



Click <**Continue**> to open the user confirmation window. Use your fingerprint again to confirm your identity.

The DCR will be electrically submitted with the next data transfer to ERT data management for processing.



Make sure to print one version of the Data Correction Form for your source documentation. The form can be printed using the MasterScope.

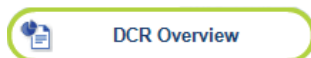
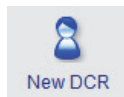


It is not necessary to fax or e-mail the DCR form (Data Correction Form) since it will automatically be transmitted by your MasterScope with the next data transfer to ERT data management.

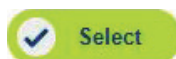
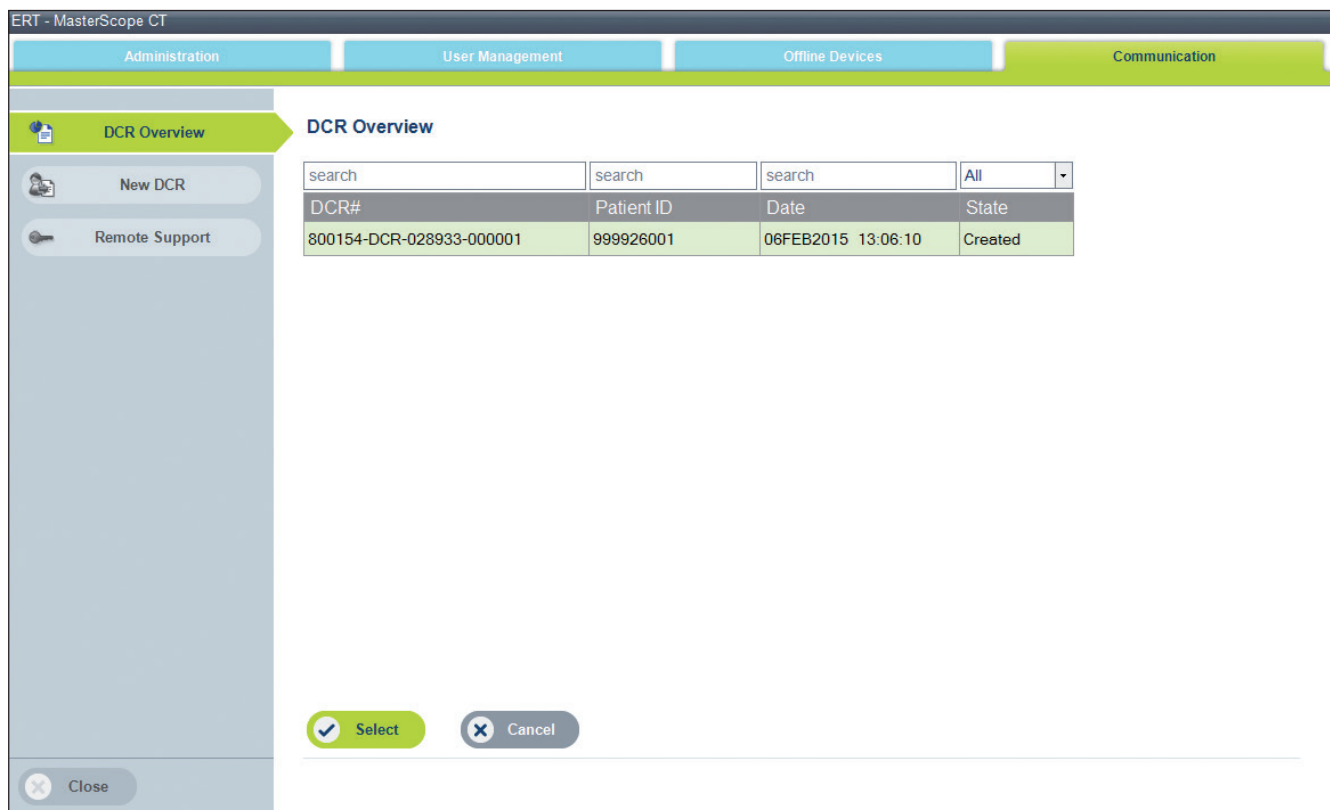
16.2 DCR Overview

Refer to the following steps:

1. Click on **<New DCR>** in the menu bar on the right-hand side of the screen.
2. Select the **<Communication>** tab.



3. Click **<DCR Overview>** to get an overview of the created DCRs. The following screen will appear:



- Select the appropriate DCR and confirm with **<Select>**.

The selected DCR will be displayed in detail:

ERT - MasterScope CT

Administration User Management Offline Devices Communication

DCR Overview

New DCR

Remote Support

DCR Detail

800286-DCR-998811-000001

Recipient:

Sender:

Date / Time: 04JAN2015 23:25:31 State: Created

Content

eRT Clinical Services
Data Correction Form

ERT
Getting It Done. Right.
Protocol SIMULATION STUDY 01

To: eRT Clinical Services (Fax: +49 931 3296 200)

From: inv inv

DCR#: <800286-DCR-998811-000001>

Close Print

Close



Click <**Close**> to exit the screen.

