Communication EarSwitch EAR001B Clinical Investigation Instructions for Use

EXCLUSIVELY FOR CLINICAL INVESTIGATION

Communication EarSwitch Instructions For Use (IFU)

Glossary of terms

Communication EarSwitch	The name of the device, including software and hardware.
EarClick	The term used to refer to the voluntary movement of the tensor tympani muscle also known as “ear-rumbles” or “ear-rumbling”. An EarClick is the method used by the user to trigger the device.
Earpiece sensor	Cylindrical component incorporating a miniature camera. This is held within the ear-canal by the "earbud" which is worn within the ear concha (bowl of the outer ear)
Configuration Software	Used to set up the Communication EarSwitch unit
Handle	A rigid component with an inner ball that fits into the Earbuds and through which the “Earpiece sensor” is passed to create the earpiece
Hook	Flexible Limb of the Earbud (Cymba hook)
User	Refers to an individual that interacts with, operates, or utilises the Communication EarSwitch to achieve specific tasks or goals. For example, the patient.
Operator	Assisting the user typically refers to an individual responsible for overseeing the operation and functioning of the Communication EarSwitch to aid the user in achieving their objectives effectively and safely. For example, the carer.

1. Introduction to the device

1.1. The Communication EarSwitch consists of an earpiece "sensor" *and "earbud unit"*, a "lapel clip" and a "*control box"*.

1.2. The earpiece, worn in the ear concha, incorporates a miniature camera. The earpiece sits within (but does not normally contact) the ear canal. The camera detects voluntary movement from the tensor tympani muscle as presented at the eardrum and the EarSwitch system translates this movement as a "Click" to an external virtual keypad or similar to allow the user to communicate non verbally (an "EarClick").

1.3. The Lapel Clip contains electronics and two status LEDs. It links to the sensor with a non-removable cable. The lapel clip is designed to be clipped onto fabric such as clothing/ bedding or furnishings close to the user's ear.

1.4. The Control Box contains further electronics and has sockets to connect to the lapel clip and to connect the device to a computer, an auxiliary device and/or a power source. The control box is designed to be strapped to a bed or wheelchair, or placed on a flat surface.

1.5. The Communication EarSwitch is non-invasive and is intended for short term use of less than 24 hours continuous use.

1.6. The Communication EarSwitch earbud should be removed from the ear when not in use.

2. Intended Purpose:

2.1. The Intended Use of the Communication EarSwitch is as a communication tool for users with conditions that restrict their ability to communicate. The Communication EarSwitch is designed to translate voluntary movements of the eardrum into predefined key or mouse button presses, to generate an action, to enable communication, via a computer screen or mobile device.

2.2. The Intended User includes users with neurological conditions such as Locked-in Syndrome (LIS) or Motor Neurone Disease (MND/ ALS). Additionally, users with conditions that affect their coordination or ability to control their movements such as severe cerebral palsy may also benefit from this device.

2.3. EAR001B units are for observational clinical investigation and should not be used as a primary means of communication.

2.4. These instructions are specifically for product revision EAR001B, developed for Phase B clinical investigation. The EAR001B is representative of the production-intent Communication EarSwitch.

3. Indications and contraindications.

3.1. Active inflammation or infection of the ear/ ear-canal/ ear-drum or middle ear, as indicated by ear pain/ discharge or irritation.

3.2. Known allergy to earpiece components (See Section 5 Warnings for list of skin-contacting materials)).

3.3. During Phase B clinical Investigation, the Communication EarSwitch is not suitable as a sole means of communication.

3.4. suitable for adult use only, not for paediatric use

4. Precautions

4.1. The Communication EarSwitch is designed as a communication aid only and must never be used to control physical devices nor to undertake critical tasks.

4.2. The Communication EarSwitch EAR001B for clinical investigation is intended for multiple use. Clean thoroughly between uses according to the cleaning instructions.

4.3. Inspect all parts of the device before and after use for signs of wear and damage. Devices showing damage or wear must not be used and should be returned to the manufacturer for refurbishment.

4.4. For use only as a communication tool following guidelines laid out in the Phase B Clinical Investigation Plan.

5. Warnings (outputs from the hazards and risk analysis)

5.1. The Lapel Clip should be clipped onto clothing or fabric and positioned so as to provide sufficient cable length to the earbud to allow for movement of the head.

5.2. The EarSwitch should never be used to control physical equipment nor to undertake critical tasks.

5.3. The device may be susceptible to EMC emissions from other devices. This device may be affected by external Radio Frequency sources and also produces some low-level electrical noise. Occasionally, in use, the device sensitivity may be affected by external influences, this is entirely normal.

5.4. The device may produce electromagnetic noise that may affect other sensitive electronic equipment within close proximity. The device meets EMC emission requirements for use in hospital settings. In home settings, if equipment is affected by the operation of this product, then the Communication EarSwitch should not be used in the vicinity of the affected equipment.

5.5. Earbud materials contacting user's skin in normal use are:

5.5.1.1. Cable to EarSwitch Sensor: FEP - N3180 fluoropolymer

5.5.1.2. EarSwitch Sensor skin-contacting parts: Smooth-Sil 945 silicone rubber

5.5.1.3. Earbud: Smooth-Sil 945 silicone rubber

5.6. If skin irritation occurs, the use of the Communication EarSwitch should be ceased and if symptoms continue they should seek the advice of the healthcare professional.

5.7. The Communication EarSwitch is only for use with the supplied power supply, model number AMF18US05.

6. Overview of components

6.1. The Communication EarSwitch consists of:

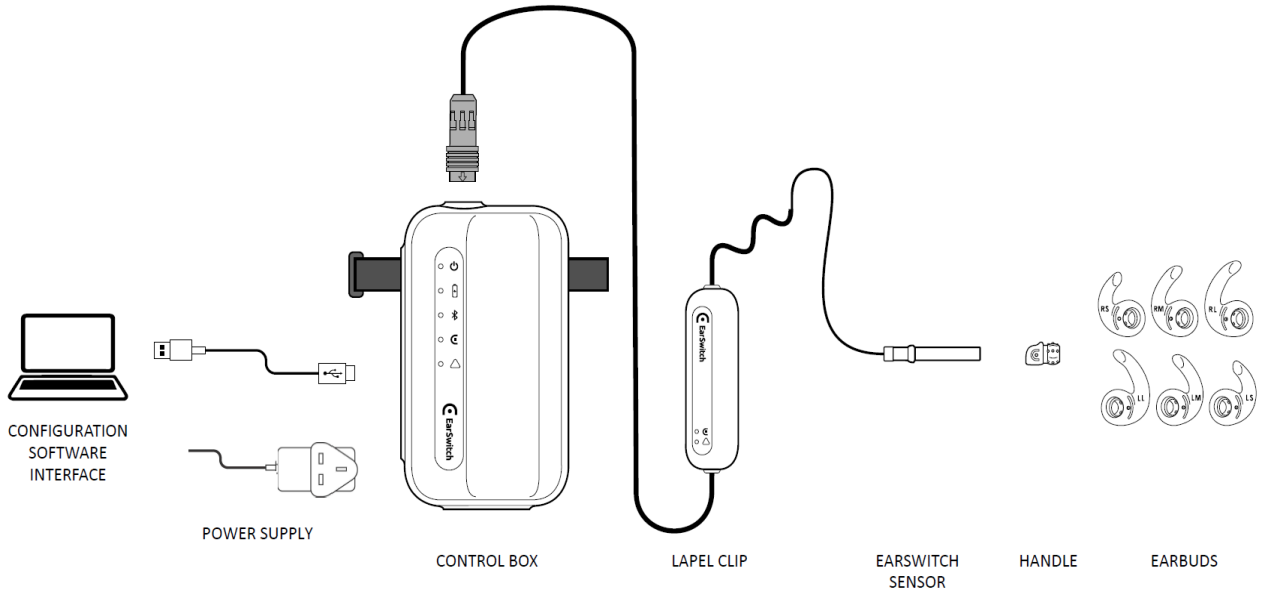
6.1.1. Configuration software that is used to set up the Communication EarSwitch unit. The control software can be accessed through USB via a web browser (instructions provided below).

