idiag

ST MEDICAL®

RESPIRATORY THERAPY

Operating Manual

EN

Overview of changes			
Date Document	Software version	Originator	Approved by Name / date
19.3.12	M 1.4	bz	AT 19.3.12

List of chapters

Information about the Operating Manual

User

It is recommended that the use and maintenance of the ST Medical® device is restricted to trained persons, who are completely familiar with the ST Medical® device and along with this Operating Manual. Any repair or service should be performed by authorized personnel only.

Further applicable documents

None

User information

This manual is also available in PDF format. Hyperlinks and bookmarks allow a fast and effective retrieval of links. The search function allows a fast retrieval of keywords.

Symbols in this manual

This operating manual uses the following icons to indicate especially important comments:

	**Danger!** Immediate and imminent DANGER for life and limb. Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
	**Warning!** Signals potential harm to equipment or user if instructions are not followed.
	**Caution!** Indicates potential harm to equipment if instructions are not followed.

Note!
Information and recommendations to make optimal use of the ST Medical®.

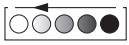
Operating buttons of the Base Station

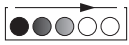

Enter button, confirmation


Up button, increasing the value, switching


Down button, decreasing the value, switching

Direction of the indicator lights


From right to left side (inhalation)


From left to right side (exhalation)

Symbols used on the ST Medical®

Attention, consult accompanying documents.

The device must not be disposed of in the same way as normal domestic waste. If you wish to discard this product, please contact your local authorities or dealer and ask for the correct method of disposal.

Device of Type BF (Protection against electric shock)

The CE-Indication declares that the requirements of the EC-Guidelines are met and a designated confirmation valuation act has been accomplished.

Direct Current

Battery

Important security advice

- Use the ST Medical® after you have read and understood this Operating Manual.
- Keep this manual with the ST Medical®.

Intended use / Indications

- ST Medical® is intended to be used for the purpose of respiratory muscle therapy to improve pulmonary function, physical performance and secretion mobilisation.
- A mobile system for respiratory muscle therapy, the ST Medical® device helps patients with limited respiratory capacity or with specific respiratory diseases such as stable chronic obstructive pulmonary disease (COPD) or stable cystic fibrosis (CF).
- The utilization of this device is restricted to the predefined purposes and applications as stated in these Instructions for Use. See also “Operating, transport and storage conditions”, page 33.

- The ST Medical® principle is based on forced respiration with controlled CO_2 rebreathing, the so-called isocapnic hyperpnoea.
- The ST Medical® device serves to improve lung function and the awareness of respiratory distress and secretion mobilisation, which has a beneficial effect upon physical condition and quality of life.
- Unless prescribed differently by a doctor, the ST Medical® therapy is performed approx. 4-5 times a week in sessions of up to 30 minutes. Depending upon the clinical symptoms the duration and frequency of the therapy sessions may vary.
- Respiratory muscle therapy is practised as a supplementary treatment to the existing therapy methods for the respective disease.
- In the majority of cases respiratory muscle therapy is a permanent therapy that is used to halt or slow the progression of the disease, but cannot provide a cure.
- The ST Medical® device allows patients to carry out the therapy by themselves in an outpatient setting or at home.
- A combination with other devices is not allowed.
- No modification of this equipment is allowed.

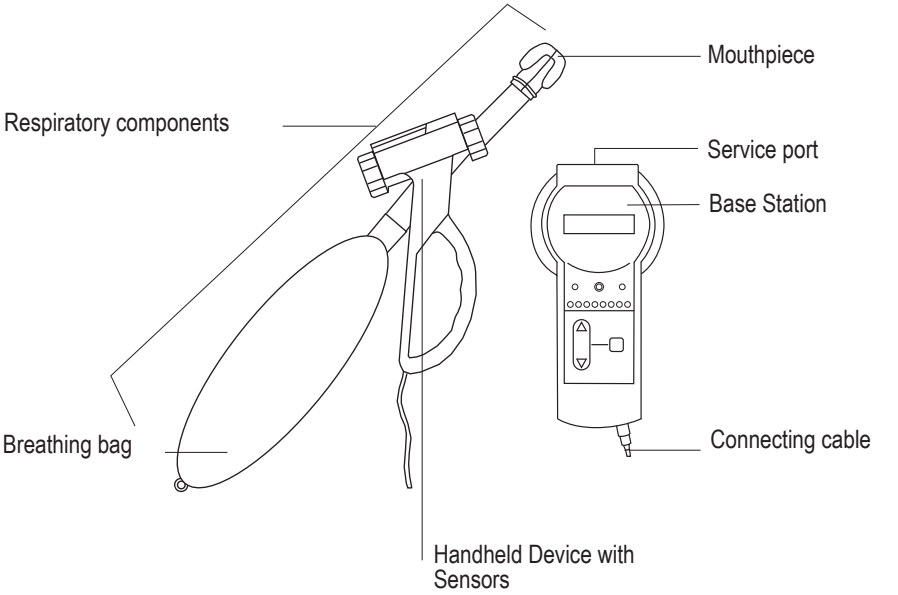
Warning statements

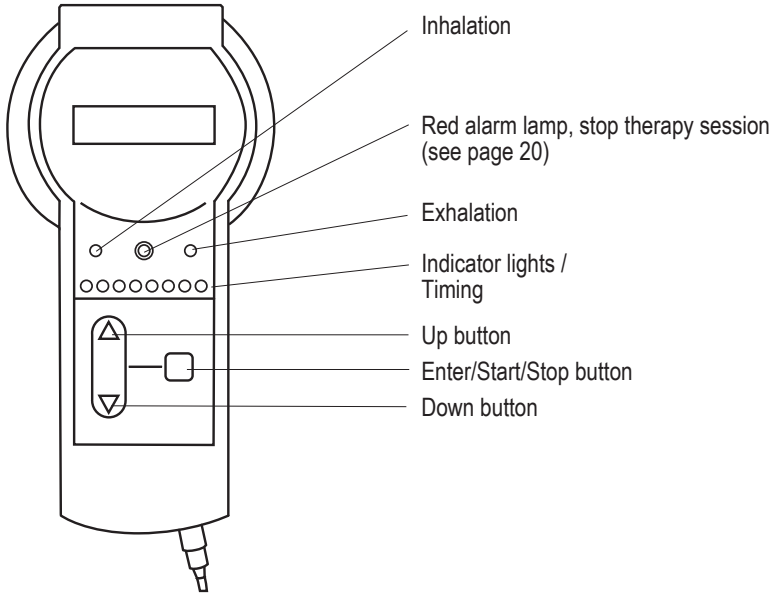
The utilization of this device is restricted to the predefined purposes and applications as stated in these Instructions for Use.

