

INSTRUCTIONS FOR USE (Version 1.4)

IntegraMouse Plus

including accessories



CE

ENGLISH

EN

DEAR CUSTOMER,

Thank you for choosing a LIFEtool product and for choosing to use the IntegraMouse Plus as a valuable input device for your computer. These instructions for use contain useful and important information. Please read this manual carefully before using IntegraMouse Plus for the first time. LIFEtool and your authorised IntegraMouse dealer will be happy to answer your questions. We wish you every success with your IntegraMouse Plus.

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1. CONTACT



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2. NOTES ON THE INSTRUCTIONS FOR USE



Please read these instructions for use completely before first use and keep them for reference for later use.



The triangle symbol indicates warnings, i.e. when failure to follow the instructions may result in hazardous situations.



The information symbol indicates general notes and information.



The symbol with the snake on a green star indicates subject-specific information, e.g. for medical personnel or hospital visitors.

Instructions for use are valid for the "IntegraMouse Plus" device version and its specific accessories.

Issue date: 2012-09. Technical changes reserved.

3. PRODUCT INFORMATION AND USE AS PER REGULATIONS

IntegraMouse Plus is a medical product made using the latest technology. It complies with European standards and harmonised norms that are based on the Medical Device Directive and has therefore been awarded the CE mark. Details of this can be found in Chapter 17 "Declaration of Conformity".

IntegraMouse Plus is a fully adequate computer mouse that is operated with the mouth. For the operation of computer games, a joystick mode and a cursor mode are provided. This allows persons who are no longer able to operate a traditional mouse to use a computer. According to the Medical Device Directive IntegraMouse Plus compensates for disabilities to enable the operation of a computer.

Possible users are persons with high-level paraplegia, with arms amputated on both sides or advanced diseases such as muscular dystrophy, amyotrophic lateral sclerosis or multiple sclerosis.

IntegraMouse Plus is connected to the computer by a USB cable and is Plug-and-Play capable, i.e. it is recognised and installed completely automatically as a Human Interface Device (HID). Power is also supplied via the USB cable. Alternatively the IntegraMouse Plus can communicate with the computer via a wireless radio link connection in the 2.4 GHz ISM Band. With this option, the power is supplied from the inbuilt battery or the power pack included.

IntegraMouse Plus is mainly designed to be used in dry rooms, in stationary settings on a PC or laptop. These include living rooms, clinics, rehabilitation centres, institutes, schools, universities and similar. However, usage in dry outside areas i.e. on patios, is also possible. The ambient temperatures during application must be between 10°C and 40°C. Avoid direct sunlight.

The placing and positioning of the IntegraMouse Plus must not be changed during use (tilt etc.) Also, the IntegraMouse Plus must not be influenced by external forces (for example, accelerations).

The mouthpiece can be changed. Cleaning is possible according to Chapter 9 "Hygiene, maintenance and testing". In clinical areas, the one-time use of the mouthpiece is strongly recommended. Through this, hygiene and cleanliness are guaranteed, also during use by several users (for example in public institutions) or during use in clinics and rehabilitations centres, where the risk of an infection by more resistant germs is present.

4. SAFETY INSTRUCTIONS



As with every medical product, there are a few things that must be noted in order to ensure the safe and smooth operation of the IntegraMouse Plus:

- Use this product only for the intended purpose according to these instructions for use. Any other use is improper and therefore dangerous. The manufacturer cannot be held responsible for damages which are caused by inappropriate or improper use.
- Good head control and mouth motor skills are required for the operation of the IntegraMouse Plus. Therefore the IntegraMouse Plus must not be used by persons who suffer from e.g. uncontrolled spasms, Tourette's syndrome or epilepsy.
- Only connect the device to sources of power as described in the instructions for use. Otherwise dangers may occur.
- Do not expose the device to extreme temperatures and avoid direct sunlight. This can cause damage, especially to the built-in battery. Do not expose the device to any shaking (knocking, dropping) and protect it from dirt and damp. However, should the device be exposed to these conditions, allow your contract partner to examine it in order to ensure that it is safe and usable.
- If you do not use the device for extended periods of time, switch the device off and store it according to Chapter 11 "Ambient conditions".
- Use within strong electromagnetic fields can cause the device to malfunction.
- The device must not be opened by the user as this would invalidate the manufacturer's guarantee. Repairs may only be carried out by the manufacturer or its authorised partners. Incorrect handling of the internal battery can especially lead to hazards.
- Persons who produce a large amount of saliva must not use the IntegraMouse Plus.
- The IntegraMouse Plus may be used in combination with the attached IntegraMouse Plus silicon tube, only by such persons that are not in danger of swallowing such objects.
- The IntegraMouse Plus must not be used on moving systems (e.g. wheelchairs) or on systems with changes of position (e.g. changes of inclination).
- The IntegraMouse Plus must not be used for the operation of life-supporting or safety devices such as emergency call installations, medication-dosing apparatus, medical expert systems, etc.
- Children under 3 years of age are not permitted to operate the IntegraMouse Plus.
- The IntegraMouse Plus must not be used in connection with HF surgical units or defibrillators.
- A combination with other devices than those described in Chapter 10 "Permissible system" is not permissible. Any other combination with medical products or other

products leads to the system integrator becoming the system manufacturer and also taking on responsibility for the product.

- During highly infectious diseases, the mouthpiece must only be used once. The interval between changes of the mouthpiece must be determined by a doctor or an expert advisor.
- Take regular breaks when you are working with computers. Physical signs of tiredness include eye pain, neck stiffness and other accompanying signs. A ten-minute break per hour of work is recommended.
- The device must not be used in atmospheres enriched with oxygen or other combustible gases.

5. SCOPE OF SUPPLY



After opening the packaging, please check the delivery for completeness and check whether the IntegraMouse Plus or the accessories show any sign of damage or defects. If this is the case, contact your dealer immediately.

