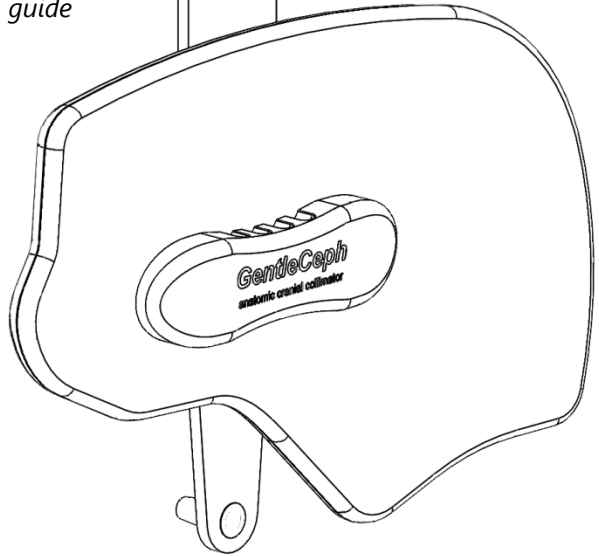


GentleCeph

anatomic cranial collimator

*Product documentation
+ installation guide*



Product version :

Purchase date, customer

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Serial N°

2014-002-300

www.GentleCeph.com

Original English language version by manufacturer

Other available languages:

- Dutch

About the Anatomic Cranial Collimator

Thank you for purchasing the Anatomic Cranial Collimator (ACC). This product is developed by GentleCeph BV, the Netherlands. The ACC has proved to be an effective aid for reduction of radiation doses associated with diagnostic cephalometric imaging. Implementing this product in your dentistry- or orthodontic office helps you to reduce the probability of negative effects caused by X-Ray radiation in accordance with the ALARA principle as laid out in European radiation protection guidelines (EURATOM ⁱ⁾ and guidelines for Radiation Protection in Dentistry (NCRP ⁱⁱ⁾).

This product should only be used by an accredited dentist or dental specialist qualified under applicable law and regulations to operate diagnostic X-Ray equipment. The size of the product is based on research of anatomic measurements amongst persons aged 7 years and above. It is NOT advised to use this product for diagnostic imaging for children under 7 years old, as diagnostic information may be shielded by the product for patients from this age group.

The ACC is compatible with most cephalometric X-Ray units. It is indicated on the front page of this document which fixtures are supplied with this product. The ACC can be used in combination with both left and right orientated cephalometric X-Ray machines (meaning: from the viewpoint of the x-ray source patient looking to the left- or to the right side).

GentleCeph cannot be held responsible for the consequences of misuse and wrong installation of the product. Please read this manual carefully and keep in a safe place for future reference and servicing purposes.

May any questions remain after reading the product documentation or if you encounter any problems during the use of this product, please contact us. Our contact details can be found on the rear side of this document.

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Product details

Classification

Anatomic Cranial Collimator, model-/ serial number: 2014-002-300



conform medical device directive 93/42/EEG – class I rule 1

Safety according to design guidelines:

NEN-EN-IEC 61331-1:2002, NEN-EN-IEC 61331-3:1999

Technical specifications

Attenuation properties (=Lead equivalent): 1 mm Pb: CEI 1331-1:1994

Attenuation material: Lead (Pb 99,9% pure)

Product weight: 0,3 kg (0.7 lbs)

Minimal product lifespan: 10 years
(under normal and intended use, according to prescriptions)

Suitable for cephalometric X-Ray devices with:

