

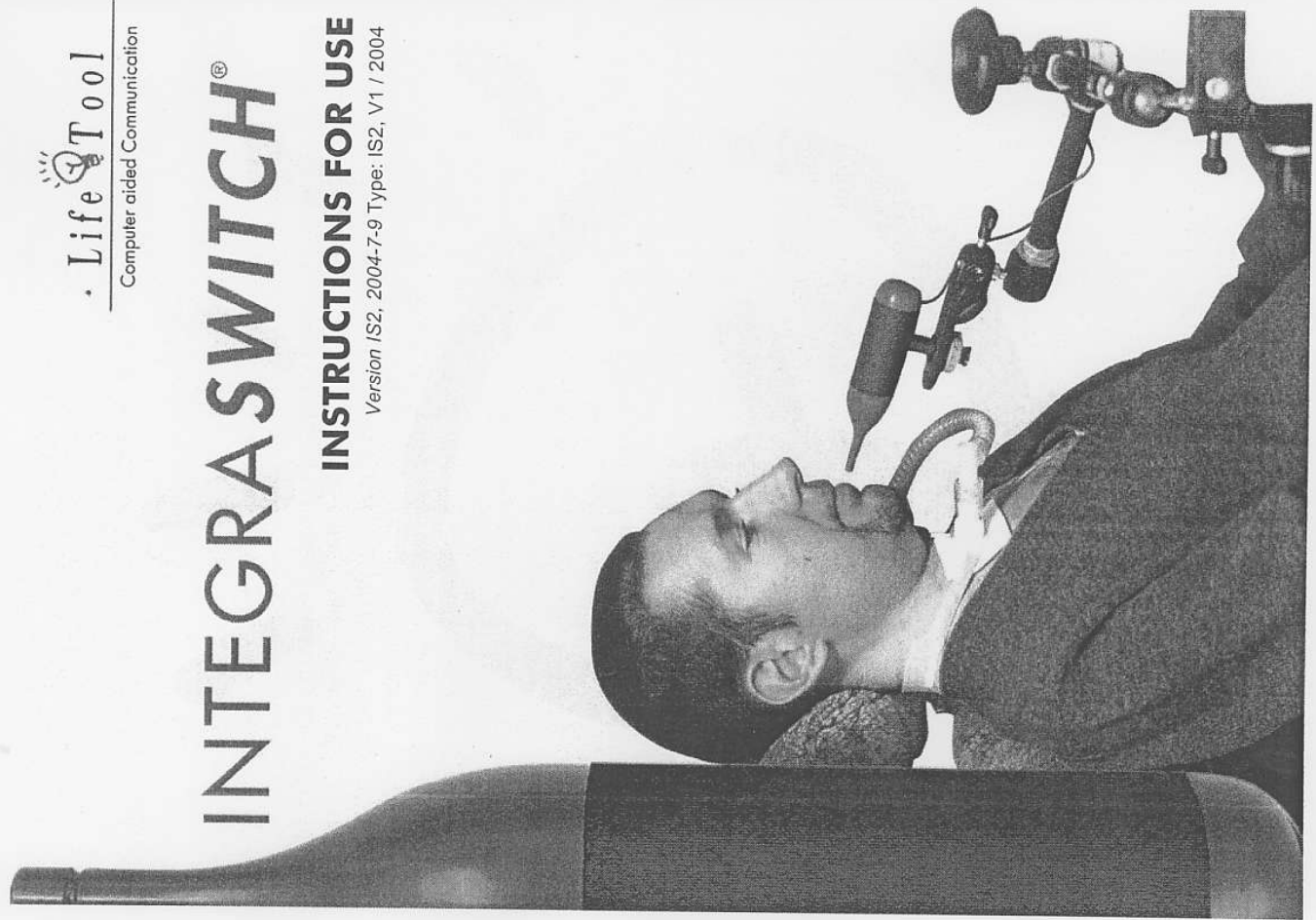


Computer aided Communication

INTEGRASWITCH®

INSTRUCTIONS FOR USE

Version IS2, 2004-7-9 Type: IS2, V1 / 2004



DEAR CUSTOMER

By purchasing the INTEGRASWITCH® you have acquired a technical support that will help you to manage better with your day to day life. You have made a good choice, because you will now be able to have a little influence on your environment.

