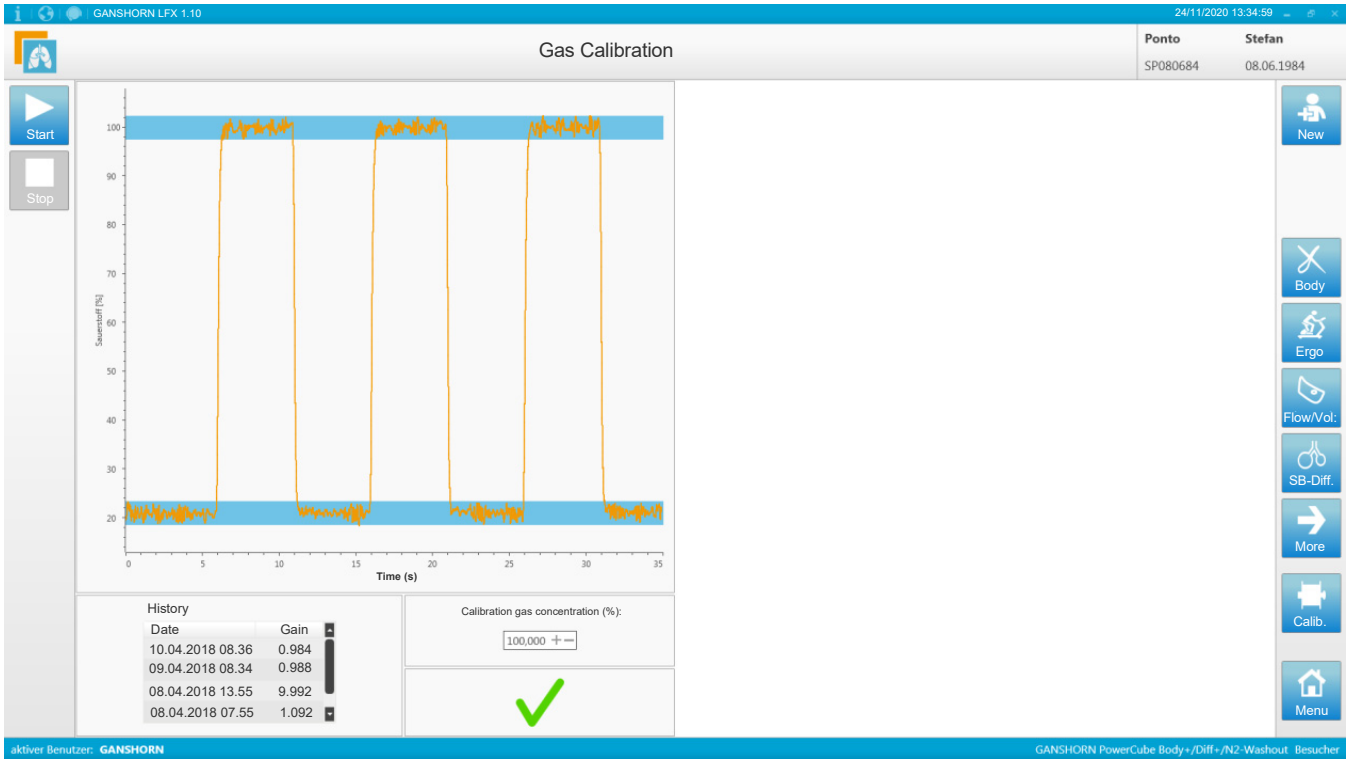
8. Check/enter the gas percentage of oxygen.
   – Note that since the bottle's content is not a mixture but a single gas, the concentration is always 100%.
9. Click the **Start** button.
   – A message appears, reporting that the gas calibration has started.

Preparing gas calibration. Please wait . .

   – The gas calibration starts, and the percentage of oxygen is displayed.
   – A success message is given when the gas calibration has been successfully completed.



10. Upon completion, you are prompted to remove the gas tube from the test inlet and replace it on the patient sensor inlet. Replace the safety cover on the test gas inlet (see step 7).

Check that the gas tube has been reconnected to the flow tube of the patient interface.

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5.7.2 Calibration Factors

Based on the ATS/ERS guidelines, a maximum calibration factor of ± 3% is allowed.

The LFX gas calibration does not show the actual gain value immediately when the calibration has been completed. Exit and re-enter the calibration screen to see the past gas-calibration gain values and trends.

5.7.3 Calibration Errors

If it is impossible to calibrate the gas, repeat the calibration correctly. If the calibration still fails, possible causes of error are as follows:

Possible Cause	Remedy
• The gas valve is not ON	➜ Open the gas valve fully.
• The gas bottle is empty	➜ Check the pressure on the gas bottle (minimum of 5 bar). ➜ Replace the gas bottle.
• Incorrect Gas concentration entered	➜ Check the O_2 concentration and check that 100% concentration has been entered in the calibration program (and gas cylinder content)
• Gas leakage	➜ Visually check the gas tubes for signs of any damage or leaks.
• Hardware malfunction (PowerCube+ Series module (under the cabin)	➜ Contact GANSHORN.

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5.8 Oscillometry (OS)

- When using the optional sensor Thorasys tremoflo® C-100 Airway Oscillometry System, the calibration can be triggered by the LFX software.
- Tremoflo uses the “Forced Oscillatory Technique”
- The calibration must be carried at least once a day prior use.
- Refer for the Tremoflo calibration procedure of the Thorasys instruction for use.

5.8.1 Procedure

1. From the Patient screen click the **Calib button.**
2. Click on **Tremoflo** to start the Thorasys software calibration procedure. For the calibration procedure on this screen refer to the Thorasys instruction for use.

➜ After the successfully calibration it will return to the LFX software.

➜ For measuring see para. 5.8 Oscillometry (OS), page 66.

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6 Recording Measurements

6.1 General

⚠ WARNING

- ▲ The disposable PFT bacterial filter is a single-use disposable patient mouthpiece designed to eliminate the danger of cross-contamination.
  - – Do not use it for more than one patient.
  - – Do not attempt to clean.
  - – Dispose of the PFT bacterial filter after use.
- ▲ Before attaching a new filter before a test, check that the filter is undamaged and that there are no loose parts in the filter that the patient might inhale.
- ▲ To maintain hygiene see:
  - – 1.8 Infection control/cross contamination
  - – 2.8 PFT Bacterial Filter
  - – 14 Cleaning and Disinfection

⚠ CAUTION

Patient Data

- ▲ To guarantee the predicted values and diagnosis is correct, patient data must be entered correctly; in particular, date of birth, gender, ethnicity, height and weight.

System Calibration

- ▲ The system must be verified/calibrated before use (see para.5, Calibration, page 49).

6.1.1 Influences on Predicted Norm Values

Norm values come from a series of scientific publications. The norm values available will be determined by your market. There many modules available, generally however most countries and installations will select from a standard set of norm values. The formulas and how the reference modules are defined can be seen in the Reference settings (see para.13.23, References and Formula, page 147).

⚠ CAUTION

Patient Data

- ▲ Predicted values will vary according to the Norm value selected and the patient. It is therefore important that patient data is entered correctly, in particular the following:
  - – Gender
  - – Date of birth (age is calculated by the program)
  - – Height
  - – Weight
  - – Ethnic origin

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6.1.2 Positioning the Patient

- For Spiro recordings and diffusion, the patient can be either in or outside of the cabinet with the door open.
- For body recordings, the patient is positioned inside the cabinet. The program provides a prompt on when to close the door.
- Position the patient comfortably (sitting or standing), then position the sensor level with the patient's mouth.
- Before closing the cabin door, check that the patient is not holding the cabin frame to prevent pinching.

6.1.3 Post Recording

- Post-tests can be performed to check, e.g. the effect of asthma medications or other medications, allergic tests, or regime changes on a patient. Usually, asthma-relieving medication is administered immediately after preforming an FVC or SVC test (pre-test). After 10 to 20 minutes (duration until the medication has developed its full effect), another FVC or SVC test is performed. Different durations may be applicable for different medications. Afterwards, the results of the pre and post-test are compared.
- If a measurement is made with the same patient on the same day, Post is automatically set.
- Any medication the patient has taken before their hospital visit should not be entered in Medication but entered in Notes.

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6.1.4 Quality Control Guidance During the Measurement

During the measurement, the quality control guidance assists you in determining if end-of-test criteria are reached. The end-of-test criteria are reached when:

- The exhalation time is ≥ 6 seconds (≥ 3 seconds in children aged < 10 years).
- When the volume change is < 25 ml for ≥ one second.

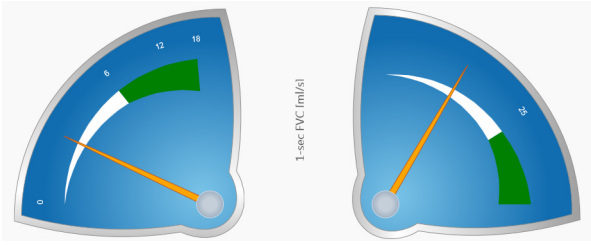
According to the ATS/ERS guidelines, the end-of-test criteria are met when at least one of these two criteria is met. Therefore, it is not necessary that both criteria are reached to meet the guidelines.

The two quality control guidance indicators on the bottom of the screen show the following:

- The left indicator shows the exhalation time.
- The right indicator shows volume change.

In both cases, the criteria are reached when the pointer is in the green area.

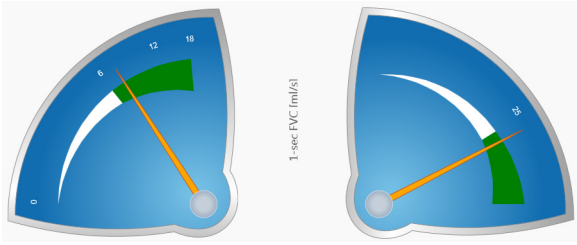
End criteria not reached



Exhalation time
< 6 sec (< 3 sec, age < 10 years)

Volume change
> 25 ml for ≥ 1 sec

End criteria reached



Exhalation time
≥ 6 sec (≥ 3 sec, age < 10 years)

Volume change
< 25 ml for ≥ 1 sec

As an alternative, when the arrow to the side of the quality display is clicked, three candles are displayed. This may be easier for paediatric or frail patients to understand. When all three candles are extinguished, the criteria are reached.

End criteria not reached

End criteria reached

The slider to the side of the candles increases/decreases the sensitivity.

- To help encourage young or frail patients, the candles can be manually set as follows:
  - Press the letter ‘a’ on the keyboard to light the candles.
  - Press the letter ‘z’ on the keyboard to extinguish the candles.

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6.2 Preliminaries

⚠ WARNING

▲ For a new patient, always use a new PFT bacterial filter.
(see para.2.8, PFT Bacterial Filter, page 32)

- To help minimise potential measurement problems and guarantee a good quality recording:
  - Prevent drafts, keep all windows and doors closed during the tests
  - Switch OFF any air conditioning in the room.
  - Breath slowly to avoid flow peaks

Preliminaries must be performed as follows (in accordance with ATS/ERS 2019):

1. Ask the patient about their smoking habits and any illnesses. This information can be filled out in the Patient data (previous page).
2. Record the type and dosage of any inspired, oral, or injected medication that may alter lung function and when the drugs were last administered. Record observed signs or symptoms such as cough, wheezing, dyspnea, or cyanosis.
3. Measure the weight and height of the subject without shoes.
4. Check the following points and record any deviations:
   - No smoking, vaping or water pipe use within one hour of testing; this avoids acute bronchoconstriction due to smoke inhalation.
   - No consumption of intoxicants within 8 hours of testing; this avoids problems in coordination, comprehension, and physical ability.
   - No vigorous exercise within one hour of testing; this avoids potential exercise-induced bronchoconstriction.
   - Not wearing clothing that substantially restricts full chest and abdominal expansion; avoids external restrictions on lung function.
5. Check that the patient is relaxed and wearing comfortable clothing.
6. Explain the test's purpose and that patients' cooperation is fundamental for successful lung function testing.
7. Instruct and, if necessary, demonstrate the breathing manoeuvre with the patient and explain the important points.
8. Instruct the patient not to talk during the measurement.
9. Instruct the patient to adopt the correct posture with their head slightly elevated.
10. Place the nose clip correctly on the patient's nose.
11. Instruct the patient to take the PFT filter into the mouth with the teeth biting lightly and the lips sealed around the tube. The patient must only breathe through the PFT filter; a bad seal or air escaping from the corners of the mouth can result in false readings.

Flow-Volume measurements right after a Thoracic Gas Volume (TGV) measurement

12. Instruct the patient before starting the measurement to execute 3-5 normal breathing. This prevents drift in the measurements.

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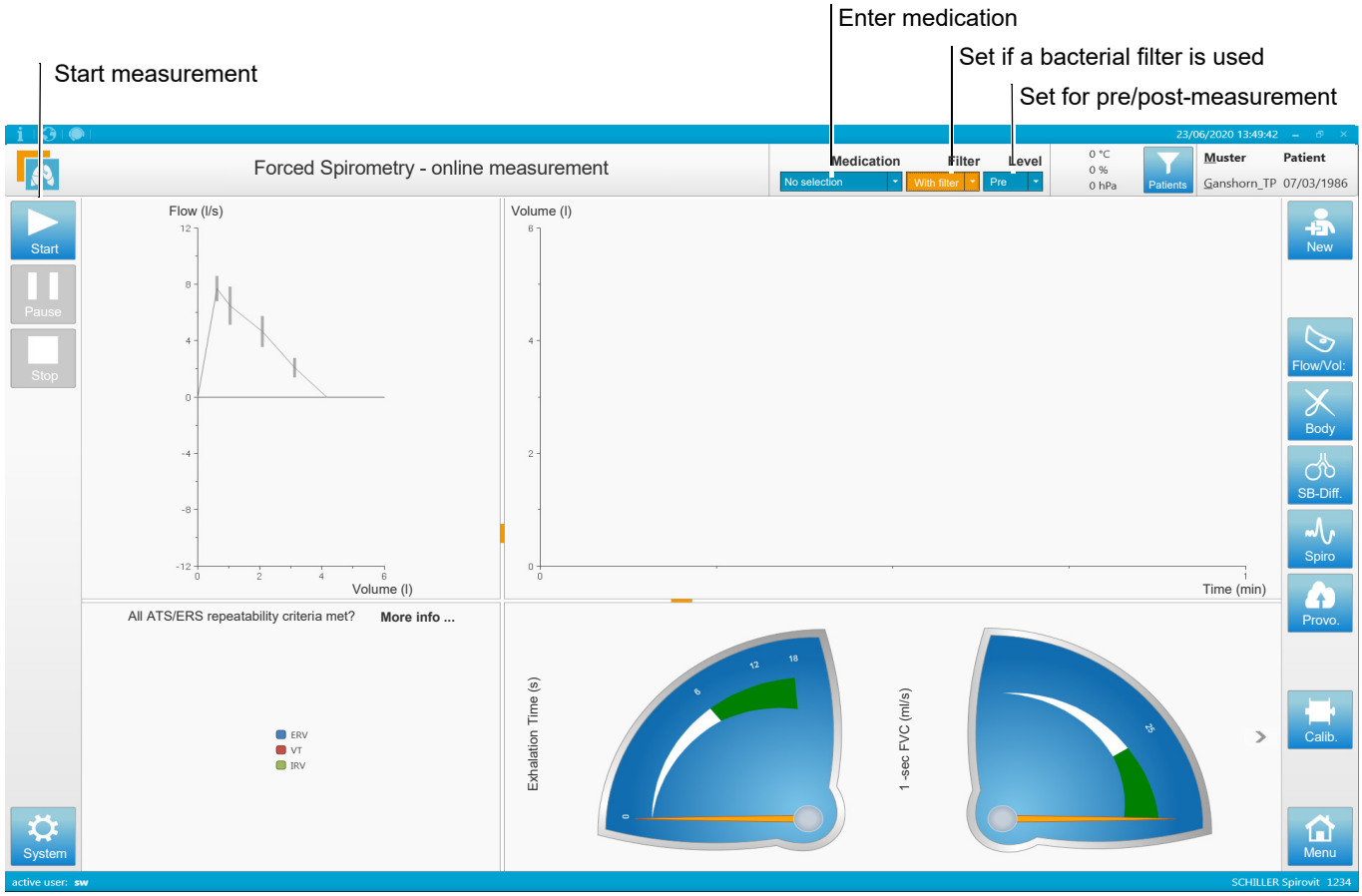
6.3 Forced Spirometry Measurement

1. Perform the preliminary checks (see para.6.2, Preliminaries, page 70).
2. Select a patient or register a new patient (see para.4.2, The Work/Patient Screen, page 38).
3. Click the **Flow/Volume** button.
   – The Forced Spirometry screen is displayed:



4. Position a new PFT bacterial filter on the sensor.
5. Set/check the following settings (top of the screen):
   – **Medication** - Enter medication from the pull-down menu. Note that the medication can be edited as required (see para.4.3, Editing User-Defined Drop-Down Lists, page 43).
   – **Filter** - If the bacterial filter is used, set it here.
   – **Level** - Set for pre-test/post-test.

⚠ CAUTION

▲ The measurements may not be accurate if the filter setting is not correct.

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6. Instruct the patient on how to perform the test and what is expected.
   – The patient should be relaxed (shoulders down and relaxed).
   – Before starting the measurement, close the patient's nasal airways with a nose clip.
   – Instruct the patient before starting the measurement to execute 3-5 normal breathing (if measurement is executed right after a TGV measurement).

7. Click the **Start** button 

   – Instruct the patient to breathe regularly and steadily until the breathing level (FRC level) is stable. This usually requires at least three tidal breathing manoeuvres.
   – When the FRC level is stable, the forced vital capacity can be measured.
   – Instruct the patient to inhale until the TLC level is reached (IC is measured). Then the patient should exhale forcefully and completely until the RV level is reached (FVC and FEV1 are measured), followed by a complete inhalation until the TLC level is reached again (FVC measured).

8. Click the **Stop** button to end the measurement 

After starting, the **Start** button changes to **Restart**. The button can then be used to restart the measurement, erasing any data of the running measurement; saved measurements are not erased.

9. **Repeat the test at least three times.**

Adding a New Trial

The **Add trial** enters the screen to take a new trial to add to the measurement.

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10. At the end of the test observe all cross-contamination procedures and safety notes described in the chapters:
    - 1.8 Infection control/cross contamination
    - 2.8 PFT Bacterial Filter
    - 14 Cleaning and Disinfection

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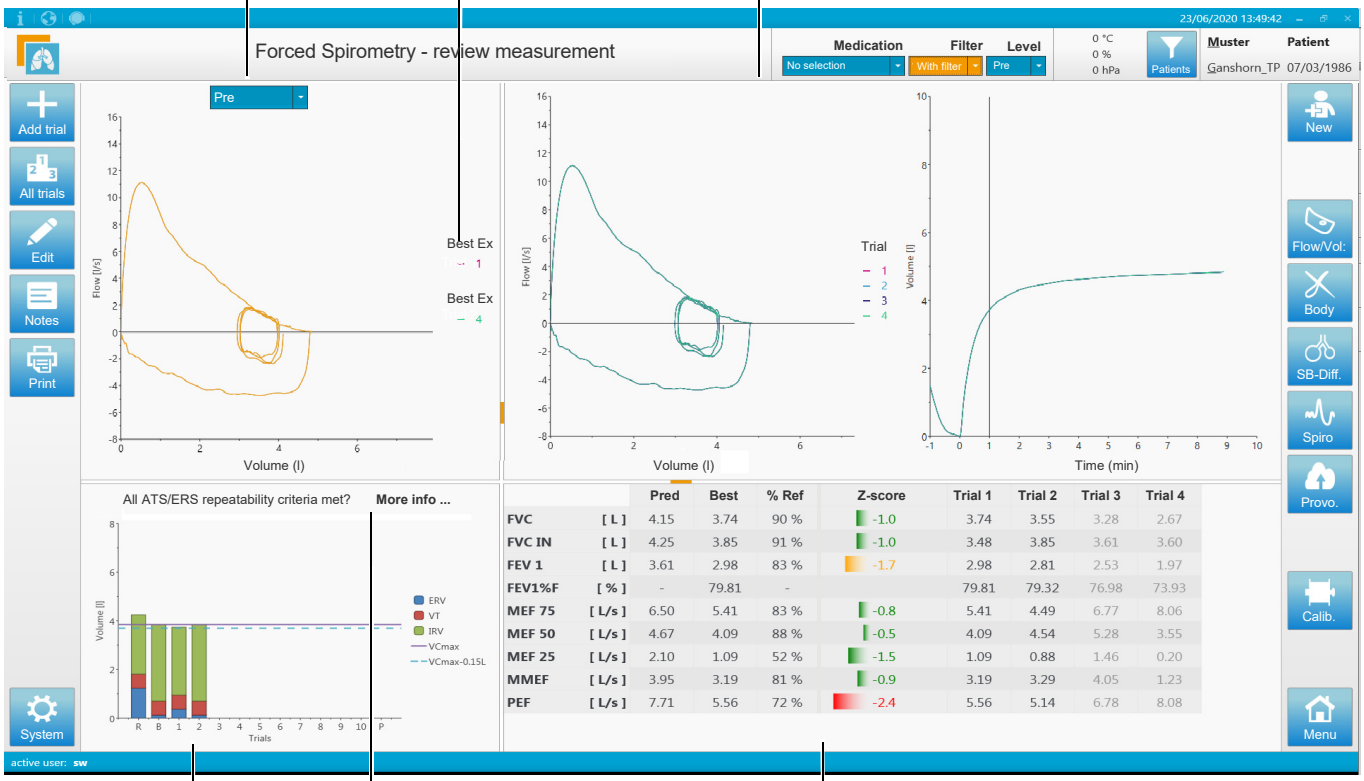
6.4 Forced Spiro Review

Select pre or post + pre

Best trials (see the next page)

Selected trial graphs (see the next page)



		Pred	Best	% Ref	Z-score	Trial 1	Trial 2	Trial 3	Trial 4
FVC	[L]	4.15	3.74	90 %	-1.0	3.74	3.55	3.28	2.67
FVC IN	[L]	4.25	3.85	91 %	-1.0	3.48	3.85	3.61	3.60
FEV 1	[L]	3.61	2.98	83 %	-1.7	2.98	2.81	2.53	1.97
FEV1%F	[%]	-	79.81	-		79.81	79.32	76.98	73.93
MEF 75	[L/s]	6.50	5.41	83 %	-0.8	5.41	4.49	6.77	8.06
MEF 50	[L/s]	4.67	4.09	88 %	-0.5	4.09	4.54	5.28	3.55
MEF 25	[L/s]	2.10	1.09	52 %	-1.5	1.09	0.88	1.46	0.20
MMEF	[L/s]	3.95	3.19	81 %	-0.9	3.19	3.29	4.05	1.23
PEF	[L/s]	7.71	5.56	72 %	-2.4	5.56	5.14	6.78	8.08

Display ATS/ERTS repeatability criteria compliance

Quality control bar graph

Tabular results

6.4.1 Setting the Data in the Results

From the review screen, click the **Settings** button to add, remove or change the order of the parameters in the tabular display.

Drag, drop and position as required.

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6.5 Best Result and Predicted Values

6.5.1 Definition of Best

In accordance with the ATS/ETS Spirometry Standard, the best measurement is defined as follows:

largest sum of FVC + FEV1

The following values are replaced with the highest respective value from the three best manoeuvres:

FVC, FIVC, FEV (all parameters), FIV (all parameters), PEF, PIF. In addition, FET is taken from the largest FVC of the three best manoeuvres.

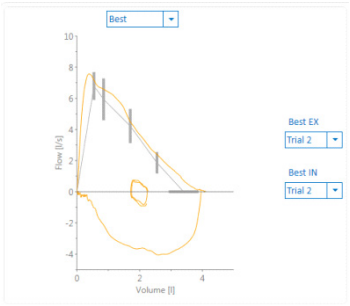
6.5.2 Best Trial

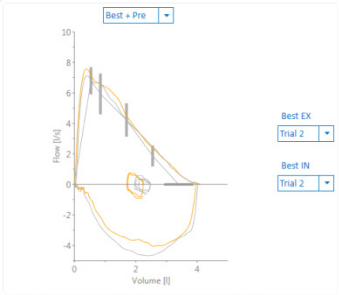
This left-side graph shows the best pre or pre + post curve. The software automatically selects the trial with the highest vital capacity. It is possible to select a different best trial for the inspiratory and expiatory flow-volume curve in the all trials screen (see para.6.5.7, Displaying all Trials, page 77).

Pre, Post or Pre + Post

When a post-recording has been made, the best curve graph can show the pre-, post, or an overlay of the best pre-and post-test measurements. This is selected from the drop-down option at the top of the best curve graph window.

The best curve of the pre-test is shown as a grey curve; the best curve of the post-test is an orange curve.





6.5.3 Selected Trial Graphs

The selected trial graphs show two graphs with a graphical overlay of selected measurements that have been performed. Volume-time graphs are on the left, and flow-volume graphs are on the right. Each trial has a unique colour.

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6.5.4 Quality Control Bar Graph

The quality control bar graph is used to display the between-trial and within-trial criteria of the Spirometry measurement according to the ATS/ERS guidelines as follows:

- The between-trial criteria for the VCmax.
- An indicator that shows if the trials have met the ATS/ERS repeatability criteria.

The purple line represents the highest measured VCmax value. The dotted blue line is the indicator for the between trial criteria for the VCmax, which is VCmax - 0.15 L.

Criteria

A forced Spirometry trial is acceptable when:

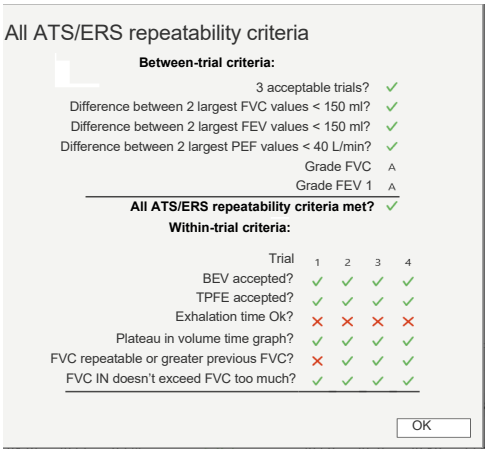
1. A satisfactory exhalation is measured:
   – Exhalation time is ≥ 6 seconds (≥ 3 seconds in children aged > 10 years)
   – A plateau in the volume time graph is reached (volume change < 25 ml for ≥ 1 second)
   – If the patient cannot or should not continue to exhale
2. And are free from the following artefacts:
   – Air leakage around the mouth
   – Hesitation during the manoeuvre
   – Obstruction of the mouthpiece, e.g. biting the mouthpiece too hard or the tongue is in the way.

A minimum of three acceptable VC trials must be obtained, and the difference between the two largest VCmax values must be within 0.150 litres.

   – If the difference is more than 0.150 litres, more manoeuvres should be performed up to (but usually no more than) four manoeuvres can be performed with a rest period of 1 minute between the trials.

Between Trial and within Trial Criteria for Forced Spirometry

When the **More Info . . link** in the quality control graph area is clicked, the ATS/ERS repeatability criteria compliance information is displayed with an overview of the between-trial and within-trial criteria.



ATS/ERS compliance is indicated at the top of the quality control bar graph. A green tick indicates compliance, and a red cross indicates non-compliance.

For the within-trial criteria, 3 out of 4 criteria must be fulfilled for the trial to be compliant.

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6.5.5 Tabular Results

The Tabular results give the results of the parameters for all trials and the percentage difference from the predicted (calculated using patient data and norm value defined).

6.5.6 Z-score

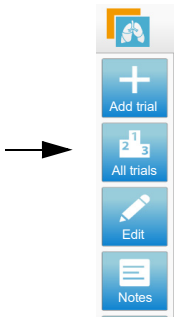
The Z-score gives an objective indication of the statistical quality of the results and is calculated as follows:

- Z-score = (Measured Value - Reference Value)/Standard Deviation

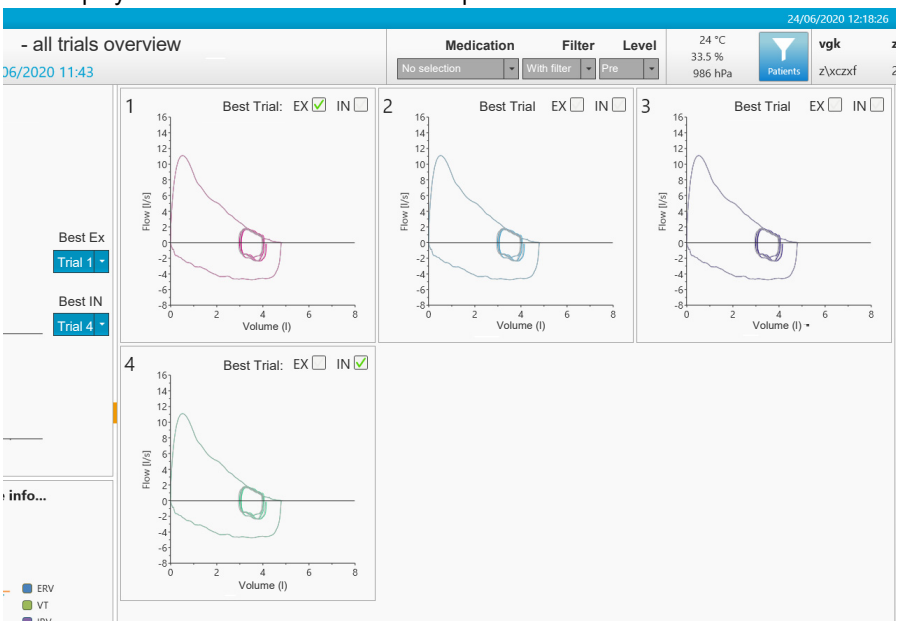
A colour-coded indication of the measurement is given as follows:

- Green - measurement within the expected normal range.
- Orange - measurement within range but close to the margins. Examine the other measurements, and consider taking more trials.
- Red - measurement out of the expected normal range.

