ERT®
Innovating Better Health™

Instructions for Use

Peak Flow Meter AM3
Option G+

781195

Version 02.01
for Firmware ≥ 9.40

Table of Contents

This Instructions for Use is for the patient only. For all medical personal, please use the more detailed MasterScope IFU (article no. 782126).

If you have any questions or problems with your device please contact your responsible physician.

Indications for Use

The Asthma Monitor AM3/AM3 BT/AM3 GSM/G+ is an electronic measurement device to monitor the lung function (determination of the respiratory flows and volume) with high reproducibility wherever and whenever there is a need of. The AM3 measures the flow during expiration serving for the calculation of further parameters as FEV1.

The AM3 is used to monitor the respiratory status of adult human beings in the areas of asthma, chronic obstructive pulmonary disorder and in areas like occupational medicine, clinical trials and disease management.

The patient is informed of the results by numeric values for the selected parameters (e.g. PEF, FEV1). Furthermore, a visual control unit, displayed in the form of traffic lights, allows an immediate indication of the measurement based on criteria defined by the patient's physician.

The device saves the results of a measurement (always with date and time) automatically in an internal database. In addition, questionnaire functionality can be called up by the use of a software package (AMOS) to record e.g. the "Quality of Life" status. When enabled, the AM3 can be programmed with a couple of questions, where the patient can then select from a couple of different answers. This information is also stored in the internal database and can be transmitted for evaluation to a standard PC using the software package AMOS.

The AM3 is designed to replace an ordinary peak flow meter, diary and pencil by a single system. Easy handling, sturdy and handy design allow the Asthma Monitor AM3 to be used in healthcare, clinical and home use environments/settings.

⚠ CAUTION US FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN. (Rx only)

The application of this system is restricted to trained users who can guarantee for the correct usage of the device.

The AM3 is powered with a Lithium-ion battery. No energy is transferred to the users.

Notes on Safety in Instructions for Use

Following the **ANSI** recommendations (American National Standards Institute) for safety notes, specific passages of the instruction manual are clearly marked as safety notes.

Degree of Danger	Injury to Persons	Damage to Property	Use in case of:
DANGER	X		**DANGER** indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury. This signal word is to be limited to the most extreme situations.
WARNING	X		**WARNING** indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
CAUTION	X	(X)	**CAUTION** indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices.

Additional icons shown in the instruction manual:

			Important and useful information. Information does not warn of dangerous or harmful situations.
			Hints for use.

Declaration of Conformity

The original document of the Declaration of Conformity can be found in the Accompanying Documents.

1. The Peak Flow Meter AM3

The AM3 Equipment comprises of:

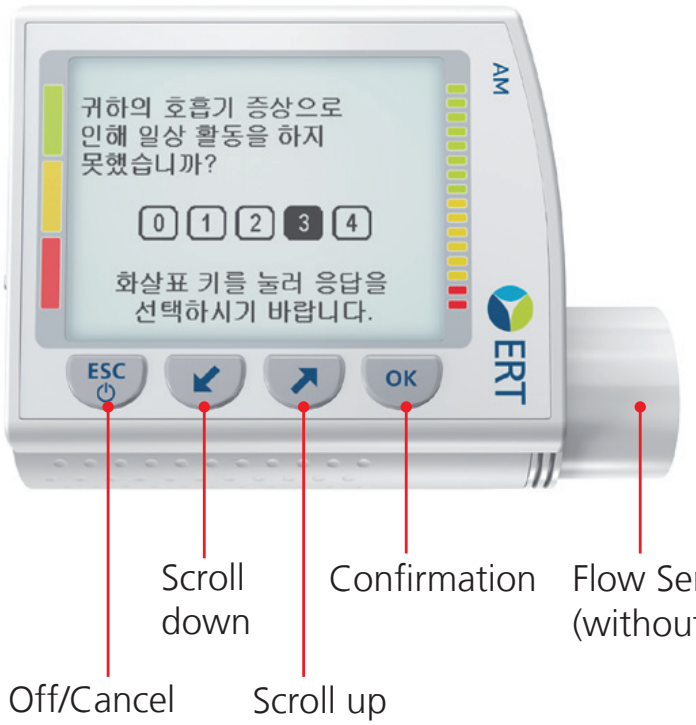
- AM3
- Power supply
- Bag

Before using the AM3 for the first time, the batteries must be charged for 30 minutes (see chapter "Power Management").

The AM3 is a medical device that combines a spirometer with a symptom diary. This device displays questions concerning asthma symptoms to be answered twice a day and measures and evaluates the Peak Flow (PEF = Peak Expiratory Flow [L/min] and/or FEV1 (FEV = Forced Expiratory Volume) as well as other expiratory parameters.

The device keeps a diary of measurements by automatically recording in its memory all answers and measurements with date and time.

Front view:



Bottom view:

Warning

The AM3 can assist in monitoring airway function on a day-to-day basis, but it is not supposed to provide an entire diagnosis of your state of health. The use of the AM3 will not replace a medical examination or other tests if you are not feeling well.

