UltraFit

USERS MANUAL

Revision 1.2

Headset for holding a probe during ultrasound investigations of speech

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Definitions

US Ultrasound

Warranty

Articulate Instruments Ltd warrants the UltraFit headset against defects in materials and workmanship for a period of 18 months from receipt by the user. During that warranty period, Articulate Instruments will either, at its option, repair or replace products, which prove to be defective. Articulate Instruments can accept no responsibility if the UltraFit headset is used other than in accordance with the instructions supplied. This warranty applies to the initial purchaser only and is not transferable. Full Terms and Conditions are contained in the Warranty Terms and Conditions enclosed with the device.

Safety

CAUTION :
Please read this information before using the UltraFit headset.

WARNING:
In the event of detecting a discrepancy regarding client safety requirements (occurrence or probability of risk) you must inform the manufacturer immediately

Equipment protection

To protect your UltraFit headset, follow these precautions:

- excessive bending or twisting of cables can cause a failure or intermittent operation;
- improper cleaning or disinfecting of any system part can cause permanent damage, for cleaning and disinfecting instructions see chapter below;
- do not use solvents such as thinner/benzene/alchohol on any part of the system;
- incorrect assembly or configuration may damage the headset.

Biological Safety Warning

To minimise the risk of neck strain and/or back strain, under normal circumstances, the duration of use should not be longer than sixty (60) minutes.

The headset makes contact with the head in 5 places each of which is padded with a removable nylon/neoprene/Velcro pad.

1. Crown pad 2. Left temple pad 3. Right temple pad 4. Forehead pad 5. Occipital pad

To avoid potential transmission of skin viruses, bacteria, fungi and protozoa (e.g. nits) one or more of the following precautions should be taken:

- A disposable barrier such as a surgical cap placed between the pads and the client's head
- The pads should be removed and either replaced or disinfected between use with different clients (See maintenance for cleaning instructions)

Ultrasound waves/exposure

The headset is designed to hold an ultrasound probe from ultrasound systems approved by the manufacturer. These include the EchoB and Micro systems sold by the manufacturer. Users should seek written approval from the manufacturer for use of any other system in conjunction with this headset. All efforts should be made to minimise exposure of ultrasound waves to the headset wearer. To this end the following precautions should be taken:

- The probe should be in contact with the client for as short a time as is necessary for the study or intervention. E.g. fit the probe after all other preparations are completed.
- During a study or intervention the ultrasound system should be set to the "Frozen" state when not being actively used.
- "Power" setting on the ultrasound system should be set to the minimum value that provides a satisfactory image.

Contraindication

This device is contraindicated for clients who have recently experienced bruising or trauma to the head and for children under the age of 3.

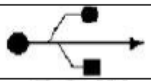
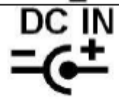
Accuracy

The accuracy of measurements made using the headset is determined not only by the functioning of the headset, but also by adherence to fitting protocols.

Labelling

Table 1 describes the purpose and location of safety labels and other important information provided on the equipment.

Table 1

LABEL / SYMBOL	DESCRIPTION	LOCATION
	**Caution, consult accompanying documents** This symbol advises the reader to consult the accompanying documents for important safety-related information such as warnings and precautions that cannot, for a variety of reasons, be presented on the device itself	ID Label
	**Type BF Equipment** (man symbol) IEC 878-02-03 indicates BF type equipment which is providing a particular degree of protection against electric shock, particularly regarding allowable LEAKAGE CURRENT and reliability of the PROTECTIVE EARTH CONNECTION if present.	External (probe outlet)
	**Consult instructions for use** NOTE This symbol advises the reader to consult the operating instructions for information needed for the proper use of the device	ID Label
	The symbol indicating separate collection for electrical and electronic equipment (Annex IV of Directive 2002/96/EC)	ID Label
	**CE mark** This mark is a declaration by the manufacturer that the respective component complies with the relevant directives and standards as issued by the European Union.	ID Label
	USB connector. This label indicates USB connector.	Rear panel
	+5VDC power input	Rear panel
	Manufacturer name and address	ID Label
	Model / Catalogue number	ID Label
	Date of manufacture **YEAR -MONTH- DAY**	ID Label
	Serial number	ID Label

Overview

Inspection

Upon receipt of your UltraFit headset, it should be examined immediately for any evidence of damage. Damaged shipments should be reported promptly to the carrier, who is normally liable for such damage.
All documentation, airway bills and packing materials should be retained in order to establish claims. After notifying the carrier of shipping damage, please also advise Articulate Instruments so that we may assist in damage claims and supply replacement equipment if necessary.

