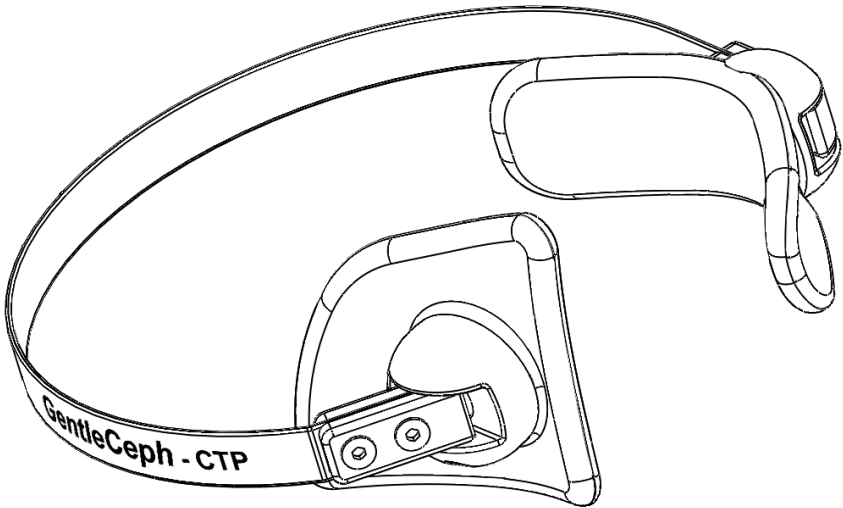


GentleCeph

cephalographic thyroid protector (CTP)

Product documentation



Model:

Left version (as displayed above)

Product code: 0200-0100L

Right version

Product code: 0200-0100R

Serial №

2015-001-300

Date of purchase, customer

.....

.....

versie 1.0_EN

Original English language version by manufacturer

Other available languages:

- Dutch

About the Cephalographic Thyroid Protector

Thank you for purchasing the Cephalographic Thyroid Protector (CTP). This product is developed by GentleCeph BV, the Netherlands and has proved to be an effective aid for reduction of radiation doses associated with diagnostic cephalometric imaging. With the CTP the thyroid gland can be shielded without obstructing the view on the cervical spine, in order to allow for evaluation of the patient's maturation.

Implementing this product in your dental- 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).

For maximum reduction of unwanted radiation it is recommended to use both the CTP and ACC (Anatomic Cranial Collimator). With the ACC the cranial zone can be protected against X-Ray radiation.

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.

In principle the CTP can be used with any type and make of cephalometric X-Ray equipment. The only aspect that has to be taken into account is the orientation of the equipment; Is the patient looking to the left- or to the right side from the viewpoint of the X-Ray source. In which case the CTP has to be worn respectively on the left or right side of the patient's throat. It is indicated on the front page of this document as well as on the shield housing (marking **L** of **R**), which version of the product has been supplied.



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

Should any questions remain after reading the product documentation or if you encounter any problems during the use of this product, please contact us or the local (sales) representative. Contact details can be found on the rear side of this document.

Table of content

About the Cephalographic Thyroid Protector.....	3
Product details.....	5
<i>Classification</i>	5
<i>Technical specifications</i>	5
Instructions for use	6
<i>General usage</i>	6
<i>Product overview</i>	8
<i>Placing of CTP on patient</i>	9
A - Positioning of the CTP when depiction of the cervical vertebrae is desired.....	10
B - Positioning of the CTP when depiction of the cervical vertebrae is not desired	14
<i>Maintenance</i>	16
Cleaning	16
Adjust rotating friction of the shield	17
Check functioning	17
Other	18
<i>Disposal</i>	18
Notes.....	19
Literature references.....	19

Product details

Classification

Protective device against diagnostic medical X-radiation: protective patient shield.
Suitable for direct skin contact.



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

designed and produced according to:

NEN-EN-IEC 61331-1:2014, NEN-EN-IEC 61331-3:2014

NEN-EN-ISO 10993:2013

Technical specifications

Product name: Cephalographic Thyroid Protector



Serial number :

2015-001-300



Manufacturer:

GentleCeph B.V.

Attenuation properties (=Lead equivalent): 1,0 mm Pb: IEC 61331-1:2014

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

Suitable for cephalometric X-Ray devices with
tube voltage between: 50-100 kV

Recommended patient age: 7 years and older

Product weight: 0,1 kg

Instructions for use

General usage

The use of protective devices against radiation reduces the irradiated surface of the patient and decreases the radiation dose absorbed by the patient during X-Ray examination.