You should call your study doctor **immediately** if you show any symptoms of

- severe trouble breathing
- severe cough that will not stop
- trouble talking or walking
- severe chest tightness or wheezing
- over-inflated chest or ribs
- lips or fingernails which are bluish rather than pink

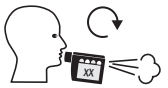
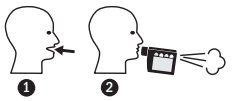
or if you

- require treatment with oral or parenteral glucocorticosteroids.
- have been admitted to hospital (including emergency room treatment).
- are concerned about your condition during the study.

Trouble-free operation of the AM3 is guaranteed for temperatures from +10° to +40°C (50° to +104°F).

It is recommended NOT to perform measurements in direct sunlight, as the sensor could be damaged.

1.1 Display symbols

Symbol	Explanation		
	Settings menu		Transfer stored data manually
			Display signal strength and provider
			Information
			Perform test transfer
			Activate/Deactivate Airplane mode
	Assessment		
	Repeat measurement		
	Optional measurement		
	Data transfer in progress		
	Data transfer successful		
	Data transfer failed		
	Memory capacity almost full (80%)		
	Memory capacity full		
	Battery low		

2. General Handling

2.1 Turning the Device ON

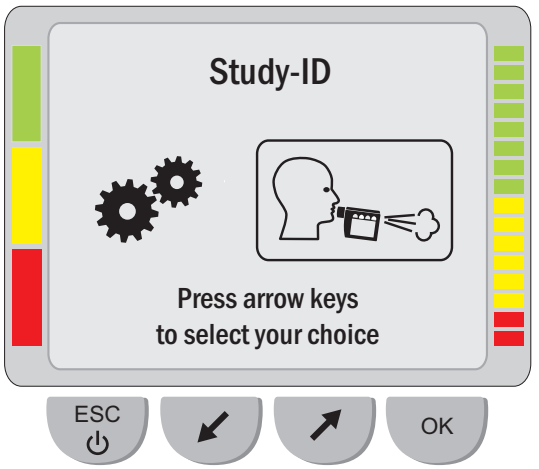
Press the ESC button and the OK button at the same time and hold both buttons for approximately 2 seconds. After releasing the buttons the device will switch on.

2.2 Turning the Device OFF

The device is turned OFF by pressing ESC.

3. Performing Assessments and Transferring Data

The AM3 has an integrated antenna to transfer the data via SMS. As in any mobile phone, a sufficient signal strength is needed to transfer data. If the signal strength is too weak, you should search for a place with sufficient signal strength. It is important that the device is not shielded by any objects (particularly metal) or thick walls (e.g. cellar).



After switching on the AM3, a start screen will appear. This screen will show the study-ID and contain two selectable options:

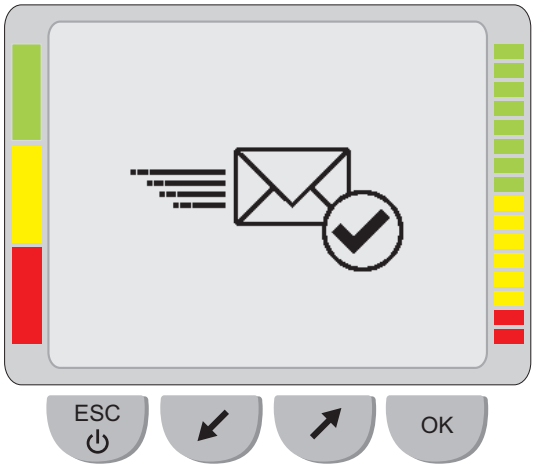

"Settings"

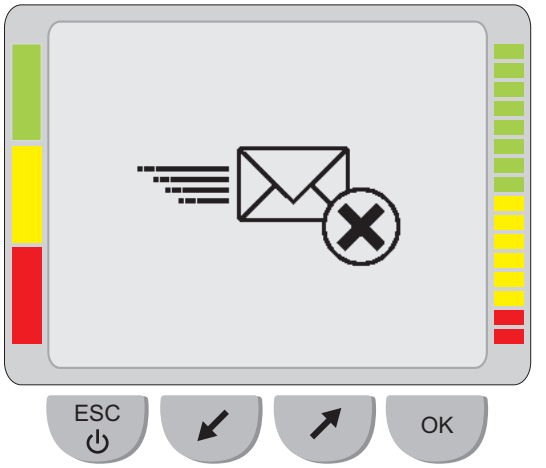

"Assessment".

By selecting the **"Assessment"** icon you will be asked to answer the first question of the questionnaire or to perform the PEF measurements. After finishing the assessment, the data transfer will start automatically.

This screen indicates that the data transfer is in progress. Please wait until the next screen appears.