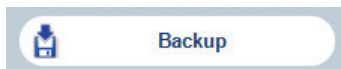
17. Troubleshooting

Resolving problems will be much easier if you follow these guidelines:

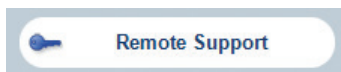
- Immediately stop when you recognize a problem exists. Further action may result in incorrect data, data loss or damage.
- Print a copy of the screen **<End Prnt Scrn>**.

The troubleshooting tools should be used only by instructed staff. The investigator should use these tools only if requested by the CRA or the ERT Customer Care.

The following options are available:



Saves all data to a backup medium (A or B).



Enables ERT support personnel to remotely access your system.

17.1 Fingerprint Sensor

There is no red light in the sensor window but my computer is working.

- Check the cable connections and make sure that the fingerprint sensor is connected properly to the notebook computer via the USB port.
- Restart the computer.

In case the problem persists, contact the ERT Customer Care or the CRA.

The sensor is not reading my fingerprint.

- Make sure your finger is not wet.
- Always press your finger flat on the sensor.
- There is no need to “roll” your finger on the fingerprint device.
- Wait until the software responds before lifting your finger.
- Don’t press your finger very hard on the system.
- Very dry fingers may cause problems.
- Clean the finger print sensor using adhesive tape.

In case the problem persists, contact the ERT Customer Care or the CRA.

17.2 Backup Medium

The back-up produces an error message referring to an invalid medium.

- Replace the medium.

In case the problem persists, contact the ERT Customer Care or the CRA.

17.3 Notebook

The computer does not start.

- The battery may be discharged completely.
- Check the connection to AC power. Make sure that the cord is firmly connected to the computer and a power outlet.

In case the problem persists, contact the ERT Customer Care or the CRA.

I have forgotten my start-up password.

- Contact the ERT Customer Care or the CRA.

My computer is switched on, but the MasterScope software will not start.

- Contact the ERT Customer Care or the CRA.

My mouse is not working.

- Check the mouse connection.
- You may have connected the mouse after you turned the computer on. Turn OFF the computer, make sure the mouse is firmly connected and turn the computer ON.

In case the problem persists, contact the ERT Customer Care or the CRA.

17.4 Equipment Bag

There is no need for troubleshooting the equipment inside the bag. If you suspect that the equipment in the bag is the cause of the problem, please call the ERT Customer Care.

17.5 Printer

Print cartridge light is flashing (one or both)

- The top cover of the printer may be open. Close the top cover.
- Verify that the proper print cartridges are installed.

Power light is flashing

- When the power light is flashing, the printer is preparing to print.

Power light and Resume light are flashing

- Printer may have a paper jam. Remove paper from the tray. Open the lid and remove any pieces of paper that may be stuck in the printer.

Power light is on and Resume light is flashing

- Printer is out of paper. Refill the paper tray, and then press the Resume button.

All lights are flashing

- Printer needs to be restarted by ...
 - ... pressing the Power button to turn off the printer, and then press the Power button to turn it back on.
 - ... Disconnect the printer from the power source by unplugging it. Reconnect the printer to the power source. Press the Power button to turn it on.

18. Hygiene Wireless Spirometry Sensor Unit

In the course of lung function testing, certain parts of the equipment can be contaminated by germs, which creates the risk that these germs can be transferred to the next test subject. For cross-contamination to occur, the test subject would need to be in direct contact with the contaminated object or transport media such as droplets or aerosols. Contaminated aerosols may be transported through the respiratory flow and may affect the next test subject.



Always be sure to disconnect the devices/systems from the mains power before cleaning or disinfecting.

The possible risk of infection can only be avoided if all of the contaminated parts are thoroughly disinfected!

18.1 Hygiene Regulations

In case of normal contamination all single-use items can be disposed of with the regular waste. In case of dangerous infectious diseases (e.g. tuberculosis, blood...) single-use items must be disposed of through hazardous waste.

18.2 How often should Contaminated Parts be Exchanged?



Single-Use ERT PT with mouthpiece

- Dispose after every patient



Nose clip

- dispose nose clip pads after every subject



ERT PT and mouthpiece are parts for single use only. These parts must be disposed after each single use. If reused, infection may occur.

Reprocessing may deteriorate the part, resulting in reduced stability and leakage through micro cracks or releasing micro particles that could be inhaled. Should any of these parts be recycled and misused intentionally, ERT takes no responsibility nor can be made liable for the consequences arising from reusing these parts.

Wiping
disinfection



DANGER

18.3 Surface Cleaning and Disinfection

The surface disinfection of the wireless spirometry sensor unit and charging station must be performed on a regular basis.