- The ST Medical® device may only be used on the recommendation of a doctor and following therapy by a healthcare professional approved by the manufacturer. The device should only be used under medical supervision.
- Correct device setup is required for a successful therapy.
- The therapy must be abandoned when symptoms of malaise or illness occur.
- The ST Medical® may not be used with other physical activities simultaneously.
- A ST Medical® therapy can in some cases result in dizziness, loss of breath, light headedness, headache, and nausea. If any of these symptoms surface immediately stop the therapy. Contact a doctor for further information.
- The medical expert is fully responsible for any kind of medical or therapeutical treatments. Therefore idiag declaims any kind of responsibility for medical or therapeutical treatments.
- The user accepts all responsibly for his or her therapy. Idiag is not liable for any side effects following ST Medical® therapy.
- Observe the hygiene requirements set forth in section “Maintenance”, page 22.
- Never use the device without the valve in place or an individual breathing bag. The bag size must be adjusted according to individual needs.
- The transparent breathing bag and the transparent mouthpiece delivered by the ST Medical® manufacturer are made of silicone. Other breathing bags and mouthpieces may contain latex. Latex can provoke allergic reactions. In case of a latex allergy use only breathing bags and mouthpieces made of silicone.
- Check the therapy-specific personalized data before each therapy.
- Never use the device if the base station or electronic monitoring system are not switched on.
- During therapy always hold the device on a horizontal line.
- Only breathe through your mouth during therapy. If necessary, use a nose clip.
- Unless otherwise directed by a doctor, only use the ST Medical® device in accordance with the instructions contained in this Operating Manual.
- The device should not be used near flammable gas mixtures of air, oxygen or nitrous oxide (i.e. anaesthetic).
- The RS232 service port of the ST Medical® may be connected only with devices which correspond to an IEC-standard.
- Only use the device after you have read this Operating Manual and have understood its contents.
- Store this Operating Manual alongside the device.

Parts

You first need to assemble the respiratory components, following the directions on page 12.





Batteries are part of the delivery

Introduction

The STMedical® is an ergonomic and handy respiratory therapy device. It has been developed in co-operation with the Federal Technical University of Zurich (ETH) and the Interstate College for technology of Buchs (NTB, Switzerland).
For people with pulmonary diseases, snorers and their partners, the consistent use of STMedical® promises a great improvement of their quality of life. In case of illness and rehabilitation the STMedical® may only be used on medical recommendation and under medical supervision.

The STMedical® consists of two components, a Handheld Device and the Base Station.

The Base Station is a computerized unit that stores the information that helps you to regulate your respiration and to control breathing. It has a lighted panel and acoustic sounds, which help you to keep up the pace you choose and displays digital information that leads you through the therapy session. The Base Station records the data from your therapy session. There, the most important data is saved.

The Handheld Device with its built in STMedical® valve technology and breathing bag offers extensive protection against hyperventilation, hypoventilation and dizziness, if you use the STMedical® correctly.

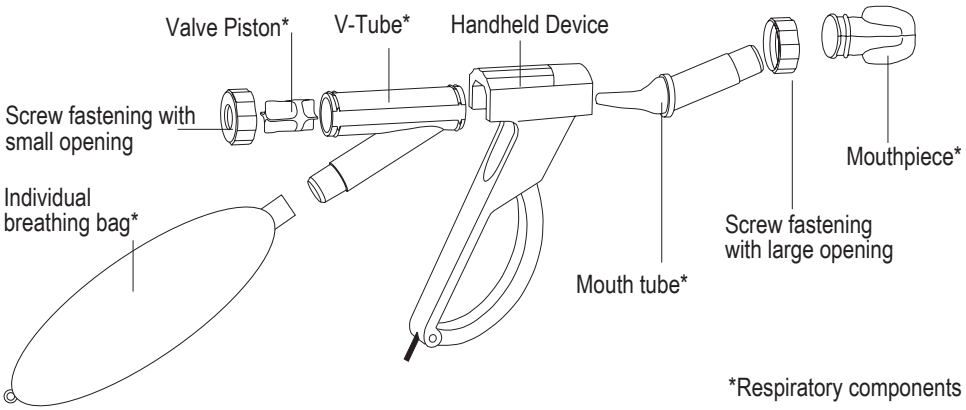
Indications

See “Intended use / Indications”, page 7

Contraindications

- Age < 6 years
- A doctor has recommended you avoid physical stress
- During pregnancy
- Acute illnesses of the respiratory system (e.g. colds, respiratory tract inflammation and pneumonia)
- Spontaneous or traumatic pneumothorax
- Pulmonary hypertension
- Artificial respiration
- Sinusitis (inflammation of the paranasal sinuses)
- Injuries to the eardrum
- Fresh wounds in the thoracic region
- Fractures in the torso region (e.g. broken ribs)
- The acute phase following a heart attack
- Acute heart failure

Installation of the Handheld Device

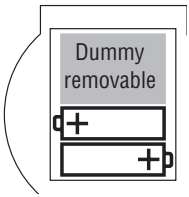


Clean the ST Medical® before the first use in accordance with chapter ‚maintenance'. Pages 22-29.

Mounting the Respiratory components

1. Place all parts on a table as shown above.
2. Insert the valve piston into the V-tube as shown above, and secure the opening with the screw fastening (small opening).
3. Insert the V-tube into the Handheld Device.
4. Insert the mouth tube into the V-tube and fix it with the second screw fastening (large opening).
5. Slide the breathing bag over the open end of the V-tube and put the mouthpiece over the mouth tube.
6. Use the connection cable to connect the completed Handheld Device to the Base Station.

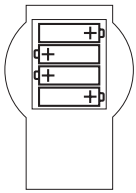
Setup the Base Station



2 Batteries

1. Insert the batteries as shown.

The battery compartment of the ST Medical® holds up to 4 batteries. (The ST Medical® may also run on 2 batteries, which reduces their life span accordingly.)