- tube voltage between 50-100kV

- magnification factor between (= object: image) 1: 1,10-1,15

Recommended patient age: 7 years and older

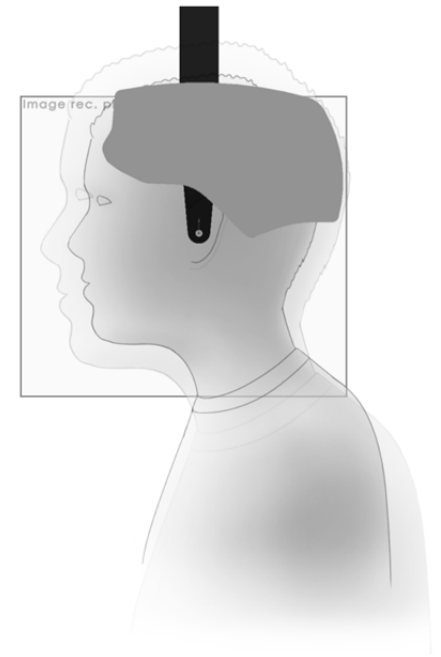
Instructions for use

General usage

The attenuation properties of this product are achieved by a lead barrier with a thickness of 1mm (0.39in).
(= 1mm lead equivalence ⁱⁱⁱ)

When applying a 70kV tube voltage this results in 99.6% of radiation to be absorbed by the lead barrier, with 90kV the reduction is 99,0%. ^{iv}

The shape of the lead barrier is based on a number of anatomic measurements. On average the surface of the patient to be exposed will reduce with 25-35%. This percentage varies and is based on the field size of the device and the head size of the patient.



Validation studies^v prove that the use of the ACC rarely results in loss of diagnostic information and thus a retake of the image. By reducing the irradiated surface of the patient the absorbed radiation dose by the patient will decrease. Hence the chance of detrimental stochastic effects of radiation will decrease. Especially for children being more sensitive for such effects this is important.

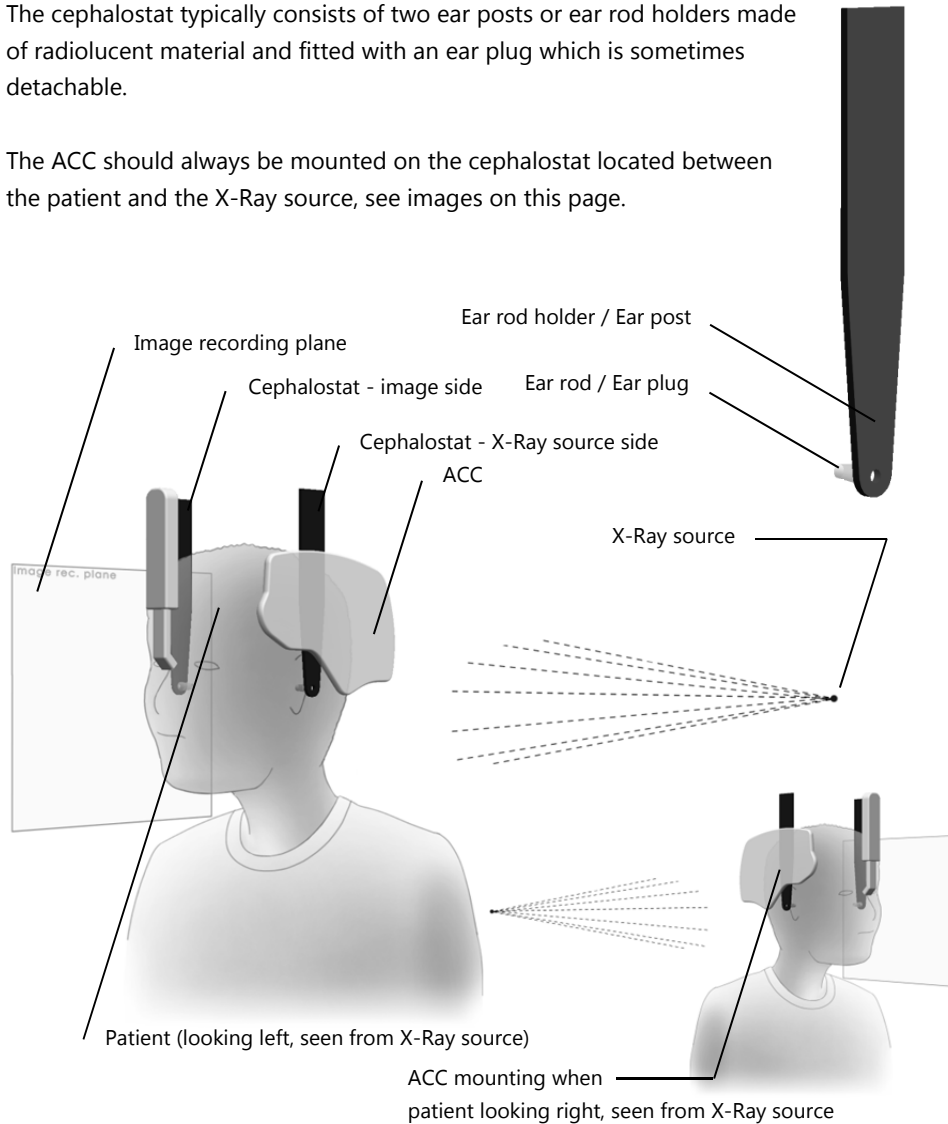
Application of the ACC follows the ALARA principle, which stands for applying the dose of X-Ray radiation that is: 'As Low As Reasonably Achievable'.