Afterwards, the following screens will appear implying whether the data transfer has been successful or not:



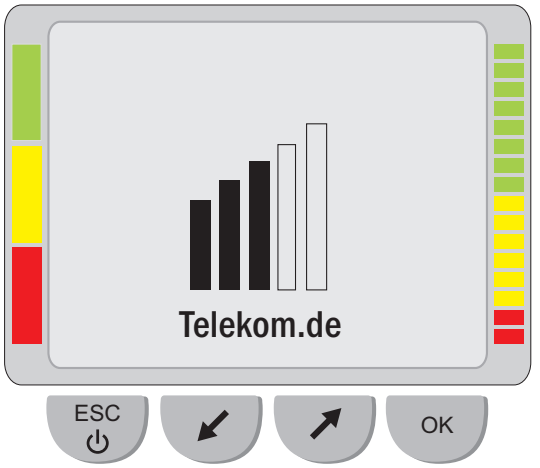


By selecting  on the start screen the following options will be available:

Manual data transfer:

If the automatic data transfer was not possible, you can transfer the stored data manually any time by selecting .

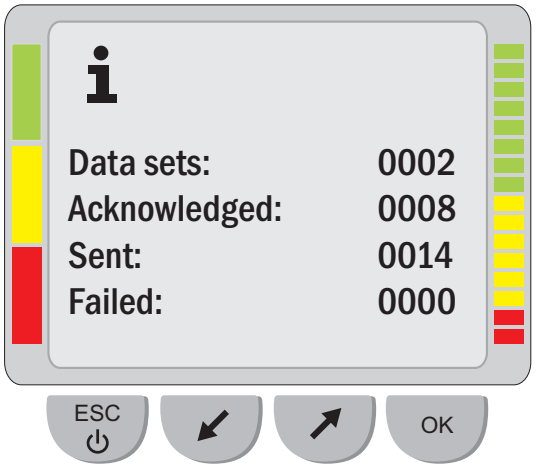
The device will establish a connection and start the data transfer of stored data which has not yet been transferred.



Signal and provider:

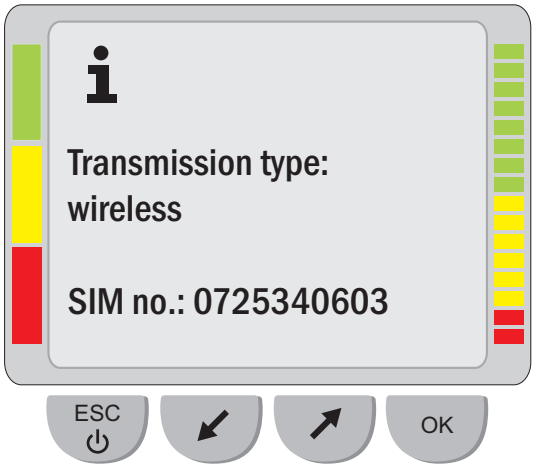
You can check the signal strength and the network provider by selecting .

The more black bars are visible, the better the signal strength. At least one bar is necessary to successfully transfer data.



Info:

Select to indicate the number of data sets which have been stored, acknowledged, sent and failed.



By confirming the first information screen with OK this screen will appear indicating the transmission type and SIM number.

Test transfer:

To test if the data transfer works correctly, a test transfer can be performed by selecting .

This test transfer can be performed independent of study time windows and will not contain any data.

Airplane mode:

When travelling by airplane, turn "Off" mobile communication (airplane mode active) to prevent possible interference with aircraft systems by selecting .

During activated Airplane mode the Bluetooth and the mobile communication function are disabled. As long as the airplane mode is active, a small airplane icon is displayed in the upper right corner of the start screen.

4. Lung Function Measurements with the AM3

4.1 Preparing for the Measurement

Prior to starting the measurement, place the flow sensor into the AM3 as shown below and remove the sealing cap from the flow sensor.

When inserting the flow sensor into the AM3, medical assistants must adhere to the general hygiene standards valid for hospitals and private practices.

If the flow sensor is inserted into the AM3, the notes on cleaning as described under the chapter "Cleaning" must be followed.

The flow sensor can be used multiple times but should only be used by the same person to prevent contamination.

4.2 How to Perform Measurements with the AM3

To perform a valid PEF measurement with the AM3, the following steps must be followed:

1. Inhale deeply and hold your breath until you have positioned the inlet of the flow sensor into your mouth.

Do not breathe in through the AM3.

2. Now you must exhale as hard as possible for **at least 2 seconds** to obtain a satisfactory measurement.

You should

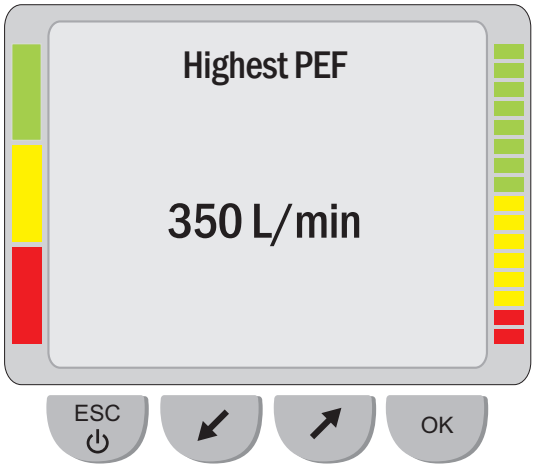
- pause for about a second and then blow out hard and fast as you can.
- not cough.
- not block the inlet of the flow sensor with your tongue.
- not block the outlet of the flow sensor with your hand.