System Features

- Designed to securely hold 20mm convex and 10mm microconvex probes from EchoB and Micro ultrasound systems. It may also grip other probes such as the 60mm convex. Probes from other systems may or may not fit the headset.
- Set-up time < 2 minutes
- Quick release <5 seconds
- No tools required for set-up
- Lightweight (0.3kg)*
- Doesn't obstruct ears, eyes or jaw
- Adjustable for a large range of head sizes including children
- Washable removable neoprene padding

* Probe with cable will add extra weight

UltraFit Headset Description

The device consists of a nylon headmount that fits over the head and carries a probe holder on an arm. Free movement of the arm allows the probe to be positioned and then locked in place using two knobs. It can be adjusted to fit different head shapes without the need for tools of any sort.

The headmount

The headset design is based on a review of head geometry studies on the anatomy of kids (over six years old) and adults from different world regions. The headset fits by sliding together two halves with ergonomically curved temporal pads to grip all head shapes just above the ears. UltraFit is manufactured principally from lightweight, resilient nylon and is held in place by the locked sliding mechanism and one quick release Velcro strap at the rear. Stability arises from firm contact with the cranium at the forehead (neoprene padded Velcro strap), temporal cranial region above the ears and

the nape of the neck(neoprene padded Velcro strap). All points of contact are padded for comfort. Neoprene padding can be wiped down or removed and washed for easy hygiene control.

Probe attachment

There are two probe holders. One for the 20mm convex probe and one for the 10mm microconvex probe. Each probe holder is designed to clamp firmly around the probe allowing no movement but not applying pressure that could crack the probe. The clamp is then locked onto the headmount with a single screw. Front/back/up/down and rotational movement in the midsagittal plane are catered for by the side arm and rotation of the probe arm. Lateral position is adjusted by slackening the clamp and sliding it to one side along the probe arm.

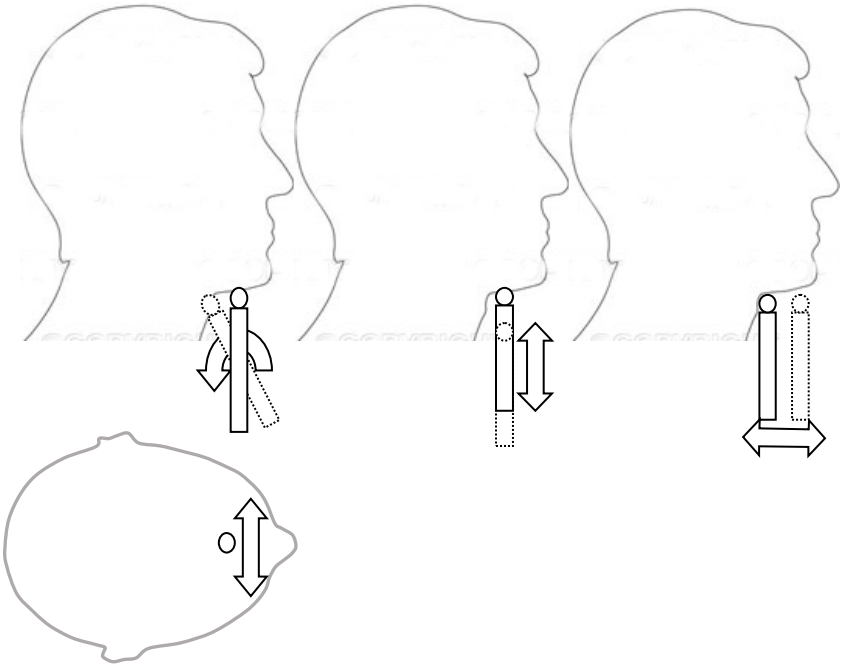
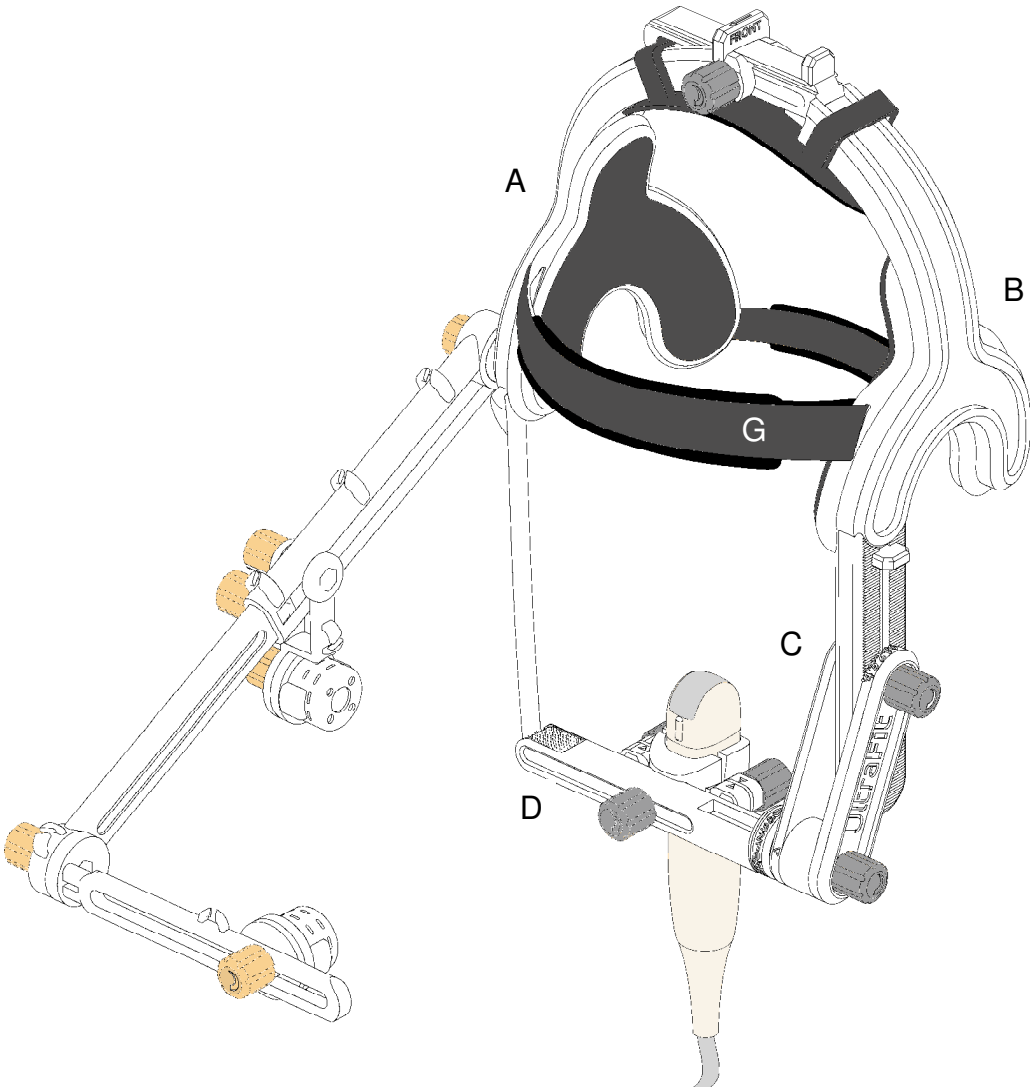


