

Specificație Tehnică Completată

Anexa 1 Bodypletismograf, NR:DM000836087

Model: PowerCube + Series

Producător: GANSHORN Medizin Electronic GmbH

Țara: GERMANIA

Specificarea tehnică deplină solicitată, Standarde de referință	Specificația tehnică propusă de ofertant
Descrierea funcției și utilizarea Bodypletismograf pentru efectuarea testelor funcționale complexe întru evaluarea funcției pulmonare II. Specificații principale Parametrii măsurați: Spirometrie: VC Pre/Post, FVC Pre/Post, MVV, FEV1, FEV1/FVC, MFEF 25-75, FEF 25, FEF 50, FEF75, PEF test de provocare Volume statice, dinamice, Curbe de debit (volum/timp sau FVC), curbe flux volum, curbe MVV Bodyplethosmografie: Volumul TGV, TLC, FRC, FRCpleth, RV, Rezistența căilor respiratorii - RAW, sRAW, GAW, sGAW, Pre/Post	Descrierea funcției și utilizarea Bodypletismograf pentru efectuarea testelor funcționale complexe întru evaluarea funcției pulmonare II. Specificații principale Parametrii măsurați: Spirometrie: VC Pre/Post, FVC Pre/Post, MVV, FEV1, FEV1/FVC, MFEF 25-75, FEF 25, FEF 50, FEF75, PEF DA, pag.87,88 din Power Cube body+ manual test de provocare DA, pag.72 din Power Cube body+ manual Volume statice (Volum rezidual RV, Capacitatea pulmonară totală TLC, Volumul de aer curent VT, Capacitatea reziduală funcțională FRC, Volumul inspirator de rezervă IRV, Volumul expirator de rezervă ERV) DA, pag.14,87 din Power Cube body+ manual Volume dinamice (Volum expirator forțat FEV1, Capacitatea vitală forțată FVC) DA, pag.87 din Power Cube body+ manual Curbe de debit (volum/timp sau FVC), curbe flux volum, curbe MVV DA, pag.44,88 din Power Cube body+ manual Bodyplethosmografie: Volumul TGV, TLC, FRC, FRCpleth, RV DA, pag.88 din Power Cube body+ manual Rezistența căilor respiratorii - RAW, sRAW, GAW, sGAW, Pre/Post DA, pag.14,86 din Power Cube body+ manual

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Mecanica respirației: Presiunea maximă la inspir/expir (MIP/MEP) Capacitatea de difuziune a CO: DLCO prin metoda single-breath, DLCO corrected by Hb VA, KCO Rezistența căilor respiratorii: Rezistența ocluziunilor (Pre și Post BD) Specificații: Măsurarea fluxului: Flow range 0-14 L/s acuratețea $\leq \pm 2\%$ sau 20mL/s Diapazon: 0-12L Rezistența $< 1.0 \text{ cmH}_2\text{O/L/s}$ @14L/s Multi-analizator de gaze: Monoxid de carbon și Metan (CO/CH₄) sau Monoxid de carbon și Heliu (CO/He). Hardware: Volum în interiorul cabinei: 800 - 1000l Cabină dotată cu scaun adaptabil pe înălțime, care suportă greutate corporală de peste 130 kg Porturi: USB A-8, RS-232, HR-TTL	Mecanica respirației: Presiunea maximă la inspir/expir (MIP/MEP) DA, pag. 14 din Power Cube body+ manual Capacitatea de difuziune a CO: DA, pag. 88 din Power Cube body+ manual DLCO prin metoda single-breath, DA, pag. 14 din Power Cube body+ manual DLCO corrected by Hb DA, pag. 14 din Power Cube body+ manual VA, KCO DA, pag.67 din Power Cube body+ manual Rezistența căilor respiratorii: Rezistența ocluziunilor (Pre și Post BD) DA, pag.14,62 din Power Cube body+ manual Specificații: Măsurarea fluxului: Flow range 0-20 L/s DA, pag. 86 din Power Cube body+ manual acuratețea $\pm 2\%$ DA, pag. 86 din Power Cube body+ manual. Diapazon: 0-20L DA, pag. 86 din Power Cube body+ manual Rezistența 0.002 kPa/l/s = approx. 0.02 cmH₂O/l/s DA, pag.86 din Power Cube body+ manual Multi-analizator de gaze: Monoxid de carbon și Metan (CO/CH₄) DA, pag.88 din Power Cube body+ manual Hardware: Volum în interiorul cabinei: 940l DA, pag.84 din Power Cube body+ manual Cabină dotată cu scaun adaptabil pe înălțime, care suportă greutate corporală de peste 125 kg. DA, pag.15,84 din Power Cube body+ manual Porturi: USB A-8, RS-232, HR-TTL DA, pag.18,84 din Power Cube body+ manual
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100 -240V $\pm 10\%$ 50/60Hz Software: Interfața- minim limba engleză, eventual română Programe de calibrare integrate Posibilitate de stocare date ATS/ERS quality check Completații: Camera Bodypletismograf PC minim i7, minimum 16GB RAM, minim 512 GB SSD Cărucior p/u PC și componente PC, cu fixator pentru 3 butelii de gaze Tastatură, mouse, monitor LCD 24" Modul p/u DLCO Posibilitate de atașare ulterioară a modulului pentru oscilometru, opțional	100 -240V $\pm 10\%$ 50/60Hz DA, pag.85 din Power Cube body+ manual Software: Interfața- limba engleză DA Programe de calibrare integrate DA, pag.31 din Power Cube body+ manual Posibilitate de stocare date DA, pag.85 din Power Cube body+ manual ATS/ERS quality check DA, pag.86 din Power Cube body+ manual Completații: Camera Bodypletismograf PC i5, 4GB RAM, 1T HDD DA Echipamentul medical propus este însoțit de Certificat CE în configurația actuală, ceea ce atestă că sistemul (inclusiv software-ul și unitatea PC aferentă) îndeplinește toate cerințele de conformitate și siguranță prevăzute de legislația europeană aplicabilă. Software-ul furnizat este optimizat pentru a funcționa în mod stabil și eficient pe configurația PC inclusă în ofertă. Testarea și validarea clinică a produsului s-au realizat pe această configurație, fără a fi necesare resurse hardware suplimentare. Menționăm că unitatea PC nu va fi utilizată pentru activități suplimentare (navigare, editare documente, aplicații externe etc.), ci exclusiv pentru rularea aplicației medicale dedicate. Cărucior p/u PC și componente PC, fixator pentru butelii de gaz DA, pag.15 din Power Cube body+ manual Tastatură, mouse, monitor LCD 24" DA Modul p/u DLCO DA, pag.14 din Power Cube body+ manual Posibilitate de atașare ulterioară a modulului pentru oscilometru, opțional DA, pag.14 (ROCC Oscillatory Resistance) din Power Cube body+ manual
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Butelii: gaz de calibrare, gaz p/u DLCO, adaptarea presiune. Piese bucale cu filtru accesibile în țară 100 buc. Toate consumabilele și piesele necesare incluse pentru buna funcționare a dispozitivului medical. III. Cerințe de energie electrică Tensiune de alimentare: 220 ± 10 V, AC, 50/60 Hz. Manual de operare și întreținere Instalarea și mentenanța: Ofertantul trebuie să garanteze, că echipamentul să fi instalat de către personal certificat sau calificat. Orice precondiții pentru instalare vor fi comunicate beneficiarului în prealabil, descrise în detaliu în formă scrisă. Ofertantul va furniza un plan cuprinzător de întreținere. Costul planului de întreținere urmează, să fie definit și garantat pe perioada de garanție. Serviciul să aibă personal competent, infrastructură, adecvată și piese de schimb necesare pentru a putea răspunde la orice reclamații și necesități privind buna funcționalitate a dispozitivului medical. Instruire: Ofertantul va oferi instruire utilizatorilor (inclusiv modul de utilizare și întreținere a echipamentului). Piese de schimb: Echipamentul trebuie să fie asigurat pe un termen de 10 ani cu piese de schimb	Butelii: gaz de calibrare, gaz p/u DLCO, adaptarea presiune. DA Piese bucale cu filtru accesibile în țară 100 buc. DA, pag.23 din Power Cube body+ manual Toate consumabilele și piesele necesare incluse pentru buna funcționare a dispozitivului medical. DA III. Cerințe de energie electrică Tensiune de alimentare: 220 ± 10 V, AC, 50/60 Hz. DA, pag.85 din Power Cube body+ manual Manual de operare și întreținere DA Instalarea și mentenanța: Ofertantul trebuie să garanteze, că echipamentul să fi instalat de către personal certificat sau calificat. DA Orice precondiții pentru instalare vor fi comunicate beneficiarului în prealabil, descrise în detaliu în formă scrisă. DA Ofertantul va furniza un plan cuprinzător de întreținere. DA Costul planului de întreținere urmează, să fie definit și garantat pe perioada de garanție. DA Serviciul să aibă personal competent, infrastructură, adecvată și piese de schimb necesare pentru a putea răspunde la orice reclamații și necesități privind buna funcționalitate a dispozitivului medical. DA Instruire: Ofertantul va oferi instruire utilizatorilor (inclusiv modul de utilizare și întreținere al echipamentului). DA Piese de schimb: Producătorul și operatorul economic vor asigura disponibilitatea pe un termen de 10 ani a pieselor de schimb pentru echipamentul medical DA
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PowerCube Series Body+ and Diffusion+

Pulmonary Function Testing

Art. no.: 011400702 Rev. 01

User Guide



GANSHORN

SCHILLER GROUP

Sales and Service Information

The GANSHORN sales and service center 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>



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CE 0123

The PowerCube Body+ / Diffusion+ system 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 the Annex I of the Medical Device Directive 93/42/EE regarding safety, functionality and labeling. 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

1.1 Intended Use



- ▲ The PowerCube Body+ / Diffusion+ is a PC-based ultrasonic system for measuring and analysing breath flow and volume. It is intended for use in hospital and clinic settings to measure and analyse lung function parameters in adult and paediatric patients over 5 years of age.
- ▲ The PowerCube Body+ / Diffusion+ is indicated in the following situations:
 - To detect the presence or absence of pulmonary dysfunction
 - To determine the effect of lung disease
 - To screen individuals at risk for lung disease
 - To assess preoperative risk
 - To assess the potential effects or response to environmental or occupational exposure
 - To assess impairment and/or disability
 - To monitor the effects of therapy
 - To describe the progression of lung diseases
 - To monitor for adverse reactions to drugs with known pulmonary toxicity

Bodyplethysmography

- ▲ Additionally, bodyplethysmography analyses the following:
 - Airway resistance
 - Lung volume detection

Diffusion

- ▲ The diffusion option analyses the following:
 - Single Breath Diffusion
 - Real time Single Breath Diffusion

1.2 Contraindications



- ▲ The use of the PowerCube Body+ / Diffusion+ is not indicated in the following situations:
 - Haemoptysis of unknown origin
 - Unstable cardiovascular status
 - Thoracic, abdominal or cerebral aneurysms
 - Presence of any acute disease that might interfere with test performance
 - Chest or abdominal pain of any cause
 - Oral or facial pain exacerbated by a mouthpiece or other accessories necessary for the tests
 - Recent surgery of thorax or abdomen
 - Stress incontinence
 - Dementia or a confused state
 - Children less than 5 years old

1.3 User profiles

The PowerCube Body+ / Diffusion+ is suitable for use by the following:

- Pulmonary specialists
- Allergists
- Paediatricians
- General practitioners
- Occupational health practitioners and nurses

1.3.1 Training

An introduction of at least an hour is recommend before using the device.

1.4 Organisational Measures



- ▲ Before using the PowerCube Body+ / Diffusion+, ensure that an introduction regarding the functions and the safety precautions has been provided by a medical product representative.
- ▲ This user guide, and especially these safety notes, must be read and observed.
- ▲ These operating instructions do not override any statutory or local regulations for the prevention of accidents and environmental protection.
- ▲ Ensure this operating instruction manual is always complete, legible and available at the point of use of the PowerCube Body+ / Diffusion+.
- ▲ Portable communication equipment, HF two-way radios and devices marked with the  symbol can affect the system (see para.10.9, Measures to Prevent Electromagnetic Interferences, page 90).
- ▲ Only use accessories and disposables recommended or supplied by GANSHORN. Use of other than recommended or supplied parts may result in inaccurate information and/or damage to the unit.
- ▲ If uncertain about the accuracy of any measurement, check the patient by alternative means and ensure the unit is correctly calibrated.
- ▲ If unexpected readings are obtained, make sure the equipment is functioning correctly, check the connections, check the calibration, 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 areas of medical locations where an explosion hazard may occur. An explosion hazard may result from the use of flammable anaesthetics, skin cleansing agents and disinfectants. Furthermore, the device is not suitable for application in an oxygen-enriched atmosphere. The atmosphere is considered to be oxygen-enriched when the room air contains more than 25% of oxygen or nitrous oxide.

1.5 General Condition of the Patient



- ▲ Before starting a pulmonary function test, check the patient's general condition to ascertain that the test can be carried out without any risk for the patient. This is especially important in the case of forced breathing manoeuvres.
- ▲ Measurements that may be hazardous to the patient may only be performed if a physician is present all the time. Observe the intended use and contraindications.

1.6 Data Security



- ▲ If the computer is part of a network, (LAN, WLAN, HIS, etc.), 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 of the network is the sole responsibility of the user.

Data Backup

- ▲ Ensure adequate data backup facilities are in place and backup is regularly performed to external storage media (ZIP drive, streamer, CD-ROM etc.)

1.7 Responsibility of the User



- ▲ The system must be calibrated at regular intervals as defined in this user guide.
- ▲ The numerical and graphical results and any interpretation given must be examined with respect to the overall clinical condition of the patient and the general recorded data quality. The quality of the measurements must be considered when interpreting the results. It remains the physician's responsibility to correctly perform the measurement, establish a diagnosis and initiate a suitable therapy.
- ▲ The quality of the measurements must be considered when interpreting the results. The quality of the pulmonary function test results is largely dependent on the patient's cooperation. It is the users responsibility to instruct and motivate the patient to perform tests of acceptable high quality.
- ▲ It is the owner's responsibility that the valid regulations for safety and prevention of accidents are observed.
- ▲ All persons working with the system must read this user guide of the PowerCube Body+ / Diffusion+ and the operating instructions of any ancillary equipment. In particular the safety instructions of the system must be read and understood.
- ▲ Operating any system or ancillary equipment with defective cables, defective hoses, defective connectors, or defective casing, etc., constitutes a danger to the patient or the user. Immediately replace a damaged unit, damaged cables or hoses, and connections.
- ▲ The safety, reliability and performance of the device can only be guaranteed when the maintenance intervals as stated in the Maintenance section are observed.

1.8 Hygiene and 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 given in this book.
- ▲ Do not use solvent or abrasive cleaners on either the unit, hoses or cable assemblies.
- ▲ Do not under any circumstances, immerse the unit, cable assemblies, hoses, or transducers in liquid.
- ▲ Do not use high-temperature sterilisation processes (such as autoclaving). Do not use E-beam or gamma radiation sterilisation.
- ▲ Do not reuse disposable accessories marked with the symbol  to prevent cross infection. The PFT bacterial filter is a single use disposable.

1.9 Maintenance



- ▲ The PowerCube Body+ / Diffusion+ system is only allowed to be installed, put into service and maintained in accordance with the valid regulations and standards. Installation, initial operation, modifications and repairs, and technical safety inspections may only be performed by GANSHORN or by an authorized GANSHORN partner.
- ▲ Do not open any part of the system. There are no serviceable parts inside. Refer servicing to qualified technicians authorised by GANSHORN only.
- ▲ The system must not be altered or modified in any way by non-authorised persons.
- ▲ Inspection and calibration must be carried out on a regular basis as detailed in the Maintenance section ([see para.8, Maintenance, page 73](#)).

1.10 Electrical



Electric Circuit, Wall Sockets

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

Portable Multiple Outlets

- ▲ Do not place portable multiple outlets on the floor to prevent liquids from penetrating and to protect them from mechanical damage.
- ▲ It is not permitted to use the multiple sockets provided with the system for connection of 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 Body+ / Diffusion+ and the PC. Do not replace this cable.

1.11 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 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.
- ▲ If the device and/or device data and/or device purpose change as a result of upgrades, modification or repair, all labels and documents must be updated.
- ▲ Accessory equipment must be certified according to the respective IEC standards (e.g. IEC/EN 60950 for data processing equipment, IEC/EN 60601-1 for medical equipment, clause 16 of IEC 60601-1:2005). Furthermore all configurations shall comply with the current version of the system standard IEC/EN 60601-1-1. Anyone who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, consult the technical service department or your local representative.
- ▲ 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, the use of 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 communication equipment (mobile phones, DECT telephones), RF two-way radios and devices marked with the  symbol can affect the system ([see para.10.9, Measures to Prevent Electromagnetic Interferences, page 90](#)).

1.12 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 can result in danger to the patient and inaccurate measurements.
- ▲ Regularly check the measurement gas tube, gas valve and pressure gauge for any signs of damage or modification. If you notice any form of damage or modification you must 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 - 8 bar.
- ▲ Before using the gas ensure 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 filling state 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.

1.13 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 Symbols and Pictograms

The safety level is classified according ANSI Z535.4. The following overview shows the safety symbols and pictograms used in this user guide.



For a direct danger which could lead to severe personal injury or to death.



For a possibly dangerous situation, which could lead to serious bodily injury or to death.



For a possibly dangerous situation which could lead to personal injury.



For general safety notes.



Important or helpful user information or safety information.



Reference to other guidelines.



Notified body of the CE certification (TÜV P.S.).

1.14.1 Symbols Used on the Device and Accessories



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



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



The unit/component can be recycled.



Follow the instructions in the accompanying documentation.



Potential equalisation



Indoor use only



May cause or be susceptible to electromagnetic disturbances ((see [para.10.9, Measures to Prevent Electromagnetic Interferences, page 90](#))).



Keep away from rain (keep dry).



Microphone Connector



Splash-proof safety rating against dust and water ingress.



Manufacturer details: GANSHORN.



The date of manufacture in the yyyy-mm format. The country of origin is indicated to the right of the date.



Disposable item - single use, do not use twice.



Safety control sticker detailing the date of the next planned maintenance.



Reference and serial number of the unit.

2 Introduction

The PowerCube Body+ / Diffusion+ is a PC-based system designed to measure and take Spirometry and Bodyplethysmography recordings. The standard for the PowerCube is **slow and forced Spirometry** and, according to system setup and options installed, any of the following:

- Bodyplethysmography
- Diffusion
- P 0.1 / P Imax (P 0.1 = pressure at 0.1 second after start of inhalation
P Imax = the maximum inhaled pressure)
- ROCC Oscillatory Resistance
- Additionally a provocation atomizer is available as an option for Provocation recordings

Recordings are made with an ultrasound sensor. This sensor has a disposable single use PFT Bacterial filter that is changed for every patient helping to prevent patient cross contamination.

2.1 Measurements

2.1.1 Spirometry

Spirometry determines the lung volume and partial volumes including inspiratory and expiratory vital capacity VC and Slow vital capacity and Forced vital capacity.

2.1.2 Bodyplethysmography

Bodyplethysmography determines the thoracic gas volume (TGV) and specific airway resistance (sRaw) as primary measures. In combination with deep expirations and inspirations, total lung capacity (TLC) and residual volume (RV) can be determined. Airway resistance (Raw) is calculated as the ratio of sRaw to TGV. For determining sRAW, the movement of the chest is monitored with a delta volume measured with pressure sensors in a sealed cabin. TGV is calculated as a ratio of mouth pressure and delta volume.

2.1.3 Diffusion

Single Breath Diffusion is a non-invasive method to measure the diffusion capacity and the volumes of the lung. The subject inhales a mixed gas consisting of 18% He, 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 the CO is diffused into the lung and blood. After 10 seconds the subject exhales and the exhaled gas is measured and analysed. Based on the fraction of CO and He, the diffusion capacity (DLCO) and the lung volumes (TLC, RV) are calculated.