6.5.7 Displaying all Trials



This displays an overview of all the forced spiro trials:



The best trial is indicated with a green check mark. The user can select a different best trial for expiration and inspiration by checking the box. Other bests trials can be selected for both pre-measurements and post-measurements.

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6.5.8 Editing the Recording

The edit trial screen allows you to manually adjust each Spirometry trial's TLC, VT, FRC and RV levels. Select the trial and edit the values as required. The values that are influenced are changed simultaneously in the tabular results.

Any edited measurements are reset to the program-generated values when the **Reset** icon is clicked (blue when a recording has been edited).

6.5.9 Printing

Click the **Print** or **Report** button to print/generate a report and select the print where the report is to be printed (see para.4.6, Printing or Generating a Report, page 45). The published report shows the best values when both pre and post-levels have been measured.

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6.6 SVC Measurement

1. Perform the preliminary checks (see para.6.2, Preliminaries, page 70).
2. Select a patient or register a new patient (see para.4.2, The Work/Patient Screen, page 38).
3. Click the **Spiro** button.
   – The SV screen is displayed:

4. Position a new PFT bacterial filter on the sensor.
5. Set/check the following settings (top of the screen):
   – **Medication** - Enter medication from the pull-down menu. Note that the medication can be edited as required (see para.4.3, Editing User-Defined Drop-Down Lists, page 43).
   – **Filter** - If the bacterial filter is used, set it here.
   – **Level** - Set for pre-test/post-test.

⚠ CAUTION

▲ The measurements may not be accurate if the filter setting is not correct.

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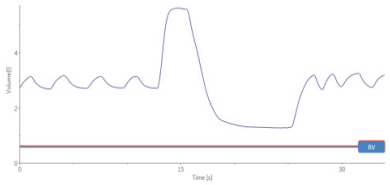
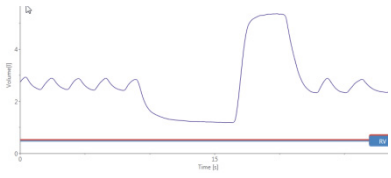
6. Before starting the measurement, close the patient's nasal airways with a nose clip and click the **Start** button 

7. Instruct the patient to breathe regularly and steadily until the breathing level (FRC level) is stable. This usually requires at least three tidal breathing manoeuvres.

8. When a stable FRC level is reached, Perform the slow vital capacity by either performing the IVC or EVC manoeuvre.



– **VC Ex** Instruct the patient to fully exhale until RV level is reached (ERV is measured). Then the patient should inhale completely until the TLC level is reached (IVC is measured). After a period of tidal breathing, the manoeuvre is completed.



– **VC In** Instruct the patient to inhale until the TLC level is reached (IC is measured). Then the patient should exhale fully until the RV level is reached (EVC is measured). After a period of tidal breathing, the manoeuvre is completed.

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9. Click the **Stop** button to end the measurement 

. The results of the measurement are shown.
10. Repeat the test at least three times

Adding a New Trial

The **Add trial** enters the screen to take a new trial to add to the measurement.

- After starting, the **Start** button changes to **Restart**. This button can be used to restart the measurement, erasing any data of the running measurement; saved measurements are not erased.
- If the measurement sequence must be interrupted for a short time, the measurement is put on hold by clicking on the **Pause** button 

11. At the end of the test observe all cross-contamination procedures and safety notes described in the chapters:
   - 4.2.2 Entering New Patient Data
   - 2.8 PFT Bacterial Filter
   - 14 Cleaning and Disinfection

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6.7 SVC Review

The following data is given:

6.7.1 Best Trial

This window shows the best, pre and post or post-curve. The best curve is the trial with the highest vital capacity. The user can also manually define a different best trial if required (see para.6.7.5, Displaying all Trials, page 85).

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Best or Best + Pre

When a post-measurement has been taken, the best curve graph can show an overlay of the best pre and post-slow Spirometry measurement. This is defined from the drop-down menu at the top of the best curve graph window. The best curve of the pre-test is shown as a grey curve, and the best curve of the post-test is the trial colour.

6.7.2 Quality Control Bar Graph.

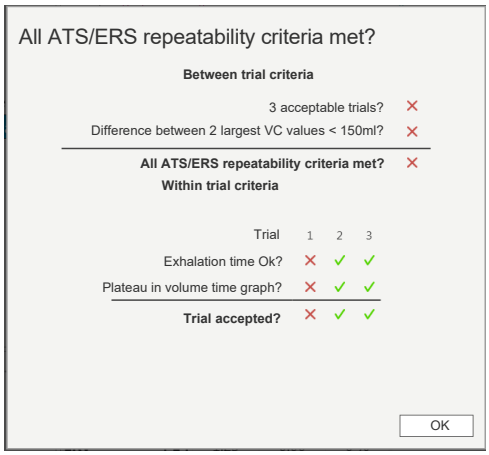
The quality control bar graph is used to display the between-trial and within-trial criteria of the slow Spirometry measurement according to ATS/ERS guidelines as follows:

- The between-trial criteria for the VCmax.
- An indicator that shows if the trials have met the ATS/ERS 2005 repeatability criteria.

The purple line represents the highest measured VCmax value. The dotted blue line is the indicator for the between trial criteria for the VCmax, which is VCmax - 0.15 L.

Within-trial and Between-trial Criteria for Slow Spirometry

When the **More Info . . link** in the quality control graph area is clicked, the ATS/ERTS repeatability criteria compliance information is displayed with an overview of the between-trial and within-trial criteria.



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Within-trial Criteria

A slow Spirometry trial is acceptable when:

1. A satisfactory exhalation is measured:
   – Exhalation time is ≥ 6 seconds (≥ 3 seconds in children aged > 10 years)
   – A plateau in the volume time graph is reached (volume change < 25 ml for ≥ 1 second)
   – If the patient cannot or should not continue to exhale.
2. They are free from the following artefacts:
   – Air leakage at the mouth
   – Hesitation during the manoeuvre
   – Obstruction of the mouthpiece, e.g. biting the mouthpiece too hard or the tongue is in the way.

Between-trial Criteria

A minimum of three acceptable VC trials must be obtained, and the difference between the two largest VCmax values must be within 0.150 litres.

If the difference is more than 0.150 litres, more manoeuvres should be performed up to (but usually no more than) four manoeuvres can be performed with a rest period of 1 minute between the trials.

ATS/ERS Repeatability Criteria

ATS/ERS compliance is indicated at the top of the quality control bar graph. A green tick indicates compliance, and a red cross indicates non-compliance.

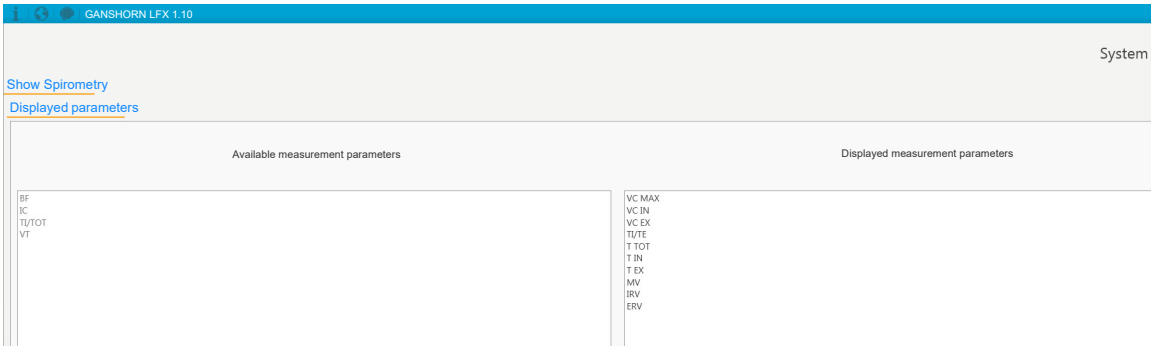
6.7.3 Tabular Results

The tabular results give the results of the slow Spirometry parameters for all trials and the percentage difference from the predicted (using patient data and defined norm). The Z-score gives an objective indication of the measurements (see para.6.5.6, Z-score, page 77).

6.7.4 Setting the Data in the Results

From the review screen, click the **Settings** button to add, remove or change the order of the parameters in the tabular display.

Drag, drop and position as required.



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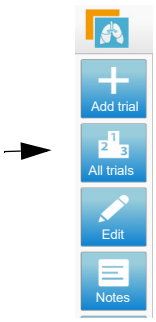
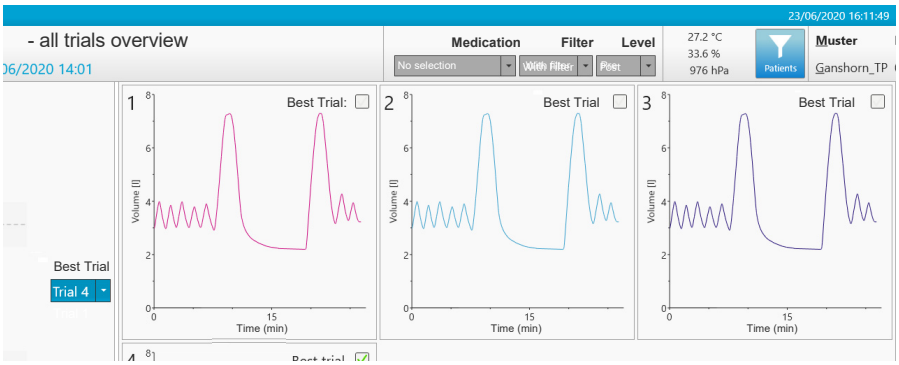
6.7.5 Displaying all Trials

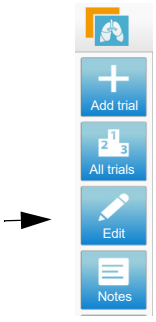


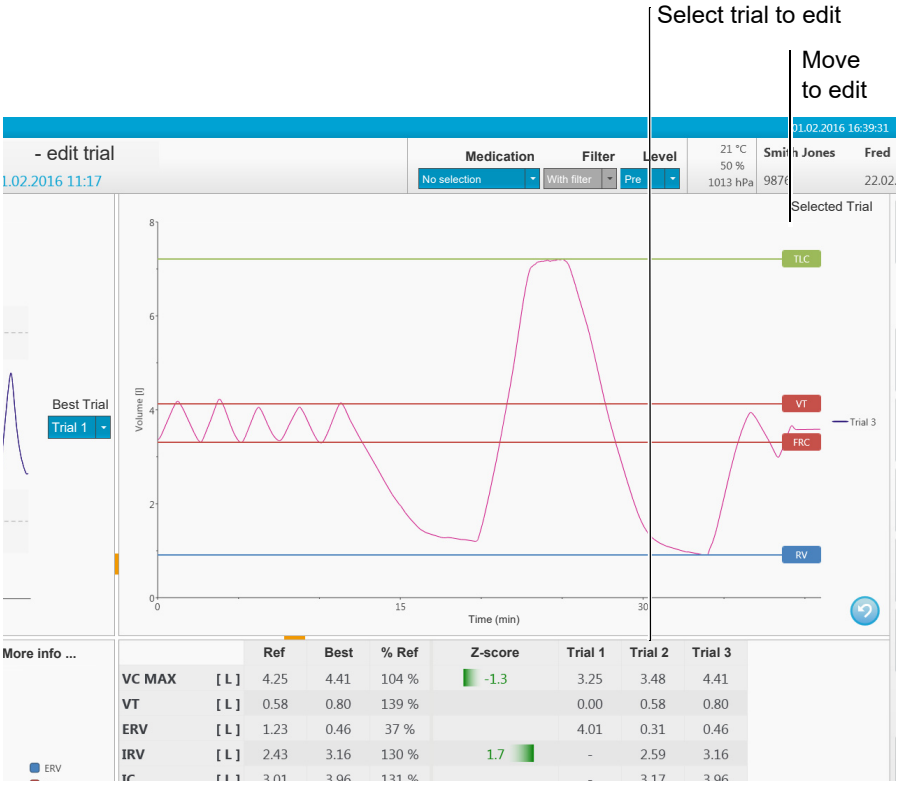
This displays an overview of all the SV trials:



The best trial is indicated with a green check mark. The user can select a different best trial by checking the box.

6.7.6 Editing the Recording





The edit trial screen gives you the possibility to manually adjust the Total Lung Capacity (TLC), Tidal Volume (VT), Functional Residual Capacity (FRC) and Residual Volume (RV) levels of each slow Spirometry trial. Select the trial and edit the values as required. The values that are influenced are changed simultaneously in the tabular results.

6.7.7 Printing/Generating a Report

Click the **Print** or **Report** button to print/generate a report and select the print where the report is to be printed (see para.4.6, Printing or Generating a Report, page 45). The published report shows the best values when both pre and post-levels have been measured.

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6.8 Maximum Voluntary Ventilation MVV

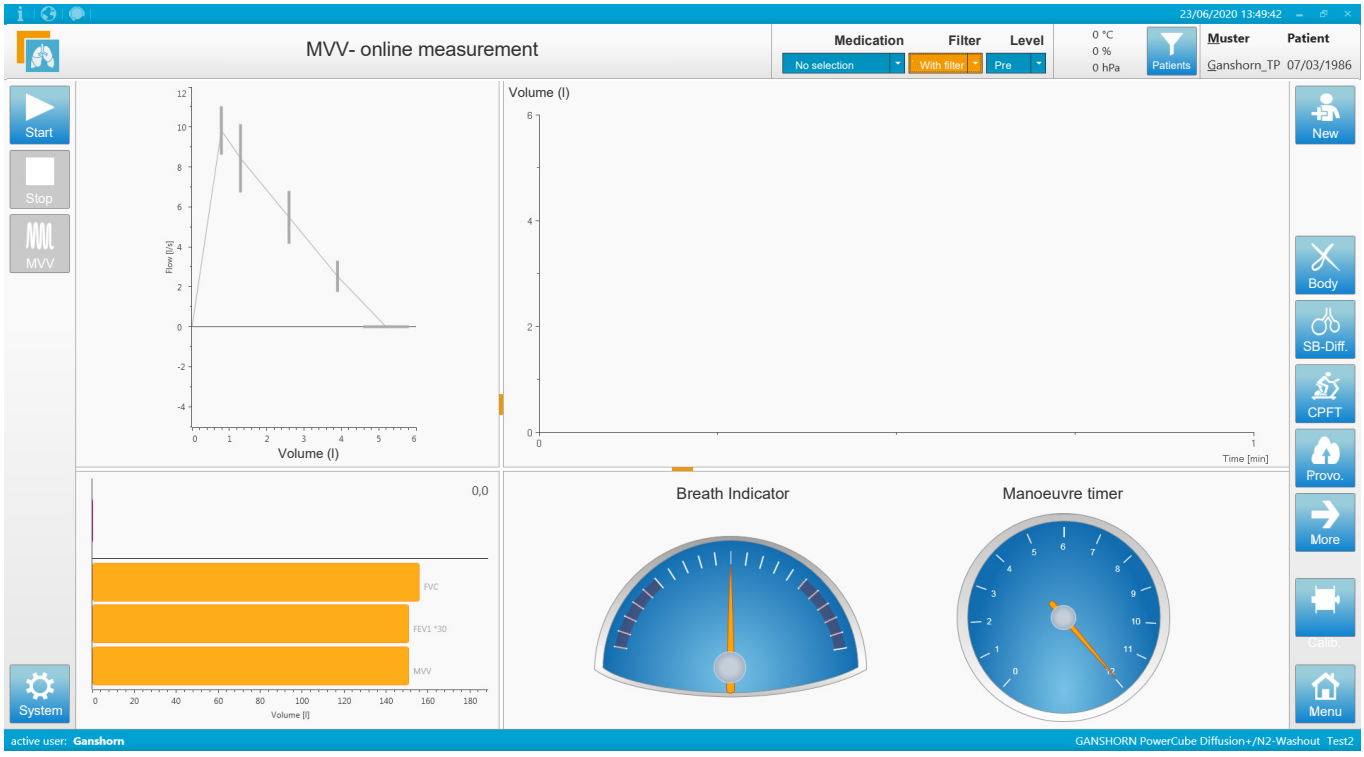
For this test, the patient should breathe as deeply and rapidly as possible over 12 seconds (or the time set in MVV settings). The result is extrapolated from 12 seconds (or for the time period set in MVV settings) to show what could be achieved over one minute.

The time period that the patient performs the MVV manoeuvre can be set in system settings between 1 and 60 seconds. The default is 12 seconds.

⚠ CAUTION

▲ Care should be exercised when performing this test, as hyperventilation is dangerous. The patient must be sitting down.

1. Perform the preliminary checks (see para.6.2, Preliminaries, page 70).
2. Select a patient or register a new patient (see para.4.2, The Work/Patient Screen, page 38).
3. Click the **MVV** button.
   – The MVV screen is displayed:



4. Position a new PFT bacterial filter on the sensor.

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5. Set/check the following settings (top of the screen):
   – **Medication** - Enter medication from the pull-down menu. Note that the medication can be edited as required (see para.4.3, Editing User-Defined Drop-Down Lists, page 43).
   – **Filter** - If the bacterial filter is used, set it here.
   – **Level** - Set for pre-test/post-test.

⚠ CAUTION

▲ The measurements may not be accurate if the filter setting is not correct.

6. Instruct the patient on how to perform the test and what is expected
   – The patient should be relaxed (shoulders down and relaxed).
   – Before starting the measurement, close the patient's nasal airways with a nose clip.
7. Instruct the patient to breathe regularly and steadily until the breathing level (FRC level) is stable. This usually requires at least three tidal breathing manoeuvres.
   – As soon as a stable FRC level is reached, MVV can be measured.
8. Click the **Start** button 

9. Instruct the patient to breathe as deeply and rapidly as possible for 12 seconds).
   – Instruct the patient to keep the breathing indicator moving between the two darker blue areas of the dial. If the dial does not reach these areas, tell the patient to breathe deeper and quicker.
   – The manoeuvre time starts the test countdown from 12 seconds.

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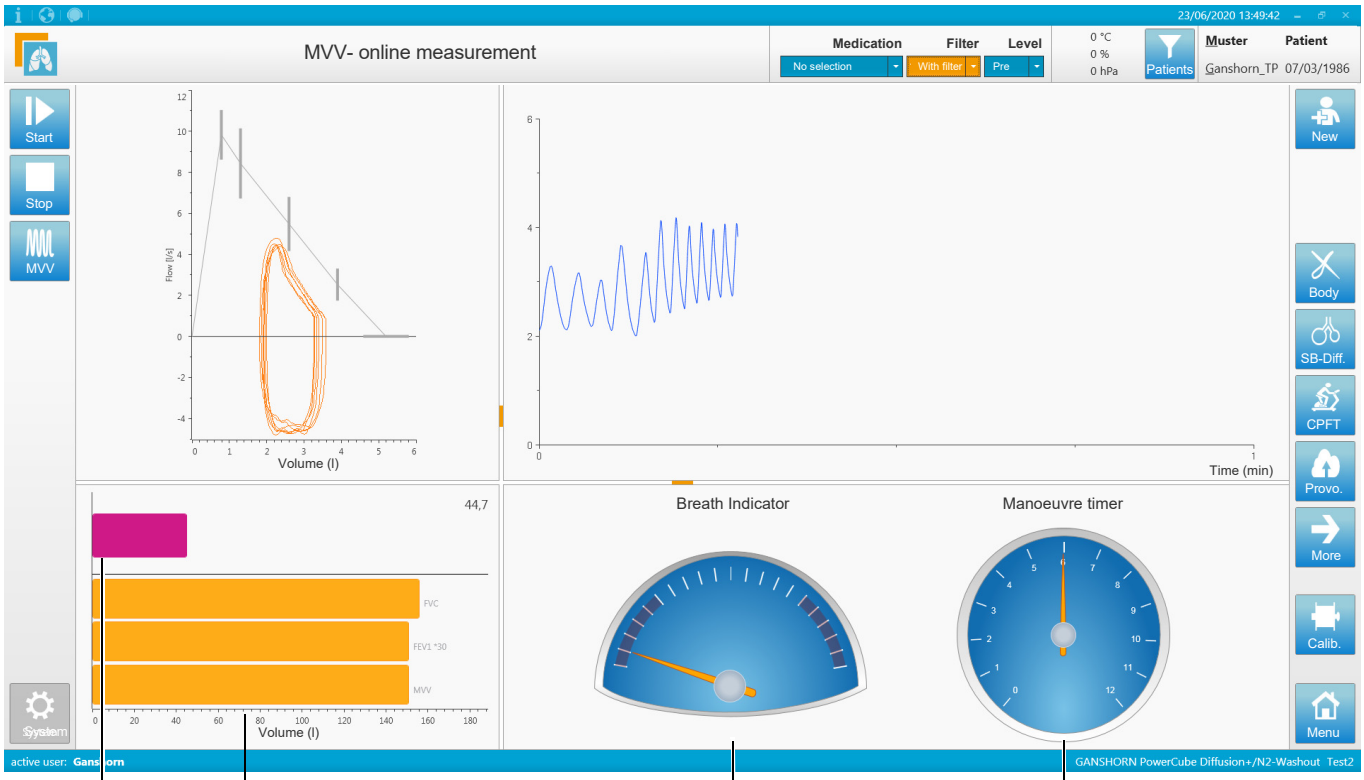
10. The test stops automatically after 12 seconds (or the time period set in MVV settings).



Reference values

Exhaled air during the test becomes longer with every breath as the exhaled air is accumulated.

Breath indicator

Manoeuvre timer

11. At the end of the test observe all cross-contamination procedures and safety notes described in the chapters:
    - 1.8 Infection control/cross contamination
    - 2.8 PFT Bacterial Filter
    - 14 Cleaning and Disinfection

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6.9 MVV Review

Reference values and actual air exhaled.

The results are extrapolated for a minute. Post and pre-waveform can be displayed as required.

In the bottom left of the screen, the three lower lines show the reference value of MVV, FEV1*30 (the reference value in most predicted values sets for MVV) and the FVC*30.

The top line shows the accumulated exhaled air during the test.

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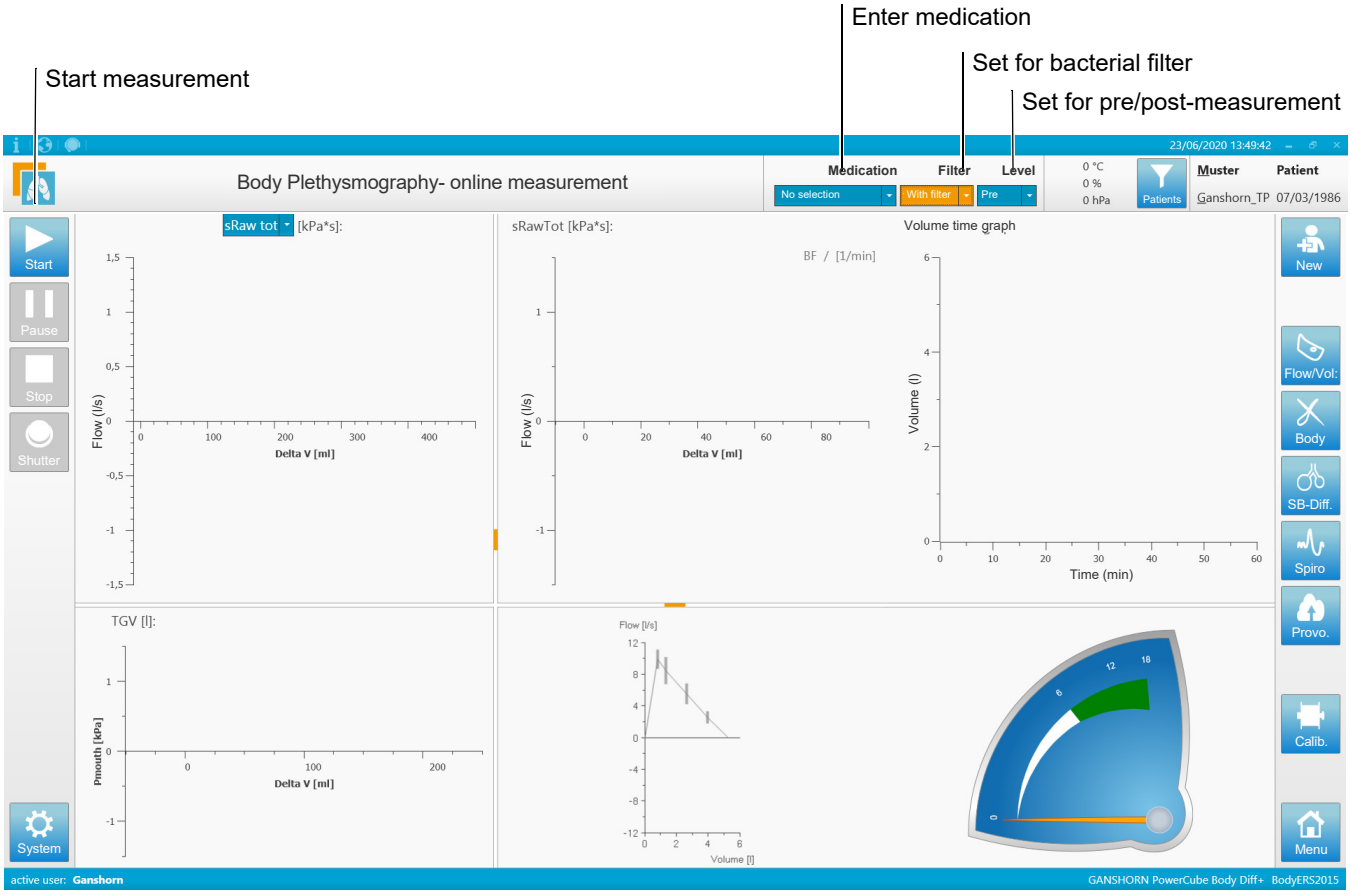
7 Body Plethysmography

7.1 Procedure

1. Perform the preliminary checks (see para.6.2, Preliminaries, page 70).
2. Select a patient or register a new patient (see para.4.2, The Work/Patient Screen, page 38).
3. Click the **Body** button.
   – The body screen is displayed



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4. Set/check the following settings (top of the screen):
   – **Medication** - Enter medication from the pull-down menu. Note that the medication options can be edited as required (see para.4.3, Editing User-Defined Drop-Down Lists, page 43).
   – **Filter** - A bacterial filter must be used; set the filter here.
   – **Level** - Set for pre-test/post-test.

⚠ CAUTION

▲ The measurements may not be accurate if the filter setting is not set.

5. Position a new PFT bacterial filter on the breathing adapter.
6. Check that the patient is comfortable either sitting or standing in the cabin. Confirm that the patient knows what is required.

▲ Being in an enclosed cabin may be disturbing for some patients. To help reassure the patient during the test:
   – Inform the patient that all instructions are given via the intercom.
   – Inform the patient that the door can be released at any time by pressing the door release button inside the cabin.

7. Close the patient's nasal airways with a nose clip and click the **Start** button to begin the measurement 

   – The message **Please close cabin door** is displayed:

Please close cabin door

8. Gently shut the cabin door until you hear the door magnets close. Push the door handle top and bottom until both door seal indicators display the three green LEDs.

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9. Instruct the patient to breathe regularly and steadily until the breathing level (FRC level) is stable.
   – A sufficient number of tidal breaths must be performed at the beginning of the measurement. Forced breathing manoeuvres can influence the tidal breath position.
   – Before starting the manoeuvre, the patient should perform at least 6 to 7 tidal breaths.
   – In many cases, the first breaths of a patient lead to invalid measuring values.
   – Restart the measurement if necessary.

10. After acquiring sufficient tidal breaths to determine the tidal breathing position and resistance, start the TGV manoeuvre.

11. TGV manoeuvre. As soon as a stable breathing level is reached and the breathing is steady and repeatable, the **Shutter** button becomes active.
12. Warn the patient that the test is going to begin and click the **Shutter** button:
   – Guide the patient to breathe normally at the same speed against the occlusion.
   – The shutter is automatically triggered at the end of expiration.
   – A TGV curve is displayed on the screen.
   – An FVC manoeuvre can be performed after the shutter has been opened if required.

13. Click the **Stop** button to end the measurement. The results of the measurement are shown.
14. Repeat the test at least three times:
   – Select **Add trial** to take a new trial to add to the measurement.