In order to make using your INTEGRASWITCH® as simple as possible from the very start, we have put together this manual for you. It contains important information and practical tips.

Please read this information carefully before you use your INTEGRASWITCH® for the first time. Your authorised INTEGRASWITCH® dealer will be happy to answer any questions you might have.

We hope that your INTEGRASWITCH® will be of great benefit to you in your everyday life.

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1. SAFETY INSTRUCTIONS FOR THE USE OF THE INTEGRASWITCH®

- The INTEGRASWITCH® is meant for use *over short periods of time only*. (The mouthpiece must not be held in the mouth for longer than 60 minutes at any one time.)
- Sufferers of epilepsy and people with uncontrollable head movements must not use the INTEGRASWITCH®.
- The INTEGRASWITCH® must only be used with a correctly attached membrane that has been checked to ensure that it is airtight¹.
- After every change of mouthpiece the pressure must be rebalanced².
- The INTEGRASWITCH® must not be installed either directly or indirectly on electrically or mechanically driven vehicles (in particular, wheelchairs).
- The INTEGRASWITCH® mouthpiece may be covered with a section of LifeTool silicone tubing but this must not be used by persons who are liable to swallow objects of this kind.
- The INTEGRASWITCH® comes supplied with a latex membrane as standard. Anyone with a latex allergy can obtain latex-free membranes from INTEGRASWITCH® dealers³. The mouthpiece contains no latex.
- The INTEGRASWITCH® must not be used in combination with medical products of class IIa or higher (for example, with life-support machines).
- The INTEGRASWITCH® must not be used in rooms where flammable or explosive gases are used (for example, inhalation narcotics)⁴.
- Do not connect the INTEGRASWITCH® to an electrical current greater than 24 volts.

The manufacturer shall only be liable for the safety, reliability and performance of the INTEGRASWITCH® if:

- Assembly and use for the first time have been carried out in accordance with the instructions contained in this manual.
- No changes or repairs have been made to the product (other than those carried out by the manufacturer).
- The equipment is used with LifeTool accessories.
- The equipment is not used when one or more parts are damaged or defective.
- The equipment was mounted on a stand recommended by a LifeTool dealer.
- The INTEGRASWITCH® is used within the adjustable range of inhalation/exhalation intensity levels⁵.

¹ See also page 9: "Changing the mouthpiece membrane".

² See also page 9: "Re-balancing the pressure on the INTEGRASWITCH®".

³ An up to date list of all LifeTool dealers can be found on the Internet at <http://www.lifetool.at>.

⁴ e.g.: in operating theatres or intensive care wards which are usually required to have class P medical equipment or AFGs.

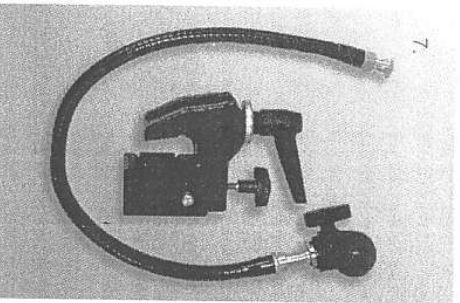
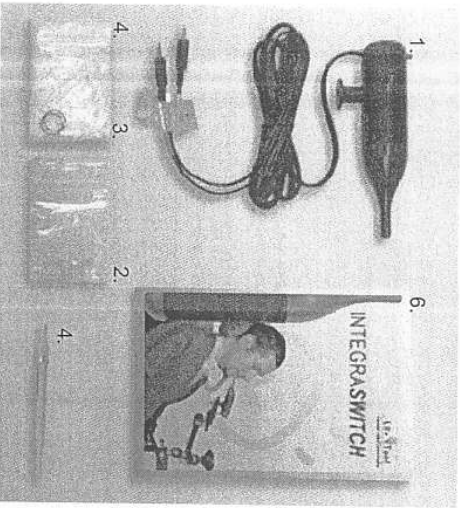
⁵ See also page 6: "Adjusting the INTEGRASWITCH®".