2.2 Installation

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

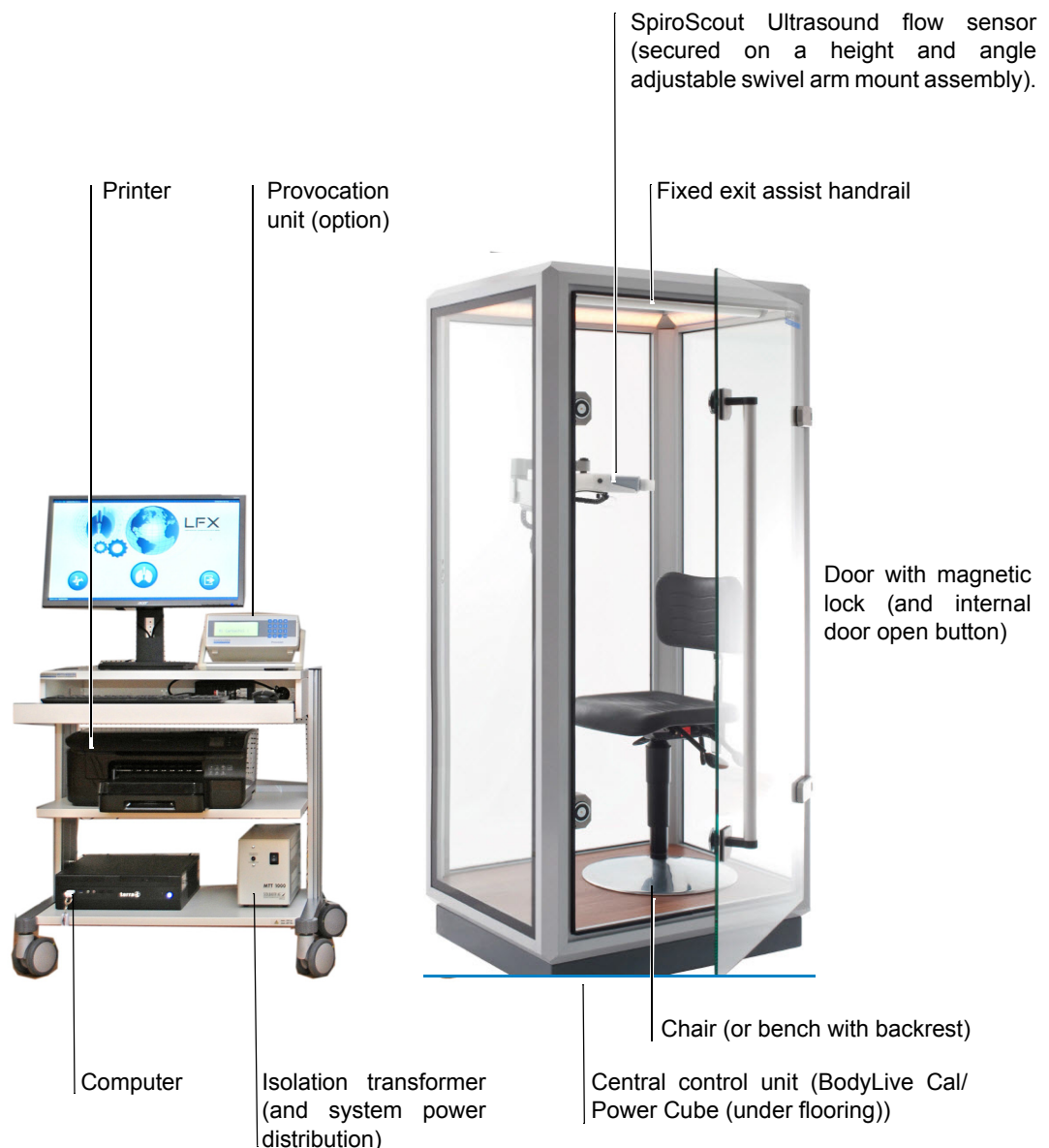


2.3 Equipment Overview

The body cabin consists of an aluminium frame, the panels are made of security glass. A handrail provides added safety when entering or leaving the cabin. The cabin door has an electromagnetic lock and can be opened from inside the cabin with an Open Door button.

The shutter and sensor unit consists of a swivelling arm and an ultrasonic transducer. The central control unit and gas analyser is located below the baseplate of the cabin. An optional swivel chair (as shown) can be installed instead of the bench with backrest.

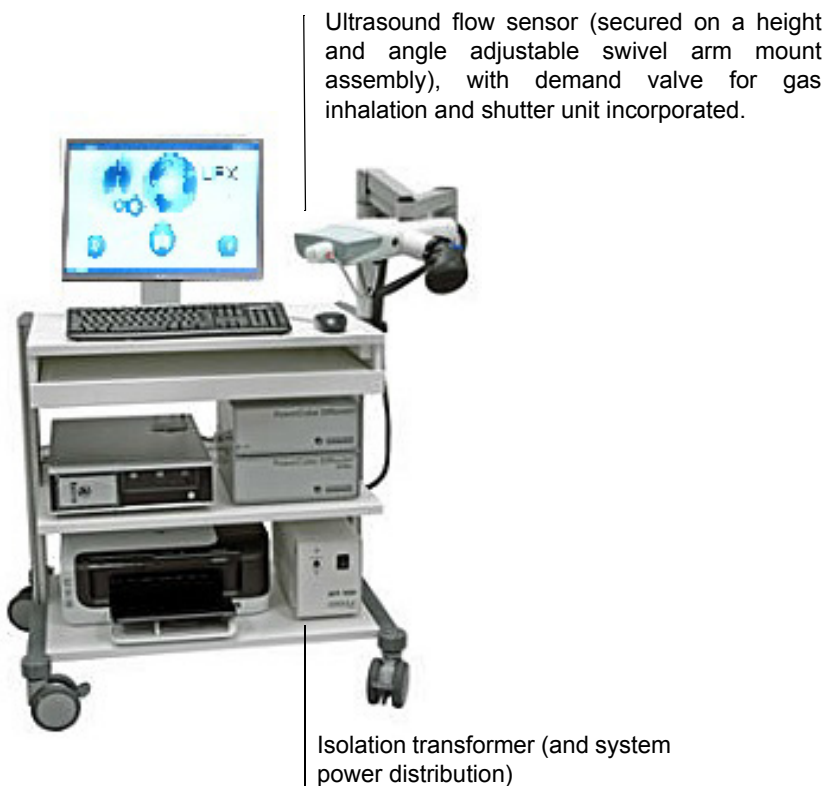
2.3.1 PowerCube Body+ (with Diffusion+)



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

2.3.2 PowerCube Diffusion+

When the PowerCube Diffusion+ is ordered alone without Bodyplethysmography, the shutter and ultrasonic transducer sensor unit are mounted on a swivelling arm secured to the computer trolley.



2.3.3 Locking the Wheels of the Trolley

The wheels of the unit 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 rolling and causing possible injury.

2.3.4 Lighting inside the Cabin (Option)



The lighting inside the cabin is controlled by the remote-control. The lighting can be switched on and off and also different colours can be selected.

2.4 Connector Panel and Control Elements

2.4.1 Mains Supply Distribution

Mains supply distribution is via the Isolation transformer.



- ▲ Only use the Isolation transformer for the power supply of system components.
- ▲ Do not use the isolation transformer for any equipment not associated with the system.
- ▲ The isolation transformer must be connected to a power supply with protective conductor.
- ▲ Any changes, modifications, or replacing of system components including the isolation transformer may only be performed by an authorized GANSHORN partner

2.4.2 Isolation Transformer Mains Supply Distribution

230V isolated mains out sockets (x8) for the power supply of all system components

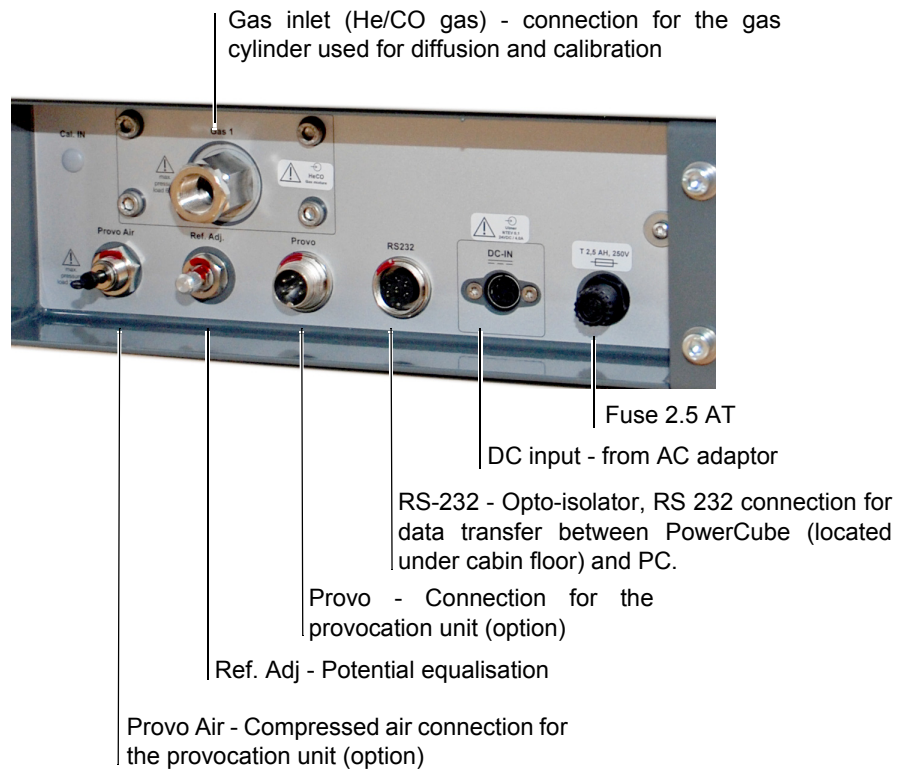


Potential Equalisation Stud

Mains in (with on/off switch). Note the main system on/off switch is on the front panel of the isolation transformer ([see para.2.7, Switching Off the System, page 20](#))

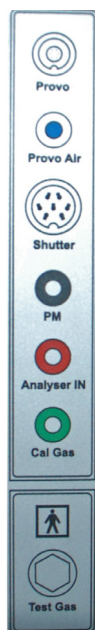
2.4.3 Back Panel

The following connectors are found on the outside at the back of the Body+ Cabin



2.4.4 Connectors and Control Buttons inside the Body Cabin

The following connectors are found on the inside the Cabin with the designation below



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

PM Luer-Lock connection for mouth pressure measurement tube

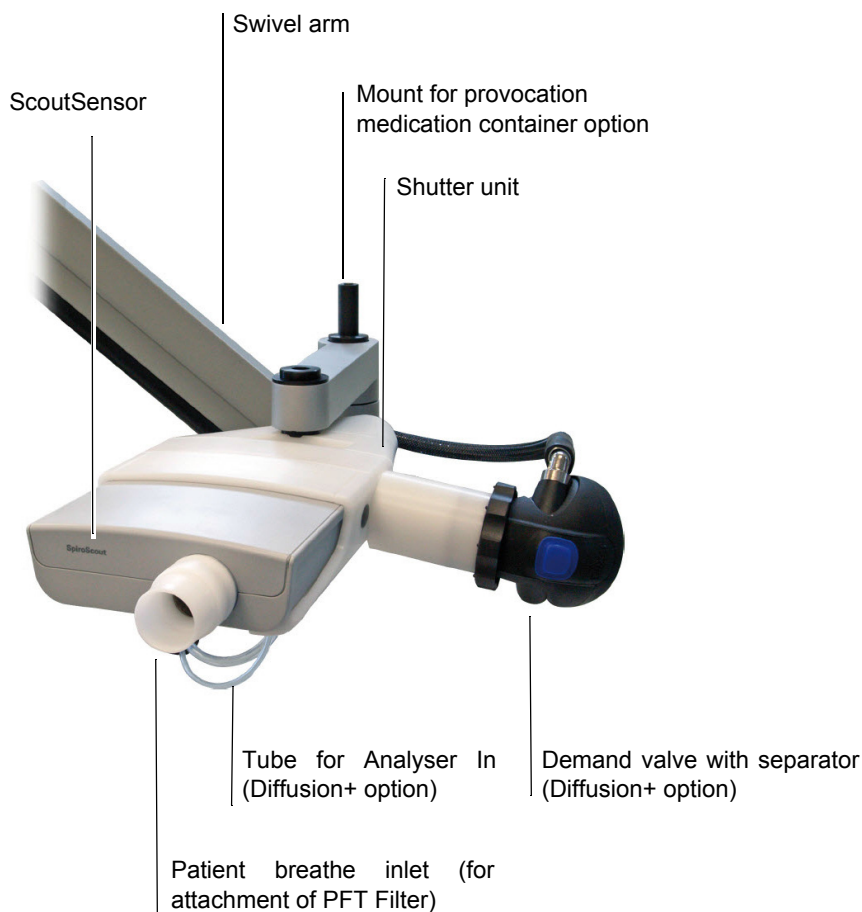
Analyse IN (Diffusion+ Option) Luer-Lock connection for mixed breathing gas after exhalation

Calibration Gas (Diffusion+ option)

Test Gas (Diffusion+ option)

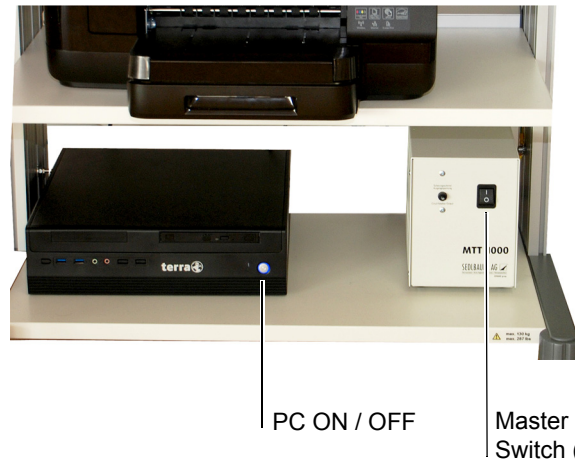
2.5 Swivel Arm and Shutter Unit

The swivel arm enables movement in all directions and positions to enable the sensor to be positioned for all patient sizes and seating positions. It is designed so that it can be extended outside of the cabin when required.



- ▲ Always hold the sensor to move the swivel arm. To avoid pinching fingers, do not move it by holding on to the weight-bearing elements or the joints.

2.6 Switching the System On



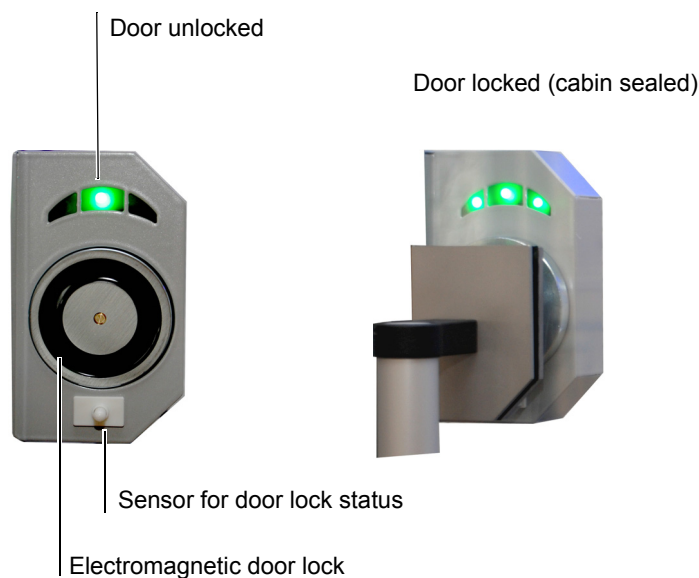
1. Press the system master ON/Off switch on the front of the Isolation transformer to the **On Position**.
 - Power is applied to all components of the system
2. Switch on the PC by pressing the PC ON / OFF button.

2.7 Switching Off the System

1. Ensure the LFX program is closed and switch off the PC in the normal way via the start icon.
2. When the PC is switched off, press the Master System ON/ OFF switch on the isolation transformer to the Off position

2.8 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 Bodyplethysmography program is activated or calibration being carried out. 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 and there is no danger inside the cabin for patients with a pacemaker.

Three green LED indicates the status as follows:

LED	Meaning
No LEDs lit	The body cabin is switched off
Middle LED Lit	Door unlocked
Right and left LED's flashing	Magnet active, door not fully closed
All LEDs lit	Magnet active, door is closed and cabin sealed

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

2.8.1 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 will flash.



- ▲ When closing the door never push directly against the upper or lower part of the door: the door will not close evenly, and this can lead to leakage.
- ▲ Never open the door by force or slam it shut: this can damage the measuring system.
- ▲ Never leave the door fully opened or swing the door open, bashing it against the hinges: this can impair the door adjustment and may lead to leakage.
- ▲ When a body measurement is not being taken, the door is adjusted such that it is always a little ajar. Never close the door completely because this cuts off the necessary air circulation.

2.8.2 Opening the Door

To open the door 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

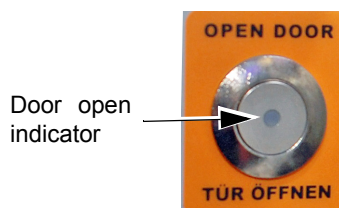
To prevent the highly sensitive pressure transducers from damage, the door opens with a delay of approximately 2 seconds.



- A malfunction or power failure will open the door automatically.

Opening Door from Inside the Cabin

The open button deactivates the magnet and enables the patient to open the door from the inside of the cabin.



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

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

2.9 Fitting the Disposable PFT Bacterial filter

WARNING



- ▲ One-time use only - do not use the PFT filter for more than one patient.
- ▲ Do not attempt to clean the filter.
- ▲ Only use bacterial filters approved by GANSHORN. Use of any other filters can cause incorrect measurements.



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

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



CAUTION

At the end of the test:

- ▲ Observing all cross-contamination procedures e.g. wearing rubber gloves, not letting clinical waste come into contact with anyone, remove and dispose of the bacterial filter in the clinical waste.

2.10 Cleaning and Disinfecting

The Spiro sensor 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 and approved cleaning materials and disinfectants are detailed in the Maintenance section ([see para.8.2, Cleaning and Disinfection, page 75](#)).

3 Program Overview

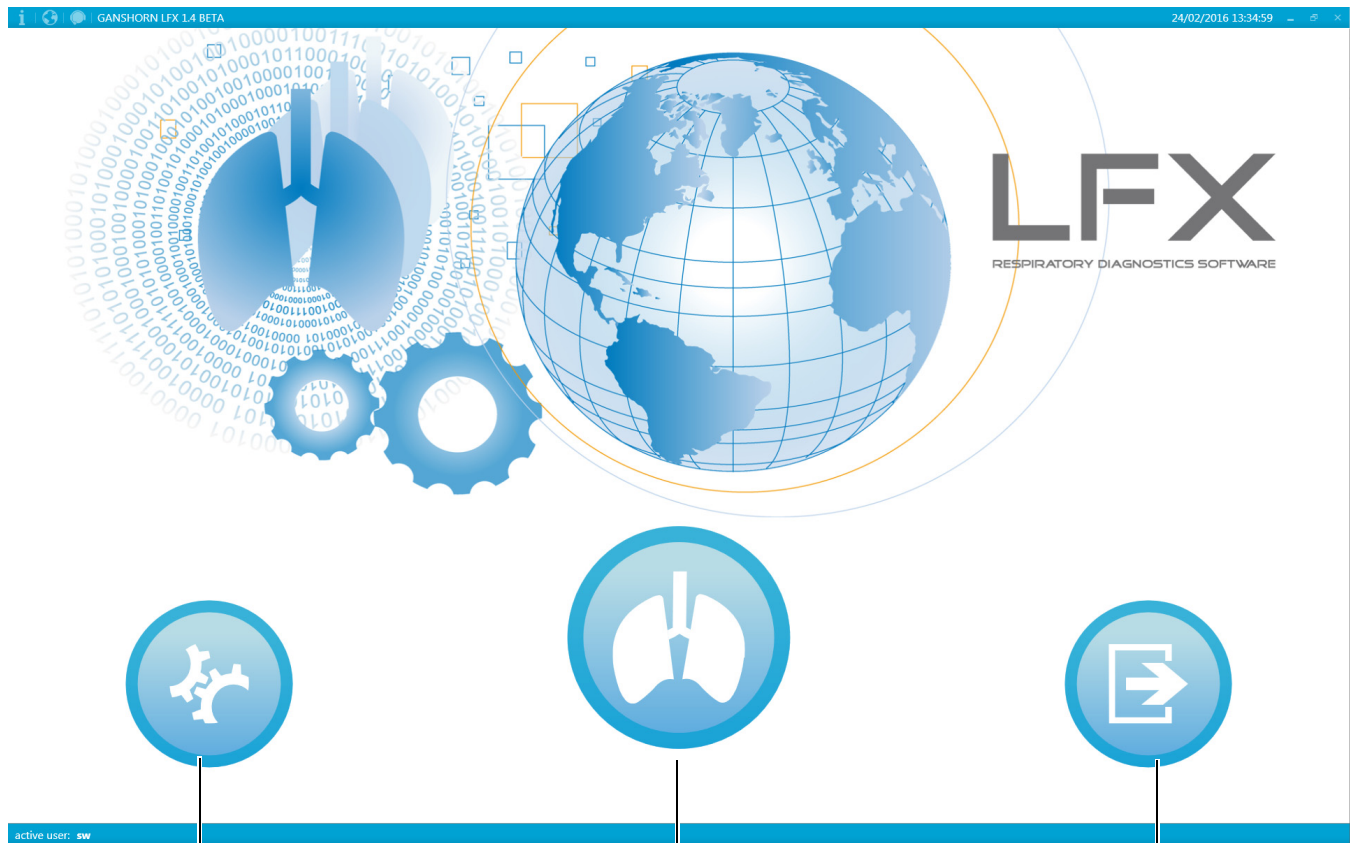
3.1 LFX Initial Screen



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

- The LFX start-up screen appears.