If there has been direct contact with the skin or if the case history/diagnosis of the patient requires it, a surface disinfection has to be performed directly after the application.

If the patient's history shows a dangerous infectious disease (e.g. tuberculosis), all parts which had been in direct or indirect contact with the patients must be disinfected.

Do not clean or disinfect the charging station or the wireless spirometry sensor unit while the devices are in operation.

18.4 Precleaning and Disinfection

A thorough pretreatment/cleaning is a precondition for an efficient disinfection of contaminated parts. Protein residue on these parts might prevent an effective disinfection.

ERT recommends the following disinfectants:

Product	Manufacturer	Concentration/ Reaction time
mikrozid® sensitive wipes	Schuelke & Mayr GmbH	1 minute
CaviWipes	Metrex	1 minute

Procedure:

Use the first cleaning wipe to cover all surfaces with detergent. Repeat the procedure with a second wipe for disinfection. Let the surface dry.



Avoid fluid (eg. detergent) getting in contact with the connector inside of the guiding tube of the sensor unit.

Protein residue on parts which are to be disinfected prevents effective disinfection. Therefore all protein residue must be removed prior to disinfection. In case of persistent residues please use an appropriate tool (e.g. soft brush) to remove the residues.

Please observe the instructions with regard to concentration and reaction time!

If a different substance is used, please follow the manufacturer's instructions.

The use of detergents and disinfectants which have not been recommended by the manufacturer might damage the products.



The manufacturer's information on the cleaning of accessories provided separately must be observed!

With suspected tuberculosis or other resistant germs, the use of an appropriate disinfectant (CaviWipes, Reaction time >3 minutes) is required.

Avoid contaminated fluids (e.g. blood) to get into the wireless spirometry sensor unit. In case of ingress of contaminated fluids, do not use the wireless spirometry sensor unit anymore.

18.5 Disposal of Single Use Items/Damaged Reusable Items

Take precautions to avoid contaminating yourself (e.g. use gloves). All single patient use items can be disposed of as domestic waste if there is a normal degree of contamination. In case of dangerous infectious diseases (e.g. tuberculosis) it is necessary to dispose of the single patient use items in special designated containers.

In addition, please note country-specific disposal regulations.



Biocompatibility

Component	Material
Mouthpiece	Styrolution PS 454N HIPS
Housing parts of the wireless spirometry sensor unit and the charging station	Cycology CX2244ME
PT-tube	Styrolution PS 454N HIPS



19. General Safety Precautions



The Instructions for Use is regarded to be a part of the instrument, and should always be kept on hand.

The Instructions for Use describes the present state of the device/system, including software and accessories, with regard to the fundamental requirements of the MDD 93/42/EEC.

Exact adherence to the instructions issued is a prerequisite for perfect and intended functioning of **ERT** instruments.



Deviation from Intended Use

Any non-observance of the procedures (such as preparation for the measurement and methods, disinfection procedures, use of accessories and replacement parts etc.) described in the Instructions for Use results in a deviation from intended use. In case of a deviation from intended use, the operator/user has to supply proof of meeting all corresponding fundamental requirements.

The operator/user is, however, responsible for performing the conformity assessment correctly and is also completely liable for defective products - i.e. the operator/user is liable for his/her modification of the medical product.

ERT only guarantees for the safety, reliability and function of the instrument if

- installation, extension, modifications, and repairs are exclusively carried out by personnel authorized for these tasks by **ERT**.
- the room in which the equipment is operated complies with the country-specific installation standard.
- the unit can be plugged into a socket with protective conductor system.
- the ambient conditions at the place of installation are suitable for the unit.
- the unit is used according to the training and Instructions for Use.

Unpack your medical device. Please check if the unit is damaged. If so, do not use it and return it for a replacement.



Report of Incidents

If you recognize or experience any serious incident that has occurred in relation to the device, you should report this to the manufacturer and the competent authority of your country.

Subject Safety according to EN 60601-1

This medical device safely insulates the subject from the mains power supply as required in the safety regulations on leakage current according to EN 60601-1, **Type BF**. Nevertheless, a subject environment must be defined. That means the subject has to keep a distance of at least 1.5 m from all open interfaces, connectors and the notebook to avoid any contact with electrical voltage.

The physician/operator must not touch any voltage-carrying parts and the subject at the same time.

 **CAUTION****Valid for all ERT devices:**

The connection of further power-operated units to your **ERT** unit may cause all the leakage currents to add-up and the safety of the subject is reduced. Due to this, the connection of further units may only be carried out on consultation with the **ERT** Customer Care.

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective EN standards (e.g. EN 60950 for data processing equipment and EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard. Everybody 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. If in doubt, consult the technical service department or your local representative.

 CAUTION**Use of Multi-Plug Sockets**

Due to increased safety requirements, medical devices/systems must only be connected to multi-plug sockets if all regulatory requirements are met.