2. PARTS SUPPLIED

Please ensure that you have all the following parts.

The following component parts have been supplied to you:

1. 1 INTEGRASWITCH® with mouthpiece
2. 50 replacement membranes
3. 2 replacement sealing rings
4. 1 silicone tube
5. 1 adjustment screwdrivers
6. 1 manual
7. (optional) 1 stand or 1 flexible adapter



3. SHORT DESCRIPTION OF THE INTEGRASWITCH®

The INTEGRASWITCH® is a respiratory device for use in the field of rehabilitation technology and can be used for inhalation or exhalation, or for both. The levels of inhalation and exhalation intensity best suited to you can be adjusted independently of each other. Both functions can be utilised at the same time.

The INTEGRASWITCH® can be used in conjunction with programmable environment control systems, communication aids, adapted toys and with any equipment which is operated by a maximum of two push buttons and uses 3.5mm jack plugs.

4. SHORT INSTRUCTIONS FOR USING THE INTEGRASWITCH® FOR THE FIRST TIME

- Assemble the stand supplied or one recommended by your Life Tool dealer.
- Attach the INTEGRASWITCH® to the stand by screwing the attachment bracket on the base of the device into the socket on the stand until the device sits tightly in place. (Illustration 2)
- To avoid damaging the thread, do not screw the device in beyond the point where you feel it meets clear resistance.
- Place the INTEGRASWITCH® in a position that is comfortable for the person using it.

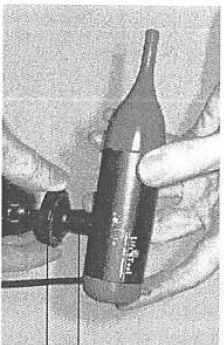


Illustration 2) Attaching the INTEGRASWITCH® to the stand

- Insert one of the two jack plugs (either for inhalation or exhalation) into the appropriate socket on the device.
- If you are using a device which can be operated with both impulses (inhalation and exhalation), insert the two jack plugs into their appropriate sockets on the device.
- Adjust the intensity of inhalation and exhalation to the level that best suits your needs.⁶

5. COMPONENT PARTS OF THE INTEGRASWITCH®

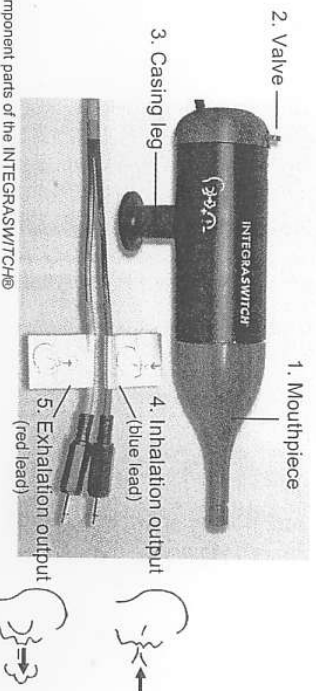


Illustration 3) Component parts of the INTEGRASWITCH®

⁶ See also page 6: "Adjusting the INTEGRASWITCH®".

The INTEGRASWITCH® comprises the following components:

1. Detachable mouthpiece⁷ with membrane and locking ring (a control device),
2. Casing leg for securing the device to the stand,
3. Adjustment screws for setting the appropriate level of inhalation and exhalation intensity,
4. Valve for ventilating the device after each change of mouthpiece,
5. Two jack plugs, one for connecting the exhalation switching contact, the other for the inhalation switching contact.