If you do not follow these instructions, the correctness of the measurement values cannot be guaranteed.

3. After full exhalation, the AM should be removed from the mouth immediately.

4. The measured PEF is displayed on the AM3.

5. The result is confirmed by pressing OK.
   After the 1st measurement, you will be asked to perform the 2nd and the 3rd PEFs (repeat steps 1- 5).

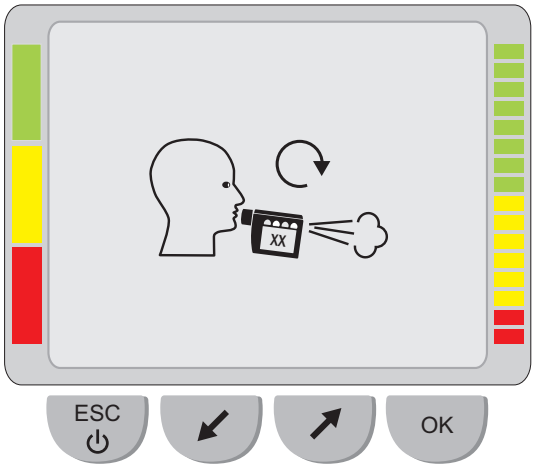


6. At the end of the session, the highest PEF will be displayed.

4.3 Validity of PEF Measurements

A PEF measurement performed with the AM3 is **valid**, if:

- Breathing volume > 0.47 L or < 10 L
- Breathing flow > 50 L/min
- FVC > FEV1



Otherwise a message will be displayed and you will be asked to repeat the measurement.

To store a result in the AM3, at least one adequate maneuver needs to be performed.

If all efforts are invalid, no measurement data will be stored on the device.

4.4 Performing Scheduled Sessions

Scheduled sessions, including questionnaire and PEF measurements, can only be performed and stored using programmed devices.

For completing your questionnaire, you can scroll through and select the appropriate answer by using ↗ and ↙ buttons and pressing OK.

At the end of the questionnaire you will be asked, if you want to change an answer; if you select “Yes“, the questionnaire will be displayed again. The answers previously entered will appear as default, and can be modified as described above.

4.5 Interrupting a Scheduled Session

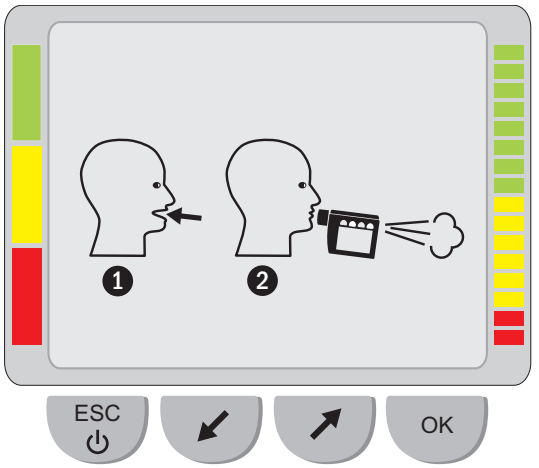
If the AM3 is turned OFF before finishing a questionnaire, all questions previously answered will not be saved.

If the AM3 is turned OFF after completing the questionnaire or between the PEF measurements, the session can be completed within the remaining time window. In this case, the AM3 has to be turned ON again and only the missing measurement may be performed - the questionnaire will not be displayed again.

4.6 Performing Unscheduled/Optional Measurements

In addition to scheduled measurements, you are able to perform unscheduled/ optional measurements. These are measurements that are:

- performed after having finished the scheduled measurements within the same time window
- performed outside of the study specific time windows



When performing an unscheduled/optional measurement, the screen on the left will be displayed after turning the device ON.

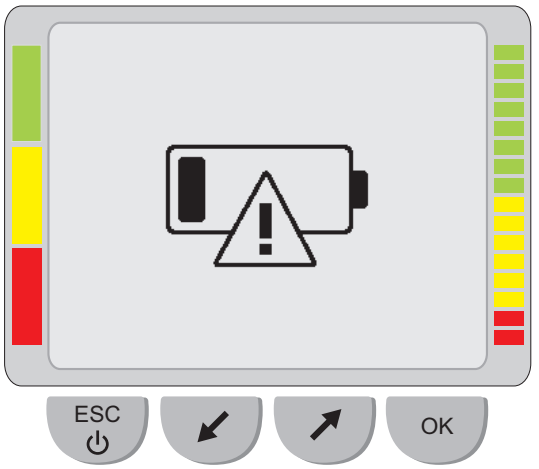
The data from unscheduled/optional measurements is for information only and will **NOT** be stored.

5. Power Management

The AM3 GSM/G+ has a Li-Ion polymer battery and a power supply to charge the battery.

Before using the AM3 for the first time, the battery must be charged for 30 minutes.

When the battery is low (at approx. 5%), the following message will be displayed:



At this point of discharge you have 24 hours to connect the AM3 to the power supply before the battery is fully discharged.