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



Enter Settings (see para.7,
Settings, page 71)

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

Exit Program

3.2 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 patient field to select

Currently selected patient

Activate recording(s) for report. Check recording to use in report (print or PDF)

Recordings of selected patient

Hide / show recording detail

Icons to:

- Edit existing / create new patient.
- Enter notes or print (recording).
- Import / Export (see para.3.5, Exporting / Importing, page 30)
- Enter system settings. The settings displayed are dependent on the screen displayed: in the **patient screen** the network settings are given, in a view or acquisition screen the measurements for display can be defined (see para.7, Settings, page 71)

Icons to:

- Create new patient (and search and select existing patient).
- Enter recording screens (see para.5, Recording Measurements, page 41).
- Validate/ Calibrate the system (see para.4, Calibration and Verification, page 31).
- Return to initial screen.

3.2.1 Patient Search

Enter the patient's name (or part name), and /or patient ID, and press the **Enter key** on the keyboard to display the patient(s) with defined entered characters. Click to select patient (and list of recordings if any).

3.2.2 Entering New Patient Data

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

The patient ID is unique and cannot be used twice. The ID of the patient can consist of digits, letters and special characters.

Patient ID

Last name / First Name

Enter the name of the patient, lower-case and upper-case letters are allowed.

Date of birth

Enter the date of birth (date format can be defined in settings ([see para.7, Settings, page 71](#))).

Height

Enter the height of the patient in cm or inches.

Weight

Enter the weight of the patient in kg or lbs.

Gender

Select the gender of the patient using the arrow keys. Default Gender is Male.

Ethnic group

Select the ethnic group of the patient:

- Caucasian (default)
- Asian
- African American
- Hispanic

Ref. module

Select the reference calculation model as required. The default reference module is ECCS1993.

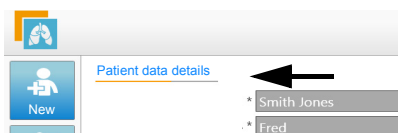
ECCS93
ECCS93_GLI
GLI 2012
ECCS93_Jones
ATS94_ITS
Hedenstrom
ECCS93_ITS
ECCS93
ATS94
ECCS93_Wasserman

BMI

The BMI definition and formula is detailed later in this section ([see para.3.2.4, Patient Calculated Values, page 27](#))

Further Patient Data Parameters

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



Arm Span

This option enables you to enter the arm span in order to estimate the height of the patient 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 patient's arms are fully outstretched. Enabling this option will display a text box where the arm span can be entered ([see para.3.2.4, Patient Calculated Values, page 27](#)).

Middle name, Maiden name, Order ID, Insurance, Physician, Technician, Ward Enter as required.

Smoker, History, Diagnosis Enter as required (see para.3.2.4, Patient Calculated Values, page 27)

3.2.3 Saving New patient data

The patient is automatically saved when the patient screen is exited (for example by entering the measurement screen, or settings screen, etc.).

The basic information (Last name, First name, ID and Date of birth) will be shown in the **Current patient** window on the upper right-hand area of the screen.

3.2.4 Patient Calculated Values

The following formulas used for calculation:

Calculated value	Explanation	Formula
BSA	Body surface area in m ² according to Mosteller ^a .	- Formula for male and female: $BSA = ((\text{height (cm)} \times \text{weight (kg)}) / 3600)$
BMI	Body Mass Index in kg/m ² according to Adolphe Quetelet:	- Formula for male and female: $BMI = \text{weight (kg)} / \text{height}^2 \text{ (m)}$
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: $\text{Rel. weight} = \text{weight (kg)} / (\text{height (cm)} - 100) \times 100$
LBW	Lean Body Weight in kg according to James ^b	- Formula for male: $LBW = (1.10 \times \text{weight (kg)}) - 128 \times (\text{weight}^2 / (100 \times \text{height (m)})^2)$ - Formula for female: $LBW = (1.07 \times \text{weight (kg)}) - 148 \times (\text{weight}^2 / (100 \times \text{height (m)})^2)$
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.): $\text{Height} = 67.90 + 0.664182 \times \text{Arm span} - 2.816 \times \text{Gender} - 4.05 \times \text{Race} - 0.0709 \times \text{Age}$ - 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 = $\frac{\text{Cigarettes per day}}{\text{Cigarettes per pack}} \times \text{Years smoked}$

a. Hallynck TH Soep HH et al. Should clearance be normalised to body surface or to lean body mass? Br J Clin Pharmacol. 1981; 11: 523-526.

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

3.2.5 Notes

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

3.2.6 Edit User Defined Drop Down Lists

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.

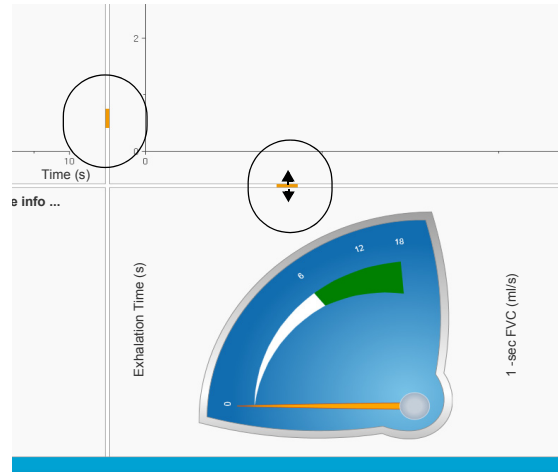
1. Click on the arrow in the Physician drop down list.
 - A list of physicians already defined is shown.
2. Click on **Edit...** to open the window for editing the physician drop down list. In this window you can add, modify, show/hide and predefine the list of entries.



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

3.3 Changing the Size of the Graphs

In some measurement and view screens the graphic size can be changed. In screen 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.



3.4 Printing/ Generating a PDF or other Format File

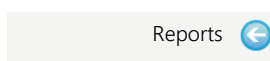
3.4.1 Printing from the Patient Screen

To print a recording or generate a file from the patient screen proceed as follows:



1. In the patient screen select the patient and then the recordings to print (see para.3.2, The Work / Patient Screen, page 25).

2. Click the **Print** button.



- ☐ Body
- ☐ Body - Trials
- ☐ Body / SB-Diff.
- ☐ Body / SB-Diff. - Trials
- ☐ Flow / Vol.
- ☐ Flow / Vol. Trials
- ☐ Provo
- ☐ SB-Diff.
- ☐ Spiro
- ☐ Spiro - Trials
- ☐ Trend - Body
- ☐ Trend - Flow / Vol.

– A number of predefined reports are shown. Depending on the software configuration, additional programs are displayed on the screen.

3. Select the data to be printed.

4. A Report viewer facsimile is displayed and reports can be printed or saved as:

- Word, rtf, etc., formats
- PDF
- XPS (Microsoft)
- Powerpoint file



Notes:

- If a data type is selected for which the selected recording has no data, a facsimile with no data is given.
- When a recording is open, and the print icon is clicked, the recording is printed to the selected location and report options are given.

3.5 Exporting / Importing



At the time of print Export is only possible to GDT systems.

3.5.1 Exporting a recording

To export a recording proceed as follows:



1. In the patient screen select the patient and then select the recording(s) to be exported by checking the recording box(es).

Notes

Print

Reports

Export

HIS

Height * 180,0 cm 70,9 inches swtte fred

Weight * 81,0 kg 178,6 lbs

Ethnic group * White

Ref. module * ECCS93

Visit ID

Date	Time	Level	Measurement
23.02.2016	15:21	Pre	Forced Spirometry
02.02.2016	11:32	Pre	Forced Spirometry
☒ 02.02.2016	10:40	Pre	Slow Spirometry
01.02.2016	11:17	Pre	Slow Spirometry

2. Click the **Export** button.
3. The file is generated in the location specified in GDT settings.

3.5.2 Importing Patient Data

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



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

4 Calibration and Verification

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

4.1 Verification and Calibration Intervals

	Spiro	Bodyplethysmography (cabin pressure)	Diffusion (gas calibration)	Provocation
Zero point calibration ^a	Automatic	Automatic	Automatic	Automatic
Volume verification ^{b c}	Verification weekly (recommended)	Verification weekly (recommended)	Verification weekly (recommended)	Verification weekly (recommended)
BodyLiveCal Calibration ^d	-	Weekly calibration	-	-
Gas Calibration	-	-	At the beginning of every day	-
Ambient Conditions ^e	Annually (control)	Annually (control)	Annually (control)	Annually (control)

- a. Zero point calibration is automatic and carried out on start up and then every 15 minutes when the program is open.
b. The ultrasound sensor technology and the in-build ambient sensors mean that volume calibration is not necessary. Verification can be carried out if necessary.
c. Flow verification can additionally be carried out after volume verification if required.
d. This is a combined calibration of mouth pressure and cabin pressure.
e. The system maintenance procedures and maintenance intervals are detailed in the maintenance section ([see para.8, Maintenance, page 73](#)).



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

4.2 Zero Point Verification

4.2.1 Zero Point

Zero point calibration is carried out automatically on switch on and subsequently every 15 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 – keep the room's windows and doors closed – and do not move any parts of the device.

4.3 Ambient Parameters



- ▲ Calibration equipment is subject to verification on a regular basis; ensure 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. It is important therefore that the ambient parameters are entered accurately and the reference values are taken from a calibrated measuring device.

Based on the values measured directly by the system, temperature [°C] and ambient pressure [hPa], as well as the manually set values, rel. humidity [%] and altitude above sea level [m], the LFX program determines the volume correction factors STPD and BTPS.



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



4.4 Volume Verification

Because of the Ultrasound technology, volume calibration is not required. For confidence in system, the volume can be verified as required as described here.



- ▲ Only use the original calibration syringe and silicon adaptor supplied or approved by GANSHORN. Calibration syringes are subject to verification on a regular basis; ensure the syringe verification is in date. Failure to do so can result in inaccurate measurements.

Volume verification and calibration is carried out 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 have been made and a message given as to the success or otherwise of the verification / calibration.

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

4.5 Volume Verification Procedure



1. Place a new PFT bacterial filter on the sensor.
2. From the Patient screen click the **Calib button**.
3. The calibration settings are displayed in 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. Connect the calibration syringe with silicone adapter to the PTF filter.
7. Ensure that there is good contact and no leakage.

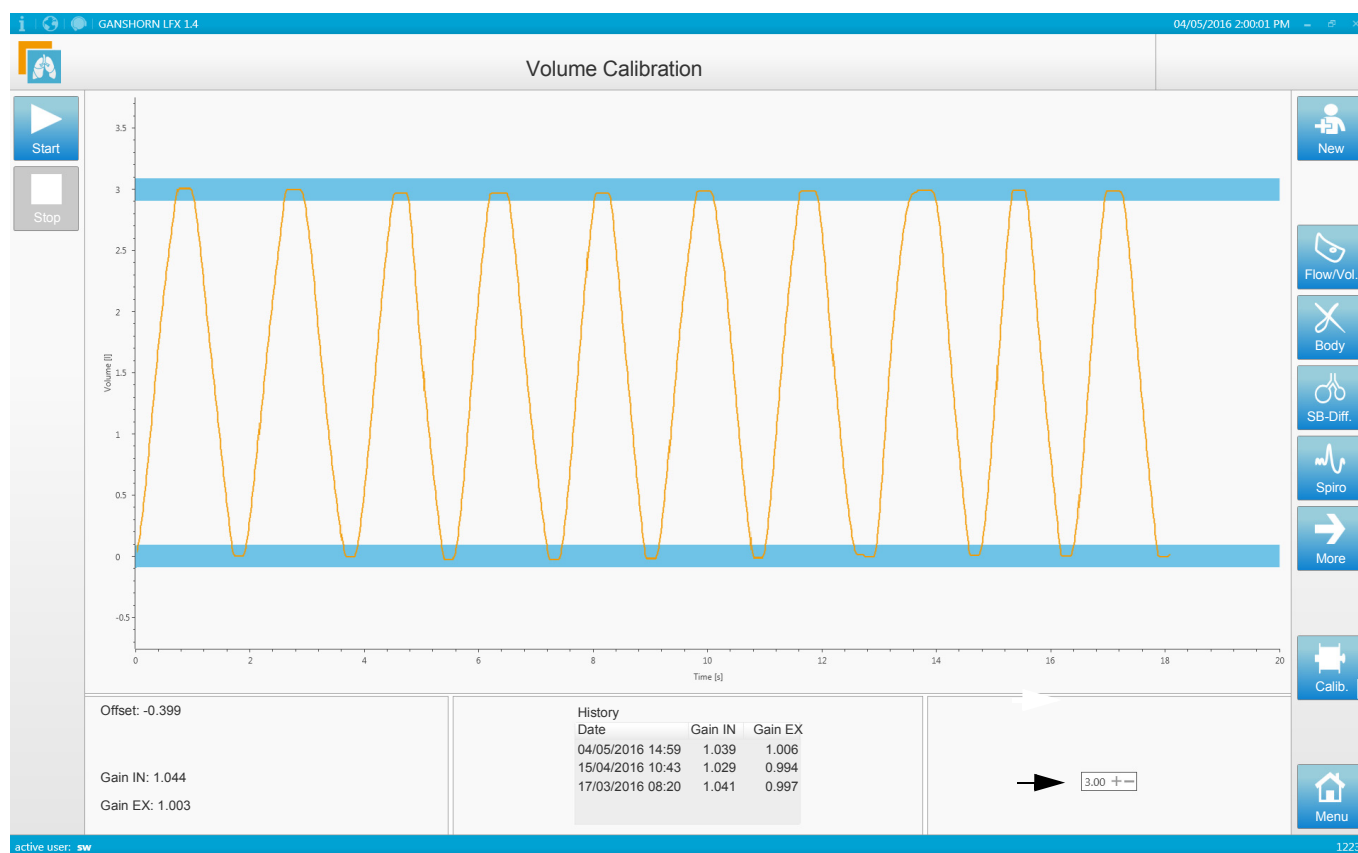


8. Click the **Start** button.
 - A message is displayed:



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

9. After a few moments the offset is calibrated and the volume screen is again displayed. Smoothly pull the piston completely back and forth and with a constant flow between 0.5 and 12 L/s.
10. After several pumps the program will automatically stop and a success or failure message is displayed.



4.5.1 Tabular Results after Verification

The volume, verification, and measurements are displayed in the tabular results. The volume at each flow should meet the accuracy requirement of $\pm 3.5\%$ (including 0.5% accuracy of the syringe). For a 3 litre syringe the measured volumes at each flow should be within 2.895 and 3.105 litre.

4.5.2 Flow Sensor Linearity Verification Procedure

Carry out the procedure as detailed for the Volume verification procedure at low flow rate of approximately 0.5 L/s, repeat at approximately 6 L/s and then at 12 L/s flow rates.

4.6 BodyLive Calibration



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

4.6.1 Overview

BodyLiveCal for body plethysmography is a fully automatic program. It includes the measurement of the cabin time constant and the simultaneous calibration of the pressure transducers in a TGV simulation (thoracic gas volume).

Simultaneous Cabin Pressure and Mouth Pressure Calibration

After measuring the time constant and a waiting a period of two minutes, a motor-driven syringe starts simultaneously applying a sinusoidal reference pressure to the cabin and the mouth pressure sensor with the frequencies of 0.25 Hz, 0.5 Hz and 1 Hz. In 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 thus part of the BodyLiveCal.

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

4.6.2 Environmental Conditions

Before calibrating the body, observe the following conditions:

- Ensure a 30 minute system warm-up time.
- The cabin must be at room temperature.
 - Ensure there have been no quick changes of temperature in the room where the cabin is causing a temperature differentiation.
- Avoid drafts.
 - Keep the room's windows and doors closed.
- Switch off air conditioning.

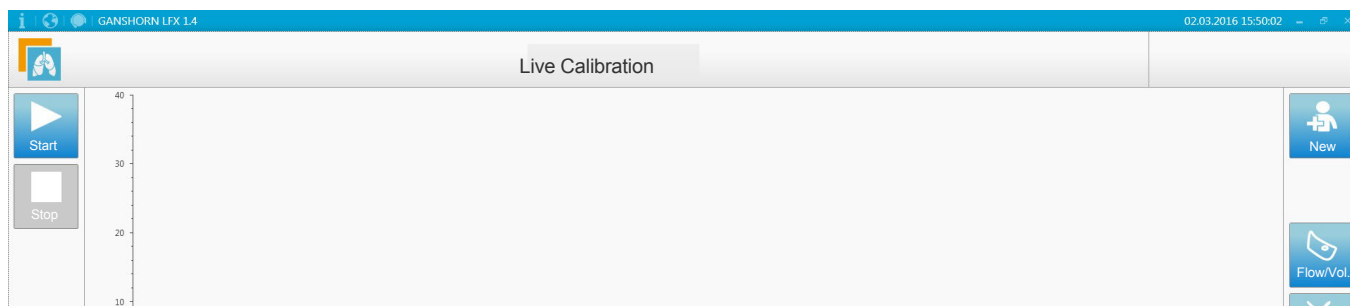
4.6.3 Calibration Requirement

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

4.6.4 Procedure



1. From the Patient screen click the **Calib** button.
2. The calibration settings are displayed in 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 commence the calibration process. The message **Please close cabin door!** is displayed:

Please Close Cabin Door

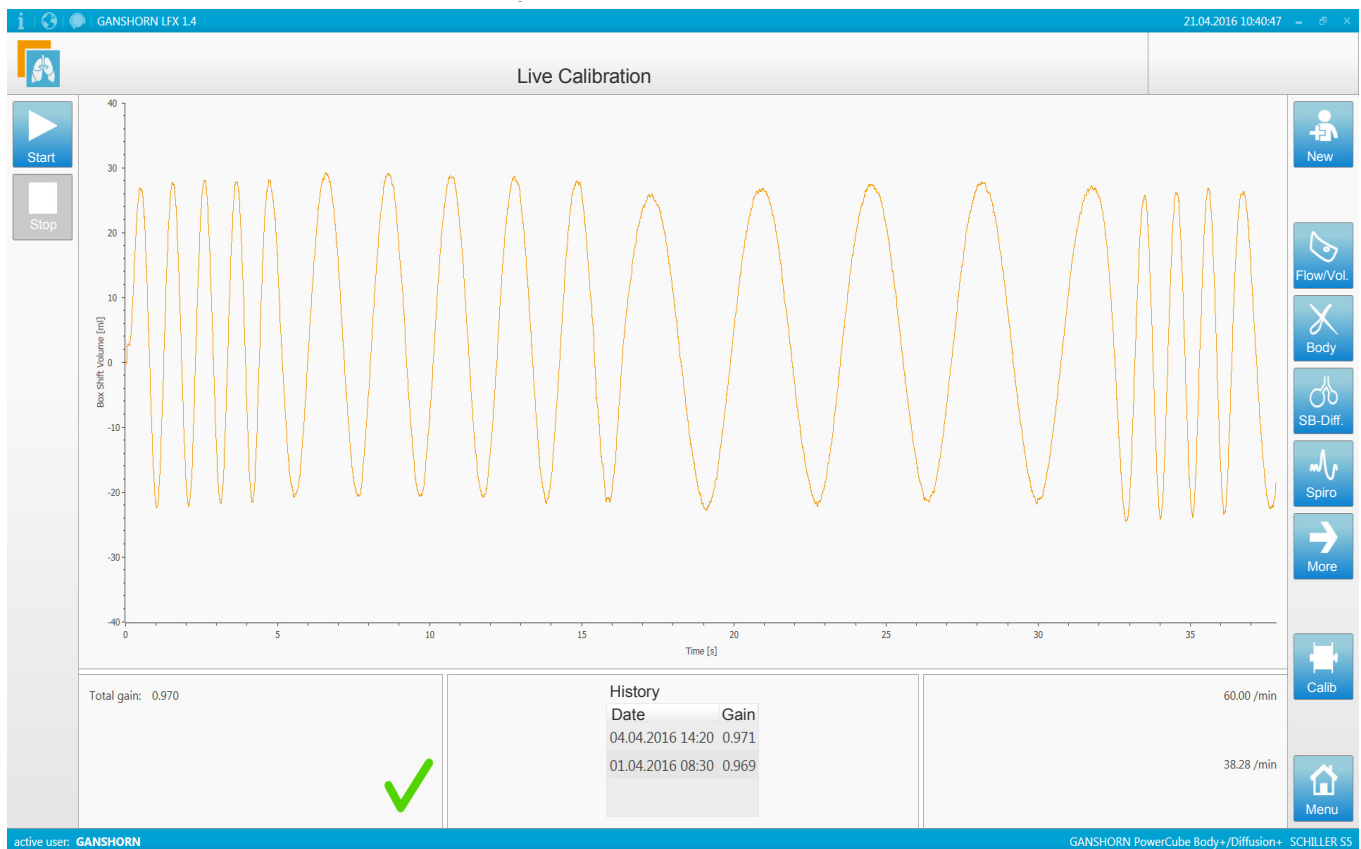
6. Gently shut the cabin door until you hear the door magnets close. Push the door handle top and bottom until both door seal indicators display the three green LEDs
 - The calibration starts automatically.
 - The message **Measuring time constant of cabin!** is displayed followed by **The time constant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



Waiting 63 seconds for temperature to stabilize

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

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



On successful calibration, the new calibration factors are saved and the program uses the new calibration factors for future calculations.