6.1.2. A “Control Box”, which connects the Communication EarSwitch to the device that it is controlling, e.g. computer.

6.1.3. A “Lapel Clip”, which can be clipped to clothing / bedding or furnishings close to the ear

6.1.4. The Communication EarSwitch earpiece “sensor” and “handle”

6.1.5. The Communication EarSwitch “earbud”



6.2. Software

6.2.1. The Communication EarSwitch includes a single board computer (custom PCB) housed in the “Control box”. This runs the “Device Software” including “Configuration Software”.

6.2.2. Configuration software is accessible through a USB-connected PC Computer running Microsoft Windows 10 or newer and is accessed via a web browser.

6.2.3. The Communication EarSwitch should be used only with computers that have up-to-date antivirus software installed and running.

6.3. Control box

6.3.1. **Overview:**

6.3.1.1. The Communication EarSwitch includes a single board computer housed in the “Control box”.

6.3.1.2. The EarSwitch earpiece sensor streams data via the lapel clip to the control box.

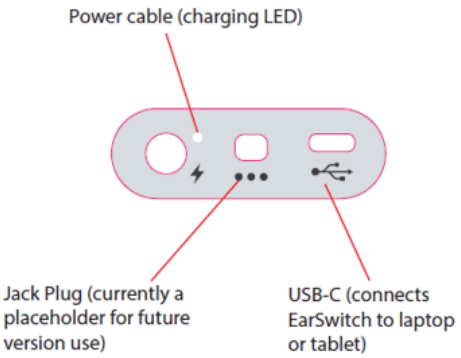
6.3.2. **Ports:**

6.3.2.1. The control box has a port to connect the earpiece sensor cable

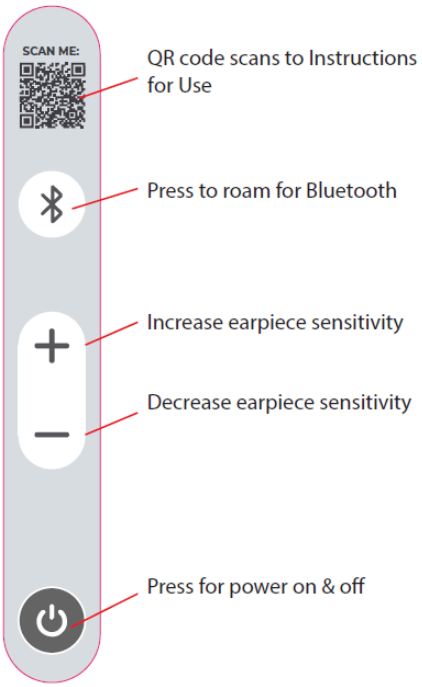
6.3.2.2. The control box contains a USB socket connection to a PC to provide configuration function and control output/ “EarClick”(HID) function.

6.3.2.3. The control box contains a barrel jack for charging.

6.3.2.4. Relay 3.5mm jack



6.3.3. **Switches:**



6.3.3.1. to power on; press and hold the power button of the Control Box until the green power LED illuminates.

6.3.3.2. The power button can be used to hard power down the Communication EarSwitch if the Control box does not respond correctly. Hold the power button for at least 5s to activate a hard power down.

6.3.3.3. The power switch will result in the device shutting down when held for at least 2s.

6.3.3.4. The +/- switches are used to alter the sensitivity setting of the device.

6.3.3.5. A simultaneous press of both sensitivity buttons will activate the self-calibration process.

6.3.3.6. Pressing either the + or - buttons during an “Out of Ear” state will reset the Communication EarSwitch; it will silence the “Out of Ear” beep and reactivate the system to allow “EarClicks”.

6.3.4. **Indicators-**The control box has five indicator LEDs on the Icons label and a single LED on the Connector label:

6.3.4.1. Power LED (Green) - illuminates when the device is on

6.3.4.2. Battery charge status LED (Green & Amber) illuminates only if the unit is powered on. (not used in the Clinical investigation during which advice is given for the unit to be plugged in continuously)

6.3.4.2.1. Green if battery level is high

6.3.4.2.2. Amber if battery level is medium

6.3.4.2.3. Amber flashing if battery level is low

6.3.4.2.4. Green flashing if battery is charging

6.3.4.3. Not used: placeholder for Bluetooth pair/status indicator (Blue)

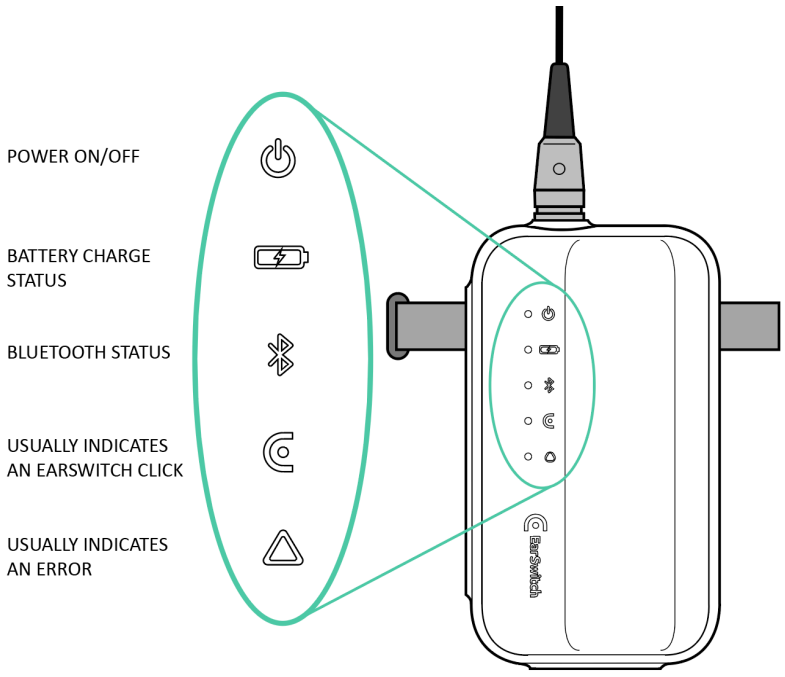
6.3.4.4. Status LED 1 (EarSwitch logo- Green)(to match the mimic LEDs on the shoulder clip) - usually indicating an EarClick

6.3.4.5. Status LED 2 (Triangle-Amber)(to match the mimic LEDs on the shoulder clip) - usually indicating an error

6.3.4.6. Connector label LED, illuminates if the unit is connected to an external power supply.

6.3.4.6.1. Continuous green: Power is present and battery is fully charged,

6.3.4.6.2. Flashing green: power is present and battery is charging



6.3.5. **Mounting straps**

6.3.5.1. A strap is used to mount the device to a suitable secure position

6.3.5.2. An additional strap (not supplied) can be used to provide extra mounting support

6.4. Lapel Clip

6.4.1. The lapel clip contains electronics and two status LEDs.

6.4.2. It links to the earpiece with a non-removable cable.

6.4.3. The lapel clip is designed to be clipped onto fabric such as clothing close to the user's ear.

6.4.4. **Indicators**

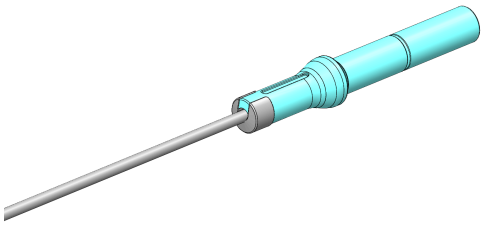
6.4.4.1. Lapel Clip Green: follows Control Box EarSwitch logo (Green)

6.4.4.2. Lapel Clip Red: follows Control Box triangle (Amber)

6.5. EarSwitch Communication sensor and earbud

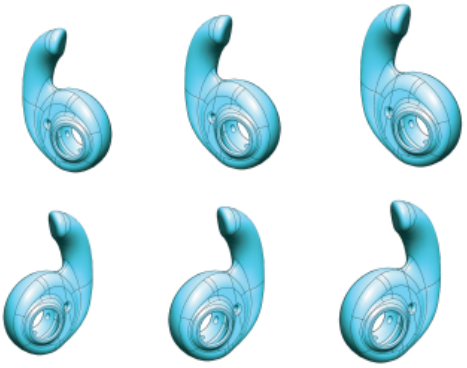
6.5.1. An earpiece sensor containing the sensing device, in this case a miniature camera sensor.

6.5.1.1. The sensing device is housed in silicone. A cable connects to the lapel clip.



6.5.1.2. The handle is a rigid component with an inner ball that fits into the Earbuds and through which the sensing device is passed to create the earpiece.