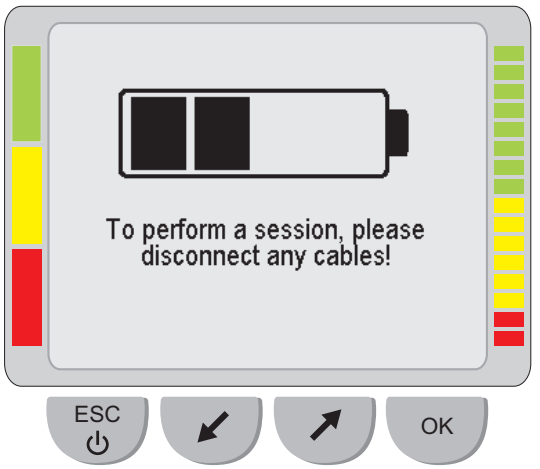
The internal clock will stop after about 5 days when the internal battery is fully discharged.

How to charge the battery

Plug one end of the wall adapter into the USB interface of the AM3 and the other end into a wall socket.

Only the original power supply delivered with the AM3 must be used for charging the device.

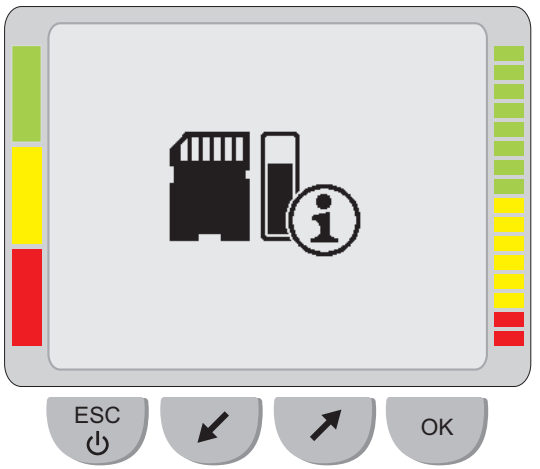
If you switch on the AM3 while the plug-in power supply is connected, the following message will be displayed:

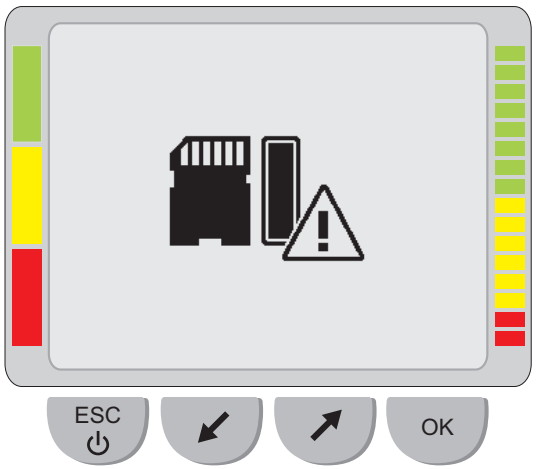


The battery symbol indicates the state of charge.

6. Memory Capacity

The following message will appear on the screen to indicate that the memory of the AM3 is almost full (80%) or completely full (no further data can be stored on the AM3).





Please bring your device to each study visit to avoid reaching full memory capacity.

7. Error Checklist

Error Description		Reason	Action
No response during power ON	**A.**	AM3 battery is empty	Charge the AM3
	B.	Buttons OK and ESC ⏻ are not pressed correctly	• Press and hold the OK button. • While holding the OK button, press and hold the ESC ⏻ button. • Hold both buttons for approximately 2 seconds.
Result of measurements is questionable	**A.**	Flow Sensor is not inserted correctly	Insert Flow Sensor correctly
	B.	Flow Sensor is dirty	Clean Flow Sensor according to cleaning instructions
	C.	Flow Sensor is faulty	Replace Flow Sensor

If the proposed actions do not lead to perfect recovery of the AM3´s normal functionality, please contact your study doctor.

8. Cleaning

8.1 Cleaning of Sensor

To clean the rotary flow sensor, release and remove sensor, rinse it with mild cleansing agent, e.g. Instruton E by ANTISEPTICA Dr. Hans-Joachim Molitor GmbH according to instructions of manufacturer, and then rinse with clean distilled water. Shake off any remaining water on the sensor. Air-dry and reinsert the sensor. Any minor discoloration in the sensor does not affect the performance of the AM3.

The Cleaning of the sensor should be performed every week or more frequently if often heavily polluted. Furthermore, it is recommended to exchange the rotary flow sensory with a new one after one year of use or 2000 measurements. If the sensor is heavily polluted frequently, the exchange with a new sensor should be performed every six months or as required. If there are any doubts that the measurement values are correct, the rotary flow sensor has to be exchanged immediately.

The sensor is intended for single patient use, only. If the AM3 is passed on to another patient, the AM surfaces will have to be cleaned and disinfected with a disinfectant. See 8.4 for cleaning of housing.

See below for information on disposal of a used sensor.

DO NOT use alcohol or any type of household cleaner!