4.6.5 Calibration Errors

If it was not possible to measure the time constant correctly, the message **The time constant is out of range** is displayed. Wait for completion of BodyLiveCal or interrupt by clicking **End**. If it was not possible to perform the leakage calibration correctly, the message **Calibration not possible / calibration not valid** will be displayed. Check for possible sources of error (also refer to the error messages) and repeat. Possible cause 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) indicating pressure fluctuations in the room. This could be caused by drafts from open doors and windows.	→ Allow at least 30 minutes warm up time. → Ensure the room is draft free. → Ensure air conditioning is switched off.
High time constant:	• Ventilation valve not adjusted correctly. • 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	• Cabin door not correctly closed. • Door seal not intact.	→ Check door magnets. → Check that the three green LED door closed indicators on the top and bottom door magnets are lit. → Check rubber door seal. If the seal is perished, cracked, or nicked, etc. contact GANSHORN for replacement.

4.7 Gas Calibration

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- ▲ Gas calibration must be performed before the first test of every day. It can also be performed at any time for verification.
- ▲ Ensure 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.

4.7.1 Procedure

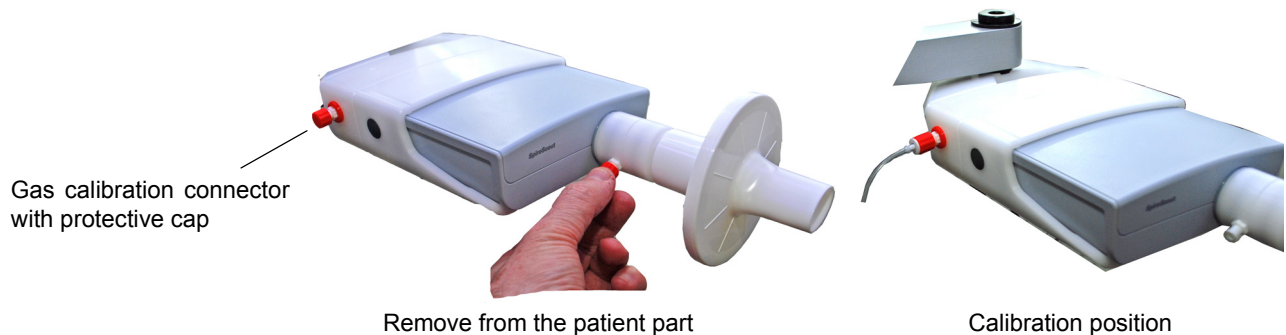


1. On the gas bottle, open the gas valve fully.
 - the valve open rotation is anti-clockwise - the open close direction is printed on the valve.
2. From the Patient screen click the **Calib** button
3. The calibration settings are displayed in the right of the screen
4. Click on **He / CO** (Helium / Carbon monoxide) to enter the calibration screen.
5. The initial calibration screen is shown and the message to connect the gas tube to the test input



Please ensure 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

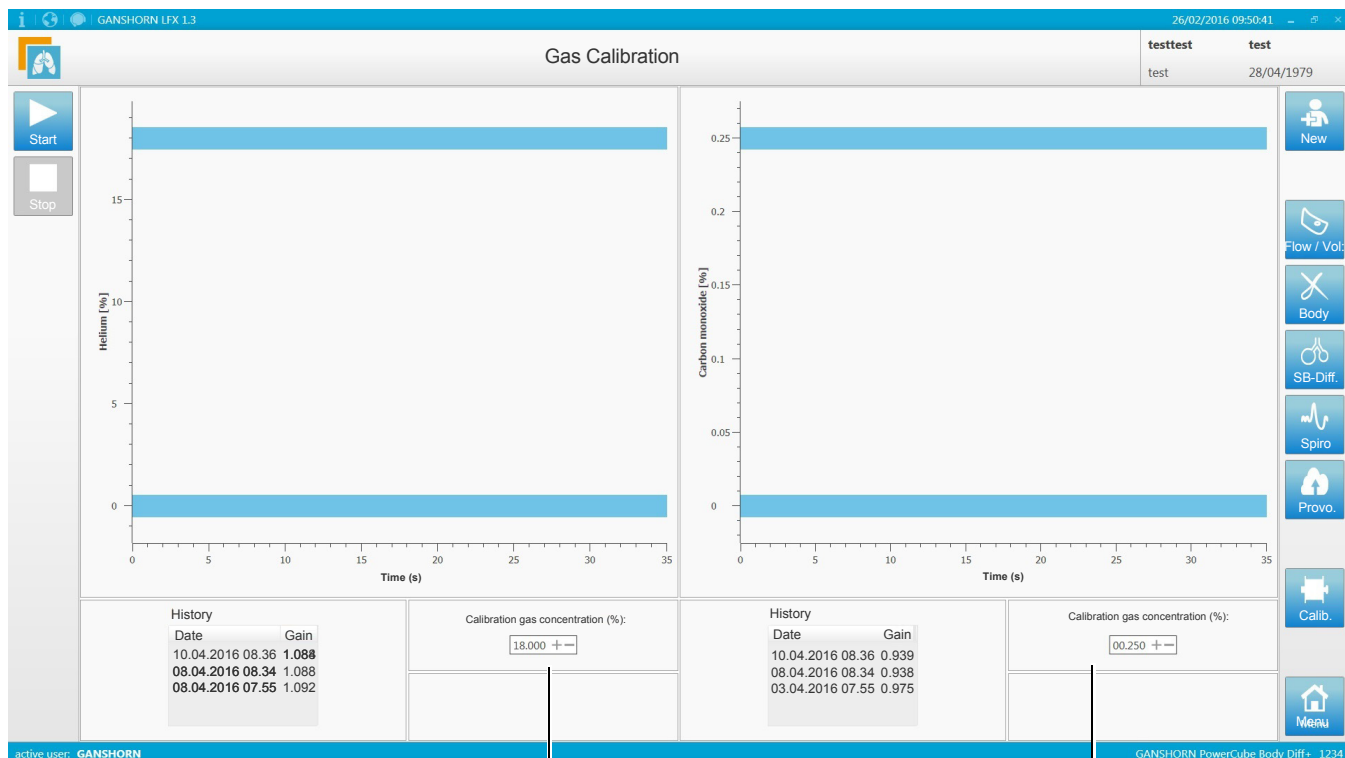


Gas calibration connector with protective cap

Remove from the patient part

Calibration position

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



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

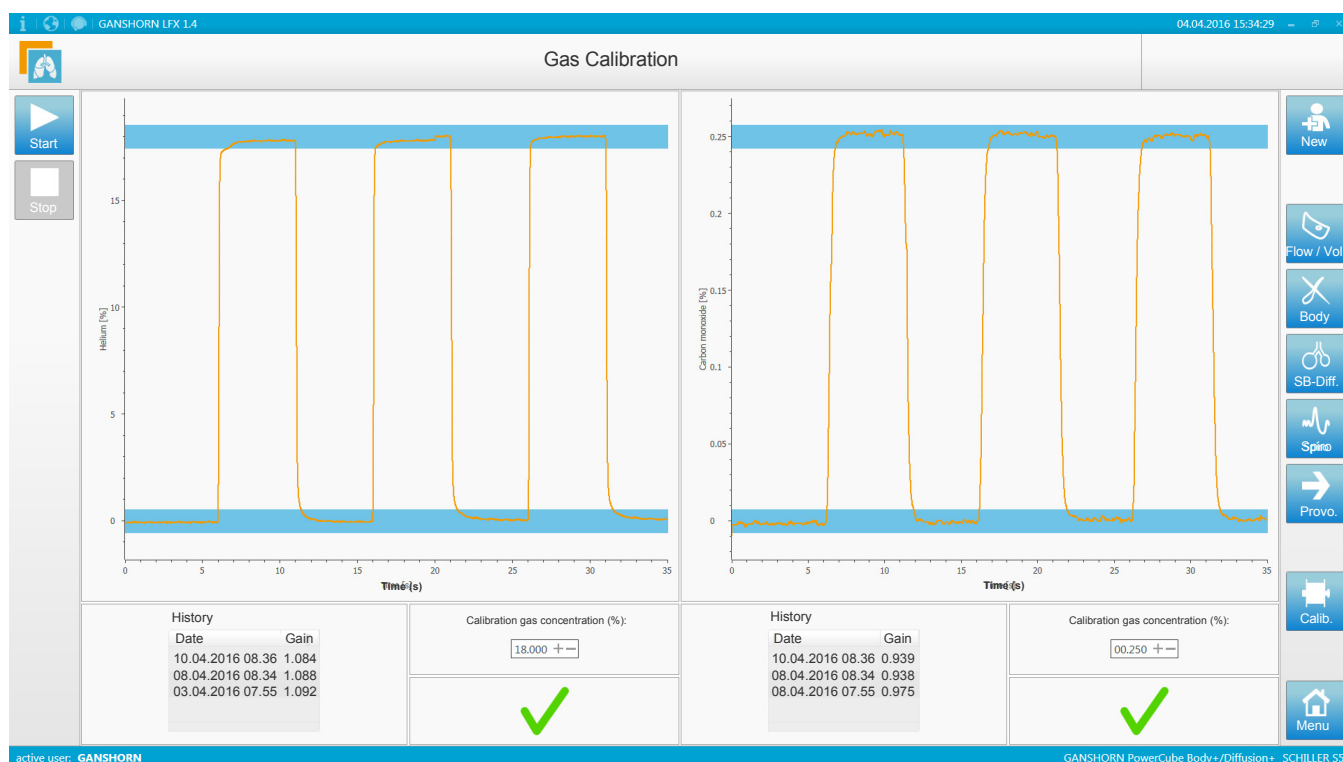
Enter / check **CO** gas percentage (written on gas bottle)

8. Click the Start button.
 - A message appears informing that 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) is displayed.
 - A success message is given when the gas calibration has successfully completed.
9. On completion, you are prompted to replace remove the gas tube from the test inlet and replace on the patient sensor inlet. Replace the safety cover on the test gas inlet (see step 6).

Please ensure the gas tube has been reconnected to the flow tube of the patient interface



4.7.2 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 completed. Exit and re-enter the calibration screen to see the past gas-calibration gain values and trend.

4.7.3 Calibration Errors

If it was not possible to calibrate the gas correctly, repeat the calibration. If the calibration still fails, possible causes of error are as follows:

Possible Cause	Remedy
• Gas valve not on	→ Open the gas valve fully.
• Gas bottle empty	→ Check the pressure on the gas bottle (minimum 6 bar). → Replace gas bottle.
• Incorrect Gas concentration entered	→ Check the helium and CO percentage concentrations (found on a label on the gas bottle), and ensure 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 (power cube module (under the cabin))	→ Contact GANSORN.

5 Recording Measurements

WARNING



- ▲ The disposable **PFT bacterial filter** is designed for one-time use to eliminate the danger of cross contamination. Do not use the mouthpiece for more than one patient.
- ▲ Do not attempt to clean **PFT bacterial filter**.

CAUTION

- ▲ In order to obtain correct predicted values and diagnosis, it is important that all patient data is entered correctly. In particular gender, date of birth, ethnicity, height and weight must be entered.

System Calibration

- ▲ The system must be verified/calibrated as follows:
 - Gas calibration (diffusion measurements), every day before use
 - Body cabin pressure calibration (BodyLiveCal), every week
 - Volume verification, every week
 - ([see para.4, Calibration and Verification, page 31](#)).

At the End of the Test

- ▲ Observe all cross-contamination procedures e.g. wearing rubber gloves, not letting clinical waste come into contact with anyone, when removing and disposing bacterial filter in the clinical waste. If using a disposable nose clip, also dispose of the nose clip in the clinical waste.
- ▲ If using a reusable nose clip, disinfect as per the instructions given for the nose clip manufacturer.
- ▲ Wipe / clean the sensor assembly with approved cleaning solution or disinfectant ([see para.8.2, Cleaning and Disinfection, page 75](#)).



Influences on Predicted Norm Values

- ▲ 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

5.1 Best Result and Predicted Values

5.1.1 Definition of Best

In accordance with the American Thoracic Society (ATS) Spirometry Standard (11. Nov 1994), the best measurement is defined as the highest value from the calculation:

$$\text{Best} = \text{FVC} + \text{FEV1 (or FEV6)}$$

The Spirometry Program takes the **best** value as defined above and defines this as **Trial1** as recommended by ATS and ERS.

5.2 Preliminaries



To help minimise potential measurement problems and ensure good quality recording:

- ▲ Prevent drafts – keep the room's windows and doors closed during the tests
- ▲ Switch off any air conditioning

Preliminaries must be performed (in accordance with ATS/ERS 2005) as follows:

1. Ask the patient about their smoking habits and enter the pack years if required. Ask about medication used prior to the test and any recent illnesses. This information can be filled out in the Patient data section of Patient management and/or in Notes.
2. Measure the weight and height of the subject without shoes.
3. The patient should be relaxed and wear comfortable clothing.
4. Explain the purpose of the test and that the patient's cooperation is fundamental for successful lung function testing.
5. Instruct and if necessary, demonstrate the breathing manoeuvre with the patient and explain the important points.
6. Instruct the patient not to talk during the measurement.
7. The patient should have the correct posture with his head slightly elevated.
8. Place the nose clip correctly on the patient's nose.
9. Instruct the patient to take the mouthpiece into the mouth with the teeth biting lightly on the mouthpiece and the lips sealing around the mouthpiece. The patient may only breathe through the mouthpiece; open corners of the mouth will result in false readings.

Literature: MR Miller et al. Series "ATS/ERS Task Force: Standardisation of Lung Function Testing", Standardisation of Spirometry" Eur Respir J 2005, 319-338
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5.2.1 Quality Control Guidance During the Measurement

During the measurement the Quality Control Guidance assists you in order to determine if end of test criteria are reached. End of test criteria are reached when:

- the exhalation time is ≥ 6 seconds (≥ 3 seconds in children aged >10 years) or
- when the volume is < 25 ml for $\geq$ one second.

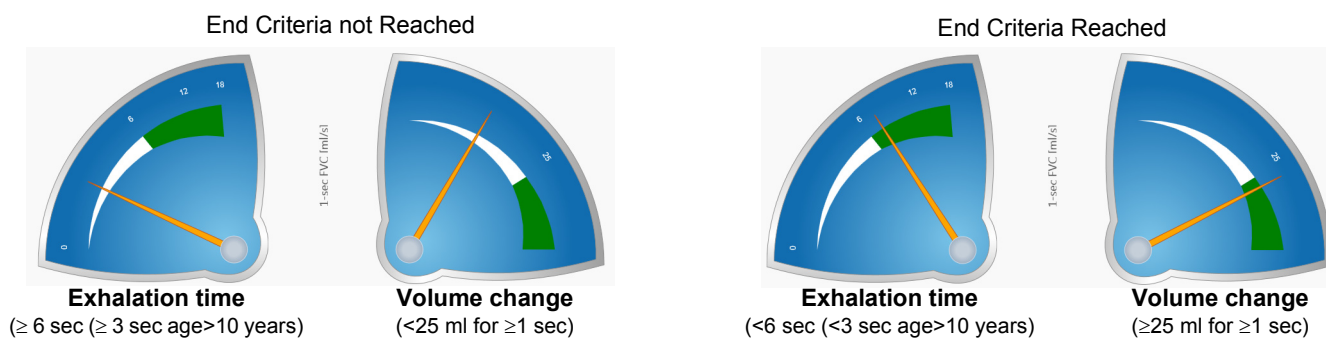
i

According to the ATS/ERS 2005 guidelines, the end of test criteria are met when at least one of these two criteria are met. Therefore, it is not needed that both criteria are reached in order to meet the guidelines.

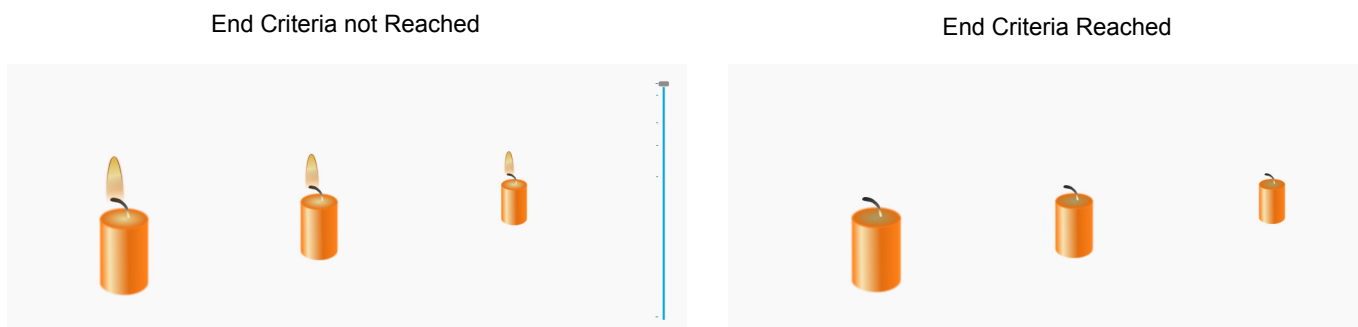
The two quality control guidance indicators on the bottom of the screen show the following:

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

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



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 patients to understand. When all three candles are extinguished, the criteria are reached.



The slider to the side of the candles is for increase/decrease the sensitivity of the exhalation.

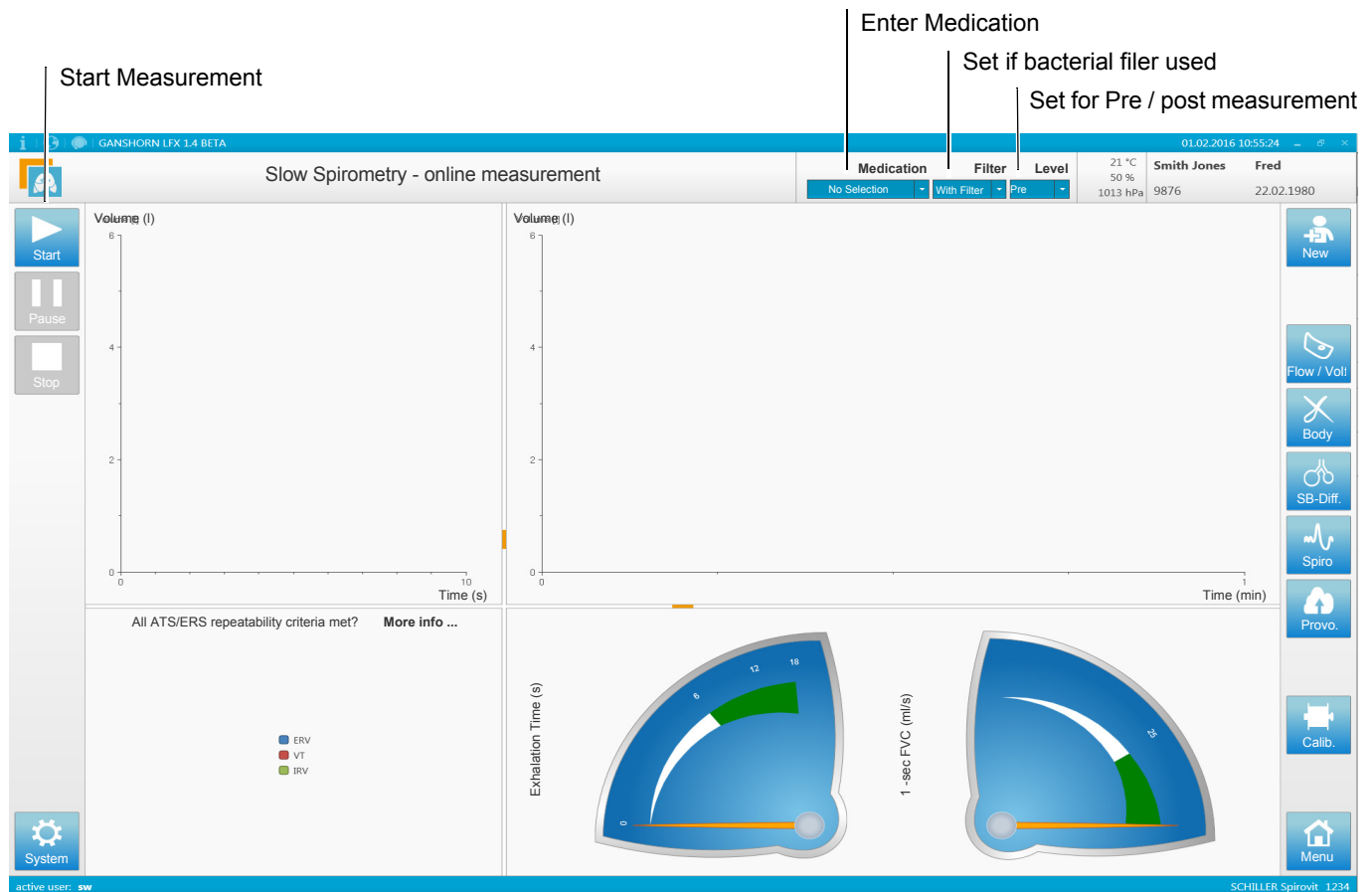
i

To help coax or encourage young or frail patients, the candles can be manually set as follows:

- Press **letter 'a'** on the keyboard to light the candles
- Press **letter 'z'** on the keyboard to extinguish the candles

5.3 SV Measurement

1. Carry out the preliminary checks (see para.5.2, Preliminaries, page 42).
2. Select patient or register a new patient (see para.3.2, The Work / Patient Screen, page 25).
3. Click on the **Spiro** button.
– The SV screen is displayed:



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

WARNING



- ▲ The bacterial filter is single use. Do not use for a different patient. Do not attempt to clean.

