

# Communication EarSwitch™ User Guide

Empowering communication  
through in-ear technology

COMMUNICATION EARSWITCH EAR001B V0.1

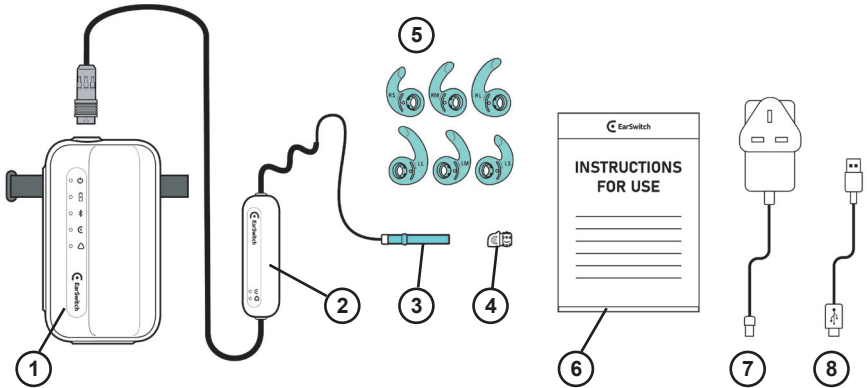
Exclusively for Clinical Investigation

# EARSWITCH USER GUIDE

The EarSwitch device is an assistive communication tool for users with conditions that restrict their ability to communicate.

This booklet is a Quick Start User Guide, intended as a brief overview of the device and how to use it. Please refer to the printed EarSwitch Instructions for Use (6) if in any doubt or need further clarity of correct use.

## YOUR EARSWITCH PARCEL SHOULD INCLUDE:



(1) 1 x Control Box

(2) 1 x Label Clip with Earpiece (3) and Handle (4)

(5) 6 x Earbuds (Right & Left in Small, Medium, Large)

(6) 1 x Instructions for Use Document

(7) 1 x EarSwitch Power Supply

(8) 1 x USB-C to USB-A Cable

## CONTENTS

<b>1. ICONS</b>	2	<b>5. AFTER-USE</b>	9
<b>2. FIRST-TIME PREPARATION</b>	3-4	Removal	
Device Set Up		Cleaning	
Software Set Up		Storage	
<b>3. INSERTING THE EARPIECE</b>	5-7	<b>6. EXTRA INFORMATION</b>	10
Insertion		Safety Precautions	
Eardrum View Examples		Trouble Shooting	
Can't Find the View?		Contact Details	
Locking the Angle			
<b>4. USE</b>	8		
Calibration			
EarClick Detection			
Battery Charging			

Scan here  
for  
instructions:



# 1. ICONS

Explanation of Icons on the Control Box and Lapel Clip.



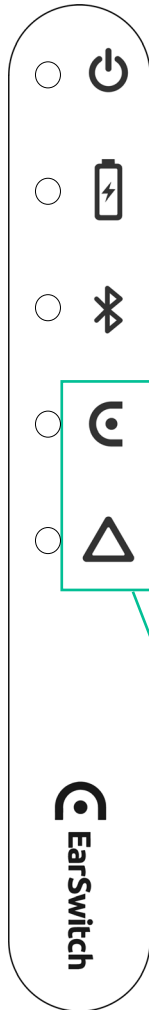
**QR CODE**  
 Scan code for further information on EarSwitch and Instructions

**BLUETOOTH**  
 Not implemented - ignore

**SENSITIVITY**  
 To adjust the ease of clicks press + & - buttons

To make EarClick easier press +  
 To prevent false EarClick press -  
 Press +/- together to reset "Out of ear detection"

**POWER ON/OFF** Press to power on or off.



**POWER**  
 Green = power on

**BATTERY**  
 Solid green light = charged  
 Flashing green light = charging  
 Solid amber light = low battery  
 Flashing amber light = critically low battery

**BLUETOOTH**  
 Not implemented - ignore

**EARCLICK DETECTED**  
 Green light = EarSwitch has detected muscle 'click'

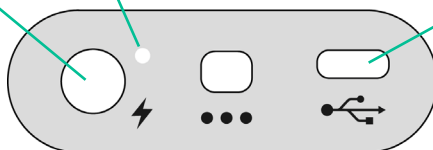
**MISALIGNMENT**  
 Amber light = EarSwitch detected potential misalignment of earpiece camera eg camera disconnected or "out of ear"

The **EARCLICK** and **MISALIGNMENT** icons and lights are duplicated on the Lapel Clip (2).