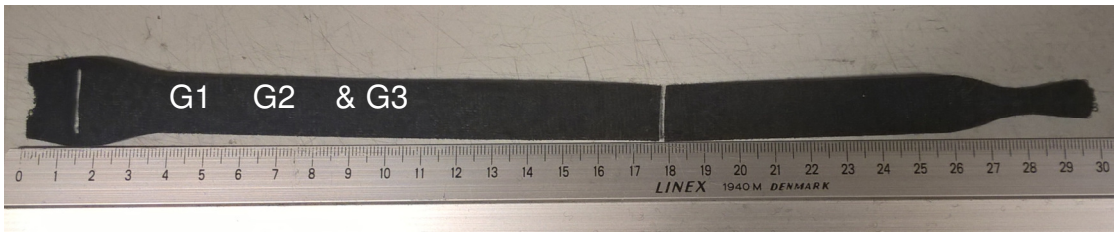
Figure 1 The degrees of freedom of probe adjustment

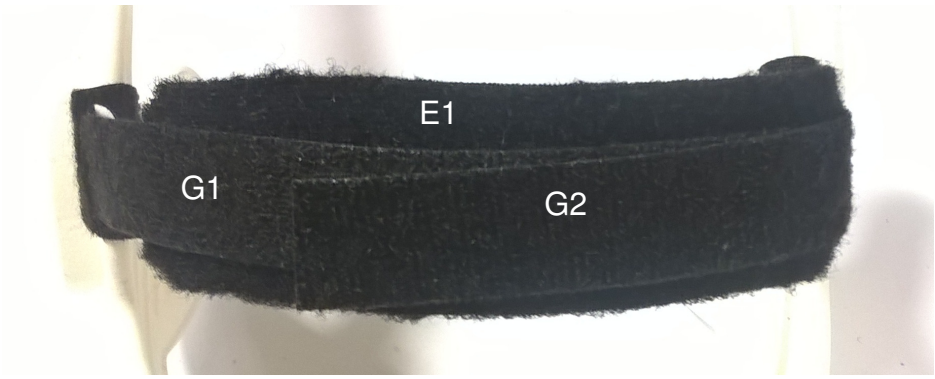
UltraFit Parts



Right headmount [A]
Left headmount [B]
Long arm
Short arm [C]
Arm washer
Probe bar [D]
Probe bar washer
20mm clamp front half
20mm clamp rear half
10mm clamp front half
10mm clamp rear half