Figure 1: Scope of supply

No.	LIFETool article number	Quantity	Description
1	11209	1	LIFETool: IntegraMouse Plus
2	11210	1	LIFETool: IntegraMouse Plus Connect (IM+Connect)
3	11211	2	LIFETool: IntegraMouse Plus mouthpiece
4	11212	1	LIFETool: IntegraMouse Plus USB cable
5	11213	12	LIFETool: IntegraMouse Plus membrane
6	11214	1	LIFETool: IntegraMouse Plus power pack
7	11218	1	LIFETool: IntegraMouse Plus silicon tube
8	11225	1	Handbook/manual

6. PRODUCT DESCRIPTION

6.1 Components and operating elements



Figure 2: Components of the IntegraMouse Plus

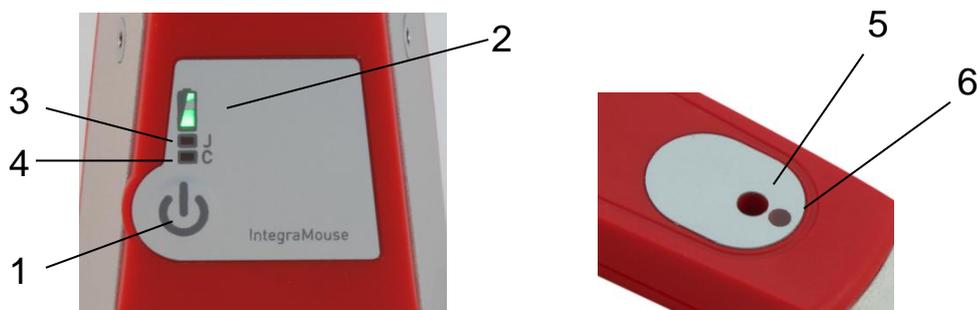


Figure 3: Operating elements on the IntegraMouse (left) and IM+Connect (right)

1. ON/OFF key and calibration
2. Battery power display
3. Joystick mode display (J): Analogue joystick with key 1 and key 2
4. Cursor mode display (C): Cursor keys, space key and enter key
5. "Connect" key
6. Standby LED
7. USB port
8. Jack socket: enables connection of an external sensor (3.5 mm mono jack) for the manual change between the three operating modes mouse - joystick - cursor



Figure 4: Reverse side of the IntegraMouse Plus



All operating elements are latex free and free from poisonous components.

6.2 Accessories and spare parts



An overview of the technical data can be found in Chapter 15 "Product and performance data".

IntegraMouse Plus Connect (IM+Connect)

The IM+Connect is plugged into the USB port of the computer and serves as a radio receiver in wireless mode.

IntegraMouse Plus mouthpiece

The mouthpiece is in direct contact with the user's lips and is therefore the applied part. The mouthpiece is removable; therefore it can be replaced or cleaned separately.



The applied part "mouthpiece" is of type B.

IntegraMouse Plus power pack

The power pack is used for charging the battery and also for supplying the IntegraMouse Plus with power in wireless mode. For safe operation, only use this power pack!

IntegraMouse Plus USB cable

The USB cable is used to connect the IntegraMouse Plus with the computer in cable-connected mode. The internal battery of the IntegraMouse Plus is also charged at the same time. For safe operation, only use this USB cable!

IntegraMouse Plus membrane

The membrane is necessary for the sucking/blowing function of the IntegraMouse Plus and also functions as a mechanical protective barrier to the electronics. The membrane should regularly be checked for damage and replaced.

IntegraMouse Plus silicon tube

If you prefer a soft surface on the mouthpiece, the silicon tube can be placed over the mouthpiece. This can make it more comfortable to use. Pay attention to the instructions for safe use of the silicon tube in Chapter 7.5. "Using the IntegraMouse Plus silicon tube".

IntegraMouse Plus mounting system



The mounting system is used for flexible installation and securing of the IntegraMouse Plus in the working position desired. The mounting system can be set up, for example, on the table or on the bed.

Not included in the scope of delivery – Contact the manufacturer or your dealer for further information.

Figure 5: Mounting system



Ensure that the IntegraMouse Plus cannot be installed with the mounting system on moving systems, e.g. on wheelchairs. There is a danger of injury, e.g. when driving over obstacles.

The following optional articles can be supplied on request as **deliverable accessories**:

LIFEtool article number	Description
11216	LIFEtool: IntegraMouse Plus membranes, 5 pack
11217	LIFEtool: IntegraMouse Plus mouthpiece, 5 pack
11218	LIFEtool: IntegraMouse Plus silicon tube
11224	LIFEtool: IntegraMouse Plus mounting system

The following optional articles can be obtained on request as **spare parts**:

LIFEtool article number	Description
11220	LIFEtool SPARE PART: IntegraMouse Plus Connect
11221	LIFEtool SPARE PART: IntegraMouse Plus USB cable
11222	LIFEtool SPARE PART: IntegraMouse Plus power pack

7. COMMISSIONING

7.1 Short introduction to initial operation

- Install the mounting system recommended by LIFEtool or by your LIFEtool dealer on your desired workstation.
- Carefully place the mouthpiece and membrane on the IntegraMouse Plus.
- Position the IntegraMouse Plus on the stand. The bracket of the IntegraMouse Plus has three openings for left, right and bottom mounting.
- Move the device into a working position which is balanced and comfortable for the user.
- For initial use we recommend operation with the cable connected, in order to guarantee the charging of the internal battery. For this, connect the IntegraMouse Plus to your computer via the USB cable supplied.
- The IntegraMouse Plus switches on automatically and the calibration process is shown through the running LEDs.



Do not move the IntegraMouse Plus during calibration!

- The operating system of your computer automatically recognises and installs the IntegraMouse Plus as a standard mouse.
- After the installation has been completed, the IntegraMouse Plus is ready for use.

Detailed instructions on initial operation and use can be found on the following pages. In addition, you can watch training videos for operation at www.youtube.com (enter keyword 'IntegraMouse').

7.2 General Installation notes

The IntegraMouse Plus and also the IM+Connect are "Plug and Play" capable and function with standard USB drives. This means that they are automatically recognised and installed by common operating systems after being plugged in. The IntegraMouse Plus is thereby automatically recognised as a standard mouse, standard joystick and keyboard.

