

INSTRUCTIONS FOR USE (Version 1.0)

IntegraMouse® AIR

including accessories



CE

ENGLISH EN

For United Kingdom (UK)

DEAR CUSTOMER!

We are pleased that you have chosen a product from IntegraTools and use the IntegraMouse AIR as a high-quality input device for your computer or mobile devices. This user manual contains useful and important information to use the many configuration options of the IntegraMouse AIR. By installing the IntegraMouse Control settings app, you can take full advantage of all configuration options. Please read these instructions carefully before using the IntegraMouse AIR for the first time. If you have any questions, please do not hesitate to contact IntegraTools and your authorized IntegraMouse AIR dealer. We hope you enjoy your IntegraMouse AIR.

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Instructions for use IntegraMouse AIR Version 1.0, release date 01-2026, subject to technical changes.

The current version of this document can be found on the IntegraMouse website under www.integramouse.com



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1. CONTACT



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AUSTRIA



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2. INSTRUCTIONS FOR USE



Read these instructions for use in their entirety before first use and follow the instructions in the instructions for use. Be sure to save them for later use!



The exclamation mark symbol indicates warnings, i.e., if disregard leads to dangerous situations, for example.



The information icon is next to general hints and information.



The symbol with the Aesculapius snake provides information on specialist information, e.g., for medical staff or hospital operators.

Instructions for use valid for the device version "IntegraMouse AIR" and for accessories specified in these instructions for use.

3. INTENDED PURPOSE AND INTENDED USE

- The Integramouse AIR is a full-fledged computer mouse that is operated with the mouth and partly with the lips or chin. A gamepad mode and a keyboard mode are provided for the operation of games. The Integramouse AIR is used to compensate for or alleviate disabilities in which the person has a motor impairment of the upper extremities (e.g., quadriplegia) in order to operate a computer or mobile devices.
- With the Integramouse AIR, such people are able to operate a PC, notebook, tablet, smartphone or similar devices using only their mouths by slight movements of the lips or mouth, by sipping or puffing and lip buttons.
- Possible users are people with high spinal cord injury, with bilateral arm amputations or with progressive diseases such as muscular dystrophy, amyotrophic lateral sclerosis or multiple sclerosis.
- The Integramouse AIR can be used from the age of 3 years.
- The Integramouse AIR is not intended to diagnose, cure, monitor, predict or predict any disease or disability. The Integramouse AIR is not life-sustaining or life-supporting.

4. GENERAL INFORMATION ABOUT THE INTEGRAMOUSE AIR

The Integramouse AIR is a medical device according to the EU Medical Device Regulation MDR (EU) 2017/745 Article 2 (1). It complies with the European regulations and harmonized standards that form the basis of the Medical Device Regulation (MDR) and is therefore CE marked. For details, please refer to the **Chapter 18 „Declaration“**.

Integramouse AIR is connected to the end device via USB cable and is plug-and-play, i.e., it is recognized and installed there fully automatically as a Human Interface Device (HID). The power supply is also via the USB cable. Alternatively, the Integramouse AIR can also communicate wirelessly via Bluetooth Low Energy (BLE). This is particularly suitable for mobile devices such as smartphones or tablets. The power supply is either via the built-in battery or a power supply included in the scope of delivery. The optional Integramouse AIR settings app *Integramouse Control* can be used to make individual adjustments and activate advanced functions.

Integramouse AIR is mainly designed to be used in dry rooms on a PC, laptop, smartphone or tablet. These include residential spaces, clinics, rehabilitation centres, institutes, schools, universities and the like. However, it is also possible to use it outdoors in dry areas, e.g., on terraces. The ambient temperatures during application must be between 0°C and 40°C.

The position of the Integramouse AIR must not change during use (tilt, etc.). In addition, no external forces must act on the Integramouse AIR (e.g., accelerations).

The mouthpiece and lip buttons are interchangeable. In the clinic area, only the single use of the mouthpiece and lip buttons per user is permitted. This ensures hygiene and cleanliness. This also applies when used by several users (for example in public facilities) or when used in clinics and rehabilitation centres, where there is a risk of infection by infectious or more

resistant germs. Cleaning is required in accordance with **Chapter 10 „Hygiene, maintenance and inspection“**, on a regular basis.

5. SAFETY



As with any medical device, a few things must be taken into account with the IntegraMouse AIR for safe, friction-free handling:

- Use the appliance only for its intended use in accordance with these instructions for use. Any use other than this is improper and can lead to dangerous situations. The manufacturer cannot be held responsible for damage caused by improper or incorrect use.
- Good head control and oral motor skills are prerequisites for operating the IntegraMouse AIR. Therefore, the IntegraMouse AIR must not be used in people who suffer from uncontrolled spasms, Tourette's syndrome or epilepsy, for example.
- Only connect the device to power sources as described in the instructions for use. Otherwise, hazards can arise.
- Do not expose the device to extreme temperatures and avoid direct sunlight. This can damage the built-in battery in particular. Do not expose the device to vibrations (bumping, dropping) and protect it from dirt and moisture. If the device has nevertheless been exposed to these influences, you should have it tested by your contractual partner for safety and usability.
- If you do not use the appliance for a long time, switch off the appliance and store it accordingly **Chapter 12 "Ambient conditions"**.
- Operation in the range of strong electromagnetic fields can lead to malfunctions of the device.
- The device must not be opened by the user, which means that the manufacturer's warranty does not apply. Repairs may only be carried out by the manufacturer or authorized partners. In particular, the incorrect handling of the internal battery can lead to hazards.
- People with high salivation are not allowed to use the IntegraMouse AIR.
- The IntegraMouse AIR in combination with the attached IntegraMouse AIR silicone attachment may only be used by persons who are not at risk of swallowing such objects.
- The IntegraMouse AIR must not be used on moving systems (e.g., wheelchair) or on systems with a change of position (e.g., change of inclination).
- The IntegraMouse AIR must not be used to operate life-sustaining or safety-relevant devices such as emergency call systems, medicationdosing devices, medical expert systems, etc.
- The IntegraMouse AIR is not suitable for controlling vehicles, such as electric wheelchairs.
- Children under 3 years of age are not allowed to use the IntegraMouse AIR.
- The IntegraMouse AIR must not be used in conjunction with RF surgery devices or defibrillators.

- A combination with devices other than those described in **Chapter 11 "Acceptable system"** is not permitted. Any other combination with medical devices or other products will result in the system integrator becoming the system manufacturer and taking responsibility for the product combination.
- In the case of highly infectious diseases, the mouthpiece and lip buttons may only be used for single use. The replacement intervals for the mouthpiece and lip buttons in medical facilities must be determined by an expert staff or doctor.
- Take regular breaks when working on the computer. Physical fatigue can lead to eye pain, neck stiffness and similar accompanying symptoms. A ten-minute break per hour of working time is recommended.
- The device must not be used in an environment enriched with oxygen or other flammable gases.

6. SCOPE OF DELIVERY



After opening the packaging, please check the delivery for completeness and whether the IntegraMouse AIR or accessories are damaged or defective. If this is the case, please contact your specialist dealer immediately.

Illustration 1: IntegraMouse AIR in transport case

Quantity	Designation
1	IntegraMouse AIR
2	Standard mouthpiece, membrane included
2 Sets	Caps for lip buttons with 4 different lengths
1	USB cable
1	Power supply
24	Replacement membrane
2	Silicone attachment
1	Replacement O-ring
1	USB-A to USB-C adapter
1	Cleaning brush
1	Quick Guide

7. PRODUCT

7.1 Components and Controls



Illustration 2: Top and bottom



Illustration 3: Back



Illustration 4: Mouthpiece with membrane



All controls are latex-free and free of toxic ingredients (e.g., PFAS).

7.2 Accessories and Spare Parts



An overview of the technical data can be found in Chapter 16 „Product and performance data“.