In order for the product to function according to the design intend it is critical that the ACC is correctly mounted onto the cephalostat of the X-Ray device. Therefore carefully read the following pages with regard to the product installation and use.

Mounting method

The cephalostat typically consists of two ear posts or ear rod holders made of radiolucent material and fitted with an ear plug which is sometimes detachable.

The ACC should always be mounted on the cephalostat located between the patient and the X-Ray source, see images on this page.



Compatibility with other X-Ray devices

May you change to another X-Ray device in the future; it is possible to keep using your ACC. At this moment fixtures are available X-Ray devices of the following manufacturers:

Carestream (former Kodak, Trophy), Gendex, Instrumentarium, Morita, Planmeca, Sirona-Siemens, Soredex.

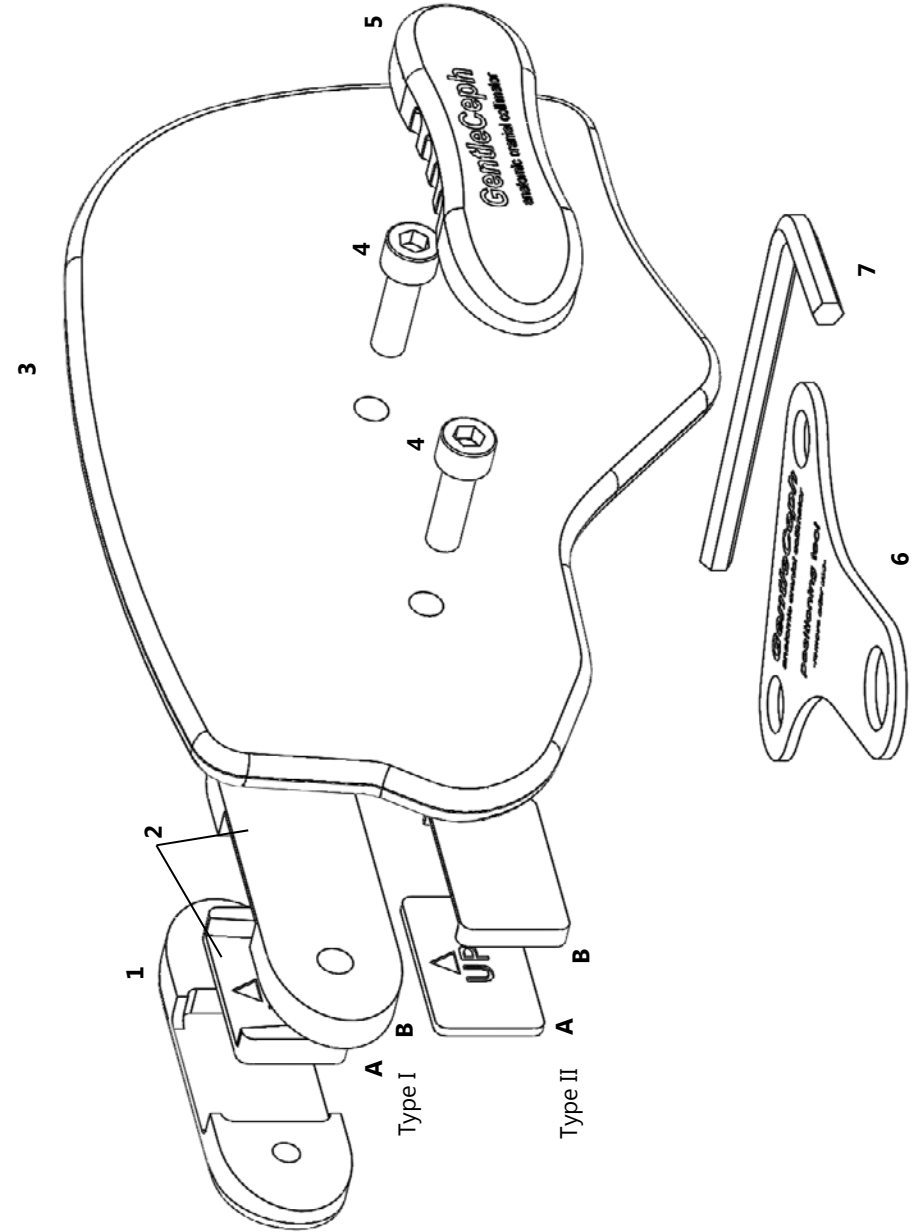
Is your device manufacturer not included in this list? We are continuously extending the compatibility with both existing and newly developed cephalometric X-Ray devices. Check the availability of fixture types on www.GentleCeph.com and/ or contact the supplier of your new X-Ray device for more information.

