ERT
Getting It Done. Right.

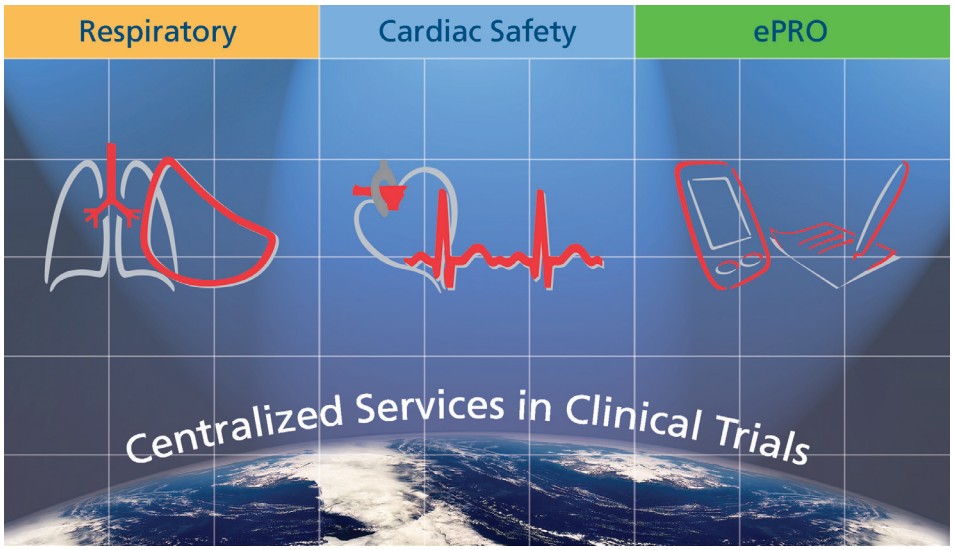
Instructions for Use

Peak Flow Meter AM3 for Trial xxxxxx

· Option AM3 GSM

782042-xxxxxxUSEN
Version 00.03

Logo



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Indications for Use

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

The AM3 is used to monitor the respiratory status of human beings in the areas 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 selected parameters (e.g. PEF, FEV1). Furthermore a visual control unit, displayed as a kind 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, a 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 select then 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 ordinary peak flow meter, diary and pencil by a single system. Easy handling, sturdy and handy design allow the Asthma Monitor AM3 being used almost everywhere: at work, at home, in school, for experts opinion, research or clinical trial purposes and in occupational medicine.

⚠ CAUTION

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

The AM can be utilized for subjects from 4 years on and older as long as they can cooperate in the performance.

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

The AM is powered with a Lithium-ion battery. No energy is transferred to the subject.

ERT Customer Care Contacts

International Support

International telephone technical support is available to all CRAs and Investigators in English; Monday through Sunday, 24 hours a day (see next page for contact details).

International Support is responsible for **all hardware and software** issues and should be contacted as soon as a problem occurs at a site.

Please have the following information available when you call:

- **Study name**
- **Site number**
- **Subject/CRF Number or Sys Number**
- **Whether this issue has been reported by the respective site to the hotline before**

  The Technical Hotline Operator will ask you for this information in order to provide the most efficient service.

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International US

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1818 Market Street, Suite 1000
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CustomerCare@ert.com

International Germany

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ERT Toll-Free Hotline

List needs to be updated if Bosnia or Tunesia are included in the study!!!!!

Country	Toll-Free Number
Argentina	0800 6660824
Australia	1800 008184
Austria	0800 293169
Belarus	8820 04910016
Belgium	0800 79185
Brazil	0800 8911518
Bulgaria	00800 1104905
Canada	1866 8415042
Chile	1230 0202398
China (North)	10800 7490031
China (South)	10800 4900031
Colombia	01800 9155750
Costa Rica	0800 0440047
Croatia	0800 222992
Cyprus	800 93295
Czech Republic	800 142391
Denmark	8088 2178
Dom. Rep.	1800 3711741
Ecuador	1800 225 528,,,(3sec)888 680 1981
Egypt	0800 0000366
Estonia	800 0049006
Finland	0800 116605
France	0800 900585
Germany	0800 1015390
Greece	00800 49129105
Guatemala	138126,,,(3sec)888 680 1981
Honduras	800 0123,,,(3sec)888 680 1981
Hong Kong	800 964138
Hungary	0680 015946
Iceland	800 8226
India	000800 4401432
Indonesia	0018 038529591
Ireland	1800 554931
Israel	180 9455201
Italy	800 786498
Japan	00531 121370
Korea	0079814 8006214