The installation process usually runs in the background (dependant on the operating system). Therefore the IntegraMouse Plus is ready to be used after only a short time.



During initial installation it takes a short time until the IntegraMouse Plus is ready for use. When plugging in the IntegraMouse Plus to a computer that is already known, the IntegraMouse Plus is ready for use straight away.

Installing the IntegraMouse Plus and components

Install the stand recommended by LIFEtool or by your LIFEtool dealer on your desired workstation. The bracket of the IntegraMouse Plus has three openings for left, right and bottom mounting. Secure the IntegraMouse Plus on the stand in the intended mounting place with the locknut (Figure 7) and then bring the IntegraMouse Plus into the final desired working position (Figure 6).



Figure 7: Installing the IntegraMouse Plus



Figure 6: Correct working position



Do not use the IntegraMouse Plus on mobile or moving systems. Ensure that the IntegraMouse Plus is positioned away from your face so that no hazards can arise, e.g. by a third person bumping into you. Be careful where you place the available cable.



In order to avoid collisions with the IntegraMouse Plus, ensure that the user first of all assumes an ergonomic sitting and working position in front of the screen and that the IntegraMouse Plus is only then brought into the mouth of the user in a fatigue-proof working position.

Ensure that you have enough space in which to work and a good view of the screen. Pay attention to your position in relation to sources of disturbance, e.g. dazzling sunlight through windows. Lack of ergonomics can lead to eye pain, headaches or muscle tension.



The IntegraMouse Plus can also be used in an inclined or lying position. It is important that the calibration, e.g. after plugging in the USB cable, only occurs after setting up the workstation. You can recalibrate the position at any time by quickly pressing the ON/OFF button.

7.3 Switching on and activating

Next you must decide in which operating mode you wish to operate the IntegraMouse Plus.

- Connected by cable, i.e. directly connected to the computer via USB cable
- Wireless transmission with battery powered operation of the IntegraMouse Plus
- Wireless transmission with operation of the IntegraMouse Plus via the power pack included

IntegraMouse Plus in cable-connected mode

1. Connect the IntegraMouse Plus to your computer via the USB cable supplied.
2. The IntegraMouse Plus switches on automatically and the calibration process is shown through the running LEDs.



If the IntegraMouse Plus is in wireless mode, cable-connected operation can be initiated during operation as described above. Wireless mode is then automatically deactivated and the battery is charged.

IntegraMouse Plus in wireless mode with battery operation

In order to use wireless mode, IM+Connect is required.

1. Insert the IM+Connect into one of the computer's USB ports.
2. Switch the IntegraMouse Plus on by pressing the ON/OFF button. The calibration process starts and will be shown by the running LEDs.
3. After successful connection, the green LED on the IM+Connect and the IntegraMouse Plus is ready for use.



Ensure that the battery of the IntegraMouse Plus is charged enough when in wireless mode. More information on the charging display can be found in Chapter 9.3 "Recharging the battery".

The IntegraMouse Plus and IM+Connect must be coupled for use. This linking-up is carried out as standard before delivery and need not be carried out by the user.

When replacing the IM+Connect or in case of problems with the wireless connection, the linking procedure can be carried out manually as follows:

Linking up IntegraMouse Plus and IM+Connect

1. Disconnect the IntegraMouse Plus from the power pack or the USB cable.
2. Switch off the IntegraMouse Plus (see Chapter 8.4).
3. Insert the IM+Connect into one of the computer's USB ports.
4. Press the "Connect" button on the top of the IM+Connect with the help of a sharp object (e.g. ballpoint pen, paper clip,...). The linking process starts. The green LED on the IM+Connect flashes.
5. Switch on the IntegraMouse Plus by pressing the ON/OFF button and keep this pressed down for about 3 seconds (Warning! The IntegraMouse must be switched off and must not be connected to the power pack). After the running lights have come on once, the blue LEDs on the IntegraMouse Plus begin to flash alternately.
6. After successful connection, the green LED on the IM+Connect and the IntegraMouse Plus is ready for use.

IntegraMouse Plus in wireless mode with supply via the power pack

1. Insert the IM+Connect into one of the computer's USB ports.
2. Connect the IntegraMouse Plus to a plug using the power pack.
3. The IntegraMouse Plus switches on automatically and the calibration process is shown through the running LEDs.
4. After successful connection, the green LED on the IM+Connect and the IntegraMouse Plus is ready for use.

7.4 Calibration

Before use, the IntegraMouse Plus must be calibrated in its relevant location. As a rule, this happens automatically directly after switching on and plugging in the IntegraMouse Plus.

Automatic calibration

Automatic calibration always occurs after plugging in and switching on the IntegraMouse Plus.



Do not move the IntegraMouse Plus during the calibration process and do not change its position or situation. This could lead to incorrect calibration and therefore to malfunctioning of the IntegraMouse Plus and make recalibration necessary.

Manual calibration

During long periods of work it can be necessary to begin a manual calibration, e.g. after readjusting the device or weight changes in the mouthpiece due to the collection of moisture or in strong changes in the light conditions (sunlight).

To begin manual calibration you have the following options:

By quickly pressing the ON/OFF button

By the following sucking/blowing combination: Blow for 3 seconds, suck for 3 seconds with max. 1 second pause in between.

The calibration occurs automatically for the selected mode and is displayed by running LEDs on the IntegraMouse Plus.



**Sucking/blowing combination for calibration by the user:
Blow for 3 seconds - Suck for 3 seconds
Maximum pause between both actions: 1 second**

7.5 Using the IntegraMouse Plus silicon tube



Figure 8: Correct placing of the silicon tube.

If you prefer a softer surface on the mouthpiece, push the silicon tube included over the mouthpiece opening, up to the second groove, see Figure 8. Carry out calibration after putting on the silicon tube. Check regularly whether the silicon tube is still completely pressed on and correct the position if need be.



Never use any other than the original silicon tube and always ensure that the silicon tube is sitting securely on the mouthpiece. Only put the mouthpiece so far into your mouth that you cannot extend your lips and teeth over the silicon tube.

The silicon tube may only be used by persons that are not in danger of swallowing such objects. Danger of suffocation!