The ACC is compatible with both left and right orientated cephalometric X-Ray machines; from the viewpoint of the x-ray source patient looking to the left or to the right side.

Product overview

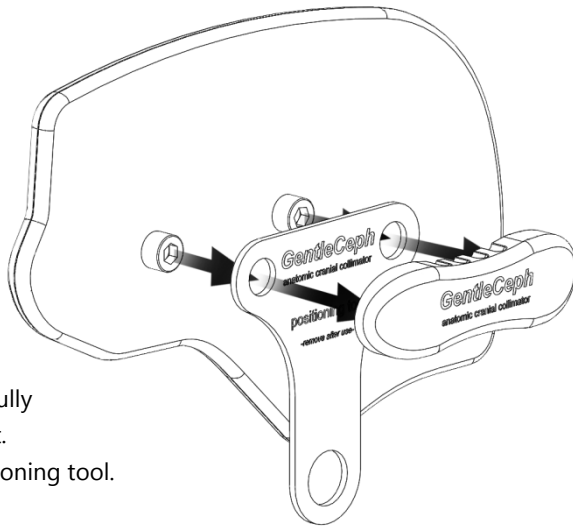
Please verify all parts listed below are supplied with your ACC:
(see also image on page 11)

- 1** Mount piece
- 2** Adaptor pieces A+B
(2 types depending on thickness of cephalostat)
- 3** ACC housing
- 4** Bolts (2x)
- 5** Screw cover
- 6** Positioning tool
- 7** 5mm Hex key