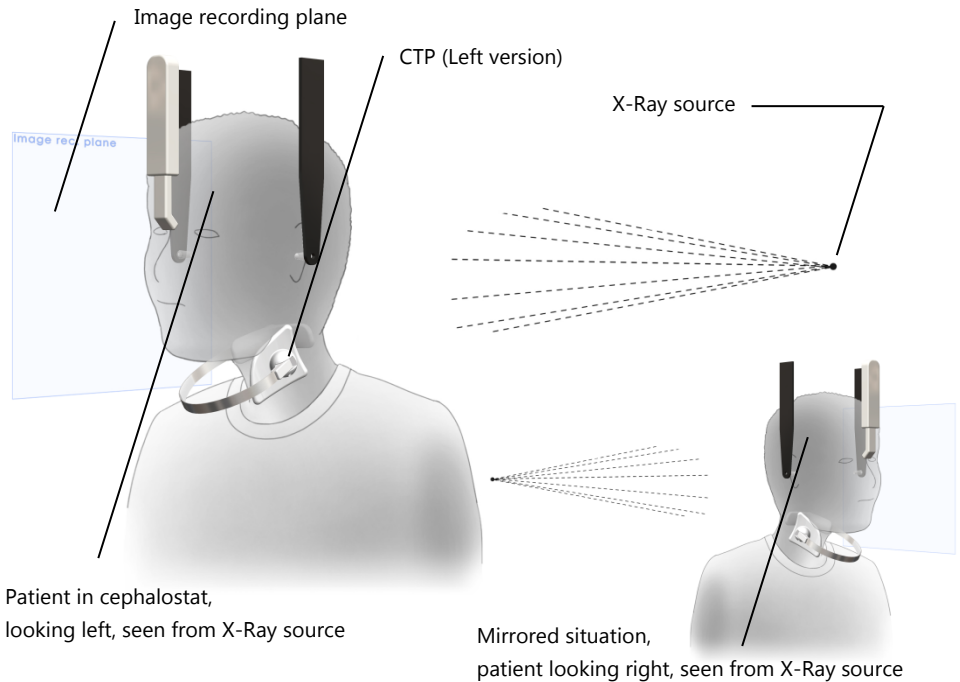
Hence the chance of detrimental stochastic effects of radiation will decrease. Especially for children being more sensitive to such effects this is important. Application of the CTP follows the ALARA principle, which stands for applying the dose of X-Ray radiation that is: 'As Low As Reasonably Achievable'.

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

Due to the increased sensitivity to radiation of the thyroid gland, shielding of this organ is very effective. When both CTP and ACC are applied the effective dose is reduced with around 60% ¹ compared to the situation in which no protective devices are used ^v. For more information on our products and background information we refer to our website: www.GentleCeph.com

The dimensions of the lead barrier are based on a number of anatomic measurements on patients' throats around the thyroid gland region. The shape of the shield has been optimized to allow comfortable and correct placement for a large target group. The use of the CTP therefore hardly affects the operating procedures of X-Ray examination.

¹ The exact value depends on the field size of the cephalometric X-Ray device and size of the patient's head.



The CTP is available in two configurations, supporting cephalometric X-Ray equipment with either left or right orientation (patient looking to the left– or to the right side from the viewpoint of the x-ray source). The marking **L** or **R** on the shield indicates which orientation is supported.