IntegraMouse AIR Mouthpiece

The mouthpiece is in direct contact with the user's lips and thus represents the application part. The mouthpiece is removable, so it can be replaced or cleaned separately.

IntegraMouse AIR Silicone Attachment

If you prefer a soft surface on the mouthpiece, the silicone attachment can be attached to the mouthpiece. This can make it more pleasant to use. The silicone attachment is in direct contact with the user's lips and thus represents the application part. The silicone attachment is removable, so it can be replaced or cleaned separately. Please note the instructions for the safe use of the silicone attachment in **Chapter 8.6 "How to use the silicone attachment"**.

IntegraMouse AIR Lip Buttons

The lip buttons are in direct contact with the lips of the user and thus represent the application part. The lip button caps are available in different lengths and are removable, so they can be replaced or cleaned separately.

The IntegraMouse AIR comes with pre-installed lip buttons (standard length 17,6 mm). The scope of delivery includes additional keycaps to extend or shorten the lip keys by 5mm.

The caps can be easily removed and clipped on. For lateral positioning, it may be useful to use keycaps of different lengths.



The very short keycaps can be used when the lip keys are a hindrance and are only activated by assisting persons.



The application parts "mouthpiece", "lip buttons" and "silicone attachment" are type B.

IntegraMouse AIR Power Supply

The power supply is used to charge the battery and also to supply power to the IntegraMouse AIR in wireless mode. For safe operation, use only the power supply supplied or specified in **Chapter 16 "Product and performance data"**!

IntegraMouse AIR USB cable, including adapter USB-A to USB-C

The USB cable is used to connect the IntegraMouse AIR to the end device in wired mode or the power adapter. The internal battery of the IntegraMouse AIR is charged at the same time.

For safe operation, only use the USB cable supplied or specified in **Chapter 16 "Product and performance data"**! To connect to a USB-C port, please use the included adapter.

IntegraMouse AIR Sealing Ring

The sealing ring closes the mouthpiece from the holder (pressure chamber) and is responsible for the friction-free function of the clicks. Check the fit of the ring regularly and replace it if necessary (in case of wear, cracks, etc.).

IntegraMouse AIR Membrane

The membrane acts as a mechanical protective barrier for saliva or other liquids towards the electronics. The membrane must be replaced every time the mouthpiece is cleaned or replaced (disposable part).

IntegraMouse AIR Cleaning Brush

The cleaning brush has a diameter of 8 mm and is used to remove stubborn dirt from the mouthpiece.

IntegraMouse AIR Mounting System



The mounting system is used to attach the IntegraMouse AIR in the desired working position. The bracket can be mounted on a table or bed, for example.

Not included – Contact IntegraTools or your IntegraMouse AIR dealer to select a suitable mounting system and for more information.

Illustration 5: Mounting system with friction arm



Please note that the IntegraMouse AIR with the mounting system must not be mounted on moving systems. The IntegraMouse AIR with the mounting system may only be mounted on a wheelchair when it is switched off or with the brakes activated. There is a risk of injury when moving, e.g., in collisions with obstacles such as door thresholds, kerbs, etc.

IntegraMouse Control

The optional *IntegraMouse Control* app can be used to make individual adjustments and activate advanced functions. The app can be downloaded free of charge from www.integramouse.com.



Illustration 6: Screenshot *IntegraMouse Control*



The *IntegraMouse Control* app not only allows the individualization of basic parameters (e.g., sensitivity of clicks), but also the activation of new functions that would not be available without the app (e.g., scroll function).

IntegraMouse AIR Packages

The following items are available as packages on request:

IntegraComplete PowerUser

Composed of:

- 2 mouthpieces
- 52 membranes
- 2 lip button sets (all sizes)
- 100 cleaning and disinfecting wipes
- 1 sealing ring
- 2 silicone attachments for the mouthpiece
- 1 cleaning brush
- 1 free screen cleaner

IntegraComplete Medical

Composed of:

- 12 mouthpieces
- 52 membranes
- 12 lip button sets (all sizes)
- 100 cleaning and disinfecting wipes
- 2 sealing rings
- 12 silicone tips for the mouthpiece
- 1 cleaning brush
- 1 free screen cleaner

8. COMMISSIONING

8.1 Quick start guide to getting started

- Install the mounting system recommended by IntegraTools or your IntegraMouse AIR dealer at the desired workstation.
- Check that the sealing ring is correctly seated in the mouthpiece holder.
- Attach a membrane to the mouthpiece or check the membrane for a good fit and any damage.
- Attach the mouthpiece with membrane to the IntegraMouse AIR – note the small pin on the mouthpiece and the guide groove in the holder. At the end, turn the mouthpiece to the left with light pressure until it clicks into place (bayonet lock).
- Mount the IntegraMouse AIR on the mounting system (1/4" thread).
- Bring the device into a comfortable working position.
- For the first commissioning, we recommend wired operation to ensure that the built-in battery is charged. To do this, connect the IntegraMouse AIR to your computer using the included USB cable.
- Turn on the IntegraMouse AIR by briefly pressing the right lip button, the calibration process is indicated by the LEDs lighting up.
- Your computer's operating system automatically detects and installs the IntegraMouse AIR as the default mouse.
- After the installation is complete, the IntegraMouse AIR is ready for use.



The mouthpiece of the IntegraMouse AIR must not be touched during calibration!



More detailed information on commissioning and use can be found in the Quick Guide. In addition, you can watch training videos on www.youtube.com operation (enter keyword "IntegraMouse").

8.2 General Installation Instructions

The IntegraMouse AIR can be connected via a USB cable or Bluetooth Low Energy (BLE). No additional drivers are required for installation (plug and play). Supported operating systems are Windows from Win11, macOS from OS 12, Android from version 14, iOS from iOS15 and Linux. The IntegraMouse AIR is automatically recognized as a standard mouse, keyboard and gamepad. If the cable is connected, the microphone of the IntegraMouse AIR is also installed.

The installation process usually runs in the background (depending on the operating system). The IntegraMouse AIR is thus ready for use after a short time.

Mounting the IntegraMouse AIR and components

Install the mounting system recommended by IntegraTools or your IntegraMouse AIR dealer at the desired workstation. Attach the IntegraMouse AIR to the underside via the threaded socket (1/4" thread) and then bring the IntegraMouse AIR to the desired working position.



Illustration 7: Mounting the IntegraMouse AIR



Do not use the IntegraMouse AIR on mobile or moving systems! Make sure that the IntegraMouse AIR is placed in front of your face in such a way that no danger can arise, e.g., from a third person. Also pay attention to careful routing of existing cables.



To avoid collisions with the IntegraMouse AIR, make sure that you first adopt an ergonomic sitting and working posture in front of the screen and only then bring the IntegraMouse AIR in front of your mouth into a fatigue-free working position. Make sure you have enough space to work and a good view of the screen. Also consider your position in relation to sources of interference, e.g., sunlight. Lack of ergonomics can lead to eye pain, headaches or muscletension.



The IntegraMouse AIR can also be used in an inclined or lying position. It is important to stress that the calibration should be done after the working position has been set up. By pressing the right lip button for 3 seconds, you can recalibrate the position at any time.

8.3 Turn on and activate

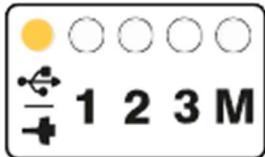
First of all, a distinction must be made between the operating mode in which you want to operate the IntegraMouse AIR:

- Cable connection, i.e., plugged directly via USB cable
- Bluetooth connection (Bluetooth Low Energy - BLE), e.g., with mobile devices

In total, the IntegraMouse AIR can be connected to up to four devices.

a) IntegraMouse AIR in wired operation

1. Connect the IntegraMouse AIR to your device using the included USB cable. If necessary, use the included USB-A to USB-C adapter.
2. Turn on the IntegraMouse AIR by briefly pressing the right lip button. The calibration process is indicated by a brief flashing of all LEDs.
3. If necessary, press the left lip button briefly to switch to the cable connection (the left LED  is orange).