Installation guide

Step 1 - disassembling



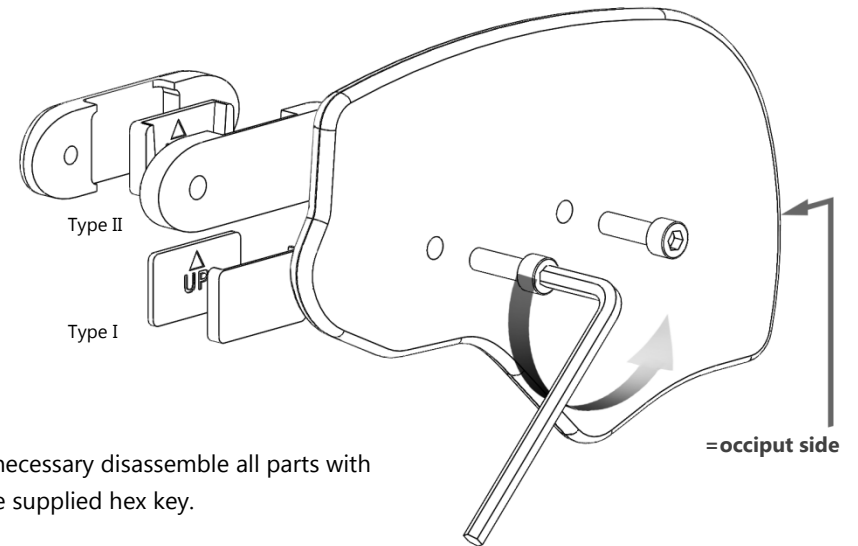
Remove screw cover by carefully pulling while keeping straight. Put aside together with positioning tool.

RECOMMENDATION:

Often the ear rod and its holder can be taken apart. In that case the ACC does not need to be fully disassembled before installation. Just slightly unscrew the bolts and slide the ACC over the ear post and continue with **step 3**.

Please check that the orientation in the pre-assembled state matches the orientation of the X-Ray device. See page 8 for more information about correct product orientation.

Step 2 - attaching



If necessary disassemble all parts with the supplied hex key.

ATTENTION!

Depending on the ear post dimensions a type I or type II adaptor is supplied with the ACC. Each type requires a different method of attaching.

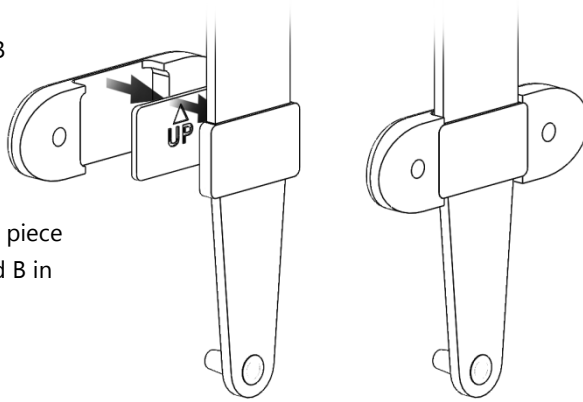
Type I: for flat ear rod plates

Type II: for ear rod plates thicker than the opening in the mounting bracket

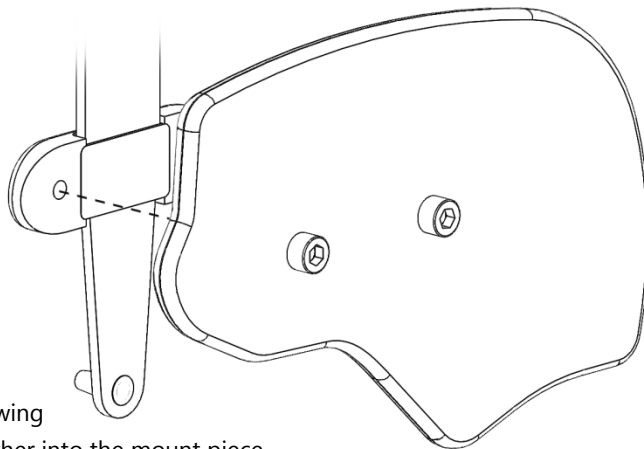
On the next pages both methods are addressed separately.

Type I:

Place mount adaptors A and B around the ear post.



Subsequently slide the mount piece around mount adaptors A and B in the indicated position.



Attach the ACC by screwing the bolts one after another into the mount piece.

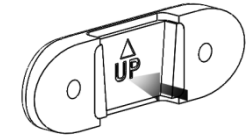
ATTENTION!