5. 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.3.2.6, Edit User Defined Drop Down Lists, page 28](#)).
 - **Filter** - If the bacterial filter is used, ensure it is set here.
 - **Level** - Set for Pre test/post test.

 CAUTION

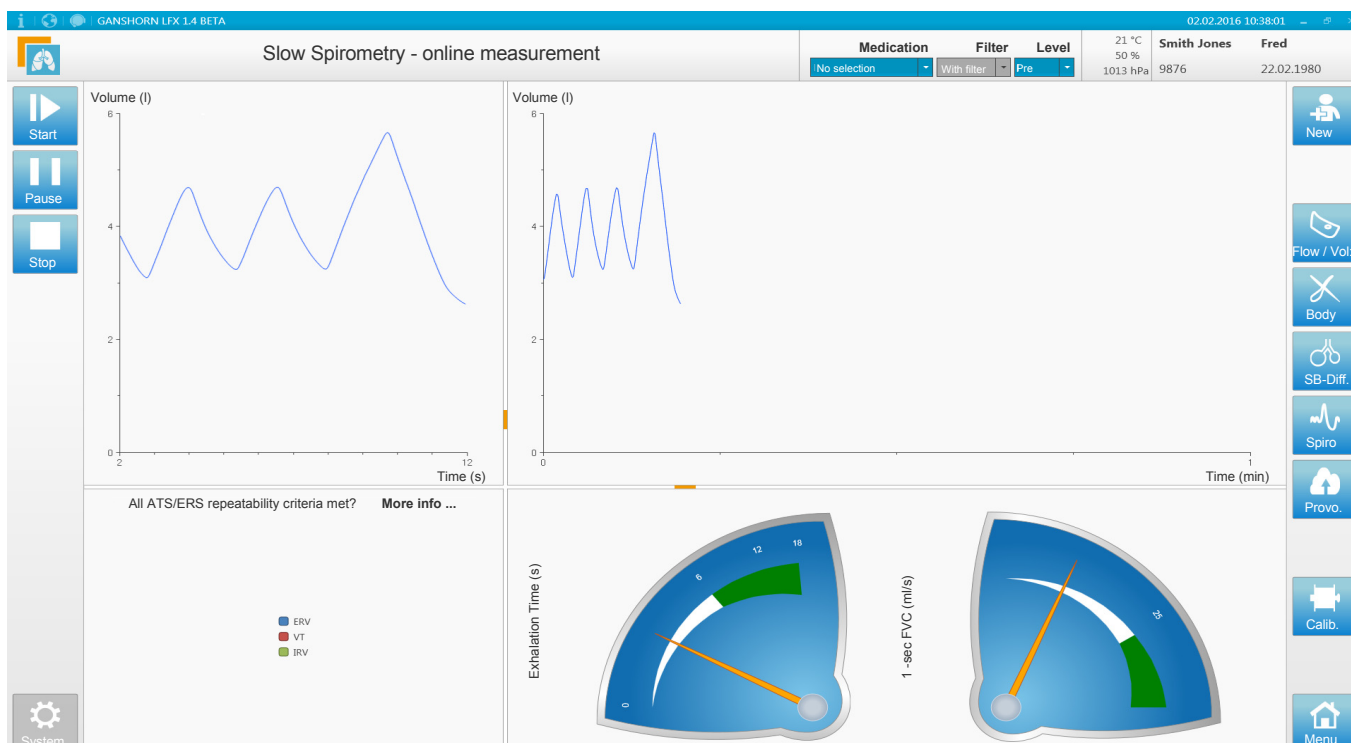
- ▲ The measurements may not be accurate if the **filter setting** is not correct.

i

- Any medication that the patient has taken prior to their hospital visit should not be entered in the Medication property. This medication should be entered under the option Notes.
 - The level setting is normally **Pre level** for measurements carried out before or without using a bronchiolar. A **post level** is normally used when a measurement is performed after using a bronchodilator. If a measurement is made with the same patient on the same day Post is automatically set.
6. Ask the patient to position himself comfortably (either sitting or standing, and position sensor so that the sensor is level with the patients mouth. Instruct the patient how carry out the test and what is expected.

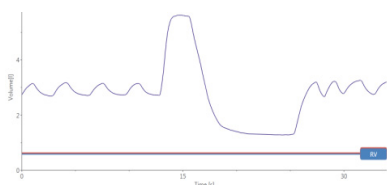


7. Just before starting the measurement, close the patient's nasal airways with a nose-clip and click the **Start** button.
 - The patient is instructed to breathe regularly and steadily for a while until the breathing level (FRC-level) is stable. This usually requires at least three tidal breathing maneuvers.

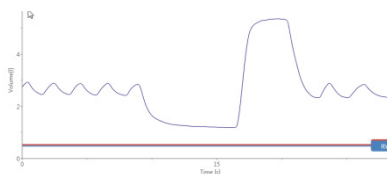


8. When a stable FRC level is reached, Perform the slow vital capacity by either performing the IVC or EVC manoeuvre.

- **IVC** 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 maneuver is completed



- **EVC** Instruct the patient to inhale completely until TLC level is reached (IC is measured). Then the patient should exhale fully until RV level is reached (EVC is measured). After a period of tidal breathing the maneuver is completed.



9. Click on the **Stop** button to end the measurement. The results of the measurement will be shown.

10. Repeat the test at least three times.

Notes:

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

i

⚠ CAUTION

At the end of the test:

- ▲ Observing all cross-contamination procedures e.g. wearing rubber gloves, not letting clinical waste come into contact with anyone, remove and dispose of the PFT bacterial filter in the clinical waste. If using a disposable nose clip, also dispose of the nose clip in the clinical waste.
- ▲ If using a reusable nose clip, disinfect as per the instructions given for the nose clip manufacturer.
- ▲ Wipe / clean the sensor assembly with approved cleaning solution or disinfectant (see para.8.2, Cleaning and Disinfection, page 75).

5.4 SVC Review



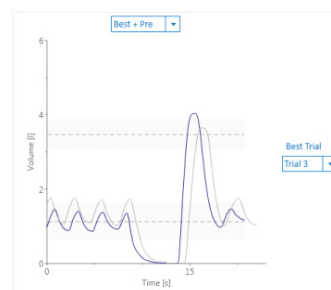
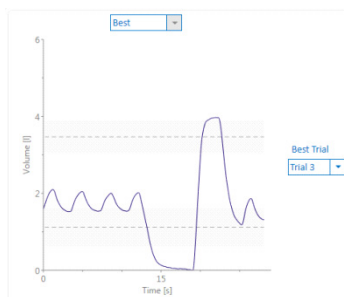
The following data is given:

5.4.1 Best Trial

This window shows the Best or Best+Pre curve of all trials. The Best curve graph shows the graphical display of the best slow Spirometry measurement amongst the trials. The software will automatically choose the trial with the highest vital capacity. It is also possible to define a different Best Trial in the Best Trial to the right of the curves. The best trail depends on the measurement.- sometimes the highest value, sometime the median.

Best or Best + Pre

When a post measurement has been taken, the Best curve graph can show an overlay of the best Pre and the best 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. The Best curve of the post test is the trial colour.



5.4.2 All Trial Graphs

This window shows all the measurement trials that have been performed. In this window you can also select which trials you want to Hide or Show. The trials are indicated by different colours.

The displayed curves can be selected to the right of the curves

5.4.3 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 2005^{*1} 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-0.15L**.

Within-trial and Between-trial Criteria for Slow Spirometry

When **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

All ATS/ERS repeatability criteria met?

Between trial criteria

3 acceptable trials? ✗
Difference between 2 largest VC values < 150ml? ✗

All ATS/ERS repeatability criteria met? ✗

Within trial criteria

Trial

1

2

3

Exhalation time Ok? ✗ ✓ ✓

Plateau in volume time graph? ✗ ✓ ✓

Trial accepted? ✗ ✓ ✓

OK

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) or
 - a plateau in the volume time graph is reached (volume change < 25 ml for ≥ 1 second) or
 - if the patient cannot or should not continue to exhale
2. They are free from the following artifacts:
 - Air leakage at the mouth
 - Hesitation during the maneuver
 - Obstruction of the mouthpiece e.g. biting the mouthpiece too hard or their 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, a red cross indicated non-compliance.

5.4.4 Tabular Results

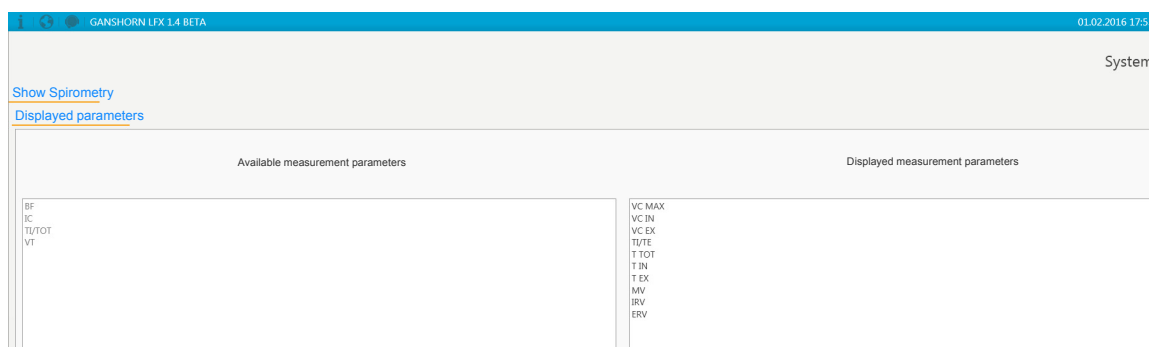
The Tabular results give the results of the slow Spirometry parameters for all trials and the percentage difference from the predicted (using patient data and defined norm). The Z-score gives a objective indication of the measurements ([see para.5.6.5, Z-score, page 57](#)).

5.4.5 Setting the Data in the Results

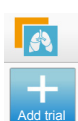


From the review screen, click the settings button to add, remove or change the order of the parameters in the tabular display.

Drag, drop and position as required



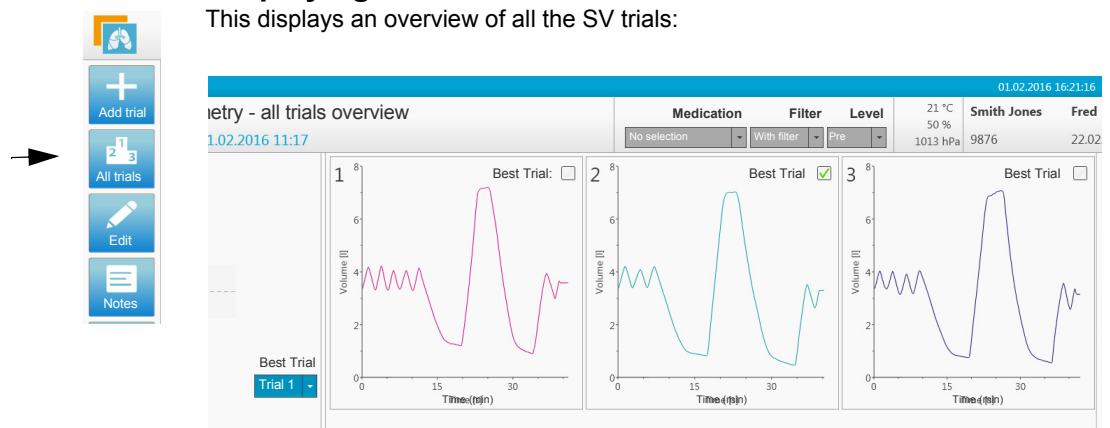
5.4.6 Adding a new Trial



This button enters the screen to take a new trial to add to the measurement.

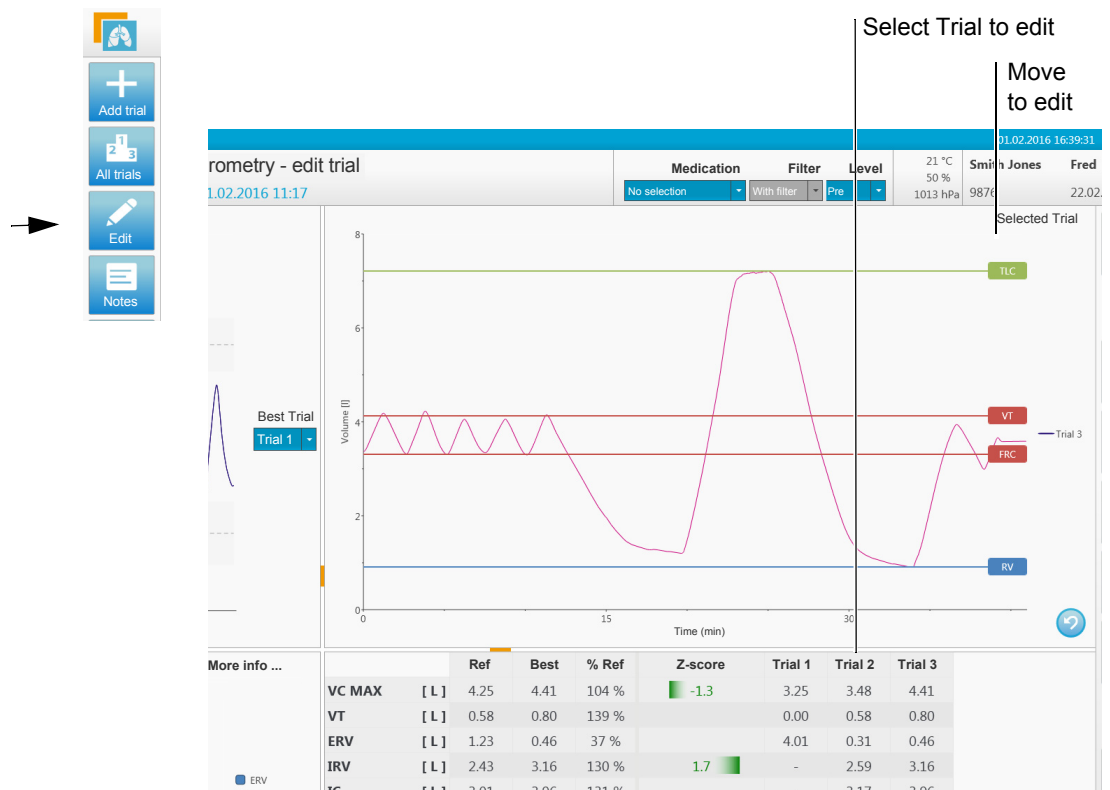
5.4.7 Displaying all Trials

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.

5.4.8 Editing the Recording



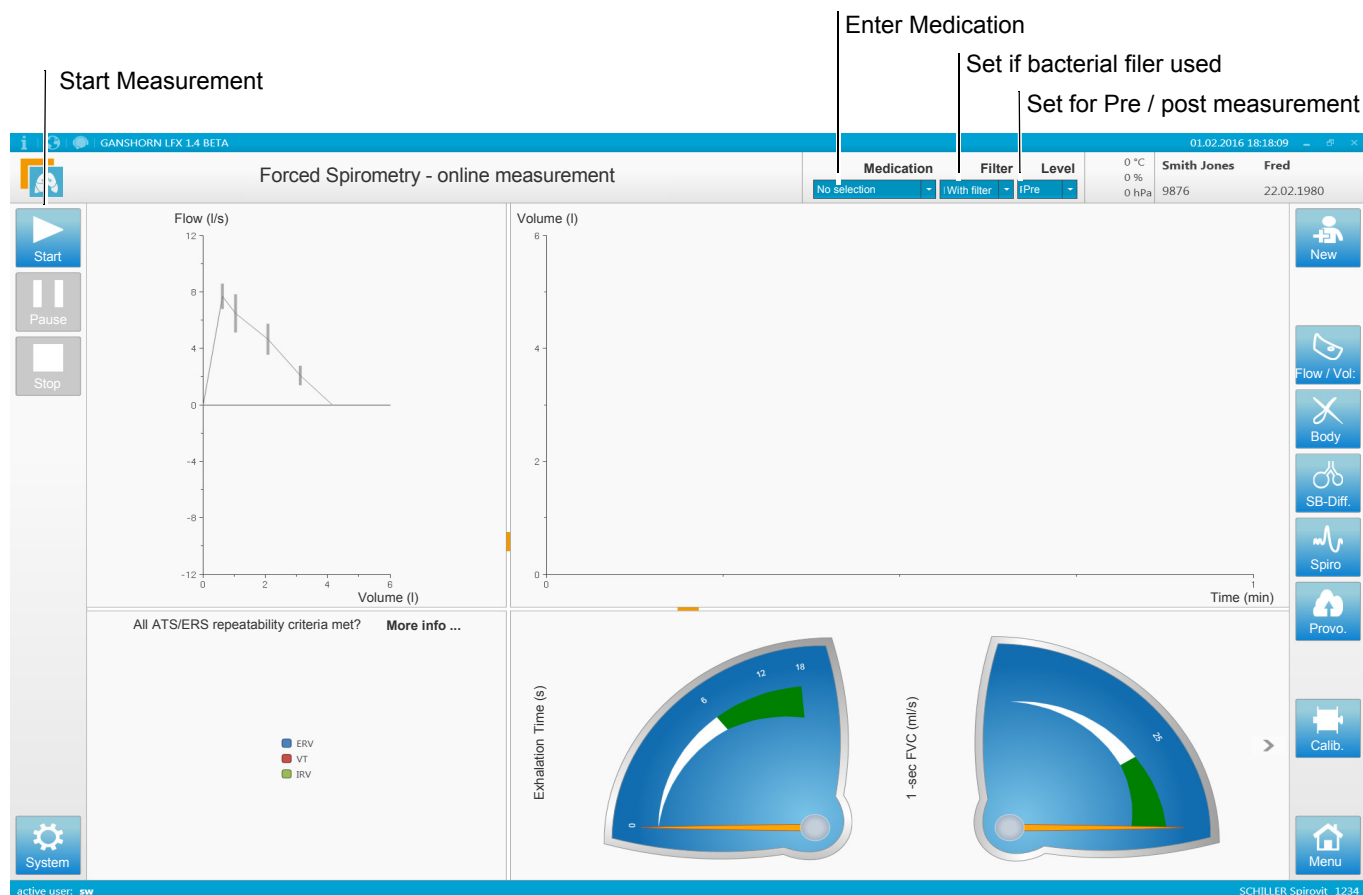
The Edit trial screen gives you the possibility to manually adjust the Total Lung Capacity (TLC), Tidal Volume (VT), Functional Residual Capacity (FRC) and Residual Volume (RV) levels of each slow Spirometry trial. Select the Trial and edit the values as required. The values that are influenced are changed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

5.4.9 Printing

Click the print button to generate a report and select the print where the report is to be printed. The created report is based on the measurements that have been performed. When both pre and post levels have been measured, the printed report will show the best values of both.

5.5 Forced Spirometry Measurement

1. Carry out the preliminary checks (see para.5.2, Preliminaries, page 42).
2. Select patient or register a new patient (see para.3.2, The Work / Patient Screen, page 25).
3. Click on the **Flow/Volume** button.
 - The Forced Spirometry screen is displayed:



4. Position a new bacterial filter on the breathing adapter

WARNING



- ▲ The PFT bacterial filter is single use.
- ▲ Do not use for a different patient.
- ▲ Do not attempt to clean.