4 Batteries

The following situations require the installation of new batteries:

please change battery

- before you first use the ST Medical®
- if “please change battery” is displayed
- when the battery power is too low to run the ST Medical®

WARNING

- Open the cover of the battery compartment on the rear side to insert the batteries as shown, making sure to align the positive and the negative poles correctly to avoid damage to the unit.
- To extend battery life, remove the batteries if ST Medical® is not likely to be used for several days or weeks.
- Note: Batteries do contain corrosive liquid. If a battery leaks: Do not expose skin, eyes, or mouth to the liquid. If you do, flush the affected body parts with water for at least 15 minutes. Consult a doctor. Do not inhale vapor. Immediately remove any liquid from the unit with a damp cloth and dispose of the cloth. Idiag accepts no responsibility for injuries to customers, or damage to the device, caused by leaking or defective batteries.
- Do not recharge non-rechargeable batteries.
- Take care of our environment; properly dispose of used batteries!

- Battery life: see ‚Technical Data‘
- Always use high quality batteries. See ‚Technical Data‘

2. Perform a function check. See page 14.

Switching the unit on and off / Function check

Switching on

The Base Station is switched on by pressing the Enter button until the unit switches on and all segments and lights are activated.
Press Enter to continue.

select person: 1

Select person number will be displayed.
The Handheld Device is activated by connecting it to the Base Station. Make sure that the plug is properly installed.


3 seconds

Switching off

The Base Station is switched off by pressing the Enter button for at least 3 seconds.
The Base Station will turn itself off, if it is not used for more than one minute.

Function check

Perform a function control before each therapy and after inserting the batteries.

- Make sure that the valve piston moves frictionless.

- Press the Enter button until the unit switches on and all segments and lights are activated.
  Afterwards | select person 1 | will be displayed.

Consult chapter ‚Problems and Solutions' on page 34, if:
- Not all of the lights switch on
- Lights seem weak or fading
- Nothing is visible on the display at all
- You see unknown signs

select person 1

Selection menu

Switch on the Base Station and use the UP an DOWN button to select your personal number (1, 2, 3 or 4). Confirm the number by pressing the Enter button. All further displays and entries will be related to this personal number.

select menu

The Enter button opens the selection menu.
Use the UP and DOWN button to scroll through the selection menu.

User specific adjustment

The Base Station can store user specific data of 4 different persons.
Prior to your first therapy session you must determine and enter the volume of your breathing bag and your respiratory rate. The ST Medical® needs these user specific data to provide you with specific therapy instructions and to avoid risk to you.

Choosing bag size

See a medical expert to have your vital capacity value (VC) determined. This may be done by using the ST Medical® software or by applying the formulas shown on page 36.
The breathing bag volume is calculated as following:

Breathing bag Volume = 0.5 * VC [liter]

If you are in good physical condition, choose the next larger standard breathing bag. If your physical condition is less satisfying, choose the next smaller bag.

Standard breathing bag volumes are: 0.5 / 1.0 / 1.5 / 2.0 / 2.3 / 3.0 liter

Calculating respiratory rate

See a medical expert to have your respiratory rate determined. This may be done by using the ST Medical® software or by applying the formulas shown on page 36.

An incorrect breathing bag volume and/or respiratory rate can lead to hyperventilation, hypoventilation, dizziness or disturbance of equilibrium.

How to program bag volume and respiratory rate

select menu set parameters

Select -> Switching on -> Person number -> Parameter of therapy -> ENTER

bag volume 2.5 liter

Use the UP and DOWN buttons to select the established the volume of the bag and confirm the selected value with ENTER.

respiratory rate 30/minute

Use the UP and DOWN buttons to select the established respiratory rate and confirm the selected value with ENTER.

resp. volume
112 liter / min.

The Base Station now determines your personal respiratory rate-volume per minute.
If you do not change the calculated value, you may go back to the selection menu by pressing the ENTER button.
If you want to change the established value, the program allows you to enter new values for bag volume and respiratory rate.
See page 41.

WARNING

Prior to your first therapy session or after changing the settings:

- have the settings determined and cleared by a medical professional.
- enter the volume of your breathing bag and your respiratory rate. ST Medical® needs these user specific data to provide you with specific therapy instructions and to avoid risk to you.
- connected the Base Station to the Handheld Device.
- perform at least your first workout in the presence of a medical.
- perform a function control before each therapy session. See page 14
- A ST Medical® therapy can in some cases result in dizziness, loss of breath, light headedness, headache, and nausea. If any of these symptoms surface immediately stop the therapy. Contact a doctor for further information.

Start therapy

```
select person
     1
```

Switch on the Base Station and select your personal number 1, 2, 3 or 4 with and .
Confirm the selection by pressing the ENTER button.

```
select menu
start therapy
```

Press ENTER .

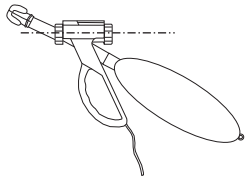
```
duration
20 min.
```

The program needs the value of the desired duration of therapy (UP and DOWN buttons) Range: 1-99 minutes
Start therapy with ENTER.

```
running
time:    00:03
```

The time of therapy is displayed (minutes: seconds)

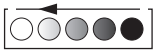
Remember: Keep the Handheld Device in a horizontal position while therapy.



The ST Medical® signals each change from inhalation to exhalation and vice versa with a short beep while the running lights change direction.

Exhale!

Take the mouthpiece into your mouth. Inhale deeply and start exhaling while the indicator lights run from left to right.



Inhale!

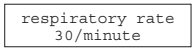
Start inhaling at the beep, the indicator lights now run from right to left.

You are inhaling

You are exhaling

The two green lights are helping you to synchronize your breathing: The lights are indicating whether you are at the end of an inhalation or exhalation cycle.

Changing the respiratory rate during therapy



During therapy the respiratory rate can be changed with UP and DOWN. The new rate stays valid until the unit switches off. Next time you switch on the ST Medical® the originally selected values will be in effect again (see 15).

More time to exhale

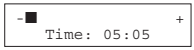
The time between inhaling and exhaling can be changed from the ratio of 1:1 to the ration of 1:2 (select menu /device setup > sound 2). This gives the patient more time to exhale.
To return to a ratio of 1:1 between inhaling and exhaling choose ‚short', ‚long' or ‚off' in the ‚sound' menu.

Displays and messages during therapy

The bars on the display indicate the actual respiratory depth during your therapy session:

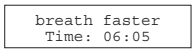
Optimal breathing for the set values and the selected breathing bag.

Breathing is too heavy or breathing bag too small.