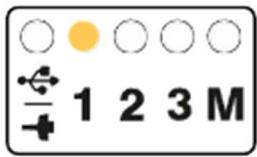


In the case of mobile devices such as tablets or smartphones, operation via cable connection may only work to a limited extent or not at all due to the energy requirements of the IntegraMouse AIR. The use of appropriate adapters or an active USB HUB, which ensures simultaneous charging of the mobile device, can remedy this.

b) Use IntegraMouse AIR with Bluetooth connection

The IntegraMouse AIR can be connected to up to three devices via Bluetooth (BLE).

1. Turn on the IntegraMouse AIR.
2. Press the left lip button for 3 seconds until the LED 1 starts flashing orange.
3. Short press the left lip button to select the desired channel (LED 1, 2 or 3).
4. Wait a few seconds for the chosen LED to start flashing blue.
5. Open the Bluetooth settings on the desired device (e.g., smartphone, tablet, ...) and select "IMAIR x" from the list of available devices, where x stands for the chosen channel.
6. Confirm the pairing request. The LED stops flashing and lights up orange – the IntegraMouse AIR is ready for use (e.g., here: LED 1)



Make sure that the battery of the IntegraMouse AIR has enough charge for Bluetooth connection. You can find more information about the charge level indicator in Chapter 10.3 "Charging the battery".

Delete an existing Bluetooth connection

To delete a Bluetooth connection, start the pairing process as described above. Switch to the channel you want to delete (LED 1, 2, or 3). Wait for the LED to stop flashing blue on its own (about 30 seconds). The connection is now deleted.



Attention: The device whose connection is to be deleted must not be nearby. Remove it from range or disable its Bluetooth connection.

Charging IntegraMouse AIR

- Use only the included power supply and the included USB cable to charge the IntegraMouse AIR.
- While charging, the rear LED flashes green. (Attention: The LED goes out when there is inactivity.)
- If the charging LED is solid green, the battery is fully charged. (Attention: The LED goes out when there is inactivity.)
- The IntegraMouse AIR is also charged when connected to a terminal device via cable.



When the Bluetooth connection is active, an orange flashing LED (1, 2 or 3) indicates that the battery level is low. In this case, connect the IntegraMouse AIR to the power adapter or a device.

8.4 Calibration

Automatic calibration

Automatic calibration always takes place after the IntegraMouse AIR is switched on and at regular intervals during operation.

Manual calibration

Sometimes it can be useful to trigger a calibration manually, e.g., after changing the mouthpiece or after changing position.

To trigger manual calibration, press the right lip button for 3 seconds until all LEDs start flashing.



Do not change the position of the IntegraMouse AIR or touch the mouthpiece during the calibration process. This could lead to incorrect calibration values and thus to a malfunction of the IntegraMouse AIR and make a recalibration necessary.

8.5 Lip button customization

The IntegraMouse AIR comes with pre-installed lip buttons (standard length 65 mm). The scope of delivery includes additional keycaps to extend or shorten the lip keys by 5mm.

The caps can be easily removed and clipped on. If positioned at an angle, it may make sense to use keycaps of different lengths.



The very short keycaps can be used when the lip keys are a hindrance and are only activated by assisting persons.

8.6 How to use the silicone attachment



If you prefer a softer surface on the mouthpiece, slide the enclosed silicone attachment over the mouthpiece tip (at least 5 mm beyond the groove). After applying the silicone attachment, perform a calibration. Check regularly whether the silicone attachment is still fully connected and correct the position if necessary.

Illustration 8: Mouthpiece with silicone attachment



Never use any other than the original silicone attachment and always make sure that the silicone attachment is firmly seated on the mouthpiece! Only put the mouthpiece in your mouth so that your lips and teeth do not protrude beyond the silicone attachment.



The silicone attachment may only be used by those persons who are unlikely to be in danger of swallowing such objects! Suffocation!

9. APPLICATION AND FUNCTIONALITY

The IntegraMouse AIR is an input device for your computer and mobile devices such as smartphones or tablets. The input device works as a computer mouse (mouse mode), optionally also as a keyboard (keyboard mode) or as a gamepad (gamepad mode). Movements of the mouthpiece through the mouth are recorded by a sensor. A slight deflection of the mouthpiece is sufficient to make the control part respond. In addition to movement, pressure changes on the mouthpiece – "sipping" and "puffing" – are also used for input (e.g., left and right mouse clicks).



Always insert the mouthpiece into your mouth only as far as your teeth reach the groove on the mouthpiece! If you have attached the silicone attachment, make sure it fits well and only put the mouthpiece in your mouth so that your lips and teeth do not protrude beyond the silicone attachment.

9.1 Turning on the IntegraMouse AIR

The IntegraMouse AIR can be turned on by briefly pressing the right lip button.

When switched on, the IntegraMouse AIR is calibrated, all LED indicators light up in the possible colors. The IntegraMouse AIR is then in mouse mode in the last device connection used.



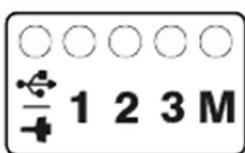
The IntegraMouse AIR must not be moved or the mouthpiece touched during calibration!



You can also detect possible defective LEDs when switching through the different colors if they do not light up.

9.2 Three operating modes: mouse – keyboard – gamepad

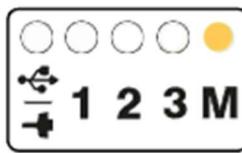
The active operating mode is indicated by the different colors of the right LED ("M") on the top of the IntegraMouse AIR. In keyboard mode, the LED glows blue, in gamepad mode orange. If the LED does not light up when switched on, mouse mode is active.



Mouse



Keyboard



Gamepad



After switching on, the IntegraMouse AIR is always automatically in mouse mode.



If there are problems with the different operating modes or if they are not needed, they can be deactivated in the *IntegraMouse Control* app.

Mouse Mode

Slight deflections of the mouthpiece allow the mouse cursor to move accordingly on the screen. Like an ordinary computer mouse, it can be moved continuously and dynamically, from very slow to very fast across the screen and positioned with pixel precision. To control the mouse cursor, place the mouthpiece between your lips and press it with lip movements in the desired direction in which you want the mouse pointer to move across the screen.

The mouse buttons are made by slight pressure changes in the oral cavity - "sipping" and "puffing". In the standard setting, a short sip at the mouthpiece opening triggers the left mouse button and a short puff into the mouthpiece opening triggers the right mouse button.

Two short sips cause a double-click with the left mouse button. The short sip and holding the pressure allow objects to be dragged and dropped across the screen.



Certain properties of the mouse functions, e.g., the pointer speed or the assignment of clicks, can be individually adjusted via the *IntegraMouse Control* app. You can download the app from the IntegraMouse homepage www.integramouse.com for free. The advantage of using the settings app over changes via the operating system is that all settings made are stored in the IntegraMouse AIR and are available on all devices used.



If it is not possible to trigger the mouse clicks via sipping and puffing, additional external sensors can be used, which are connected to the rear 3.5mm stereo jack. Another alternative can be the use of auto-click software. Your IntegraMouse AIR dealer will be happy to advise you on this.



In order to be able to operate a full-fledged keyboard, e.g., to enter letters or entire texts, to compose e-mails..., the operating system of your computer usually provides an on-screen keyboard.

Keyboard Mode

The keyboard mode allows the operation of computer games and programs, which can be controlled with the arrow keys or keys WASD, the space bar and the enter key. The four directions are triggered by the movement on the mouthpiece. The space bar and the enter key are available via sipping and puffing. The activated keyboard mode is indicated by the blue glow of the LED 5 (M).