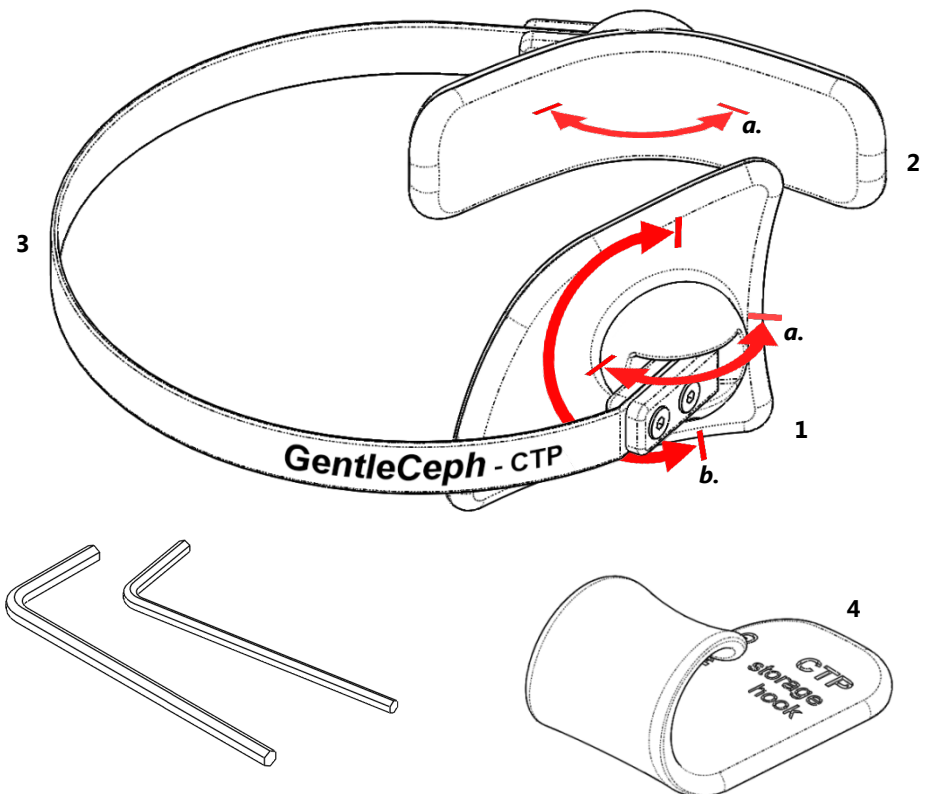
In order for the CTP to function according to the design intend it is critical that the shield always faces the X-Ray source (see image). In addition it should be accurately placed onto the patient by the practitioner and/ or the appointed operator of the X-Ray equipment.

Please carefully read the following pages with regard to the working principles and application of the CTP.

Product overview

The CTP consists of the following components:

- 1 Shield**
(rotates and hinges with restriction)
 - 2 Neck support**
(hinges with restriction)
 - 3 Spring arc**
(contains critical product information)
 - 4 Storage hook**
(self-adhesive)
- # 2mm and 2,5mm hex key



The attenuating shield is kept in place on the patient by slight counter pressure of the spring arc which is applied by the neck support. The neck support is to be placed on the rear side of the neck opposite the attenuating pad.

Both parts hinge freely around the spring arc within a fixed range (**a**). For optimal positioning the attenuating shield can additionally rotate around its axis with slight friction (**b**). The neck support does *NOT* rotate around the spring arc.

If needed the hex keys can be used to adjust the friction at which the shield rotates around its axis. This procedure is described on page 17.

The self-adhesive storage hook can be affixed in a convenient location near the X-Ray device in either a vertical orientation or below a horizontal surface. Apply onto a suitable surface that is smooth and sufficiently rigid, clean the surface before applying.

GentleCeph takes no responsibility for any aspects regarding the application and use of the supplied storage hook.

Placing of CTP on patient

Applying the CTP allows for shielding of the radiosensitive thyroid gland, while the cervical spine remains visible for evaluation of the patient's maturation. However this does require the operator to correctly position the CTP onto the patient. The instructions on the next pages describe the steps that are needed in order to do so.

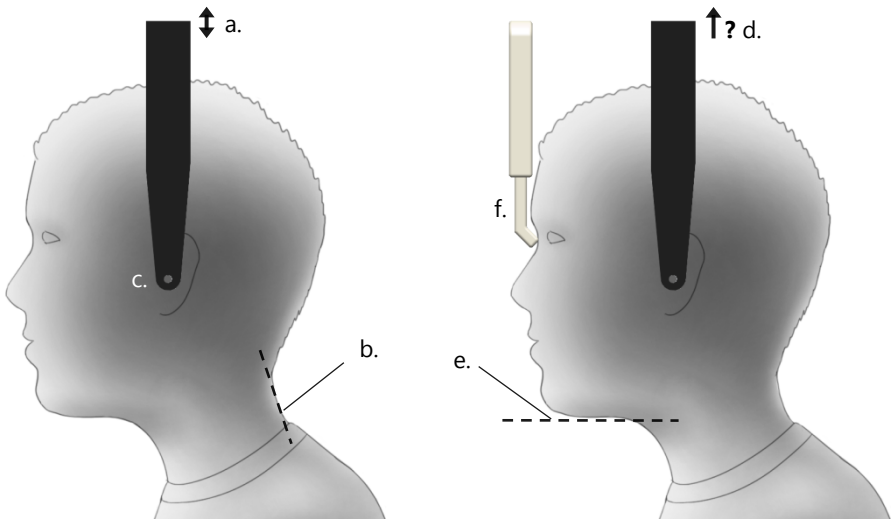
If the cervical spine does not contain relevant information for the treatment(planning), shielding of the cervical spine does not need to be avoided. (this applies usually to children aged below 8½ years old, girls above 14 years and boys above 16 years old)

See under **B** (page 14) the instructions that apply in the situation where the cervical spine does not need to be visible on cephalogram.