Country	Toll-Free Number
Latvia	8000 0266
Lithuania	8800 30046
Luxembourg	800 26390
Macedonia	0800 98152
Malaysia	1800 808847
Malta	800 62476
Mexico	001866 8415042
Monaco	800 93366
Netherlands	0800 0235262
New Zealand	0800 443629
Norway	800 11592
Panama	001800 5071923
Peru	0800 52161
Philippines	1800 14910008
Poland	00800 1211385
Portugal	800 812743
Puerto Rico	1 888 680 1981
Romania	0800 896647
Russia	8108002 4883011
Serbia	0800 190144
Singapore	800 1204116
Slovakia	0800 004982
Slovenia	0800 80885
South Africa	0800 995609
Spain	900 994964
Sweden	02079 8198
Switzerland	0800 562403
Taiwan	00801 137512
Thailand	001800 120664985
Turkey	0811 2880001,,,(3 sec)888 7922117
Ukraine	0800 503275
United Kingdom	0800 7314027
United States	1800 7049698
Uruguay	000413 5983021
Uzbekistan	8,6417440010,,,(3 sec)888 680 1980
Venezuela	800 1006321

If the above numbers are not available or active, please dial +49 9305 720 9891.
You will be called back as soon as possible if the support line is busy and you leave a message.
***Before dialing 888 ... please wait until you are prompted by the operator.**

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 Ambulatory Monitoring Equipment

The Ambulatory Monitoring Equipment comprises of:

- Tutorial Peak Flow Meter AM
- Subject Peak Flow Meter AM
- Power supply
- Mouthpiece
- Bag

With the help of the Peak Flow Meter, the subject records his/her symptoms and performs peak flow measurements.

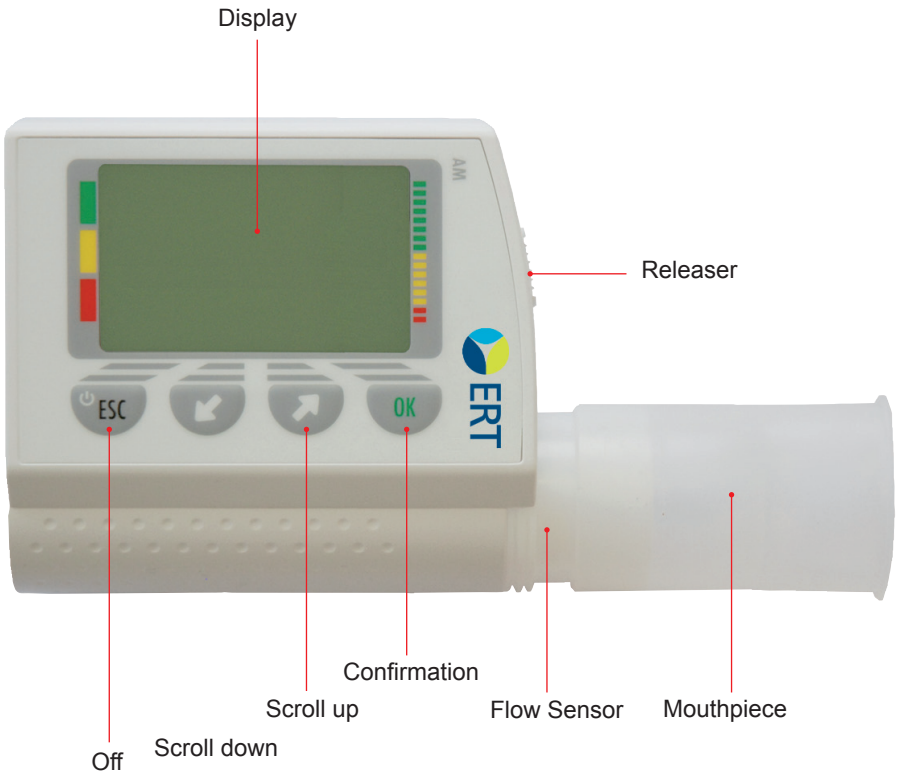
2. The Peak Flow Meter AM3

Study specific

The AM is an instrument that combines a peak flow meter 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]).

The device keeps a diary of subject measurements by automatically recording in its memory all answers and PEF measurements with the date and time. Every time the subject visits the center, the data will be downloaded by using the analogue modem.

Front view:



Bottom view:

Warning

The AM can assist in monitoring airway function on a day-to-day basis, but it **CANNOT** provide an entire diagnosis of the subject's state of health. The use of the AM will not replace a medical examination or other tests if the subject is not feeling well.