Rear strap neoprene [E2]
Front strap neoprene [E1]
Left temporal neoprene pad [H1]
Right temporal neoprene pad
Crown neoprene pad [H2]
Crown foam spacer
Velcro straps front (right and left) and rear right [G1,G2]
Velcro strap rear left [G3]
Velcro strap (white) for probe bar tensioning



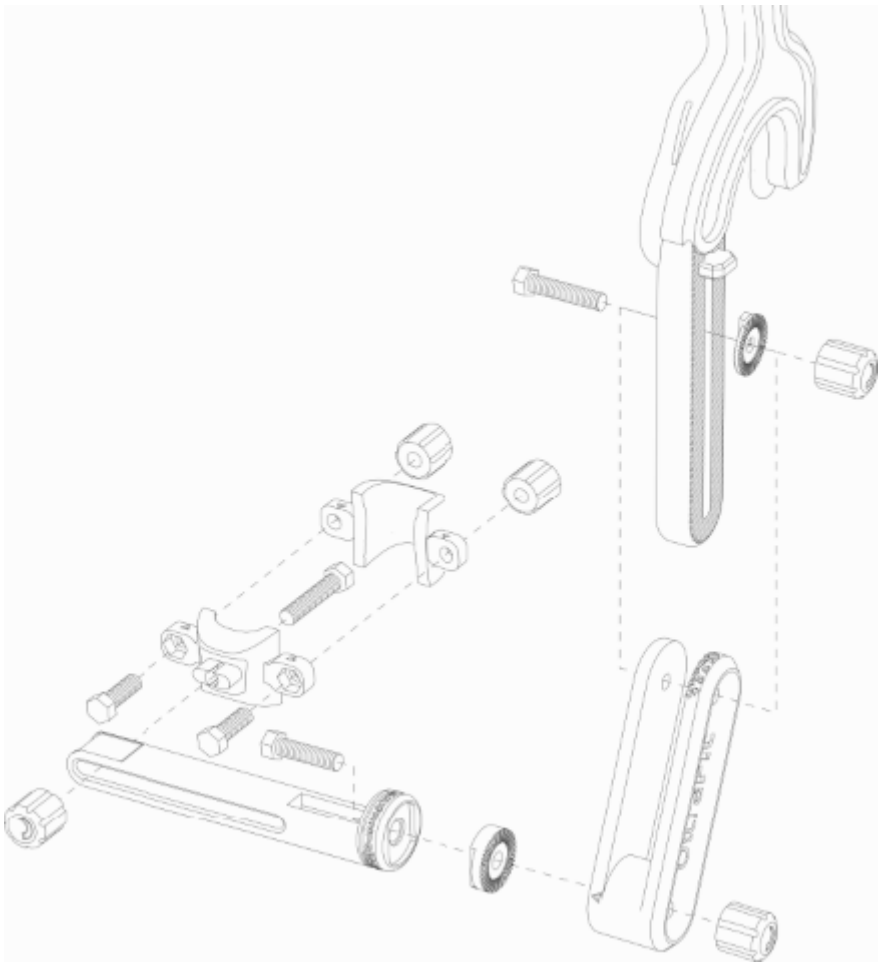


Front Straps and pad

Rear Straps and pad

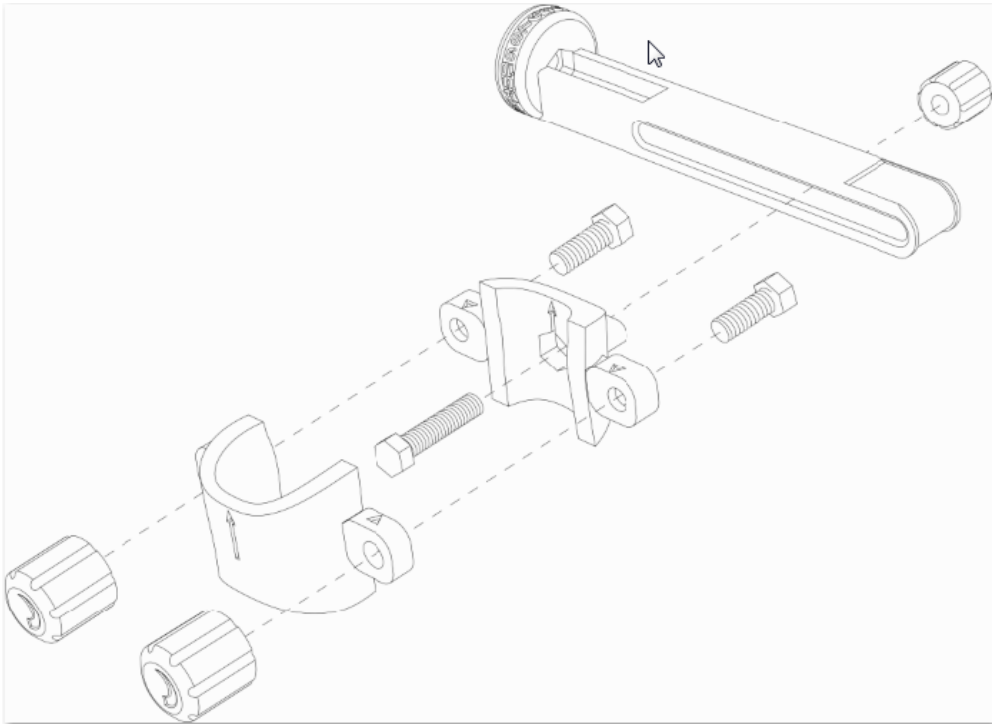
How to replace the long arm with the short arm