**POWER**  
 Plug the provided DC charging cable (7) into here to charge device. Green light = charging.

**CHARGING**  
 Solid green light = Power present & charged  
 Flashing green light = Power present & charging

**USB-C**  
 connect device to computer via USB-C cable (8)

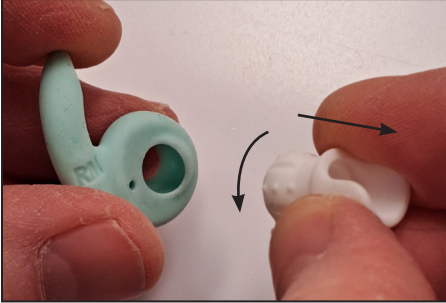


## 2. FIRST-TIME PREPARATION

### DEVICE SET UP - CHOOSING YOUR EARBUD

Chose the best ear for EarSwitch to be used in (Left or Right), and pick the most comfortable and secure size (S/M/L). To swap earbud (5) size, gently twist and pull the Handle (4) out the earbud (5), careful not to tear the silicone bud.

The size and L&R letters need to be visible on the outside face of the ear. While holding the earbud (5) with initials facing you, rotate and push the Handle (4) into the new earbud size until the 'ball' section is covered by silicone.



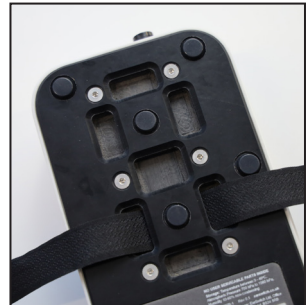
### DEVICE SET UP - ATTACHING THE CONTROL BOX

Push the large black connector into the Control Box (1) until it clicks. The white arrow should be facing the front.

Decide where you want to mount the Control Box (1) (eg. back of chair, bed frame etc) and use the Velcro strap to secure.



The strap has multiple configurations to suit user's mounting requirements. To change the orientation, pull out the velcro and push into a different slot.



## DEVICE SET UP - CONNECTING TO PC AND POWER

Connect the Control Box (1) via USB-C cable (8) to a Windows PC (running Windows 11 or later).

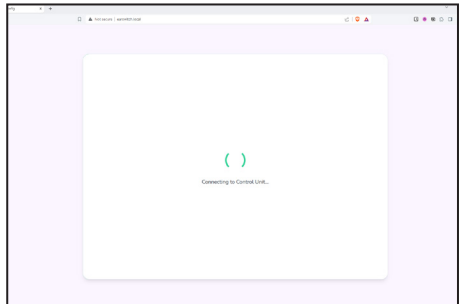
Connect the control box to its power supply (7). A green LED should illuminate next to the socket.



## SOFTWARE SET UP

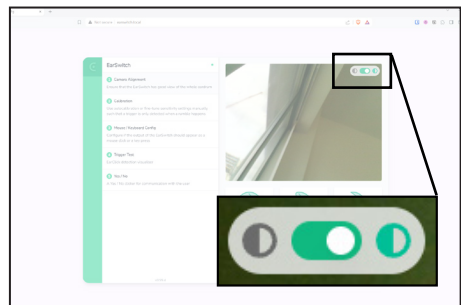
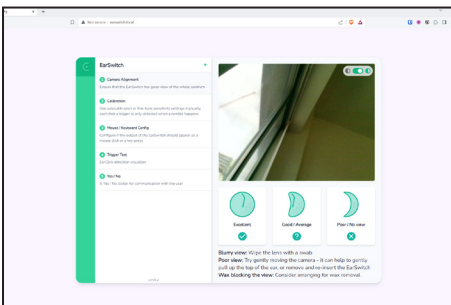
Press and hold the power button on the Control Box until a green power LED illuminates. White LEDs will illuminate at the tip of the camera.