- Additional mobile multi-plug sockets must not be connected to power sockets of medical devices/systems.
- Mobile multi-plug sockets of medical devices/systems must not be placed on the floor.
- Equipment (for example vacuum cleaner, radio, etc.) and devices which are not part of the medical device/system must not be connected to the multi-plug sockets.

 WARNING**Entanglement or strangulation by cables**

Take care in arranging subject and cables to avoid risk of subject entanglement or strangulation.

 WARNING**Radiated Interference**

The ERT device meets the regulations according to EN 60601-1-2 regarding the interference radiated and received. It is recommended not performing a measurement with the device directly next to other equipment or in combination with other devices in a stacked form, as this may result in faulty operation. The device should not be installed in the vicinity of high-frequency devices, X-ray equipment, motors or transformers with high installed power rating since electric or magnetic interference fields may falsify the result of measurements or make taking measurements impossible. Due to this, the vicinity of power lines is to be avoided as well. Existing environmental interferences may cause deviations of the measurement values without impairing the device's function. Therefore, it is recommended to keep a distance of about 2 meters from possible error sources when using the device.

More detailed information can be found in the EMC tables of the instruction manual of your device/system.

Devices connected to the MasterScope can also cause radiated interference. Therefore the regulatory and safety related notes of the respective device manufacturer must be followed.

 WARNING

Using other accessories, other transformers and other cables than those specified or provided by the device's manufacturer can result in increased electromagnetic radiation or reduced electromagnetic immunity of the device and can lead to an incorrect operation.

 **WARNING**

Portable RF communication equipment (transmitters) (including their accessories, such as antenna cables and external antennas) should be operated with a minimum distance of 30 cm (21 inch) to the MasterScope's components and cables specified by the manufacturer. Non-observance may lead to a reduction of the device's performance.

 DANGER**Ambient Conditions**

The medical device must not be operated in rooms or in the presence of flammable anaesthetic mixture with air or flammable anaesthetic mixture with oxygen or nitrous oxide. The medical device must be operated in rooms where only non-conductive pollution occurs; however, occasional temporary conductivity due to condensation is to be expected. The medical device is designed for operation in medically used rooms.

The medical device has to be effectively protected against moisture. Ventilation slots must be kept free of obstructions in order to enable air circulation.

 CAUTION**Interfaces**

Only optional devices or external devices approved by ERT are allowed to be connected to the interfaces.

The physician/operator must not touch any voltage-carrying parts and the subject at the same time.

 WARNING

Only connect the ethernet cable (RJ-45) of the device to the network connection. Only connect the modem of the device to an analog telephone network (max. 60V).

 CAUTION**Putting the Unit into Operation**

Always consult the nameplate on the device/system for compliance of the unit's own data with those of the local power supply system (mains voltage and mains frequency) before actually connecting the unit.

Connect only if all data comply!

Inspect the mains connection cable, plug, and receptacle for visible damages prior to establishing the connection. Damaged cables or plugs must be replaced immediately. Installation and assembly of the device must be done only in compliance with this Instructions for Use.

After the first setup or if the setup has been changed (e.g. exchanging of the pneumotach), a function test (e.g. calibration) has to be performed.

To separate the device from power supply, disconnect the plug from electricity grid. The device contains no unit to separate it from the power supply.

It must be ensured that no risk of stumbling/tripping is caused by cables connected to the device.

 WARNING

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

 CAUTION**Medical Supervision**

A qualified physician must reassess all measurements. An interpretation by the medical device is significant only when considered together with other clinical findings. During the measurement the subject must not be unattended. The performance of the spirometer can be affected by the subject spitting or coughing into the spirometer during expiration or by extremes of temperature, humidity and altitude.

 **WARNING****Contraindications and possible adverse effects:**

According to "ATS/ERS TASK FORCE: STANDARDISATION OF LUNG FUNCTION TESTING" (ERS Journals Ltd 2005) performing lung function tests can be physically demanding for a minority of subjects. It is recommended that subjects should not be tested within 1 month of a myocardial infarction.

In the S2 guideline "Spirometry" (German Airway League, German Respiratory Society and German Society of Occupational and Environmental Medicine, 2015), contraindications of spirometry are divided into absolute and relative contraindications:

Absolute contraindications for Forced Maneuvers

Acute, life threatening diseases of every description, e.g.

- Acute Myocardial Infarction
- Acute Fulminant Pulmonary Embolism
- Large Ascending Aortic Aneurysm
- Tension Pneumothorax

Relative contraindications for Forced Maneuvers

- Massive Pneumothorax (within the first weeks)
- Abdominal or Thoracic Surgery (depending on the findings 1 to 4 weeks post-operatively)
- Surgery of the Eyes, Brain, or Ears (variable, consultation with the surgeon)
- Special care must be taken when dealing with Hemoptysis of unknown origin

 WARNING**Cleaning and Hygiene**

Prior to every application, all parts which come in contact with the subject and which are intended for reuse must be cleaned or disinfected (unless otherwise instructed).