- After starting, the **Start** button changes to **Restart**. This button can be used to restart the measurement, erasing any data of the running measurement; saved measurements are not erased.
- Instruct the patient to breathe a little faster if the resistance loops are too small or irregular. Good resistance loops require a sufficiently high respiratory flow.
- Check the patients breathing during the TGV manoeuvre: apnoea, removing the mouthpiece from the mouth, too high or too low pressure may falsify the measured values and leads to very different closing pressure curves.

15. At the end of the test observe all cross-contamination procedures and safety notes described in the chapters:
   – 1.8 Infection control/cross contamination
   – 2.8 PFT Bacterial Filter
   – 14 Cleaning and Disinfection

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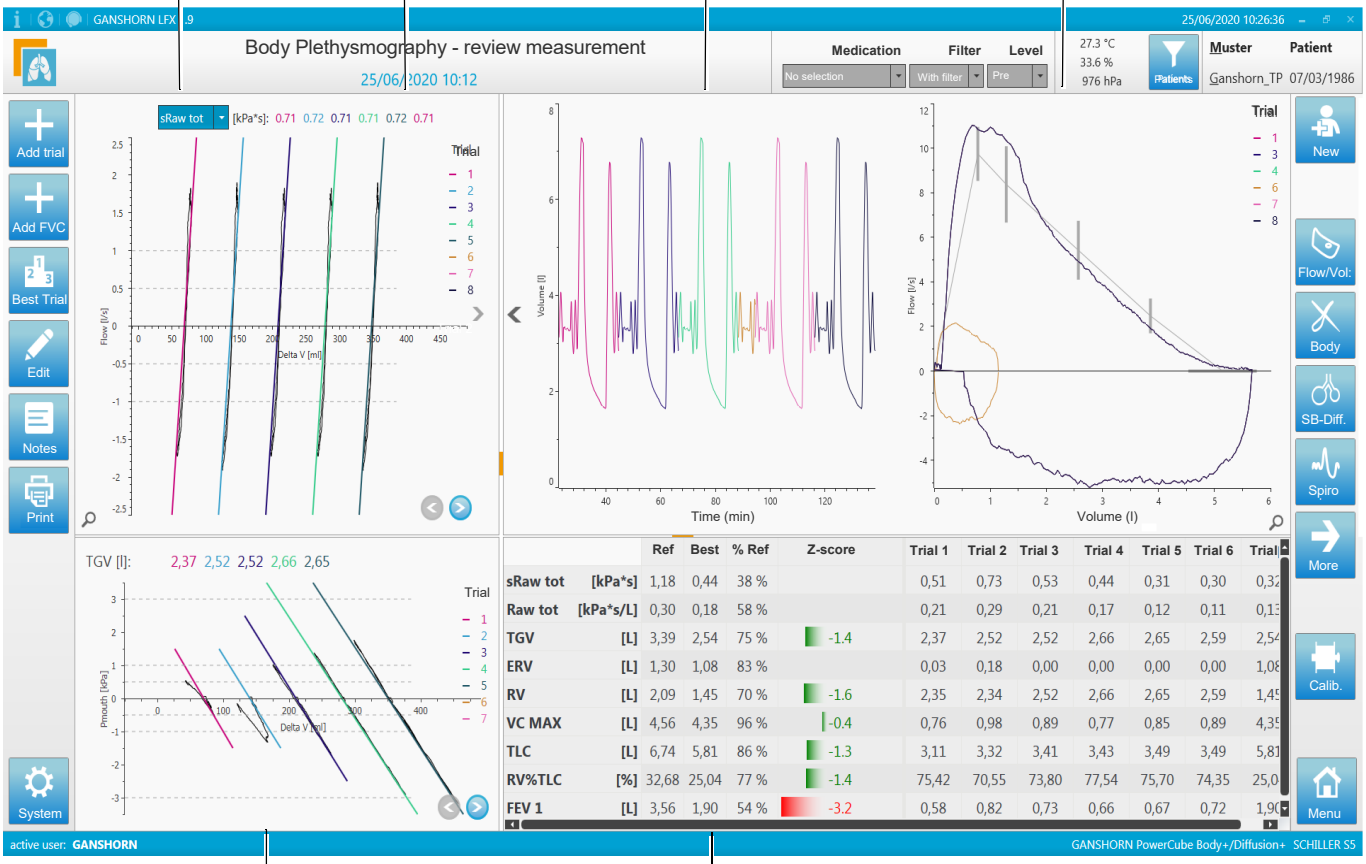
7.2 Body Plethysmography Review

Airway resistance calculation method (see below)

Resistance loops best trials of sRAW loops

Volume trials. All trials of Spirometry performed after each TGV manoeuvre.

FV trials. All trials of forced Spirometry performed after each TGV manoeuvre.



TGV trial

Tabular results of the FV trials

Volume displacement is calculated from the cabin pressure change. The review measurement screen gives tabular and graphical results of resistance, lung volume and FV trials.

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Thoracic Gas Volume

The numeric value of a Thoracic Gas Volume (TGV) manoeuvre is indicated directly above the point where the curve crosses the zero line.

- X-axis = Delta V (ml) volume displacement (cabin pressure)
- Y-axis = PM (mouth pressure)
- Grey line Calculated regression line

Resistance Loops

- X-axis = Delta V (ml) volume displacement (cabin pressure)
- Y-axis = Flow

Notes

The defaults are defined in settings (see para.13.1, Body Plethysmography, page 129).

- The following airway resistance can be selected:
  - sRaw tot
  - SRaw eff
  - sRaw mid
  - sRaw peak
  - sRaw 0.5

Best Trial Determination

- The median or average can be selected.

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7.2.1 Editing the Recording and View Measurements

The recording can be edited by clicking the **Edit** button 

(previous page).

When the **Return** button is clicked, edited changes are saved.

The Total Lung Capacity (TLC), Tidal Volume (VT) and Residual Volume (RV) levels of the selected trial are shown relative to the TGV measurement and can be edited by moving the marker. The trial to which the values relate is selected in the measurement table (see below). The values that are influenced are changed simultaneously in the tabular results.

		Ref	Pre	% Ref	Z-score	Trial 1	Trial 2	Trial 3
sRaw tot	[kPa*s]	1,18	0,62	53 %		0,67	0,62	0,62
Raw tot	[kPa*s/L]	0,30	0,15	51 %		0,16	0,15	0,15
TGV	[L]	3,39	4,06	120 %	1.1	4,12	3,99	4,06
ERV	[L]	1,60	1,70	106 %		0,73	0,59	1,70
RV	[L]	1,79	2,36	132 %	1.4	3,39	3,40	2,36
VC MAX	[L]	5,49	6,36	116 %	1.6	1,41	1,18	6,36
TLC	[L]	7,30	8,72	119 %	2.0	4,80	4,58	8,72
RV%TLC	[%]	25,66	27,06	105 %	0.3	70,71	74,22	27,06
FEV 1	[L]	4,38	5,08	116 %	1.4	-	-	5,08

The editing slope of the flow and the TGV trial can be edited. Click the slope. Circles appear either end of the slope and the line can be moved as required (see the next page).

Tabular results change according to edited changes.

Click the trial to select the trial on which the TGV, VT etc is based (and shown in top right segment (see the next page).

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When the **Return** button is clicked, edited changes are saved.

When **Hide** is checked, the measurement is taken out of the averaged calculation, e.g. if the measurement is incorrect and cannot be edited and is shown as a dotted line.

Select the trials for calculation and viewing. At least one trial must be selected. Deselected trials are not shown in the measurements table (bottom right segment). If the trial on which the TGV/VT level is based is deselected, the lines are not displayed and cannot be edited.

Circles indication edit mode. The line can be moved and rotated as required. The (edited) TLC, VT and RV values in the top right of the graphic and the measurement table change according to the edit.

Reset edits

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8 Single Breath Diffusion

8.1 Safety

⚠ WARNING

- ▲ **Carbon Monoxide**. Carbon monoxide can be dangerous even in small amounts when inhaled over time.
- ▲ Always close the main valve of the gas bottle after use.
- ▲ Improper handling of pressurised gas bottles creates a potential danger. Check that the gas bottle is secure and cannot fall over.
- ▲ Before using the gas mixture, check the values of the individual gas components to confirm that they are as required for the test. Never work with gas bottles without the individual analysis certificate.
- ▲ Gas bottles are subject to safety inspections.

⚠ CAUTION

Repetition of CO-Diffusion Measurements

- ▲ CO is harmless to health in low amounts and washed out of the blood while breathing. However, it replaces the oxygen in the blood due to its high affinity to haemoglobin. A repetition of the CO diffusion measurement should only be performed after a lapse of a minimum of 4 minutes. The half-life of CO in the blood amounts to several hours, and within one hour, no more than three CO-Diffusion measurements should be performed. If a headache is experienced due to a lack of oxygen, the patient can accelerate the CO wash-out by exercising in the fresh air.

The single breath diffusion procedure detailed is the same for both standalone diffusion installations or when the diffusion sensor is incorporated with body plethysmography. The picture below shows a patient in the body plethysmography cabin, but it is equally applicable to all installations.

8.2 Procedure

The PowerCube+ Series gas analyser system requires a warm-up time of 30 minutes before the first test can be performed.

1. Perform the preliminary checks (see para.6.2, Preliminaries, page 70).
2. Make sure that the pressure regulator of the gas bottle is open.
   – Verify that the output pressure is a minimum of 6 bar.
3. If this is the first trial of the day, perform a gas calibration (see para.5.6, Diffusion Gas (He/CO), page 59)
4. Select a patient or register a new patient (see para.4.2, The Work/Patient Screen, page 38).
5. Click the **SB-Diff** button (single breath diffusion). The diffusion screen is displayed, or a calibration message is displayed:

> The last gas sensor calibration was performed more than xx hours ago. You need to perform a calibration to obtain correct results. Do you want to calibrate the gas sensors now?

6. Calibrate the system if required (see para.5.6, Diffusion Gas (He/CO), page 59).

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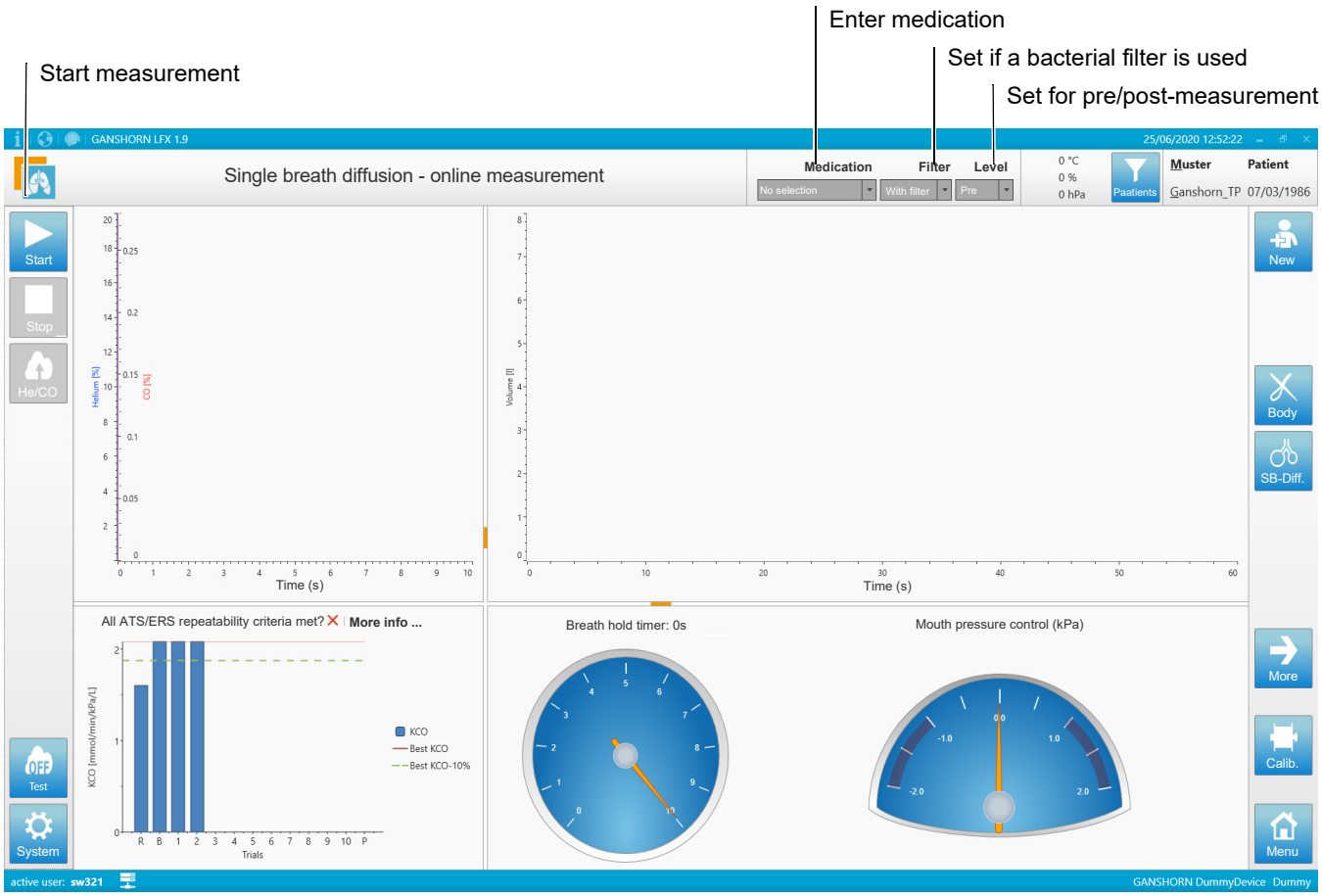

7. Set/check the following settings (top of the screen):
   - **Medication** - Enter medication from the pull-down menu. Note that the medication can be edited as required (see para.4.3, Editing User-Defined Drop-Down Lists, page 43).
   - **Filter** - A new PFT bacterial filter must be used for all patients; set it here.
   - **Level** - Set for pre-test/post-test.

⚠ CAUTION

▲ The measurements may not be accurate if the filter setting is not correct.

▲ During this test, a low percentage of Carbon monoxide is inhaled by the patient.

8. Position a new PFT bacterial filter on the breathing adapter.
9. Check that the patient is comfortable sitting in or out of the cabin. Confirm that the patient knows what is required. Close the patient's nasal airways with a nose clip.

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10. Start the measurement - Click the **Start** button
    - Instruct the patient to breathe regularly and steadily until the breathing level (FRC level) is stable.
    - The program monitors the breathing (breath indicator), and the flow is displayed on the screen.

11. After four or more tidal breathing manoeuvres, instruct the patient to perform a Slow Vital Capacity (SVC) manoeuvre to ensure a stable FRC.
    - Fully empty lungs until a plateau appears on the graph (the lowest point has been briefly maintained), then,
    - Fully fill the lungs until it is at the maximum point, and check that the patient maintains an upright position and that there is a good seal around the mouthpiece (this does not need to be a forced inspiration).
    - Empty the lungs again until the plateau has been reached again.
    - The patient should then go back to normal tidal breathing.

The operator may decide not to perform an SVC test before the test starts to ensure a stable FRC level. Importing a previous or later performed separate SVC measurement is also possible. Importing SVC measurements can be completed in **Edit** mode.

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Gas Inhalation/Breath Hold Manoeuvre

12. **Gas inhalation/Breath hold manoeuvre**
    - As soon as a stable breathing level is reached and the breathing is steady and repeatable, the **Gas** button, **He/CO,** becomes active.
    - Instruct the patient to fully and completely exhale, inhale a single breath as quickly and as fully as possible[1] and then hold the breath for 10 seconds. During the exhalation, click the **Gas** button **He/CO** so that when the patient maximally inhales, the patient breathes in all the He/Co gas from the gas supply.
    - After inhalation, instruct the patient to hold the breath for 10 seconds for quality control, the clock counts from 10 down to 0, and the control panel shows the pressure during the occlusion.
    - After 10 seconds, instruct the patient to exhale and breathe normally.
    - At an occlusion pressure above 3 kPa, the system automatically stops measuring.

Hold the breath timer, the patient holds their breath for 10 seconds while the breath hold timer is counting.

Mouth Pressure meter - gauge must be kept between the -1 and +1, i.e. not go into the dark blue area whilst the breath is being held.

A setting is available (see para.13.17, Single Breath Diffusion, page 143) for patients who cannot hold their breath for a prolonged period. When this is set, the diffusion test is performed without a breath hold, and the patient must exhale very slowly.

1. Based on the ATS/ERS guidelines, the inhalation should be at 90% within a max of 2 seconds of inhalation.

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13. Click the **Stop** button to end the measurement. The results of the measurement are shown.
14. Repeat the test up to three times.

If a subsequent test is requested and it is less than 4 minutes since the last test, a warning message is displayed:

> Warning: Patient has inhaled test gas in the last four minutes.
>
> The ATS/ERS guidelines recommend to wait for at least four minutes between tests. Do you want to run anyway?

15. At the end of the test observe all cross-contamination procedures and safety notes described in the chapters:
    - 1.8 Infection control/cross contamination
    - 2.8 PFT Bacterial Filter
    - 14 Cleaning and Disinfection

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8.3 Single Breath Diffusion Review

Best trial (see the note below)

Click to toggle the view between the time scale of the sample segment or the time scale of the sample segment with a pre-sampling tidal breathing curve.

Trials 1, 2 and 3 are displayed as selected.

		Ref	Best	% Ref	Z-score	Trial 1	Trial 2	Trial 3
DLCO	[mmol/min/kPa]	12.12	15.48	128 %	2.4	16.96	15.48	14.21
DLCOc	[mmol/min/kPa]	12.12	14.88	123 %	2.0	16.31	14.88	13.66
KCO	[mmol/min/kPa/L]	1.66	2.64	159 %	2.4	2.90	2.68	2.53
VA	[L]	7.15	5.86	82 %		5.86	5.77	5.61
TLC	[L]	7.30	6.03	83 %	-1.8	6.03	5.94	5.78
VC IN	[L]	-	4.86	-		4.86	4.76	4.66
RV	[L]	1.75	0.01	0 %	-4.2	0.01	1.18	1.12
FRC	[L]	3.37	3.69	109 %	0.5	3.69	4.33	4.27
RV%TLC	[%]	24.90	0.12	0 %	-4.5	0.12	19.86	19.34

Quality control showing the summary of all Single Breath trials:

- R = Reference trial
- B = Best-trial
- 1, 2 .. = Trial
- P = Post-trial

The repeatability is displayed when more info is clicked (see the next page)

Tabular results

Display time/volume

For each graph:

- The blue line shows the He curve.
- The red line shows the CO curve.
- The grey line shows the volume curve.
- The green vertical marker shows the VD and VS points. These can be edited (see the next page).

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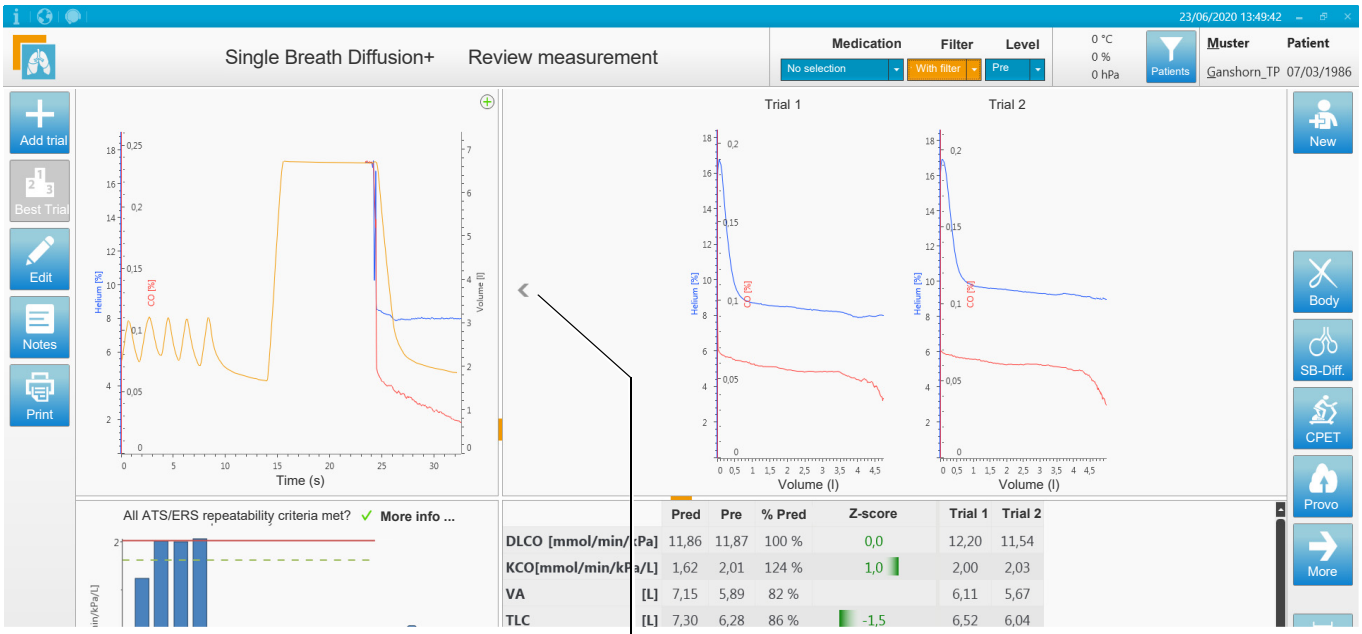
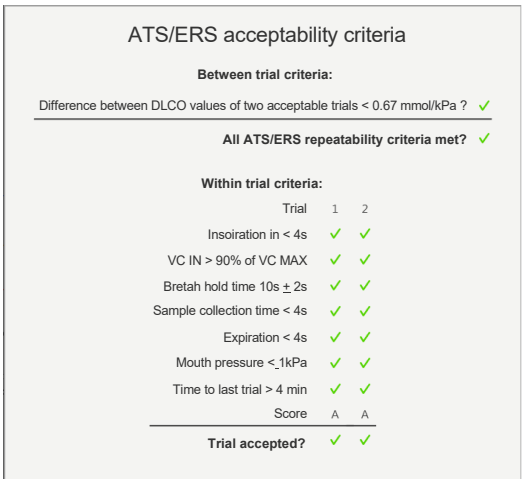
Volume Display



Click the arrow by the side of the screen to toggle between the time/volume graphs

Repeatability

When **More info ..** is clicked in the repeatability box (bottom left), details of the repeatability criteria are given:



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8.3.1 Editing the Recording

Click the **Edit** button to display the edit screen. The edit screen shows an enlarged graph of the trial screen. The sample gas measuring start time Volume Dead space (VD) and the volume of expired gas measured as Volume of Sampled gas (VS) is displayed in the top right of the screen.

The vertical green bar represents the sample space where the expired gas is the sample and the expired sample volume (bar width).

Select the trials for calculation and view. At least one trial must be selected. Deselected trials are not shown in the measurements table.

The trial on which the levels are based (and selected in the measurement table below (by clicking on the header (Trial 1, Trials 2 . .))

Edit VD

Edit VS

		Ref	Post	% Ref	Z-score	Trial 1	Pre	Pre%Post
DLCO	[mmol/min/kPa]	11,99	19,00	158 %	5.0	19,00	12,87	48%
KCO	[mmol/min/kPa/L]	1,64	2,61	159 %	2.4	2,61	1,68	55%
VA	[L]	7,15	7,29	102 %		7,29	7,67	-5%
TLC	[L]	7,30	7,46	102 %	0.2	7,46	7,84	-5%
VC IN	[L]	5,49	5,86	107 %	0.7	5,86	5,59	5%
RV	[L]	1,79	1,58	88 %	-0.5	1,58	2,26	-30%
FRC	[L]	3,39	3,93	116 %	0.9	3,93	4,94	-20%
RV%TLC	[%]	25,66	21,16	82 %	-0.8	21,16	28,75	-26%

Tabular results are recalculated as the VD and VS values are edited.

Click on **Trial** to use in the edit screen above.

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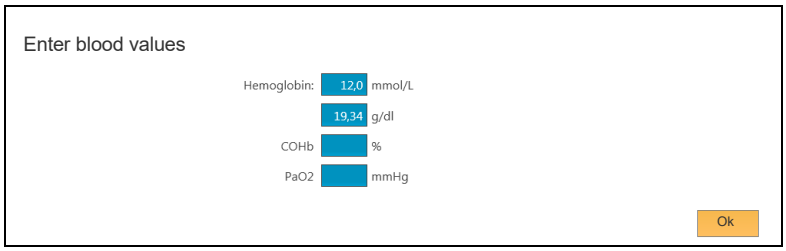
Editing the Dead Space and Expired Gas Volume

The dead space (where the expired gas is sampled) and the expired gas volume are edited with the up/down arrows by the side of the VD and VS volumes indicators. The green vertical bar is representative of VD and VS and changes as the values are edited. The measured values for trial 1 are also recalculated as the measuring point, and the sampling volume is changed.

When the edit screen is exited, the VD and VS points are remembered and reflected in the review screen.

Entering Haemoglobin Blood Values

When the **Blood** button is clicked, manually measured blood levels can be entered:



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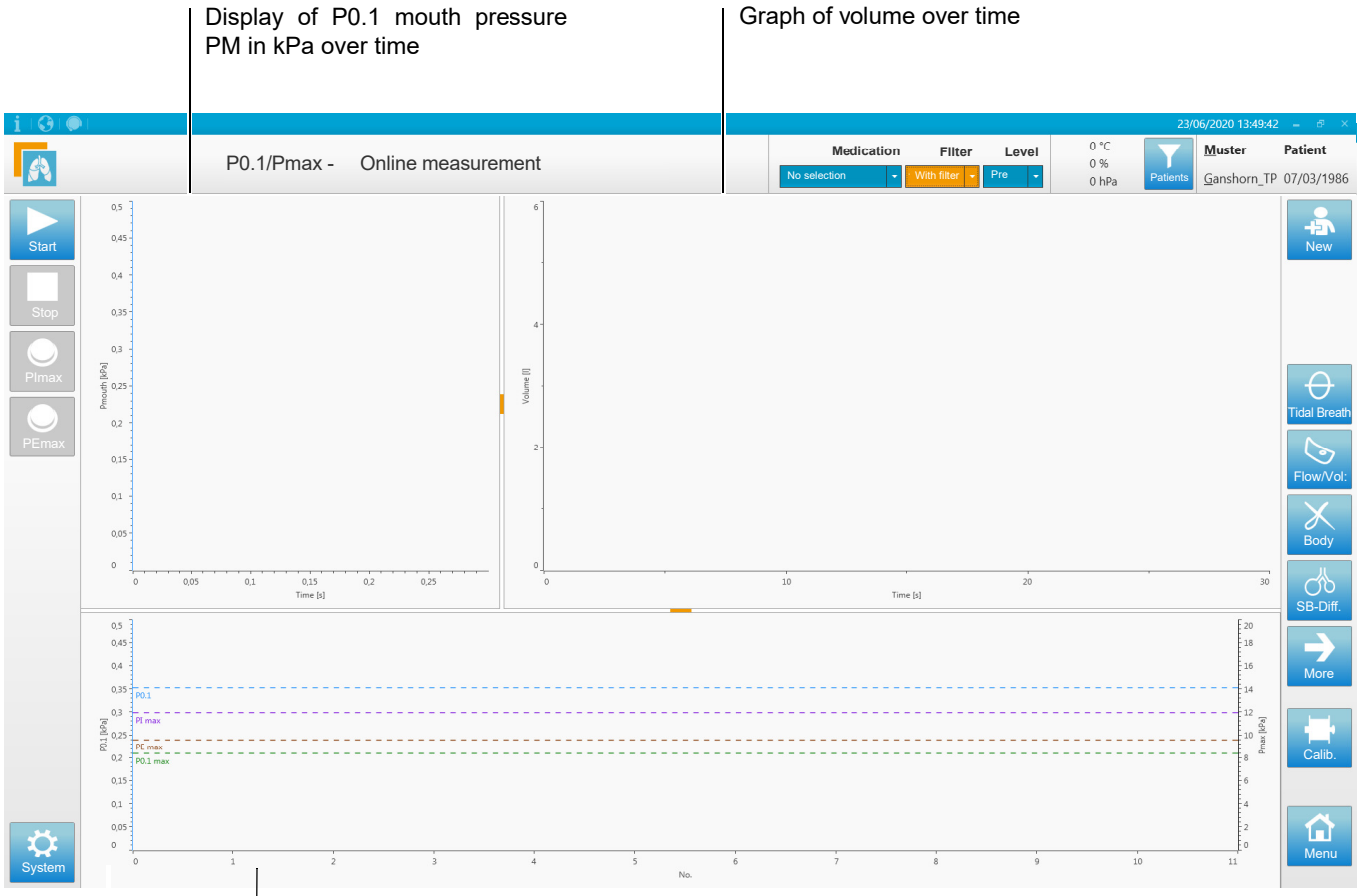
9 P0.1/Pmax

9.1 System Preparation

P0.1/Pmax measurements need a shutter unit. When working with the PowerCube Body+, the measurement can be performed with the cabin door open. The system preparation may change according to the GANSHORN system hardware used.

9.2 Procedure



1. Attach a new mouthpiece or PFT bacterial filter and perform the preliminary checks (see para.6.2, Preliminaries, page 70).
2. Select a patient or register a new patient (see para.4.2.1, Patient and Worklist Search, page 39).