Launch a web browser on the computer and type in the address bar of your browser: **earswitch.local**



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

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



### 3. INSERTING THE EARPIECE

**\*\* CHECK USER IS COMFORTABLE THROUGHOUT THE INSERTION PROCESS \*\***

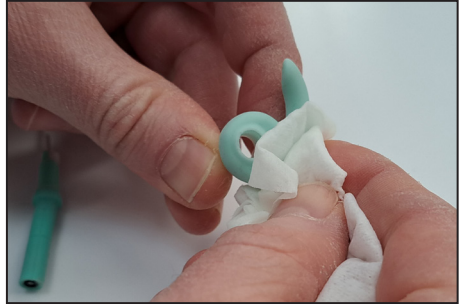
#### CLIP POSITIONING

With clean hands, attach the Lapel Clip (2) onto user's clothing or pillow. Check there is enough slack in the cable from the earpiece to the clip, to prevent dislodging from any movement.



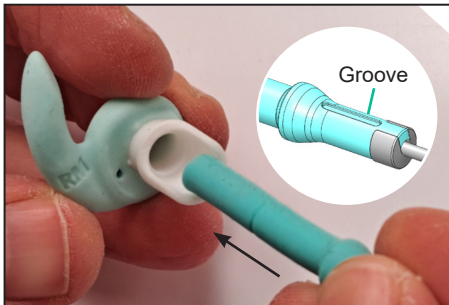
#### INSERTION

The Earpiece (Earbud, Sensor & Handle) should be cleaned before each use, using a non-alcoholic antimicrobial wipe, and allowed to dry before insertion.



Holding the Earpiece Sensor so the 'groove' is pointing upwards, insert the sensor (3) into the Handle (4). The cable should be the same side as the size letters.

For easiest insertion, start with the earpiece camera flush to the earbud (5) as per image below.



Gently pull the top of the ear upwards and insert the flush earpiece (3) into the ear.

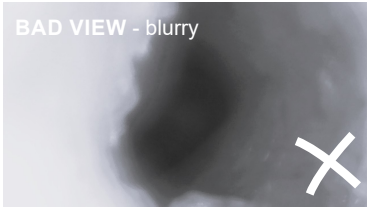
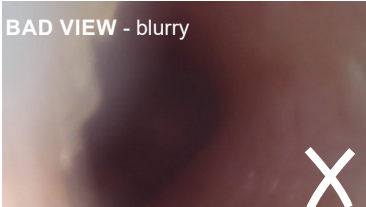
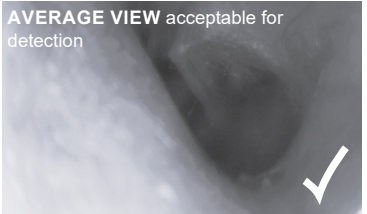
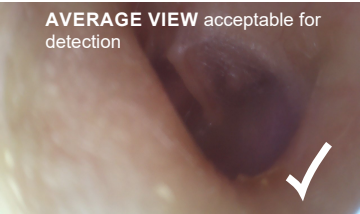
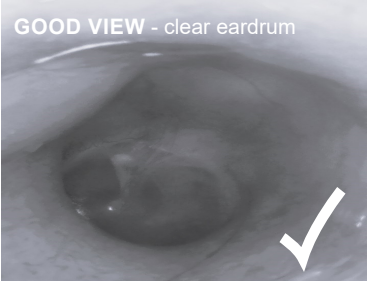
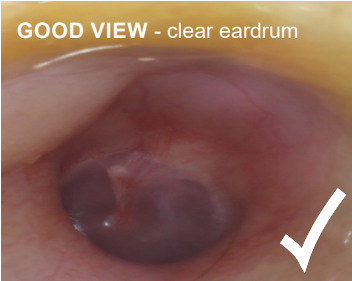
Adjust length of earpiece by gripping rigid Handle (4) with thumb and finger, and push or pull the earpiece in and out with the other hand whilst viewing the live camera feed.



**CHECK CAMERA LIVE FEED IS VISIBLE ON THE CONFIGURATION TAB BEFORE INSERTING THE EARPIECE.**

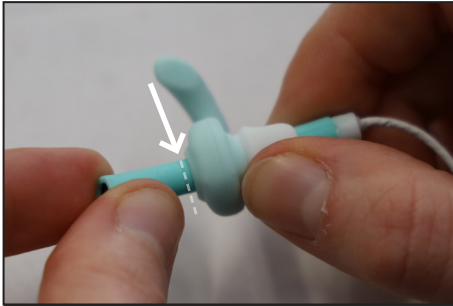
**CAMERA VIEW - SAMPLE IMAGES**

You are aiming to face the camera towards the eardrum, so it can detect movement of the muscle. You will need to adjust the angle and length of the earpiece in order to achieve the most optimum view. Below shows images of good, average and unacceptable views. The rotation of the eardrum image does not impact use. You can toggle between black+white or colour camera feed.