The markings "△" should always point upwards, facing the ear post.

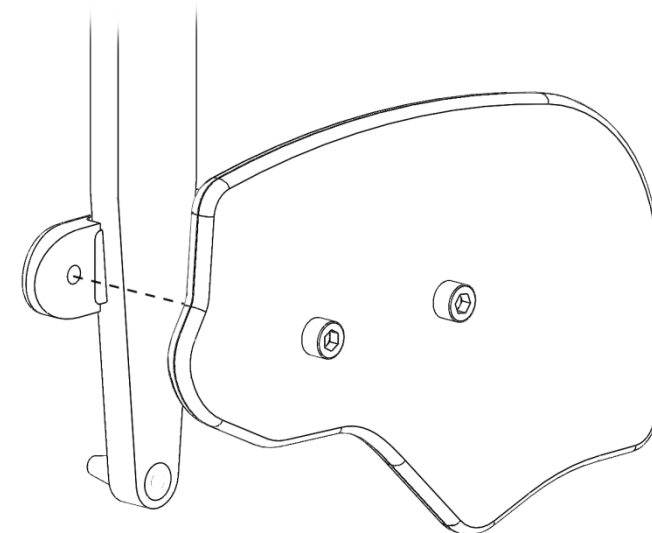
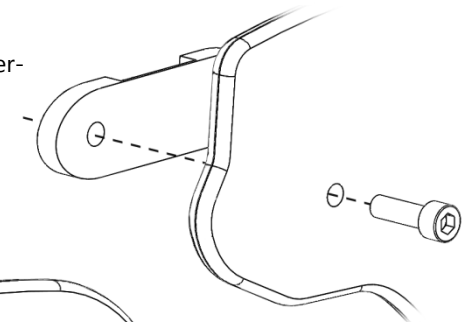
Do not fully tighten the bolts at this stage, so the ACC's position can still be modified.

Type II:

Press mounting adaptor A in the mounting piece in the position as indicated.



Join the ACC and mounting adaptor B by piercing at least one bolt trough these parts



Place the mount piece (with adaptor A) around the ear post, keep in place if needed, and screw the pre-pierced bolt in the mount piece. Assemble the second bolt in the same way .

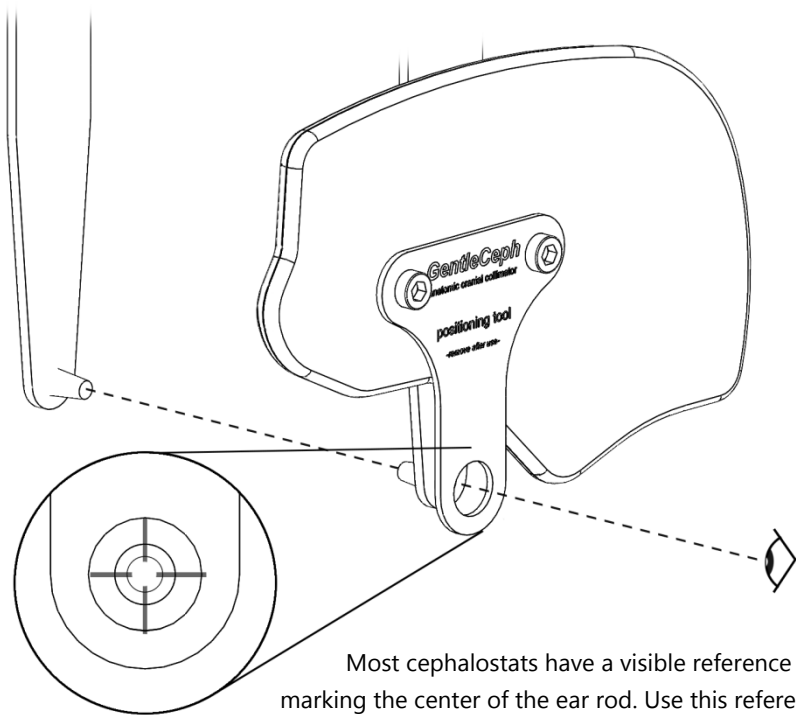
ATTENTION!