8.2 Checking the Sensor

If your AM3 does not measure accurately, exchange the sensor or contact the responsible Monitor or ERT Customer Care Helpdesk.

8.3 Disposal of Sensor and Mouthpiece

It is absolutely vital to avoid the patient, medical assistant or sensor becoming contaminated with sputum during disassembly of the disposable sensor.
Therefore, release and remove the sensor by pulling the disposable sensor downwards (see picture). Dispose of it immediately.

8.4 Cleaning of Housing

If the device is polluted or passed on to another patient, the AM surfaces have to be cleaned and disinfected with a disinfectant. We recommend combined cleansing and disinfecting agents with basic substance quaternary ammonium compound, for example „Cleanisept Wipes“ by Dr. Schumacher GmbH.

The method of application provided by the disinfectant manufacturer have to be considered.

9. Safety Precautions AM3

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

The instruction manual 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 preparing for the measurement and methods, disinfecting 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. This is possible by performing a corresponding conformity assessment procedure within in-house manufacture (see § 12, paragraph 1 last sentence of MPG (= Medizinproduktegesetz/ Medical Products Act).

The operator/user is, however, not only responsible for performing the conformity assessment correctly but is also completely liable for defective products - i.e. the operator/user is not only liable for his/her modification of the medical product.

ERT only guarantees for the safety, reliability and functioning of the device if:

- installation, extension, modifications, and repairs are exclusively carried out by personnel authorized for these tasks by **ERT**.
- the ambient conditions at the place of installation are suitable for the device.
- the device is used according to the 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.

The user has to follow the instructions. If the user doesn't obey the safety precautions this can lead to hazardous situations which can lead to injury or death of the patient and/or destruction of the device.

⚠ CAUTION

Electrical Safety

The AM3 is powered from an internal Lithium-Ion rechargeable battery, the battery can be charged over a direct plug-in power supply (unit).

Attention:

- Only the original power supply delivered with the AM3 must be used for charging the device.
- Do not perform measurements if the AM3 is connected to another device.
- Data transfer is not permitted during measurement.

⚠ CAUTION

Patient Safety according to EN 60601-1

The subject has to keep a distance of at least 1,5 m from a connected modem or notebook to avoid any contact with electrical voltage.

⚠ CAUTION

Valid for all ERT Devices

Additional equipment connected to medical electrical equipment must comply with the respective EN or ISO standards (e.g. EN 60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems. Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the ERT Customer Care.

⚠ WARNING

Radiated Interference

The ERT device meets the regulations according to EN 60601-1-2 regarding 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.

However, if performing a measurement is required in the manner described above, the devices should be observed to ensure they work properly.

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 results 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 measuring 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.

Use ERT approved accessories or spare parts for this medical device only. Use of unapproved equipment can result in increased electromagnetic interference or reduced electromagnetic immunity of the medical device and can lead to faulty operation.

Other portable RF communication equipment (including their accessories, such as antenna cables and external antennas) should not be spaced less than 30 cm (or 12 inches) from the parts and leads of the AM3. Failure to do so may result in a reduction in the performance of the AM3.

DANGER

Ambient Conditions

AM3 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. AM3 has to be effectively protected against moisture. Therefore, it is required that the AM3 is always stored in the corresponding bag. The device corresponds to IP 22 degree of protection. Measurements in the rain or in the shower are not allowed.

CAUTION

Measuring Mode

As the combination with an IEC 60950-1 proofed PC or modem can lead to a summation of the leakage current, the AM3 must not be connected to a PC or modem during the measurement.

Should the measuring values of the AM3 be changed after a longer period of use, a new sensor should be used.

⚠ CAUTION

Interfaces

The AM3 must only be connected to a PC that corresponds to EN 60950 standards.

If the connection cable is defective, it has to be replaced by a new one. The operator must not touch the Interfaces during measurement.

⚠ CAUTION

Medical Supervision

A qualified physician has to reassess all AM3 measurements. An interpretation by the AM3 is only important if it is considered in connection with other clinical findings.

⚠ WARNING

Contraindications and possible adverse effects:

According to "ATS/ERS TASK FORCE: STANDARDISATION OF LUNG FUNCTIONTESTING" (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 rare cases spirometry testing can lead to syncope due to extensive exhalation.

Furthermore, the following conditions probably lead to suboptimal lung function results:

- Chest or abdominal pain of any causes,
- Oral or facial pain exacerbated by a mouthpiece,
- Stress incontinence,
- Dementia or disorientation.

According to "German Airway League, German Respiratory Society and German Society of Occupational and Environmental Medicine, 2015" (S2 guideline "Spirometry") forced manoeuvers should not be performed in case of

- acute, life threatening diseases of every description (e.g. acute fulminant pulmonary embolism, large ascending aortic aneurysm, tension pneumothorax)

- massive pneumothorax (within the first weeks)
- abdominal or thoracic surgery (depending on the findings 1 to 4 weeks postoperatively)
- surgery of the eyes, brain, or ears (variable, consultation with the surgeon)
- Special care must be taken when dealing with hemoptysis of unknown origin

CAUTION

Putting the Device into Operation

Temperature changes may give rise to condensation in the device. Consequently, the device has to adapt to the ambient temperature before putting it into operation.