3. Click the **P0.1/Pmax** button. The initial P0.1/Pmax screen is displayed.
4. Click the **Start** button to begin the test
   - The P0.1 measurement demands steady, slightly accelerated tidal breathing.
   - Data acquisition begins with the next exhalation.

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5. Check tidal breathing on the display and perform the shutter closures:
   – Start the measurement by determining the tidal breathing position (approx. 10 breaths), then click **Shutter** at random intervals to trigger the shutter.
   – Try to perform the shutter closures simultaneously in the breathing flow.
   – The patient should not be able to guess when the shutter closes next.
   – The shutter shuts off the patient's breath for 0.1 seconds at the beginning of the next inhalation.
   – The patient inhales involuntarily (not consciously or forced) against the shutter.
   – Let the patient breathe normally at least 3 to 5 times between two manoeuvres.
   – The patient must breathe steadily. Check the screen for optimum flow.
   – Perform a minimum of 3 manoeuvres with similar results before ending the measurement.

6. The measurement ends automatically after 10 shutter closures or **Stop** is clicked.

Performing Pmax Manoeuvres

▲ The breathing manoeuvre for Pmax measurement can be exhausting for the patient. Therefore, it is not normally possible to perform it more than once or twice.

1. Click the **Pimax** or **Pemax** icon.
2. Determine the tidal breathing position and check that a good technique is obtained from the patient (approx. 10 breaths).
3. Click **Start** to begin the test.
4. Perform the test:
   – Check that the patient breathes deeply and calmly through the mouthpiece before you initiate the Pmax manoeuvre.
   – **Pemax** - instruct the patient to breathe normally and then exhale maximally (until ERV).
   – **Pimax** - instruct the patient to breathe normally and then inhale maximally (until IRV).
   – Press the **Pemax/Pimax** icon to activate the shutter:
   – The shutter shuts off the airflow for approx. 2 seconds (the default) with the next inhalation/exhalation. The patient should exhale (Pemax) or inhale (Pimax) as quickly and with as much effort as possible against the shutter immediately after reaching the point where the breathing direction changes.
   – After performing the upward slope of the Pmax curve, check that the waveform is very steep (indicates good patient cooperation). Pemax/Pimax values that are significantly different from the predicted values are normally due to slow Pmax breathing manoeuvres and may indicate a lack of patient cooperation
   – Coach the patient during the manoeuvre by giving suitable instructions.

5. Check the quality of the manoeuvre and repeat the measurement if necessary.
6. When **Stop** is clicked, the best (maximum) result is saved.
7. At the end of the test observe all cross-contamination procedures and safety notes described in the chapters:
   – 1.8 Infection control/cross contamination
   – 2.8 PFT Bacterial Filter
   – 14 Cleaning and Disinfection

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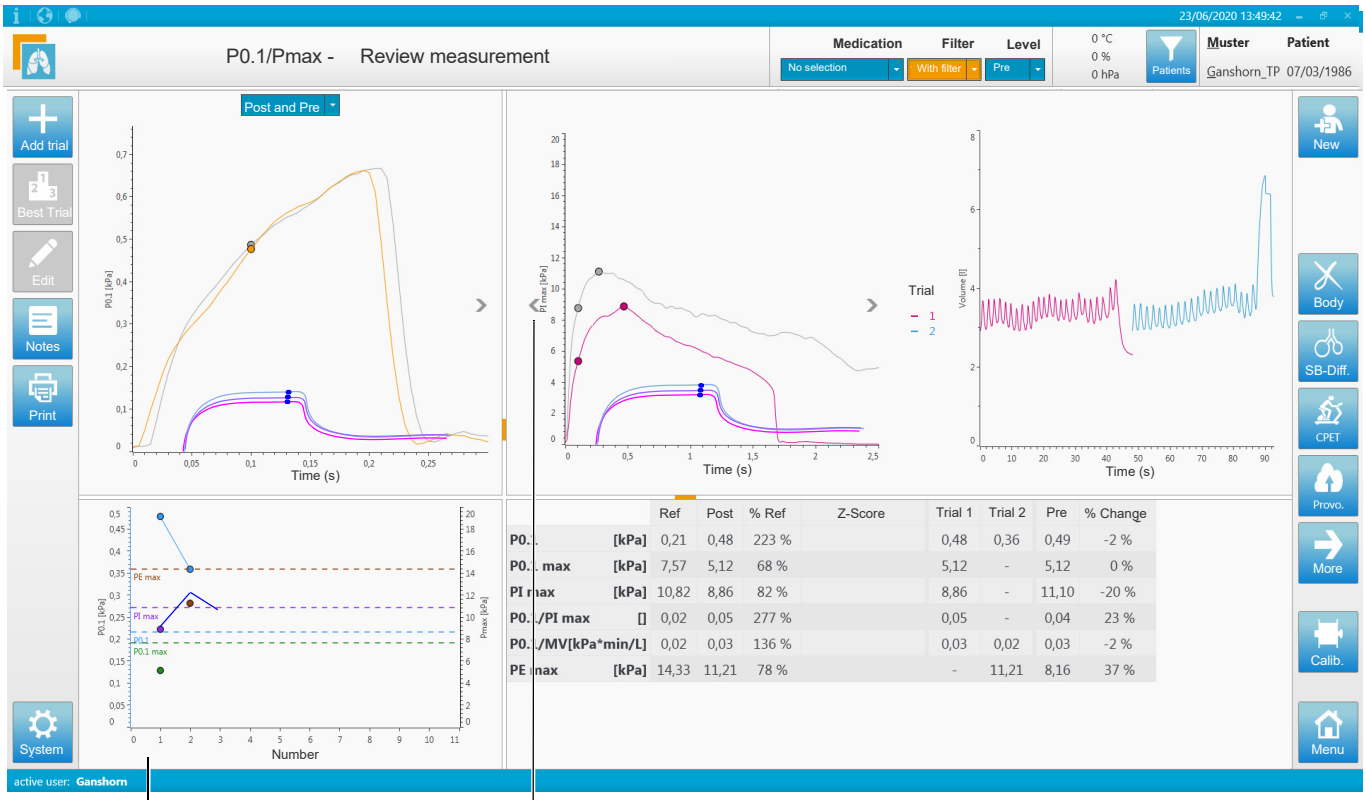
9.3 P0.1/Pmax Review



– X-axis number of shutter closures (measurements)
– Y-axis P0.1 in kPa

Toggle between P0.1 and Pmax

Notes:

- It is possible to display up to 10 manoeuvres.
- Pimax is the determined maximum inspiratory pressure.
- P0.1max is the maximum P0.1 value determined during the Pimax manoeuvre.

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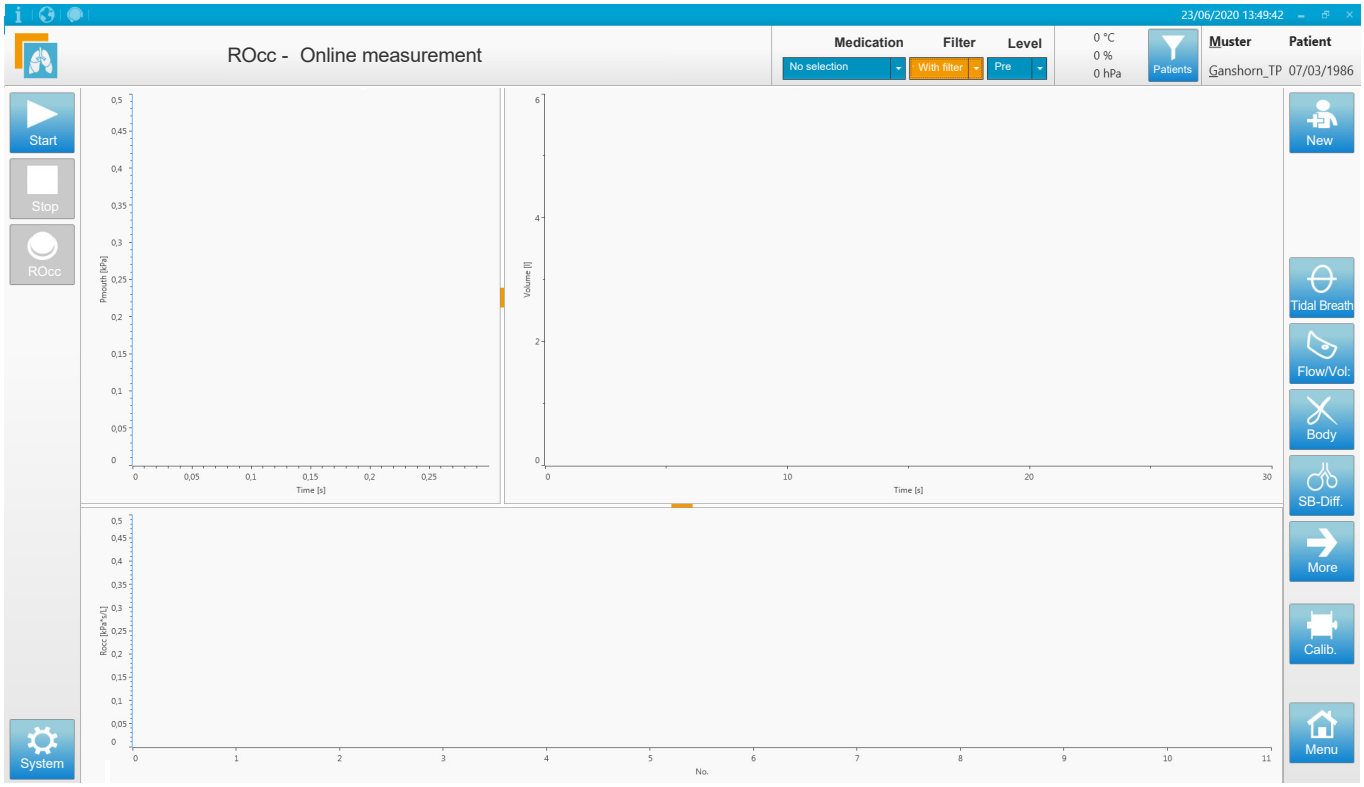
10 ROcc

10.1 System Preparation

ROcc measurements require a shutter unit incorporated with the sensor. When working with the PowerCube Body+, the measurement can be performed with the cabin door open. The system preparation may change according to the GANSHORN system hardware used.

10.2 Procedure



1. Attach a new mouthpiece or PFT bacterial filter and perform the preliminary checks (see para.6.2, Preliminaries, page 70).
2. Select a patient or register a new patient (see para.4.2.1, Patient and Worklist Search, page 39).

3. Click the **ROcc** icon. The initial recording screen is displayed.

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4. Click **Start** to begin the test:
   - Data acquisition begins with the next exhalation.
   - Instruct the patient to breathe in and out deeply and steadily.
   - The ROcc manoeuvres can be triggered manually or automatically, depending on the system configuration.
   - When the flow is sufficient, the shutter triggers a closure.
   - No closure is triggered when breathing is too shallow (< 1 l/s). Check that the necessary flow speed is reached.
   - The measurement ends automatically after 10 shutter closures or when Stop is selected.
5. At the end of the test observe all cross-contamination procedures and safety notes described in the chapters:
   - 1.8 Infection control/cross contamination
   - 2.8 PFT Bacterial Filter
   - 14 Cleaning and Disinfection

10.2.1 ROcc Review

Averaged display of the ROcc manoeuvres (PMouth over time)

Display of the ROcc manoeuvres with the reference value

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11 Nitrogen Washout

The nitrogen washout test is used to calculate the functional residual capacity of the lungs and airflow and the Lung Clearance Index (LCI). The patient inhales pure oxygen, and the residual nitrogen is measured.

11.1 Safety

⚠ WARNING

- ▲ Check that the room is well-ventilated.
- ▲ Never use grease or oil on the valve or any hose connection.
  - – Pure oxygen at high pressure can react violently with common materials, such as oil and grease.
- ▲ Check that the hoses and valves are kept in good condition. A leaking valve or hose in a poorly ventilated room or confined space can quickly increase the oxygen concentration to a dangerous level.
- ▲ If using a gas bottle:
  - – Always close the main valve of the gas bottle after use.
  - – Improper handling of pressurised gas bottles creates a potential danger. Check that the gas bottle is secure and cannot fall over.
  - – Never work with gas bottles without the individual analysis certificate.
  - – After exchanging a gas bottle, check the certificate against the gas specification.
  - – Gas bottles are subject to safety inspections.
- ▲ If using the hospital O_2 supply port:
  - – Always close the main valve port after use.

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The nitrogen washout procedure is the same for both standalone installations or when the washout sensor is incorporated with body plethysmography. The pictures show the patient in the body plethysmography cabin but are equally applicable to all installations.

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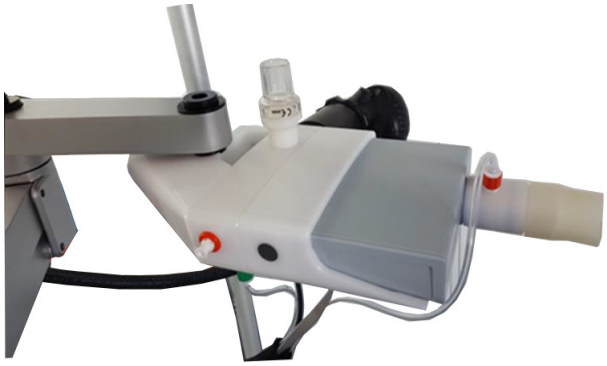
11.2 Equipment

For the nitrogen washout option, the shutter unit is adapted to include a valve assembly in the upper part of the shutter assembly. A rubber cap must be removed for nitrogen washout measurements:

The rubber cap is in place for all measurements (except nitrogen washout)



The rubber cap is removed for nitrogen washout measurements

11.3 Procedure

The PowerCube+ Series gas analyser system requires a warm-up time of 30 minutes before the first test can be performed.

1. Perform the preliminary checks (see para.6.2, Preliminaries, page 70).
2. Remove the rubber cap on the sensor (see above).
3. Open the valve of the pressure regulator on the O_2 gas bottle.
   – Verify that the output pressure is a minimum of 5 bar.
4. If this is the first trial of the day, perform a gas calibration (see para.5.7, Nitrogen Washout Gas (O_2), page 63)
5. Select a patient or register a new patient (see para.4.2, The Work/Patient Screen, page 38).
6. 

Click the **N2 washout** button. The N2 washout screen is displayed, or a calibration message is displayed:

   > The last gas sensor calibration was performed more than xx hours ago. You need to perform a calibration to obtain correct results. Do you want to calibrate the gas sensors now?

7. Calibrate the system if required (see para.5.7, Nitrogen Washout Gas (O_2), page 63).

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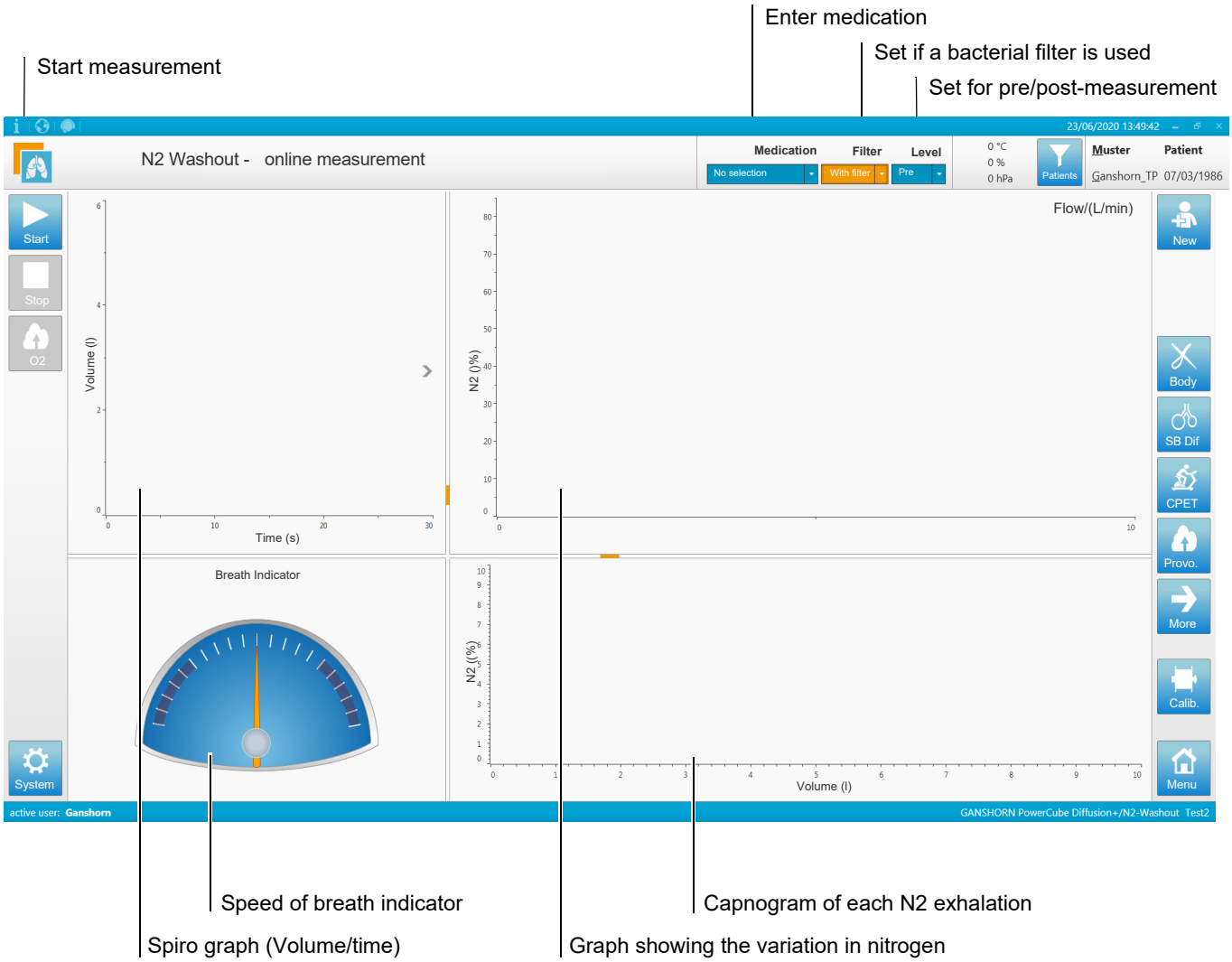

8. Set/check the following settings (top of the screen):
   - **Medication** - Enter the medication from the pull-down menu. Note that the medication can be edited as required (see para.4.3, Editing User-Defined Drop-Down Lists, page 43).
   - **Filter** - A new PFT bacterial filter must be used for all patients; set it here.
   - **Level** - Set for pre-test/post-test.

⚠ CAUTION

- ▲ The measurements may not be accurate if the filter setting is not correct.
- ▲ During this test, pure O_2 is inhaled by the patient.

9. Position a new PFT bacterial filter on the breathing adapter.
10. Check that the patient is comfortable sitting in or out of the cabin. Confirm that the patient knows what is required. Close the patient's nasal airways with a nose clip.

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During the measurement, the mouth of the patient may feel dry; this is normal. It is recommended that the patient takes some water before starting to help alleviate any dryness in the mouth.

11. Start the measurement and click the **Start** button
    - Instruct the patient to breathe regularly and steadily until the breathing level (FRC level) is stable.
    - The program monitors the breathing (breath indicator), and the flow is displayed on the screen.

12. After four or more tidal breathing manoeuvres, instruct the patient to perform a Slow Vital Capacity (SVC) manoeuvre to ensure a stable FRC.
    - Fully empty lungs until a plateau appears on the graph (the lowest point has been briefly maintained), then
    - Fully fill the lungs until their maximum point, check that the patient remains in an upright position and maintains a complete closure of the mouth around the mouthpiece (this does not need to be a forced inspiration), then
    - Empty the lungs again until the plateau has been reached again.
    - The patient should then go back to calm, normal tidal breathing.

The operator may decide not to perform an SVC test before the test starts to ensure a stable FRC level. Importing a previous or later performed separate SVC measurement is also possible in this case. This can be completed in **Edit** mode.

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13. **Gas Inhalation**
    - As soon as a stable breathing level is reached and the breathing is steady and repeatable, the **Gas** button O_2 becomes active (blue).
    - Instruct the patient to keep the tidal breathing.
    - Check breath frequency. The breath frequency indicator should be green, and the breath volume gauge between the two dark blue areas (see the following screen view).
    - Click the **O_2** button to activate the oxygen supply.
    - The patient continues to breathe normally, and the measurement will continue for approximately two minutes until the amount of nitrogen concentration over volume per breath reaches a concentration below 2%. The measurement stops automatically when this level has been reached three consecutive times.

CAUTION

14. Replace the rubber cap on the sensor.
15. At the end of the test observe all cross-contamination procedures and safety notes described in the chapters:
    - 1.8 Infection control/cross contamination
    - 2.8 PFT Bacterial Filter
    - 14 Cleaning and Disinfection

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11.3.1 During the Measurement

Stop measurement

Breath frequency:

- Green = Correct breathing frequency
- Red = breath frequency too slow or too fast

Breath speed indicator. Keep within the middle section

Nitrogen volume graph

Accumulated exhaled volume

Nitrogen measurement for each breath

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11.4 Nitrogen Washout Review

Change of nitrogen over exhaled volume

Accumulated exhaled volume (logarithmic value)

N2 measurement for every breath showing variation of nitrogen over time

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11.4.1 Calculated and Measured Values

Calculated and measured values that can be given in the result table are as follows:

TLC **Total Lung Capacity:** the volume in the lungs at maximum inflation.

FRC **Functional Residual Capacity:** volume of air present in the lungs at the end of passive exhalation.

LCI **Lung Clearance Index:** a measure of ventilation inhomogeneity within the lung, calculated by Cumulative Exhaled Volume (L)/FRC (L).

RV **Residual Volume:** remaining air in the lungs after full exhalation.

CEV **Cumulated Exhaled Volume (exhale):** exhaled volume during the complete measurement.

VC IN **Vital Capacity (inhale)**

VC EX **Vital Capacity (exhale)**

TEX **Time Exhale:** means the exhalation time.

Scond Indices of ventilation heterogeneity in the conductive airways.

Sacin Indices of ventilation heterogeneity in the acinar airways.

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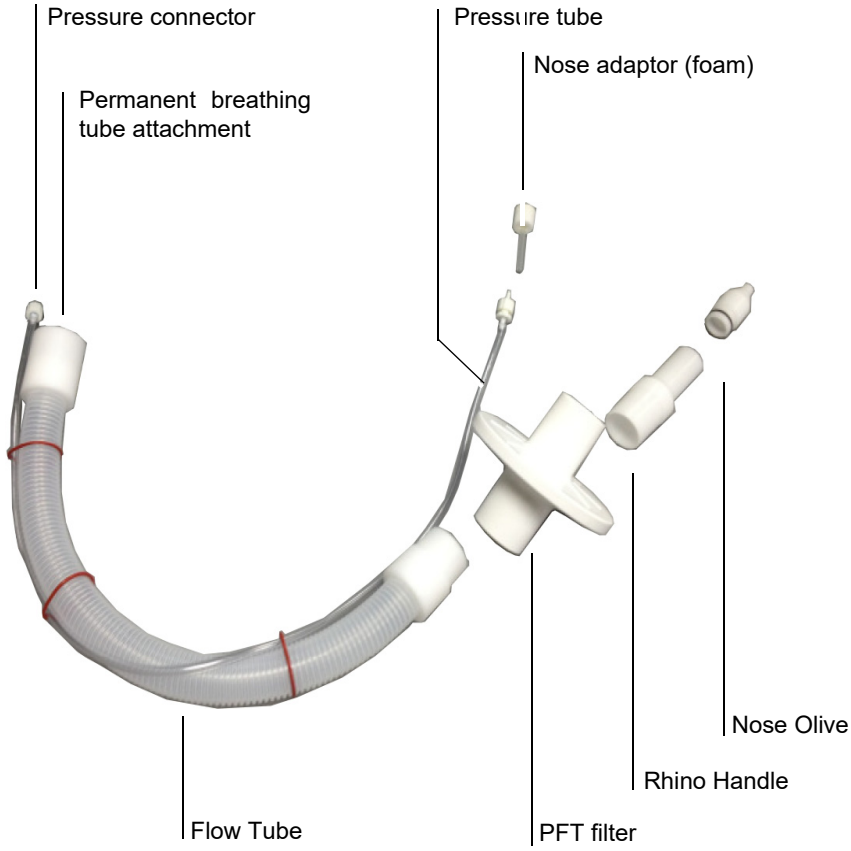
12 Rhinomanometry

12.1 Preparation

1. Attach the rhino flow tube (larger adapter) to the permanent breathing tube of the sensor.
2. Remove the black pressure hose below the ScoutSensor.
3. Attach the rhino pressure hose to the pressure hose and secure it by tuning it a quarter of a turn.
4. Attach the foam nose adapter to the pressure tube by pushing the silicone tube of the nose adapter firmly onto the connection adapter of the pressure tube.
5. Attach a PFT filter to the flow tube adapter.
6. Attach the handle to the PFT filter.
7. Attach the nose olive to the handle.



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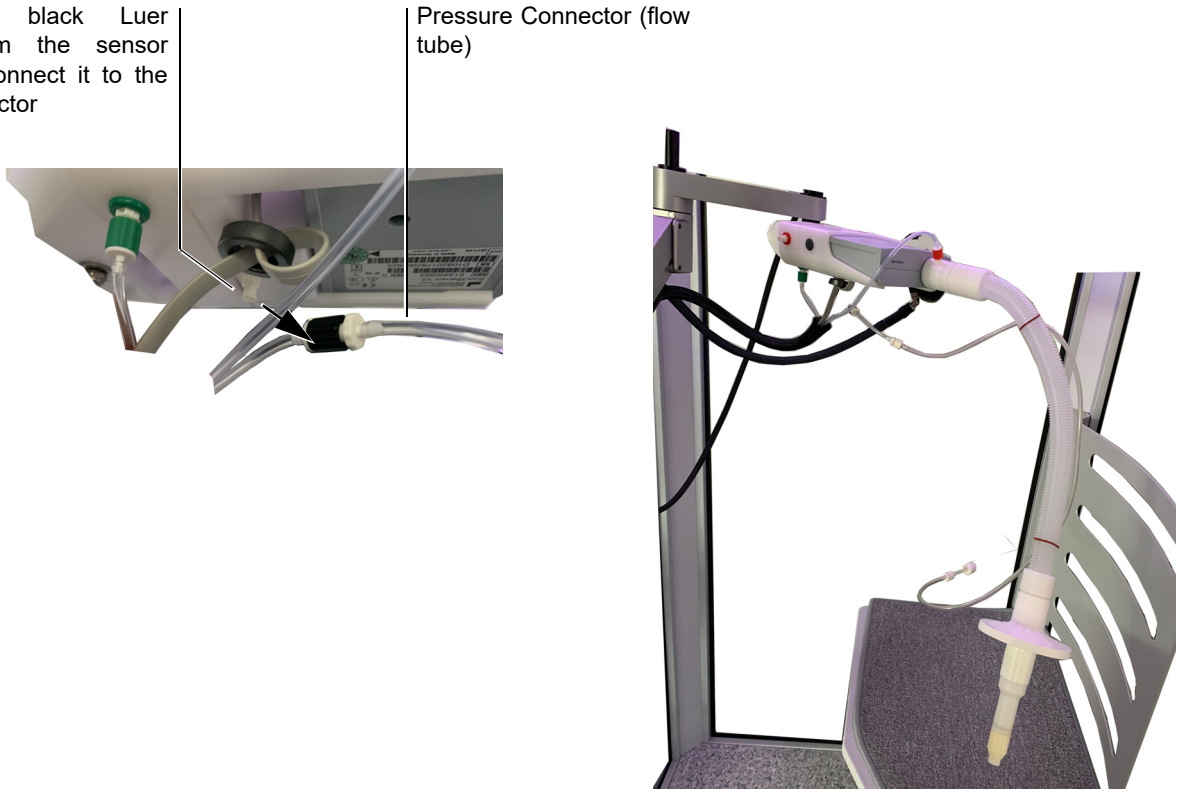

Details of the spare parts and consumables are given in the accessories section (see para.16, Accessories, page 160).

12.2 Recording Procedure

⚠ CAUTION

- ▲ The PFT bacterial filter and the foam adaptor are single-use and must be disposed of after each patient.
- ▲ Do not use it for a different patient.
- ▲ Do not clean.

1. Attach a new PFT filter, a new nose adapter and a new nose olive on the hose unit and assemble as shown on the previous page.
2. Perform the preliminary checks (see para.6.2, Preliminaries, page 70).
3. Select a patient or register a new patient (see para.4.2, The Work/Patient Screen, page 38).
4. Prepare the patient for the measurement:
   - The patient should be relaxed and have the necessary space for the measurement.
   - Explain to the patient what is measured with the test and that his active cooperation is important for the successful execution of the test.
   - Practice the breathing manoeuver with the patient and draw his attention to important points when performing it.
   - Point out to the patient that he should not speak during the measurement.