The subject should be instructed to call the study doctor **immediately** if he/she shows 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
- The subject has required treatment with oral or parenteral glucocorticosteroids.
- The subject has been admitted to hospital (including emergency room treatment).
- The subject is concerned about his/her condition during the study.

Trouble-free operation of the AM 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.

2.1 Handling

2.1.1 Turning the Device ON in Subject Mode

Press and hold the OK button. While holding the OK button, press and hold the ESC button. Hold both buttons for approximately 2 seconds.

2.1.2 Turning the Device ON in Investigator Mode

To turn ON the device, press and hold the button. While holding the button, press and hold the OK button. Hold both buttons for approximately 2 seconds. After releasing the buttons the investigator password is requested.

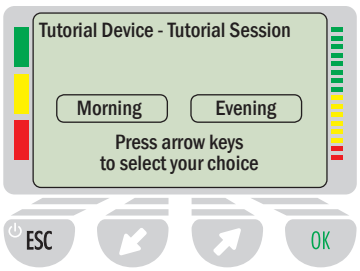
The investigator password is distributed during the study training or is available from the ERT Hotline.

The Investigator Mode needs to be turned ON, whenever there is a need to enter or change settings on the Peak Flow Meter or the modem.

2.1.3 Turning the Device OFF

The device is turned OFF by pressing ESC.

2.1.4 TUTORIAL Devices

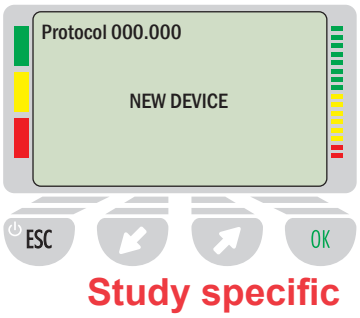


Each site receives a "TUTORIAL DEVICE" to train site staff and subjects on how to operate the device correctly.

In Tutorial Mode, it is possible to have the subject simulate morning and/or evening sessions. The site staff can also simulate administrative functions such as dispensing the AM or closing the AM.

TUTORIAL devices DO NOT STORE any data. That is why it is not possible to use them as subject devices.

TUTORIAL devices **CANNOT** be changed into subject devices.



Study specific

2.1.5 New Subject Devices

New subject devices are locked, and cannot be used until they are programmed with a subject number.

2.1.6 Assigned Subject Devices

After programming the AM with the subject's unique number, the device is ready to be used by the subject.