8. APPLICATION AND FUNCTIONALITY

The IntegraMouse Plus is an input device for your computer. The input device works as a standard computer mouse (mouse mode) or optionally as a joystick (joystick mode) or as a keyboard (cursor mode). Movements of the mouthpiece by the mouth are captured by a sensor. A small deflection of the mouthpiece is enough to cause the controller to respond. As well as movement, sucking and blowing on the mouthpiece are also used for input (e.g. left and right mouse click).



Only put the mouthpiece so far into your mouth that your teeth reach the groove on the mouthpiece. If you have put the silicon tube on, ensure that it is seated securely and only put the mouthpiece so far into your mouth that you cannot extend your lips and teeth over the silicon tube.

8.1 Switching on the IntegraMouse Plus

The IntegraMouse Plus can be switched on in the following ways:

- Plug in the live USB cable or ensure a power supply via USB (switching on the computer).
- Plug in the power pack and connect to the mains.
- Hold the ON/OFF button for at least 300 ms.

During switching on, the IntegraMouse Plus is calibrated; all LED displays light up one after the other as running lights. The IntegraMouse Plus is then in mouse mode.



The IntegraMouse Plus must not be moved during calibration.



During the running light sequence you can also recognise possible defective LEDs as these will not light up.

8.2 Three operating modes: Mouse – Joystick – Cursor

The active operation mode is shown by blue LEDs on the front of the IntegraMouse Plus (see table 1). The display LED for joystick mode is marked with "J"; the one for cursor mode with "C". If one of the two LEDs is lit, the relevant mode is active. If neither of the LEDs is switched on, the mouse mode is active.

LED "J"	LED "C"	Mode
Off	Off	Mouse mode
blue	Off	Joystick mode
Off	blue	Cursor mode

Table 1: Diagram of the operating modes



After plugging in and activating, the IntegraMouse Plus is automatically in mouse mode.

Mouse mode (mouse function)

Small movements of the mouthpiece cause the mouse pointer on the screen to move correspondingly. In the same way as a normal computer mouse it can be moved across the screen in a continuous and dynamic way, from very slowly to very quickly and placed accurately to the pixel. To steer the mouse pointer, place the mouthpiece between your lips and press it with lip movements in the desired direction in which the mouse pointer should move across the screen.

The mouse buttons are activated by sucking and blowing. In the standard configuration the left mouse button is activated by short sucking on the mouthpiece opening and the right button is activated by short blowing on the mouthpiece opening.

Two short sucks equate to a double click of the left mouse button. A short suck and holding the air in the mouthpiece enables objects to be moved across the screen ("drag & drop").



The characteristics of the mouse pointer, e.g. the speed, can be set individually in the respective operating system. The assignments of left and right clicks can also be changed there. For more information: see the help function of your operating system.



If it is not possible for the user to activate the mouse clicks by sucking and blowing, the clicks can be actioned through additional auto-click software. Your LIFEtool dealer would be glad to advise you about this.

In some cases, other, external sensors can also be used. Your LIFEtool dealer would be happy to advise you about the choice of suitable sensors and switch interfaces.

Joystick mode (joystick configuration)

The joystick mode enables the operation of computer games, which can be played using a Windows standard joystick with two buttons. The movement of the mouthpiece effects the analogue deflection of the joystick. Movements can be carried out dynamically from slowly (small displacement) to quickly (larger displacement). Sucking and blowing correspond to the joystick keys 1 and 2. Activated joystick mode is indicated by the lighting-up of the corresponding blue LED.



The basic calibration and further settings of the joystick can be carried out individually in the settings menu of the respective operating system. For more information see the help function of your operating system.

Cursor mode (keyboard function)

Cursor mode enables the operation of computer games and programmes that can be controlled with the cursor keys (arrow keys), the space key and the enter key. The four/eight directions are actuated by the movement of the mouthpiece. The space key and the enter key are available through sucking and blowing. Activated cursor mode is indicated by the lighting-up of the associated blue LED.

Additional notes (apply to all three operating modes)



Many games enable the adaptation of controls and the configuration of the keys for operation. For this, use the instructions for your game.



In order to operate a complete keyboard, e.g. in order to enter letters or whole texts, to compose e-mails, and so on, the operating system of your computer usually makes an on-screen keyboard available. Your LIFEtool dealer will be glad to advise you on more powerful on-screen keyboards that are available at cost (with additional setting options).



Many applications, especially games, can be terminated using the ESC key. This function is also available to users of the IntegraMouse Plus by means of the following sucking/blowing combination:

In quick succession: blow for 3 seconds – briefly suck 2 x – briefly blow 1 x.

Switching between the modes

After plugging in and activating, the IntegraMouse Plus is in mouse mode as standard. In order to switch between modes, you have the following options:

- By connecting and using an external sensor.
- By the following sucking/blowing combination: two quick blows, then two quick sucks (within 2 seconds) and one quick blow (within 1 second).

Through this the modes are switched through in turn:

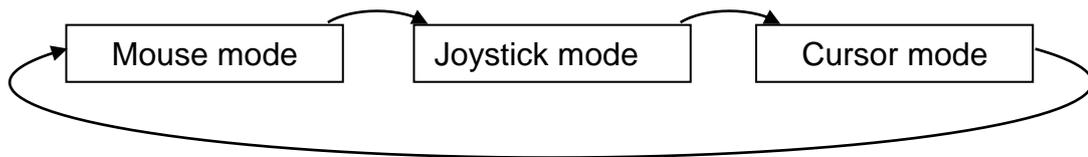


Figure 9: Sequence of the operating modes



**Sucking/blowing combination for a change of modes by the user:
In quick succession: 2 blows - 2 sucks - 1 blow.**



The modes can only be used one after another, not at the same time. The operation of programmes which require the use of several input devices (e.g. games with keyboard and joystick) is only possible if the input devices are not used at the same time.