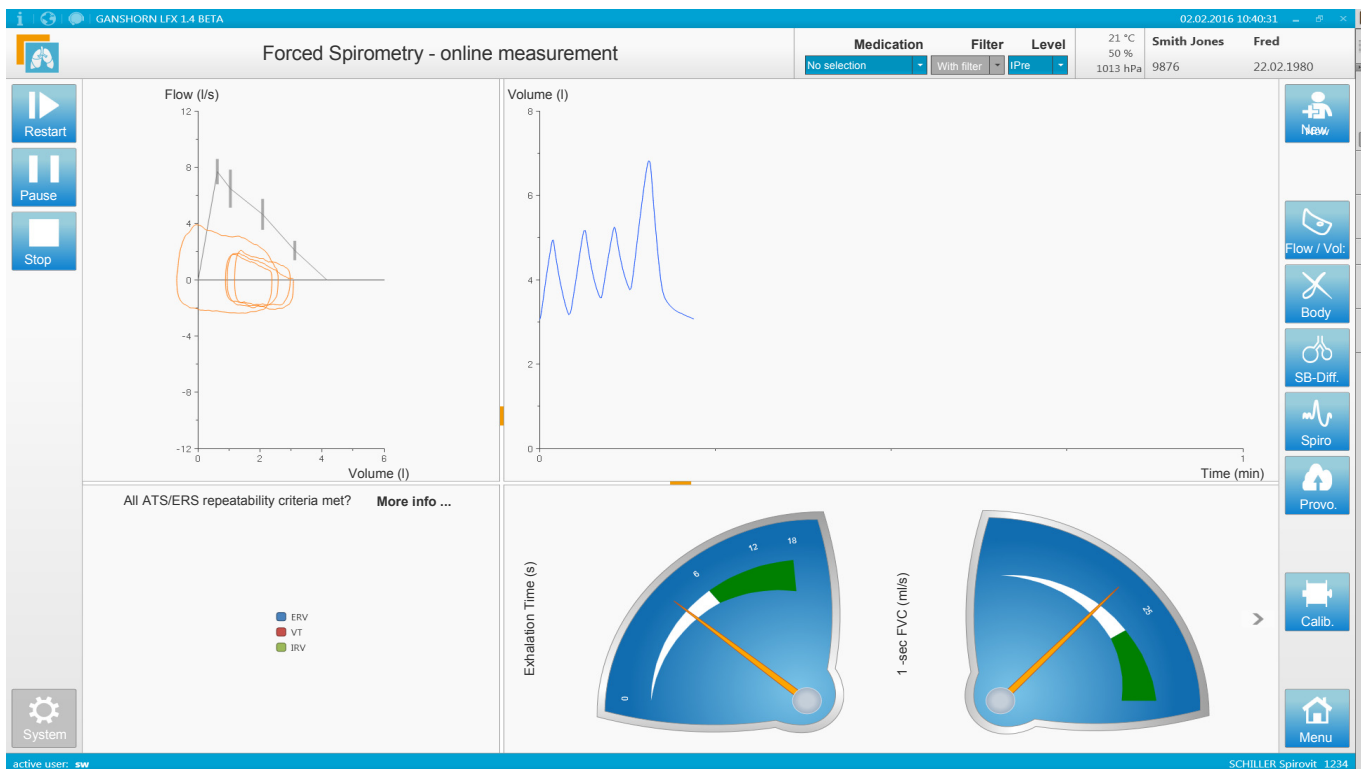
5. Set/check the following settings (top of screen):
 - **Medication** - Enter medication from the pull down menu. Note that the medication can be edited as required ([see para.3.2.6, Edit User Defined Drop Down Lists, page 28](#)).
 - **Filter** - If the bacterial filter is used, ensure it is set here.
 - **Level** - Set for Pre test/post test.



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



- Any medication that the patient has taken prior to their hospital visit should not be entered in the Medication property. This medication should be entered under the option Notes.
 - The level setting is normally **Pre level** for measurements carried out before or without using a bronchiolar. A **post level** is normally used when a measurement is performed after using a bronchodilator. If a measurement is made with the same patient on the same day Post is automatically set.
6. Ask the patient to position himself comfortably (either sitting or standing, and position sensor so that the sensor is level with the patients mouth. Instruct the patient how carry out the test and what is expected
 - The patient should be relaxed (shoulders down and relaxed).
 - Just before starting the measurement, close the patient's nasal airways with a nose-clip.



**7. Click the **Start** button**

- The patient is instructed to breathe regularly and steadily for a while until the breathing level (FRC-level) is stable. This usually requires at least three tidal breathing maneuvers.
- As soon as a stable FRC level is reached, the forced vital capacity can be measured.
- Instruct the patient to inhale completely until TLC level is reached (IC is measured). Then the patient should exhale forcefully and completely until RV level is reached (FVC and FEV1 are measured), followed by a complete inhalation until RV level is reached again (FIVC is measured).

8. Click on the **Stop button to end the measurement. The results of the measurement will be shown.****9. Repeat the test at least three times.****i****Notes:**

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

**▲ At the end of the test:**

- Observing all cross-contamination procedures e.g. wearing rubber gloves, not letting clinical waste come into contact with anyone, remove and dispose of the PFT bacterial filter in the clinical waste. If using a disposable nose clip, also dispose of the nose clip in the clinical waste.
- If using a reusable nose clip, disinfect as per the instructions given for the nose clip manufacturer.
- Wipe / clean the flow sensor with approved cleaning solution or disinfectant ([see para.8.2, Cleaning and Disinfection, page 75](#)).

5.6 Forced Spiro Review



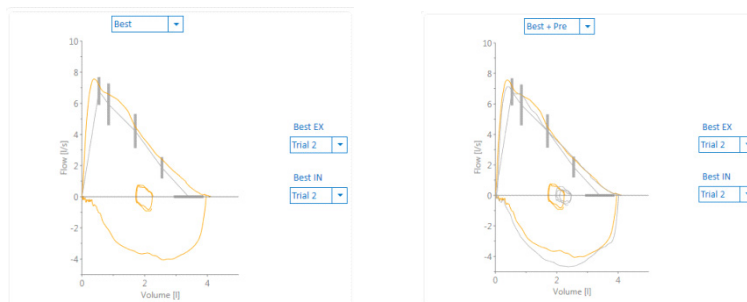
5.6.1 Best Trial

This window shows the Best or Best+Pre curve of all trials. The Best curve graph shows the graphical display of the best Spirometry measurement amongst the trials. The software will automatically choose the trial with the highest vital capacity. It is possible to select a different Best Trial for the inspiratory and expiratory flow-volume curve yourself. The curves are selected in the **Best IN** and **Best Ex** boxes to the right of the curve.

Best or Best + Pre

If the forced Spirometry is measured in the pre and post level, the Best curve graph can show an overlay of the best pre and the best post forced Spirometry measurement. This can be done by making the selection from the drop down list 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 shown as an orange curve



5.6.2 All Trial Graphs

The Measurements Trials window shows two graphs with a graphical overlay of all the forced Spirometry measurements that have been performed: the volume-time graphs on the left and the flow-volume graphs on the right. Each trial has its own unique colour.

Hide		
	EX	IN
1	☒	☒
2	☒	☒
3	☒	☒
4	☒	☒
5	☒	☒

Select / Hide Trial graphs and Include / Exclude for Editing and Quality Control

One or more trials of the inspiratory and/or expiratory curves can be hidden. Selection is in the right-hand part of the Measurement Trials window. Check/uncheck the check boxes as required. Additionally:

- When a trial is 'hidden' the trial column in the Tabular results are also greyed.
- The ATS / ERS repeatability (see following) report will not include the trial. This means that the criteria could be met when all trials are included by could fail when any trials are not included.
- In the Edit screen only the selected trials can be edited.

5.6.3 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 ATS/ERS 2005 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-0.15L**.

Within-trial and Between-trial Criteria for Forced Spirometry

When **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

All ATS/ERS repeatability criteria met?

Between trial criteria

3 acceptable trials? ✗

Difference between 2 largest VC values < 150ml? ✗

All ATS/ERS repeatability criteria met? ✗

Within trial criteria

Trial	1	2	3
Exhalation time Ok?	✗	✓	✓
Plateau in volume time graph?	✗	✓	✓
Trial accepted?	✗	✓	✓

Within-trial 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) or
 - a plateau in the volume time graph is reached (volume change < 25 ml for ≥ 1 second) or
 - if the patient cannot or should not continue to exhale
2. They are free from the following artifacts:
 - Air leakage at the mouth
 - Hesitation during the maneuver
 - Obstruction of the mouthpiece e.g. biting the mouthpiece too hard or their 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, a red cross indicated non-compliance.

5.6.4 Tabular Results

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

5.6.5 Z-score

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

- $Z\text{-Score} = (\text{Measured Value} - \text{Reference Value}) / \text{Standard Deviation}$

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

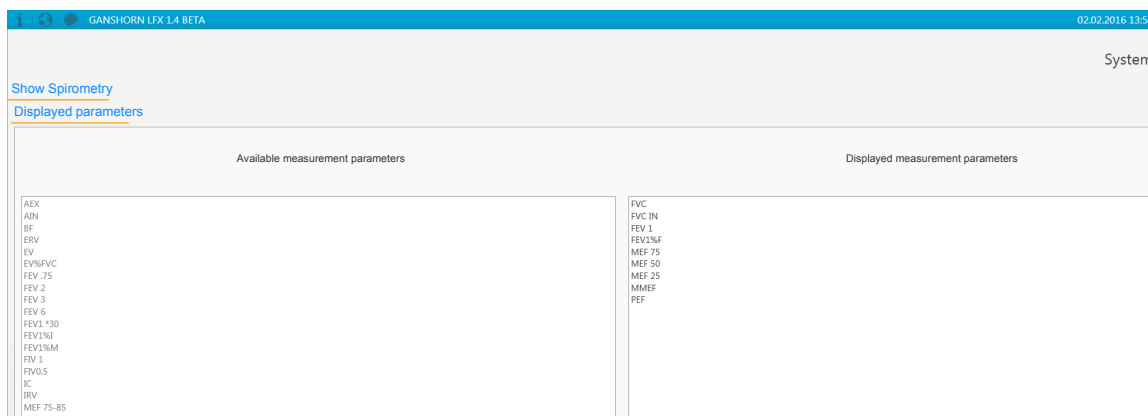
- Green - measurement within expected normal range
- Orange - measurement within range but close to margins. Examine the other measurements, consider taking more trials
- Red - measurement out of expected normal range

5.6.6 Setting the Data in the Results

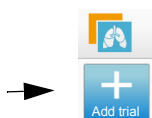


From the review screen, click the settings button to add, remove or change the order of the parameters in the tabular display.

Drag, drop and position as required



5.6.7 Adding a new Trial



This button enters the screen to take a new trial to add to the measurement.

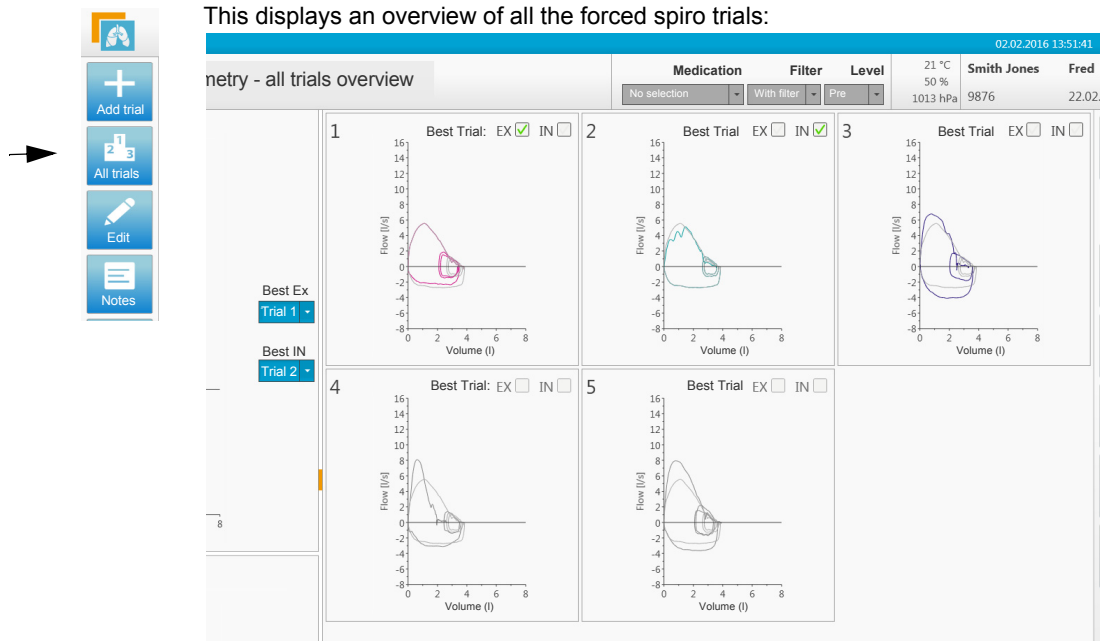
5.6.8 Printing



Click the print button to generate a report and select the print where the report is to be printed. The created report is based on the measurements that have been performed. When both pre and post levels have been measured, the printed report will show the best values of both.

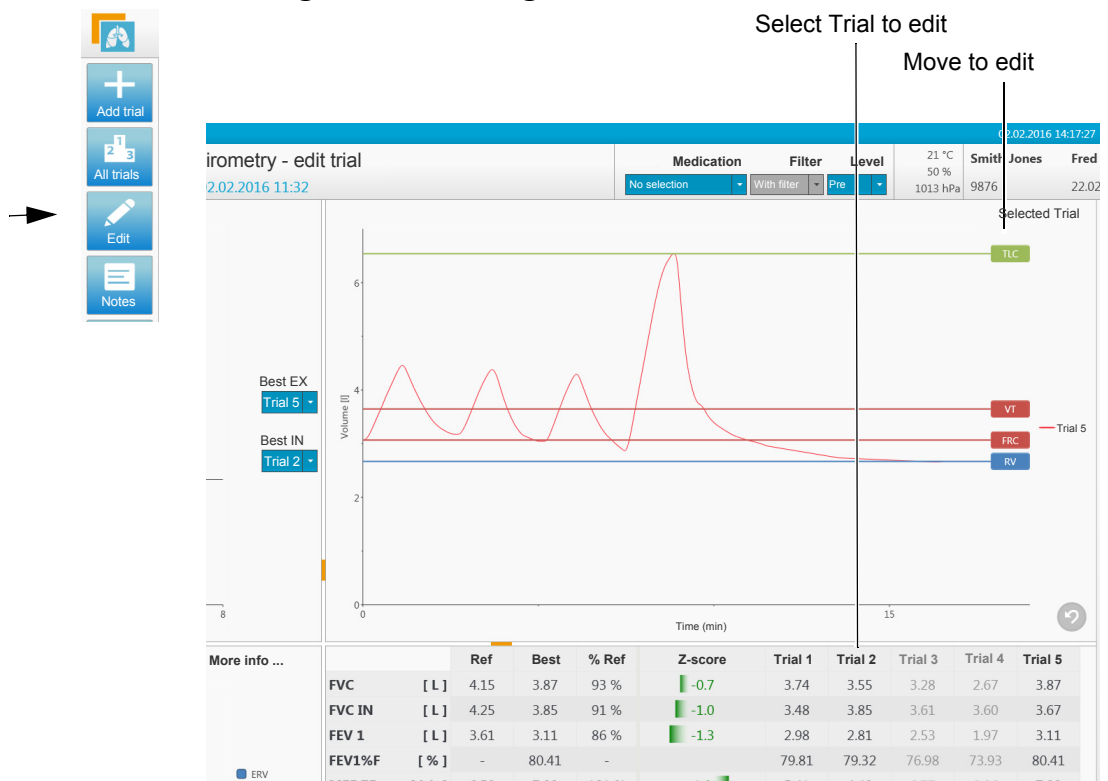
5.6.9 Displaying all Trials

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 by checking the box.

5.6.10 Editing the Recording



The Edit trial screen gives you the possibility to manually adjust the TLC, VT, FRC and RV levels of each Spirometry trial. Select the Trial and edit the values as required. The values that are influenced are changed simultaneously in the tabular results.

5.7 Bodyplethysmography

5.7.1 Procedure

1. Carry out the preliminary checks (see para.5.2, Preliminaries, page 42).
2. Select patient or register a new patient (see para.3.2, The Work / Patient Screen, page 25).
3. Click on the **Body** button.
– The body 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.3.2.6, Edit User Defined Drop Down Lists, page 28).
 - **Filter** - If the bacterial filter is used, ensure it is set here.
 - **Level** - Set for Pre test/post test.



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



- Any medication that the patient has taken prior to their hospital visit should not be entered in the Medication property. This medication should be entered under the option Notes.
 - The level setting is normally **Pre level** for measurements carried out before or without using a bronchiolar. A **Post level** is normally used when a measurement is performed after using a bronchodilator. If a measurement is made with the same patient on the same day Post is automatically set.
5. Position a new PFT bacterial filter on the breathing adapter



- ▲ The PFT bacterial filter is single use. Do not use for a different patient. Do not clean

6. Ensure the patient is comfortable either sitting or standing in the cabin. Ensure the patient knows what is required. Close the patient's nasal airways with a nose-clip.



7. Click the **Start button** to commence 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.

9. Instruct the patient to breath regularly and steadily for a while until the breathing level (FRC-level) is stable. This usually requires at least 3, to 5 or more, tidal breathing maneuvers.



10. **TGV maneuver.** As soon as a stable breathing level is reached and the breathing is steady and repeatable the **Shutter button** becomes active.

11. Warn the patient that the test is going to begin and click the **Shutter button**:
 - Guide the patient to breathe normally in the same speed against the occlusion. A TGV curve is displayed on the screen.
 - A FVC manoeuvre can be performed after the shutter has been opened if required.

12. Click on the **Stop** button to end the measurement. The results of the measurement will be shown.

13. Repeat the test at least three times.



Notes:

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



▲ **At the end of the test:**

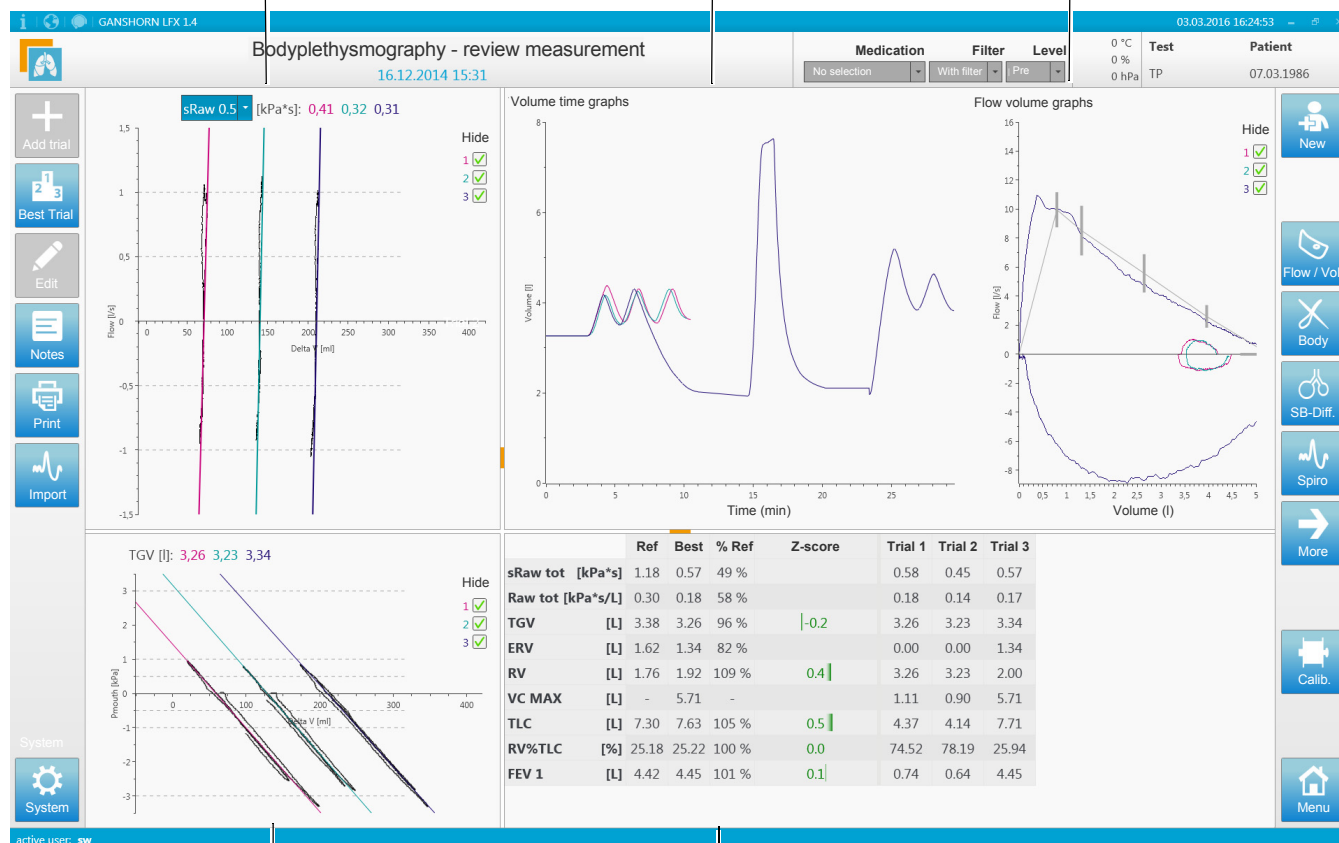
- Observing all cross-contamination procedures e.g. wearing rubber gloves, not letting clinical waste come into contact with anyone, remove and dispose of the PFT bacterial filter in the clinical waste. If using a disposable nose clip, also dispose of the nose clip in the clinical waste.
- If using a reusable nose clip, disinfect as per the instructions given for the nose clip manufacturer.
- Wipe / clean the flow sensor with approved cleaning solution or disinfectant ([see para.8.2, Cleaning and Disinfection, page 75](#)).

5.8 Bodyplethysmography Review

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

The review measurement screen gives tabular and graphical results of resistance, lung volume and FV trials.