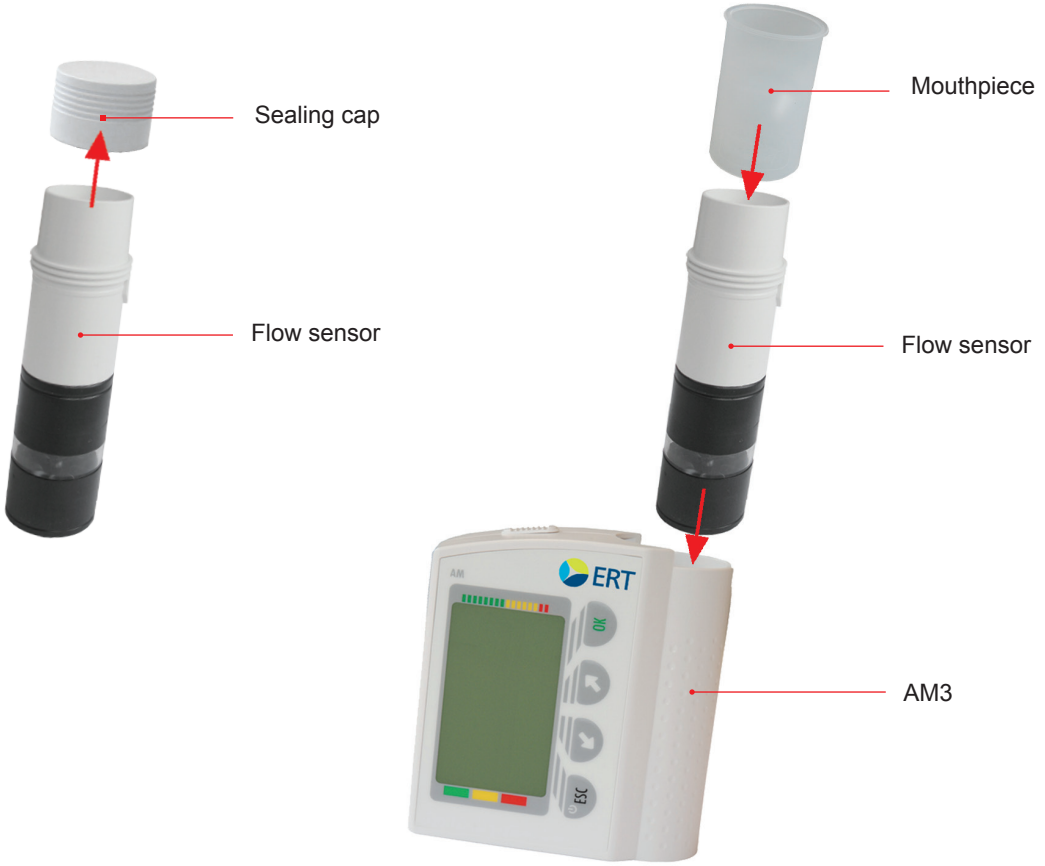
2.2 PEF Measurements with the AM

2.2.1 Preparing for the Measurement

Prior to starting the measurement, place the flow sensor into the AM as shown below. Remove the sealing cap from the flow sensor and put on the mouthpiece.

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

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



The flow sensor and the mouthpiece are intended for single subject use only.

Study specific

2.2.2 Performing Scheduled Sessions

Scheduled sessions, including questionnaire and PEF measurements, can only be performed and stored using programmed subject devices. Following the study protocol, the subject has to carry out two scheduled sessions per day.

The subject can scroll through and select the appropriate answer by using and buttons and pressing OK.

At the end of the questionnaire the subject is asked, if he/she wants to change an answer; if the subject selects "Yes", the questionnaire will be displayed again.

The answers previously entered will appear as default, and can be modified as described above. After answering the last question, the subject should complete the three PEF measurements.

2.2.3 How to Perform PEF Measurements with the AM

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

1. The subject inhales deeply and holds the breath until he/she has positioned the mouthpiece of the AM into his/her mouth.

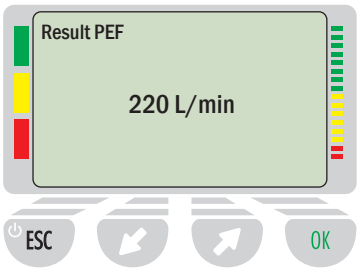
The subject should not breathe in through the mouthpiece.

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

The subject should:

- not cough.
- not block the mouthpiece with his/her tongue.
- not block the outlet of the flow sensor with his/her hand.
- be instructed to pause for about a second and then blow out hard and fast as he/she can.

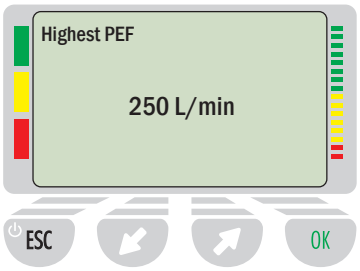
3. After full exhalation, the AM should be removed from the mouth immediately.



4. The measured PEF is displayed on the AM.

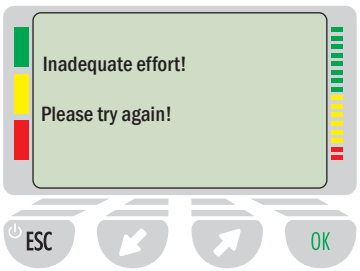
5. The result is confirmed by pressing OK.

After the 1st measurement, the subject will be asked to perform the 2nd and the 3rd PEFs (repeat steps 1- 5).



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

2.2.4 Validity of PEF Measurements



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

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

If a PEF measurement is **invalid**, a message will be displayed and the subject will be asked to repeat the measurement.

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

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

2.2.5 Interrupting a Scheduled Session

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

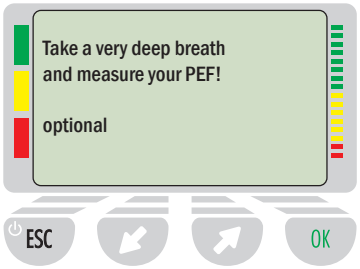
If the device is turned OFF after completing the questionnaire or between the PEF measurements, the session can be completed within the remaining time window. In this case, the device has to be turned ON again and only the missing PEF measurements may be performed - the questionnaire will not be displayed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

Study specific

2.3 Performing Unscheduled/Optional PEF Measurements

In addition to scheduled PEF measurements, the subject is able to perform unscheduled/optional PEF measurements. These are measurements that are:

- performed after having finished the scheduled measurements within a 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.

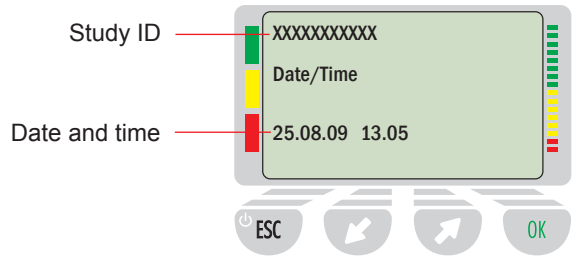
The data from unscheduled/optional measurements will **NOT** be stored.