6.5.1.3. Earbuds are of 3 sizes (Small, Medium and Large) for each of the Right and Left ear.



7. Using the device for the first time

7.1. Content of box

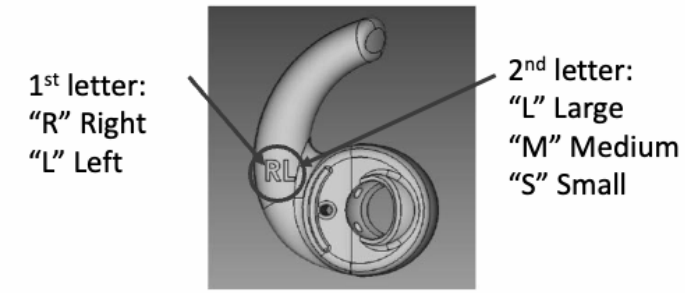
7.1.1. Control Box
7.1.2. Earpiece Sensor
7.1.3. EarBud (SML) Right and Left pack-A selection of six soft elastomer earbuds (Small, Medium and Large in Left and Right orientation.
7.1.4. Lapel Clip
7.1.5. Power Supply
7.1.6. USB cable
7.1.7. Instructions for Use

7.2. Unboxing

7.2.1. To perform the initial device set-up, it is recommended that a PC running Windows 10 or newer is available that can be plugged into the EarSwitch device by USB C cable.
7.2.2. A quick-start guide, together with an electronic version of this document is available at http://www.earswitch.co.uk/communicationtool
7.2.3. The link above can be accessed directly by scanning the QR code on the side of the device using suitable QR scanning software, for example on a mobile phone.
7.2.4. The Communication EarSwitch must be checked for signs of damage or wear before each use.
7.2.5. Please quarantine and return any units showing damage or wear to the manufacturer.
7.2.6. The EarSwitch must be cleaned before each use using a non alcoholic antimicrobial wipe, for example Clinell sanitising wipes (product code CW200), and should be allowed to dry before insertion.

7.3. Sizing and Preparing EarBud

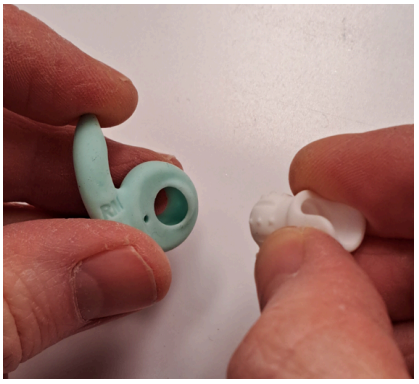
7.3.1. The Communication EarSwitch can be used in either the left or right ear. There are Small, Medium and Large earbuds available for the Left and right ear.
7.3.2. The Communication EarSwitch device is provided with the 'Handle' inserted in the Earbud to demonstrate as an example (please change size accordingly as below).
7.3.3. Choose which ear to use. Some people find it easier to perform the EarClick on one side, but other factors such as the natural resting position of the head and ear geometry may also affect the choice, so it is important to try both and see which works best.
7.3.4. Visually estimate and select an earbud size (marked "S" Small, "M" Medium and "L" Large). Place the earbud in the selected outer ear to check size, making sure the correct side earbud is selected (marked "L" for Left or "R" for Right; e.g. Large Left marked "LL"). The earbud insert should fit snugly in order to firmly locate the EarSwitch camera.



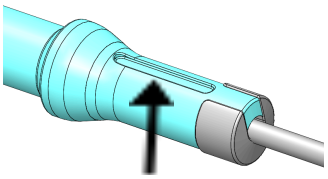
7.3.5. NOTE: Earbuds are multiple use items but should not be shared or transferred between users.

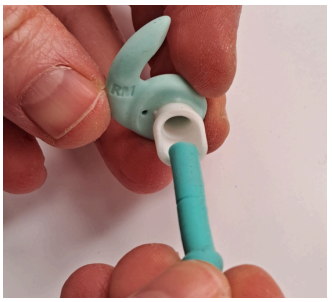
7.3.6. Once the optimum earbud size has been determined, remove the earbud from the ear.

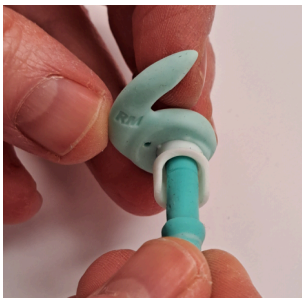
7.3.7. While holding the earbud with the letters facing you, firmly push the ball of the 'Handle' component into the selected earbud, ensuring the open section of the handle is pointing towards the tip of the hook of the earbud.



7.3.8. Hold the earpiece sensor with the grove pointing upwards and insert into the Handle so the camera lens tip is flush with the back face of the earbud. See photo for reference. The grove in the sensor should be pointing towards the tip of the hook of the earbud.







7.3.9. Attach the lapel clip cable to the control box , Push the large black connector into the Control Box until it clicks. The white arrow should be facing the front.

7.3.10. Decide where you want to mount the Control Box (eg. back of chair, bed frame etc) and use the velcro strap to secure.

7.3.11. Ensure the control box is connected to its power supply. A green LED should illuminate next to the power socket on the control box. The green LED may be constant or may flash, see 6.3.4.2 the description above for more information.

7.3.12. Now proceed to the next stage: Launching the software and obtaining a view from the camera

7.4. **Launch Software**

7.4.1. For home use and home-use demonstration: Connect the EarSwitch Control Unit by USB-C to a PC running Windows 10 or newer with a suitable web browser installed.

7.4.2. For Research staff only; for face to face recording software: Connect the EarSwitch Control Unit by USB-C to the designated research computer and launch the EarSwitch research software. Select the EarSwitch camera to obtain a camera view.

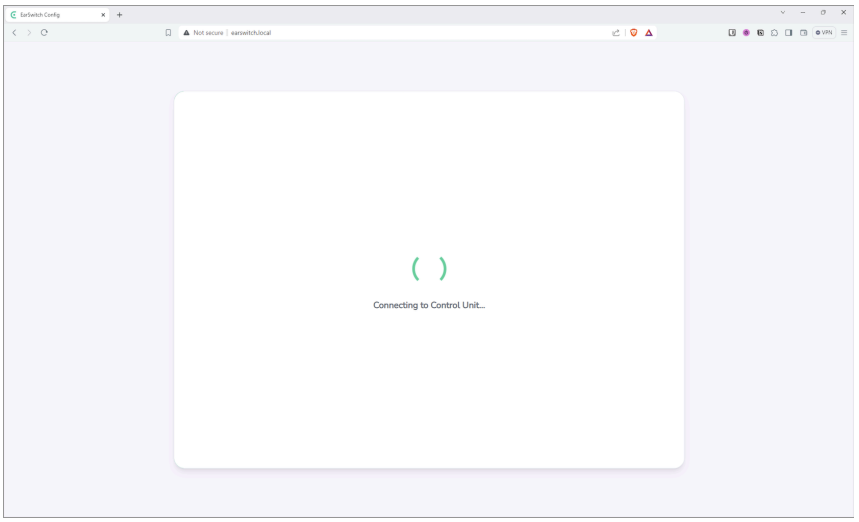
7.4.3. Press and hold the power button of the Control Box until the green power LED illuminates (release the button once the LED illuminates otherwise it may shutdown after long hold)

7.4.4. Connect the Control Box via the USB C cable to the windows computer.

7.4.5. Launch a web browser on the windows computer and in the address bar type:

earswitch.local (this link is present on the web page accessed from the QR code on the device)