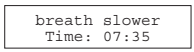


Breathing is too light or breathing bag too big.

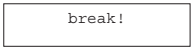
If the given pace is not respected, the bars disappear and one of the following instructions appears:



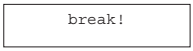
Breathe faster.



Breathe slower.



If the valve piston does not move for more than 10-15 seconds, the display will indicate ‚break!'. This may be caused by an interruption of therapy session, insufficient breathing (too light) or a falsely chosen breathing bag (too big). The ST Medical® will switch off, if the therapy is not continued within the next minute.

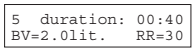


Mind! A ‚break!' does not mean that you have to take a break!

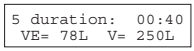
If the instructions are continually ignored, the ST Medical® will stop the therapy session. See page 20.

End of therapy session / Storage of data

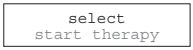
After you have finished or interrupted your therapy session (ENTER) or after a faulty-therapy session, the following information is displayed:



After one second



- Number of therapy session
- Duration of therapy session (min: sec)
- Bag volume (BV, liter)
- Respiratory rate (RR, per minute)
- Breathing volume per minute (VE, liter per min)
- Entire breathing volume during therapy session (V, liter)



The therapy session data is stored by pressing ENTER and the selection menu appears.

Error messages

Red alarm lamp is on

Danger of injury!
Therapy despite red alarm lamp may lead to dizziness and falls with injuries.
Interrupt therapy session!
If instructions are continually ignored, the ST Medical® therapy session is stopped (see page 19) and the red alarm lamp is switched on.

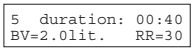
!! error !! press enter	The therapy session has stopped. After pressing the ENTER button, the display shows the reason for the therapy break-off.
	Possible reasons for the interruption:
no valve detection valve! malfunction!	No respiratory noticeable Valve piston not installed or jammed Respiratory components not installed
respi. components not connected	Connection cable not connected
too slow! too fast!	Your breathing was slower / faster than the set respiratory rate.
set a higher respiratory rate	Your breathing was too deep. Use the UP-button to increase the respiratory rate or choose a bigger breathing bag.
set a lower respiratory rate	Your breathing was too shallow. Use the DOWN-button to reduce the respiratory rate or choose a smaller breathing bag.
5 duration: 00:40 BV=2.0lit. RR=30	By pressing ENTER you can switch back to the display readings described in chapter, End of therapy / Storage of data‘. See page 19.
	Check the bag size and your personal therapy data if the ST Medical® interrupts your therapy more than once or twice (page 15).
OUT OF ORDER!	Cannot read or write date. Please return the device to your local dealer for repair work or directly to Idiag.
therapy data deleted!	This message appears after a program update and informs you that logbook and personal therapy data have been deleted.

Logbook

After a therapy session the data will be transferred to the logbook. The logbook can store up to 20 therapy sessions. More about storing data on page 19.

You must switch off the device before calling in the therapy data of a different person. After restarting the ST Medical® you may then choose the personal data (person 1-4) desired.

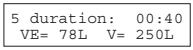
From the selection menu you can reach the logbook by using the UP and DOWN buttons.



Open the logbook with ENTER and the following data shows you the beginning of the last entry:

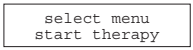
- Number of therapy
- Duration of therapy (min: sec)
- Bag volume (BV, liter)
- Respiratory rate (RR, per minute)

After one second the bottom line of the display is replaced by the following values:



- Breathing volume per minute (VE, liter per min)
- Entire breath-volume during the therapy (V, liter)

Using the UP and DOWN buttons you can switch from one therapy session to the next.



Press ENTER to get back to the Selection Menu.

Maintenance menu

The Base Station menu “maintenance” may only be used by authorized service personal.

Inspection by the user

A close inspection of the ST Medical® is necessary before each therapy session. If you suspect that the ST Medical® may be malfunctioning, send it to your local distributor to be examined and/or repaired. Necessary repair work should only be carried out by Idiag or an authorized customer service center. Faulty components which may affect the safety of the ST Medical® equipment must be replaced by genuine spare parts.

- Clean and disinfect or clean and sterilize the respiratory components before the first use in accordance with chapter ‚maintenance‘. Pages 22-29.
- Make an inspection of the ST Medical® before each therapy session.
- Do not use a ST Medical® which has not passed an inspection.
- Do not use a ST Medical® that is damaged or does not function properly.
- Do not use a ST Medical® if a battery leaks.
- Do not open the Handheld Device or the Base Station (except the battery compartment).

Interval	Scope	Method
Before each therapy	• Perform a function control (see page 14).	Inspection
	• Make sure that the piston moves frictionless.	Inspection
	• Make sure that the ST Medical® is in hygienically perfect condition. See chapter, Maintenance‘ pages 23-29.	Inspection
	• Make sure that breathing bag and mouthpiece have no leak parts or cracks.	Inspection
	• Look for damaged components, labels and warning signs.	Inspection
	• Check all cables (damage, breakage).	Inspection
	• Make sure that nobody can be injured with the ST Medical®.	Inspection

General information regarding hygiene

The following chapters deal with the sanitary handling of the ST Medical®.

- For hygienic reasons, we recommend using a personal mouthpiece and breathing bag or a personal user kid consisting of all respiratory components (definition see page 12).

- Clean and disinfect or clean and sterilize the respiratory components, especially the breathing bag, after each therapy. Respiratory components: Sterilization preferred where possible (see page 29). If sterilization not possible then high-level chemical disinfection required (see page 26).

- Check the breathing bag and the mouthpiece for cracks and leaky parts regularly.
- Wearing parts, especially breathing bag and mouthpiece, must be replaced for hygienic and safety reasons (intervall see “Lifespan”, page 31).
- Immediately replace defective parts with original spare parts.

- Cleaning, disinfection and sterilizing can change the color of the items.

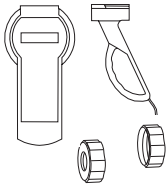
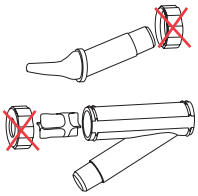
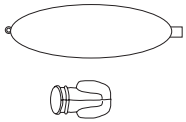
Drying

- Make sure that all parts can dry properly (see also page 25).
- Always let the breathing bag dry with the opening downwards.
- Respiratory components should be air dried. Place all pieces on a clean absorbing surface and do not cover.