2.4 Device Settings (Service Mode)

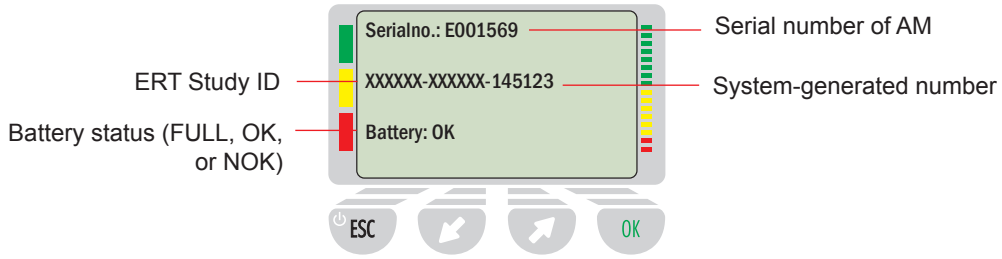
The Service Mode must be activated to view the following AM settings:

Study ID, date and time, serial number of the AM, ERT Study ID, Site and Subject number, battery status, the percentage of stored measurements and answers, the date of last data transfer and some technical settings.

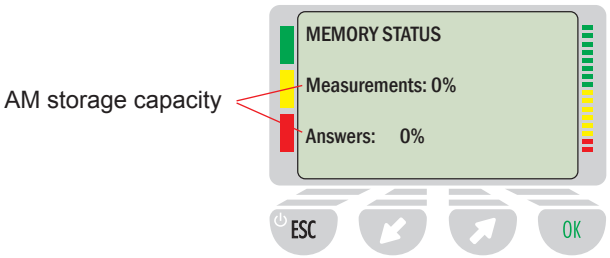
To turn the AM ON in Service Mode, press and hold the button. While holding the button, press and hold the ESC button. Hold both buttons for approximately 2 seconds. The following screen will appear:



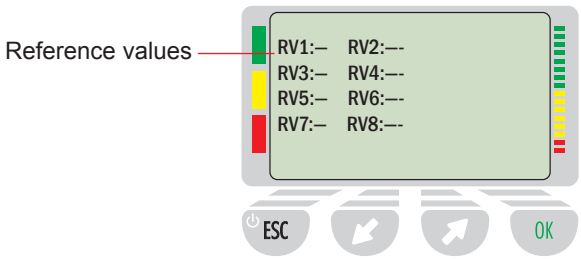
After pressing OK the following screen is displayed:

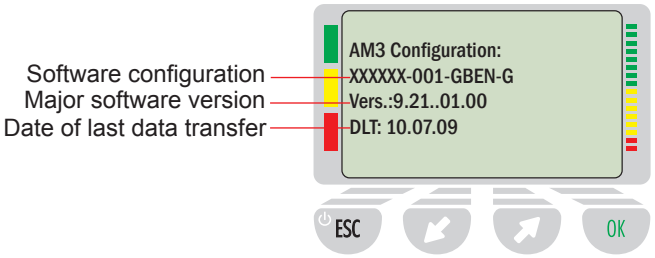


After pressing OK the following screen is displayed:



OK After pressing OK again, further technical AM settings are displayed.





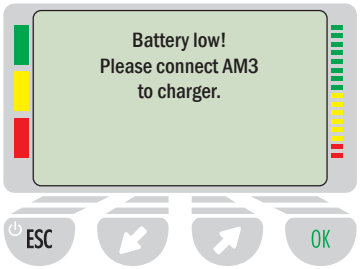
OK Pressing OK will turn the device OFF.

Settings can only be checked, **NOT** changed.
Contact your CRA or the ERT Hoteline if you have any concerns regarding the displayed settings.

2.5 Power Management

Before using the AM for the first time, the batteries must be charged for 30 minutes.