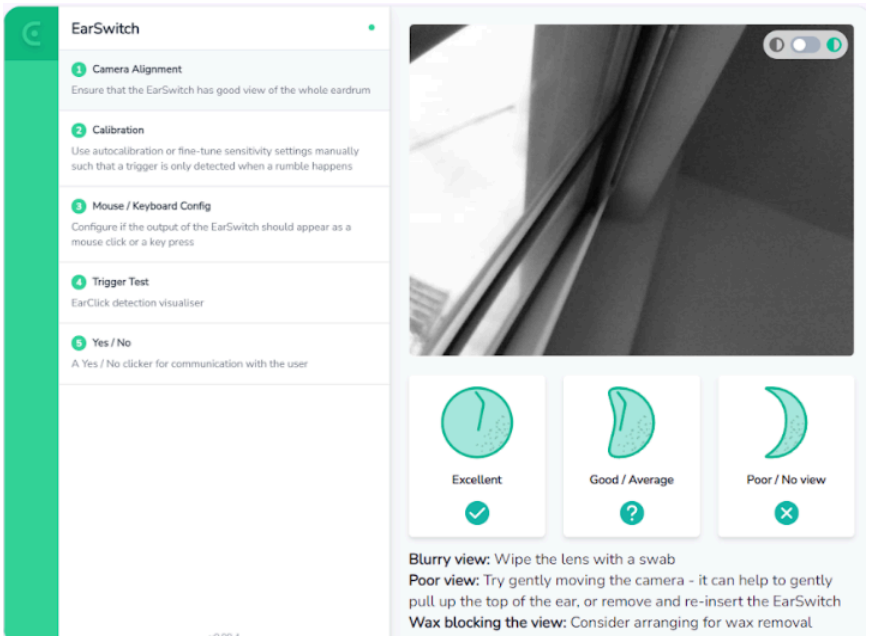
and press enter. You should see the following screen:



7.4.6. If there is an issue with DNS routing to earswitch.local please use the given IP address 169.254.1.1

7.4.7. On start-up the EarSwitch is not set up to generate EarClicks to prevent inappropriate triggering of events when placing the EarSwitch however it will beep on detecting movement.

7.4.8. After a few seconds, the screen should change to a setup option screen with a camera view:



7.4.9. The view can be toggled between black and white and colour using the toggle switch at the top right of the image, see image

7.4.10. Next, continue with the setup procedure by following the instructions below to insert the earbud and obtain a view of the eardrum.

7.5. Insert EarBud into ear and adjust

7.5.1. The EarSwitch earbud is adjustable, with control over barrel length and angle. The length and angle are held by friction and do not need to be locked

7.5.2. The optimum earbud size, barrel length and angle is determined by altering these to suit the individual wearer.

7.5.3. When inserted correctly the hook of the Earbud is pointing upwards towards the top of the head and is tucked in within the coil of the outer ear as below.

7.5.4. At insertion intermittent beeps (detecting movement) will be heard.

7.5.5. Set the length short as described in 7.3.8 to aid initial fitting.

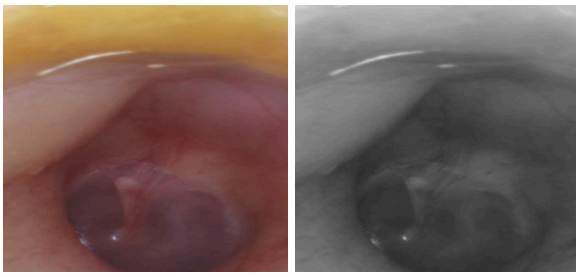
7.5.6. Place the EarSwitch into the participant's ear, securing the earbud into the bowl of the ear with the hook positioned comfortably in the coil of the ear. If the EarSwitch is loose, consider a larger earbud. If the EarSwitch is overly tight or difficult to secure, consider a smaller earbud.

7.5.7. Gently pull up the top of the ear on insertion to help locate the EarSwitch

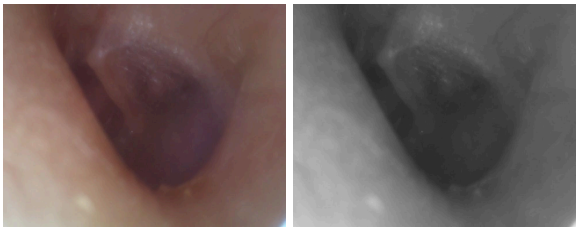
7.5.8. At every stage of earbud placement and adjustment any operator helping the user should check with the user for any discomfort, and remove and/or reposition until a comfortable, user acceptable positioning is achieved.

7.5.9. Looking at the image from the camera using the configuration software- start to position the device in the ear until a good view of the eardrum is seen as seen below (both image options are shown in colour or black and white):

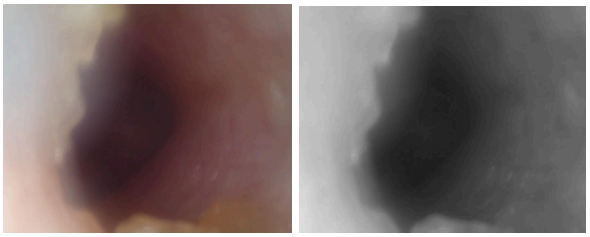
Good View Example: A clear view of the eardrum (the rotation of the eardrum image does not impact use)



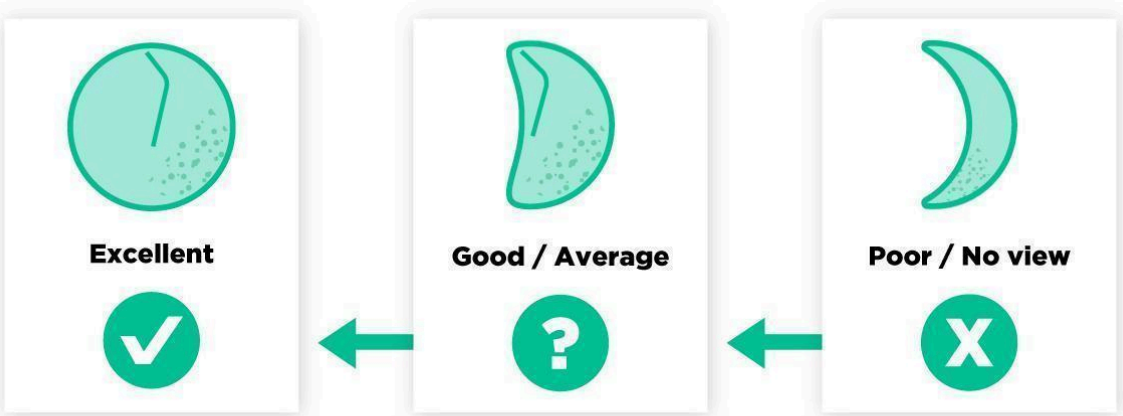
Average View Example: Partial view but sufficiently clear to detect trigger in most instances



Bad View example: Blurred view. Consider cleaning



7.5.10. The view of the eardrum on the image on the Configuration software should be similar to the optimum view as shown below (and this instruction is replicated on the App). Compare camera image with the images below to assess whether a useful position has been achieved.



Blurry view - Wipe the lens with a swab.

Poor view - Try gently moving the camera. It can help to gently pull up the top of the ear, or remove and reinsert the EarSwitch.

Wax blocking the view - Consider arranging for wax removal.

7.5.11. Once the suitable view of the eardrum is found, temporarily remove the earpiece from the ear by gently pulling the barrel. Then lock the earpiece by bending the end section up to allow the cable to be positioned over and behind the ear. Alternatively the user/ operator may opt to leave the wire directed in alternative directions if for the user this provides a stable system, for example bent down.

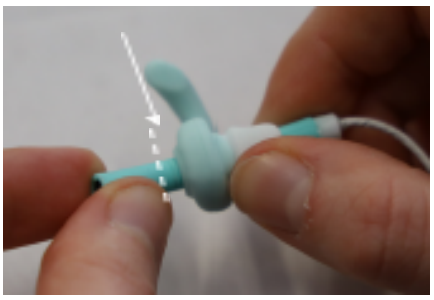
7.5.12. If you continue to hear a regular beep, press the + or - button to reset the out of ear detection warnings.

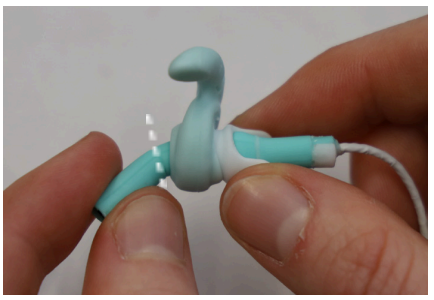
7.5.13. Clip the Lapel clip to clothing/ bedding or furnishings to provide a stable positioning of the wire, without undue movement or tension.

7.5.14. The cable length between the Earpiece and Clip should be positioned to avoid excess slack. However adjust the position of the Clip if the cable is taut to allow for unrestricted head movement.