5.9 Single Breath Diffusion



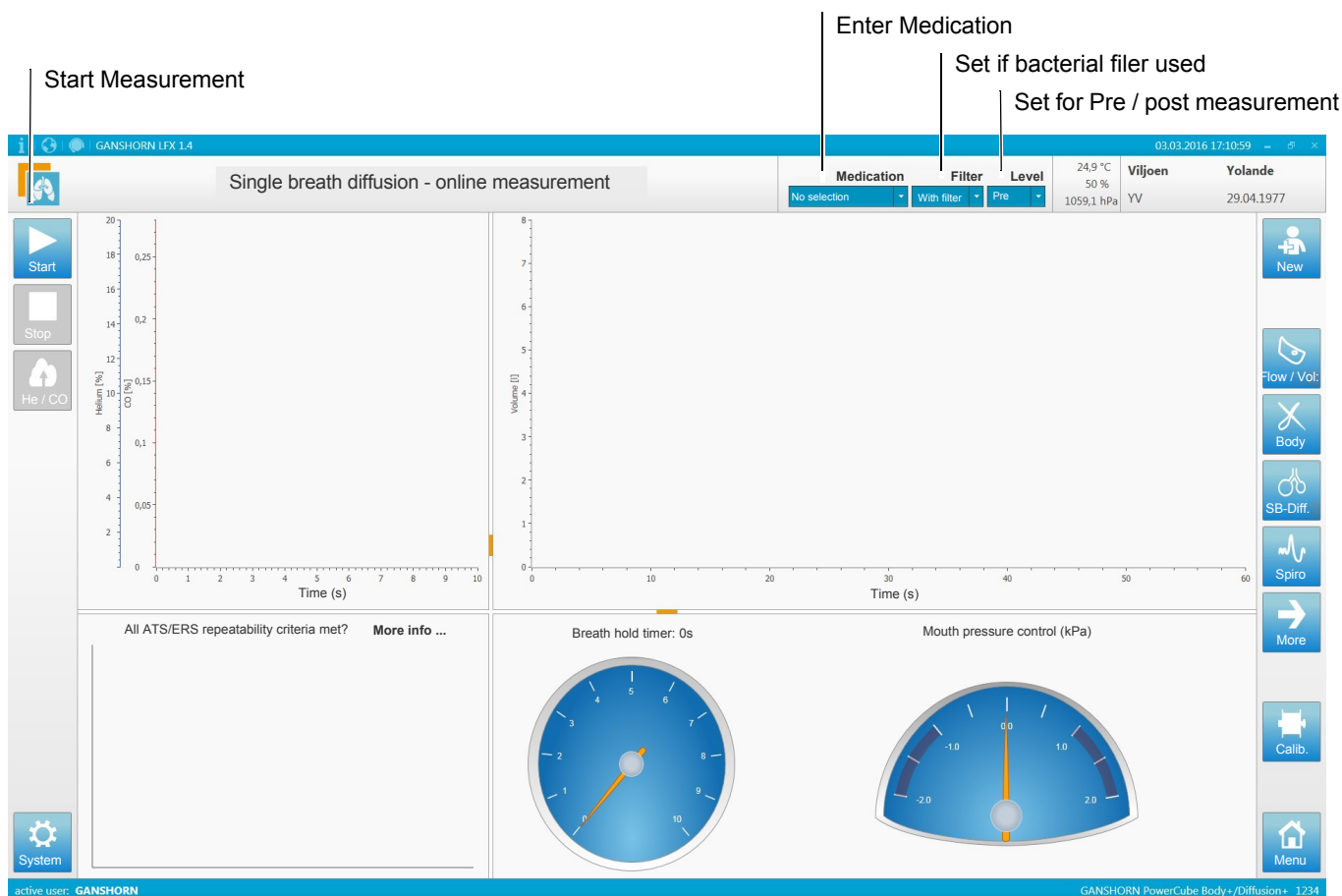
The single breath diffusion procedure detailed is the same for both standalone diffusion installations or when the diffusion sensor is incorporated with Bodyplethysmography. The pictures given here show the patient in the Bodyplethysmography cabin but are equally applicable to all installations.

5.9.1 Procedure

1. Carry out the preliminary checks (see para.5.2, Preliminaries, page 42).
2. Make sure that the pressure regulator of the gas bottle is open.
– Verify that the output pressure is min 6bar.
3. If this is the first trial of the day, carry out a gas calibration (see para.4.7, Gas Calibration, page 38)
4. Select patient or register a new patient (see para.3.2, The Work / Patient Screen, page 25).
5. Click on the **SB-Diff button** (Single Breath diffusion). The diffusion screen is displayed or a calibration message is 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. 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.3.2.6, Edit User Defined Drop Down Lists, page 28](#)).
 - **Filter** - If the PFT bacterial filter is used, ensure it is set 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 low percentage Carbon monoxide is inhaled by the patient.

i

- Any medication that the patient has taken prior to their hospital visit should not be entered in the Medication property. This medication should be entered under the option Notes.
 - The level setting is normally **Pre level** for measurements carried out before or without using a bronchiolar. A **post level** is normally used when a measurement is performed after using a bronchodilator. If a measurement is made with the same patient on the same day Post is automatically set.
7. Position a new PFT bacterial filter on the breathing adapter

WARNING



- ▲ The PFT bacterial filter is single use.
- ▲ Do not use for a different patient.
- ▲ Do not clean.

8. Ensure the patient is comfortable either sitting in or out of the cabin. Ensure the patient knows what is required. Close the patient's nasal airways with a nose-clip.



9. Click the **Start button**
 - Instruct the patient to breathe regularly and steadily for a while until the breathing level (FRC-level) is stable. This usually requires at least three tidal breathing maneuvers
 - The program monitors the breathing and the flow is displayed on the screen



10. Gas inhalation / Breath hold maneuver

- 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 exhale completely and then to inhale a Single Breath as quickly and fully as possible¹ and then to 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 3kPa the system automatically stops measuring.



Hold breath timer

Pressure meter

11. Click on the **Stop** button to end the measurement. The results of the measurement will be shown

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

12. Repeat the test at least three times.



Notes:

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

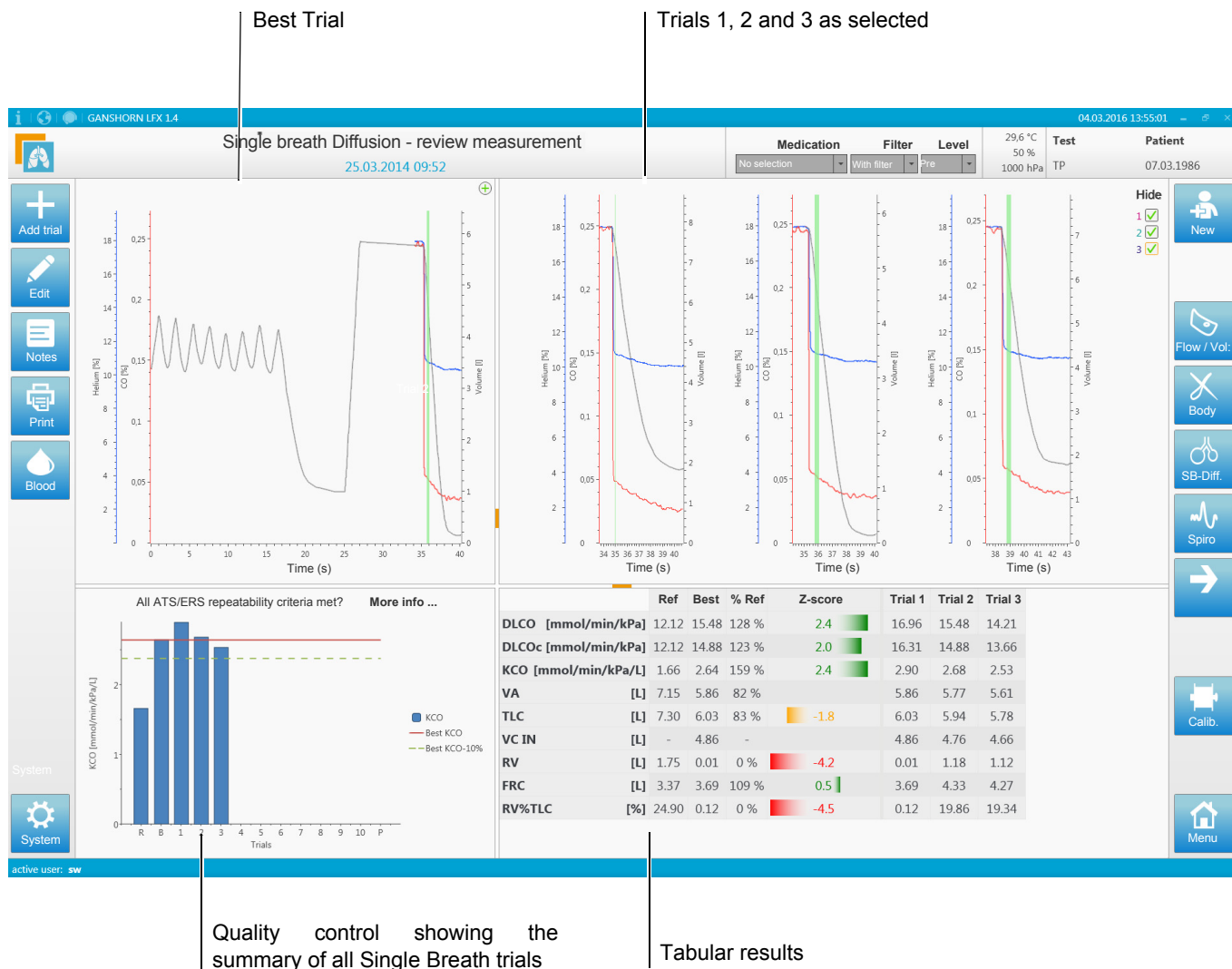
The ATS/ERS guidelines recommend to wait for at least four minutes between tests. Do you want to run anyway?

 CAUTION

▲ **At the end of the test:**

- Observing all cross-contamination procedures e.g. wearing rubber gloves, not letting clinical waste come into contact with anyone, remove and dispose of the PFT bacterial filter in the clinical waste. If using a disposable nose clip, also dispose of the nose clip in the clinical waste.
- If using a reusable nose clip, disinfect as per the instructions given for the nose clip manufacturer.
- Wipe / clean the ScoutSensor with approved cleaning solution or disinfectant ([see para.8.2, Cleaning and Disinfection, page 75](#)).

5.10 Single Breath Diffusion Review



For each graph:

- The **Blue line** shows the **Helium** 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 next page)

5.10.1 Editing the recording

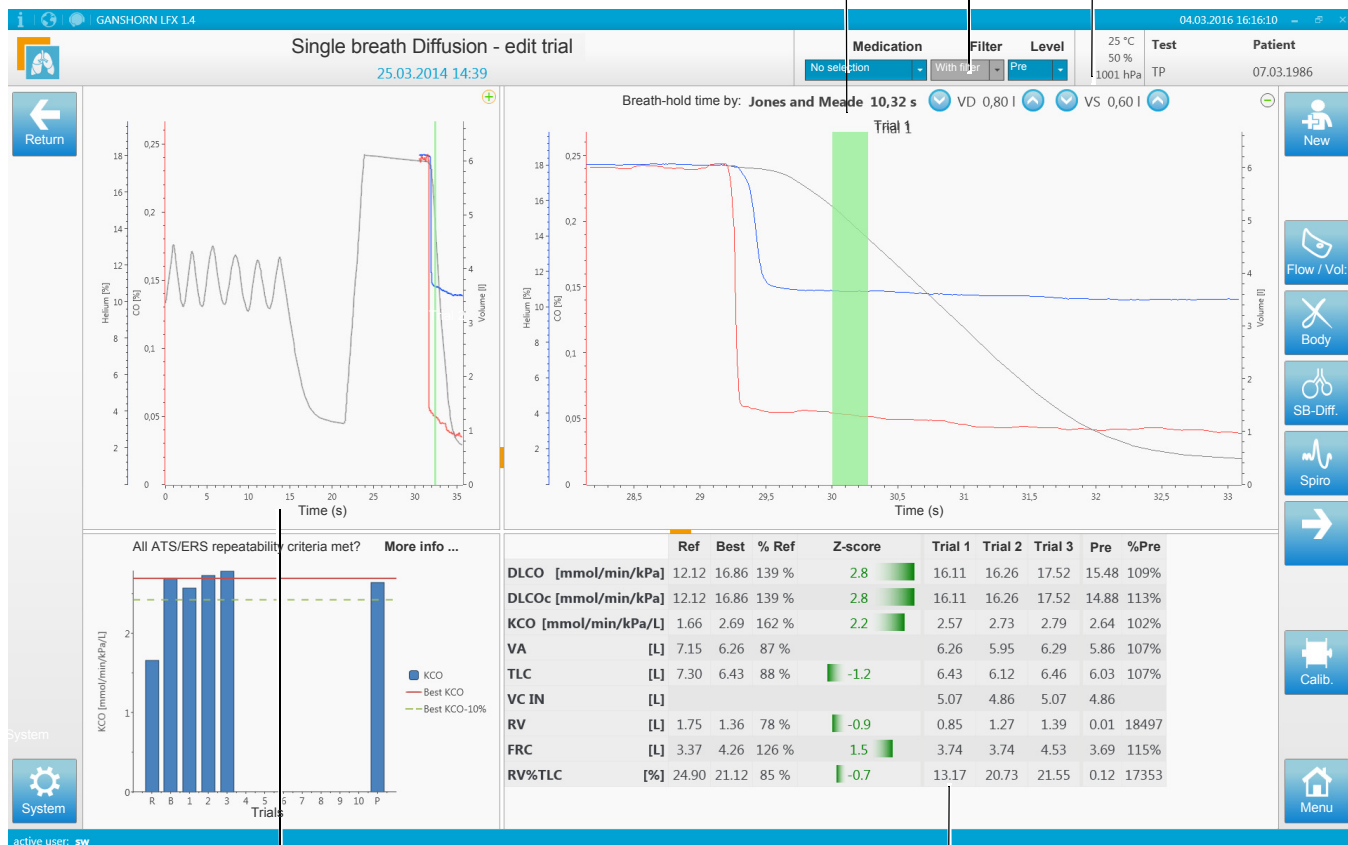


Click the Edit button to display the edit screen. This shows an enlarged graph of trial one. The sample gas measuring start time **VD (volume dead space)**, and the volume of expired gas that is measured **VS (volume of sampled gas)**, is displayed in the top right of the screen.

Vertical green bar representing the sample space (that is where the expired gas is sampled), and expired sample volume (bar width).

Edit the dead space volume (VD)

Edit the sample volume of the expired gas (VS)



The dead space (where the expired gas is sampled), and the expired gas volume is 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 sampling volume are changed.

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

6 Troubleshooting

6.1 General

- In the event of any malfunction visually check the mechanical connections and equipment:
 - Connection to the mains power and electrical connections
 - Tubing
 - Enclosures
 - Operator and display elements
 - Connection to external system components
 - Ensure all system components are connected to each other correctly.
- Switch on the system and start the software
 - Perform all necessary calibrations and check calibration trend ([see para.4, Calibration and Verification, page 31](#)).
 - Perform a test measurement or check reports for unusual measurement results.
 - Make a note of any error messages - contact GANSHORN service for possible suggestions.

6.1.1 Data Communication with PowerCube Body

Error Message /Condition	Check / Procedure / Possible Cause	Check
No Data Communication with PowerCube Body	• System has lost communication port with the sensor, or incorrect device or port defined • Check power supply • Check green cabin door LED • Program does not start, Power cube malfunction, any other errors	• Check in system settings that the correct device and port is defined (see para.7, Settings, page 71). • In system settings, select the Remove device option to remove the device. Then Add device with correct device / port to have a clean installation • Check that the device is connected to the mains and switched on. • If the LED is not lit, remove the system from the mains supply by removing the mains plug, and check fuses on isolation transformer and on the back of the cabin. Only replace fuse with the same type and rating as defined by GANSHORN (see para.8.3, Changing the Fuses, page 81). • Carry out calibration/ verification procedures if possible (see para.4, Calibration and Verification, page 31). • Contact GANSHORN service.

6.1.2 Measurement or Other Errors

Error Message	Check / Procedure / Possible Cause	Check
Zero point/ baseline error message	Zero point is performed automatically when the LFX is switched on and during use every 15 minutes. If the deviation is too large an error message is displayed.	- Ensure a warm-up time of at least 30 minutes. - Check the sensor is kept still during zeroing. - Ensure the room is draft free and even temperature. Close windows. - Switch off any room air conditioning. - Ensure no breath affects zeroing - move the patient / operator away from the sensor. - Replace the PFT bacterial filter.
SB Diffusion errors /Gas Calibration not possible / Time Constant out of range	- Incorrect test gas percentage defined. - Gas not calibrated	- Ensure correct gas concentration has been entered (from gas bottle label). - Replace the PFT bacterial filter. - Perform gas calibration.
Body measurement errors		- Ensure a warm-up time of at least 30 minutes. - Ensure the room is draft free and even temperature. - Check the three green LEDs above the two door magnets are on before the measurement. - Check the door seal for any damage (visual inspection). - Ensure the correct setup. - Perform volume verification.

6.1.3 Spiro Measurement and Communication Errors

Error Message /Condition	Check / Procedure / Possible Cause	Check
No Data Communication with spiro sensor	System has lost communication port with the sensor, or incorrect device or port defined	- Check in system settings that the correct device and port is defined (see para.7, Settings, page 71). - In system settings, select the Remove device option to remove the device. Then Add device with correct device / port to have a clean installation.
Not possible to take a Spiro Recording	- Faulty PFT filter - Faulty sensor tube	- Replace PFT filter - Remove and clean the flow sensor (see para.8.2.4, Assembly and Disassembly of the Ultrasonic Flow Transducer, page 77). - Replace the flow sensor



All calibration and verification procedures along with calibration trouble shooting are detailed earlier in this book ([see para.4, Calibration and Verification, page 31](#)).

7 Settings



This section gives an overview of the options in the LFX settings and is provided for information only. The settings section is for GANSHORN approved personnel.



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

The following options are available:

Language

Select language and preferred region. The preferred region will set the data and time format options and these are displayed below the setting.

Forced Spirometry

- **Displayed Measurement Parameters.** Here the default measurements, given on the results table after an FVC measurement is taken, are defined. The measurement results can also be defined in the Spiro screen at any time.
- **Report Measurement Parameters.** Here the default measurements that are printed / generated on report are defined.

Slow Spirometry

- **Displayed Measurement Parameters.** Here the default measurements, given on the results table after an SV measurement is taken, are defined. The measurement results can also be defined in the Spiro screen at any time.
- **Report Measurement Parameters.** Here the default measurements that are printed / generated on report are defined.

Single Breath Diffusion

- **Measurement Settings.** Define the **Breath hold time** - select between 8 and 12 seconds, and **Breath hold calculation type** - select between Jones and Meade, ERS, or Ogilvie, and **Test Gas oxygen fraction** - select between 17% and 21%.
 - Note the He and CO percentage of the test gas is entered during gas calibration ([see para.4.7, Gas Calibration, page 38](#)).
- **Displayed Measurement Parameters.** Here the default measurements, given on the results table after a measurement is taken, are defined. The measurement results can also be defined in the Body screen at any time.
- **Report Measurement Parameters.** Here the default measurements that are printed / generated on report are defined.

Bodyplethysmography

- **Measurement Settings.**
 - These are the different types of curve calculations. tot, eff and mid describes the method of evaluation.
 - Define the shutter closing time (1-5 s), and the sRaw data displayed. Select between sRaw tot, sRaw eff, sRaw mid, sRaw peak, sRaw 0.5.
- **Displayed Measurement Parameters.** Here the default measurements, given on the results table after a measurement is taken, are defined. The measurement results can also be defined in the Body screen at any time.
- **Report Measurement Parameters.** Here the default measurements that are printed / generated on report are defined.

Bronchial provocation test (option)

- **Configuration.** Here the default test sequence are displayed, and can be edited and new sequences defined. The sequences defined or shown here are available for selection when taking a provocation test.
- **Provocation Parameters.** Here the default measurements for Bodyplethysmography and for forced Spirometry, given on the results table after a measurement is taken, are defined. The measurement results can also be defined in the provo at any time.
- **Control Parameters.** Here the % calculation of PD (exceed or under-run), for Raw tot and FEV1 are defined.

GDT

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

Sema Integration

These settings define the SCHILLER SEMA database and import / export directories if networked with a SCHILLER SEMA3 server.

Device Management

In this screen the measuring devices connected to the LFX are defined and the serial number and COM port displayed and defined on installation. The measuring devices that must be defined include: GANSHORN PowerCube Body, GANSHORN PowerCube Body with diffusion, GANSHORN PowerCube Diffusion, GANSHORN SpiroScout.

License

This is the license screen for program registration (usually, this will be registered by the installation team). Options are given for **Automatic activation** (enter customer details and product key (obtained from GANSHORN), **Manual activation** (activated by an activation key generated via the GANSHORN website), or **Phone activation** (activated by an activation key given by GANSHORN after confirming your product hardware and product key over the phone).