When the batteries are low, the following message will be displayed:

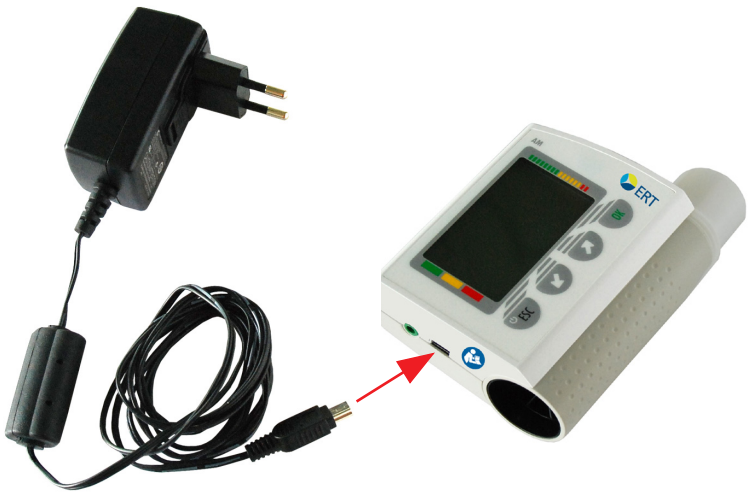


The internal clock will stop after about 5 days when the internal battery is discharged.

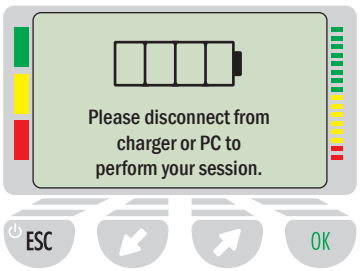
How to charge the batteries:

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

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



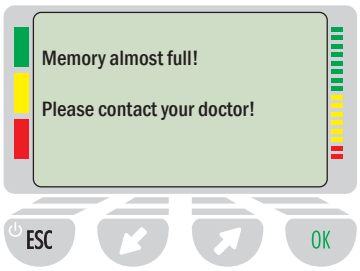
If you switch on the AM3 while the plug-in power supply is connected, the following message will be displayed:



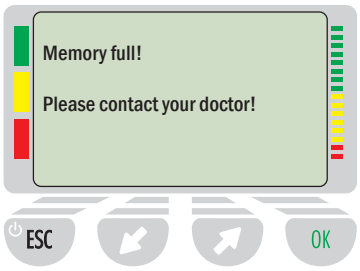
The battery symbol indicates the state of charge.

2.6 Memory Capacity

The following message will appear on the screen to alert the subject that the memory of the AM is almost full (80%).

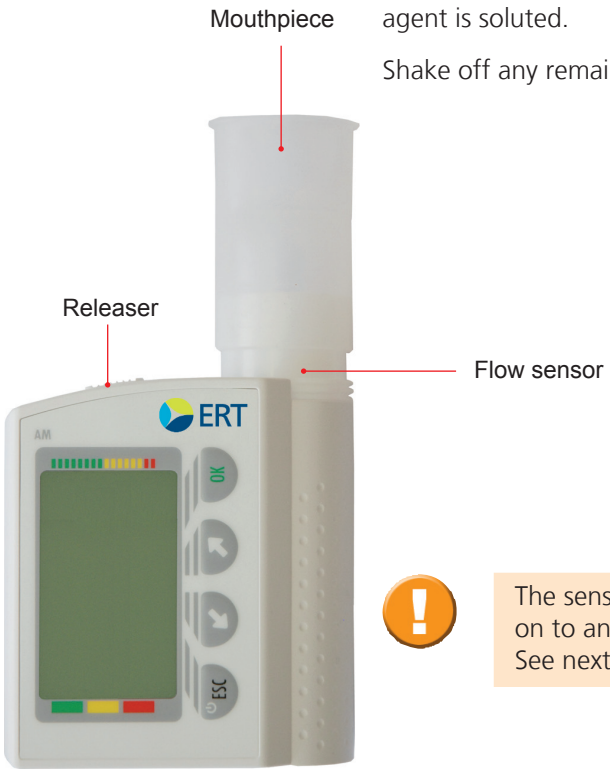


As soon as the memory is full, no further data can be stored on the AM.



Please advise subjects to bring their devices to each study visit to avoid reaching full memory capacity.

3. Cleaning



Sensor Cleaning:

Release and remove sensor, rinse it with distilled water in which a mild cleansing agent is soluted.

Shake off any remaining water on the sensor. Air-dry and reinsert the sensor.

The sensor is intended for single patient use, only. If the AM is passed on to another patient, the AM surfaces will have to be cleaned.
See next page for information on disposal of a used sensor.

3.1 Disposal of Sensor

The sensor is intended for single-patient use, only. Dispose of used sensors if the AM is passed on to another patient.

The mouthpiece is intended for single-patient use, only. Dispose of used mouthpieces if the AM is passed on to another patient.

Disposal:

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.

3.1.1 Cleaning the Disposable Mouthpiece/Rotary Flow Sensor

To clean the rotary **sensor** of the AM3, release the sensor by moving the **releaser** sidewards. It is recommended to clean the outer parts of the sensor every 4 weeks with a damp (not wet) cloth or tissue and letting the sensor air-dry at room temperature. Place the sensor back in the AM.