7.5.15. Select the video feed on the Configuration interface tab. With reference to the video feed, adjust the EarSwitch sensor length and angle to obtain a clear view of the eardrum. This may require an operator to remove the EarSwitch earbud assembly and adjust the angle and or depth, and then reposition the earbud.

7.5.16. To angle the camera further, remove the ear-piece from the ear, and observe where the bend line on the silicone is. Gently hold the tip and bend the earpiece to slightly angle it. DO NOT bend nearer the tip of the sensor than the indicated bend line.





7.5.17. If excessive wax blocks a view of the eardrum, do not attempt to clear the blockage using the device, or any other object. Refer to the investigation documentation for further information.

7.5.18. Once the view of the eardrum on the image on the Configuration interface is similar to the optimum view as shown above , the cable positioning and security of anchoring (e.g. behind the ear) should be rechecked and adjusted as necessary.

7.5.19. The view of the eardrum on the Configuration interface should be confirmed as being satisfactory again, and if necessary the repositioning and checking process shall be repeated.

7.5.20. Recheck the comfort with the user, and reposition and/or remove as required.

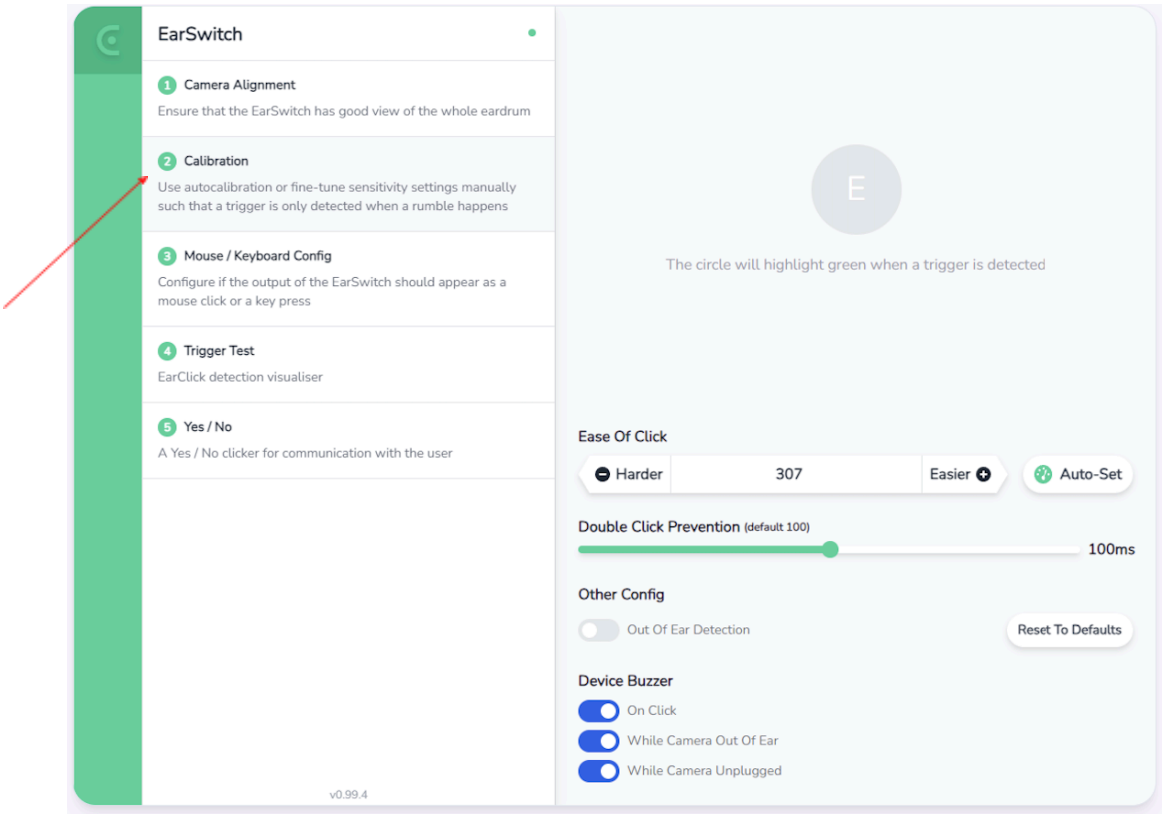
7.5.21. Should irritation occur, cease to use the device.

7.6. First Setup and Calibration

7.6.1. If you continue to hear a regular beep, press the + button to reset the “out of ear detection” warnings.

7.6.2. The following assumes setup and calibration is performed using the configuration interface from a windows computer. On first set-up, the configuration interface should always be used to set up the device.

7.6.3. On the configuration interface, click on Option 2 (Calibration) in the left hand menu



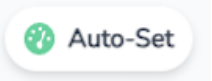
7.6.4. There is a single parameter to calibrate the Ease of Click of the Communication Earswitch. This should be checked after every fitting and whenever it is suspected that the device may be missing EarClicks or generating phantom or double EarClicks.

7.6.5. The user has the option to Reset to defaults at any stage of the calibration process. it will go back to the Ease of Click value of 307 and Double Click prevention value of 100ms.

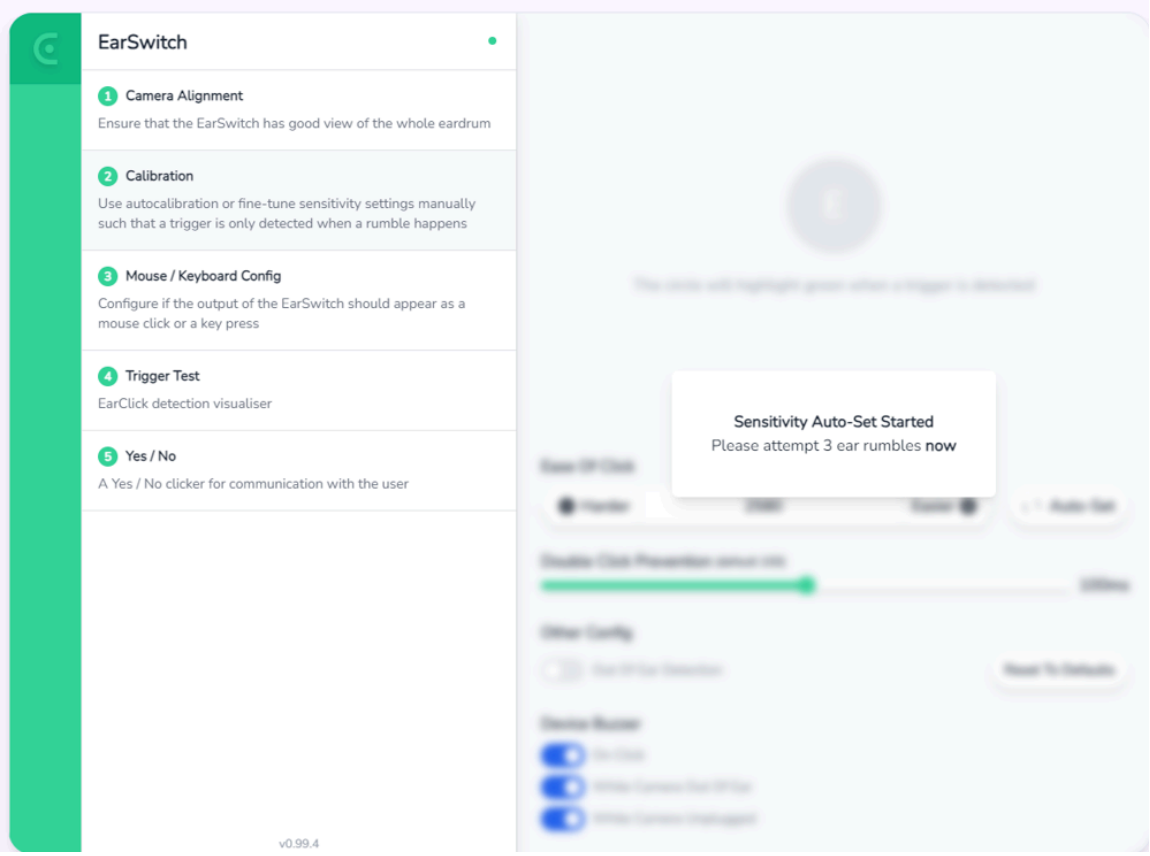
7.6.6. **Automatic sensitivity adjustment (from configuration interface)**

7.6.6.1. Automatic sensitivity adjustment requires the user to EarClick (also known as Ear rumble) three times within a 5 second period. From this, the Communication EarSwitch identifies the optimum calibration. This can then be fine-tuned using manual adjustment, where needed.