The markings "△" should always point upwards, facing the ear post.

Do not fully tighten the bolts at this stage, so the ACC's position can still be modified.

Step 3 - aligning

Place the positioning tool over the hexagon socket bolts' heads. Use the center hole to align the ACC with the ear rod and/ or ear post.



Most cephalostats have a visible reference point marking the center of the ear rod. Use this reference point during the alignment process. Make sure to look from the same

height as the center of the ear rod. A detachable ear rod can be left out during this process. This way both left and right ear rod reference points are visible, allowing for more accurate alignment.

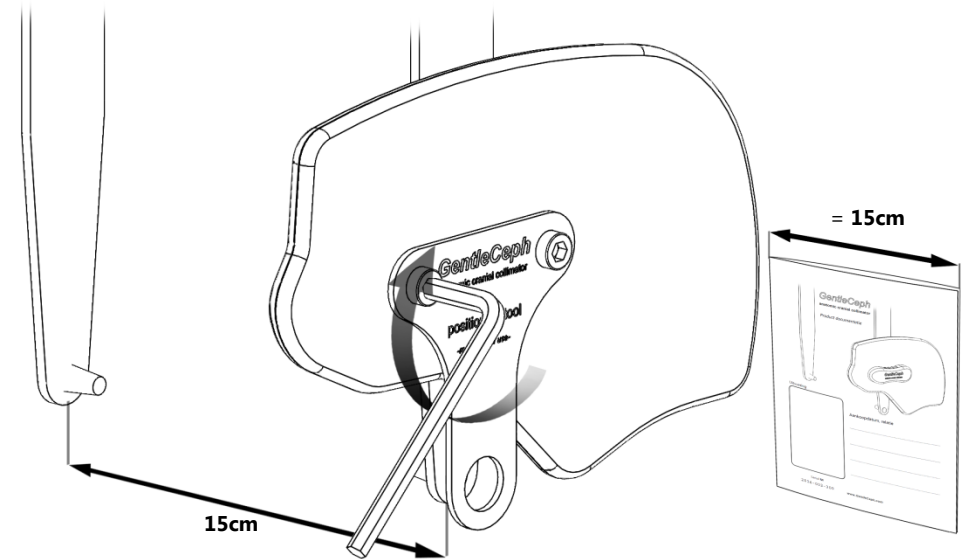
Especially the height adjustment is critical as the mount adaptors are shaped according to the ear post and will restrict movement in any other direction.

WARNING:

DO NOT use excessive force during the alignment process as this might damage or de-calibrate your X-Ray equipment.

Step 4 - calibration

After aligning the ACC through visible inspection fixate its position by gently tightening the bolts, make sure that the ACC does not slide. If applicable re-attach the earplug.