6. USING THE INTEGRASWITCH®

- You can use the INTEGRASWITCH® either when you are lying flat or in a sitting position.

! The INTEGRASWITCH® must not be attached to a wheelchair!

! In order to avoid accidental collision with the INTEGRASWITCH®, please ensure that:

1. the user first of all adopts a comfortable sitting or lying position
2. only then should the INTEGRASWITCH® be placed at the user's mouth in a position where it can be used without causing fatigue!

- Place the mouthpiece in your mouth only as far as the point where your teeth touch the groove in the mouthpiece and no further.
- If you prefer a soft surface on the mouthpiece, slide the supplied Life Tool silicone tube over the mouthpiece aperture till it is fully aligned with the aperture and sits securely.
- ! The silicone tube must only be used by persons who are in no danger of swallowing objects of this kind!

7. ADJUSTING THE INTEGRASWITCH®

The levels of inhalation and exhalation intensity can be adjusted independently of each other to suit individual needs by means of the adjustment screw situated on the respirator's casing.

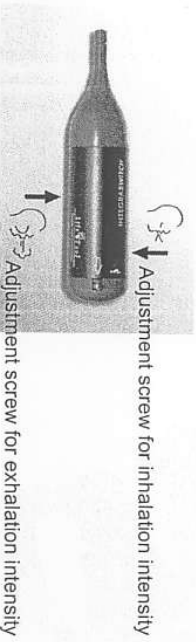


Illustration 4) Location of the respective adjustment screws

⁷ Bio-compatible material containing no latex.

! Only use the screwdriver supplied for setting the switching thresholds!

- Place the screwdriver in the adjustment screw head and change the inhalation or exhalation intensity to the desired level by turning the screw to the right or the left.
- Turn the screw to the right if less intensity is required.
- Turn the screw to the left if greater intensity is required.
- ! Only turn the respective adjustment screw to the point where you feel it meets resistance in any one direction!

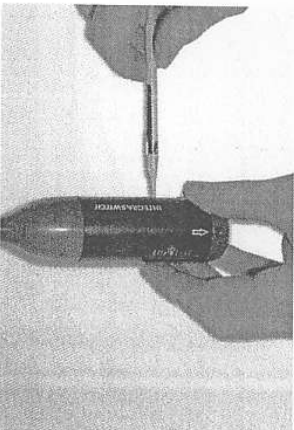


Illustration 5) Setting the desired inhalation level

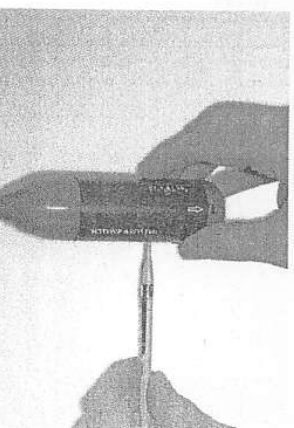


Illustration 6) Setting the desired exhalation level

8. HYGIENE REQUIREMENTS FOR USING THE MOUTHPIECE

A patented mouthpiece has been developed for hygienic use of the INTEGRASWITCH®. The mouthpiece should be cleaned/disinfected⁸

- before it is used for the first time,
- before every change of user.

If the INTEGRASWITCH® is in regular use we recommend that the mouthpiece be cleaned once a week.

Changing and cleaning the mouthpiece

⁸ If the silicone tube is used, it must be cleaned together with the mouthpiece.

- Hold the controlling device firmly in one hand and using the thumb and index finger of your other hand pull the mouthpiece from the INTEGRASWITCH® with a gentle twist (Illustration 6).