1. Remove the knob that locks the long arm in position to reveal the end of the bolt
2. Push the bolt out and lay to one side
3. Remove the arm being careful to leave the washer in position
4. Fit the short arm onto the headset in position over the washer
5. Replace the bolt so that the hexagon head slots into the hexagon recess
6. Replace the Knob



How to fit the clamp

1. Select the probe clamp that matches the probe
2. Remove the knobs and separate the two halves of the clamp
3. Note the notch on the probe. This should face towards the rear half of the clamp.
4. Fit the two halves around the probe making sure the clamp halve are the right way up (the arrows pointing to the top)
5. Replace and tighten the two knobs until the probe is firmly gripped.
6. Feed the front clamp bolt through the probe bar slot and fit the knob making sure to have the knob facing to the front.



Fitting the crown foam spacer

The crown spacer will only be required for wearers with small heads such as children. The purpose of the crown foam spacer is to raise the headset so that it sits ABOVE the ears. The crown spacer is easier to fit before placing the headset on the participant. To fit:

1. Separate the folded neoprene pad and insert the foam spacer between the folds.

Removing and refitting the neoprene pads

Temporal pads

Carefully peel away the neoprene pad from the Velcro on the headmount. Left and right temporal pads are asymmetrical so make sure that the left pad is refitted to the left headmount and the right pad is refitted to the right headmount.

Crown pad

Carefully peel away and separate the neoprene from the loops of Velcro around the headset leaving the Velcro loops in place.
When replacing, fit so that the opening in the folded neoprene faces to the rear.

Front and rear pads
Carefully peel away the neoprene from the straps. When replacing, try to keep the straps centred on the neoprene.

UltraFit Setup

Recommended procedure for fitting and removing the headset

A video can be found here:
https://www.dropbox.com/s/pxwpb9dou8o1n0g/How_to_fit_UltraFit%5B1%5D.mp4?dl=0

Preparation before fitting the headset.

1. Judge the size of the wearers head. If they are very small then the cranial pad can be inserted in between the flaps of the neoprene padding to raise the headset above the subject's ears.
2. Slacken the rear headband.
3. Slacken the side bar and lower to its lowest position.
4. Slacken the probe bar so that it is free to rotate
5. Optionally the probe/probe holder may be fitted to the headset before or after fitting.

Fitting the headset

1. Gently place the headset on the wearer's head from above taking care that the probe doesn't catch on the wearer's chin.
2. Slide the two halves together and make sure the headset is sitting evenly above the ears.
3. Adjust the front strap so that it fits snugly with the headset positioned above the ears.
4. Pull and tighten the rear strap securing using the Velcro.
5. Make any necessary fine adjustments and tighten the top knob

IMPORTANT NOTE: Take care not to slide the two halve together too much at the top causing the sides to bend outwards as this will result in the probe bar sitting at an angle. And if the probe bar is not horizontal the probe will not sit vertical.

Adjusting the probe position

1. Slacken the side arm and probe arm knobs so that the when holding the probe it can easily be moved to the desired position under the chin.

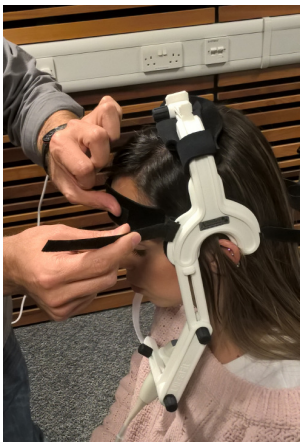
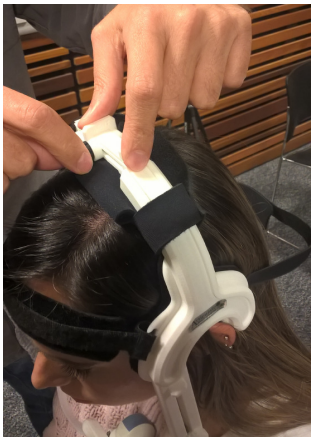
2. Move the probe into position and tighten the knobs to lock it in that position.
3. If the probe is not on the midline slacken the probe clamp knob and slide left or right
4. Attach the white Velcro strap to hold the probe in the fully adjusted position.