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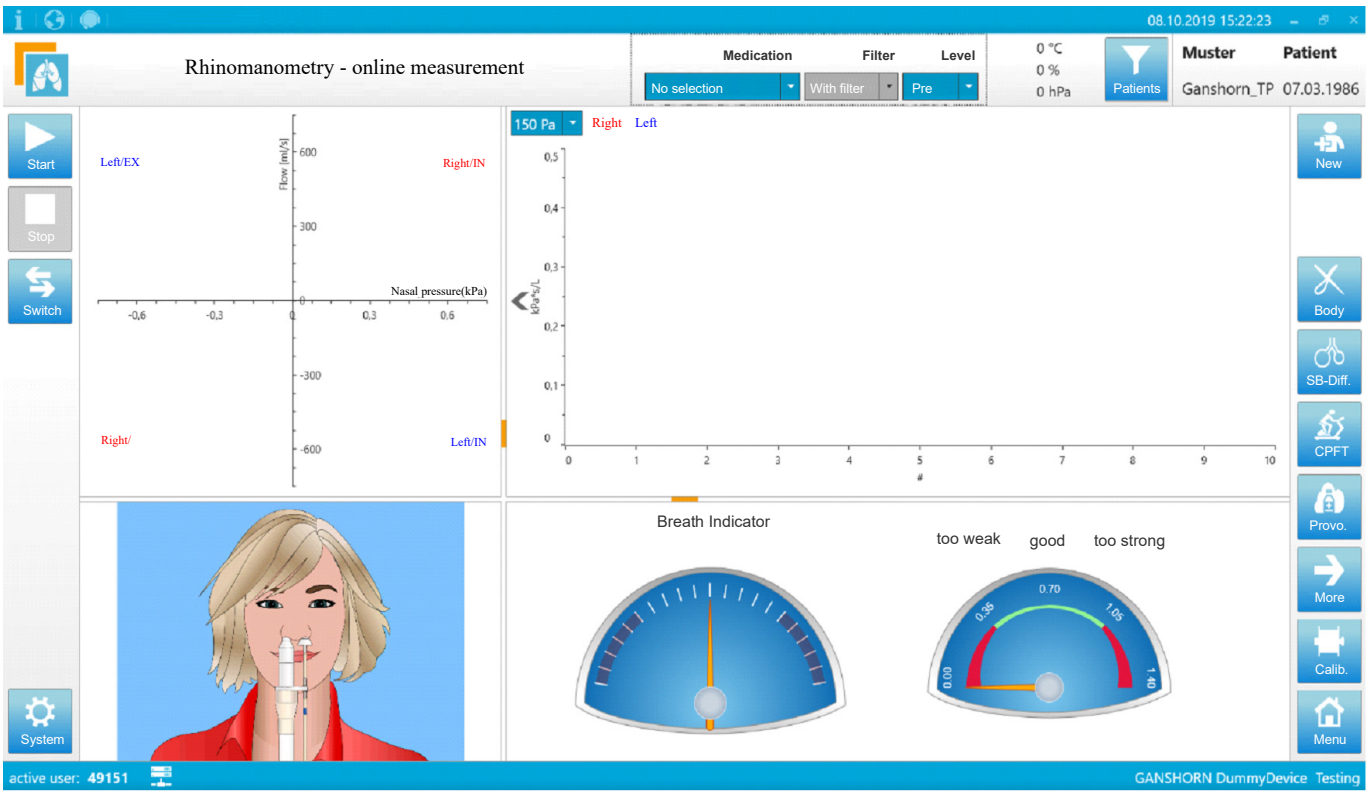
5. Insert the nose adapter (foam) into the left nostril (measuring the pressure) and the nasal olive into the right nostril (measuring the flow).
   – The patient may only breathe through the nose.

6. Click the **Rhino** button.
   – The Rhinomanometry screen is displayed:



7. Click the **Start** button 

   – Data acquisition begins with the next exhalation through the nose.
   – Instruct the patient to breathe in and out deeply and steadily.
   – For each breath, a pressure-volume loop is recorded, and the corresponding flow at the set pressure is displayed on the main screen. The pressure can be set to 75 Pa, 150 Pa, or 300 Pa. The default is 150 Pa.
   – Check the assistance screen at the bottom for guidance on the ideal breathing range of the patient.
8. After a sufficient number of stable breaths (usually 5 to 10), click the **Stop** button to end the measurement 

Auto stop can be set (in Rhino settings) to stop the trial after a defined number of breaths (between 3 and 40) have been detected within a specified tolerance (1 to 50%).

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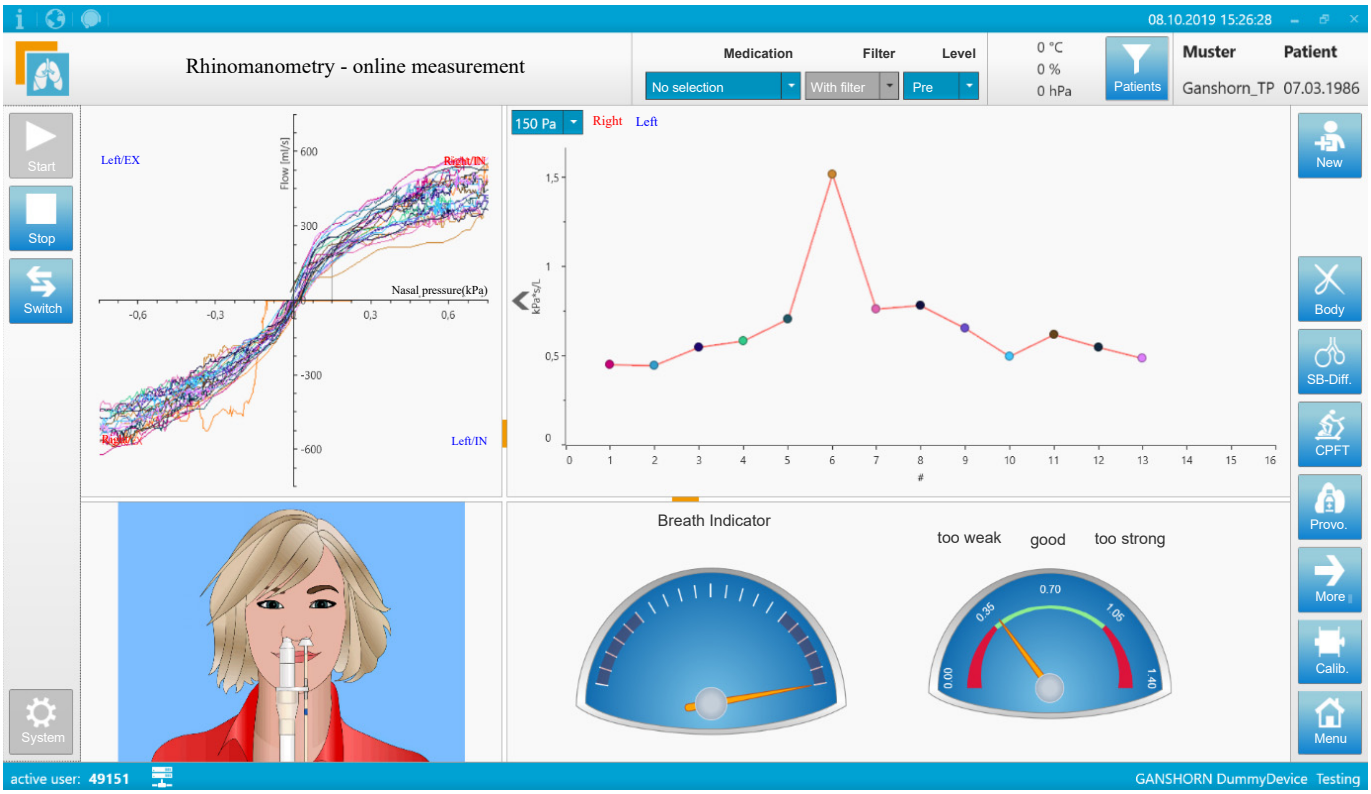

9. After a sufficient number of accepted trials have been taken and the trial is stopped, click **Switch**  to trail the left nostril.
10. Switch to the patient's other nostril, and attach the nose adapter (foam) into the right nostril (measuring the pressure) and the nasal olive into the left nostril (measuring the flow).
11. Click the **Start** button to analyse the second nostril and repeat for the left nostril as described previously.
12. After a sufficient number of stable breaths (usually 5 to 10), click the **Stop** button to end the measurement 

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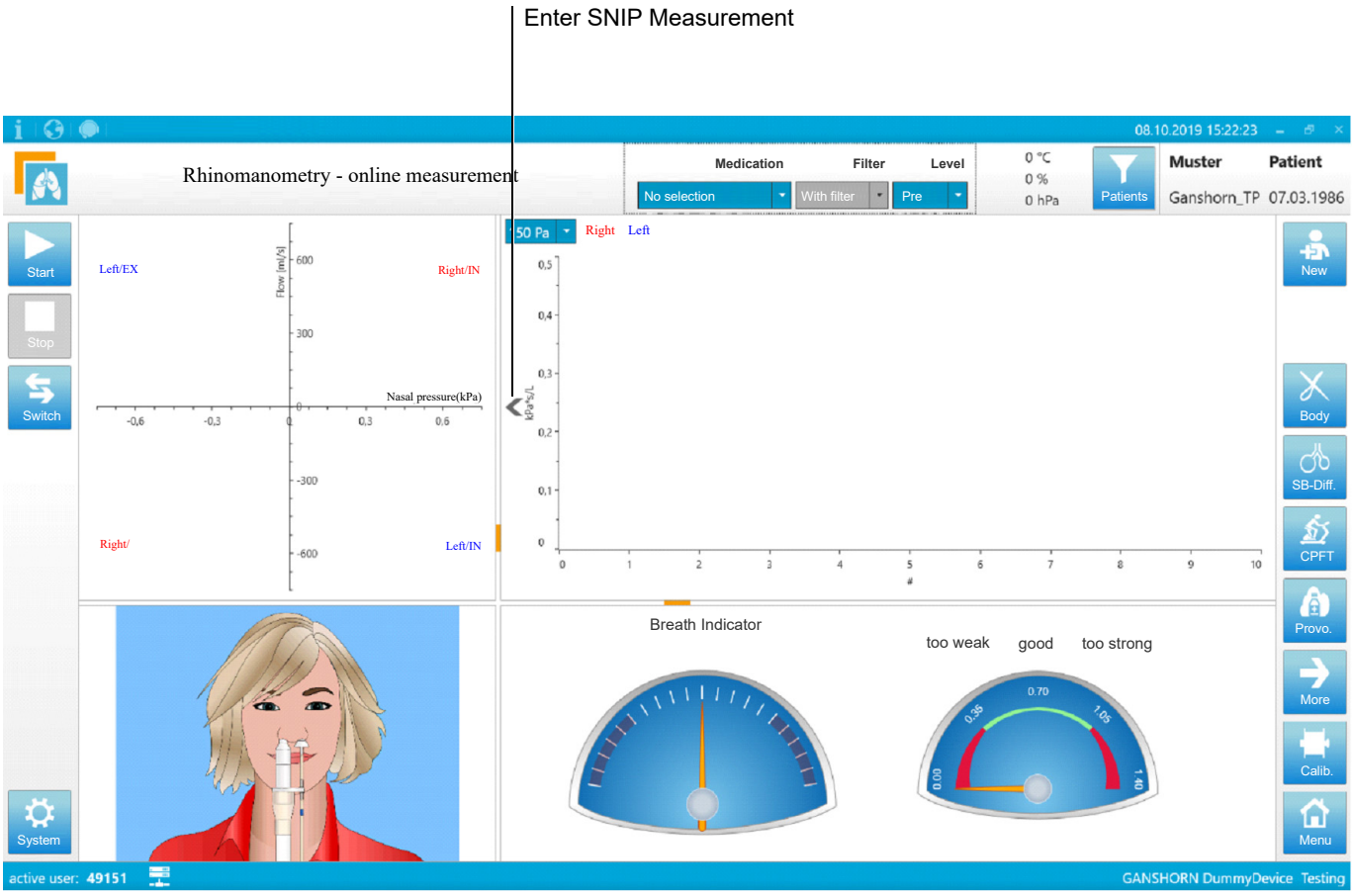
12.2.1 SNIP Rhino Measurement

Sniff Nasal Inspiratory Pressure (SNIP) is a sub-measurement part of the rhinomanometry program and provides a reliable means of measuring inspiratory muscle strength.

SNIP Recording Procedure

1. Perform the preliminaries for a Rhino test and enter the initial Rhinomanometry screen as described previously.
2. Insert the nose adapter (foam) into the left nostril (measuring the pressure). The patient may only breathe through the nose.
   – The nasal olive and the PFT filter are not required.
3. Click the arrow by the side of the pressure screen to display the SNIP screen.



4. Click the **Start** button 

   – Instruct the patient to perform strong inhalations through the selected nostril. Normally three to five inhalations are sufficient.
   – After a sufficient number of stable breaths, click the **Stop** button to end the measurement 

.
5. Click **Switch** 

and repeat with the other nostril if you want to analyse the other nostril.

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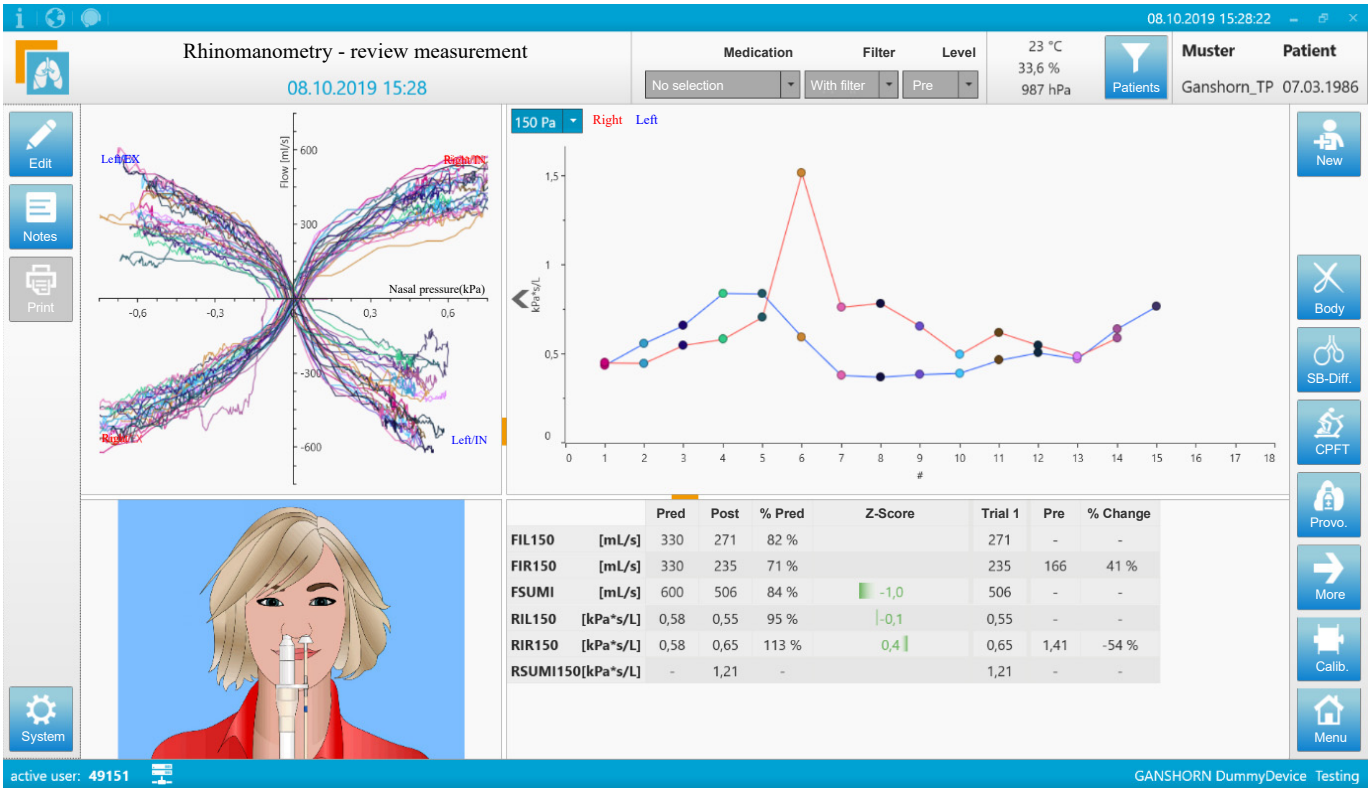
6. At the end of the test observe all cross-contamination procedures and safety notes described in the chapters:
   - 1.8 Infection control/cross contamination
   - 2.8 PFT Bacterial Filter
   - 14 Cleaning and Disinfection
   - 14.4 Rhinomanometry Olives and Flow Tube (Option)

12.2.2 Rhinomanometry Review



Results are displayed for the right and left nostrils. The pressure can be changed.

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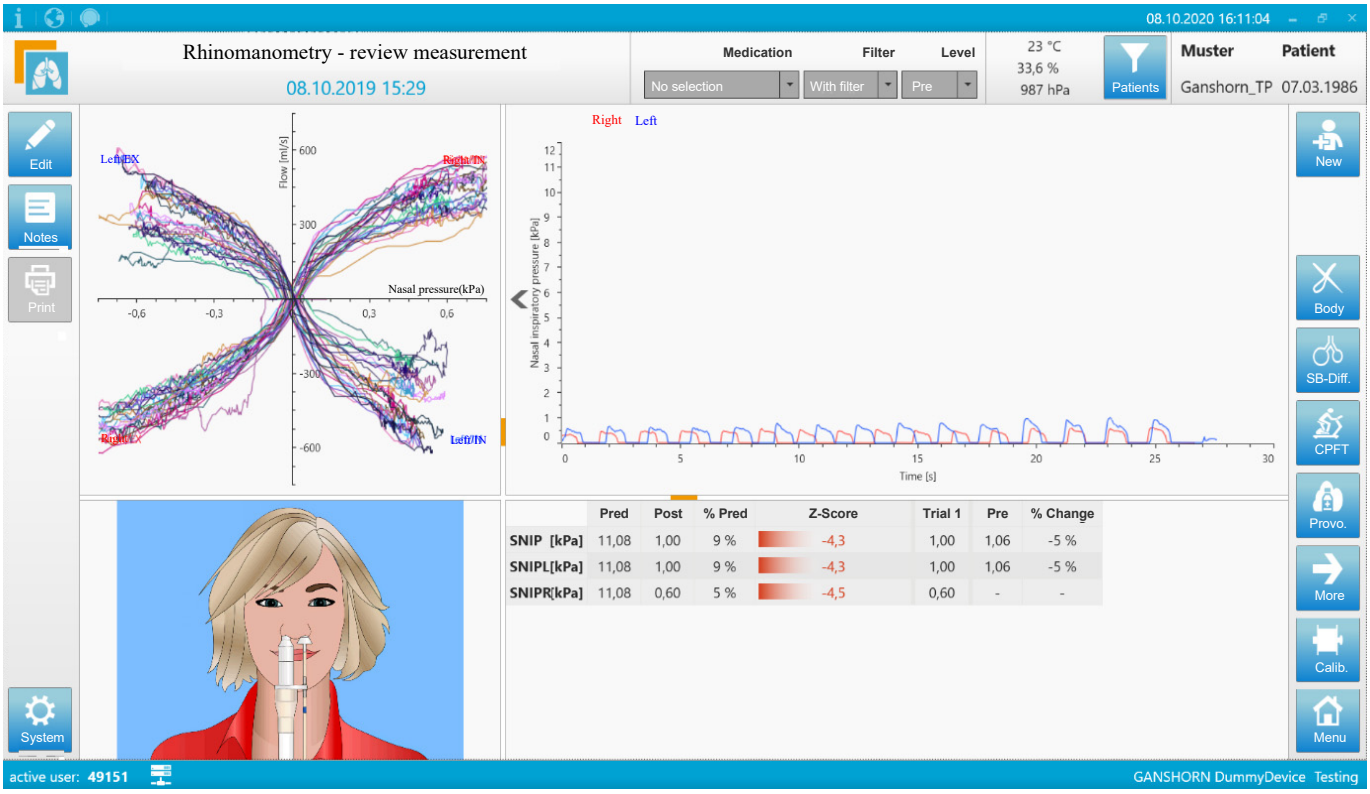
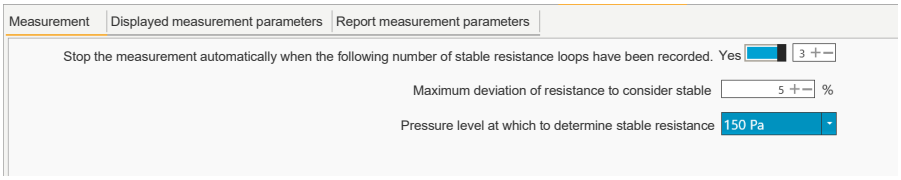
12.2.3 Rhinomanometry SNIP Review



12.2.4 Rhinomanometry Measurement Settings

Select **Rhinomanometry** from the settings screen or the **System tab** 

from the rhinomanometry screen**:**



Stop measurement automatically

Yes or No. When Yes is selected, the trial stops after the number of defined breaths have been detected. The number of breaths can be set between 3 and 40 (the default is 10).

Maximum deviation of trials

To consider a breath to be accepted in the trial, it must be within a percentage flow. This is the maximum deviation of flow at pressure level (the default is 150 kPa - see the following) allowed, compared to average results, that it is considered in the average result.

The percentage can be set between 1 and 50% (the default is 5%).

Pressure level

Pressure level at which to determine stable resistance. Set to 75 Pa, 150 Pa (the default) or 300 Pa. The pressure can be changed during measurement and in review mode.

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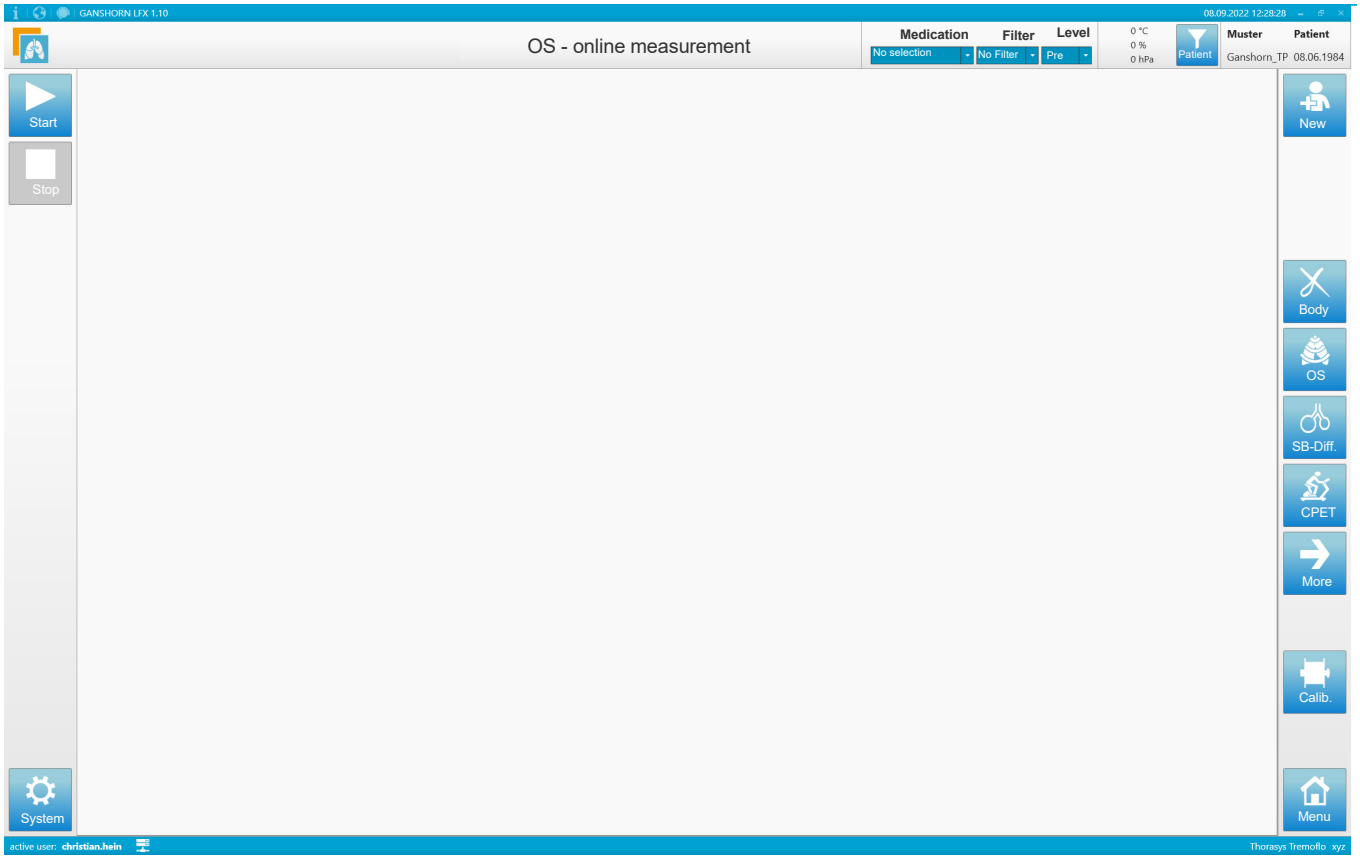
12.3 Oscillometry (OS) measurements

The optional Forced oscillatory technique measurement (Thorasys tremoflo®) will be proceed by the Thorasys software. The following can be executed and set by the LFX:

- Start/Stop OS measurement (Thorasys software remote start/stop by LFX)
- Setting medication
- Level for Pre and Post tests. After one test LFX automatically switches to POST but can be reset to PRE manually again.

12.3.1 Procedure

1. Carry out the preliminary checks (see Thorasys instruction for use).
2. Select patient or register a new patient (see para.4.2, The Work/Patient Screen, page 38).
3. Click on the **OS button**.
   – The OS screen is displayed:



4. Set/check the following settings (top of screen):
   – **Medication** - Enter medication from the pull down menu. Note that the medication can be edited as required (see para.4.3, Editing User-Defined Drop-Down Lists, page 43).
   – **Level** - Set for Pre test/post test

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5. Click the **Start** button 

.
   – Data acquisition begins with the Thorasys software application.
   – Follow the instruction of the Thorasys instruction for use

➜ Click on the **Stop** button to abort the measurement 

.

No data will be transmitted to the LFX application.

6. When the measurement is completed, Thorasys application will be closed and the following LFX OS -review measurement screen will be displayed:

Best trials

All trials

Graphical display R5 values [hPa*s/L] of all trails

Display of different parameters for all trials. The displayed parameters can be defined in the OS Settings. (see para.12.3.2, Setting the OS measurements & report parameters, page 128)

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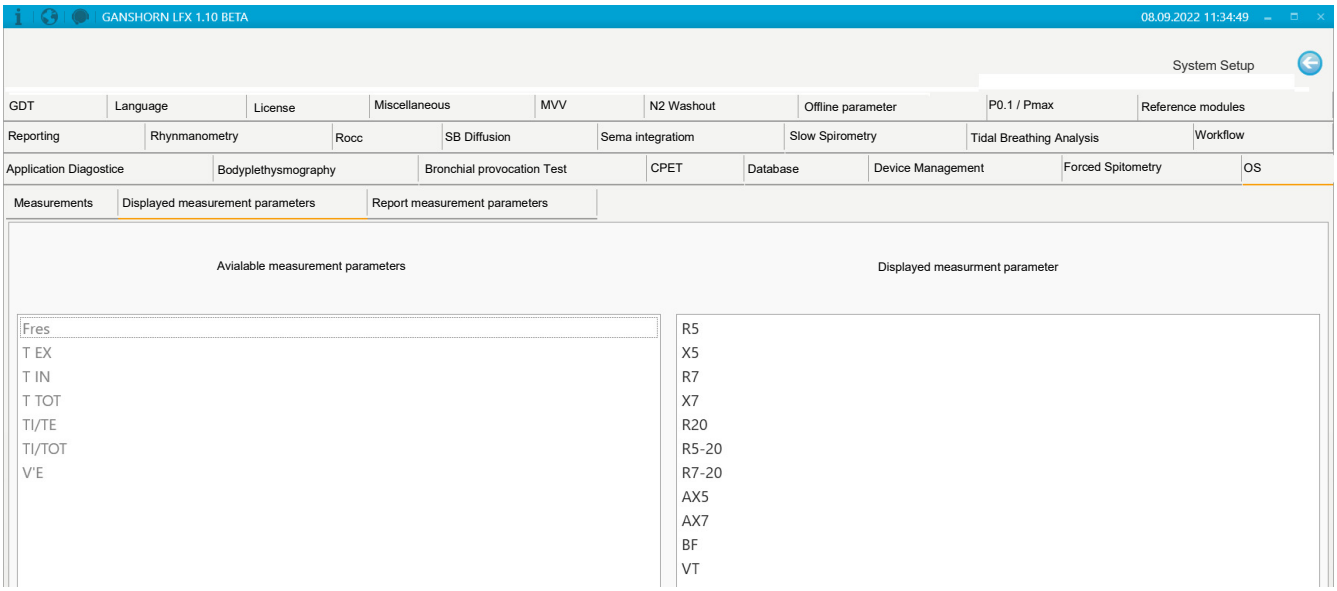
12.3.2 Setting the OS measurements & report parameters

From the OS review screen, click the settings button to add, remove or change the order of the parameters in the tabular display.