By default, the cursor keys are output in keyboard mode. Use the *IntegraMouse Control* app to change the assignment to WASD.



The keyboard mode is also very suitable for scrolling in documents or on web pages.

Gamepad mode

The gamepad mode allows the operation of computer games, which can be controlled with a Windows gaming joystick with 2 buttons. The movement of the mouthpiece causes the analog deflection of the joystick. The movement can be performed dynamically from slow (low deflection) to fast (stronger deflection). Sip and puff correspond to gamepad buttons 1 and 2. The activated gamepad mode is indicated by the orange glow of the LED 5 (M).



Further settings of the gamepad can be individually adjusted in the *IntegraMouse Control* app.



Additional adapters may be required to use gamepad mode on devices without a Windows operating system. For complex games, it is recommended to combine it with additional gaming hardware such as the XBOX Adaptive Controller.

Switching between modes

After switching on, the IntegraMouse AIR is in mouse mode by default. To switch modes, you can:

- Short press the right lip button
- By connecting and using an external sensor

The modes are switched through one after the other.

Overview of the basic functions

The standard assignments in the respective modes can be found in the following table

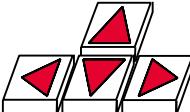
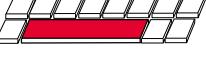
	Mouse	Keyboard	Gamepad
Moving the mouthpiece up Moving the mouthpiece down Moving the mouthpiece to the left Moving the mouthpiece to the right			
Sip	Left-click 	Learning 	Button 1 
Puff	Right-click 	Enter-taste 	Button 2 

Illustration 9: Standard assignment of the basic functions in the different modes

9.3 Microphone

The IntegraMouse AIR has a microphone on the underside that can be used for voice assistance and dictation functions. The microphone is automatically logged in to the operating system when the IntegraMouse AIR is connected with a cable.



The microphone can only be used with the device that is connected to the IntegraMouse AIR via cable.



If you have problems with the microphone and especially if you don't want to use the microphone, you can deactivate it in the *IntegraMouse Control* app.

9.4 Power saving mode of the IntegraMouse AIR

To save battery power, the IntegraMouse AIR has a built-in power saving mode. The power saving mode is automatically exited when:

- the mouthpiece is moved or a lip button is pressed briefly.
- a live USB cable is plugged in.



In principle, the energy-saving mode is not noticeable to the user, as the IntegraMouse AIR activates immediately when it is used again. Attention: only when moving the mouthpiece or pressing a lip button, but not when sipping or puffing.



The energy-saving mode also requires energy from the battery. If you no longer need the Integramouse AIR or do not use it for a long time, turn it off completely.



To additionally save energy, you can also manage the luminosity and burn time of the LEDs in the *Integramouse Control* app. This can also be useful if the LEDs are annoying, e.g., in dark environments.

9.5 Turning off the Integramouse AIR

The Integramouse AIR can be turned off by pressing the right lip button for at least 6 seconds. All LEDs on the Integramouse AIR go out.



The Integramouse AIR switches off automatically if the battery level is too low. When switched off, no more energy is drawn from the battery.

10. HYGIENE, MAINTENANCE AND INSPECTION

To ensure a long and safe operation of the Integramouse AIR, the following activities are required:

- Regular cleaning and regular replacement of the mouthpiece (and silicone attachment – if used)
- Regular control and change of the membrane
- Regular inspection of the sealing ring
- Regular cleaning and regular change of lip buttons
- Regular cleaning of the device and the mounting system
- Regular, proper charging of the battery in Bluetooth mode
- Regular inspection (visual inspection) and maintenance
- And a general careful handling of the individual components

The individual points are described in more detail below.



If you have any faults or problems with the Integramouse AIR, do not attempt to repair the product or any of its accessories. This can void the warranty claim and cause serious damage to the device. Always contact the manufacturer or your specialist dealer.



The service life of the Integramouse AIR is defined by the manufacturer as 5 years (from the date of manufacture – see serial number of the device). After that, no service can be guaranteed.

10.1 Cleaning the mouthpiece, silicone attachment and lip buttons

The IntegraMouse AIR comes with two mouthpieces, 2 silicone attachments and also the keycaps for the lip buttons in double numbers and 4 different lengths to enable regular cleaning with undisturbed operation.



The replacement and subsequent cleaning of the mouthpiece, the silicone attachment and the keycaps must be carried out about once every 2 weeks in the area of home use. If during intensive use of the IntegraMouse AIR the LED to the left with the mouthpiece symbol starts flashing, the cleaning of the mouthpiece and lip switches must be carried out earlier. In case of heavy soiling or in case of illness, more frequent cleaning is recommended. The membrane is intended for single use only and must not be cleaned or reused, as this endangers the membrane tightness.



The IntegraMouse AIR has a cleaning reminder function, which is indicated by a flashing LED with the mouthpiece symbol (LED on the far left). The LED will not stop flashing until the cleaning/change is confirmed by pressing both lip buttons at the same time for 3 seconds.



If damage or signs of wear are visible on the mouthpiece, silicone attachment or keycaps, please replace them immediately.



After each mouthpiece change, calibrate by pressing the right lip button for 3 seconds until all LEDs are lit.

For thorough cleaning, disinfection with hot steam (**steam sterilization**) is recommended. Proceed as follows:

1. Turn the mouthpiece to the right and pull it forward in a straight motion.
2. Remove the membrane by peeling it off the mouthpiece and discard it (single-use product).
3. If you are using the silicone attachment: Pull the silicone attachment off the mouthpiece.
4. Pull the keycaps off the lip keys in a straight motion.
5. Carefully insert the mouthpiece, keycaps and silicone attachment into a steam sterilizer (e.g., Philips Avent SCF291/00 or a comparable device) in a vertical position. Use attachment aids for the mouthpiece and the silicone attachment, e.g., a draining rack.
6. Make sure that all parts are completely accessible to the water vapour.
7. Leave the parts in the steam sterilizer for at least 10 minutes, ideally 15 minutes.
8. Remove the parts with an aid (e.g., plastic pliers) and let them drain and dry on a clean surface.

9. In case of heavy soiling, it is necessary to clean the inside of the mouthpiece with a cleaning brush. The brush removes any remaining residue after steam sterilization. Please clean the brush after use.
10. Before using the cleaned mouthpiece, silicone attachment, and keycaps, make sure they are completely dry and cooled to room temperature.
11. Any limescale residues can be removed with a soft cloth.
12. After drying and cooling, put a new membrane onto the mouthpiece. Make sure that the membrane is completely attached to the mouthpiece.
13. If you are using the silicone attachment: Put the silicone attachment onto the mouthpiece (at least 5 mm above the groove on the mouthpiece).
14. Check the fit of the black sealing ring (O-ring) in the mouthpiece holder.
15. Carefully insert the mouthpiece into the mouthpiece holder, note the guide groove and the spigot, and turn the mouthpiece to the left at the end.
16. Put the keycaps back on the lip buttons.

Alternatively, the mouthpiece, keycaps and silicone attachment can also be boiled in a saucepan with water:

1. Bring water to a boil
2. Prepare components as described above and add to the saucepan with a spoon.
3. Make sure that all components are completely covered with water and do not have any air enclosures.
4. Leave the components in the boiling water for at least 5 minutes.
5. Then carefully remove all components from the water with a spoon and drain on a clean surface and let dry.
6. Follow the further instructions as described above (steps 9 to 15)



Caution! Risk of scalding due to the hot steam! Please also observe the safety instructions of the respective steam sterilizer you are using.



A final disposal of the mouthpiece, the silicone attachment and the keycaps is recommended for home use after a maximum of 6 months.



