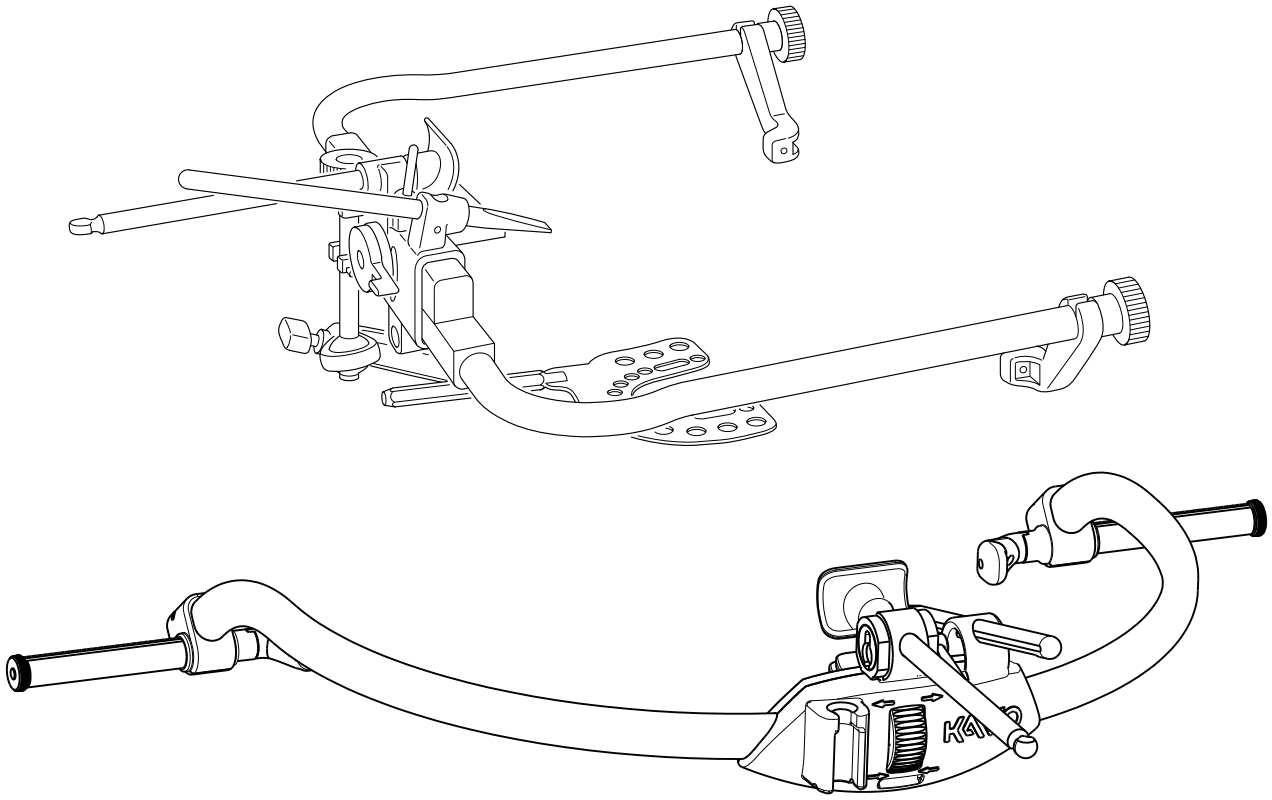
Instructions for use

ARCUSevo - 1.005.0900 / ARCUS - 0.622.5000



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CE

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1 User instructions

1.1 User guide

Requirement
Read these instructions prior to first startup to avoid misuse and prevent damage.

1.1.1 Abbreviations

Abbreviation	Explanation
IfU	Instructions for use
CI	Care instructions
AI	Assembly instructions
TI	Technician's instructions
SC	Safety checks
IEC	International Electrotechnical Commission
RI	Repair instructions
EMC	Electromagnetic compatibility
PI	Processing instructions

1.1.2 Symbols

	See the Safety/Warning Symbols section
	Important information for users and technicians
CE	CE mark (European Community). A product bearing this mark meets the requirements of the applicable EU directive.
▶	Action required

1.1.3 Target group

This document is for dentists and dental office staff.

1.2 Service

Service-Hotline:
+49 7351 56-1000
Service.Zahntechnik@kavokerr.com or Service.laboratory@kavokerr.com
Please indicate the product serial number in all requests!
For further information, please visit: www.kavo.com

1.3 Warranty provisions

The following warranty conditions apply to this KaVo medical device:

KaVo provides the end customer with a warranty of proper function and guarantees zero defects in respect of material and processing for a period of 12 months from the date of the invoice, subject to the following conditions:
In case of justified claims, KaVo will honour its warranty with a free replacement or repair. Other claims of any kind whatsoever, in particular with respect to compensation, are excluded. In the event of default, gross negligence or intent, this shall only apply in the absence of mandatory legal regulations to the contrary.
KaVo shall not be liable for defects and consequences thereof that have or may have arisen from natural wear, improper handling, improper cleaning, servicing or care, non-compliance with operating or connection instructions, calcination or corrosion, contaminated air or water supplies as well as chemical or electrical influences that are deemed abnormal or non-permissible in accordance with KaVo's instructions for use or other manufacturer's instructions. The warranty granted does not usually extend to lamps, optical fibres made of glass and glass fibres, glassware, rubber parts, and the colourfastness of plastic parts.
All liability is excluded if defects or consequences thereof originate from manipulations of or changes to the product made by the customer or a third party without authorisation by KaVo.
Service warranty claims will only be accepted if the product is submitted along with proof of purchase in the form of a copy of the invoice/delivery note. The dealer, purchase date, type, and serial number must be clearly evident from this document.