Removing the headset

1. Slacken off the rear strap
2. Slacken and lower the side arm to its lowest position
3. Slacken the top screw and slide the two halves apart.
4. Hold the probe in one hand and the top of the headset in the other and lift upwards and forward, being careful to keep the probe away from the face and clothing. If the subject is wearing glasses, ask them to either take them off before lifting the headset or simply to hold the glases while the headset is being removed.


Slacken all the knobs and widen the headset to its maximum width. Fit the headmount from the front and above, holding the probe away from the face.

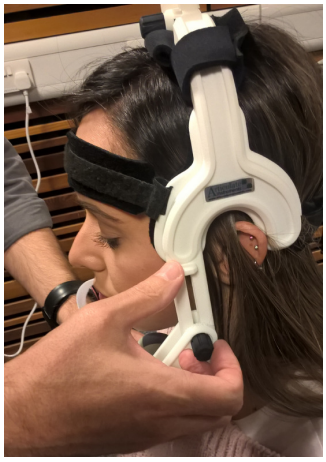
Squeeze the two halves of the headset together until they gently grip the head at the sides. Make sure it rests ABOVE the ears. If it is covering the ears, remove and fit the foam spacer.


Release the front strap if necessary in order to position headmount over the ears. Tighten lock the headmount halves together. Velcro the front strap so that the forehead rests against the strap in that position.