In the clinical field, it is highly recommended to use the mouthpiece, membrane, silicone attachment and keycaps as disposable products! The change intervals must be determined by a doctor or expert staff (nurses, hygiene officers, ...)! Special safety precautions must be taken into account if contagious diseases are suspected.



In the clinical area, the use of the same mouthpiece, membrane, silicone attachment and keycaps by several users is prohibited.



The mouthpiece, silicone attachment, keycaps or other components of the IntegraMouse AIR are not designed for any form of steam sterilization above 134°C, also not for gamma sterilization, for example.

10.2 Cleaning the device

Clean the device and the mounting system regularly, about once every two weeks. The housing of the IntegraMouse AIR, the power supply and cable and the mounting system can be cleaned at any time with a slightly damp, lint-free cloth or cleaning cloth by wiping.



Never use harsh detergents to clean the components, this could destroy the surface! The IntegraMouse AIR contains sensitive electronics, never immerse them in water and do not use running water for cleaning, otherwise you could damage or destroy the device!

Wipe disinfection



In the clinical field, it is necessary to regularly carry out wipe disinfection on the device. The disinfection intervals must be determined by a doctor or expert staff (nurses, hygiene officers, ...)! Special safety precautions must be taken into account if contagious diseases are suspected.

The IntegraMouse AIR can be disinfected with any surface disinfectant suitable for disinfecting LEXAN polycarbonate. Under no circumstances should the body of the IntegraMouse AIR be subjected to steam or wet sterilization (with the exception of the mouthpiece, the silicone attachment and the lip button caps).

The following cleaning agents can be used, for example:

- Mikrozid Sensitive Liquid or Mikrozid Sensitive Wipes from Schülke & Mayr GmbH (www.schuelke.com)
- Alcohol Preps from Romed Netherlands



Carry out the wipe disinfection according to the manufacturer's instructions and make sure that no moisture penetrates the IntegraMouse AIR!

What to do if the pressure chamber is contaminated

If a mouthpiece without a membrane was accidentally used with the IntegraMouse AIR, or if it was discovered after use that the membrane was torn or otherwise leaking, the mouthpiece holder/pressure chamber and pressure sensor may have been contaminated with germs.



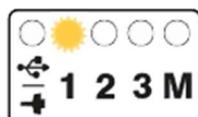
In this case, in home use, wipe down the pressure chamber with disinfectant! To do this, use a cotton swab and one of the cleaning agents recommended above.



In clinical settings, if the pressure chamber and pressure sensor become contaminated, these components must be replaced! Please discontinue use of the IntegraMouse AIR and return it to the manufacturer immediately!

10.3 Charging the battery

Battery level indicator



LEDs 1 to 3 on the top of the IntegraMouse AIR indicate the current Bluetooth connection with an orange glow. An orange flashing of these LEDs (here: LED 1) during normal operation indicates a low battery charge level, in which case charge the IntegraMouse AIR promptly.

Charging

The battery is charged via the included power adapter or via the USB cable when connected. In both cases, use the USB-C socket on the back of the IntegraMouse AIR. Charging starts immediately after plugging in and takes 2 to 2.5 hours. The status of the process can be seen via the charging LED on the back of the IntegraMouse AIR:

Charging LED is off.	Battery won't charge.
Charging LED flashes grün.	Battery is charging.
Charging LED is solid green.	Battery is full.



The charging LED behaves like the other LEDs on the top; that is, it turns off depending on the setting, even when the battery is charging. Press one of the lip buttons to activate the charging LED.



Only use the included medical power adapter and the included USB cable to charge or operate the IntegraMouse AIR! Even if you have another power adapter (e.g., from tablets) available, you must not use it with the IntegraMouse AIR!



Never change the battery yourself! If you suspect a battery problem, contact the manufacturer or an IntegraMouse AIR dealer.

10.4 Metrological review

Every medical device – especially when used in a clinical environment – should be regularly checked for safety. The periodic safety inspection – at a maximum of 24 months – can be carried out either by the operator, by authorised service providers or by the manufacturer, e.g., in Austria and Germany, in accordance with the Medical Devices Operator Ordinance and the relevant standards (e.g., EN 62353:2015). The responsibility for compliance lies with the operator of the IntegraMouse AIR.

11. ACCEPTABLE SYSTEM

The IntegraMouse AIR is intended to serve as an input device for a computer (PC or notebook) or mobile device such as a tablet or smartphone. Please use only the supplied USB cable or use the Bluetooth connection (BLE). Make sure that your end devices and all other devices connected to them (printers, etc.) comply with the relevant regulations (EN 62368-1, which replaces EN 60950-1 since 20.12.2020).



In rooms used for medical purposes, the protective provisions are to be observed in accordance with the patient environment. The patient area will be defined 1.5 meters around the user. Within this area, only medical devices may be used. The IntegraMouse AIR and its accessories are medical devices. The computer is usually an office device, but it can also be a special medical computer. There are the following options for implementation:

1. Computers inside the patient area
 - o Medical computer according to EN 60601-1 and EN 60601-1-2
 - o Computer according to EN 62368-1, if necessary, with limitation of the contact current by using an additional protective earthing or an isolating transformer
2. Computers outside the patient area
 - o Using Bluetooth Mode and Ensuring Patient Environment Compliance
 - o Computer according to EN 62368-1, if necessary, with limitation of the contact current by using an isolating transformer

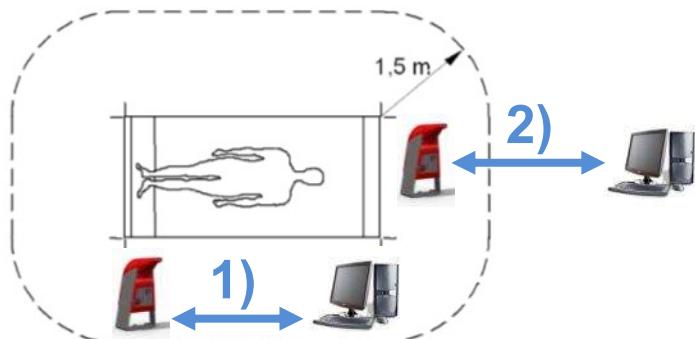


Illustration 10: Definition of the patient area according to EN 60601-1. Computers inside the patient area (1), and computers outside the patient area (2)



The operator connecting the IntegraMouse AIR to the computer must comply with the provisions of EN 60601-1 and the relevant laws and standards for electrical installations. If a connection is made with devices outside the same medically used room, it may be necessary to integrate a separation device into the data line.



A combination with devices other than those defined above does not comply with the conformity intended by the manufacturer. The system integrator must reassess the conformity on its own responsibility.

External sensors

The built-in 3.5mm stereo jack socket on the back of the IntegraMouse AIR can be used to connect suitable sensors, which can be assigned the functions of the two lip buttons or the click functions ("sip" and "puff").

Standard assignment one sensor	Right lip button
Standard assignment of two sensors	Right/Left Lip Button



A splitter cable is required for the connection of 2 sensors (available as a separate accessory).



The assignment of the functions can be changed via the *IntegraMouse Control* app.



Only potential-free sensors may be used. Ask the manufacturer or your IntegraMouse AIR dealer for more information.

Other medical devices in the patient sector

In principle, it is possible to use other medical devices in the patient area that are not directly coupled with the IntegraMouse AIR (e.g., ECG, ventilators). In any case, follow the instructions for use of the other medical device and follow the protective distances from **Chapter 17 "Electromagnetic compatibility"**.



Note that the simultaneous use of several medical devices can lead to an increase in leakage currents and the generation of new risk potentials.