Prior to taking measurements on a subject, his/her medical history is to be checked in order to avoid a contamination of the device and a resulting cross-contamination of the next subject.

While performing a calibration check, a new disposable Pneumotach must be used to prevent cross-contamination between the calibration syringe and the parts. This will prevent contamination of the syringe and allow for its reuse.

Always be sure to disconnect the devices/systems from the mains power before cleaning or disinfecting. The Charging Station corresponds to protection class IP21, the Wireless Spirometry Sensor Unit to class IP20.

The device may not be soaked in liquid of any kind. Liquid inside the device/system may lead to harm of the user and can destroy the device. The device can be cleaned with a damp (but not soaked) cloth, which does not produce lint.

More detailed information can be found under "**Hygiene**" in this Instructions for Use. Chemicals required for operation or care of the unit must always be stored, prepared, and made available in specially marked vessels to prevent any accidental use.

 **WARNING****Maintenance**

No part of the medical device may be replaced by the customer.

Use only **ERT** approved accessories and spare parts for this medical device.

If applied parts (e.g. handle/Sensor Unit) have been exposed to extreme mechanical stress, a function test (e.g. calibration check) has to be performed. If function is lost, the defective part is to be replaced. Damaged parts, e.g. frayed plugs, receptacles, pressure regulators, a damaged handle, and defective cables should be replaced immediately by an authorized specialist or engineers of the **ERT** Customer Care. The device must not be opened. If it is opened without authorization the guarantee entitlement expires. The **ERT** Customer Care is always at your disposal with help and assistance in case of problems.

Before turning on the device/system you should always check whether power cable, power plug, outlet and power input of the device as well as modem cable are free from defects.

Additional preventive inspection/maintenance except the daily visual check before turning on the device/ system is not required. The **ERT PT** is precalibrated by the manufacturer and therefore it is not required to perform a volume calibration before starting a spirometry measurement. Further safety-related checks are not necessary to be performed within the product life-cycle of 7 years if the following is assured:

- the unit has not been mechanically stressed in the extreme (e.g. the cable is made defective by running over it with a heavy object or dragging it)
- no liquid got inside the unit
- the handle and its cable are not damaged/the Sensor Unit is not damaged
- cables and/or multiple connectors are not defective
- coverings are not broken
- rubber connectors don't show cracks

If there are any technical problems or doubts regarding the reliability of the product contact ERT Customer Care. Additional national regulations have to be considered where appropriate.

 WARNING

Children should not get into contact with disposables, accessories and packing material and cleaning and disinfection substances.

Recurrent Test

Medical Electrical equipment needs a recurrent testing and testing after repair of the equipment according to EN 62353.

The calibration syringe itself has to be calibrated at regular intervals as determined by the manufacturer and as indicated on the syringe. The calibration syringe must be checked for an accuracy of ± 12 mL.

 CAUTION**Recycling**

Adhere to the national law of the country when disposing the medical device and its accessories.

Improper disposal of the device and/or its accessories can result in serious environmental hazards.

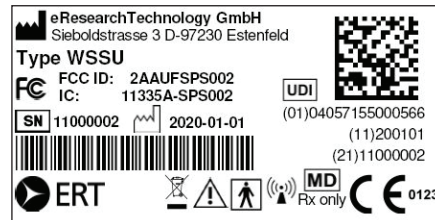


19.1 Graphical Symbols



The typeplate on the Wireless Spirometry Sensor Unit is positioned at the left side.

The typeplate of the Charging Station can be found at the bottom side.



Alternating current



Direct current



Stand by



Note Instructions for Use



Caution! Consult accompanying documents.



Attention! See Instruction for Use



Date of manufacture



Manufacturer



Single Use only



Handling of spirometer handle



Type BF applied part



Use by date



Pile limitation by the number of pieces



Separate collection for waste of electrical and electronic equipment

IP20

Protection against intrusion of solid objects with a diameter $\geq 12,5\text{mm}$;
no protection against liquid intrusion

IP21

Protection against intrusion of solids $\geq 12,5\text{mm}$ diameter;
protection against dripping water

SN

Serial Number

REF

Catalogue Number

LOT

Batch code



Fragile, handle with care



Keep dry



Temperature limitation



Up



Manufacturer logo



CE mark with code number of the Notified Body.

The certified quality management system of **eResearchTechnology GmbH** corresponds to the international standard of ISO 13485.

CAUTION:

Rx only

FEDERAL U.S. LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.



FCC (Federal Communications Commission)



Non-ionizing radiation

IC

IC ID (Industry Canada)



UDI (Unique Device Identifier)



Medical Device

19.2 Safety Precautions for Lithium Ion Rechargeable Batteries

The Wireless Spirometry Sensor Unit is powered by an internal Lithium-Ion Polymer battery.