Tighten rear strap

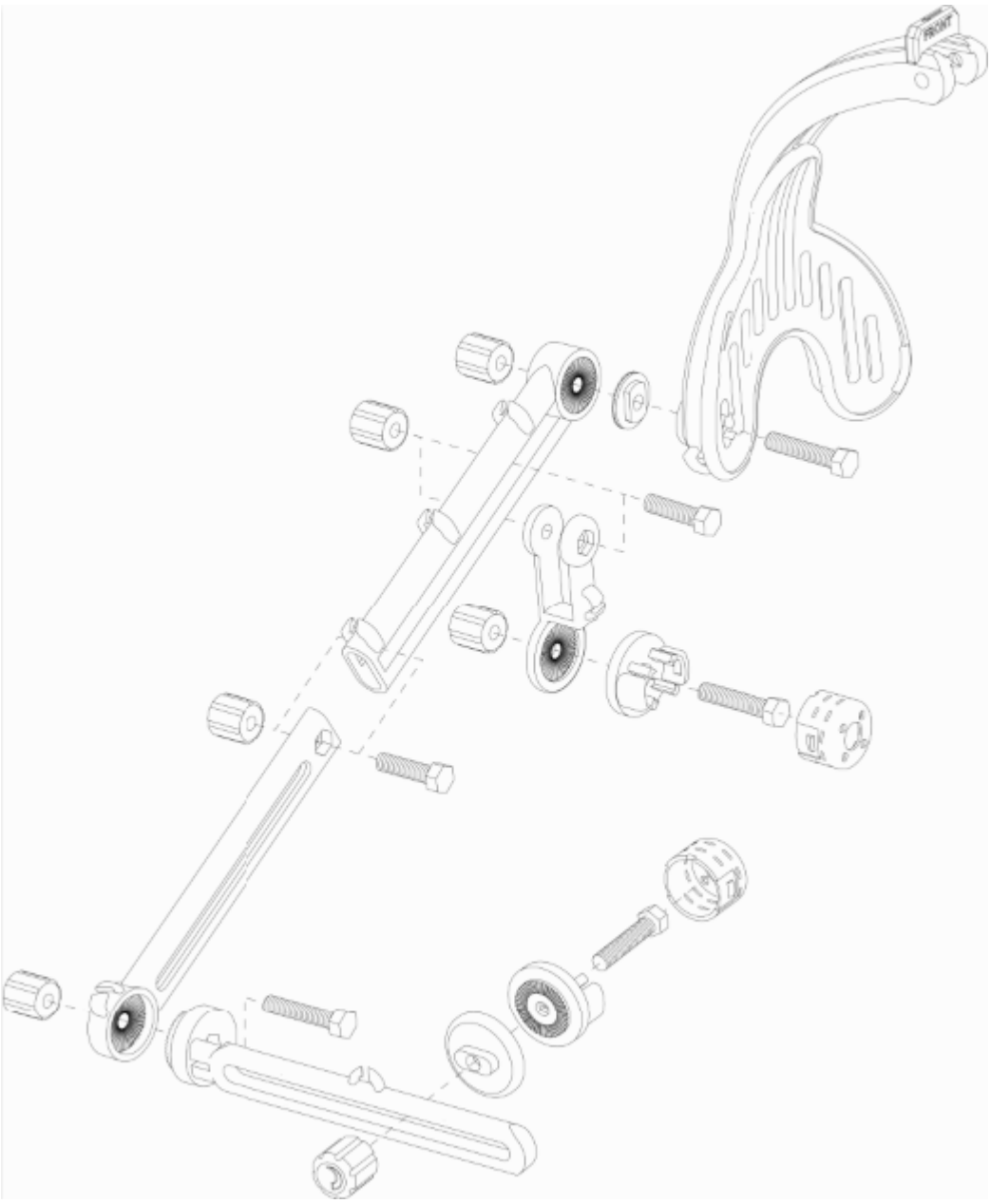



Adjust probe position laterally and vertically


Tighten knob to lock probe arm in position. Tighten knob to lock probe bar in position

Attach probe bar tensioning strap

Camera Arm



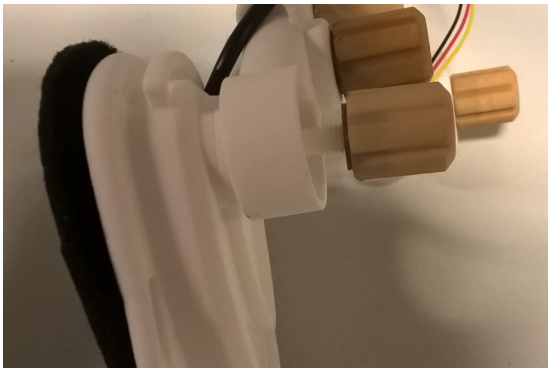
The camera arm is an optional extra attachment for the headset providing adjustabvle positioning of an NTSC micro camera. It allows for EITHER front or side mounting and holds the camera in a fixed position relative to the head.

Fitting the UltraFit camera arm

Peel back adhesive backed white Velcro and insert Nylon screw.

Add washer

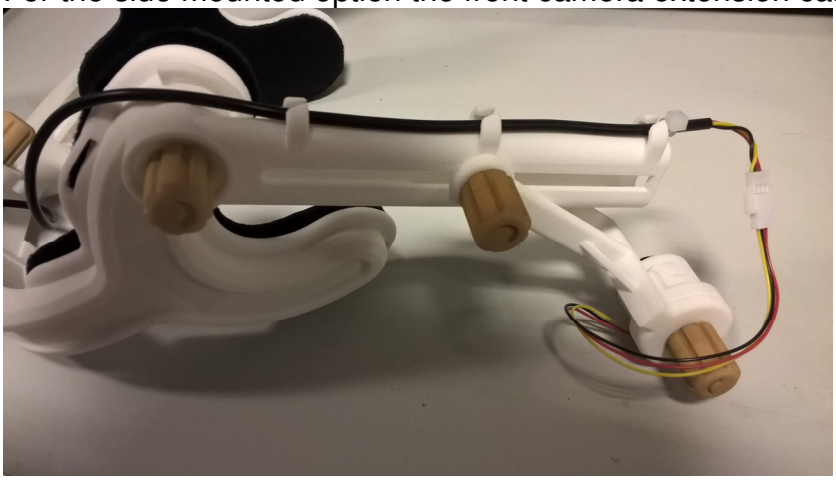
Rotate it until it fits neatly in place.



Add the camera arm and secure in place with the knob

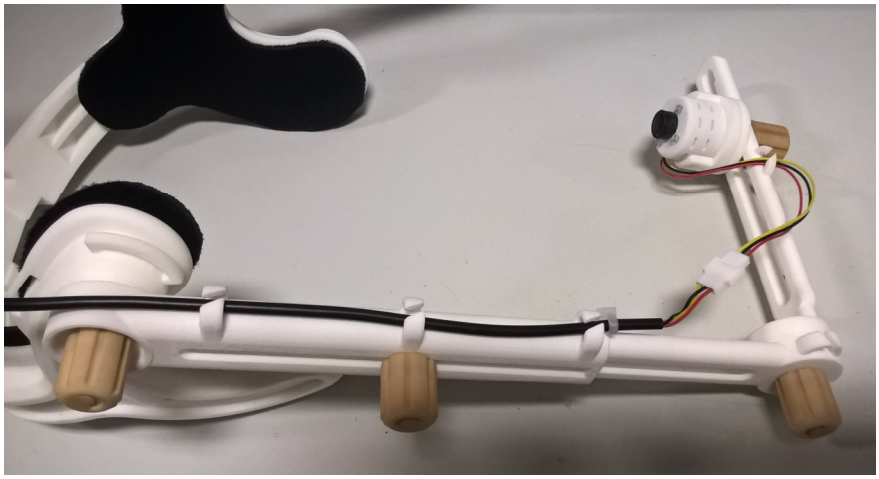
Side camera configuration

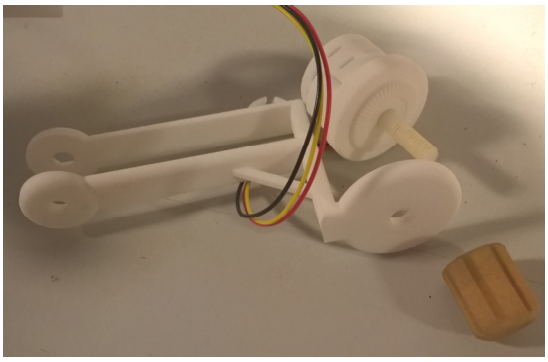
For the side mounted option the front camera extension can be removed