Storage

- Place the dry respiratory components and breathing bag between use, especially between longer therapy absences, into a clean fiber/lint free towel (i.e. dishtowel) and store in a dry, dust free area.
- Storage of the disinfected/sterilized parts: Make sure that the parts are completely dry. The storage must coincide with general hygienical rules and guidelines.
- See “Storage conditions”, page 33

Hygiene overview

Situation	Base Station Handheld Device Screw fastenings	Respiratory components Without: • breathing bag • mouthpiece	Breathing bag Mouthpiece
			
Before the first use		• Clean and disinfect or • Clean and sterilize	Breathing bag: sterile packed Mouthpiece: • Clean and disinfect or • Clean and sterilize
After each use	• Clean if necessary	• Clean and disinfect or • Clean and sterilize	• Clean and disinfect or • Clean and sterilize
Before change of user	• Clean and disinfect	• Clean and sterilize	• Clean and sterilize
After 30 therapy sessions or at latest once a month	• Clean and disinfect		
Replacement	• see “Lifespan”, page 31		

Page references

- Cleaning: see page 25
- Disinfecting: see page 26
- Sterilizing: see page 29

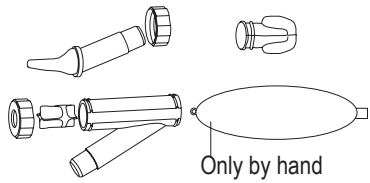
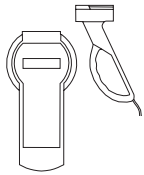
“Disinfect” means: “High-level disinfection”

Cleansing

Interval
- See table “Hygiene overview”, page 24
- Clean items before disinfecting and before sterilizing
- Clean the ST Medical® equipment whenever necessary

Methods
- Cleaning with soap and water
- Handheld Device and Base Station: Wiping off the surfaces
- Respiratory components: Rinsing by hand, cleaning in the dishwasher or in an ultrasonicator

Preparation
- Remove the batteries before cleaning the ST Medical®
- Dismount respiratory components (see page 12)

Cleaning	Rinse by hand, clean in the dishwasher or ultrasonicator.  	By wiping off the surfaces 

Procedure

CAUTION

- Make sure that no water or other liquids can enter the Handheld Device or Base Station. This precaution prevents electrical short-circuits and corrosion forming on sensitive electronic parts and mechanical components.
- Never use corrosive, solvent, polishes or abrasive detergents.
- Alcohol and solvents may cause the material to dull or crack.
- To clean the display of the Base Station, never use a cleaner containing alcohol or solvent.

- Handheld Device and Base Station: Wipe the surfaces with a lint free cloth moistened with mild soap and water.
- Rinse the respiratory components by hand.
- Respiratory components – except for the breathing bag – may be cleaned in the dishwasher.
- The breathing bag must be flushed by hand and dried with the opening downwards.
- Make sure that all parts can dry properly.
- Dry the breathing bag with opening downwards.
- See also chapter “Drying”, page 23 and “Storage”, page 23.

Maintenance, **Disinfection**

Disinfecting

Interval
- See table “Hygiene overview”, page 24
- Disinfect the ST Medical® equipment whenever necessary.

Methods of disinfection
- Chemical methods (see below)
- Respiratory components need a “high-level disinfection” or a sterilization.
- Respiratory components can be disinfected by boiling (see page 28).

Preparation
- Remove the batteries before you start disinfecting.
- Dismount the respiratory components (see page 12).
- Clean all parts before disinfecting (see page 25).

Chemical disinfection

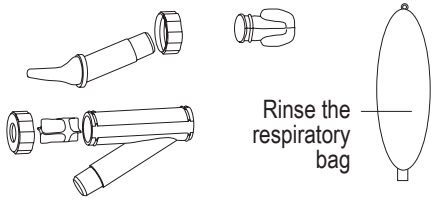
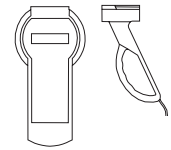
- The method of disinfection must conform with the legal regulations and guidelines regarding disinfection and explosion protection.

CAUTION

- Use a disinfectant that does not contain substances harmful to health and that does not leave any residues.
- Use a disinfectant suitable for plastic.
- Use a disinfectant that is compatible with the materials (respiratory components: PSU, polysulphone).
- Use a disinfectant that has been certified by the DGHM, Deutsche Gesellschaft für Hygiene und Mikrobiologie (German Society for Hygiene and Microbiology), e.g. Sanosil S003 or another similar type of disinfectant.
- Alcohol and solvents may cause the material to dull or crack. To disinfect the display of the Base Station, never use a disinfectant containing alcohol or solvent.
- Never use corrosive, solvent or abrasive disinfectants.
- Do not use toluene based solvents.
- Do not expose the ST Medical® equipment to an alcohol based disinfectant for more than 5 minutes.
- Do not soak the Handheld Device or Base Station in disinfectant.
- Disinfection by spraying is not recommended because disinfectant solution may enter the ST Medical® equipment.

DANGER

If you have used a disinfectant which may produce explosive gas-mixtures, make sure they have evaporated, before switching on the ST Medical® equipment.

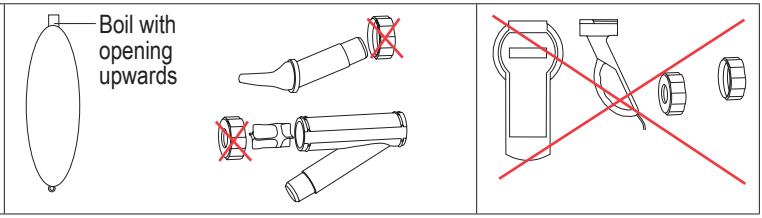
Chemical disinfection	By wiping off the surfaces or in a bath  	Only by wiping off the surfaces 

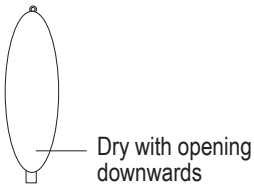
Procedure
- Disinfect Handheld Device, Base Station and connecting cables by wiping off the surfaces with a lint free cloth moistened with disinfectant.
- Disinfect the respiratory components in a disinfection bath consulting the disinfectant instructions.
- Rinse the breathing bag with the disinfectant.
- Make sure that all parts can dry properly.
- Dry the breathing bag with opening downwards.
- See also chapter “Drying”, page 23 and “Storage”, page 23.