12. AMBIENT CONDITIONS

Service conditions

Ambient temperature: +5°C to +40°C
Relative humidity: 20 to 80% non-condensing
Ambient: 750 to 1080 mbar

The electrical installation must comply with the relevant regulations (in Austria: EN 50110-1, ÖVE/ÖNORM E8001 as applicable)

Storage conditions

Ambient temperature:	-5°C to +45°C
Relative humidity:	20 to 80% non-condensing
Ambient:	750 to 1080 mbar

Always store the device in its original undamaged packaging. After a long period of storage, it may be necessary to recharge the battery and disinfect the device. Make sure that there is no mechanical influence (weight load from other objects, vibrations, etc.) during storage.



The maximum life for the membrane and silicone attachment could expire during storage. Be sure to replace them after a long storage period.

Conditions

Ambient temperature:	-10°C to +45°C
Relative Humidity:	20 to 80% non-condensing
Ambient:	750 to 1080 mbar

The transport takes place in the original packaging. Make sure that there is no mechanical influence (weight loading by other objects, vibrations, etc.) during transport.

13. DISPOSAL

The IntegraMouse AIR is to be disposed of as old electrical and electronic equipment in accordance with Directive 2012/19/EU WEEE (Waste of Electrical and Electronic Equipment) (valid in the European Union and other European countries with a separate collection system).



This symbol on the product or on the packaging means that this product must not be treated as household waste. Instead, this product should be taken to the appropriate disposal point for the recycling of electrical and electronic equipment. If the product is disposed of correctly, you help to prevent negative environmental influences and damage to health that could be caused by improper disposal.

Recycling material will preserve our natural resources. For more information about recycling this product, please contact your household waste collection service, the manufacturer of the IntegraMouse AIR or your IntegraMouse AIR dealer.



Individual non-electrical components – including mouthpieces, lip buttons, silicone attachments and membranes – can be disposed of with household waste. Observe hygienic aspects. Contact, where applicable, the municipal authority responsible for disposal

14. FREQUENTLY ASKED QUESTIONS AND ANSWERS



For an up-to-date list of FAQs, visit www.integramouse.com.

Do I need specific drivers or software to install it?

No. The Integramouse AIR is automatically recognized as the default mouse (or standard joystick and keyboard) and installed on your operating system (plug & play for operating systems from Windows 11, macOS 12, Linux, Android 14, iOS 15). With the optional Integramouse Control app for Windows and macOS, settings can be adjusted and additional functions can be activated.

I don't have the necessary strength to operate the mouse buttons by "sipping" or "puffing". Can I change the sensitivity of the sip/puff pulse?

Yes, the force required for "sipping" and "puffing" can be adjusted in the Integramouse Control app. Alternatively, you have the option of using auto-click software or connecting external sensors to trigger the left and/or right mouse button in an alternative way. Your specialist dealer will be happy to advise you.

Can I adjust the speed of the mouse cursor?

Yes, in the Integramouse Control app or in the mouse control options of your operating system.

Can I change or swap the assignment of the mouse buttons?

Yes, in the Integramouse Control app or in the mouse control options of your operating system.

Can I adjust the double-click speed?

Yes, in the mouse control options of your operating system.

Can I write texts with the Integramouse AIR?

Yes, all common operating systems offer on-screen keyboards for this purpose.

After changing the mouthpiece, the mouse cursor can no longer be moved!

Make sure that the mouse is correctly connected and ready for use. Control the current mode (control of LEDs). Check the mouthpiece for correct fit and perform a new calibration or turn the Integramouse AIR off and on again.

After changing the membrane, the mouse buttons can no longer be triggered!

Check the fit of the mouthpiece, membrane and sealing ring. Perform a new calibration or turn the Integramouse AIR off and on again.

The mouse cursor moves independently across the screen?

Perform a new calibration and check the dead zone in the IntegraMouse Control app. A low value increases the probability of independent mouse cursor movement (default value: 6)

Can I use the IntegraMouse AIR for environmental control?

The IntegraMouse AIR is a computer mouse and may only be connected to environmental control systems intended for use with a computer mouse.

15. EXPLANATION OF THE SYMBOLS



Manufacturer



Medical



Application Part Type B



CE mark (conformity with MDR 2017/745)



FCC mark (compliance with electromagnetic radiation levels for the US market)



Swiss Responsible Person (name and address see last page)



UK Responsible Person (name and address see last page)



Disposal in accordance with the WEEE Directive 2012/19/EU



Website for users, caregivers and patients



Follow the instructions for use



Product identification - serial number in format *Hardware Version – Firmware Version – Year of Production – Production Month – 4-Digit Sequential Number*, e.g., 1113-2025-04-0001



Device Identification - Global Trade Item Number



DataMatrix code that contains the serial number and GTIN, which corresponds to the UDI



Protection against foreign objects larger than 12.5 mm and against water droplets at an angle of less than 15°.



Direct current



Usable until: YYYY-MM

16. PRODUCT AND PERFORMANCE DATA

IntegraMouse AIR

Voltage:	5 V
Current:	0.5 A
Wireless Interface:	BLE – Bluetooth Low Energy 5.0
USB-Schnittstelle:	USB-C
Jack plug:	3.5 mm stereo jack socket
Sensitivity:	Mouthpiece excursion $\pm 1,5$ mm Dynamic response Movement from approx. 10 g deflection force Minimum trigger force for clicks: 5 mbar
Protection:	IP22
Operating time with battery:	approx. 12 hours with continuous use approx. 48 hours with average use approx. 140 hours standby mode
Dimensions:	165 x 52 x 54 mm (including mouthpiece)
Weight:	171 g (with mouthpiece and standard keycaps)
Compatibility	From USB 2.0, Plug & Play for Windows 11 operating systems, macOS 12, Linux, Android 14, iOS 15

Battery IntegraMouse AIR

Designation:	Model 103450
Type:	Lithium Polymer
Rated Voltage:	3.7 VDC
Capacity:	7.4 Wh
Max. Ladestrom:	2000 mA
Max. Entladestrom:	2000 mA
Charging time	First charge at least 4-5 hours, normal 2 to 2.5 hours
Nominal capacity:	2000 mAh
Safety:	PCM element (over-discharge and short-circuit protection)
Dimensions:	50 x 34 x 10 mm
Weight:	34 \pm 1 g

Power supply

Designation:	Mean Well Model NGE12I05-USB
Input Voltage:	85 to 264 VAC, 47 to 63 Hz
Input:	0.5 to 0.25 A
Output voltage:	5 VDC
Output:	2.4 A
Output Port:	USB-A (socket)
Degree of protection:	IP21
Protection class:	II
Adapter kits for:	AC PLUG-EU4=European Blade, AC PLUG-US4=North America Blade, AC PLUG-UK4=United Kingdom Blade, AC

Dimensions:	PLUG-AU4= Australian Blade, AC PLUG-CN4 = Chinese Blade
Weight:	48 mm x 28 mm x 55 mm (without plug attachment)
	71 g (without plug attachment)

USB cable

Designation:	goobay USB 2.0 sync- & charging cable
Color:	Black
Finish:	shielded, PVC, nickel-plated connectors
Length:	1.8 m
Connections:	USB Type A Male – USB Type C Male
Weight:	49 g

Mouthpiece

Designation:	IntegraMouse AIR Mouthpiece
Material:	SABIC LEXAN HP3REU
Application Part:	Type B ♂
Dimensions:	65 x 27 x 43 mm
Weight:	9 g

Lip buttons

Designation:	IntegraMouse AIR Lip buttons
Material:	SABIC LEXAN HP3REU
Application Part	Typ B ♂
Dimensions Cap 1:	10 x 10 x 8,6 mm
Weight Cap 1:	ca. 0,4 g
Dimensions Cap 2:	10 x 10 x 12,6 mm
Weight Cap 2:	ca. 0,6 g
Dimensions Cap 3:	10 x 10 x 17,6 mm; Standardlänge
Weight Cap 3:	ca. 0,8 g
Dimensions Cap 4:	10 x 10 x 22,6 mm
Weight Kappe 4:	ca. 1 g