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A - Positioning of the CTP when depiction of the cervical vertebrae is desired

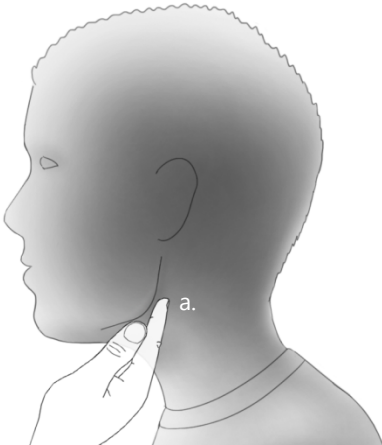
1. Position patient in cephalostat



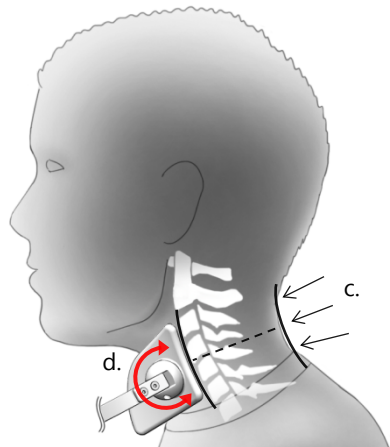
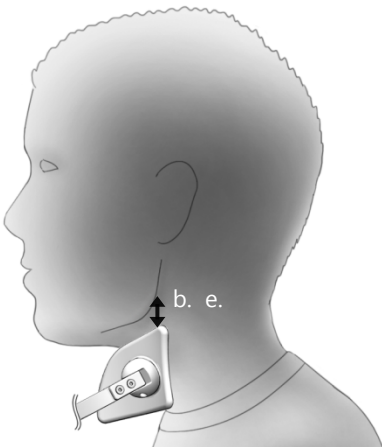
- a. Ensure correct height adjustment of the cephalostat
- b. The posture of the patient should be upright with neck stretched
- c. Place earplugs in ear canals

- d. If needed: raise the cephalostat in order to achieve proper stretching of patient's neck
- e. Ensure correct horizontal head positioning
- f. Apply the nasion- or forehead support

2. Place CTP

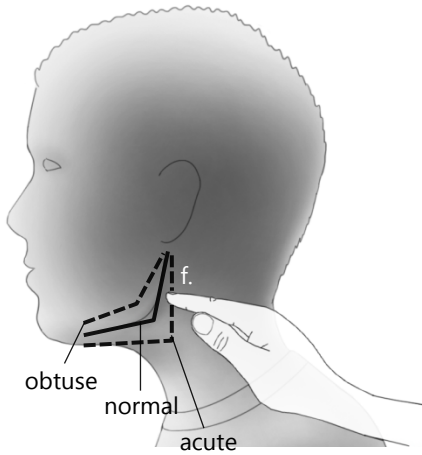


- a. Locate the angle of the mandible by palpating with the fingers

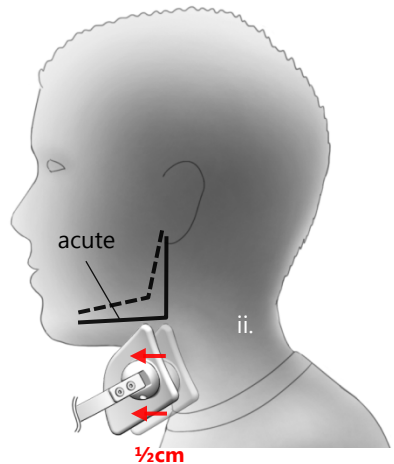
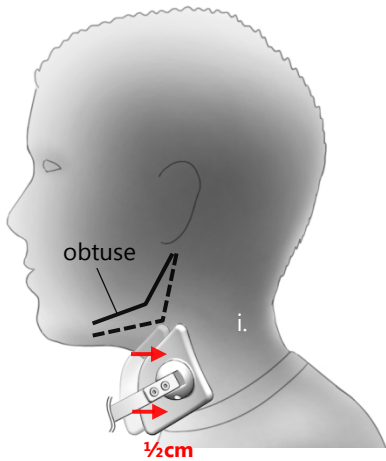