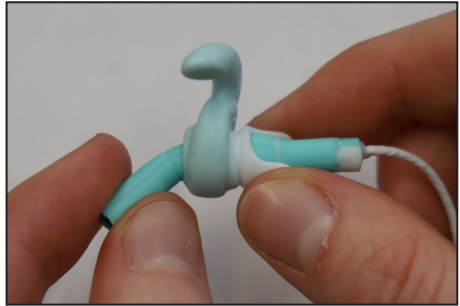


### EXTRA ANGLE ADJUSTMENT

To angle the camera further, remove the earpiece 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.



### VIEW IS BLURRY OR OBSCURED?

It is normal for earwax to obscure the camera view at times. Remove earpiece and wipe lens. Check camera is giving a clear picture before reinserting. If wax is blocking the view, consider arranging for wax removal.

Do *not* attempt to remove wax with the Earpiece. **Still not getting a view?** Straighten the earpiece and start the insertion process again. For more Troubleshooting, see page 10, or refer to the Instructions for Use.

**FOR MORE INFORMATION AND ADVICE, PLEASE REFER BACK TO THE CLINICAL INVESTIGATION PLAN. THIS IS FOR CLINICAL INVESTIGATION USE ONLY.**

### LOCKING THE VIEW

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.





## 4. USE

### CALIBRATION

Before the User starts to EarClick, the sensor needs to be calibrated. Within the EarSwitch software, click on the **'Auto-Set'** button to start automatic calibration. You will hear a long beep to indicate the automatic calibration process has started.

The user should now attempt **three EarClicks within a 5 second period**. The Control Box will emit a short beep every second. A prolonged beep will sound at the end of the calibration process.

From this test, the EarSwitch will identify an optimum calibration level. The User can now attempt to EarClick. Successfully detected EarClicks will show a highlighted green circle on the sensitivity control screen and will also illuminate a green light next to the EarSwitch logo (see 'EARCLICK').

NOTE: If you find a click movement is occurring but the sensor is *not* detecting it, or phantom EarClicks are occurring, try adjusting the sensitivity manually via the EarSwitch software, or by pressing the + or - buttons on the Control Box. Refer to Instructions for Use (7.6-8) for more detail.

To start using the EarSwitch as the chosen mouse click or keystroke, close the EarSwitch.local webpage. Leaving the webpage open will prevent EarSwitch from working.

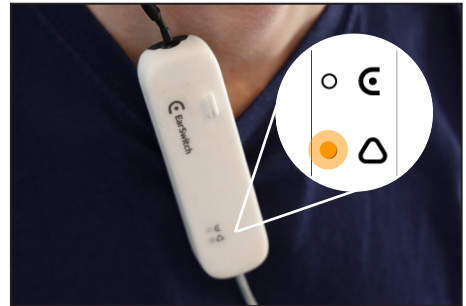
### EARCLICK

Move ear muscle to EarClick. When a 'click' is detected, duplicate LEDs on the Lapel Clip (2) and Control Box (1) will flash. To get familiar with the system.



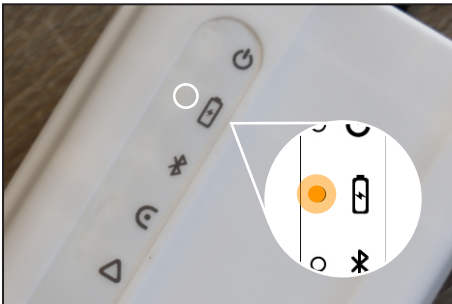
### MISALIGNMENT

If the earpiece falls out during use, an amber *Advisory* LED will appear on the lapel clip (2) and Control Box (1). If this LED appears, firstly check with the user they are okay, then reposition the earpiece and press + or - button to reset the device

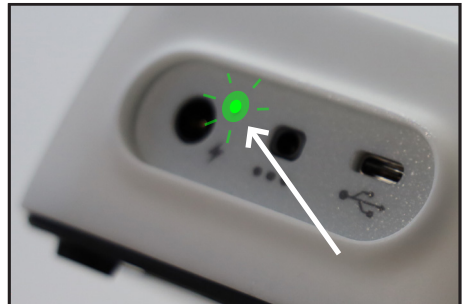


### BATTERY

When Control Box (1) battery is low, the green light will change to amber. When battery critically low, the amber light will flash.