Drag, drop and position as required.



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13 Settings Overview

Displaying all Settings from the Home Screen

- The settings are entered by clicking the **Settings** button on the main screen.
- You are prompted to enter a password. The password is:
  - sstartlfx

Displaying the Settings of a Specific Measurement

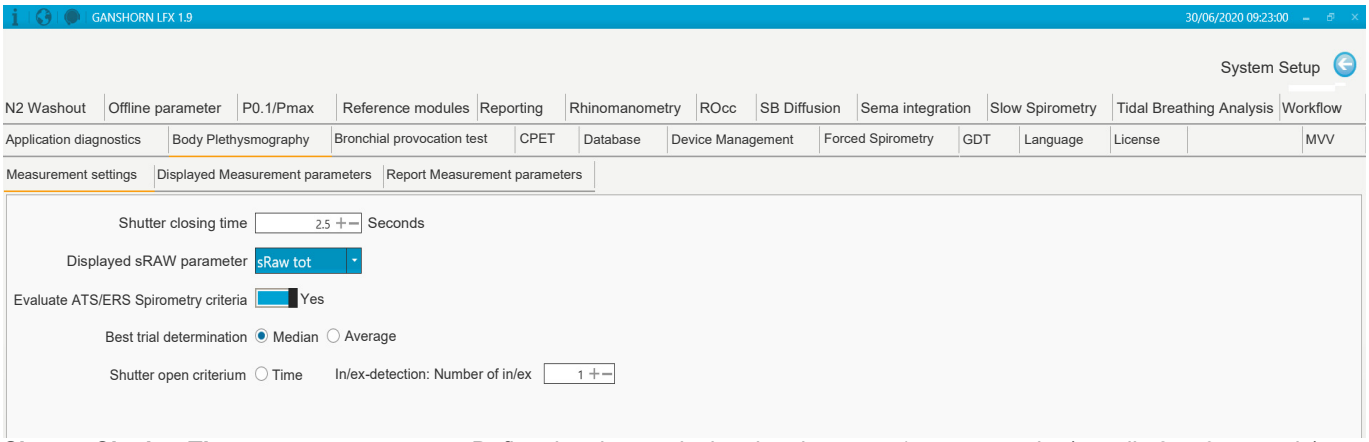
- When on the measurement screen, the measurements' settings are given when the system is clicked.

The setting screens give general and specific system, measurement and parameter settings for the various tests, options and equipment available with the LFX.

The following gives a general overview of the settings available for the LFX. If a setting is not displayed, unavailable, or greyed out and cannot be selected, the option is unavailable or licensed for the current installation.

13.1 Body Plethysmography

13.1.1 Measurement



Shutter Closing Time Define the shutter closing time between 1 to 5 seconds. (usually 2 to 3 seconds)

Displayed sRaw parameter This is the regression line for sRAW. Select between:

- sRAW tot (sRaw total)
- sRAW eff (sRaw effective)
- sRAW mid
- sRAW peak
- sRAW 0.5

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Evaluate ATS-ERS Spirometry criteria

Yes/**No** - Spirometry guidelines can be analysed (see para.6.5.4, Quality Control Bar Graph, page 76). If forced Spirometry is not to be performed as part of a body test (or you do not wish o have the Spirometry criteria), the screen can be off.

Best trial determination

Select **Median** or Average. For example, if 2, 4, or 15 were recorded:

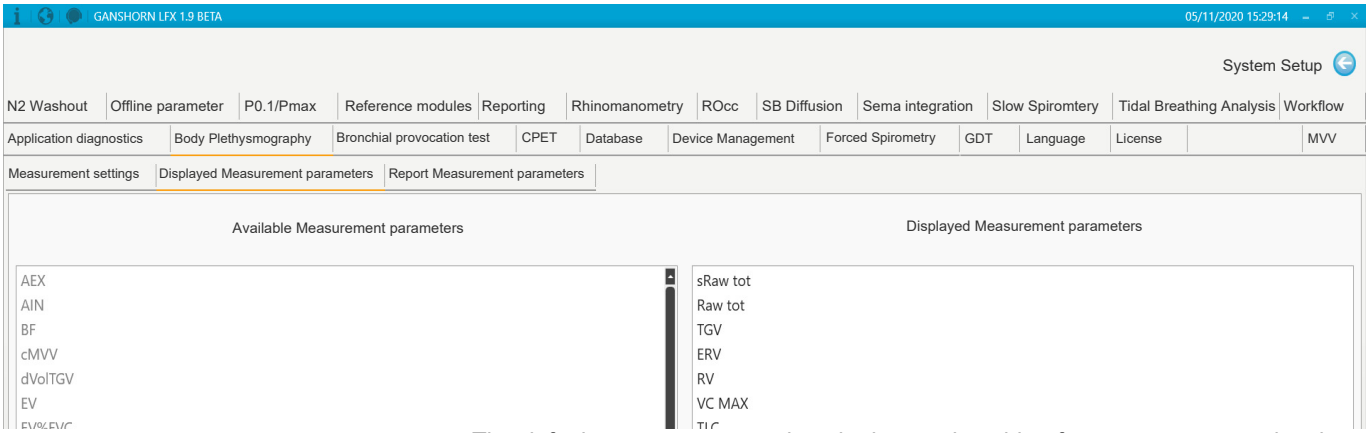
– The average would be 7, and the median would be 4.

ERS/ATS recommends an average; however, the median is better against outliers.

Shutter open criteria

Select between time or in/ex detection. When in/ex detection is selected, the number of breaths can be specified. This means the shutter opens after 1, 2, or 3 seconds when time is selected, or 2, 3 detected breaths against shutter when in/ex selected. The number of breaths is considered better for measurement quality, but the shutter is closed for a longer time, and some patients might find that uncomfortable.

13.1.2 Displayed Measurement Parameters



The default measurements, given in the results table after a measurement is taken, are defined here. Drag and drop parameters as required.

13.1.3 Report Measurement Parameters

The default measurements printed/generated in the report are defined here.

13.2 Bronchial Provocation Test

The GANSHORN Provo. X instruction for use gives details on defining the provocation sequence.

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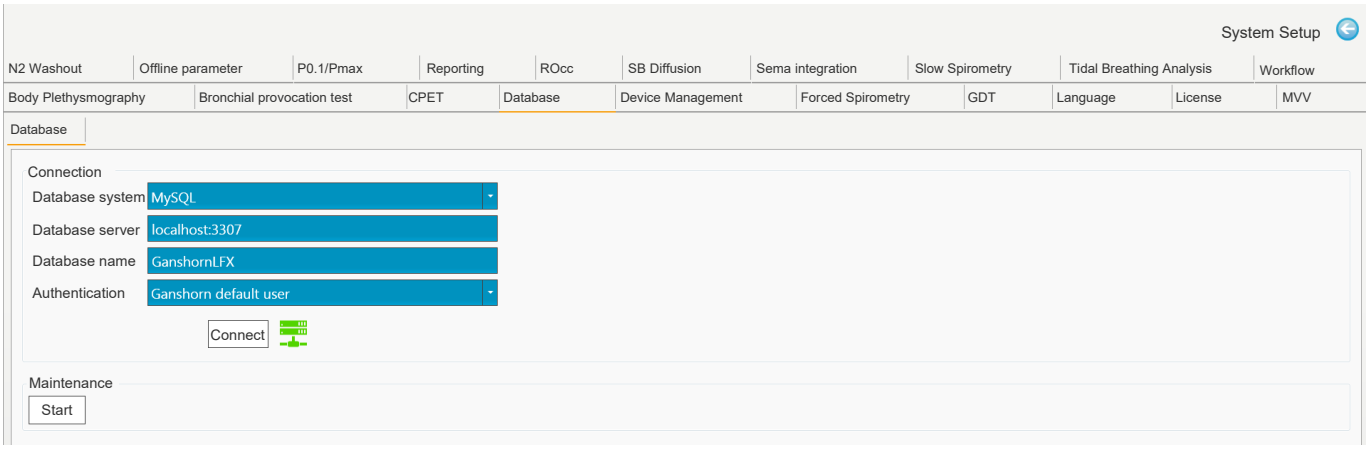
13.3 Database



13.3.1 Connection

Define the database the LFX uses for patient and recording storage; if the LFX is installed standalone, select (localhost:3307) for the database server. Define the name and authentication (security). Security aspects are defined during program installation and do not usually need to be changed.

Click the **Connect** icon to check the connection. A message is displayed indicating a successful connection or not.

13.3.2 Database Maintenance

Over time the database can get fragmented, causing slow operation. Clicking the **Database maintenance** button effectively de-fragments the database and removes unnecessary files. Complete this operation at regular intervals.

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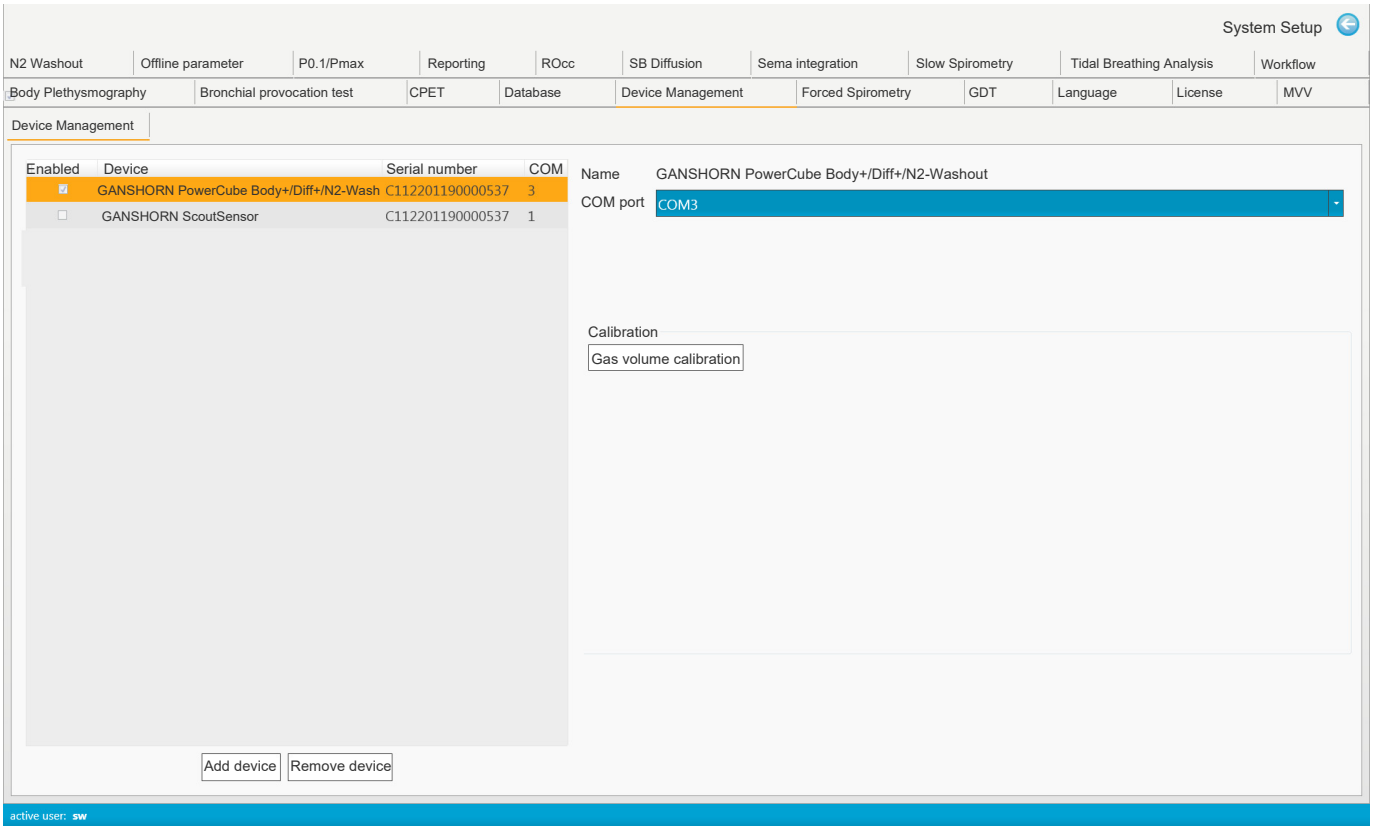
13.4 Device Management

In this screen, the measuring devices connected to the LFX are defined. The serial number and COM port are displayed as defined on installation.



The gas volume calibration tab enables volume calibration when inhaling diffusion gas. The properties of the ultrasound are different when gas is in the tube, mainly because of the helium. This is carried out in the factory during installation. It does not need to be repeated and is for service personnel only.

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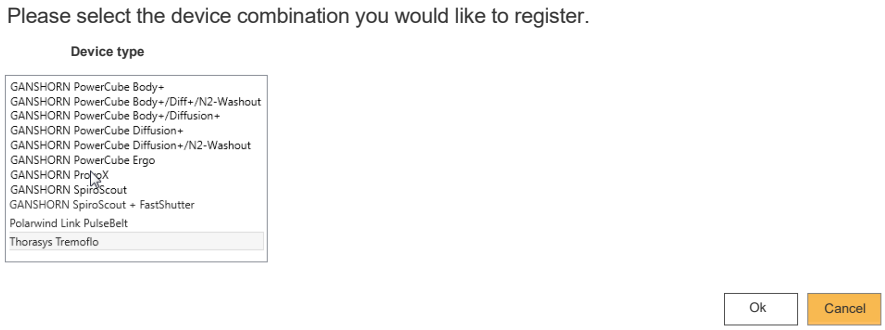
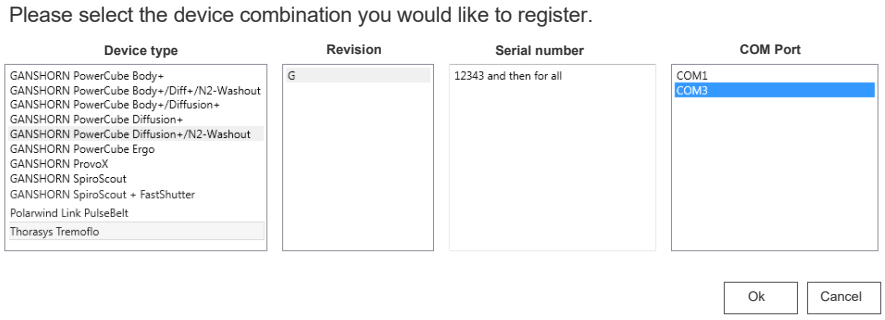
13.4.1 Adding a New Device

When new is selected on the initial screen, you are prompted to select the device and enter the revision, serial number and COM port for all devices.

The COM port is usually 1 if a serial connection is used. The driver allocates the COM port if a USB to RS-232 converter is used. The COM port can be looked up in the Windows device management.





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13.5 Forced Spirometry

13.5.1 Measurement

Flow-volume-inspiration displayed or not displayed.

13.5.2 Displayed Measurement Parameters

The default measurements, given in the results table after an FVC measurement is taken, are defined here. The measurement results can also be defined on the Spiro screen at any time.

13.5.3 Report Measurement Parameters

The default measurements printed/generated in the report are defined here.

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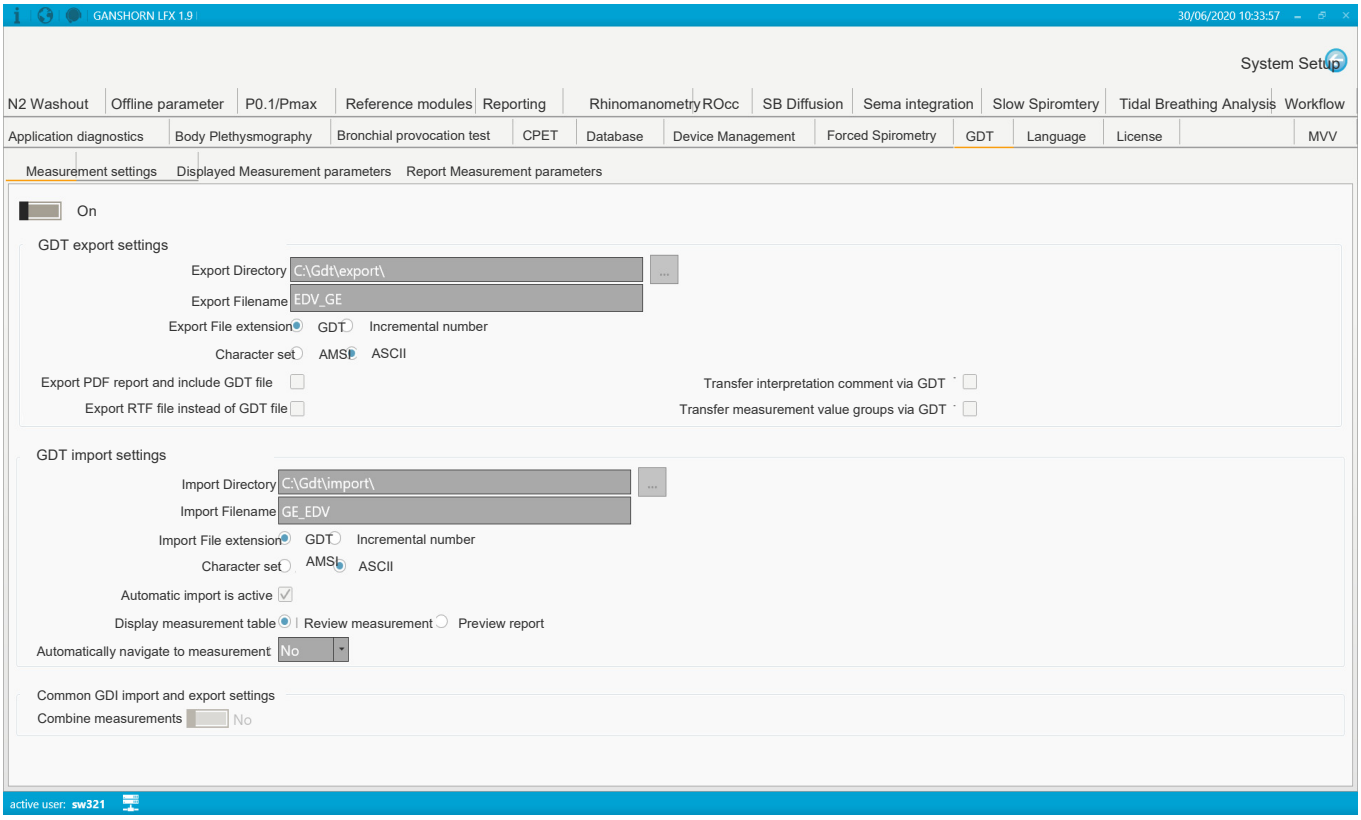
13.6 GDT



These settings define the GDT database and import/export directories if networked with a GDT system.

Enable GDT import/export ON or OFF in the top left of the GDT settings screen.

13.6.1 GDT Export

Enter your device (computer) identification; any combination of characters can identify the unit. The external DB may define the device ID format. Note that the ID must use standard windows file name characters.

Export Directory — The (local) location of recordings and GDT message for export to an external system.

Export File-name — Define the extension here if the external system requires a fixed file name. The fixed files box must be checked (see next entry).

Export file extension — Check this box if the external system requires a fixed file name. The extension is defined above (fixed file name extension). Note that a file in the export directory is overwritten by a later one with the same name. The file name extension counts up for each recording if the incremental number is checked. Set this according to the system used (see the system administrator).

Export PDF report and include to GDT file — Check to export recordings as PDF files with the GDT file.

Export RTF instead of GDT File — Check to export recordings as RTF files.

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13.6.2 GDT Import

Import Directory	The (local) location of received recordings and GDT messages.
Import Filename/Import file extension	(see above)
Automatic Import	Check this box to import recordings when received.

13.7 Language and Units

13.7.1 Language

Select the language and preferred region. The preferred region sets the data and time format options displayed below the setting.

13.7.2 Units

Height	cm, feet or inches
Weight	kg, lbs, stone
Temperature	Centigrade, Fahrenheit
Pressure	hPa, cmH_2O
Mouth Pressure	hPa, mmHg, PEF L/s, L/min
DLCO (diffusing capacity of the lungs for carbon monoxide)	mmol/min/kPa, ml/min/mmHg
sRaw	kPa*s, $cmH_2O/(L/s)/L$
Blood gas	mmHg or kPa
Haemoglobin	mmoL/L or g/d

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13.8 License

The license screen is for program registration (usually registered by the installation team). Options are given for automatic activation by entering the customer details and product key obtained from GANSHORN. Manual activation can be activated by an activation key generated via the GANSHORN website or over the phone. For phone activation, GANSHORN provides an activation key after confirming your product hardware and product key over the phone.

13.9 MVV

13.9.1 Measurement

Define the manoeuvre duration up to 60 seconds (the default is 12 seconds).

13.9.2 Displayed Measurement Parameters

The default measurements, given in the results table after a measurement is taken, are defined here. The measurement results can also be defined on the View screen at any time.

13.9.3 Report Measurement Parameters

The default measurements printed/generated in the report are defined here.

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13.10 N2 Washout

13.10.1 Measurement

Define the waiting time for gas supply activation between 5 to 60 breaths.

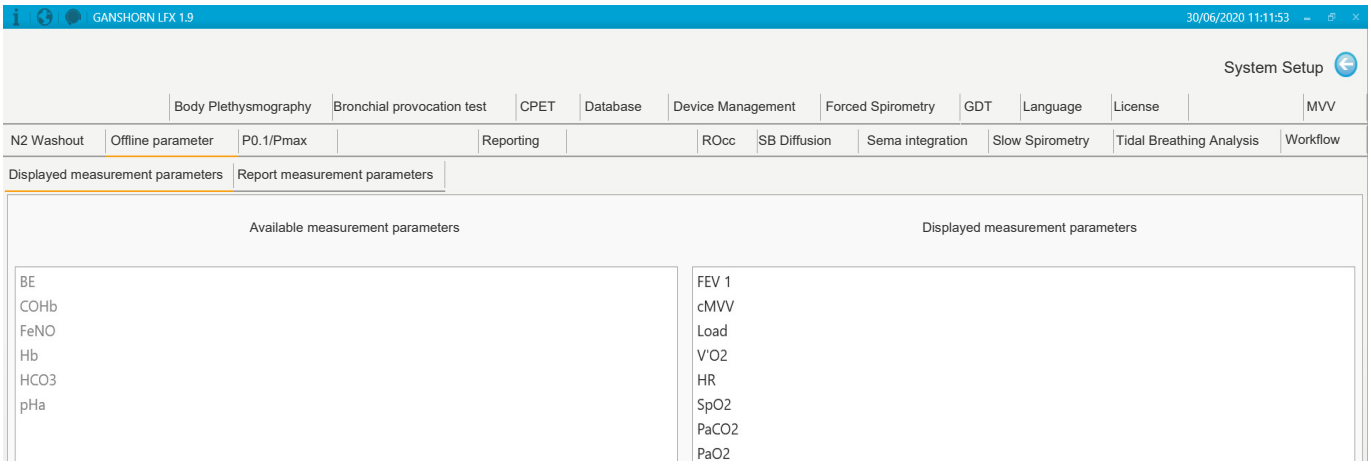
13.10.2 Displayed Measurement Parameters

The default measurements, given in the results table after an N2 washout measurement is taken, are defined here.

13.10.3 Report Measurement Parameters

The default measurements printed/generated in the report are defined here.

13.11 Offline Parameters



After a recording has been taken, measurements not measured by the system can be entered manually. Offline parameters that are available are displayed in the left-hand column. Entry parameters, i.e. those given in the report, are displayed in the right column and can be moved as required. When a recording is opened, the offline parameters can be entered using the **Offline** parameter icon. (see para.4.9, Offline Parameters, page 47).

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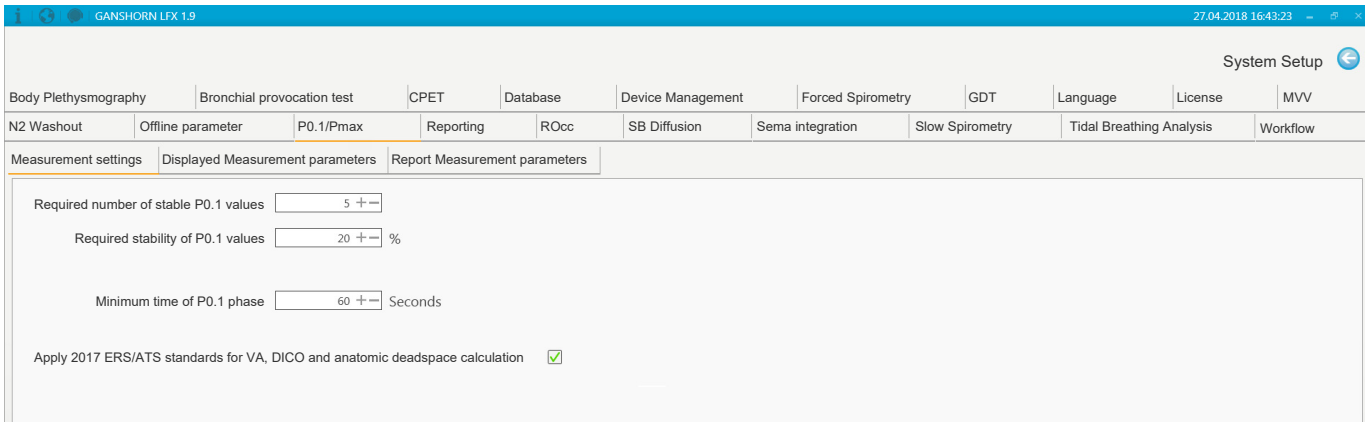
13.12 P0.1/Pmax



13.12.1 Measurement

Required number of stable P0.1 values

Select between 2 and 10 (the default is 5)

Required stability of P0.1 values

Select between 1 and 50% (the default is 20%)

Minimum time of P0.1 phase

Select between 0 and 300 seconds (the default is 60 seconds)

13.12.2 Displayed Measurement Parameters

The default measurements, given in the results table after a P0.1/Pmax measurement is taken, are defined here. The measurement results can also be defined on the Spiro screen at any time.

13.12.3 Report Measurement Parameters

The default measurements printed/generated in the report are defined here.

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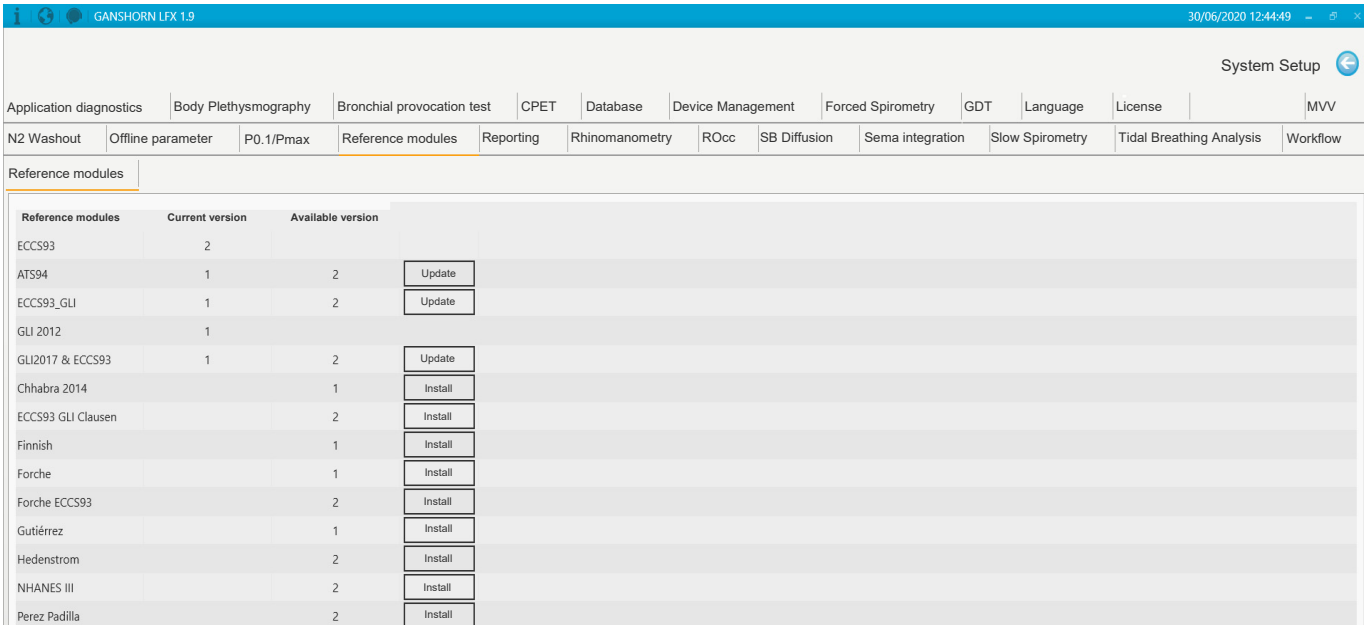
13.13 Reference Modules

Here the Spiro reference modules can be installed and updated as required.