- b. Position the shield with its upper point just below the angle of the mandible
 c. Evaluate the contour of the back of the neck
 d. Rotate the rear edge of the shield parallel to the rear neck contour
 e. Check if the point of the shield is still correctly positioned under the angle of the mandible, correct if needed >>

Correction based on jaw line

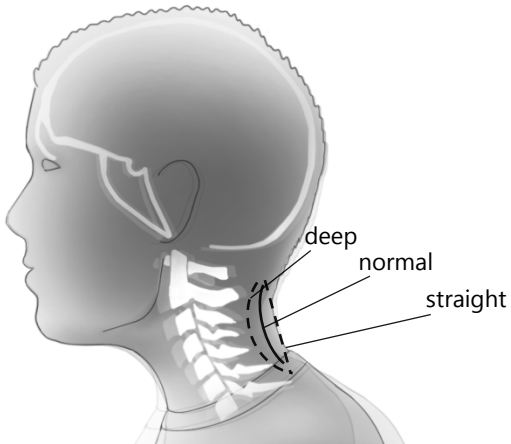


f. Evaluate the jawline at the mandible angle

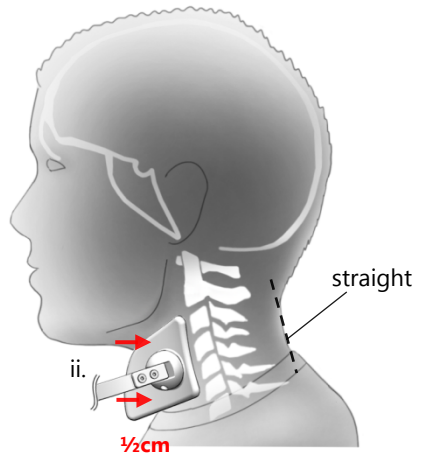
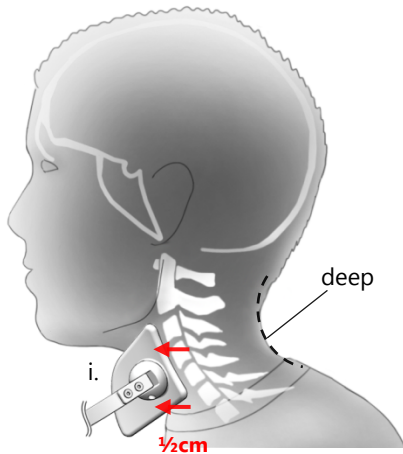


- i. if the angle of the jawline is obtuse, (this is when the rear contour of the mandible slopes forward) move the shield 1/2 cm backward
- ii. if the angle of the jawline is acute (this is when the rear contour of the mandible points straight down) move the shield 1/2 cm forward

Correction based on posture, rear neck contour



g. Evaluate the contour of the back of the neck



- i. if hollow/ deep: move the shield $\frac{1}{2}$ cm forward
- ii. if shallow/ straight: move the shield $\frac{1}{2}$ cm backward

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3. Instruct patient:

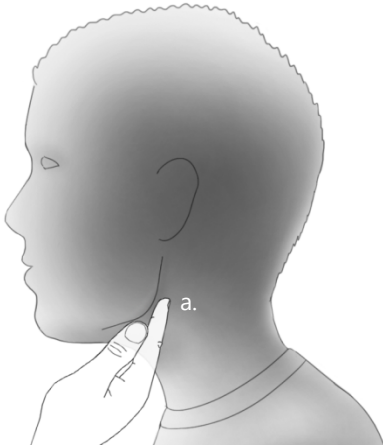
- a. To stand still
- b. To bite in correct occlusion
- c. To close the mouth with the lips in repose

B - Positioning of the CTP when depiction of the cervical vertebrae is not desired