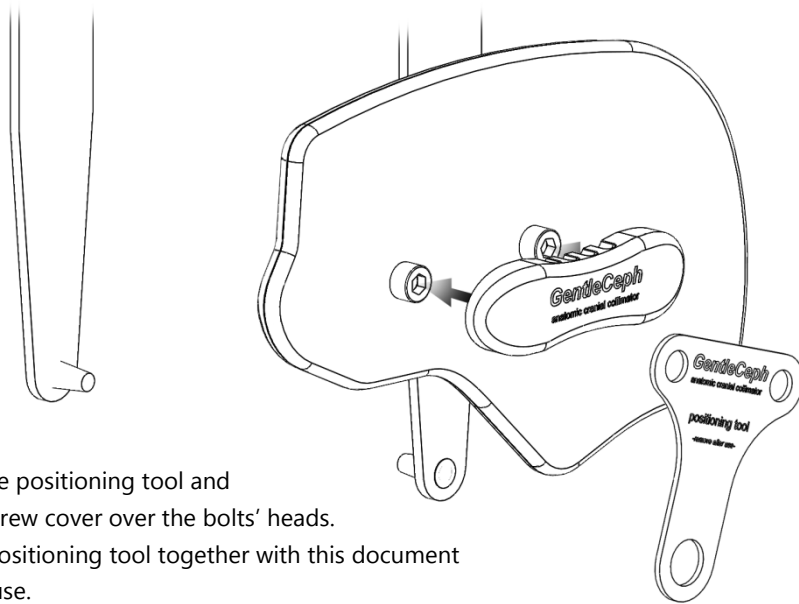


After visual alignment of the ACC it is recommended to verify the position by recording an image in the cephalometric mode of the X-Ray device, without patient, using the lowest possible tube current setting and the shortest exposure time.

Verify the alignment on the X-Ray image (if needed using treatment/ analysis software). If alignment is unsatisfying steps 3-4 should be repeated until the correct position is found. Especially when the ear posts or ear rods do not have a distinctive marker these steps may have to be repeated.

After having found the correct position make a final recording or future reference. For a reliable comparison it is critical to maintain a distance of **15cm (5.91in)** between the ear posts, measured on the inside near the ear rods (= width of this booklet, see images on this page).

Step 5 - finish installation



Remove the positioning tool and slide the screw cover over the bolts' heads. Keep the positioning tool together with this document for future use.

Register the installation of the ACC using the journal pages at the end of this document. (It may be required in your region to keep a record of the maintenance of X-Ray equipment and its accessories.)

Maintenance

The ACC and its components can be disinfected with surface disinfectant such as 70% isopropyl alcohol or equivalent. If dirt accumulates between the product and the X-Ray machine's ear post where it cannot be removed; demount the product for cleaning. After remounting the ACC make sure to repeat the calibration procedure.

Do not submerge the product in water or other fluids, do not clean in dishwasher or sterilization machine nor clean with aggressive and/ or abrasive cleaning products.

The correct functioning of the product should be verified at least yearly by comparing an actual recording against the filed calibration recording (step 3-5). Preferably this check-up should be combined with the periodical inspection of the X-Ray equipment that the ACC is attached to.

It may be required in your region to keep a record of the maintenance of X-Ray equipment and its accessories. The journal at the end of this document can be used for this purpose.

If the ACC has been exposed to a direct mechanical impact the same procedure should be followed. If necessary repeat the calibration procedure (step 3-5 of the installation guide). If for any reason an undesired situation occurs due to the application of the ACC, (temporarily) uninstall the ACC.

For questions about the ACC, its functioning and installation procedure contact GentleCeph and/ or the supplier of the cephalometric X-Ray device that the ACC is attached to.

Termination of use

Do not dispose of product as regular waste. Hand in the product in at your local recycler or return to supplier.



The ACC contains lead that should be separated from regular waste. Other materials in the product are suitable for recycling.

Sources and references

- ⁱ European Atomic Energy Community;
European guidelines on radiation protection in dental radiology -
The safe use of radiographs in dental practice, EURATOM, Issue N° 136, 2004
- ⁱⁱ National Council on Radiological Protection and Measurement;
Report No. 145, Radiation Protection in Dentistry, NCRP, Bethesda, MD, USA, 2003
- ⁱⁱⁱ NEN-EN-IEC 61331-1:2002 Protective devices against diagnostic medical X-radiation - Part 1:
Determination of attenuation properties of materials
- ^{iv} Attenuation properties of diagnostic x-ray shielding materials, Archer - 1994
<http://dx.doi.org/10.1118/1.597408>
- ^v Validation of anatomically shaped cranial collimation (ACC) in orthodontic lateral cephalography,
Hoogeveen - 2014
<http://dx.doi.org/10.1259/dmfr.20130396>

Notes

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Initial installation date by.....

Remarks initials.....

Inspection scheme (it is recommended to verify the ACC's positioning at least every year)

Inspection date Conducted by

Status/ Action initials.....

Inspection date Conducted by

Status/ Action initials.....

Inspection date Conducted by

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