Illustration 7) Detaching the mouthpiece

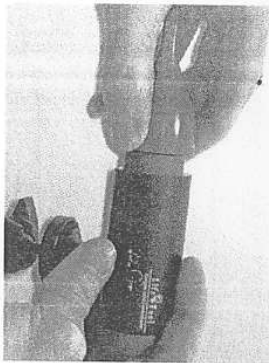
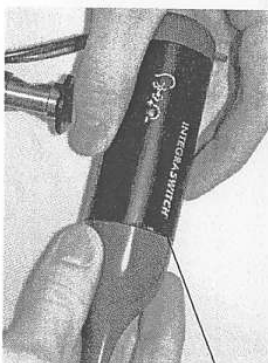


Illustration 8) Replacing the mouthpiece



Gap

- We recommend a change of membrane every time you clean the mouthpiece.
- For cleaning the mouthpiece it is recommended that a dishwasher be used. The mouthpiece should be placed, tip upwards, in the cutlery basket, or stuck onto one of the upright spikes on the tray. However the mouthpiece is placed, it is important to ensure that the water reaches the inner surfaces which have come into contact with saliva. The smaller detached parts (membrane and locking ring) should be placed in the cutlery basket. Using a dishwasher to clean the mouthpiece has practically no adverse affect on the mouthpiece's service life (unlike the effect of cleaning in boiling water).
- If you suspect there has been contact with germs (previous user has infectious disease and the germs have escaped with the saliva: e.g. suppurating in the area of the mouth), the mouthpiece must be disinfected before it can be used by another person. This is best achieved using boiling water (100 °C). The mouthpiece should be completely submerged in the boiling water for two to three minutes.⁹
 - 1 The mouthpiece must not be subjected to temperatures over 100 °C and is not designed for any form of sterilisation!
 - 1 No liquid must be allowed to penetrate the gap between the mouthpiece and the controlling device!
- Before using the cleaned mouthpiece again, ensure that it is completely dry and has cooled down to room temperature.
- Disinfecting the mouthpiece with chemical disinfectants is not recommended.
- After it has been cleaned and dried insert the mouthpiece back into the opening on the INTEGRASWITCH®.

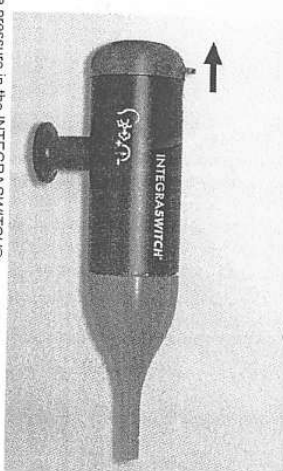
⁹ Note that over-frequent boiling can reduce the mouthpiece's service life.

- The mouthpiece is correctly inserted when there is a small gap left between the controlling device and the mouthpiece (0.3 to 0.4 mm) (Illustration 8).

Re-balancing the pressure on the INTEGRASWITCH®

- Press the valve – as shown in Illustration 9 – in the direction of the arrow and hold it in this position for one to seconds.

Illustration 9) Re-balancing the pressure in the INTEGRASWITCH®



Changing the mouthpiece membrane

If the device is used regularly the membrane should be changed once a week and in every instance where:

- the membrane is no longer airtight or has become porous,
- the membrane's surface is not taut and smooth,
- the colour of the membrane has changed.

1 To ensure that the inhalation/exhalation sensors function properly, only LifeTool membranes should be used!¹⁰

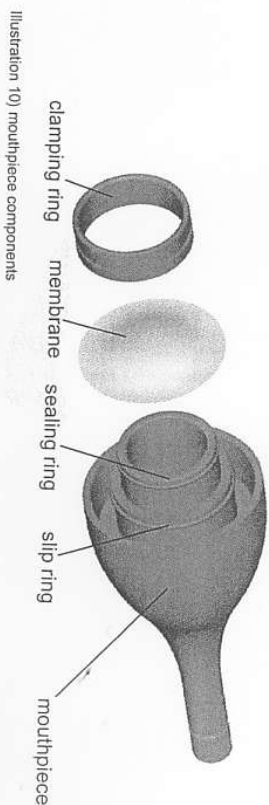


Illustration 10) mouthpiece components

¹⁰ Original membranes can be ordered from your LifeTool dealer

- To change the membrane squeeze the control ring between your thumb and index finger and pull it out of the mouthpiece with short twists to the left and right (Illustration 11).