Membrane

Designation:	IntegraMouse AIR Membrane
Material:	Hard part: SABIC PP PCG H10
	Soft tissue: TPE - HTM8505/02
Application Part:	Type B ♂
Dimensions:	Diameter: 17mm, Height: 6mm
Weight:	<1 g

Silicone attachment

Designation:	IntegraMouse AIR Silicone Attachment
Material:	Peroxide-cured silicone
Application Part:	Type B 
Hardness:	Shore Hardness A62
Diameter	inside/outside 6/10 mm
Length:	28 ±0.5 mm
Approvals:	ISO 10993 & USP Class VI biokompatibel

17. ELECTROMAGNETIC COMPATIBILITY



The IntegraMouse AIR is a medical electrical device and is therefore subject to special precautions with regard to electromagnetic compatibility. Therefore, install and use the IntegraMouse AIR only according to the specifications specified in this instruction manual. The IntegraMouse AIR, together with the supplied, specified accessories (see Chapter 6 "Scope of delivery" and Chapter 16 "Product and performance data") and when used as intended (see chapter 3 „Intended purpose and intended use“ and also Chapter 5 „Safety“) meet the prescribed limit values. The use of other accessories or coupling with other devices is not intended and can lead to increased radiation emission or reduced immunity to electromagnetic influences. Also keep in mind that the radio waves of the IntegraMouse AIR can affect other medical electrical devices.



Always keep a protective distance of at least 10 cm between IntegraMouse AIR and other medical electrical devices!

Please also note the guidelines in the tables below.

Guidelines and Manufacturer's Declaration – Electromagnetic Interference Emissions		
IntegraMouse AIR and its accessories are intended to operate in the electromagnetic environment specified below. The customer or user of the IntegraMouse AIR and its accessories should ensure that it is used in such an environment.		
Interference emission measurements	Agreement	Electromagnetic Environment - Guidelines
RF Emissions according to EN 55032/CISPR 32	Class B	IntegraMouse AIR and its accessories are intended for use in all facilities, including residential areas and those directly connected to a public utility network that also serves buildings used for residential purposes.
Harmonics according to IEC 61000-3-2	Class A	
Releases from Voltage fluctuations/flicker according to IEC 61000-3-3	Clause 5	

Guidelines and Manufacturer's Declaration – Electromagnetic Immunity

IntegraMouse AIR and its accessories are intended to operate in the electromagnetic environment specified below. The customer or user of the IntegraMouse AIR and its accessories should ensure that the device is used in such an environment.

Immunity tests	IEC 60601-1-2 Prüfpegel ETSI EN 301-489	Match Level	Electromagnetic Environment - Guidelines
Discharge of static Electricity (ESD) according to IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	Floors should be made of wood or concrete or have ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Fast transient electrical disturbances/ bursts according to IEC 61000-4-4	±2 kV for mains lines ±1 kV for input and output lines	±2 kV for mains lines ±1 kV for input and output lines	The quality of the supply voltage should match that of a typical business or hospital environment.
Surge Voltages (Surges) according to IEC 61000-4-5	±1 kV Voltage Outer Conductor-Outer Conductor ±2 kV Voltage Outer Conductor-Earth	±1 kV Voltage Outer Conductor-Outer Conductor ±2 kV Voltage Outer Conductor-Earth	
Immunity tests	IEC 60601-1-2 Test Level ETSI EN 301-489	Match Level	Electromagnetic Environment - Guidelines
Voltage dips, short-term interruptions and fluctuations in the supply voltage (short interrupt) according to IEC 61000-4-11	Voltage dips: 0% Residual voltage for 10ms (230Vac to 0Vac) 3 times at 0°-315° 0% Residual voltage for 20ms (230Vac to 0Vac) 3 times at 0°-315° 70% Residual voltage for 500ms (230Vac to 161Vac) 3 times at 0°-315° Short interrupt: 0% Residual voltage for 5s (230Vac to 0Vac) 3 times at 0°	Voltage dips: 0% Residual voltage for 10ms (230Vac to 0Vac) 3 times at 0°-315° 0% Residual voltage for 20ms (230Vac to 0Vac) 3 times at 0°-315° 70% Residual voltage for 500ms (230Vac to 161Vac) 3 times at 0°-315° Short interrupt: 0% Residual voltage for 5s (230Vac to 0Vac) 3 times at 0°	The quality of the supply voltage should match that of a typical business or hospital environment. If the user of the IntegraMouse AIR and its accessories requires continued operation even in the event of power interruptions, it is recommended that the IntegraMouse AIR and its accessories or the connected computer be powered from an uninterruptible power supply or battery.
Magnetic field at supply frequency (50/60 Hz) (magnetic field immunity) according to IEC 61000-4-8	30 A/m @ 50Hz sinusoidal horizontal, vertical, vertical 90°	30 A/m @ 50Hz sinusoidal horizontal, vertical, vertical 90°	Magnetic fields at the frequency of care should correspond to the typical values found in the business and hospital environment.

NOTE: U_T is the mains AC voltage before applying the test levels.

Guidelines and Manufacturer's Declaration – Electromagnetic Immunity

IntegraMouse AIR and its accessories are intended to operate in the electromagnetic environment specified below. The customer or user of the IntegraMouse AIR and its accessories should ensure that the device is used in such an environment.

Immunity tests	IEC 60601-1-2 Prüfpegelacc. Table 4, 5 & 9 ETSI EN 301-489	Match Level	Electromagnetic Environment - Guidelines
Conducted immunity (RF) disturbances according to IEC 61000-4-6 Radiated electromagnetic field sweep & spot frequencies according to IEC 61000-4-3	0.15MHz to 80MHz Test level 6V Modulation AM 80%, 1KHz Step size 1% Source impedance 150ohm Duration for each Frequency step 1s 10V/m (80MHz to 6GHz) Modulation AM 80%, 1kHz Polarization H/V 0-270° Duration for each Frequency step 1s Test levels and modulation according to table 1 Polarization H/V 0-270° Duration for each Frequency step 5s	0.15MHz to 80MHz Test level 6V Modulation AM 80%, 1KHz Step size 1% Source impedance 150ohm Duration for each Frequency step 1s 10V/m (80MHz to 6GHz) Modulation AM 80%, 1kHz Polarization H/V 0-270° Duration for each Frequency step 1s Test levels and modulation according to table 1 Polarization H/V 0-270° Duration for each Frequency step 5s	<p>Portable and mobile radios are used at no less distance from the IntegraMouse AIR or its accessories, including the lines, than the recommended protective distance, which is calculated according to the equation suitable for the transmission frequency.</p> <p>Recommended protective distance:</p> $d = 1.2\sqrt{P} \text{ 150 kHz to 80 MHz}$ $d = 1.2\sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.3\sqrt{P} \text{ 800 MHz to 2.5 GHz}$ <p>with P as the nominal power of the transmitter in watts (W) according to the transmitter manufacturer and d as the recommended protective distance in meters (m).</p> <p>According to an on-site investigation, the field strength of stationary radio transmitters is lower than the conformity Pegel at all frequencies.</p> <p>Interference is possible in the vicinity of devices bearing the following symbol.</p> 

NOTE 1: The higher value applies to 80MHz and 800MHz.

NOTE 2: These guidelines may not apply in all situations. The propagation of electromagnetic waves is influenced by absorptions and reflections from buildings, objects and people.

^a The field strength of stationary transmitters, such as base stations of radio telephones and mobile land radio services, Amateur stations, AM and FM radio and television stations, cannot theoretically be precisely predetermined become. In order to determine the electromagnetic environment as a result of stationary RF transmitters, a Investigation of the site is recommended. If the determined field strength is at the location of the IntegraMouse AIR and of its accessories exceeds the compliance level specified above, the IntegraMouse AIR and its accessories can be observed for their normal operation at each application site. If unusual performance characteristics, it may be necessary to take additional measures, such as the Reorientation or implementation of the IntegraMouse AIR and its accessories.