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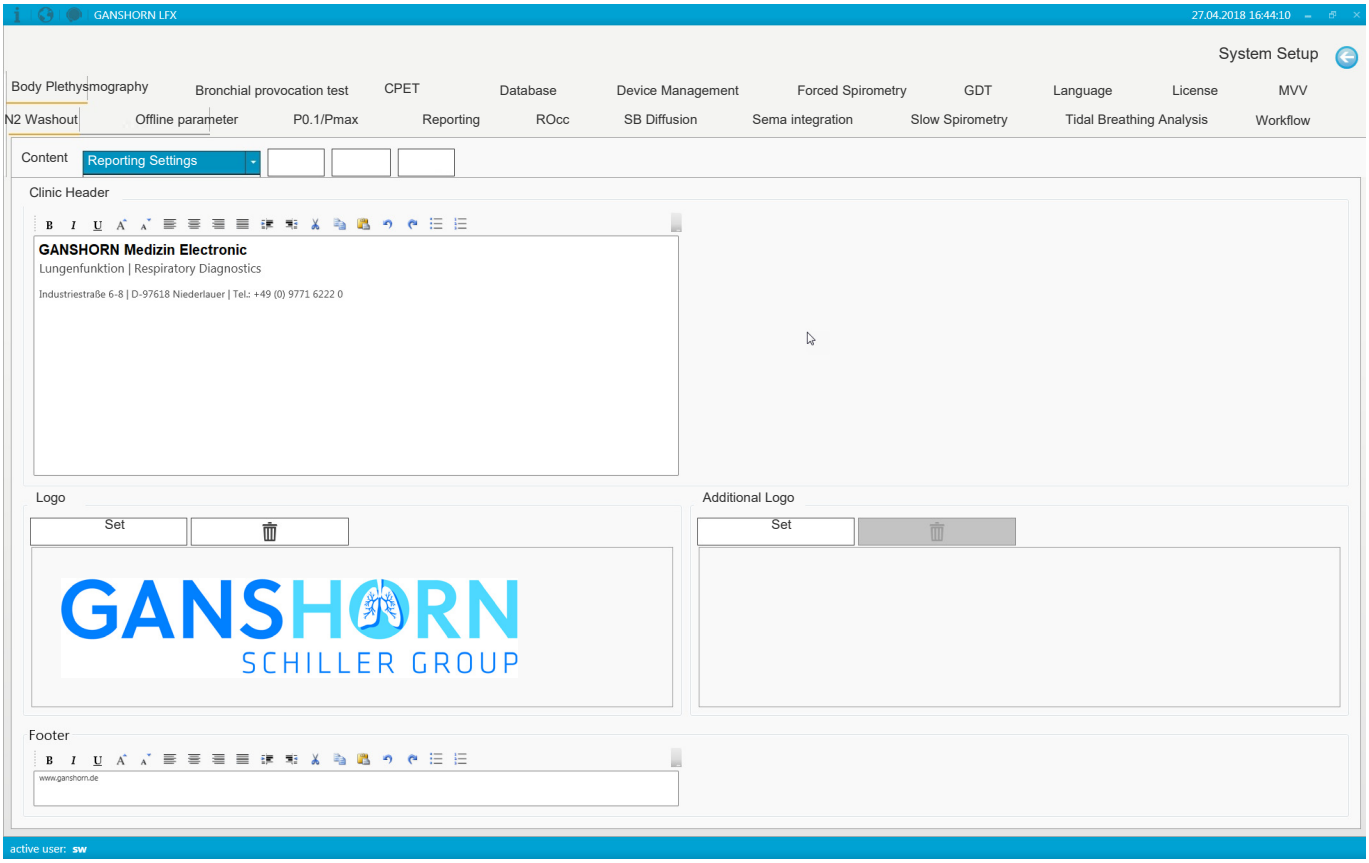
13.14 Reporting

13.14.1 Content

Here the header with a practice address, footer, and logo are included when a printout or report is generated. The logo can be any standard illustration/photo format, e.g. jpg, png, or bmp.

13.14.2 Reporting Settings

Here the default report settings are defined as follows:



Content Settings

Default action - print to the default printer, export as a PDF file, and define the directory location where the file is to be stored.

Default report - here, the data for SV, FVC, Body plethysmography, SB diffusion, and combined report is defined.

Report management

Here, any combination of trials can be identified and then imported, deleted or exported. When exported, an XML file for every trial is generated, and the import/ export directory must be specified.

13.15 Rhinomanometry

Details are given in the Rhinomanometry instruction for use.

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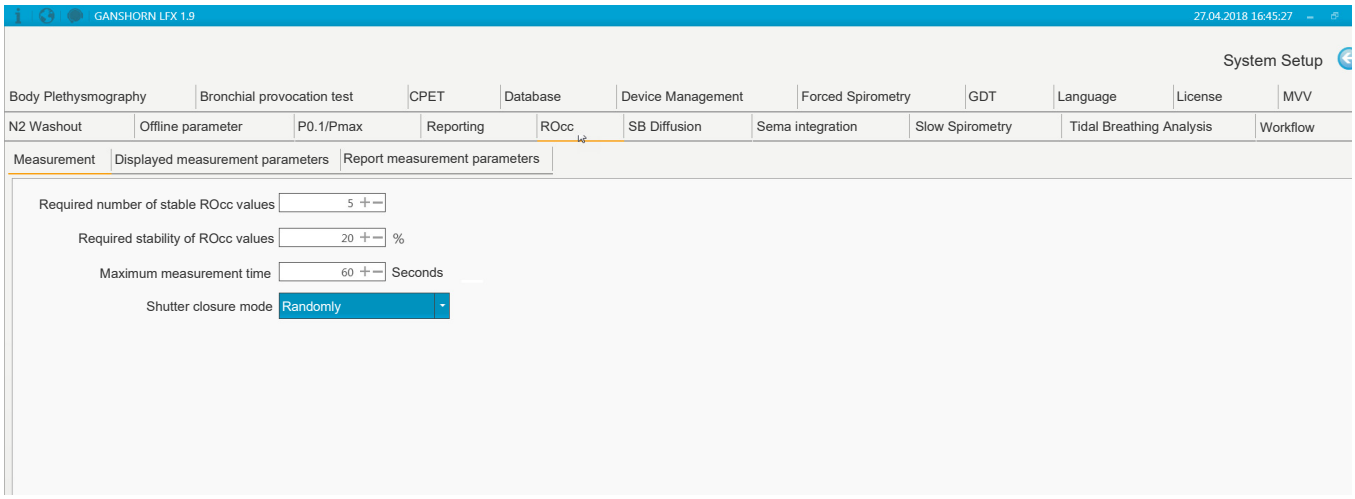
13.16 ROcc



13.16.1 Measurement

Required number of stable ROcc values

Select between 2 and 10.

Required stability of ROcc values

Select between 1 and 50%.

Maximum Measurement time

Select between 5 and 300 seconds.

13.16.2 Displayed Measurement Parameters

The default measurements, given in the results table after a ROcc measurement is taken, are defined here. The measurement results can also be defined on the Spiro screen at any time.

13.16.3 Report Measurement Parameters

The default measurements printed/generated in the report are defined here.

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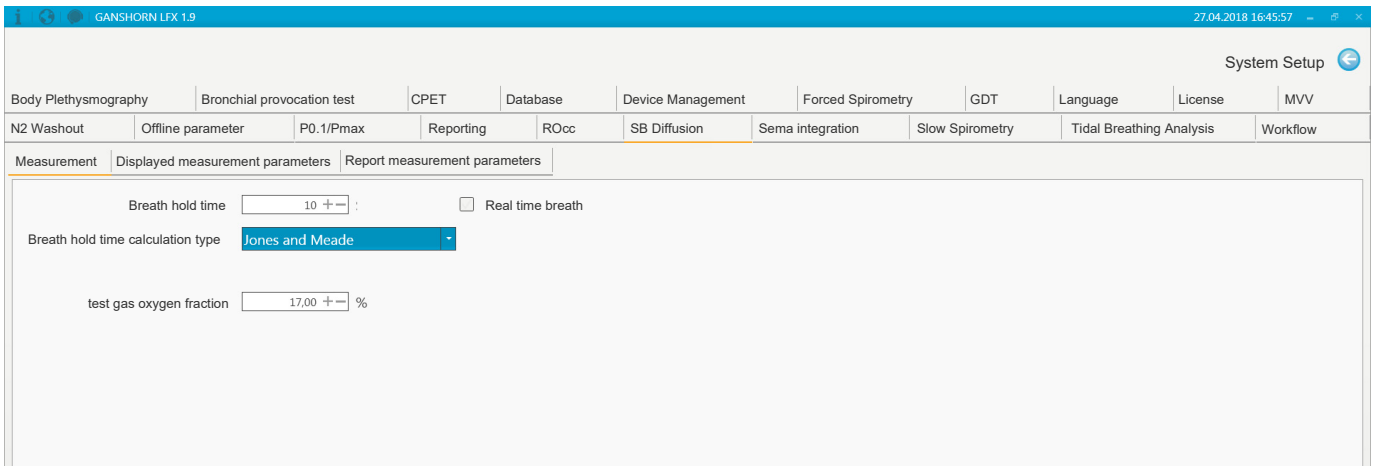
13.17 Single Breath Diffusion



13.17.1 Measurement

Breath Hold Time

Select between:

- 8 and 12 seconds
- Real-time breath
  - Real-time breath is for patients who cannot hold their breath for a prolonged period. When this option is checked, the diffusion test is performed without the patient holding their breath. The patient must exhale very slowly.

Breath Hold Calculation Type

Select between Jones and Meade, ERS, or Ogilvie.

Test Gas Oxygen Fraction

Select between 17 and 21%

Note that the He and CO percentage of the test gas is entered during gas calibration (see para.5.6, Diffusion Gas (He/CO), page 59).

13.17.2 Displayed Measurement Parameters

The default measurements, given in the results table after a measurement is taken, are defined here. The measurement results can also be defined on the Body screen at any time.

13.17.3 Report Measurement Parameters

The default measurements printed/generated in the report are defined here.

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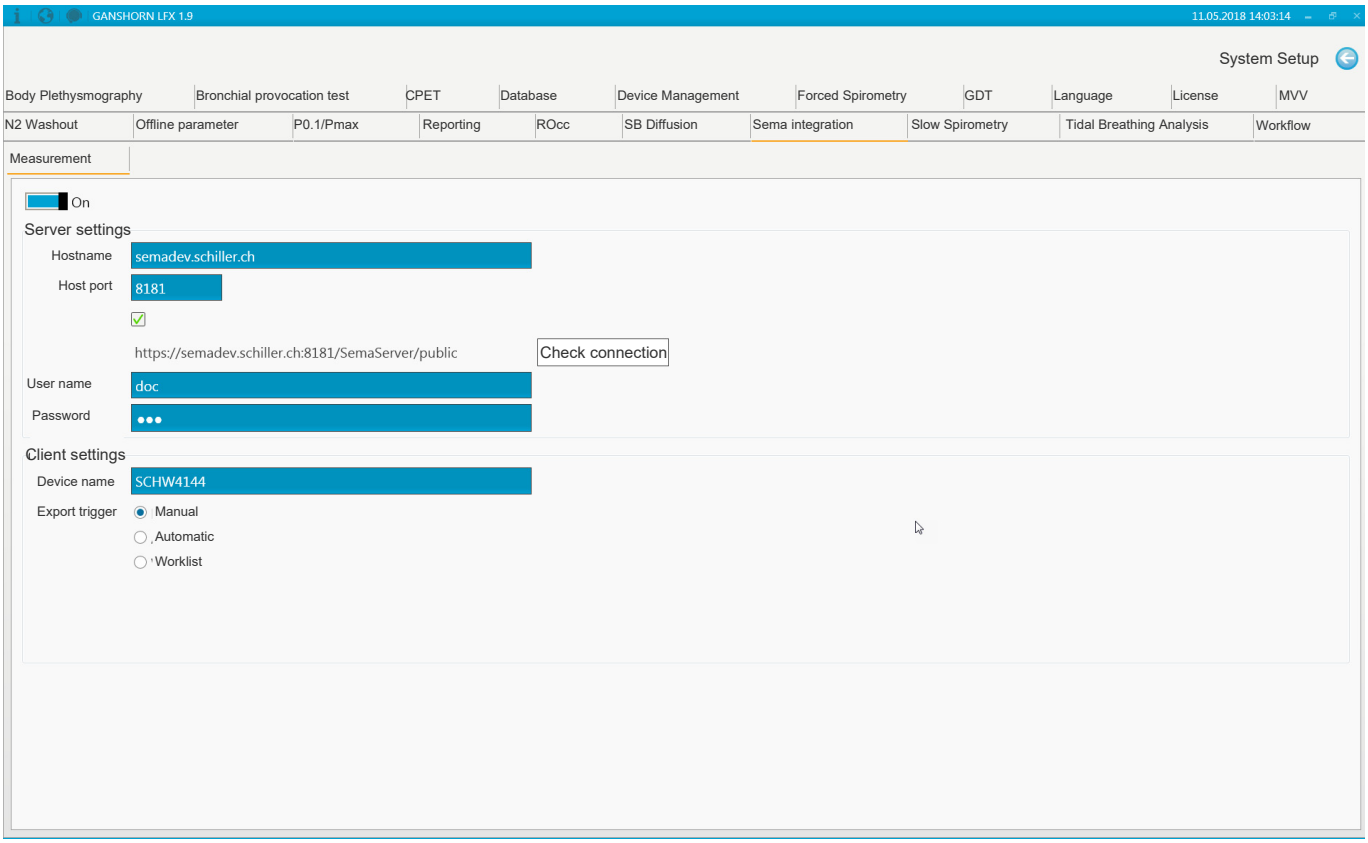
13.18 SEMA Integration



These settings define the SEMA database if networked with a SEMA system. The SEMA integration screen gives the current server connection settings and details usually defined on installation.

Enable the SEMA connection in the top left of the SEMA settings screen.

13.18.1 Server Settings

Hostname and Port

The path is defined in the hostname and the port number (the default is 8080 or 8181). The URL path is automatically entered in the URL field as the host is defined.

The user name and password must be set (defined on the SCHILLER Server - see system administrator).

13.18.2 Client Settings

The device name must be defined in the SCHILLER Server exactly as defined here.

Export Trigger

Define to export recordings to SEMA:

- Export automatically after every recording.
- Export manually
- Worklist - export recordings made after a worklist request recording has been completed.

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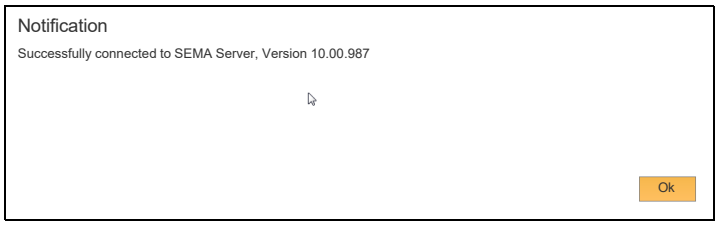
Check Connection

When the **Test server connection** button is clicked, the program pings the server to check the connection. When a connection is established, a message is displayed, as below.



13.19 Slow Spirometry

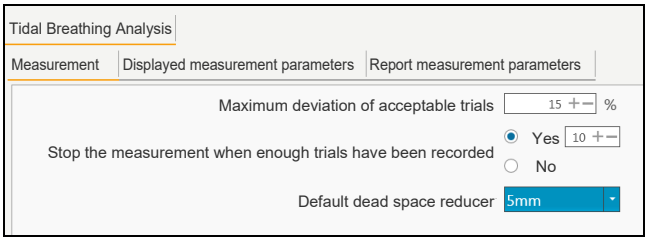
13.19.1 Displayed Measurement Parameters

The default measurements, given in the results table after a measurement is taken, are defined here. The measurement results can also be defined on the View screen at any time.

13.19.2 Report Measurement Parameters

The default measurements printed/generated in the report are defined here.

13.20 Tidal Breathing Analysis



Maximum deviation of acceptable trials

Select between 1 and 20% (the default is 15%).

Stop the measurement when enough trials have been recorded

Yes or No. When Yes is selected, define the number of acceptable trials before stopping the test. Select between 5 and 40 breaths (the default is 15).

Default dead space reducer

Select 8 mm, 5 mm, or none (the default). The dead space reducer size is displayed and defined before a new test is requested.

13.20.1 Displayed Measurement Parameters

The default measurements, given in the results table after a measurement is taken, are defined here. The measurement results can also be defined on the View screen at any time.

Report Measurement Parameters

The default measurements printed/generated in the report are defined here.

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13.21 Oscillometry (OS)

•

- Thorasys software can be installed by using a user included password. To run Thorasys, LFX must be set up with the related username including the password.
- After installation the Thorasys software
  - the GDT directory for the data transmission in between LFX and Thorasys must be set up.
  - The Tremoflo sensor must be added as a new device see para. 13.4.1 Adding a New Device, page 133
- The following setup must be set up identical in LFX and Thorasys software:
  - User name
  - Password
  - Local name
  - Local Short name
  - Remote name
  - Remote short name

➜ For Thorasys GDT settings refer to Thorasys IFU

13.21.1 OS settings

Tremoflo Executable	Path for location of the executable file (Tremoflo.exe)
GDT Directory	Path for Tremoflo GDT data
User name	User name (same as in the Thorasys)
Password	Password for the Thorasys Tremoflo software (same as in the Thorasys)
Local Name	Local Name same as in the Thorasys (same as in the Thorasys)
Locals Short Name	Local Short Name (same as in the Thorasys)
Remote Name	Remote name (same as in the Thorasys)
Remote Short Name	Remote Short Name (same as in the Thorasys)
Advanced logging for current session	This will be requested to be activated in case there are technical issues in the communication in between Thorasys and LFX. If activated the LFX Logfiles collects more detailed information. Default is off.

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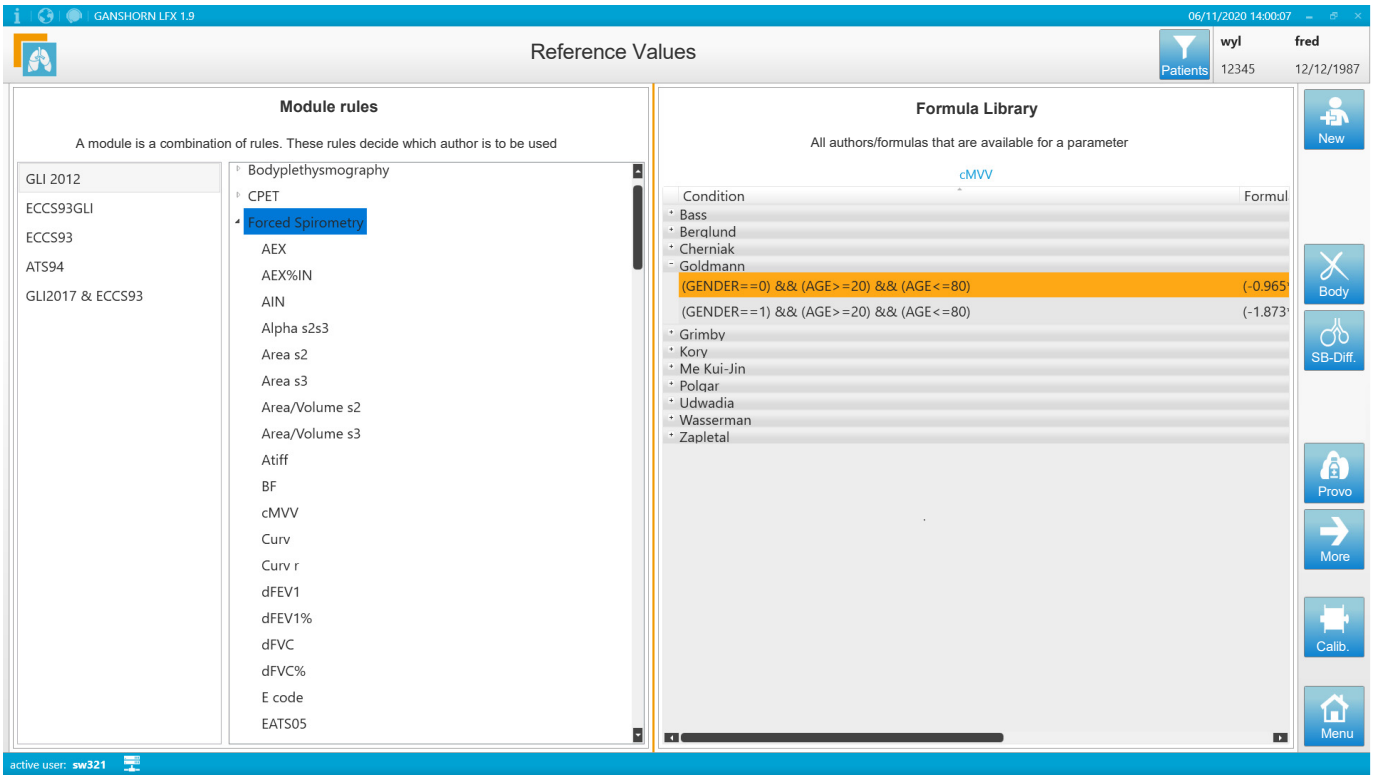
13.22 Workflow

A workflow file is defined by SEMA or HIS. The file defines work files and some settings so that different installations can have the same workflow. Select the file location to import a defined workflow.

13.23 References and Formula

The norm values available and to which measurements they apply are displayed by selecting the **References** button 

on the patient/online screen.



- The norm values are shown in the left column. Select a norm to display all parameters. Expand a parameter to display the formula available for the selected parameter.

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14 Cleaning and Disinfection

⚠ CAUTION

- ▲ Switch OFF and disconnect the device from the mains by removing the plug before cleaning.
- ▲ Observe the following safety notes when cleaning/disinfecting the device:
  - – Never immerse the device or cabling in liquid.
  - – Never pour or spray liquid directly onto the device.
  - – Make sure that no liquid penetrates the connections or openings.
  - – The device must not be autoclaved or sterilised with steam.
- ▲ Never use the following solutions or similar products to clean the equipment: ethyl alcohol, acetone, hexane, abrasive or scouring powder or similar material, or any cleaner that damages plastic.
- ▲ Unit connectors must not come in contact with soap or water. Do not immerse in liquid when cleaning, and do not spray the unit directly. Only clean the device and cables with a damp cloth slightly moistened (not wet) on the surface.
- ▲ Always follow the instructions provided by the manufacturer of the detergent/disinfectant regarding the use and dilution of the detergent/disinfectant.
- ▲ When cleaning, check that all labels and safety statements, whether etched, printed or stuck to the unit, remain in place and are always readable.
- ▲ Some patients have intolerances (e.g. allergies) to disinfectants or their components. If you have such a patient or you are unsure, remove possible residues with careful cleaning.
- ▲ Wear protective gloves (e.g. butyl rubber) is recommended.

Before cleaning/disinfecting the unit thoroughly inspect for any signs of damage.

- ▲ Do not spray the device directly.
- ▲ Make sure that no liquid penetrates the device.

- ▲ Clean the PowerCube+ Series with a damp cloth **slightly moistened (not wet)** on the surface only. Use cleaning agents that are mild and diluted with water that are suitable for Acrylonitrile Butadiene Styrene (ABS).

Use a clean lint-free cloth moistened with detergent and wipe the unit to clean.

Wipe off any excess cleaning solution. Do not let the cleaning solution run into or accumulate in connector openings or crevices. If liquid penetrates the device or connectors this can interfere with correct functioning: dry the area with warm air, and then check the equipment to confirm that it operates properly. Leave the device and sensors in a warm, dry room for 48 hours and then check the equipment to confirm that it operates properly. If the functioning is still affected, contact GANSHORN.

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14.1 Approved Cleaning Solutions

The list of cleaning solutions and disinfectants are provided as a general guide. If in doubt about the suitability of a cleaning solution or disinfectant, check that the solution is suitable for the materials used in the construction of the sensor assembly PC/ ABS (polycarbonate-ABS) / Polyethylene. The following can be used:

- 50 % isopropyl alcohol
- neutral, mild detergent
- all products designed for cleaning plastic.
- all disinfectants that are listed in the "List of disinfectants and disinfection methods tested and approved by the Robert Koch Institute" see website www.RKI.de

Recommended

GANSHORN recommends the following:

Cleaning Solution	Manufacturer
Mikrozid AF wipes	Schülke und Mayr GmbH
Mikrozid universal wipes premium	Schülke und Mayr GmbH

14.2 Cleaning Materials that must not be used

Never use products containing the following:

- Ethyl alcohol
- Chloride
- Acetone
- Hexane
- Abrasive cleaning powder
- Plastic-dissolving products

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14.3 Disinfection

Use commercially available disinfectants intended for clinics, hospitals and practices to disinfect the device. Disinfect in the same way as described for cleaning (previous page).

14.3.1 Admissible Disinfectants

- Isopropyl alcohol 50%
- Propanol (35%)
- Ethyl hexanal
- Aldehyde (2-4%)
- Ethanol (50%)
- all products that are suitable for PC/ABS plastic

Recommended

GANSHORN recommends the following:

Disinfectant	Manufacturer
Descogen I	Antiseptica chem.-pharm. Produkte GmbH
Gigasept FF	Schülke und Mayr GmbH

14.3.2 Non-admissible Disinfectants

Never use products containing the following:

- Organic solvents
- Ammonia-based detergent
- Abrasive cleaning agents
- 100% alcohol, Virex, Sani-Master
- Sani-Cloth, Ascepti or Clorox wipes
- HB Quat
- Conventional cleaner (e.g. Fantastic, Tilex, etc.)
- Conductive solution
- Solutions or products containing the following ingredients:
  - Acetone
  - Ammonium chloride
  - Betadine
  - Chlorine, wax or wax compound
  - Ketone
  - Sodium salt

Using these products or products containing similar components can cause discolouration of the product, corrosion and reduction of the product life, and may render the warranty invalid.

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14.3.3 Manufacturing Materials

Acrylonitrile Butadiene Styrene (ABS) is used to construct the ScoutSensor. Only use compatible cleaning materials.

With time, the device casing may become less resistant for the following reasons:

- If an alkaline cleaner or a cleaner with a high alcohol concentration is left for a long time on the surface.
- If a warm disinfectant or detergent is used.

For this reason, Ganshorn recommends using only cleaning agents with an alcohol content that is adequate for sensitive materials, such as Polycarbonate (PC), at room temperature (approx. 20°C).

14.3.4 Before Cleaning

Before cleaning the sensor assembly, or any part of the system, thoroughly inspect for signs of damage.

- Look for any signs of damage and any improper mechanical function.
- Gently bend and flex cables, inspecting them for damage or extreme wear, exposed wires, or bent connectors.
- Confirm that all connectors engage securely.

14.3.5 Cleaning Interval

The ScoutSensor comes into contact with the patient, and it is recommended that it is cleaned after each use. If there is any visible soiling, the device must be cleaned immediately.

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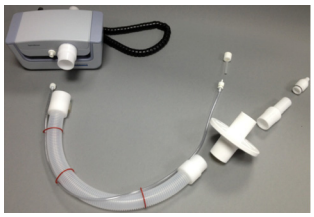
14.4 Rhinomanometry Olives and Flow Tube (Option)



Cleaning Frequency

The nasal olive must be disinfected after each use by immersion in a suitable hospital grade disinfectant. For immersion times and dilution levels consult accompanying documents accompanying the disinfectant.

The flow tube and pressure tube is not in direct patient flow when a PFT filter is used the possibility of contamination is reduced. It is not a requirement therefore, that the flow tube and pressure tube is cleaned after every patient. However, cleaning and placing in a suitable disinfectant solution at regular intervals is required and we recommend that this is carried out when the permanent breathing tube is cleaned.

The rhino flow tube, rhino pressure hose and the breathing tube must be cleaned and disinfected regularly. If in daily use, disinfection and cleaning must be carried out every week. If not in daily use, the disinfection interval can be extended but must be carried out minimally every month.

The permanent breathing tube must be cleaned as defined in chapter 14.4.1 Permanent Breathing Tube.

⚠ CAUTION

- ▲ Disassemble to clean - do not clean/disinfect the flow tube / nasal olive assembly as a complete unit.
- ▲ Observe cross-contamination procedures. Wear rubber gloves to disassemble.

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14.4.1 Permanent Breathing Tube

The ultrasonic breathing tube is designed for use with the PFT bacterial filters. The breathing tube should be cleaned and disinfected every week. The breathing tube is heat resistant to temperatures up to 60°C.

- Remove the breathing tube from the shutter block (see below).
- Unscrew the shutter adapter from the breathing insert (if used).
- Clean the breathing tube and shutter adapter with clear water.
- Immerse the parts in a hospital-grade disinfectant. Follow the dilution and immersion time instructions given with the disinfectant.
- Rinse the parts with clear water, then shake the parts to remove the water. Leave to air dry.
- Screw the shutter adapter onto the breathing insert.
- Insert the breathing insert correctly in the ScoutSensor.