7.6.6.2. Click on the Auto-Set button to start automatic calibration. You will hear a long beep to signify auto-calibration has been initiated



7.6.6.3. The user should now attempt three EarClicks (also known as Ear rumble). The Control Box will emit a short beep every second.



7.6.6.4. A prolonged beep will sound at the end of the calibration process.

7.6.6.5. Successfully detected EarClicks will show a highlighted green circle on the sensitivity control screen and will also illuminate EarSwitch Logo LED

7.6.6.6. **Test a calibration**

7.6.6.6.1. Calibration is best tested by asking the user to EarClick once. The circle will highlight green when a trigger is detected. If no EarClick is detected, or multiple EarClicks are detected then the sensitivity and double click prevention may need manual adjustment.

7.6.6.6.2. Manual adjustment of sensitivity is performed using the “harder” and “Easier” buttons. If no “EarClicks” are being detected, the sensitivity is increased by pressing the “Easier” button. If the device is producing phantom EarClicks, the sensitivity is reduced using the “Harder” button.

7.6.6.6.3. If double clicks are occurring, the double click prevention should be increased. Note that a high value of double click prevention may limit the speed at which the user can “EarClick”when they are familiar with using the Communication EarSwitch.

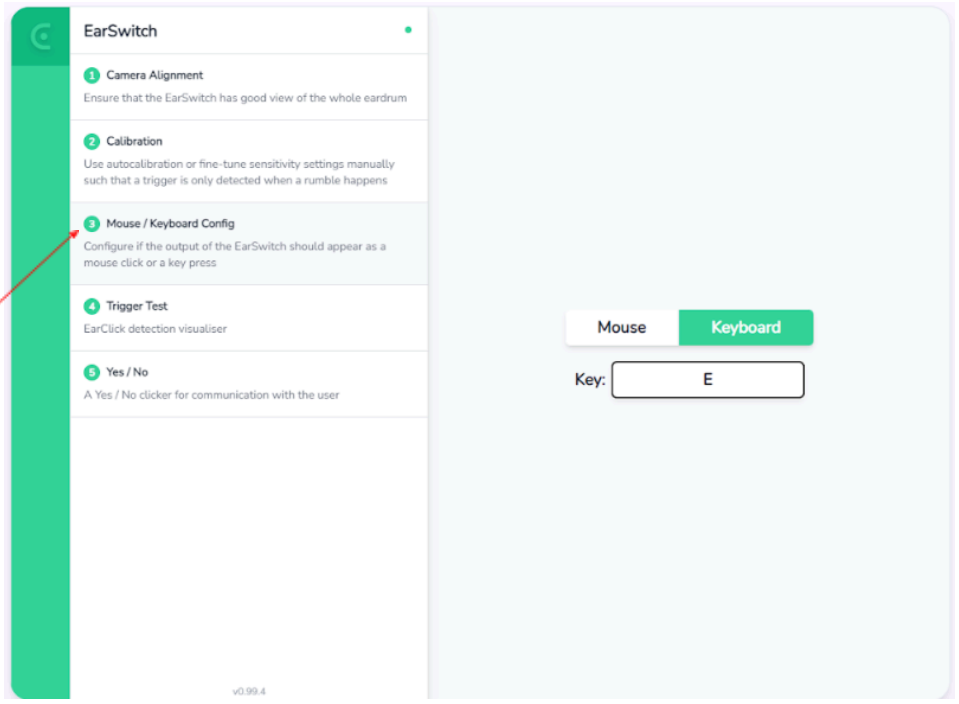
7.6.6.6.4. After the initial setup, calibration can be adjusted using Automatic Sensitivity Adjustment, via the Control Box sensitivity buttons (see Section 8) or using the sensitivity settings provided in the configuration interface. We recommend using the configuration interface whenever possible, as this provides the means to test if the settings are correct.

7.6.6.7. “Out of Ear Detection” toggle enables or disables this function. If the earpiece is dislodged from the ear the “Out of Ear Detection” causes a regular beep to sound from the Control Box, and EarClick’s will be disabled. This function is reset by pressing the + or - buttons on the Control Box; this switches off the beep and allows the user to EarClick again (see 6.3.3.5)

7.6.7. Mouse / Keyboard configuration

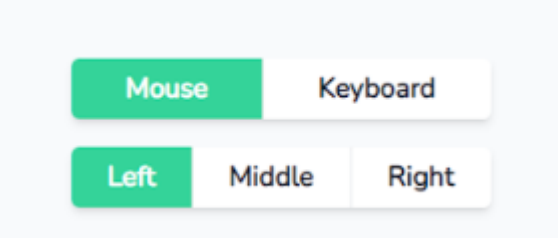
7.6.7.1. The action that occurs when an EarClick is performed is set by adjusting the settings in setup section 3.

7.6.7.2. Click on menu option 3 (Mouse / Keyboard Configuration)



7.6.7.3. Select either Mouse or Keyboard modes.

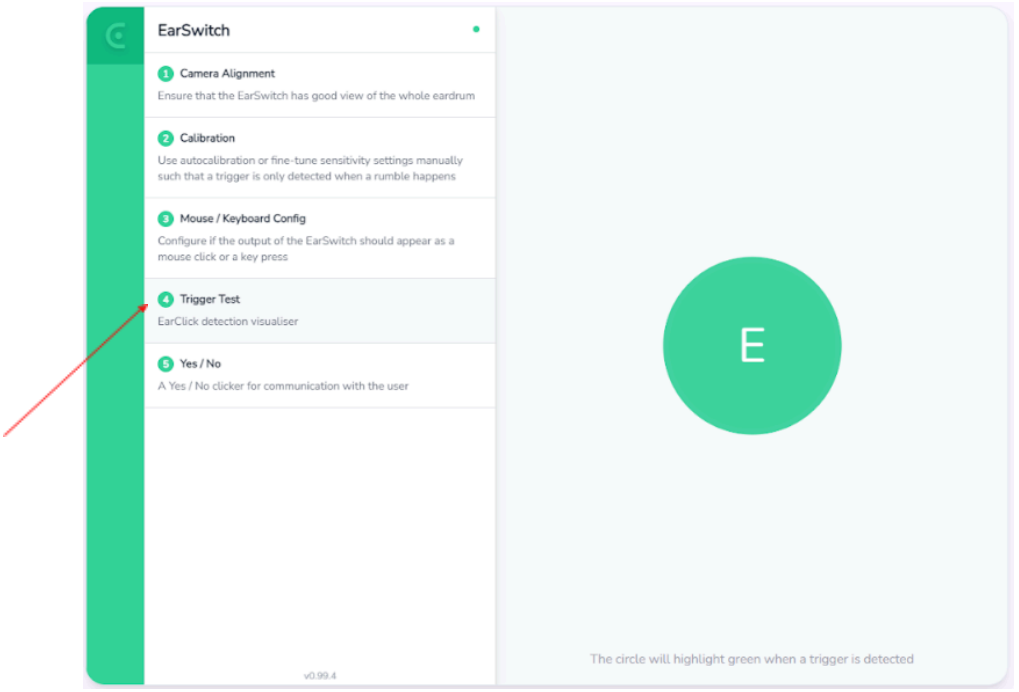
7.6.7.3.1. If selecting a mouse button mode, select which of the left, middle or right buttons the EarSwitch should emulate.