Disinfection by boiling

Boiling may be used if the respiratory components get used by only one person. The respiratory components have to be sterilized if they are used by several persons (see page 29).

Disinfection by boiling





Procedure
- Make sure the parts are fully covered by water and do not contain air.

WARNING

Hot water!
Risk of burns.

- Fill the breathing bag with hot water before boiling it.
- Make sure that no air remains inside the breathing bag (opening upwards).
- Make sure that the breathing bag is kept open and is not folded during boiling.
- Start counting the duration when the water reaches a rolling boil.
- Duration: 8-10 minutes

- Make sure that all parts can dry properly.
- Dry the breathing bag with opening downwards.
- See also chapter “Drying”, page 23 and “Storage”, page 23.

Sterilizing the respiratory components

Interval
- See table “Hygiene overview”, page 24
- Sterilize the respiratory components whenever necessary.

Methods of sterilization

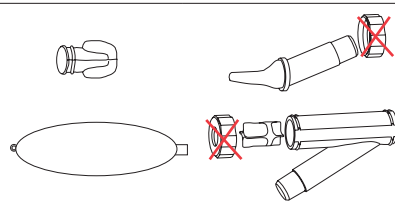
Respiratory components can be sterilized by “Pressure Steam Sterilization” (Autoclaving) or by “Ethylene oxide gas”, see page 30

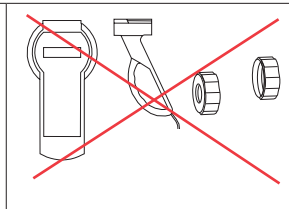
CAUTION

- Never sterilize Base Station or Handheld Device!
- Only respiratory components may be sterilized.
- Do not apply a “dry heat sterilization” (Hot Air Oven).

Preparation
- Dismount the respiratory components (see page 12) before sterilizing.
- Clean all respiratory components before sterilizing (see page 25).
- Make sure that the breathing bag is kept open and is not folded during sterilization.

Pressure steam sterilization (Autoclaving)

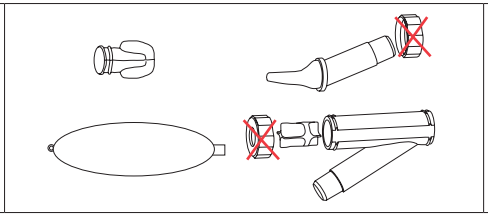
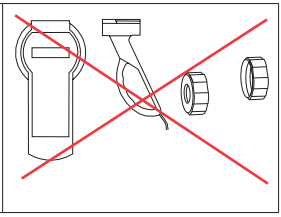




Procedure
- See autoclave manual

- Make sure that all parts can dry properly.
- Dry the breathing bag with opening downwards.
- See also chapter “Drying”, page 23 and “Storage”, page 23.

Method	Temperature	Pressure	Duration	Maximum number of applications
Pressure steam sterilization (Autoclaving)	121 °C 250 °F	1,1 bar 16 psi	20 min.	Breathing bag, mouthpiece: 100 Other respiratory components: 150

Ethylene oxide gas sterilization		

Procedure
- See “Ethylene oxide gas Sterilization” manual
- Make sure that the Ethylene oxide is completely evaporated before use.
- Dry the breathing bag with opening downwards.
- See also chapter “Drying”, page 23 and “Storage”, page 23.

Method	Temperature	Pressure	Duration	Maximum number of applications
Ethylene oxide gas sterilization	50-60 °C 122-140 °F	ambient pressure	2-24 hours (Function of gas concentration)	100

Technical data

Dimensions Handheld Device approx. 30 x 5 x 15 cm / approx. 12 x 2 x 6 in
(w/o Breathing bag)
Base Station: approx. 23 x 4 x 12 cm approx. 9 x 1.6 x 4.7 in
Serial cable: length approx. 130 cm / 50 in

Weight Handheld Device: ca. 350 g / 12.4 oz
Base Station: ca. 350 g / 12.4 oz

Lifespan Handheld Device, Base Station: 5 yrs.
Respiratory components: 1 year
Breathing bag, Mouthpiece: daily use: 3 months, maximum 1 year

Batteries Base Station 2 or 4 batteries Idiag recommends: Alkaline Batteries Size AA 1.5V

Lifespan at 30 minutes therapy per day: approx. 3 months (4 batteries)
approx. 1.5 months (2 batteries)

Display of therapy duration: Range: max. 99 min. 59 seconds
Resolution: 1 second

Therapy duration input range: 1-99 min.

Classification: Base Station: Degree of protection against electric shock: Type BF
Handheld Device: Degree of protection against electric shock: Type BF equipment.
Classification according to the degree of protection against ingress of water: IPXO - Not classified.

Safety Certifications: CAN / CSA C22.2 No.60 IEC 60601-1 UL 2601-1

Sterilsation and disinfection methods:

Never sterilize Base Station or Handheld Device!
Only respiratory components may be sterilized, see page 29.
Sterilization: see chapter “Sterilizing the respiratory components”, page 29
Disinfection: see chapter “Disinfecting”, page 26

Degree of safety of application in the presence of flammable anaesthetic mixture with air or with oxygen or nitrous oxide:
Equipment not suitable for use in the presence of flammable mixtures.

Mode of operation: Continuous.

Information regarding interference and interference avoidance:
This equipment has been tested and found to comply with the limits for EMV and the limits for medical devices in IEC 601-1-2:1994. These limits are designed to provide reasonable protection against harmful interferences in a typical indoor installation. This equipment can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interferences to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment on and off, the user is encouraged to try to correct the interference by one or more of the following measures:

- Increase the distance between interfering components.
- Consult the manufacturer or field service technician for help.

Important therapy recommendations

- Respiratory therapy requires good coordination and patience. A few sessions are required to consider the concept and the flow of the therapy.
- At the beginning, just focus on a regular respiratory rate. Once you are successful in holding the pace try to adjust the respiratory depth.
- At the beginning of the respiratory therapy a slow respiratory rate (approx. 20 breathing cycles per minute) and a short duration (approx. 2-3 minutes) should be chosen.
- Therapy intensity should be increased gradually for achieving the desired effects. Initiating by continuously increasing the duration of the therapy, followed by increasing the respiratory rate.
- Give attention to appropriate breathing techniques and coordination.
- To optimize the therapy intensity and effects, therapy sessions should be considered strenuous, if not increase the respiratory rate.
- If it is not possible to complete a therapy session at a selected intensity we recommend reducing the respiratory rate until the desired duration can be reached.
- Unless prescribed otherwise by the doctor, therapy sessions between 15 and 30 minutes per day subdivided into 1-3 sessions, 2-5 times weekly are recommended. To maintain performance at least two therapy sessions per week are required.
- Variations in breathing techniques, duration and frequency of therapy sessions depend on disease pattern, functional deficiencies and personal objectives.
- A decisive factor in the success of the therapy is the regular application.
- Only breathe through the mouth during therapy. If nasal respiration occurs use the given nasal clamp.