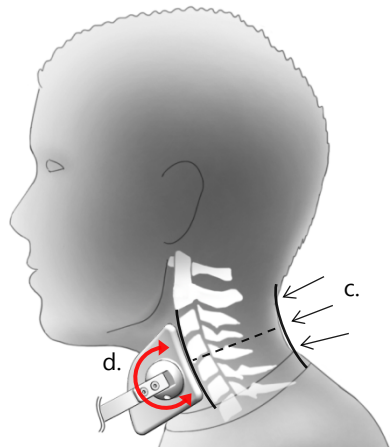
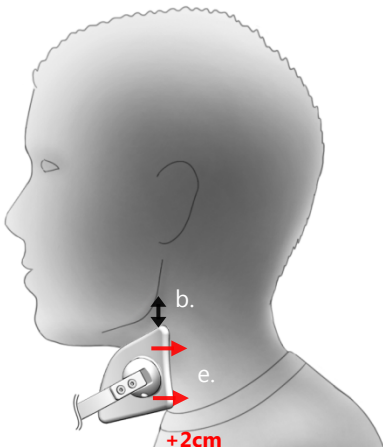
1. Position patient in cephalostat as in method A

see under A

2. Position CTP



- a. Locate the angle of the mandible by palpating with the fingers



- b. Position the shield with its upper point just below the angle of the mandible
- c. Evaluate the contour of the back of the neck
- d. Rotate the rear edge of the shield parallel to the rear neck contour
- e. Move the shield 2 cm backward >>

3. Instruct patient:

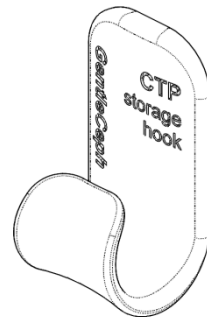
- a. To stand still
- b. To bite in correct occlusion
- c. To close the mouth with the lips in repose

Maintenance

Storage when not in use

No specific storage requirements apply for this product.

It is recommended to use the supplied hook to store the CTP when it is not being used.



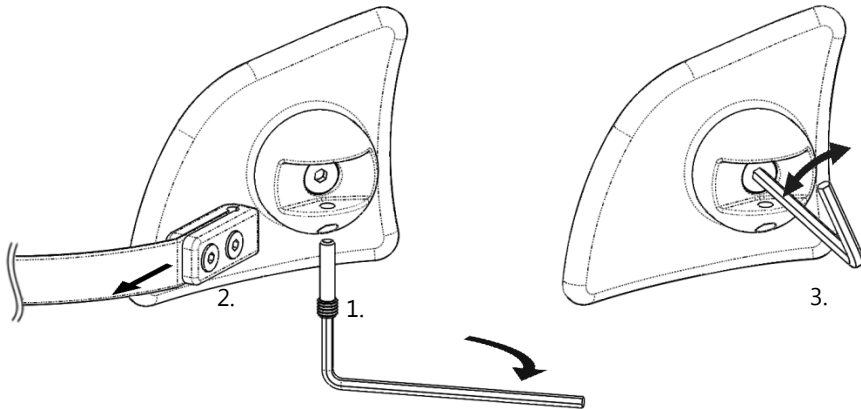
Cleaning

The CTP and its components can be disinfected with a surface disinfectant such as 70% isopropyl alcohol or equivalent. For hygienic reasons it is recommended to disinfect the product after each time it has come in touch with a patient or to make use of a disposable plastic cover to be put around the shield and neck support in order to avoid skin contact and contamination.

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

Adjust rotating friction of the shield

If needed the friction at which the shield rotates around its axis can be adjusted. The procedure for this is as follows:



1. Remove the pin using the supplied 2mm hex key
2. Take the shield from the spring arc
3. Tighten or loosen the central bolt using the 2,5mm hex key until the desired adjustment has been reached.

Re-assemble the CTP by reversing step 1-2

Check functioning

Each time the CTP is used it needs to be verified that the product is in good condition; parts moving according to the description on page 8-9. On the cephalogram the lead barrier should not show any signs of deformation or cracks.

If the product shows any flaws or defects (for example as a result of mechanical impact) it is recommended to stop using the product and contact the supplier for repair and/ or replacement of the damaged product parts.

For questions regarding the functioning and/ or compatibility of the CTP with the cephalometric X-Ray equipment, please contact your equipment (maintenance) supplier and or the supplier of the CTP.

Other

It may be required in your region to keep a record of the maintenance of X-Ray equipment and its accessories, therefore keep this document available at all times.

Disposal

Do not dispose 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.

Literature 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 see also: NEN-EN-IEC 61331-1:2014
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 Dose reduction in orthodontic lateral cephalography; Dosimetric evaluation of a novel
Cephalographic Thyroid Protector (CTP) and the Anatomical Cranial Collimation (ACC),
Hoogveen ea. - 2015
<http://dx.doi.org/10.1259/dmfr.20140260>

Notes

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Dealer stamp:



GentleCeph

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