^b Over the frequency ranges from 150 kHz to 80 MHz, the field strength is less than 3 V/m.

Recommended protective distances between portable and mobile RF communication devices and the IntegraMouse AIR and its accessories

IntegraMouse AIR and its accessories are designed to operate in an electromagnetic environment where radiated RF interference is controlled. The customer or the user of the IntegraMouse AIR and its accessories can help to prevent electromagnetic interference by maintaining minimum distances between portable and mobile RF communication equipment (transmitters) and the IntegraMouse AIR and its accessories, as recommended below according to the maximum output power of the communication device.

Rated power of the transmitter W	Protective distance according to transmission frequency 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 whose power rating is not specified in the table above, the distance can be determined using the equation belonging to the respective column, where P is the rated power of the transmitter in watts (W) as specified by the transmitter manufacturer.

NOTE 1 An additional factor of 10/3 was used to calculate the recommended protective distance of transmitters in the frequency range of 80 MHz to 2.5 Ghz in order to reduce the probability that a mobile/portable communication device inadvertently introduced into the patient area would cause interference.

NOTE 2 These guidelines may not apply in all situations. The propagation of electromagnetic waves is influenced by absorptions and reflections from buildings, objects and people.

18. DECLARATION

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EU KONFORMITÄTSERKLÄRUNG / EU DECLARATION OF CONFORMITY

IntegraTools als Hersteller des Medizinprodukts **IntegraMouse AIR** gemäß EU-Medizinprodukteverordnung MDR (EU) 2017/745 Artikel 10 mit der Registrierungsnummer SRN: **AT-MF-000023570** erfüllt die Vorschriften der Verordnung (EU) 2017/745 über Medizinprodukte ("MDR"), die Datenschutzgrundverordnung (EU) 2016/679 („DSGVO“), die Elektromagnetische Verträglichkeit gemäß Richtlinie 2014/30/EU („EMV“), die Funkanlagen-Richtlinie 2014/53/EU („RED“), RoHS Richtlinie 2011/65/EU + 2015/863/EU zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten, und der Batterieverordnung 2023/1542/EU.

*IntegraTools, as the manufacturer of the medical device **IntegraMouse AIR** in accordance with EU Medical Device Regulation MDR (EU) 2017/745 Article 10, with single registration number (SRN): **AT-MF-000023570**, complies with the requirements of Regulation (EU) 2017/745 on medical devices ('MDR'), the General Data Protection Regulation (EU) 2016/679 ('GDPR'), Electromagnetic Compatibility Directive 2014/30/EU ('EMC'), Radio Equipment Directive 2014/53/EU ('RED'), RoHS Directive 2011/65/EU + 2015/863/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and the Battery Regulation 2023/1542/EU.*

Die IntegraMouse AIR mit seiner Zweckbestimmung als portable Eingabe- und Steuerungshilfe, welche dazu dient, Menschen mit eingeschränkten, angeborenen oder erworbenen motorischen Einschränkungen bei der Bedienung von Geräten zu unterstützen bzw. die motorischen Einschränkungen zu kompensieren, mit seiner **Basis UDI-DI (GMN) 912013911IMAIR2V** hat folgende Produktspezifikationen:

The IntegraMouse AIR, with its intended purpose as a portable input and control aid to assist people with limited, congenital or acquired motor impairments in operating devices or to compensate for motor impairments, with its base UDI-DI (GMN) 912013911IMAIR2V, has the following product specifications:

Produktbezeichnung / product name	IntegraMouse
Modell / model	IntegraMouse AIR
Systemkomponenten	Hauptgerät, Mundstück, Membran, Lippentaster, USB Kabel, Netzteil <i>main unit, mouth piece, membrane ,lip sensor, USB cable, power supply unit</i>
Systems components	<i>main unit, mouth piece, membrane ,lip sensor, USB cable, power supply unit</i>
Klassifizierung nach MDR (EU) 2017/745, Anhang VIII Classification acc. MDR (EU) 2017/745, annex VIII	Klasse I nach Regel 5 <i>Class I according rule 5</i>
Medizinprodukte Nomenklatur Codes / Medical Device Nomenclature Codes	EMDN Y2109, GMDN 30967, 30968, 30969 EMDN Y2109, GMDN 30967, 30968, 30969

Konformitätsbewertung / assessment details

Verfahren nach MDR (EU) 2017/745 Route according MDR (EU) 2017/745	Anhang IV (EU-Konformitätserklärung) Annex IV (EU-declaration of conformity)
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Web: <https://www.integratools.at/>



Angewandte Normen / used standards

Harmonisierte Normen / harmonized standards EN 60601-1:2006+A1:2012+A2:2020 (3rd Edition), EN 60601-1-2:2015/A1:2021 (Edition 4.1), EN 60601-1-11:2016+A1:2020, ISO 21856:2022, EN ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 10993-5:2009, EN ISO 10993-10:2020, EN ISO 10993-23:2021, EN ISO 14971:2019, IEC 62304:2006+A1:2015, IEC 62366-1:2015/AMD1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021v

Die IntegraMouse AIR umfasst folgende Produktkomponenten mit den UDI-DI (Universal Device Identifier – DI) Bezeichnungen zur eindeutigen Identifikation

IntegraMouse AIR – Hauptgerät	UDI-DI 9120139110096	IntegraMouse AIR – Silikonaufsatzt	UDI-DI 9120139110140
IntegraMouse AIR – Mundstück	UDI-DI 9120139110102	IntegraMouse AIR – USB-Kabel	UDI-DI 9120139110157
IntegraMouse AIR – Membran	UDI-DI 9120139110119	IntegraMouse AIR – Netzgerät	UDI-DI 9120139110164
IntegraMouse AIR – Lippentaster	UDI-DI 9120139110126	IntegraMouse AIR – Netzadapter	UDI-DI 9120139110171
IntegraMouse AIR – Dichtring	UDI-DI 9120139110133	IntegraMouse AIR – Transportcase	UDI-DI 9120139110188
IntegraComplete PowerUser	UDI-DI 9120139110195	IntegraComplete Medical	UDI-DI 9120139110201

Diese Konformitätserklärung für die IntegraMouse AIR ist gültig bis 01.12.2030.

This Declaration of Conformity for the IntegraMouse AIR is valid until 1st of December 2030.

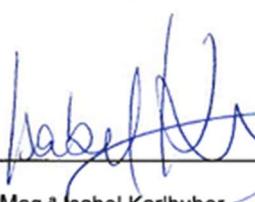
Wir erklären in alleiniger Verantwortung, dass das oben beschriebene Produkt und Zubehör in der gelieferten Ausführung den Anforderungen der MDR (EU) 2017/745 und des österreichischen Medizinproduktegesetzes BGBI. 122/2021 i.d.g.F. entsprechen. Die Produkte werden mit der CE-Kennzeichnung versehen.

We declare under sole responsibility that the product including accessories described above as delivered are in compliance with MDR (EU) 2017/745 and the Austrian medical-device-law BGBI. 122/2021 in the presently valid edition. The products are CE marked.

Linz, 01.12.2025



Mag. a Isabel Karlhuber
Geschäftsführerin


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Dipl.-Ing. Manfred Bammer, MAS
Person Responsible for Regulatory Compliance

19. SUPPORT

For technical questions or safety alerts, please contact only the manufacturer or its distributor/reseller; UKRP in the UK or CH REP in Switzerland.

Manufacturer

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CH REP – Swiss Responsible Person

NN

UKRP – UK Responsible Person

Regen Marketing Ltd
Ivy Cottage
Bridgnorth Road
Stourton, DY7 5BH
United Kingdom

Distributor / Reseller (optional)