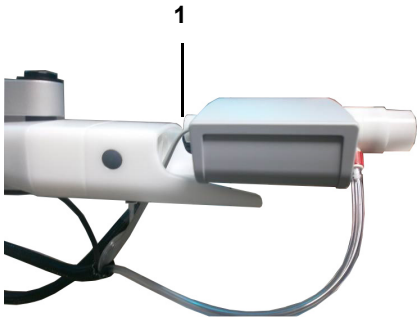
14.4.2 Assembly and Disassembly of the Ultrasonic Flow Transducer

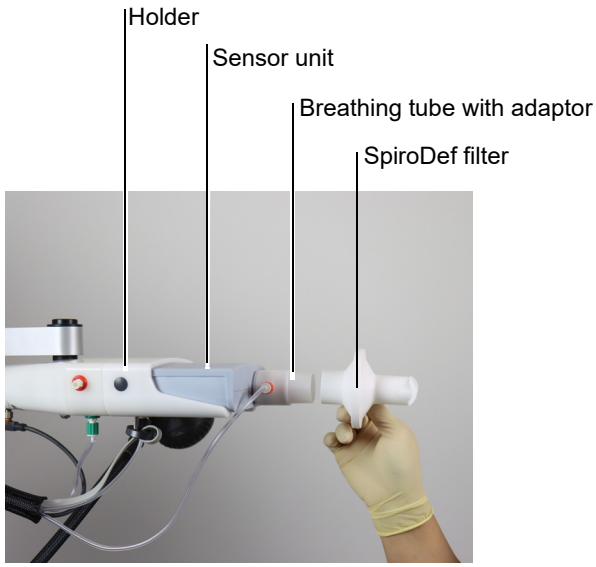
Removal of the Sensor Unit

1. Remove the gas tube (Luer lock) (red) from the adapter.
2. Remove the adaptor by unscrewing the breathing insert.
3. Secure the holder with your free hand, overcome the resistance and pull the ScoutSensor along the guide rail towards the front and off the holder.

If resistance is felt, a wide flat-bladed screwdriver can be used as leverage from the underside between the SpiroScout and the holder.

4. Unplug the power cord (1) at the back end of the ScoutSensor.





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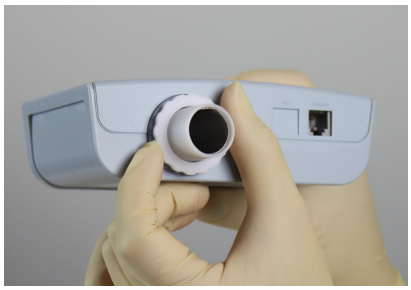
Replacement of the Sensor Unit

1. Correctly fit the permanent breathing tube and place the ScoutSensor on the guide rail.
2. Plug in the power cord at the back end of the ScoutSensor and push the ScoutSensor towards the holder until it clicks in place.
3. Screw the adaptor onto the breathing insert and connect the gas tube (red) with the Luer lock connector.

Removing the Breathing Tube

To remove the permanent breathing tube:

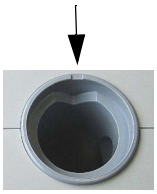
1. Unscrew the counter nut from the back of the unit and pull out the breathing tube from the front of the unit, turning it counterclockwise, if needed.



Replacing the Breathing Insert

1. Screw the appropriate shutter adapter onto the permanent breathing insert.

2. Introduce the permanent breathing insert into the ScoutSensor all the way.
3. Align the arrow on the permanent breathing insert with the notch in the ScoutSensor and fasten the permanent breathing insert in the ScoutSensor using the counter nut.



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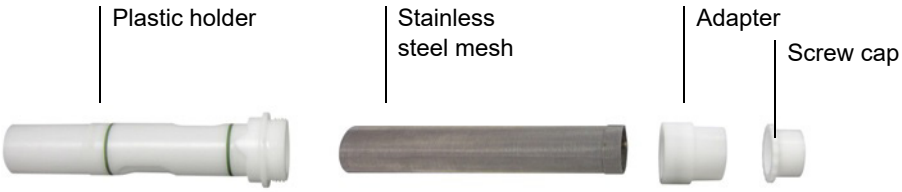
Reusable Breathing Insert Assembly

The reusable insert consists of four parts.



The stainless steel mesh should not be removed for cleaning.

Check that the steel mesh has not moved during cleaning. Adjust if necessary.

Screw the adapter onto the plastic holder

Position the breathing insert in the ScoutSensor.

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15 Maintenance

⚠ WARNING

- ▲ There are no user-replaceable parts inside the device, do not open any part of the system.
- ▲ Only maintenance procedures detailed in this book, e.g. calibration, visual inspection, and cleaning, may be performed by the user.
- ▲ Only GANSHORN or an authorised GANSHORN partner is permitted to perform the 12 monthly maintenance procedures or perform any other service or replacement procedures on the system.

15.1 Unit Maintenance Schedule

The following table indicates the maintenance intervals, the maintenance requirement, and the person authorised to perform the procedure.

Interval	Service	Responsible
After every patient	• Remove the PFT bacterial filter • Wipe clean/disinfect the sensor assembly	→ User
Every day	• Visual system check • Backup[a] • Gas calibration	→ User
Every week	• Body calibration • Volume calibration (if required) • Clean and disinfect the ultrasonic flow transducer • Disinfect the gas hoses	→ User
As Required	• Clean the cabin and cable assemblies • Check pressure (minimum of 6 bar), and change the test gas bottle as necessary	→ User
Every 6 months	• Visual inspection of the cabin, cabin seals, and cables.	→ User
Every 12 months as defined by local regulations.[b]	• Functional tests according to the service handbook • Technical safety inspection • Technical inspection of the measuring system • Recurrent test and test after repair according to IEC/EN62353	→ Service staff authorised by GANSHORN

a. If the unit is networked and linked to an external database, a backup is performed as defined by the network administrator. If the unit is operated standalone, it is essential that the system backup is performed according to standard practice.
b. A check sticker is attached to the device detailing the data of the last inspection and the date for the next inspection.

- ▲ Defective units or damaged cables must be taken out of service or replaced immediately.

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15.1.1 Daily and Weekly Maintenance

System Visual Check

Before each use, visually check the system cables, hoses and connectors. If you detect damage or impaired functions which may result in a hazard to the patient or the operator, the system must be removed from service and repaired by a GANSHORN-approved agent.

Backup

It is recommended that data backup is carried out every day and archiving is carried out regularly in accordance with local policy. Data backup can be to a USB drive, external hard disk, or network drive.

The database backup can be performed from the SQL server manager.

Calibration

Calibration must be carried out before the system is used at the following intervals defined in the calibration section (see para.5.1, Calibration Intervals, page 49).

Cleaning Ultrasonic Flow Transducer

Flow Sensor

(see para.14.4.1, Permanent Breathing Tube, page 153).

15.1.2 Maintenance Every 6 months

Visual Inspection

Visually inspect the cabin, sensor assembly and all cable assemblies, hoses and connections for the following:

- ➜ **Computer table, computer,** - not broken, chipped, cracked, or otherwise visibly damaged.
- ➜ **Cabin**, clean the glass and check that the glass is not cracked or chipped. Check that the cabin is upright, not tilted, and the feet are even. Check that the door opens and closes freely. Examine the rubber door seal for cracks, nicks, perishing or any other signs of damage or wear.
- ➜ **Mains cable, all data cable assemblies and gas hoses** - check that the sheathing and connectors are undamaged and the mains cable has no kinks, abrasion or wear in any cable assembly or gas hose.
- ➜ **Input/output connectors -** all pins and sockets are undamaged, straight and with no signs of excessive wear. Check that all Luer connectors are secure and working correctly.

15.1.3 Every 12 Months or as Defined by Local Regulations

Contact an authorised GANSHORN facility for recurring tests or tests after repair, according to IEC/EN62353.

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15.2 Changing the Fuses

15.2.1 Isolation Fuse

⚠ DANGER

- ▲ Before any fuse is changed, the device must be disconnected from the mains by removing the plug from the wall socket and the cabin.
- ▲ The fuse may only be replaced by the fuse type, as detailed in the table below.

15.2.2 Cabin/Control Module Fuse

Cabin/Control Module Fuse types

Voltage range	Number	Fuse type
100 to 240 VAC	1	Eska T 2.5A/250D

Procedure

1. **Disconnect the device from the mains.**
2. From the back of the cabin, unscrew the fuse holder.

3. Replace the fuse and screw the fuse holder back in place.

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15.3 Decommissioning

Observe the following points concerning the decommissioning and storage of the equipment:

- Back up all LFX program data.
- Disconnect all couplings and connections.
- Remove the breathing insert before packing and transporting the ScoutSensor.
- Clean all devices and components and disinfect them if necessary.
- Correctly pack and, if applicable, correctly mark/label each component.
- Observe the environmental conditions for storage and transportation (technical data of your GANSHORN system).

15.4 Disposal

15.4.1 Electronic Parts

At the end of their life cycle, the GANSHORN device and its accessories must be disposed of in accordance with the applicable international and national waste control regulations for electronic components. Parts must be collected separately from ordinary unsorted municipal waste when marked with the label for separate collection of electronic and electric waste.

Contact your GANSHORN partner or GANSHORN if you have any questions concerning the disposal of your equipment.

15.4.2 Consumables

Consumables must be disposed of in compliance with national and international rules and regulations. Contact your GANSHORN partner or GANSHORN for up-to-date information about the disposal of consumables.

Contamination Risk

Depending on their classification, consumables may be disposed of as domestic or clinical waste.

⚠ CAUTION

▲ Consumables may be contaminated. The operator/customer must establish a quality management system for handling contaminated waste.

▲ The pertinent risk analysis must include the accessories and consumables, especially the disposables intended for single use.

PFT bacterial filters and other single-use consumables

Single-use disposables and PFT bacterial filters must be disposed of in the waste according to the instructions of your quality management system.

Nose Clips and other reusable consumables

Clean and disinfect reusable consumables before discarding them with domestic waste or uncontaminated laboratory waste according to the instructions of your quality management system.

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16 Accessories

⚠ CAUTION

▲ Use only accessories supplied or recommended by GANSHORN. Use accessories according to your facility's standards and manufacturer's recommendations. Always refer to the manufacturer's directions for use. To order accessories, contact GANSHORN or authorised representative.

For a complete current list of all spare parts, contact Ganshorn.

16.1 Spare Parts

General

Part Number	Description
019420626	Permanent breathing tube
019500558	Gas analysis intermediate adapter for a permanent breathing tube
019410701	Silicone mouthpiece for adults (blue)
019410702	Silicone mouthpiece for children and teenagers (natural)

Verification, Calibration, Gas and Regulators

Part Number	Description
019420869	GANSHORN pressure regulator for He/CO
019420863	GANSHORN pressure regulator for O_2
019900521	Test gas cylinder (He/CO/O_2/N).
019420701	Gas cylinder trolley
019420009	3000 ml calibration pump
019600835	Rubber adapter for calibration pump

Power Cables

Contact GANSHORN or authorised representative.

Rhinomanometry Spare Parts

Part Number	Description
019600928	Hose kit for Rhinomanometry for PowerCube+ Series
019500545	Mounting for Rhinomanometry
019500548	Nasal olives (adults)
019500549	Nasal olives (children & teenagers)

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16.2 Consumables

Part Number	Description
019420660	SpiroDef Mouthpiece, PFT Bacterial Filter
019410908	NoseClip pack of 28
019420664	SpiroDef Mouthpiece with NoseClip, pack of 100
019420655	GANSHORN extra safe filter pack (PFT bacterial filter, NoseClip and mouthpiece) pack of 50

Rhinomanometry Consumables

Part Number	Description
019420649	GANSHORN PFT filter/round mouthpiece (pack of 100)
019500540	Foam nose adapter; size: small 12 mm (pack of 50)
019500541	Foam nose adapter; size: medium 15 mm (pack of 50)
019500542	Foam nose adapter; size: large 18 mm (pack of 50).

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17 Technical Data

17.1 PC Requirements

The PC requirements apply to the LFX program being use on stand-alone system. If additional programs are used at the same time, for example ECG software or network software, the requirements increase accordingly.

Safety	Compliance with standard IEC 62368
Operating system	Microsoft Windows® 10, 64 Bit or 32 Bit, the Net Framework 3.5 Features must be activated
Processor	Intel® i3 or AMD equivalent Processor 2.00 GHz or better
Performance index	1.0 (4.0)
RAM	4 GB
Free memory on hard drive	20GB
Grafic	512 MB of VRAM (1 GB recommended)
Monitor resolution	1366x768 pixel display with 16-bit color
Interface	USB

17.2 Body+ and Diffusion+

Manufacturer	GANSHORN GmbH
System Control Stand	Wheeled stand for computer, monitor. Front wheels lockable.
Body Cabin	
Material	Aluminium frame, security glass panels and doors
Dimensions	86 x 185 x 71 cm (without door handle), 77 cm (with door handle)
Weight	Approx. 150 kg (with PowerCube installed below the cabin)
Volume	940 L
Max Load	• Bench, 160 kg • Chair, 120 kg
Door Lock	Electromagnetic
Software	LFX for Windows
Classifications	
Device	Active medical product, class IIa
Applied part	• Body Cabin inside Typ BF • Provo.X Typ BF • ScoutSensor Typ BF • Systembox Typ B
Corrections	
F/V	ERS or ATS
Inhalation	BTPS (environment module) or real-time BTPS correction

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Gas volume	STPD (environment module) or real-time BTPS correction
Computer interface	
Data transfer to PC	RS-232
Signal transmission	Opto isolated RS-232 interface, 57.600 Baud
Database	
Local	• GANSHORN SQL • Authentication user defined
GDT	Import and export with user-defined settings
SEMA3	SCHILLER SEMA3 integration

17.3 Ambient Conditions

Operation	
Ambient temperature	+15 to +35°C
Atmospheric pressure	700 to 1060 hPa
Relative humidity	10 to 95% (no condensation)
Max. warm-up time	• 0 (not measurable at stable ambient conditions) • Twenty minutes for CO (diffusion), an error message is given if measurement is attempted before the 20-minute warm-up time.
Ambient conditions, storage and transport	
Ambient temperature	-20 to +50°C
Atmospheric pressure	600 to 1060 hPa
Relative humidity	10 to 95% (no condensation)

17.4 Standards

Quality management	ISO 13485
MDD 93/42/ECC	CE Marked
Electrical safety	EN 60601-1 (Edition 3.2)

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17.5 Flow and Volume

Sensor	GANSHORN ScoutSensor, standalone or mounted on swivel arm
Material	Polyethylene
Patient protection and hygiene	Single patient use, disposable PFT bacterial filter - see 17.5.1 PFT Bacterial Filter
Dead space, complete	200 cm^3
Pre/post-measurement	Comparison pre/post medication possible.
Prediction equations	Pre-installed predicted value sets and on request others (see para. Ref. module, page 40)
Standards compliance	• ATS • ERS
Flow measurement	
Measurement method	Ultrasound transit time measurement
Measuring range	0 to 18 l/s
Accuracy	< ± 2.0% or 50 ml/s for 0 to ± 16 l/s (the larger value applies)
Resolution	0.01 l/s = 10 ml/s
Volume measurement	
Measurement method	Digital integration
Measuring range	Not limited, graphical display 20 l
Accuracy	± 2%
Resolution	1 ml

17.5.1 PFT Bacterial Filter

Type	Single patient use, electrostatic filter, fleece with a protective membrane.
Bacterial/viral protection	• Viral filtration efficiency (VFE) at 99.975% • Bacterial filtration efficiency (BFE) at 99.999%
Steady Flow Resistant	• maximal 0,083 kP/l/s at 3 l/s • maximal 0,096 kP/l/s at 6 l/s • maximal 0,123 kP/l/s at 12 l/s
Dead space	85 ml
Material	White polypropylene

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17.6 Body Plethysmography

Pressure Mouth Sensor	
Measurement principle	Piezo resistive pressure sensor
Measuring range	3 kPa
Accuracy	± 1%
Resolution	0.025 mbar = 0.00250 kPa
Cabin pressure	
Measurement method	Piezo resistive pressure sensor
Measuring range	± 0.136 kPa
Accuracy	± 1%
Resolution	0.01 kPa
Shutter closing time	User defined between 1 and 5 seconds
Measurements	Spirometry/flow-volume, MVV, Body plethysmography (resistance loop: SRtot, SReff, Rtot, Reff, Rin, Rex, lung volume: TGV, TLC, RV, RV%TLC), ROcc, PImax/ PEmax/P100, offline input of blood gas values

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17.7 Diffusion

Measured curves	He and CO
Standards	Determination of diffusion capacity (TLCO) and VA meet the 2017 ERS/ATS standards
Hold breath time	User sets between 4 and 12 seconds
Breath-hold time calculation	• Jones and Meade • ERS • Ogilvie
Test gas oxygen fraction	17 to 21%
Test gas Helium fraction	He - 18%, CO 0.25%
Test gas CO fraction	CO - 0.20 to 0.30%

17.7.1 CO Analyser

Method	Non-dispersive Infrared Analyser
Range	0 to 3000 ppm CO
Accuracy	± 2.5% FSO

17.7.2 He Analyser

Method	Ultrasound
Range	0 to 20 Vol.% He
Accuracy	± 2.5% FSO

17.8 Nitrogen Washout

Measured curves	O_2
Standards	ERS/ATS
Test gas oxygen fraction	> 99.99%

17.8.1 Oxygen Analyser

Method	Ultrasound
Range	10 to 100%
Accuracy	± 1%

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17.9 Installing Updates

Only GANSHORN or authorised GANSHORN partners are permitted to install the software to guarantee optimal set-up of the system.

No additional safety considerations must be observed for the installation or decommissioning of a system.

17.10 Uninstalling the Software

Delete the LFX installation directory (e.g. C:\LFX) and all its subdirectories. This will remove LFX from your system. During installation, no entries to other files, such as Windows® registry, or ".ini" files, are made.

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18 Electromagnetic Disturbances

18.1 Preventing Electromagnetic interferences

"Non-ionising electromagnetic radiation"

The user can help avoid electromagnetic disturbances by keeping the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the PowerCube+ Series. The distance of 0.3 m depends on the output performance/frequency of the communication device, as indicated below.

HF source Wireless communication devices	Transmitter frequency [MHz]	Testing frequency [MHz]	Max. power P [W]	Distance d [m]
Various radio services (TETRA 400)	380-390	385	1.8	0.3
- Walkie-talkies (FRS) - Rescue service, police, fire brigade, servicing (GMRS)	430-470	450	2	0.3
LTE band 13/17	704-787	710/745/780	0.2	0.3
- GSM800/900 - LTE band 5 - Radiotelephone (microcellular) CT1+, CT2, CT3	800-960	810/870/930	2	0.3
- GSM1800/1900 - DECT (radio telephone) - LTE Band 1/3/4/25 - UMTS	1700-1990	1720/1845/1970	2	0.3
- Bluetooth, WLAN 802.11b/g/n - LTE Band 7 - RFID 2450 (active and passive transponders and reading devices)	2400-2570	2450	2	0.3
WLAN 802.11a/n	5100-5800	5240/5500/5785	0.2	0.3

⚠ CAUTION

- ▲ Portable HF telecommunication devices must not be used within a radius of 0.3 m from the PowerCube+ Series and its cables.
- ▲ Do not place the PowerCube+ Series on top of other electric/electronic devices, i.e. maintain a sufficient distance from other devices (this includes the patient cables).
- ▲ Using accessories, transducers and cables other than those specified or provided by the equipment manufacturer could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

For permanent HF telecommunication devices (e.g. radio and TV), the recommended distance can be calculated using the following formula: $d = 1.2 \times \sqrt{P}$ for 150 kHz to 800 MHz and $d = 2.3 \times \sqrt{P}$ for 800 MHz to 2.5 GHz

d = recommended minimum distance in meters
P = transmitting power in Watts

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18.2 Manufacturer's Declaration

18.2.1 Electromagnetic Emissions

The device is intended for use in an electromagnetic environment, as described below. Customers and users must check that the device is only used in such environments.

Emission Measurements	Compliance	Electromagnetic Environment - Guidance
RF-emissions according to CISPR 11	Group 1	The device uses RF energy exclusively for its internal function. RF emission is very low, and nearby electronic devices are unlikely to be disturbed.
RF emissions acc. to CISPR 11 Emission of overtones acc. to IEC 61000-3-2 Emission of voltage fluctuations/flicker acc. to IEC 61000-3-3	Class A Class A Complies	The device is a professional medical device, i.e. intended for use by healthcare professionals. It is not intended for home use or to be used in a domestic environment

18.2.2 Electromagnetic Immunity

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic environment guidance
ESD IEC 61000-4-2	± 8 kV Contact ± 15 kV Air	± 8 kV Contact ± 15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the Relative Humidity (RH) should be at least 30%.
EFT IEC 61000-4-4	± 2 kV Power supply lines ± 1 kV I/O lines	± 2 kV Power supply lines ± 1 kV I/O lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0,5 cycle at angle 0, 45, 90, 135, 180, 225, 270, and 315 degrees. < 5% U_T (95% dip in U_T) for 1 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 seconds	< 5% U_T (> 95% dip in U_T) for 0,5 cycle at angle 0, 45, 90, 135, 180, 225, 270, and 315 degrees. < 5% U_T (95% dip in U_T) for 1 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. The unit shut off during the > 95% for 5-second disturbance. If the device user requires continued operation during power mains interruptions, it is recommended that the device is powered from an uninterrupted power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
Note. U_T is the AC mains voltage before the application of the test level.			

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18.2.3 Emissions equipment and systems

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic environment guidance
			Portable and mobile communications equipment should be used no closer to any part of this device, or cable, than the recommended separation distance (d) calculated from the equation applicable to the frequency of the transmitter **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 Vrms outside ISM band 6 Vrms in the ISM & amateur radio band 150 kHz to 80 MHz	$[V_1]$ = 3Vrms $[V_1]$ = 6Vrms (150 kHz to 80 MHz)	$d = \frac{3.5}{V_1} \times \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 to 2700 MHz	$[E_1]$ = 3 V/m 80 to 2700 MHz	$d = \frac{6}{E_1} \times \sqrt{P}$ for 80 to 2700 MHz
Proximity fields from RF wireless communications equipment IEC 61000-4-3	see para. 18.2.4 Immunity to proximity fields from RF wireless communications equipment, page 171	see para. 18.2.4 Immunity to proximity fields from RF wireless communications equipment, page 171	$d = \frac{6}{E_1} \times \sqrt{P}$ for tested frequencies Tested Frequency, see para. 18.2.4 Immunity to proximity fields from RF wireless communications equipment, page 171
			P is the maximum power in watts, and d is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site[a] survey, should be less than the compliance[b] levels (V_1 and E_1). Interference may occur in the vicinity of equipment marked with the following symbol  non-ionizing radiation

Note 1. At 80 and 800 MHz, the higher frequency range applies.
Note 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts, and TV broadcasts, cannot be predicted theoretically with accuracy. An electromagnetic site survey should be considered to access the electromagnetic environment due to fixed RF transmitters. If the measured field strength in the location where the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

b Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.

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18.2.4 Immunity to proximity fields from RF wireless communications equipment

Test frequency [MHz]	Band[a] [MHz]	Service	Modulation	max. power P [W]	Distance d [m]	Immunity level [V/m]
385	380-390	Various radio services (TETRA 400)	Pulse modulation[b] 18 Hz	1.8	0.3	27
450	430-470	- Walkie-talkies (FRS) - Rescue service, police, fire brigade, servicing (GMRS)	FM [c] ± 5 kHz ± 1 kHz sine	2	0.3	28
710 745 780	704-787	LTE band 13/17	Pulse modulation 217 Hz	0.2	0.3	9
810 870 930	800-960	- GSM800/900 - LTE band 5 - Radio telephone (microcellular) CT1+, CT2, CT3	Pulse modulation 18 Hz	2	0.3	28
1720 1845 1970	1700-1990	- GSM1800/1900 - DECT (radio telephone) - LTE Band 1/3/4/25 - UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400-2570	- Bluetooth, WLAN 802.11b/g/n - LTE Band 7 - RFID 2450 (active and passive transponders and reading devices)	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11a/n	Pulse modulation 217 Hz	0.2	0.3	9

a. For some services, only the uplink frequencies are included.
b. The carrier shall be modulated using a 50% duty cycle square wave signal.
c. As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be the worst case

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18.2.5 Recommended separation distances

For fixed installed HF transmitters (z.B Radio and TV transmitters), the following minimum distance to the transmitter can be calculated as follows:

Maximum Power Output [Watts]	**Separation distance according to the frequency of the transmitter [m]**	
	150 kHz to 80 MHz $d = \frac{3.5}{V_1} \times \sqrt{P}$	**80 MHz to 2700 GHz** $d = \frac{6}{E_1} \times \sqrt{P}$
0.01	0.04	0.06
0.1	0.11	0.19
1	0.35	0.6
10	1.1	1.9
100	3.5	6

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the transmitter's frequency. P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer.

Note. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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19 Troubleshooting

19.1 General

- In the event of a malfunction, visually check the mechanical connections and equipment:
  - Check the connection to the mains power and electrical connections.
  - Tubing
  - Enclosures
  - Operator and display elements.
  - Connection to external system components.
  - Check that all system components are connected correctly.

- Switch on the system and restart the software:
  - Perform calibration and check calibration trend (see para.4.9, Offline Parameters, page 47).
  - Record any error messages, then contact GANSHORN service for possible suggestions.

Error Message	Check/Procedure/Possible Cause	Check
No data communication with ScoutSensor.	• The system has lost the communication port with the sensor or the incorrect device or port defined.	• Check system settings that the correct device and port are defined (see para.13, Settings Overview, page 129). • In system settings, select the remove device option to remove the device. Then add the device with the correct device/port for a clean installation.
Not possible to take a SpiroScout recording.	• Faulty PFT bacterial filter. • Faulty flow tube.	• Replace PFT bacterial filter. • Remove and clean the flow tube (see para.14.4.2, Assembly and Disassembly of the Ultrasonic Flow Transducer, page 153). • Replace the flow sensor.
Zero point/ baseline error message.	• Zero point is performed automatically when the LFX is switched on and every 15 minutes during use. If the deviation is too large, an error message is displayed.	• Warm-up time must be at least 30 minutes. • Check the sensor is kept still during zeroing. • Check that the room is draft free and an even temperature is maintained. Close all windows. • Switch off any air conditioning in the room. • Check that nothing affects sensor zeroing, e.g. breath. Move the patient/ operator away from the sensor. • Replace the PFT bacterial filter.

All calibration procedures are detailed earlier in this book (see para.5, Calibration, page 49).

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20 Revision History

Rev 1	22.02.2016	Initial release
Rev 2	18.05.2016	Update software 1.7
Rev 3	18.05.2016	Update TÜV Assessment 60601. Software 1.8
Rev 4	05.10.2020	Update for software release 1.9
Rev 5	8.06.2022	Update following chapters 1.17.1/1.17.2 and 1.17.3 14.2.8 Add Chapter 21 Symbols
Rev 6	23.03.2023	Update EMC information Update and revision for LFX software 1.10

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16 Appendix – Symbols and Pictograms

This appendix lists all general symbols that may be present on the device, label and accessories. Not all of those symbols are necessarily present on your device.

	Identification of the manufacturer
	Identification of the manufacturing date
	Identification of the distributor
	Identification of the importer
MD	Medical device
SN	Serial number
REF	Reference number
LOT	Batch code
GTIN	Global trade item number
CAT	Catalogue number
QTY	Quantity
UDI	UDI: unique device identification as QR code machine readable and human readable as number, e.g. (01) 0 7613365 00210 2 (21)xxxx.xxxxxx
	Number of pieces in the packaging
CE XXXX	Notified body, e.g. CE 0123 marking notified body TÜV SÜD
CE	CE marking affirms its conformity with European Standards
UK CA	UK Conformity Assessed

Art. no.: 011400721 Rev. draft06_d

	The regulatory compliance mark for the Australian Standards
	The device is recyclable
	The symbol for the recognition of electrical and electronic equipment. The device must not be disposed of in the household waste.
	The symbol for the recognition of a battery. The battery must not be disposed of in the household waste.
	The packaging is made see below and can be recycled. • 2 high-density polyethene • 4 low-density polyethene • 5 polypropylene • O others
	Federal law (USA) restricts this device to sale by or on the order of a physician.
	Non-ionising electromagnetic radiation. To indicate that the device contains a Radio Frequency (RF) transmitter to transmit data. e.g. Bluetooth or Wi-Fi
	The device contains a Bluetooth module
	Do not reuse
	Used by date (expiry date of battery, electrodes or other consumables)
	Temperature range for the storage or transport, respectively
	The pressure range for the storage or transport, respectively
	Humidity range for the storage or transport, respectively
	Consult the Instruction for Use (indicates the need for the user to consult the Instruction for Use)
	Caution: Consult the warning and safety information in the instructions for use
	Use within X day after opening (electrode or other consumables)

Art. no.: 01140721 Rev. draff06_d

	Keep the device dry (store the device in a dry location)
	Keep the device away from sunlight (protect the device from direct sunlight)
	Fragile device, handle the device with care
	Transport the device upwards (this way up)
	Do not use hooks
	EIP = electronic information product (does not contain any toxic and hazardous substances or elements above the maximum concentration values (the product can be recycled and re-used).

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