Overview of the assignment of the actions in the relevant modes

The standard assignments in the relevant modes can be seen in this table:

Mouthpiece action	Mouse mode	Joystick mode	Cursor mode
Movement up	Mouse pointer goes up	Joystick up	Arrow up
Movement down	Mouse pointer goes down	Joystick down	Arrow down
Movement left	Mouse pointer goes left	Joystick left	Arrow left
Movement right	Mouse pointer goes right	Joystick right	Arrow right
Sucking	Left mouse button	Button 1	Space key
Blowing	Right mouse button	Button 2	Enter or Return

Table 2: Standard assignments in the relevant operating modes

Combined movements are also possible, e.g. diagonals.

8.3 IntegraMouse Plus energy saving mode

In order to save power during battery operation, the IntegraMouse Plus has an in-built energy-saving mode. This begins automatically, when:

- the device is not used for 30 seconds.
- the computer to which the IntegraMouse Plus is connected goes into standby mode.

Energy-saving mode ends automatically, when:

- the user moves the mouthpiece or quickly presses the ON/OFF button (do not hold down).
- a power-supplying USB cable is plugged in.
- the computer to which the IntegraMouse Plus is connected wakes up from standby mode again.



Energy-saving mode is basically not noticeable to the user, because the IntegraMouse Plus activates again immediately on interaction. (Attention: only with movement of the mouthpiece, but not sucking or blowing!)



Energy saving mode also uses battery power. When you no longer need the IntegraMouse Plus or will not use it for a longer time, switch it completely off.

8.4 Switching off the IntegraMouse Plus

The IntegraMouse Plus can only be switched off in active mode (LEDs for the battery power display light up). If the IntegraMouse Plus is in energy-saving mode, this can be exited by a short press of the ON/OFF key.

By pressing the ON/OFF key for at least 3 seconds the IntegraMouse Plus can be switched off. All LEDs on the IntegraMouse Plus go out.



When battery power is low, the IntegraMouse Plus switches itself off automatically. When it is switched off, no more energy is needed from the battery.

8.5 Wake on USB

The "Wake on USB" function permits the inactive computer to activate the connected IntegraMouse Plus on the USB port. This function must be supported by the hardware and by the operating system. Further information can be found in the instructions for your computer and in its operating system.



"Wake on USB" with the IntegraMouse Plus only works via the connected USB cable (not in wireless mode) and only on the USB ports of the computer that are directly on the mainboard.

9. HYGIENE, MAINTENANCE AND TESTING

In order to guarantee the long and safe operation of the IntegraMouse Plus, the following activities are necessary:

- Regular cleaning and regular changing of the mouthpiece.
- Regular changing of the membrane
- Regular cleaning of the device
- Regular, proper charging of the battery in wireless mode
- Regular metrological testing and maintenance
- General care when dealing with the individual components

The individual points are described below in more detail.



In the case of errors or problems with the IntegraMouse Plus, do not try to repair the product or its accessories. This can invalidate the guarantee and severely damage the device. Always contact the manufacturer or your dealer.



The life expectancy of the IntegraMouse Plus has been set by the manufacturer at 5 years (from the date of manufacture - see the serial number of the device). After this date, no service can be guaranteed.

9.1 Cleaning the mouthpiece and changing the membrane

Two mouthpieces are included with the IntegraMouse Plus in order to ensure regular cleaning without interrupting use.



The replacement and subsequent cleaning of the mouthpiece should be carried out in the home about once per week. In the case of higher levels of contamination or in the case of illness, more frequent cleaning is recommended.

If there is visible damage or there are signs of wear and tear on the mouthpiece, use a new mouthpiece and dispose of the old mouthpiece.

For thorough cleaning, disinfection with boiling water (**thermo disinfection**) is recommended. Then proceed as follows:

1. Pull the mouthpiece off forwards in a **straight** movement. Removal is very simple and possible without using larger amounts of force (see Figure 10).



Figure 10: Removing the mouthpiece

2. Remove the membrane by pushing and dispose of it (see Figure 11)



Figure 11: Removing the membrane

3. Heat pure, clear water and bring it to the boil (100°C).
4. Place the mouthpiece carefully into the boiling water. In order to do this, use an aid, e.g. a spoon.
5. When doing this, ensure that the mouthpiece is completely covered with water. Possible air bubbles on the surface of the mouthpiece, also on the inner side, must be removed (e.g. by stirring), so that the surface is completely covered with boiling water.
6. Leave the mouthpiece for at least 3 minutes and ideally 5 minutes, in boiling water. Ensure that the water temperature does not fall below 93°C.
7. Remove the mouthpiece with a tool (e.g. spoon) and leave the mouthpiece to drip and dry on a clean surface.
8. Before you use the cleaned mouthpiece again, ensure that it is completely dry and has cooled to room temperature.

9. Any limescale can be removed using a soft cloth.
10. After drying and cooling, place a new membrane on the mouthpiece (see figure 12). Ensure that the membrane is properly placed on the mouthpiece (see figure 13).



Figure 12: Placing the membrane



Figure 13: Correct position of the membrane

11. Carefully place the mouthpiece on the IntegraMouse Plus again. Pay attention to the direction in which you placed it on and move the mouthpiece in a **straight** movement without using force (see figure 14).



Figure 14: Placing the mouthpiece



Warning! Danger of scalding!



Disposal of the mouthpiece is recommended after no more than 6 months.



In the clinical sector the mouthpiece should be treated as a disposable product. The interval between changes of the mouthpiece must be determined by a doctor or by specialist staff (advisor, hygiene representative...). Special safety precautions must especially be obeyed when there is suspicion of infectious diseases.



The mouthpiece or other components of the IntegraMouse Plus are not intended for any kind of sterilisation, not even e.g. for sterilisation with steam or gamma sterilisation.

9.2 Cleaning the device

Clean the device regularly, about once a week. The parts of the IntegraMouse Plus, mouthpiece, IM+ connect, power pack including cable and stand can be cleaned at any time by wiping with a damp, lint-free cloth.



Never use sharp cleaning objects to clean the components as this could destroy the surface. The IntegraMouse Plus and IM+Connect contain sensitive electronics. Never immerse these components in water and also never use running water to clean them, otherwise you could destroy the device.