The following safety precautions are valid for Lithium-Ion batteries:

- Dispose of Lithium-Ion batteries according to local regulations.
- Do not shortcut the battery.
- Protect the battery against excessive heat!
- Protect the battery against direct sun light!
- Protect the battery against fire!
- Do not dismantle or manipulate the battery.
- Do not replace the battery. Improper replacement can lead to fire, excessive heat or explosion.
- The fluid in the battery is toxic and flammable - leaky batteries or batteries with dents must not be used any longer!
- Do not come in contact with the fluid in the battery. If the fluid comes in contact with your skin, immediately rinse the affected part with water and contact a doctor!
- To charge the Wireless Spirometry Sensor Unit, use only the Wireless Spirometry Charging Station and observe the instructions in the manual!
- For the Charging Station use only the provided power supply.

**USA**

"This device complies with Part 15 of the FCC Rules. Operation is subjected to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including that may cause undesired operation."

Wireless Spirometry Sensor Unit: FCC ID: 2AAUFSPS002

Wireless Spirometry Charging Station: FCC ID: 2AAUFWSCS01

Canada

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Wireless Spirometry Sensor Unit: IC: 11335A-SPS002

Bluetooth:

Frequency Band	Transmission Frequency Range	Maximum Output Power
2400 MHz (BT)	2402 to 2480 MHz	12 dBm

Wireless Charging:

Frequency Band	Transmission Frequency Range	Maximum Output Power
Qi (wireless charger)	112 to 205 kHz	37 dBm



The safety precautions and operational procedures indicated in this chapter refer to Germany. Different regulations and standards may apply to other countries.



Notes on EMC according to EN60601-1-2

The use of accessories not recommended by ERT may result in an increased electromagnetic radiation or a reduced interference immunity of the MasterScope.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions and Immunity

The MasterScope and its components use RF energy for internal function. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment. The MasterScope and its components are suitable for use in all establishments excluding domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

IEC 60601 directive	Compliance level
RF emissions CISPR 11	Group 1 Class B
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV indirect contact ± 15 kV direct air ± 8 kV direct contact
Radiated RF IEC 61000-4-3	3 V/m @ 80 MHz to 2700 MHz 9 V/m to 28 V/m @ 385 MHz to 5785 MHz applied to 4 device orientations each with vertical and horizontal antenna polarization
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode
Conducted RF IEC 61000-4-6	3 V(rms) from 150 kHz to 80 MHz 6 V(rms) in ISM bands
Magnetic field IEC 61000-4-8	30 A/m applied to all 3 axes
Voltage dips IEC 61000-4-11	tested at 100 and 240 V power supply input lines none @ 0.5 cycles and 45 degree sync angle steps none @ 1 cycle < 70% @ 25 cycles and 50 Hz < 70% @ 30 cycles and 60 Hz
Voltage interruptions IEC 61000-4-11	tested at 100 and 240 V power supply input lines none @ 250 cycles and 50 Hz none @ 300 cycles and 60 Hz

Return of Goods in Medical Institutions

Recommendations for action -

for all staff members having contact with potentially contaminated returns.

Returns or returned goods are all products returned to the producer or the supplier, irrespective of whether or not they have been used, e.g. due to complaints, repair or maintenance. Those products might have had contact with biological substances or highly active pharmaceuticals (e.g. cytostatics, radioactive medicines) and could be contaminated by them. If in doubt, the goods to be returned should be treated as contaminated products.



Due to infectious agents, pathogens or pharmaceuticals, contaminated goods pose a potential hygienic risk for all persons having contact with the returns.

This leaflet provides guidance on minimizing the potential hygienic risk when handling returned goods. Among other things, this information is based on the legal standards of the Biostoff-Verordnung (= Biological Substances Regulation) and the Employment Protection Act (both valid in Germany). A more detailed reference list of applicable rules and regulations can be obtained from the BVMed (info@bvmed.de).

In order to protect your and our employees who handle contaminated parts and to optimally examine such parts, you should consider the following:

1. Assessment of returns before reshipment

Irrespective of whether or not a contamination risk is known, products which had direct or indirect contact with biological working substances (e.g. blood, secretions or other body fluids) or with highly active pharmaceuticals (e.g. gloves of the clinical or surgical staff) should be regarded as potentially dangerous to health.

According to the regulation on biological substances, substances of risk group 3 can cause severe illness in humans and pose a serious risk to staff members (e.g. tuberculosis or hepatitis). Substances of risk group 4 cause severe illness in humans and pose a serious risk to staff members (e.g. Ebola or smallpox).

Regarding national and international regulations for the transport of potentially infectious substances (ADR, IATA-DGR), the **risk groups 2** (e.g. staphylococcus aureus) **and 3** defined by the Biological Substances Regulation are classified as **Transport Category B**.