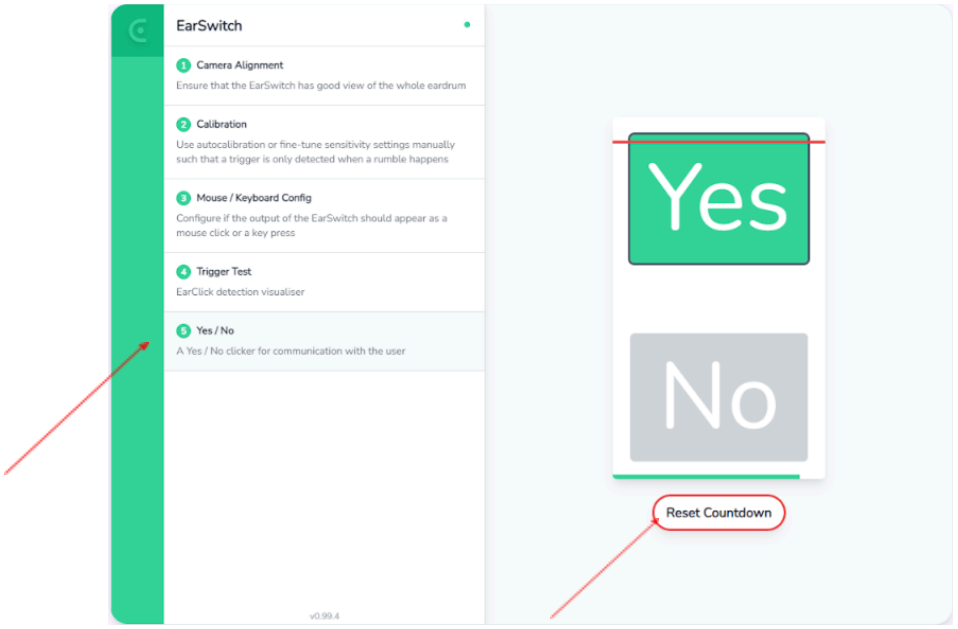
7.6.7.3.2. If selecting a keyboard button press, select Keyboard option and using the computer's keyboard, enter the key that the EarSwitch should emulate. Valid characters are uppercase A-Z, lower case a-z and numbers 0-9.

7.6.7.3.3. Special Characters are not supported.

7.6.7.4. Menu option 4 is intended to be used to check the function of the EarClick with the user. The Trigger test can be used to check the sensitivity configuration. For example, the user can be asked to “click three times” and the operator can check that the trigger is activated three times in response.



7.6.7.5. Menu option 5 is intended to be a quick tool for the user to react to Yes/No response questions. A selection slider scrolls up and down over two large buttons YES and No. The user is asked to EarClick when the correct response is highlighted. For example, the operator may ask "is the EarSwitch Communication device comfortable?" and wait for a response from the user.



7.6.7.6. The selection will automatically clear after 15 seconds, and can be reset by a User EarClick or by the Operator by clicking the Reset countdown button which is highlighted.

7.7. Using the EarSwitch to generate control output (EarClicks)

7.7.1. On start-up the EarSwitch is not set up to generate EarClicks, so as to prevent inappropriate triggering of events when placing the EarSwitch. However, it will beep on detecting movement (7.4.7).

7.7.2. Once the Calibration and Keyboard/ HID setup stages have been completed, the user is ready to use the EarSwitch to generate EarClicks to send mouse clicks or keystrokes to the USB Connected Windows computer.

7.7.3. Close the window for the web browser for the Configuration interface by clicking on the cross on the web tab.

7.7.4. Closing the window (7.7.3) activates the chosen mouse click or keystroke.

7.7.5. Leaving the interface web page open will prevent the EarSwitch from sending mouse clicks or keystrokes.

7.7.6. Once the calibration is completed on one Windows computer, the EarSwitch may be disconnected from the USB port of the calibration computer, and instead connected by USB to another Windows computer to provide the mouse clicks/ keystrokes.

8. Alternative calibration using the Control Box buttons (for advanced use, only after initial setup)

8.1. Automatic sensitivity adjustment (from Control Box)

8.1.1. To enter automatic sensitivity adjustment mode, press and hold the + and - keys together. You will hear a long beep.

8.1.2. The user should EarClick three times. The device will beep every second, with a long beep confirming the end of the 5 second calibration period.

8.2. Manual adjustment (from control box)

8.2.1. If the device is producing phantom clicks, the sensitivity needs to be turned down by pressing the "-" button. The device will beep when a change of sensitivity occurs. Each press changes the sensitivity by a small amount.

8.2.2. If the device is not responding when the operator suspects the user is attempting to click, then the sensitivity needs to be adjusted up by pressing the + button. Each press changes the sensitivity by a small amount.

8.3. Re-test after every calibration.

8.3.1. It is important to test if the calibration is correct by asking the user to perform a set of EarClicks.

8.3.2. If more than 5 presses of adjustment of sensitivity fails to improve the usability, auto calibration process should be followed.

9. Removal

9.1. Once finished using the device, hold the Handle and gently pull the whole earpiece assembly out of the ear. If the Earbud outer remains in the bowl of the ear, gently remove this by pinching the earbud with thumb and finger.

10. Storage

10.1. Store the earpiece clipped on the latch on the Lapel Clip.

10.2. You can leave the components in their pre-positioned angle and length set up, so next time you use EarSwitch it might be easier or quicker to find the correct view of the eardrum.

10.3. If you wish to change the earbud size, gently pull the earbud off the Handle and push onto the alternative earbud.

10.4. If you wish to detach the Lapel Clip wire from the Control Box, simply unclip the black connector by pulling the decoupling ring (indicated by the black arrow on the picture) gently

from the control box (however this is not advised; instead store with the wire wrapped around the box)

11. Maintenance and cleaning.

11.1. All components can be cleaned periodically using alcohol free cleaning wipes such as Clinell wipes.

11.2. Earbuds are strictly single person use and should be replaced if showing signs of wear or after 3 months of use, whichever sooner.

11.3. Spent Earbuds should be removed from the Handle and the Earpiece sensor and disposed off according to the 15.4. Fresh Earbuds would then be attached to the sensor according to the instructions given above.

11.4. Other components should be cleaned using non alcoholic antimicrobial wipes in accordance with local best practice and checked for any damage or deterioration before being reused.

11.5. Damaged devices should not be reused.

11.6. It is recommended that the device is serviced every year by the manufacturer or an EarSwitch approved service provider.

12. Troubleshooting.

12.1. If the unit doesn't send EarClicks as expected- open the configuration software and adjust sensitivity.

12.2. If the unit doesn't send EarClick as expected after adjusting the sensitivity in the configuration interface , press the + or - button to attempt to reset the out of ear detection (OOE)

12.3. If the EarClick beep sounds and/or the EarClick LED illuminates but no mouse click or keystroke is generated

12.3.1. Ensure that the web page for the Configuration interface is closed

12.3.2. Press the + or - button to reset “Out of Ear Detection”

12.4. If the camera becomes disconnected, the unit should be shut down, the camera reconnected and the unit restarted.

12.5. If the device fails to work as expected, the unit should be checked for damage (such as damage to cables). If any damage is observed, the device should be returned for repair. If no damage is observed, the steps “using the device for the first time” should be revisited.

12.6. If the device fails to work as intended, hold the power button to reboot the Control Box.

12.7. If the device fails to work as intended after the above steps, please take notes and contact the manufacturer for further advice.

13. Disposal.

13.1. The EarSwitch is to be returned to the manufacturer for disposal. Damaged or worn EarBuds can be disposed of as ordinary waste.