In the clinical sector multiple use of the mouthpiece by several users is forbidden. The re-use of the mouthpiece, the membrane or the silicon tube is also forbidden. Use these three components as disposable products and change them regularly after use, e.g. once a day. The other components should be used in accordance with the cleaning and disinfection plan.

Disinfection by wiping

In special environments, e.g. hospitals, it is necessary to carry out regular disinfection by wiping the device. The IntegraMouse Plus can be disinfected with any surface disinfectant product that is intended for the disinfection of LEXAN polycarbonate and aluminium. Under no circumstances may any components of the IntegraMouse Plus be subjected to steam or water sterilisation.

The following cleaning products can be used:

Mikrozid Sensitive liquid or Mikrozid Sensitive wipes from the company Schülke & Mayr GmbH (www.schuelke.com).

Carry out the disinfection by wiping according to the manufacturer's instructions and ensure that no moisture seeps into the IntegraMouse Plus.

9.3 Recharging the battery

Battery power display

On the front of the IntegraMouse Plus there is a display consisting of two light-emitting diodes (LEDs) in the form of a battery, which displays the battery power and the charging progress.

LED 1	LED 2	Battery power	Note
green	green	100% - 71%	Battery fully charged
green	Off	70% - 21%	Battery OK, charging not yet required
flashing orange	Off	below 20%	Low battery, please charge

Table 3: Battery power display

Charging

The charging of the battery occurs via the power pack included or by connection to the computer via the USB cable. In both cases, use the mini USB socket on the reverse of the IntegraMouse Plus. Plugging in is only possible in one direction. The charging process begins immediately after plugging in and takes 2-3 hours. Progress is indicated on the battery display:

LED 1	LED 2	Battery power	Note
orange	Off	Battery is being charged	Leave power pack plugged in until charging process is completed.
green	green	Battery fully charged	Power pack can be unplugged

Table 4: Charging process display



Only use the power pack or the USB cable supplied to charge or operate the mouse. Even when you have another power pack with mini USB available (e.g. from a mobile telephone), do not use this to charge or operate the IntegraMouse Plus. The power pack included is a special power pack for medical purposes.



Never change the battery yourself! If you suspect a problem with the battery, contact the manufacturer or your dealer.

9.4 Metrological testing

Every medical product - especially when being used in a clinical environment - should regularly be checked for safety. Regular safety testing - at the most every 24 months - can be carried out by the operator, by authorised service personnel or by the manufacturer e.g. in Austria and Germany according to the Medical Devices Operator Ordinance and the relevant standards (e.g. EN 62353). Responsibility for compliance lies with the operator of the IntegraMouse Plus.

10. PERMISSIBLE SYSTEM

The IntegraMouse Plus is intended for use as an input device for a computer (PC or laptop). Please only use the USB cable supplied, or work in wireless mode. Please ensure that your computer or laptop and all other devices which are connected to it (printer etc.) comply with the relevant regulations (EN 60950).



In rooms used for medical purposes, regulations to protect the patients' area must be adhered to. The patients' area is defined as an area of 1.5 meters around the user (see figure 15). Within this area only medical products may be used. The IntegraMouse Plus and its accessories are medical products. The computer is usually office equipment; however, it can also be a special Medical Computer. The following possibilities apply:

1. Computer within the patients' area
 - Medical Computer according to EN 60601-1 and EN 60601-1-1
 - Computer according to EN 60950, with an optional limit on touch current through the application of an additional protective earthing or an isolating transformer
2. Computer outside of the patients' area
 - Use of wireless mode and ensuring observance of the patients' area
 - Computer according to EN 60950, with an optional limit on touch current through the application of an isolating transformer

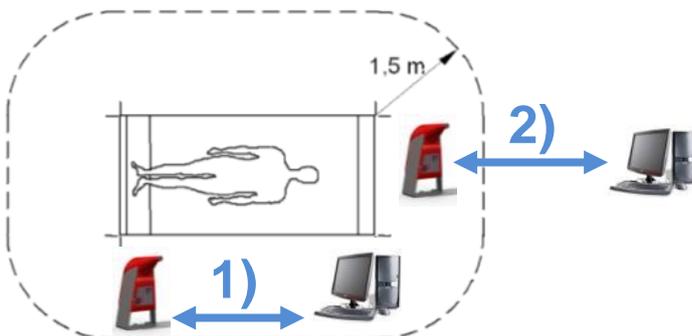


Figure 15: Definition of the patients' area according to EN 60601-1. Computer within the patients' area (1) and computer outside of the patients' area (2)



The operator who connects the IntegraMouse Plus to the computer must satisfy the requirements of EN 60601-1-1 and the relevant laws and standards for electrical installation. In the case of a connection with devices outside of the same medical rooms, it may be necessary to install a means of isolation into the data line.



A combination with other devices does not conform to the manufacturer's intended use. The system integrator is responsible for reassessing conformity.

External sensor

A suitable sensor can be plugged into the built-in 3.5 mm mono jack socket and used for switching between the operating modes (mouse, joystick, cursor mode).



Only potential-free external sensors may be used. Ask the manufacturer or your dealer for further information on this.

Figure 16: External sensor

Further medical products in the patients' area

Basically, the use of further medical products in the patients' area that are not directly coupled with the IntegraMouse Plus (e.g. ECG, breathing apparatus) is possible. In doing this, pay attention in every case to the instructions for use of the other medical product and get orientation from the protective guidelines in Chapter 16.



Be aware that the simultaneous use of several medical products can lead to a rise in leakage currents and to new risk potentials arising.

11. AMBIENT CONDITIONS

Operating conditions

Ambient temperature:	+10°C to +40°C
Rel. humidity:	20% to 80% with no condensation
Atmospheric pressure:	750 mbar to 1080 mbar
Light intensity:	<5000 Lux

The room installation must comply with the relevant regulations (in Austria: ÖVE-EN1, ÖVE/ÖNORM E8001, ÖVE EN7, ÖVE/ÖNORM E8007, as relevant)

Storage conditions

Ambient temperature:	-5°C to +45°C
Rel. humidity:	20% to 80% with no condensation
Atmospheric pressure:	750 mbar to 1080 mbar

Always keep the device in the undamaged original packaging. After storing for a long time it may be necessary to recharge the battery and disinfect the device. Ensure that no mechanical influences (weighing down by other objects, shaking etc.) occur during storage.