Reporting

- **Content.** Here the header (for example practice address), footer, and logo that is included when a printout or report is generated. The logo can be any standard illustration / photo format (jpg, png, bmp, etc.).
- **Reporting Settings.** Here the default report settings are defined as follows:
 - **Default action** - print to default printer, export to PDF file (also the directory location where the file will be stored is defined).
 - **Default report** - here the report data for SV, FVC, Bodyplethysmography, 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. The import / export directory must be specified.

Database Connection

- **Database.** Define the database that the LFX uses for patient and recording storage. If the LFX is installed standalone, select '(local)' for database server. Define the name and authentication (security)
- **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. Carry this out on a regular basis to ensure smooth database operation.

8 Maintenance



- ▲ There are no user-replaceable parts inside the device - do not open the any part of the system.
- ▲ Only maintenance procedures detailed in this book, for example, calibration, visual inspection, cleaning, may be carried out by the user.
- ▲ Only GANSHORN or an authorised GANSHORN partner is permitted to perform the 24-month maintenance procedure or carry out any other service or replacement procedures on the system.

8.1 Unit Maintenance Schedule

The following table indicates the maintenance intervals, the maintenance requirement, and the person authorised to carry out 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 verification (if required) - Clean and Disinfect the Ultrasonic Flow transducer	→ User
As Required	- Clean the cabin and cable assemblies - Check pressure (minimum 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 24-months as defined 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, backup will be carried out as defined by the network administrator. If the unit is operated standalone it is essential that system backup is carried out 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.

8.1.1 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 carried out on a regular basis in accordance with local policy. This can be done on a USB drive, external hard disk, network drive, etc.

The database backup can be carried out from the SQL Server Management.

Calibration

It must be ensured that calibration has been carried out before the system is used at the following intervals:

	Every day before use	Every Week	Yearly (part of annual check)	At any time ^a
Gas Calibration	✓			✓
Volume verification ^b		✓		✓
BodyLiveCal Calibration		✓		✓
Ambient Conditions			✓ ^c	✓

- a. Calibration can be carried out at any time for verification if required.
- b. Because of the ultrasound sensor technology, volume verification is not necessary on a regular basis. Some authorities stipulate that volume calibration is necessary and verification can be performed as required.
- c. Sensors are incorporated in the system to monitor relevant environmental parameters. The ambient parameters can also be entered at any time to offset the system sensors.

Cleaning Ultrasonic Flow Transducer / Reusable Nose Clips



- ▲ Only use the disinfectants specified here or by the nose clip manufacturer. Ensure correct dilution and immersion time in the disinfectant solution.
- ▲ Rubber gloves and eye protection, as specified by the nose clip manufacturer, are to be used during disinfection.

Flow Sensor

(see para.8.2.3, [Cleaning and Disinfecting the Ultrasonic Flow Transducer](#), page 76)

Reusable Nose Clips

If reusable nose clips are used, disinfect after every patient as follows:

1. Clean the nose clip with clean water (drinking water quality) and immerse the nose clip in a disinfection solution for the prescribed time.
2. Rinse the nose clip with clear water (drinking water quality) and let to dry thoroughly before reusing it on the next patient.

8.1.2 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, isolation transformer, and printer.** - not broken, chipped, cracked, or otherwise visibly damaged.
- **Cabin-** glass clean and ensure glass not cracked or chipped. Cabin upright and even, not tilting (feet even). Ensure 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** - sheathing and connectors undamaged. No kinks, abrasion or wear in any cable assembly or gas hose
- **Input/output connectors** - all pins and sockets undamaged, straight and no signs of excessive wear. All luer connectors secure and working correctly.

8.1.3 Every 24 Months or as Defined by Local Regulations

Return the unit to an authorised GANSHORN facility for Recurrent test and test after repair according to IEC / EN62353.

8.2 Cleaning and Disinfection

WARNING

- ▲ Switch off the system before cleaning and disconnect from the mains by removing the plug.
- ▲ Do not, under any circumstances, immerse the apparatus into a cleaning liquid or sterilise with hot water, steam, or air.

CAUTION

- ▲ Do not autoclave the Sensor or any accessories.
- ▲ Do not immerse accessories in liquid when cleaning unless the accessory manufacturer's cleaning instructions explicitly instruct you to do so.
- ▲ Use of cleaning solutions which have a high acid content or are otherwise inappropriate can cause damage to the equipment, including cracking and deterioration of the plastic case.
- ▲ Always follow the mixing/diluting instructions provided by the manufacturer of the cleaning solution.
- ▲ Never use any of the following solutions or similar products to clean the equipment: ethyl alcohol, ethanol, acetone, hexane, abrasive or scouring powder or material, any cleaning material that damages plastic.
- ▲ Ensure no liquid penetrates the device or connections. Never use a wet or dripping cloth; do not spray the equipment with cleaning solution.
- ▲ Cable assemblies and gas hoses must not be exposed to excessive mechanical stress. Whenever disconnecting, hold the plugs and not the cable or hose. Store and use cables and hoses in such a way as to prevent anyone stumbling over them or any damage being caused by the wheels of instrument trolleys.
- ▲ When cleaning, ensure that all labels and safety statements, whether etched, printed or stuck to the device, remain in place and remain readable.
- ▲ The wearing of protective gloves (e. g. of butyl rubber) during cleaning is recommended.

8.2.1 Before Cleaning

Before cleaning the sensor assembly, or any component 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.

8.2.2 General Cleaning Procedure

The casing of the sensor unit, cable assemblies and hoses can be cleaned with a cloth slightly moistened (not wet) on the surface only. Where necessary a domestic non-caustic cleaner or 50% alcohol solution can be used for grease and finger marks. Wipe the equipment with a cloth slightly moistened (not wet) with one of the approved cleaning solutions listed.

Thoroughly wipe off any excess cleaning solution. Do not let the cleaning solution run into or accumulate in connector openings, latches, or crevices. If liquid gets into connectors, dry the area with warm air, and then check the equipment to confirm that it operates properly

To clean the unit follow these steps:

1. Wipe the equipment with a cloth slightly moistened (not wet) with one of the approved cleaning solutions listed in [\(see para.8.2.5, Approved Cleaning Solutions, page 79\)](#).
2. Clean cable assemblies by gently wiping from the center of the cable. Do not allow the sheathing to be displaced.
3. Thoroughly wipe off any excess cleaning solution. Do not let the cleaning solution run into or accumulate in connector openings, latches, or crevices. If liquid gets into connectors, dry the area with warm air, and then check the equipment to confirm that it operates properly.

8.2.3 Cleaning and Disinfecting the Ultrasonic Flow Transducer

The ultrasonic flow transducer has a breathing insert designed for use with the PFT bacterial filters. This flow transducer and breathing insert should be cleaned and disinfected every week. The breathing tube of the ultrasonic flow transducer is made of stainless steel and is heat resistant to temperatures up to 60°C.

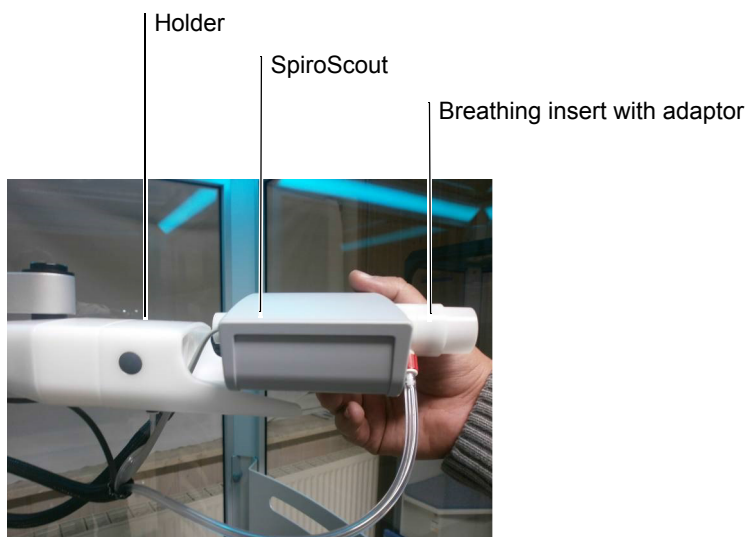
- Remove the breathing insert from the shutter block (see following)
- Unscrew the shutter adapter from the breathing insert.
- Clean the breathing insert and shutter adapter with clear water (drinking water quality).
- Immerse the parts in disinfectant for the prescribed time.
- Rinse the parts with clear water (drinking water quality), then shake the parts to remove the water or let them dry.
- Screw the shutter adapter onto the breathing insert
- Insert the breathing insert correctly in the ScoutSensor.



8.2.4 Assembly and Disassembly of the Ultrasonic Flow Transducer

Removal of the SpiroScout

1. Secure the holder and with your free hand, overcome the resistance and pull the SpiroScout along the guide rail towards the front and off the holder.
2. Unplug the power cord at the back end of the ScoutSensor and remove the gas tube (Luer lock) (red).



Replacement of the SpiroScout

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

Removing the Breathing Insert

To remove the permanent breathing insert, unscrew the counter nut and pull out the insert, turning it a little counterclockwise, if needed.

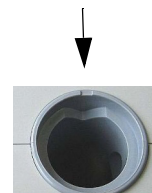


Replacing the Breathing Insert

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

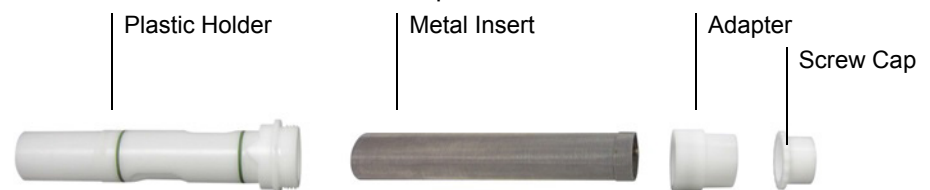


2. Introduce the permanent breathing insert into the ScoutSensor all the way.
3. Align the arrow on the permanent breathing insert with the notch in the ScoutSensor and fasten the permanent breathing insert in the ScoutSensor by means of the counter nut



Reusable Breathing Insert Assembly

The reusable insert consists of four parts



1. Introduce the metal insert completely into the plastic holder
 - Ensure that the metal tube's seam is not aligned with the open parts in the plastic holder



Correct



Not Correct

2. Screw the adapter on to the plastic holder



3. Position the breathing insert in the SpiroScout.



8.2.5 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.
- products approved for glass (cabin)

Recommended

GANSHORN recommends the following

Cleaning Solution	Manufacturer
Descogen I	Antiseptica chem.-pharm. Produkte GmbH
Bodedes forte	Bode Chemie

8.2.6 Cleaning Materials that must not be used

Never use products containing the following:

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

8.2.7 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](#)).

8.2.8 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
Lysetol V1	Schülke und Mayr GmbH
Sekusept Forte S1	Ecolab
Korsolex Basic	Bode Chemie
Korsolex Extra	Bode Chemie
Celanispet Wipes	Dr. Schuhmacher

8.2.9 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

8.3 Changing the Fuses

8.3.1 Isolation Transformer Fuse



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

Isolation transformer Fuse types

Voltage range	Number	Fuse type
100 - 240 VAC	2	ELU Siba T 6.3A /H 250V

Procedure

1. Disconnect the device from the mains.
2. Release the fuse holder by gently pushing up the fuse assembly catch with a small flat-blade screwdriver and remove the fuse holder.



3. Replace both fuses. Re-insert the fuse holder until the fuse holder snaps in place.

8.3.2 Cabin / Control Module Fuse

Cabin / Control Module Fuse types

Voltage range	Number	Fuse type
100 - 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.

8.4 Decommissioning

Please observe the following points concerning the decommissioning and storage of the equipment:

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

8.5 Disposal

8.5.1 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.

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

8.5.2 Consumables

Consumables must be disposed of in compliance with national and international rules and regulations. Please 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 as domestic waste or clinical waste.



- ▲ Consumables may be contaminated. The operator / customer is obliged to establish a quality management system for the handling of 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

Unless otherwise specified, single-use disposables, used breathing inserts and PFT filters must be disposed of in clinical 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.



9 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 your local GANSHORN representative.

9.1 Part Numbers

Part number	Description
019420862	GANSHORN pressure regulator
	Test gas cylinder (He/CO/O ₂ /N). The gas cylinder can be ordered from your distributor or directly from GANSHORN.

9.2 Consumables

Part number	Description
019420650	GANSHORN PFT Bacterial filter (pack of 100)
019410901	Nose Clip (pack of 10)
019420656	GANSHORN Safe Filter Pack (PFT Bacterial filter with Nose clip) pack of 100
019420655	GANSHORN Extra Safe Filter Pack (PFT Bacterial filter, Nose clip and mouthpiece) pack of 100
019420724	Permanent breathing tube

10 Technical Data

10.1 System

Manufacturer	GANSHORN GmbH
System Control Stand	Wheeled stand for computer, isolation transformer, monitor and printer. Front wheels lockable.
PC	
Safety	Compliance with standard IEC 60950-1
Operating system	Windows7® Professional, 64 Bit
Processor	Intel Core i5 compatible processor 4.0 GHz
Performance index	1.0 (4.0)
RAM	4 GB
Hard drive	1 TB
Interface	USB
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 power cube installed below the cabin)
Volume	940 L
Max Load	• Bench, 160 kg • Chair, 120 kg
Door Lock	Electromagnetic
Software	LFX for Windows 32 or 64 Bit
Classifications	
Device	Active medical product, class IIa
Applied part	Type BF
Corrections	
F/V	ERS or ATS
Inhalation	BTPS (environment module) or real-time BTPS correction
Gas volume	STPD (environment module) or real-time BTPS correction
Computer interface	
Data transfer to PC	USB 2.0
USB connection	Connector A – connector B / double shielded / 2 x AWG24, 2 x AWG28
Signal transmission	4 kV Opto isolator RS-232 interface, 57.600 Baud

**Power Supply**

The Mains power requirement for all system components is via an isolation transformer.

Isolation	> 4 kV
Power input	110 V to 240 V
Isolation transformer fuse rating	ELU Siba T 6.3A /H 250 V (x2)
Average power consumption	350 W(all system components active)

Database

Local	• GANSHORN SQL • Authentication user defined
GDT	• Import and export with user defined settings
SEMA3	• SCHILLER SEMA3 integration

10.2 Ambient Conditions

Operation

Ambient temperature	+15 to +35 °C
Atmospheric pressure	700 to 1050 hPa
Relative humidity	30 to 80 % (no condensation)
Max. warm-up time	0 (not measurable at stable ambient conditions)
Max. temperature gradient	N/A

Ambient conditions, storage and transport

Ambient temperature	-20 to +50 °C
Atmospheric pressure	600 to 1050 hPa
Relative humidity	10 to 90 % (no condensation)

10.3 Standards

Quality management

ISO 13485

FDA

510(k) market clearance

MDD 93/42/ECC

CE Marked

Electrical safety

EN 60601-1 (Third Edition)

10.4 Flow and Volume

Sensor	GANSHORN SpiroScout, mounted on swivel arm
Material	Polyethylene
Patient protection and hygiene	Single patient use, disposable PFT bacterial filter - see following.
Respiratory resistance	0.002 kPa/l/s = approx. 0.02 cmH ₂ O/l/s
Dead space, complete	18 cm ³
Pre / Post measurement	Comparison pre/post medication possible.
Prediction Equations	Extrapolated predicted values. • ECCS93 • Froche • Nhanes III • ECCS93_GLI • GLI 2012 • Hedenstrom • ATS 94
Standards Compliance	• ATS • ERS
Flow measurement	
Measurement method	Ultrasound transit time measurement
Measuring range	0 to + 20 l/s
Accuracy	< ± 2,0 % or 50 ml/s (the larger value applies)
Resistance	<0.05 kPa/(l/s) at 14 l/s
Resolution	1 ml/s
Volume measurement	
Measurement method	Digital integration
Measuring range	Not limited, graphical display 0 to 20 l
Accuracy	± 2%
Resolution	1 ml

10.4.1 PFT Filter

Manufacturer	GANSHORN PTF Filter
Type	Single patient use, electrostatic filter, fleece with protective membrane.
Bacterial / viral protection	99.9999% bacterial / viral filtration efficiency
Patient comfort	Ergonomically shaped mouthpiece and standard cone 22 mm
Material	White polypropylene
Resistance	@ 12 L/s 0.7 cmH ₂ O/L/s (0.07 kPa/L/s)
Effective dead space	50 ml
The PFT filter fully fulfils the latest recommendations from both the American Thoracic and European Respiratory Societies (ATS & ERS).	



10.4.2 Measured Values

• ERV	[L]
• MEF 75-85	[L/s]
• MIF50%	[%]
• MEF50	[%]
• FEV1 *30	[L/min]
• MEF 85	[L/s]
• FIV0.5	[L]
• FEV1%I	[%]
• EV%FVC	[%]
• FVC	[L]
• FVC IN	[L]
• AEX	[L *L/s]
• AIN	[L *L/s]
• FIV 1	[L]
• BF	[1/min]
• MIF 50	[L/s]
• FEV 75	[L]
• EV	[L]
• FEV 1	[L]
• FEV 3	[L]
• FEV 2	[L]
• MIF 75	[L/s]
• FEV1%M	[%]
• FEV1%F	[%]
• FEV 6	[L]
• PEFT	[sec]
• T TOT	[sec]
• IC	[L]
• MEF 25	[L/s]
• IRV	[L]
• VC EX	[L]
• VC IN	[L]
• MEF 50	[L/s]
• VT	[L]
• TI/TOT	
• VC MAX	[L] %
• PIF	[L/s]
• MEF 75	[L/s]
• TI/TE	
• MIF 25	[L/s]
• T IN	[sec]
• T EX	[sec]
• PEF	[L/s]
• MV	[L/min]

10.5 Bodyplethysmography

Cabin

Measurement method	Piezo resistive pressure sensor, volume constant
Measuring range	0 to 30 kPa
Accuracy	± 1% of the measured value
Thoracic gas volume (TGV) calibration volume	2280 ml
Calibration frequencies	0.25 Hz, 0.5 Hz, 1.0 Hz

Mouth Pressure

Measurement principle	Piezo resistive pressure sensor
Measuring range	± 30 kPa
Accuracy	± 1%
Resolution	0.01 kPa

Cabin Pressure

Measurement method	Piezo resistive pressure sensor
Measuring range	±1 kPa
Accuracy	± 1%
Resolution	0.01 kPa

Shutter closing time	User defined between 1 and 5 seconds
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Measurements	Spirometry/flow-volume, MVV, Bodyplethysmography (resistance loop: SRtot, SReff, Rtot, Reff, Rin, Rex, lung volume: TGV, TLC, RV, RV%TLC etc.), ROCC, PImax/ PEmax/ P100, offline input of blood gas values
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10.6 Diffusion

Measured Curves	Helium and CO
Standards	Determination of diffusion capacity (TLCO) and helium-FRC SB meets ERS/ATS standard
Analysis	Fast multi-gas CO/CH4/C2H2 analyser
Shutter	Shutter speed set between 1 and 5 seconds
Hold breath time	User set between 8 and 12 seconds
Breath hold time calculation	• Jones and Meade • ERS • Ogilvie
Test gas oxygen fraction	17% - 21%
Test gas Helium fraction	Helium - 16.5 - 17.5%
Test gas CO fraction	CO - 0.20 - 0.30 %



10.6.1 CO Analyser

Method	Non-dispersive Infrared Analyser
Range	0 to 0.5%
Accuracy	± 1%

10.6.2 He Analyser

Method	Ultrasound
Range	0 to 20%
Accuracy	± 1%

10.7 Installing Updates

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

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

10.8 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.

10.9 Measures to Prevent 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 unit. The distance depends on the output performance of the communication device, as indicated below.

HF source	Transmitter frequency [MHz]	Power P [W]	Distance d [m]
Radio telephone (micro cellular) CT1+, CT2, CT3	885-887	0.010	0.23
Cordless DECT telephone, WLAN, UMTS phone	1880-2500	0.25	1.17
Mobile phone, USA	850/1900	0.6	1.8
Mobile phone			
- GSM900,	900	2	3.3
- GSM850, NMT900, DCS 1800	850,900,1800	1	2.3
Walkie-talkie (rescue service, police, fire brigade, servicing)	81-470	5	2.6
Mobile telephone system (rescue service, police, fire brigade)	81-470	100	11.7
RFID (active and passive transponders and reading devices)	433 865-868	0.5	0.85 1.62



It can be deduced from the table that portable HF telecommunication devices must not be used within a radius of 3 m from the unit and its cables.

**Frequency range
80 - 800 MHz**

**Frequency range
800 MHz- 2.5 GHz**

$$d = 1.2 \times \sqrt{P}$$

$$d = 2.3 \times \sqrt{P}$$

d = recommended minimum distance in meters

P = transmitting power in Watts

Further measures to prevent electromagnetic interferences:

- The user can take the following measures to solve this problem:
- Increase distance to the source of interference.
- Turn the device to change the angle of radiation.
- Connect the potential equalisation cable
- Connect the device to a different mains connector.
- Only use original accessories (especially patient cables)..



For more information on the use in an electromagnetic environment in accordance with IEC/EN 60601-1-2, please consult the service handbook.



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