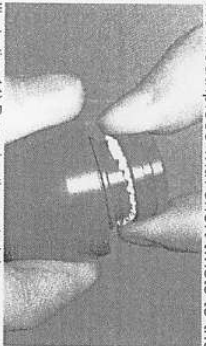


Illustration 11) Removing the control ring

- Place the new membrane on the centre of the mouthpiece and put the control ring back down over it as far as it will go.

To ensure that the membrane functions correctly, its edges must not protrude between the control ring and the mouthpiece! (Illustration 12 and 13)

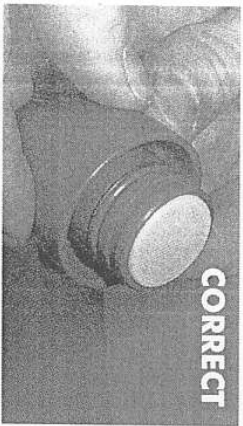


Illustration 12) Membrane correctly inserted

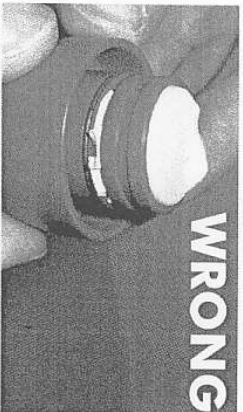


Illustration 13) Membrane wrongly inserted

- The sealing ring and the slip ring on the mouthpiece must be replaced once a year or immediately in the event of becoming damaged.

9. CONDITIONS FOR USE

- The INTEGRASWITCH® was not designed for use out of doors.
- The INTEGRASWITCH® will run perfectly in ambient temperatures of between +10 °C and +40 °C, in air pressure of between 700 and 1060 hPa and in relative humidity of between 30% and 75 %.
- Violent impact, vibration and dust can adversely affect the smooth running of the INTEGRASWITCH®.
- The INTEGRASWITCH® is a tested medical product which has been approved for use in the home, office or in comparable environments.

10. WHO TO TURN TO WITH TECHNICAL QUESTIONS ABOUT THE INTEGRASWITCH®?

Please refer any queries to an authorised LifeTool dealer¹¹, or to:

LifeTool GesbR
 Hafenstrasse 47-51
 A 4020 Linz
 Austria
 Tel: +43 (0)732 9015 5200
 Fax: +43 (0)732 9015 5201
 office@lifetool.at
 http://www.lifetool.at

11. TECHNICAL DATA AND KEY TO SYMBOLS

Safety class: 3, EN 60529/IP53
 Operable only with Safety Extra Low Voltage (SELV)

Weight: control device, total: approx. 140 g

Dimensions: total length: 160 mm

Control device diameter (without attachment bracket): 36 mm

Materials: device casing and attachment bracket: ALMGS1

Mouthpiece and cap: technical plastic "TECFORM AH MT red", tested for bio-compatibility pursuant to ISO 10993

Membrane: latex (latex-free membrane available as accessory)

Disposal: complies with current regulations for the disposal of electronic industry waste

Outputs: two floating switch outputs

Maximum contact rating per output: 24V/15mA DC

Key to symbols



Warning! Refer to manual or instructions for use

SN

Serial number

CE

Mark of conformity pursuant to EU Directive 93/42/EWG

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LifeTool GesbR
 Hafenstrasse 47-51
 A 4020 Linz
 Austria
 Tel: +43 (0)732 9015 5200
 Fax: +43 (0)732 9015 5201
 office@lifetool.at
 http://www.lifetool.at

The manufacturer of INTEGRASWITCH®

ARC Seibersdorf research GmbH
 A 2444 Seibersdorf
 Austria
 Tel: +43 (0)2622-69290-11
 Fax: +43 (0)2622 69290-24

¹¹ An up to date list of all LifeTool dealers can be found on the Internet at <http://www.lifetool.at>