The maximum life expectancy for the membrane and silicon tube could expire during storage. Always change this after having stored it for a long time.

Transport conditions

Ambient temperature:	-5°C to +55°C
Rel. humidity:	20% to 80% with no condensation
Atmospheric pressure:	750 mbar to 1080 mbar

Transport is carried out in the original packaging. Ensure that no mechanical influences (weighing down by other objects, shaking etc.) occur during transportation.

12. WASTE DISPOSAL

The IntegraMouse Plus is to be disposed of according to Directive 2002/96/EC WEEE (Waste Electrical and Electronic Equipment) as an old electrical and electronic device (valid in the European Union and other European countries with separate waste disposal systems).



This symbol on the product or on the packaging means that this product cannot be treated as household waste. Instead, this product should be brought to the designated disposal point for the recycling of electrical and electronic devices. If the product is properly disposed of, you help to avoid negative influences on the environment and harm to health, which could be caused by inappropriate disposal. The recycling of material will preserve our natural resources. For further information about recycling this product please contact your household refuse collectors, the manufacturer or your dealer.



Individual non-electric components, including mouthpieces, silicon tubes and individual membranes can be disposed of with household rubbish. Please pay attention to hygienic aspects. Contact the responsible authorities for disposal if necessary.

13. FREQUENTLY ASKED QUESTIONS AND ANSWERS

Do I need specific drivers or software for installation?

No. The IntegraMouse Plus is automatically recognised as a standard mouse (or standard joystick and standard keyboard) and installed on your operating system (plug & play for the operating systems Windows XP, Windows Vista, Windows 7, Linux, Mac OS X).

Can I also use the IntegraMouse Plus with Apple® or Linux?

Yes. The IntegraMouse Plus can be used with Mac OS X or higher versions. The IntegraMouse Plus should work with all Linux operating systems that support USBs.

I do not have the strength required to operate the mouse buttons by sucking or blowing. Can I change the sensitivity of the sucking/blowing stimuli?

The necessary sucking/blowing stimuli of the IntegraMouse Plus were set by the factory at a particular range and cannot be altered. Exertion can be reduced by carefully stretching the membrane with a suitable object (e.g. the top, round end of a ballpoint pen). However, you have the option to connect auto-click software or external sensors via suitable switch interfaces, in order to activate the left and/or right mouse button in an alternative way. Your dealer will be happy to advise you about this.

Can I change the speed of the mouse pointer?

Yes. In the mouse settings options of your operating system.

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

Yes. In the mouse settings options of your operating system.

Can I set the double-click speed?

Yes. In the mouse settings options of your operating system.

Can I write texts with the IntegraMouse Plus?

Yes. Windows 7, for example, offers a free on-screen keyboard under Start/All Programs/Accessories/Windows Mobility Center. Recommendations for more convenient on-screen keyboards that are available to buy (e.g. with predictive text) can be obtained from your dealer.

After changing the mouthpiece the mouse pointer can no longer be moved!

Ensure that the mouse is correctly connected and ready to be used (check the LEDs). Check that the mouthpiece is in the correct position and recalibrate.

After changing the membrane the mouse buttons can no longer be activated!

Recalibrate. Check that the membrane is positioned securely and is not damaged.

After cleaning, the mouthpiece cannot be placed on the control unit, or is difficult to put on.

Through warming (thermo disinfection) the mouthpiece bends and therefore no longer fits optimally on the control unit. Before you use the cleaned mouthpiece again, please ensure that the mouthpiece is completely dry and has cooled to room temperature.

The mouse pointer moves independently on the screen.

Recalibrate.

Can I set the IntegraMouse Plus to environmental control?

The IntegraMouse Plus is a computer mouse and may only be connected with those environmental control systems that are designed for use with a computer mouse.

Unable to connect IM+Connect and IntegraMouse Plus.

Check that the IntegraMouse Plus battery is charged sufficiently. If necessary, connect it to the power pack included. Follow the instructions as described in Chapter 7.3.

"Wake on USB" is not working, although everything on the computer is set correctly!

"Wake on USB" only works in cable-connected mode and only with USB ports that are located directly on the mainboard. Connect the IntegraMouse Plus to a suitable USB port with the help of a USB cable and change the USB connection if necessary.

14. KEY TO THE SYMBOLS



Applied part type B



CE mark (Conformity with Medical Device Directive 2007/47/EC)



Disposal in accordance with WEEE Directive 2002/96/EC



HF transmission (radio)



Warning: Follow the instructions for use!



Information on use



Serial number in the format *Components (M/C) Version - Year (2 digits) - 4-digit continuous number*, e.g. M1.0-11-0001



Manufacturer



Direct current



Protection class II (double insulation)



Use by: YYYY-MM

15. PRODUCT AND PERFORMANCE DATA

IntegraMouse Plus

Voltage:	5 V
Current:	0.3 A
Radio:	2.4 GHz ISM-Band, +1dBm, ~1.3 mW
Sensitivity:	Mouthpiece deflection max. 3 mm Dynamic response characteristic Movement from about 10 g displacement force
Degree of protection:	IP20
Duration of operation with battery:	about 12 hours at continuous use about 48 hours at average use about 140 hours in standby mode
Measurements:	110 x 60 x 33 mm
Weight:	75 g
Compatibility:	From USB 2.0, Plug & Play for the operating systems Windows XP, Windows Vista, Windows 7, Linux, Mac OS X

IntegraMouse Plus battery

Description:	EEMB LP552036
Type:	Lithium polymer
Nominal voltage:	3.7 VDC
Max. charging current:	1C 300 mA
Max. discharge current:	2C 600 mA
Charging time:	First time: at least 3 hours; usually 2 to 2.5 hours
Nominal capacity:	360 mAh
Fuse:	PCM-Element (Over-discharge and short-circuit protection)
Measurements:	150 x 37 x 5.8 mm
Weight:	7 ± 1 g