Products which are potentially contaminated by biological working substances of risk group 4 according to the regulation on biological substances as well as products which are potentially contaminated by pharmaceuticals posing a serious risk to health (e.g. X-ray contrast agents and cytostatics) must not be returned to the producer.

The following applies to products that are potentially contaminated by biological working substances of risk group 3 and 2 according to the regulation on biological substances and that are thus classified as Transport Category B:

Please contact ERT **before** returning the goods and observe the regulations for the transport of dangerous goods.

2. Cleaning

If the products had contact with biological working substances (for example blood or other body fluids), they have to be cleaned and disinfected in a combined cleaning and disinfection procedure, unless a differing agreement has been made with ERT.

As a rule, the products also have to be cleaned in order to minimize adhesions and bacterial contamination. Unless body fluids, tissue or contrast agents etc. have caused the product to be defective, deposits and adhesions should be removed carefully without damaging or altering the product, if possible. For this, refer to the notes on the preparation of products.

Products which have been contaminated by highly active pharmaceuticals have to be cleaned appropriately with tap water.



If in doubt, contact ERT for guidance on further actions!

3. Disinfection/Sterilization

After cleaning, the products have to be disinfected and/or sterilized (only if permitted for this medical product) in order to avoid harm to your and our employees.

If in doubt or in case of suspected material incompatibility, please consult ERT.

4. Packaging

To avoid any contamination, the cleaned and disinfected product has to be packed as follows:

a) Put it into a sealable primary packing.



Parts with sharp edges need to be packed particularly safe.

b) Put the primary packing in a waterproof secondary packing (if possible use hard packing material).

c) Pack the secondary packing with a neutral packing material.

For “**Packaging and labeling of non-contaminated products**”: see point 6.

5. Labeling

If a concrete risk of infection (e.g. HIV, Hepatitis B or C) is known to be present, this risk has to be noted on the packing of the returned goods and/or in the accompanying documents.

For **“Packaging and labeling of non-contaminated products”**: see point 6.

6. Packaging and labeling of non-contaminated products

If the procedures described under point 2 and 3 are not applied, the contaminated product has to be returned in a combined packing complying with the packaging instruction P 650 ADR after contacting ERT, if necessary. Proceed as follows:



- a) Put the product into a liquid-tight, sealable packing (e.g. tearproof plastic bag) (primary packing)
- b) Put the primary packing into a (if possible, liquid-tight) protective packing (secondary packing); for liquid materials insert an adequate amount of absorbing material between the primary and the secondary packing.
- c) Pack the secondary packing with an additional outer packaging (padded envelope or cardboard box).
- d) Label the outer packaging with the corresponding UN no. 3373 for diagnostic or clinical samples and add the note:



“Biologischer Stoff, Kategorie B/Biological Substance, Category B”

7. Dispatch

Please note that non-decontaminated returns with suspected pathogens of risk group 3 are excluded from mailing. Diagnostic or clinical samples of UN no. 3373 which have been packed according to packing instruction P 650 are not subject to any further regulations on the transportation of dangerous goods and may be transported by a forwarding agent or a parcel service.

For this purpose use the accompanying shipping documents of the forwarding agent/carrier containing the corresponding valid transportation regulations, e.g. GGVSE (Road and Railway Dangerous Goods Regulation).

The product is then dispatched to the address indicated by the manufacturer.

Address:

eResearchTechnology GmbH

Sieboldstrasse 3

97230 Estenfeld, Germany

Tel: +49 9305 720-9891

www.ert.com

Certificate of Hygiene

This certificate must be attached to ANY product complaint, ANY return of medical products and accessories, ANY repair order and ANY return of studies.

Name of product: _____

REF (ERT item no.): _____

LOT (batch no.): _____

It is herewith confirmed by signature that (please mark appropriate box):

- ☐ the enclosed medical product had **no** contact with blood or other body fluids so that it is **hygienically safe**.
- ☐ the enclosed medical product had contact with blood or other body fluids during its use. The product has been cleaned and decontaminated as follows:
 - ☐ Disinfection by wiping all accessible surfaces with
 - Disinfectant: _____
 - Concentration: _____
 - Reaction time: _____
 - ☐ Other procedure (please indicate): _____
 - ☐ Steam sterilization (3 minutes at 134 °C or 15 minutes at 121 °C)
 - ☐ the enclosed medical product could **not** be decontaminated.