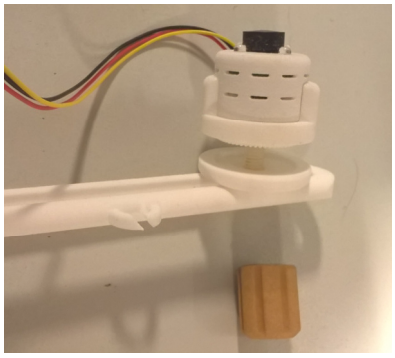


Front camera configuration

For the front mounted option the side camera extension can be removed and the camera module detatch and reattached as shown.







Maintenance

Performance and Safety Checks see in the table below:

Recommended Maintenance	Frequency
General cleaning	As Needed
Inspect the system, cables and probes	Before Use/Daily
System accuracy and performance verification	Annually

1.1 General cleaning

The headset surfaces may be cleaned with a soft cloth dampened with a neutral detergent. Do not use solutions with chlorine, ammonia, fluoro-carbons or hydrocarbons. Do not use alcohol based cleaners or wipes that may soften the nylon structure.

NOTE:
Before cleaning the unit, ensure the probe is removed and any cables are disconnected.

1.2 Inspecting the Headset

Examine the exterior for cleanliness and general physical condition. Ensure the frame is intact, all bolts and knobs are present and secure, and labelling is legible. Check that the moving parts lock securely in position when the locking knob is tightened.

1.3 Headset maintenance and disinfection

The headset is supplied non-sterile.
The following disinfectants have been tested with your headset.
Using of any other disinfectants can void the warranty contract.
The following disinfectants for soaking or wiping are recommended:

Neoprene pad Disinfectants	Rigid part Disinfectant
Decathlon Surfsystem Disinfectant Shampoo Bacterless Wetsuit Disinfectant Septimat Abyssnaut Disinfectant Mares SCUBA CLEAN disinfectant Jobe Wetsuit Cleaner Soap Shampoo Umonium Medical Spray	Mild detergent T-Spray

CAUTION:
Customers must follow the disinfectant manufacturer's instructions carefully. Do not submerge steel bolts in disinfectants.

Chemicals that Damage the headset:

Some of these chemicals, such as phenol, benzothonium chloride, pHisohex, benzoyl peroxide, hydrogen peroxide, isopropyl alcohol are commonly found in clinic or hospital settings; others are found in antibacterial skin cleaners or lotions. Use of these chemicals may cause weakening of the headset. This damage is not covered by the warranty contract.

General Cleansing for headset

These general cleaning instructions are indicated for the rigid parts of the headset.

1. After every use, wipe ultrasound transmission gel off the probe holder.
2. Wipe the probe holder with a dry or water-moistened soft cloth.
3. Clean other marks and stains using a brush or cloth and mild detergent or T-Spray.

General Cleansing for removable neoprene pads

These general cleaning instructions are indicated for the 5 removable neoprene pads that make contact with the headset wearer. It is important that the pads are cleaned according to the following procedures:

1. Remove pads carefully from headset noting that right and left temple pads are slightly different in shape.

2. Use an approved neoprene disinfectant
3. Follow the disinfectant manufacturer's instructions for use
4. Replace pads carefully

1.4 Headset accuracy and performance verification

Regular maintenance of a technical nature is not required for the ultrasound headset. Padded areas of the headset can be wiped down with disinfectant after each use or removed and washed in a domestic washing machine.

If the headset appears to be malfunctioning please contact customer support for advice, or, if necessary, to arrange the return of the unit to Articulate Instruments Ltd for repair or replacement.

The Articulate Instruments website should be regularly monitored for updated manuals.

Technical Details

Specifications

Ultrasound Headset

Dimensions	
Maximum internal width	??? mm
Minimum internal width	??? mm
Maximum internal height	??? mm
Minimum internal height	??? mm
Weight	0.3 kg
Serial Number	_____

General Environmental

Temperature (Operation)	+10 to +40°C
Temperature (Storage/Transport)	-15 to +60 °C

Troubleshooting

FAQ

Q.
A.

Contact
If you are experiencing problems with the equipment, which are not covered in this manual, you can contact

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