IntegraMouse Plus Connect

Description:	IM+Connect
Voltage:	5 V
Current:	0.1 A
Compatibility:	From USB 2.0, Plug & Play for the operating systems Windows XP, Windows Vista, Windows 7, LINUX, Mac OS
Transmission:	2.4 GHz ISM-Band, +1dBm, ~1.3 mW
Radio range:	about 5 m, without obstruction
Parallel operation:	max. 5 IntegraMouse Plus systems (with 5 IM+Connect on 5 computers)
Measurements:	75 x 25 x 11 mm
Weight:	11 g

Power pack

Description:	GlobeTek Model GTM41076-605
Input voltage:	230 VAC, 50 Hz
Output voltage:	5 VDC
Input current:	0.5A
Output current:	1.2A
Output connection:	Mini-USB
Protection class:	II 
Adaptor kits for:	North America (Japan) Blade, Q-EU(R)=European Blade, Q-UK(R)=United Kingdom Blade, Q-SAA(R)=Australian Blade
Measurements:	74 x 43.5 x 36mm (without connector cap)
Weight:	125 g (without connector cap)

USB cable

Description:	Qualtec USB cable: 3021009-06
Colour:	Black
Length:	1.8 m
Connections:	USB type standard A, USB type mini A

Mouthpiece

Description:	IntegraMouse Plus mouthpiece
Material:	SABIC Lexan HP3NREU
Application part:	Type B 
Measurement:	65 x 25 x 28 mm
Weight:	7 g

Membrane

Description:	IntegraMouse Plus Membrane
Material:	Hard part: SABIC PP PCG H10; Soft part; TPE - TM3MED
Measurements:	Diameter: 17mm, height: 6 mm
Weight:	<1 g

Silicon tube

Description:	VERSILIC S60V34B
Material:	Silicon
Hardness:	Shore A 62±5
Diameter:	inner/outer 6/10 mm
Length:	19 ± 1.5 mm
Authorisations:	European Pharmacopoeia §3.1.9, FDA 21CFR §177.2600

16. ELECTROMAGNETIC COMPATIBILITY



The IntegraMouse Plus is a medical electrical device and is therefore subject to special safety precautions with regard to electromagnetic compatibility. Therefore, install and use the IntegraMouse Plus only for the purposes set out in these instructions for use. The IntegraMouse Plus, along with the specified accessories which are also delivered (cf. chapter 5 "Scope of supply") (cf. chapter 3 "Product information and use as per regulations" and also chapter 4 "Safety instructions") fulfils the limit values prescribed. The use of other apparatus or linking with other devices is not planned and can therefore lead to increased emission of radiation or reduced interference immunity against electromagnetic fields. Also consider that the radio waves of the IntegraMouse Plus and those of the IM+Connect could influence other electrical devices.



Always keep a working clearance of at least 10 cm between IntegraMouse Plus or IM+Connect and other medical electrical devices.

Note also the guidelines in the following tables.

Guidance and manufacturer's declaration – electromagnetic emissions		
The IntegraMouse Plus and its accessories are intended for use in the electromagnetic environment specified below. The customer or the user of the IntegraMouse Plus and its accessories should assure that they are used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 22	Class B	The IntegraMouse Plus and its accessories are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The IntegraMouse Plus and its accessories are intended for use in the electromagnetic environment specified below. The customer or the user of the IntegraMouse Plus and its accessories should assure that they are 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	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the IntegraMouse Plus and its accessories requires continued operation during powermains interruptions, it is recommended that the IntegraMouse Plus and its accessories be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The IntegraMouse Plus and its accessories are intended for use in the electromagnetic environment specified below. The customer or the user of the IntegraMouse Plus and its accessories should assure that they are used in such an electromagnetic environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 V/m</p> <p>80 MHz to 2,5 GHz</p>	<p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the IntegraMouse Plus and its accessories, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>$d = 1,2\sqrt{P}$ 150 kHz to 80 MHz</p> <p>$d = 1,2\sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz</p> <p>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).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>

NOTE 1 At 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 IntegraMouse Plus and its accessories are used exceeds the applicable RF compliance level above, the IntegraMouse Plus and its accessories should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the IntegraMouse Plus and its accessories.

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

Recommended separation distances between portable and mobile RF communications equipment and the IntegraMouse Plus and its accessories

The IntegraMouse Plus and its accessories are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the IntegraMouse Plus and its accessories can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the IntegraMouse Plus and its accessories 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 can be determined 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 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 80 MHz and 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

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



17. DECLARATION OF CONFORMITY

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KONFORMITÄTSERKLÄRUNG DECLARATION OF CONFORMITY

Produktspezifikation / product details

Produktbezeichnung / product name	IntegraMouse PLUS
Type / type	IntegraMouse PLUS
Systemkomponenten / systems components	Hauptgerät, Funkempfänger, Mundstück, Membran, Netzteil main unit, RF receiver, mouth piece, membrane, power supply unit
Klassifizierung nach RL 93/42/EWG, Anhang IX / Classification according 93/42/EEC, annex IX	Klasse I nach Regel 5 Class I according rule 5

Konformitätsbewertung / assessment details

Verfahren nach RL 93/42/EWG / route of directive 93/42/EEC	Anhang VII (Konformitätserklärung) annex VII (declaration of conformity)
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Angewandte Normen / used standards

Harmonisierte Normen / harmonized standards	EN 60601-1:2006, EN 60601-1-1:2001, EN 60601-1-2: 2001/A1:2006, EN 980:2008, EN 1041:2008, EN ISO 10993-1:2009, EN ISO 10993-10:2009, EN ISO 10993-12:2009, EN ISO 14971:2007, EN 62304:2006, EN 62366:2008, RoHS2011/65/EU
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Wir erklären in alleiniger Verantwortung, dass das oben beschriebene Produkt und Zubehör in der gelieferten Ausführung den Anforderungen der Richtlinie 93/42/EWG und den österreichischen Medizinproduktegesetzes BGBl. 657/1996 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 directive 93/42/EEC and the Austrian medical- device-law BGBl. 657/1996 in the presently valid edition. The products are CE marked.



Linz, 01.12.2019


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