The **disposable mouthpiece** can be cleaned under running water.

Any minor discoloration in the sensor does not affect the performance of the AM.

DO NOT use alcohol or any type of household cleaner!

3.1.2 Cleaning the Case

Wipe off the case with a moist cloth. Then dry the case with a cotton towel.

3.1.3 Checking the Sensor

If the patient's AM does not measure accurately, clean the sensor as described above. If there are still doubts that the device is not working correctly, exchange the sensor or contact the responsible Monitor or ERT Customer Care Helpdesk.

4. Error Checklist

Error Description		Reason	Action
No response during power ON	**A.**	AM 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.
Clock is not working correctly			Reprogram AM by connecting it to the modem. If problem occurs again replace AM.
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 AM´s normal functionality, please contact the ERT Hotline.

5. General Safety Precautions

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 (= Medizinprodukte-gesetz/ 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 training manual 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.

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 AM is powered from an internal lithium Ion rechargable battery, the battery can be charged over a direct plug-in power supply (unit).

Attention:

- Only the original power supply delievered with the AM must be used for charging the device.
- Do not perform measurements if PC is connected.
- 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. The physician/operator must not touch any voltage-carrying parts and the subject at the same time.

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. 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.

If available: More detailed information can be found in the EMC tables of the Instructions for Use of your device.

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 black 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 physician must not touch the patient and live parts at the same time. 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 FUNCTION TESTING" (ERS Journals Ltd 2005) performing lung function tests can be physically demanding for a minority of patients. It is recommended that patients should not be tested within 1 month of a myocardial infarction.

In rare cases spirometry testing can lead to syncope due to extensive exhalation.

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).

Prior to measuring a subject, his/her anamnesis is to be checked in order to avoid a contamination of the device and a resulting cross contamination of the next subject.

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 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 not get in contact with disposables, accessories and packing material and 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.

5.1 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 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.
- 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!
- Keep the batteries away from children.
- To charge the AM3, use only the charger specified by the manufacturer and observes the instructions in the manual!

5.2 Safety Precautions for GSM Option

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

Safety and Hazards

Do not operate the AM3 with enabled GSM option 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 GSM modem MUST BE POWERED OFF. The AM3 with enabled GSM option can transmit signals that could interfere with this equipment. Do not operate the GSM any aircraft, whether the aircraft is on the ground or in flight. In aircraft, the GSM option MUST BE SWITCHED OFF. When operating, the GSM modem 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 GSM option may be used at this time.

RF Safety

GENERAL

The AM3 uses a GSM module based on the GSM standard for cellular technology. The GSM standard is spread all over the world. It covers Europe, Asia and some parts of America and Africa. This is the most used telecommunication standard. Your GSM module is actually a low power radio transmitter and receiver. It sends out and receives radio frequency energy. When you use your GSM 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 GSM 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 GSM. 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 GSM 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 GSM modem 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 GSM option 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.

AIRCRAFT

Turn your GSM option OFF before boarding any aircraft.

- Use it on the ground only with crew permission.
- Do not use it in the air.

To prevent possible interference with aircraft systems, Federal Aviation Administration (FAA) regulations require you to have permission from a crew member to use your terminal while the aircraft is on the ground. To prevent interference with cellular systems, local RF regulations prohibit using your GSM option while airborne.

BLASTING AREAS

To avoid interfering with blasting operations, turn your GSM option OFF when in a « blasting area » or in areas posted: « turn off two-way radio ». Construction crews often use remote control RF devices to set off explosives.

POTENTIALLY EXPLOSIVE ATMOSPHERES

Turn your device OFF when in any area with a potentially explosive atmosphere. It is rare, but your application or its accessories could generate sparks. Sparks in such areas could cause an explosion or fire resulting in bodily injuries or even death. Areas with a potentially explosive atmosphere are often, but not always, clearly marked. They include fuelling areas such as petrol stations; below decks on boats; fuel or chemical transfer or storage facilities; and areas where the air contains chemicals or particles, such as grain, dust, or metal powders.

Graphical Symbols

	Note 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.
	Possible source of interference

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

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 POOWML-C46, 2AAUFAM3G01.