To charge the battery, plug the Charger (7) into the socket on the base of the Control Box (1). A green LED will flash to indicate charging.



## 5. AFTER-USE

### REMOVAL

Gently remove bud by pulling on handle.  
To reduce set-up time for next use, keep the camera and bud in the same set-up position.



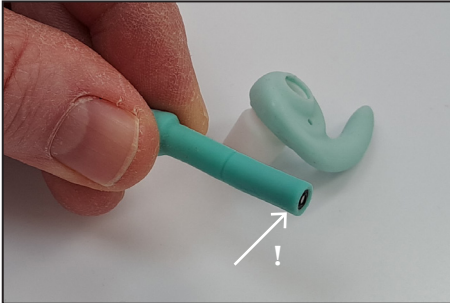
### POWER OFF

Press and hold power button to power down device until lights on front face turn off.



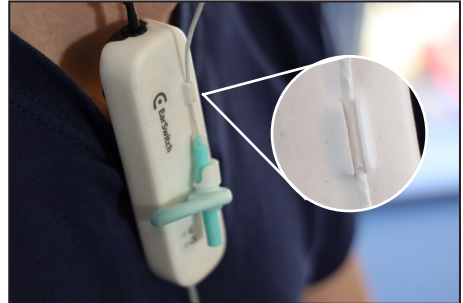
### CLEANING

Ensure camera is off. Gently wipe down the earpiece with alcohol-free wipes and a soft cloth. Avoid pushing on the delicate camera lens. see arrow below



### STORAGE OF EARPIECE

To store earpiece on the Lapel Clip (2) push the white cable into the cable slot on the front face.



### STORAGE OF UNIT

Wrap the thick cable around the Control Box (1) the clip of the Lapel clip (2) can be used to secure the cable. Alternatively, 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



### IDENTIFICATION

Optionally, add identification to the Control Box (1) label in the blank box provided.



## 6. EXTRA INFORMATION

---

### SAFETY

Do not use this device if you are already experiencing inflammation or infection of the ear/ ear-canal/ ear-drum or middle ear, as indicated by ear pain/ discharge or irritation.

**STOP USING THIS DEVICE IMMEDIATELY IF YOU HAVE AN ALLERGIC REACTION OR IRRITATION TO THE COMPONENTS.**

**IF THERE IS ANY DAMAGE TO THE UNIT, OR EXPOSED WIRES, STOP USE IMMEDIATELY AND CONTACT EARSWITCH FOR ADVICE AND NEXT STEPS.**

The EarSwitch should never be used to control physical equipment.

Users should familiarise themselves with steps on Instructions for Use document in the first instance.

Only charge the Control Box (1) with the EarSwitch charger (7) provided.

### TROUBLESHOOTING

1. If the unit doesn't send EarClicks as expected, open the configuration software and adjust sensitivity.
2. If the unit doesn't send EarClick as expected after adjusting the sensitivity in the configuration interface, press the + button to reset the Out Of Ear (OOE) detection.
3. If the camera becomes disconnected, the unit should be shut down, the camera reconnected, and the unit restarted.
4. 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.
5. If the device fails to work as intended, please take notes and contact the manufacturer for further advice.
6. If you continue to hear a regular beep, press the + or - button to reset the out of ear detection warnings.

### DISPOSAL

The EarSwitch is to be returned to the manufacturer for disposal. Damaged or worn earbuds can be disposed of as ordinary waste. It is recommended that the device is serviced every year by the manufacturer or an EarSwitch approved service provider.

### CONTACT

Please refer to Instructions for Use document ES008 1 08 07 or visit:

**[www.earswitch.co.uk/communicationtool](http://www.earswitch.co.uk/communicationtool)**

Email: [info@earswitch.co.uk](mailto:info@earswitch.co.uk)

Phone: +447745793022

EarSwitch Ltd registered in England & Wales, company number: 12358776.

Registered office address: 111 Piccadilly, Manchester, England, M1 2HY

[www.earswitch.co.uk](http://www.earswitch.co.uk)

# Earswitch Ltd

[earswitch.co.uk](https://earswitch.co.uk)

USER GUIDE V0.6 | LAST EDITED 03/05/2024

Exclusively for Clinical Investigation