WARNING

Cleaning and Hygiene

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

During cleaning, the AM3 must not be connected to a PC or modem.

Referring to humidity and water which may get into the device, AM3 corresponds to the safety degree IP 22. This means, the device can be cleaned with a damp (in no case dripping wet) cloth which does not produce fluff. More detailed information can be found under “Cleaning”. Chemicals required for operation or care of the unit have to be used in accordance with instructions of the manufacturer and must always be stored, prepared and made available in specially marked vessels to prevent any mistakes.

CAUTION

Maintenance

The device doesn’t require to perform preventive inspection, maintenance and calibration. No part of the AM3 should be replaced by the subject/doctor.

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

If the device/applied part has been exposed to extreme mechanical stress, a function test has to be performed. If function is lost, the defective part is to be replaced.

Damaged and frayed plugs, receptacles and housing or the display glass (if available) should be replaced by an authorized specialist or engineer of the **ERT** Customer Care. Device must not be opened. If it is opened without authorization, the guarantee entitlement expires. In case of service contact ERT.

CAUTION

Before turning on the device, you should always check whether the device is free from defects. **Immediate** maintenance is necessary, if:

- the display glass bursts or breaks: **Caution: risk of injury**
- the device has been mechanically stressed in the extreme (e.g. impact, damage to the housing).
- liquid got into the device.
- the connection cable is defective. The connection cable has to be replaced by a new one.
- coverings have fallen off.

WARNING

Children should neither get in contact with disposables, accessories and packing material nor with cleaning and disinfection substances.

CAUTION

Recycling

Adhere to the national law in your country when disposing the medical device and its accessories. Improper disposal of the device and/or its accessories can result in serious environmental hazard.

9.1 Safety Precautions for Lithium Ion Rechargeable Batteries

The AM3 is powered from an internal Lithium-Ion Polymer battery.

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

- Do not waste the battery.
- Do not short-circuit 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.
- The fluid of 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 AM3, use only the charger specified by ERT and observe the instructions in the manual!

9.2 Safety Precautions for Wireless Communication

For the efficient and safe operation of your AM3, please read the following information carefully.

Safety and Hazards

Do not operate the AM3 with wireless communication in areas where blasting is in progress, where explosive atmospheres may be present, near life support equipment, or any equipment which may be susceptible to any form of radio interference. In such areas, the wireless communication module MUST BE POWERED OFF. The AM3 with enabled wireless communication can transmit signals that could interfere with this equipment. Do not operate the wireless communication module any aircraft, whether the aircraft is on the ground or in flight. In aircraft, the wireless communication module MUST BE SWITCHED OFF. When operating, the wireless communication module can transmit signals that could interfere with various onboard systems.

Note: Some airlines may permit the use of cellular phones while the aircraft is on the ground and the door is open. The wireless communication module may be used at this time.

RF Safety

GENERAL

The AM3 uses a wireless communication module based on the 3G standard for cellular technology. The 3G standard is spread all over the world and is the most used telecommunication standard. The wireless communication module is actually a low power radio transmitter and receiver. It sends out and receives radio frequency energy. When you use your wireless communication application, the cellular system which handles your transfers controls both the radio frequency and the power level of your cellular modem.

EXPOSURE TO RF ENERGY

There has been some public concern about possible health effects from using wireless communication terminals. Although research on health effects from RF energy has focused on the current RF technology for many years, scientists have begun research regarding newer radio technologies, such as 3G. After existing research had been reviewed, and after compliance to all applicable safety standards had been tested, it has been concluded that the product was fit for use. If you are concerned about exposure to RF energy there are things you can do to minimize exposure. Obviously, limiting the duration of your calls will reduce your exposure to RF energy. In addition, you can reduce RF exposure by operating your cellular terminal efficiently by following the guidelines below.

EFFICIENT TERMINAL OPERATION

For your wireless communication terminal to operate at the lowest power level, consistent with satisfactory transfer quality:

Do not hold the device when the transfer is in progress. Holding the antenna affects transfer quality and may cause the wireless communication module to operate at a higher power level than needed.

General Safety

ELECTRONIC DEVICES

Most electronic equipment, for example in hospitals and motor vehicles, is shielded from RF energy. However, RF energy may affect some improperly shielded electronic equipment.

MEDICAL ELECTRICAL EQUIPMENT

Turn your wireless communication module OFF in health care facilities when any regulations posted in the area instruct you to do so. Hospitals or health care facilities may be using RF monitoring equipment.

Graphical Symbols

Follow Instructions for Use

Caution!