Reason:

Send returns to the following address:

eResearchTechnology GmbH
Abteilung Wareneingang
Sieboldstrasse 3
97230 Estenfeld
Germany

Sender's signature and address:

Technical Data Calibration Syringe

Calibration Syringe:	Volume: Accuracy:	3 L +/- 12 mL
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Technical Data Wireless Spirometer Sensor Unit & Charging Station

Measuring Range:	PEF: FEV1 and FVC:	0.1 to 16 L/s 0.1 to 8 L
Resolution:	PEF: FEV1 and FVC:	< 5 mL/s 1 mL
Accuracy:	PEF: FEV1 and FVC:	0.1 to 16 L/s: ± 10% of reading or ± 0.3 L/s 0.1 to 8 L: ± 3% of reading or ± 0.050 L
Resistance Spirometer:	max. 135 Pa/L/s at 14 L/s	
Instantaneous Flow:	0.1 – 14 L/s: +/- 5% or 0.2 L/s	
Applied Part:	ERT PT, WSSU	
Dimensions:	Wireless Spirometry Sensor Unit Charging Station	11 x 8 x 4 cm (L x W x H) 19 x 13 x 7 cm (L x W x H)
Weight:	Wireless Spirometry Sensor Unit Charging Station	0.15 kg 0.27 kg
Medical Power Supply:	Model: Input: Output: Cable length:	GTM41134-0606-1.0 100 - 240V 50-60 Hz 0.6 A 5V 1.2A, 6W 1.5 m
Battery:	Wireless Spirometry Sensor Unit	Built in rechargeable Lithium Ion battery 3.7 V, 640 mAh. Battery will last under standard operating conditions for about 3 days in standby mode and 2.5 h for constant measurements. Full charging: 2h Cycle life: 70% of rated capacity after 500 charging cycles
Protection Class:	Charging Station Wireless Spirometry Sensor Unit	n/a Internally powered
Mode of Operation:	Continuous	
Moisture Protection:	Power Supply Charging Station Wireless Spirometry Sensor Unit	IP21 IP20
Measuring Principle:	High Quality Pneumotach	
Operating Ambient:	Temperature: Relative Humidity: Barometric Pressure:	+10° C to +35° C 15% to 90% 700 to 1070 hPa
Transport/Storage:	Temperature: Relative Humidity: Barometric Pressure:	- 20° C to +50° C 15% to 90% 600 to 1200 hPa

Technical Data Ruuvitag Ambient Sensor

Ruuvitag (<https://ruuvi.com>) is an open-source sensor platform that can measure temperature, relative air humidity, airpressure and acceleration.

Bluetooth:	BLE 4.2 factory firmware default protocol	
Embedded NFC™-A tag coil		
Battery:	1000 mAh CR2477 Li/MnO2 battery included (up to 3 years battery life)	
Transport/Storage:	Temperature:	-40 to +85 °C
	Relative Humidity:	0% to 95% RH
	Barometric Pressure:	300 to 1100 hPa
Operating Range:	Temperature:	-20 to +65 °C
	Relative humidity:	0% to 95% RH (non-condensing)
	Barometric pressure:	300 to 1100 hPa
Typical Absolute Accuracy:	Temperature:	±0.5 °C @ 25 °C (±1.25 °C @ full operating range)
	Relative humidity:	±3 % @ 20 to 80 % RH and 25 °C
	Barometric pressure:	±1hPa @ full operation range
3-axis Accelerometer:	3-axis, ±2 g / ±4 g / ±8 g / ±16 g, 1 to 5300 Hz	
	Freefall and motion detection	
Dimensions:	Diameter:	52 mm (enclosure)
	Height:	12.5 mm (enclosure)
	Weight:	25 g (battery included)
Weatherproof:	IP67 certified enclosure	



Sensor accuracy information is based on sensor manufacturers' datasheets and information received from the sensor manufacturers. It's not always guaranteed that typical or absolute sensor accuracies will be met in user applications. The sensor manufacturers state that majority of the sensors do fall between the typical values informed on the datasheets. However, some sensor components delivered from the sensor manufacturers' facilities may still have up to three times worse accuracy. Sensors are factory-calibrated before assembled. Sensors are 100% tested but not individually calibrated at Ruuvi's production line. Operating temperature may have an effect to the battery life. Estimates are at room temperature (25 °C). Ruuvitag is designed for non-condensing use only.

System Requirements

Operating System:	Windows 10 or higher
Software is pre-installed on laptop included in the MasterScope package.	
Connectivity:	LAN or WiFi
Security Protection:	Windows Defender (Antivirus) Windows Firewall
Unauthorized Access Protection:	Closed System User registration required Password/Fingerprint protected

Technical Data Laptop (Fujitsu E756)

Ambient Conditions:	Temperature: Relative humidity: Altitude:	+5 °C to +35 °C 20 % to 85 % 0 m to +3048 m
Transport/Storage:	Temperature: Relative humidity: Altitude:	-15 °C to +60 °C 8 % to 85 % 0 m to +3048 m
Protection Class:	Class I	
External Power Adapter Cable Length:	1.8 m AC/1.8 m DC	

Technical Data Accessories

Cable Length Equipment Bag:	3.0 m
USB Connection Cable:	between 1.0 m and 3.0 m
Modem Cable:	3.0 m
Mouse, Optical, with USB cable:	1.9 m
Fingerprint Sensor cable:	1.8 m
Printer (dependent on model):	Power supply cable between 0.5 m and 1.8 m (AC/DC)

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