14. Technical specifications.

14.1. Device Dimensions:

14.1.1. Control Box

14.1.1.1. Maximum bounding box outer dimensions are 200x120x 60mm

14.1.2. Lapel Clip

14.1.2.1. Maximum bounding box outer dimensions are 120x40x40mm

14.2. Weight of device:

14.2.1. Earpiece target mass is less than 20g

14.2.2. Lapel box target mass is less than 60g

14.2.3. Control Box target mass is less than 600g

14.3. Class I in accordance with UK MDR 2002 (SI 2002 No 618)

14.4. **Operating Conditions**

14.4.1. Temperature Range..... -5°C to +30°C

14.4.2. Relative Humidity Range..... 15% to 93% non-condensing

14.4.3. Atmospheric Pressure Range..... 700 hPa to 1060 hPa

14.4.4. Expected Life of device……..

14.4.4.1. Non-replaceable hardware items: 5 years, 10,000 hrs total use time, 10,000 ear insert/removal cycles

14.4.4.2. Replaceable items: Earbuds will have a working life of 6 months / 300 ear insert/removal cycles

14.5. Transport and storage conditions

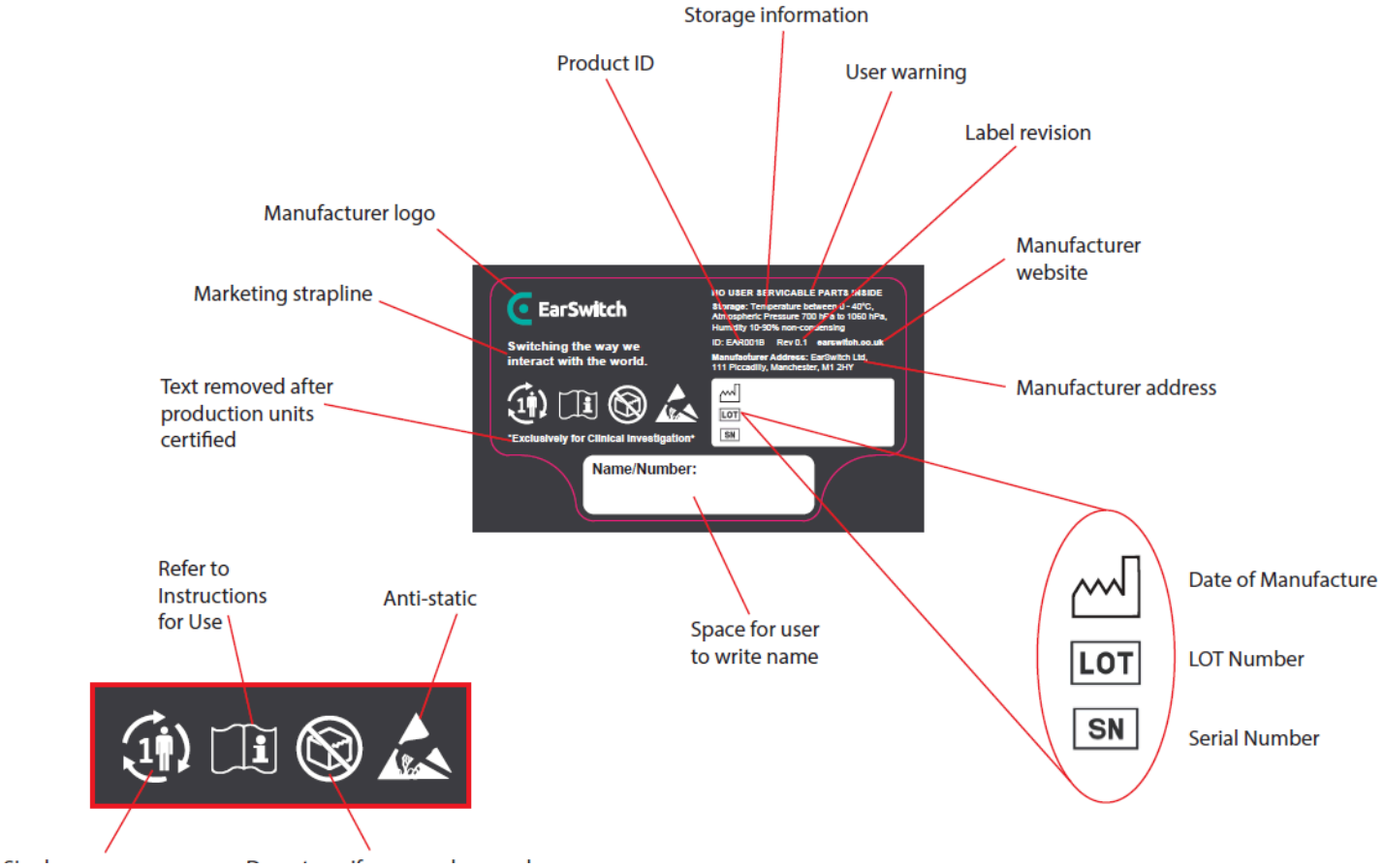
14.5.1. Temperature Range: .....0°C to +40°C

14.5.2. Relative Humidity Range..... 10% to 90% non-condensing.

15. Explanation of symbols.

15.1. EarSwitch unit label example

15.2. NOTE: For Clinical Investigation only the device may be used for multiple user use in a health care setting otherwise the device is for single person use.



Symbol	Explanation
SN	*Serial number*: Indicates the manufacturer's serial number so that a specific medical device can be identified
	Single person multiple use: Indicates a medical device that may be used multiple times (multiple procedures) on a single person
	Date of manufacture
LOT	*Batch code:* Indicates the manufacturer's batch code so that the batch or lot can be identified

	Do not use if package is damaged.
	*Consult instructions for use or consult electronic instructions for use:* Indicates the need for the user to consult the instructions for use
	The devices are sensitive to static.

15.3. EarSwitch EarBud pack ID label example:

15.4. EarSwitch Box pack label example:

15.5. Disposal

15.5.1. Damaged or worn EarBuds should be disposed of.

16. Accessories and spares.

16.1. A list of parts:

16.1.1. Control Box

16.1.2. Earpiece sensor

16.1.3. Earpiece Handle

16.1.4. EarBud (SML) Right and Left pack-A selection of six soft elastomer Earbud (Small, Medium and Large in Left and Right orientation.

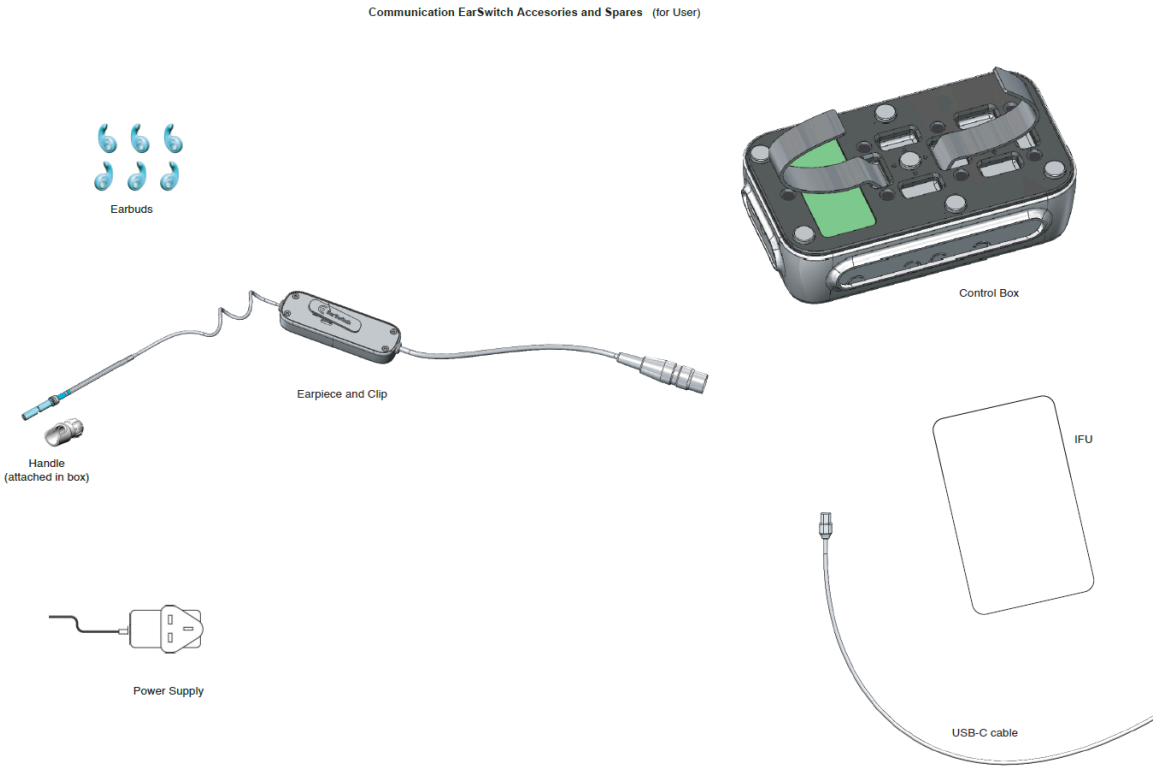
16.1.5. Lapel Clip

16.1.6. Power Supply part number AMF18US05

16.1.7. USB cable

16.1.8. Instructions for Use (IFU)

16.1.9. A QR code link to download the IFU for Communication EarSwitch.



17. Contact information for purposes of Clinical Investigation

17.1. Manufacturers Address with Symbol

EarSwitch Limited, 111 Piccadilly, Manchester, M1 2HY

17.2. Website

www.earswitch.co.uk

17.3. Contact number

+447745793022

17.4. Email

info@earswitch.co.uk

17.5. IFU Document number ES008 1 08 07. Revision number given at the top of each page. The latest version of the IFU can be obtained from https://www.earswitch.co.uk/communicationtool. Printed versions are not controlled.