Operating, transport and storage conditions

General transport and storage conditions

- The ST Medical® registers data with highly sensitive precision electronics. Shock and excessive vibration can damage these parts.
- Handle with care. Do not drop!
- Do not expose to extreme temperatures and direct sunlight.
- Do not expose to water, dampness or high humidity.
- Remove batteries for transportation and storage.
- Only use original ST Medical® packaging for transportation and storage.
- Hang up the breathing bag with the opening downwards.

Operating conditions

- Temperature: +10 °C to +40 °C (50 °F to 104 °F)
- Relative Humidity: 30% to 75%
- Atmospheric Pressure: 700 hPa to 1060 hPa

Equipment not suitable for use in the presence of flammable (e.g. anaesthetic) mixtures with air, oxygen, or nitrous oxide.

- Typical operating environment: indoor environment, office, home
- For further information see “General transport and storage conditions”, page 33.

Transportation conditions

- Temperature: -40 °C to +70 °C (-40 °F to 158 °F)
- Relative Humidity: 10% to 95%, non-condensation
- Atmospheric Pressure: 500 hPa to 1060 hPa
- Only use original ST Medical® packaging for transportation.
- Do not cover the unit with heavy objects.
- Remove batteries
- For further information see “General transport and storage conditions”, page 33.

Storage conditions

- Temperature: -40 °C to +70 °C (-40 °F to 158 °F)
  (Breathing bag: max. 25 °C / 77 °F)
- Relative Humidity: 10% to 95%, non-condensation
- Atmospheric Pressure: 500 hPa to 1060 hPa
- Always store the ST Medical® in a dust-free environment.
- Only use original ST Medical® packaging for storage.
- For further information see “General transport and storage conditions”, page 33.
- Store the breathing bag in a dark place.

Problems and solutions

Problems	Solutions
ST Medical® switches on shortly and immediately shuts off again.	To switch on, press ENTER for at least 2 seconds.
Lights do not switch on completely or seem weak or fading.	Exchange the batteries.
Nothing or unknown signals appears on the display.	Check polarity of the batteries. Exchange the batteries.
respi. components not connected	Connect the Handheld Device and the Base Station, check the plug.
The logbook shows no therapy data.	No therapy has been stored under this therapy number yet.
ST Medical® locked.	Press all 3 buttons for at least 3 seconds and start the ST Medical® again. Or: Temporarily remove all batteries and put them back in again.

If problems continue to emerge, please contact your ST Medical® retailer or Idiag. See cover for address.

Waste disposal

Protect the environment!
When disposing of this ST Medical®, do so in an environmentally friendly way.
Return old products to an appropriate collection point according (EU Directive 2002/96/EC). The ST Medical® must not be placed in the normal household waste.

Warranty

Dear Customer,

Congratulations on your purchase of a ST Medical® respiratory therapy device and thank you for your confidence in Idiag. The ST Medical® has been designed in Switzerland, incorporating the latest scientific discoveries and manufacturing methods. High-quality components and materials guarantee the ST Medical®'s reliability and durability (see below). In the unlikely event of a malfunctioning, please do not hesitate to contact us.

Terms of Warranty
Idiag warrants this product to be free from defects in material and workmanship for a period of one (1) year from the date of its original retail purchase.
Guaranty performance can only be produced, if the ST Medical® is sent back in the original package together with the original bill.

The guaranty performance includes the free of charge repair of the ST Medical®. The buyer carries the expenses for shipping, package, insurance and other costs.

The warranty excludes:
1. Batteries, breathing bag and mouthpiece.
2. Regular inspections, maintenance and repair or replacement of parts due to normal wear and tear.
3. Risks and costs of transportation, which are connected directly or indirectly with this guarantee.
4. Damages to the ST Medical® caused by:
   - Abuse or misuse of the ST Medical®, particularly when the ST Medical® has been used for other applications than those described in this manual.
   - Non-observance of operating and/or maintenance instructions.
   - Unauthorized manipulations of hardware or software. Defects may only be repaired by the manufacturer or an authorized service center.
   - Accidents or environmental factors which lie beyond the control of Idiag e.g. damages caused by water, fire, intrusions, interference and acid solutions (leaking batteries).
5. This warranty exclusively applies to parts and devices distributed by Idiag.
6. This guarantee does not limit the purchaser's national legal rights. If the applicable national law does not stipulate anything to the contrary, the rights of the purchaser are limited to this guarantee and Idiag does not take any liability, nor responsibility for direct or indirect damages or losses connected with the use of the ST Medical®.

Attachment

WARNING

The formulas are only approximations and are only valid within the scope of application provided. Please see the therapy recommendations for further information (page 32).

1. Determining the Vital Capacity (VC)

The vital capacity can be determined either though direct measurement or using the following formula. Using the vital capacity the bag size can be determined (page 15).

$$\text{Vital Capacity } VC_{Man} = (0.0576 * H) - (0.026 * A) - 4.34 \text{ [Liter]}$$
$$\text{Vital Capacity } VC_{Woman} = (0.0443 * H) - (0.026 * A) - 2.89 \text{ [Liter]}$$

H = Height in centimeters (1 feet = 30.48 cm, 1 in = 2.54 cm)
A = Age in years

WARNING

Scope of application of VC formulas:
Height: Men: 155-195 cm, Women: 145-180 cm
Age: 18-70 years (18-25 years of age must input age 25). The formulas had been validated for healthy, non-smoking Europeans.

2. Determining the Maximum Breathing Capacity (MVV)

$$\text{Maximum Breathing Capacity } MVV_{Man} = VC_{Man} * 34 \text{ [Liter / Min.]}$$

$$\text{Maximum Breathing Capacity } MVV_{Woman} = VC_{Women} * 32 \text{ [Liter / Min.]}$$

3. Determining the Minute Ventilation (AMV)

$$AMV_{Start} \text{ recommended for therapy} = 0.5 * MVV \text{ [Liter / Min.]}$$

4. Determining the Respiratory Rate (RR)

$$\text{Respiratory rate (RR)} = AMV / (\text{Bag size} * 1.2) \text{ [1 / Min.]}$$

Optimal therapy intensity lies between a respiratory rate of 20 and 40 breathes per minute.