General warning sign

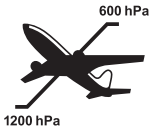
Switch the device ON and OFF

Year of production

Manufacturer

Applied Part of Type BF

Disposal in compliance with WEEE



Barometric pressure limits

IP 22

Protection against intrusion of solid objects with a diameter ≥ 12,5mm; dripping water when tilted up to 15°

SN

Serial Number

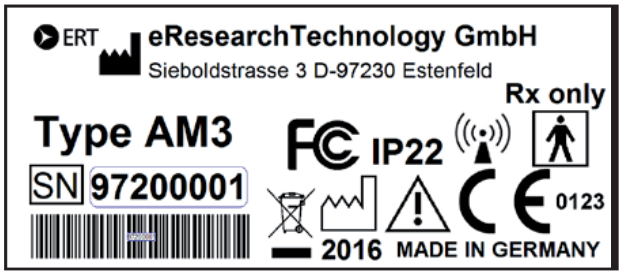
CE 0123

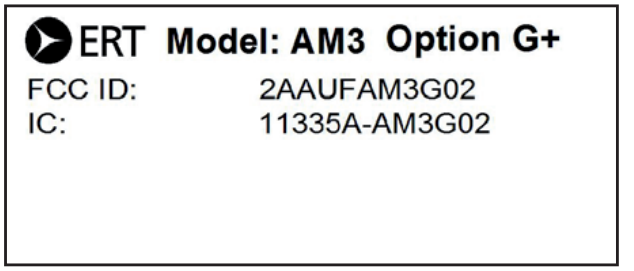
CE sign with code number of the Notified Body.
The certified quality management system of **eResearchTechnology GmbH** corresponds to the international standard of ISO 13485.

Rx only

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

The typeplate can be found at the rear side of the device.





Possible source of interference

This device complies with Part 15 of the FCC Rules

The radiation intensity of the bluetooth module is below the SAR limits which are demanded by the EC Directive 1999/519/EEC.

Approval Notes:

"Approved in accordance to R&TTE directive transmitter module marked by CE, manufactured by MITSUMI incorporated OEM product, and by Sierra Wireless incorporated OEM product."

"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."

This device contains FCC-IDs QOQBT121, 2AAUFAM3G02.

Information to the User related to the optional wireless communication module:

Changes or modifications on the radiator not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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.

IC: 5123A-BGTBT121

IC: 11335A-AM3G02

Frequency Band	Transmission Frequency Range	Maximum Output Power	Gain
UMTS B1	1922 to 1978 MHz	23 dBm (+/- 2dBm) Class 3bis	-1.74 dBi
UMTS B2	1852 to 1908 MHz	23 dBm (+/- 2dBm) Class 3bis	-1.1 dBi
UMTS B5	826 to 847 MHz	23 dBm (+/- 2 dBm) Class 3bis	-3.31 dBi
UMTS B6	832 to 838 MHz	23 dBm (+/- 2 dBm) Class 3bis	
UMTS B8	882 to 913 MHz	23 dBm (+/- 2 dBm) Class 3bis	
UMTS B19	832.4 to 842.6 MHz	23 dBm (+/- 2 dBm) Class 3bis	
GSM 850	824 to 849 MHz	2 Watts GSM, GPRS and EDGE	
E-GSM 900	880 to 915 MHz	2 Watts GSM, GPRS and EDGE	
DCS 1800	1710 to 1785 MHz	1 Watt GSM, GPRS and EDGE	-1.1dBi
PCS 1900	1850 to 1910 MHz	1 Watt GSM, GPRS and EDGE	

ERT complies with EMC guidelines according to EN60601-1-2.

ERT can provide further information on EMC properties on request.

10. Technical Data

Principle:	Determination of respiratory flow and volume via exchangeable infrared rotary flow sensor.	
Range:	Flow	0 - 840 L/min
	Volume	0.5 - 8 L
Accuracy:	Flow	± 5 % or ± 20 L/min
	Volume	± 3 % or ± 0.05 L
Storage capacity:	1200 measurements, 400 sets of questionnaires (max. 20 questions each)	
Power supply:	Built-in rechargeable lithium-ion battery 3.7 V, 1700 mAh Battery will last under standard operating conditions for about 40 days. Full charging: 2 h Cycle life: 80% of rated capacity after 300 cycles 60% of rated capacity after 500 cycles	
Dimensions:	Length x width x height	112 x 82 x 37 mm
	Weight	150 g (battery included)
Ambient conditions:	Temperature	+10 °C to +40 °C
	Relative humidity	15 % to 95 %, not condensing
	Barometric pressure	700 to 1060 hPa
Transport and storage conditions:	Temperature	-20 °C to +50 °C
	Relative humidity	15 % to 95 %, not condensing
	Barometric pressure	600 to 1200 hPa
Moisture protection:	IP 22	
Medical classification:	Active Medical Device Class IIa	

Applied part:	Type BF (whole device)
Protection class:	Battery Device
Mode of operation:	Continuous operation
Max. resistance:	0.002 kPa/L/min at 720 L/min
Interface:	USB 2.0 Bluetooth 4.2 Smart Ready 3G
Medical Power supply (battery charging):	WR9QA1200MUNMRVG2773 Model GTM41134-0605 Input 100-240 Vac, 50/60 Hz, 0.3 A Output 5 V, 1.2 A Cable length 1500 mm

The expected operational lifetime of the AM3 is 5 years.

AM corresponds to the recommendations of ATS/ERS.

Index

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