Information to the User related to the optional GSM 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:11335A-AM3G01

Frequency band	Transmission frequency range	Output	Gain
GSM 850	824 to 849 MHz	1.70 W	-2.9 dBi
E-GSM 900	880 to 915 MHz	0.86 W	-8.5 dBi
DCS 1800	1710 to 1785 MHz	N/A	-2.7 dBi
PCS 1900	1850 to 1910 MHz	N/A	-3.0 dBi

Literature

Medical Device Directive (Medical Devices Act = Medizinproduktegesetz – MPG, valid in Germany, only)

EN 60601-1 Medical Electrical Equipment
Part 1: General Requirements for Safety

EN60601-1-2 Medical electrical equipment
Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

EN 62353 Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment

DIN VDE 0100 Part 710 (IEC 60364-7-710) Electrical installations of buildings - Part 7- 710: Requirements for special installations or locations - Medical locations

Reference source:

VDE-Verlag GmbH, Bismarckstr. 33, 10625 Berlin or Merianstrasse 29,

63069 Offenbach, Germany, E-Mail: kundenservice@vde-verlag.de Beuth Verlag

GmbH, Burggrafenstraße 6, 10787 Berlin, E-Mail: info@beuth.de

The safety precautions and operational procedures indicated in this chapter refer to Germany. Different regulations and standards may apply in 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 AM3 GSM.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The AM3 GSM is intended for use in the electromagnetic environment specified below. The customer or the user of the AM3 GSM should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1 Class B	The AM3 GSM uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
RF emissions CISPR 11	Group 1 Class B	The AM3 GSM is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The AM3 GSM is intended for use in the electromagnetic environment specified below. The customer or the user of the AM3 GSM should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	6 kV contact 8 kV air	6 kV 8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	2 kV 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV differential mode 2 kV common mode	1 kV Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (> 95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 s	< 5 % UT (> 95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AM3 GSM requires continued operation during power mains interruptions, it is recommended that the AM3 GSM be powered from an uninterruptible power supply or a battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the A.C. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The AM3 GSM is intended for use in the electromagnetic environment specified below. The customer or the user of the AM3 GSM should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the AM3 GSM, including cables, that the recommended separation distance calculated from the equation applicable to the frequency of the transmitter: Recommended protection distance:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	d = 1.17 1/V * √P
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	d = 1.17 m/V * √P for 80 MHz to 800 MHz
			d = 2,33 m/V * √P for 800 MHz to 2.5 GHz
			where P is the maximum output power rating of the transmitter in watts (W) acc. to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theroretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AM3 GSM is used exceeds the applicable RF compliance level above, the AM3 GSM should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the AM3 GSM.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distance between portable and mobile RF Communications Equipment and the AM3 GSM

The AM3 GSM is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AM3 GSM can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF commnucations equipment (transmitters) and the AM3 GSM as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz d = 1.17 1/V * √P	**80 MHz to 800 MHz** d = 1.17 m/V * √P	**800 MHz to 2,5 GHz** d = 2.33 m/V * √P
0.01	Not applicable	0.12	0.23
0.1	Not applicable	0.37	0.74
1	Not applicable	1.17	2.33
10	Not applicable	3.7	7.37
100	Not applicable	11.7	23.3

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

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

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, for repair, or for 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 to all persons having contact with the returns.

This leaflet shall minimize 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

Irrespectively 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 considered 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 for products which are potentially contaminated by biological working substances of risk group 3 and 2 according to the regulation on biological substances and which are thus classified as Transport Category B:

Please contact ERT **before** returning the goods and refer to 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, body tissue or contrast agents etc. have caused the product 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 the 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 endangering of 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 safely.

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 accom-panying 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. tear-proof 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 provided 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

Principle:

Determination of respiratory flow and volume via exchangeable infrared rotary flow sensor.

Range:

Flow	0 - 840 liters/minute
Volume	0.5 - 8 liters

Accuracy:

Flow	± 5 % or ± 20 L/min
Volume	± 3 % or ± 0.05 liters

Storage capacity:	1200 measurements, 400 sets of questionnaires (max. 20 questions each)
Power supply:	LI-ION Polymer battery 3.7 V, 1700 mAh Battery will last under standard operating conditions for about 40 days. Full charging: 2 h

Dimensions:

Length x width x height	112 x 82 x 37 mm
Weight	120 g (batteries 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:	70 Pa/L/s at 14 L/s

Interface:	RS-232 (used in the modem mode and for production) USB 2.0 Bluetooth 2.0 (no EDR) GSM
Medical Power supply (battery charging):	WR9QA1200MUNMRVG2773 Model GTM41134-0605 Input 100-240 Vac, 47 - 63 Hz, 0.3A Output 5 V, 1.2 A

The expected operational lifetime of the AM3 is 5 years.

AM corresponds to the recommendations of ATS/ERS.

Index

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CE 0123

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ERT
Getting It Done. Right.