Electromagnetic compatibility (EMC)

(EMC), IEC 60601-1-2

ST Medical® needs to be installed and put into service according to the EMC information stated as follows. Use of portable phones or other radio frequency (RF) emitting equipment near a ST Medical®, may cause unexpected or adverse operation.

Compliant Cables and Accessories

ST Medical® has no accessories which affect EMC compliance.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The ST Medical® is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the ST Medical® is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	ST Medical® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	ST Medical® is suitable for use in all establishments inclusively in 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	

Caution!

ST Medical® should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, ST Medical® or system should be tested to verify normal operation in the configuration in which it is being used.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
ST Medical® is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the ST Medical® 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 contact ± 8 kV air	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	Not applicable		
Surge IEC 61000-4-5	Not applicable		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable		
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 characteristics of a typical location in a typical commercial or hospital environment.
NOTE U_T is the AC mains voltage prior to application of the test level.			

Essential performance

Respiratory rate
Supervision of the therapy

Guidance and manufacturer's declaration – electromagnetic immunity

ST Medical® is intended for use in the electromagnetic environment specified below. The customer or the user of the ST Medical® should assure 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 ST Medical®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V	$d = 1{,}2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz
			$d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (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 reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically 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 ST Medical® is used exceeds the applicable RF compliance level above, the ST Medical® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ST Medical®.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [U_1] V/m.

Recommended separation distances between portable and mobile RF communications equipment and the ST Medical®

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

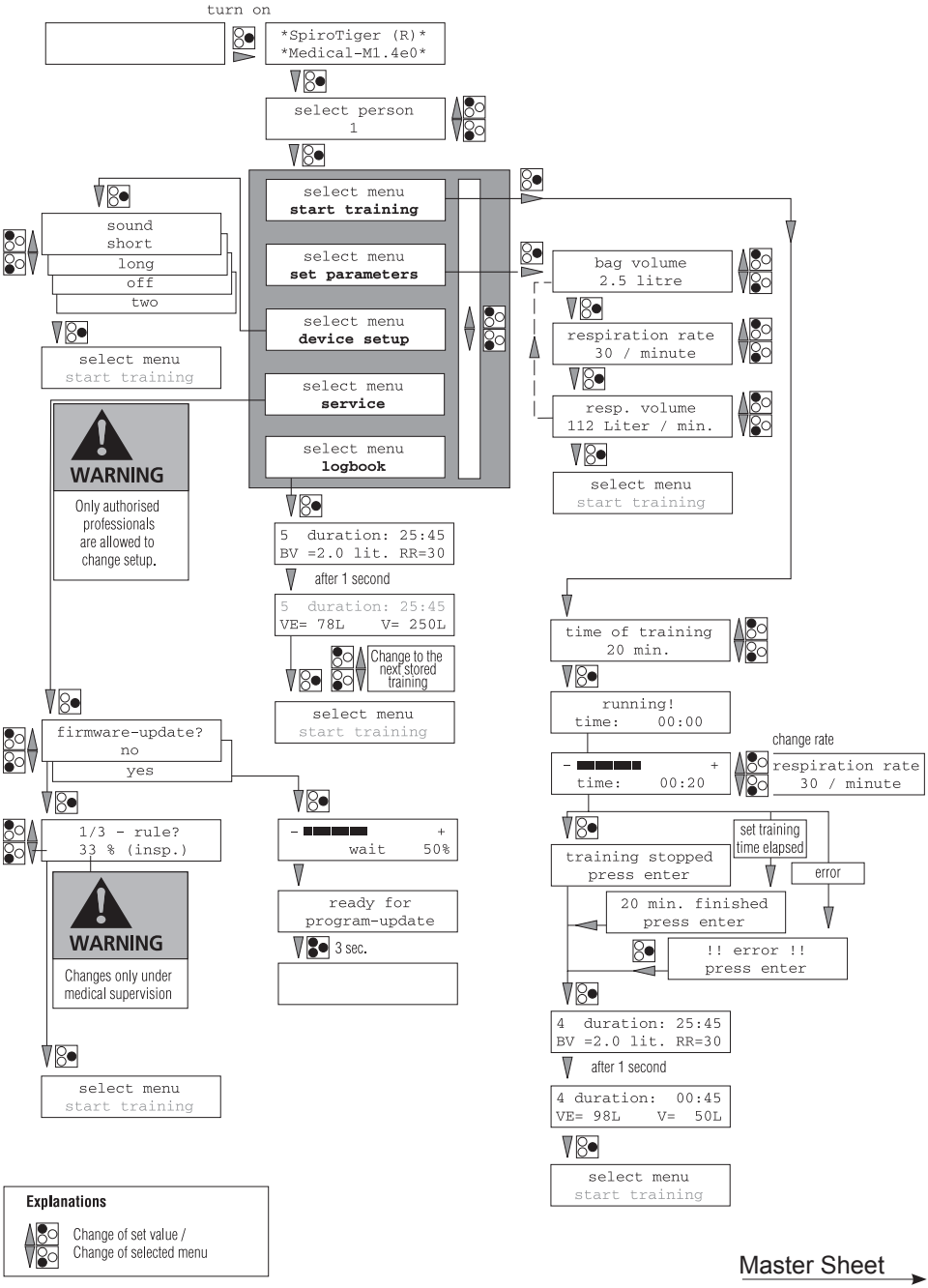
Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** **m**		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2{,}3\sqrt{P}$
0.01	0,12	0,12	0,23
0.1	0,38	0,38	0.73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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 apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Operating scheme



Master Sheet

ST Medical® therapy data sheet

Therapy # Date	Daytime	Duration [min.]	Respiratory rate Vol. Bag	VE [liter/min.]	Total breathing volume (V)	Notes

Headquarters
Switzerland: idiag AG, Mülistrasse 18
CH-8320 Fehraltorf
Phone +41 (0)44 908 58 58
Fax +41 (0)44 908 58 59
info@idiag.ch
www.idiag.ch

Germany: idiag GmbH, Schaubingerstrasse 7
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