1.4 Transportation and storage

1.4.1 Currently valid packaging regulations

Note
Only valid for the Federal Republic of Germany.

Dispose of and recycle the sales packaging appropriately in accordance with current packaging regulations, employing waste management or recycling companies. Comply with the comprehensive return system. KaVo has had its sales packaging licensed for this purpose. Please comply with the regional public waste-disposal system.

1.4.2 Damage in transit

In Germany

If the packaging is visibly damaged on delivery, please proceed as follows:

1. The recipient of the package must record the loss or damage on the delivery receipt. The recipient and the representative of the shipping company must sign this delivery receipt.
2. Leave the product and packaging in the condition in which you received it.
3. Do not use the product.

4. Report the damage to the shipping company.
5. Report the damage to KaVo.
6. Consult with KaVo first, before returning a damaged product.
7. Send the signed delivery receipt to KaVo.

If the product is damaged but there was no discernable damage to the packaging on delivery, proceed as follows:
1. Report the damage to the shipping company immediately and no later than 7 days after delivery.
2. Report the damage to KaVo.
3. Leave the product and packaging in the condition in which you received it.
4. Do not use a damaged product.

Note
Failure on the part of the recipient to comply with any of the above-mentioned obligations will mean that the damage will be considered to have arisen following delivery (in accordance with the General German Freight Forwarders' Terms and Conditions, Art. 28).

Outside Germany

Note
KaVo shall not be held liable for damage arising from transportation.
The shipment must be checked on arrival.

If the packaging is visibly damaged on delivery, please proceed as follows:
1. The recipient of the package must record the loss or damage on the delivery receipt. The recipient and the representative of the shipping company must sign this delivery receipt.
   Without this evidence, the recipient will not be able to assert a claim for damages against the shipping company.
2. Leave the product and packaging in the condition in which you received it.
3. Do not use the product.

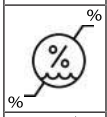
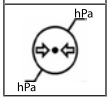
If the product is damaged but there was no discernable damage to the packaging on delivery, proceed as follows:
1. Report any damage to the shipping company immediately and no later than 7 days after delivery.
2. Leave the product and packaging in the condition in which you received it.
3. Do not use a damaged product.

Note
If the recipient fails to comply with any of the above-mentioned obligations, the damage will be considered to have arisen following delivery
(in accordance with CMR law, Chapter 5, Art. 30).

1.4.3 Information on the packaging: Storage and transportation

Note
Please keep the packaging in case you need to return the product for servicing or repair.

The symbols printed on the outside are for transportation and storage, and have the following meaning:

	Transport upright with the arrows pointing upwards!
	Fragile - protect against impact!
	Protect from moisture!
	Permissible stacking load
	Temperature range
	Humidity
	Air pressure

SN	Serial number
REF	Material number
Type	Device type
	CE mark according to Medical Devices Directive EC 93/42
	HIBC Code
	Manufacturer
	GOST R certification
	Date of manufacture - Year - Month - Day
	EAC conformity mark (Eurasian Conformity)
	Read and take note of the content of accompanying documents
	Comply with all safety-related information in the accompanying documents, such as warning notes and precautionary measures.

2 Safety

2.1 Description of safety instructions

2.1.1 Description of hazard levels

The warning and safety notes in this document must be observed to prevent personal injury and material damage. The warning notes are designated as shown below:

NOTICE

In cases which – if not prevented – could lead to material damage.

⚠ CAUTION

CAUTION

indicates a hazardous situation that can cause damage to property or mild to moderate injuries.

⚠ WARNING

WARNING

indicates a hazardous situation that can lead to serious or fatal injury.

⚠ DANGER

DANGER

indicates a maximal hazard due to a situation that can directly cause death or fatal injury.

2.1.2 Warning symbol

	Warning symbol

2.1.3 Structure

⚠ DANGER

The introduction describes the type and source of the hazard.

This section describes potential consequences of non-compliance.

- The optional step includes necessary measures for hazard prevention.

2.2 Intended use

2.2.1 General information

The functional safety and proper condition of the device must be checked before each use of the device.

This KaVo product is intended for use in dentistry only. Any other type of use is not permitted.

"Proper use" includes compliance with all instructions for use and the inspection and maintenance intervals.

The overarching guidelines and/or national laws, national regulations and the rules of technology applicable to medical devices for startup and use of the KaVo product for the intended indications for use must be applied and followed.

KaVo accepts liability for the safety, reliability, and performance of components supplied by KaVo, provided:

- installation, instructions, expansions, adjustments, changes or repairs were carried out by technicians trained by KaVo or third parties authorised by KaVo, or by the personnel of authorised distributors.
- the unit was operated in accordance with the instructions for use, servicing and assembly.

It is a responsibility of the user:

- to only use equipment that is operating correctly,
- to protect him or herself, the patient and third parties from hazards, and
- to prevent contamination from the product

The applicable national legal regulations must be observed during the use of the device, in particular the following:

- Applicable regulations governing the connection and startup of medical devices.
- Current occupational safety regulations.
- Current accident prevention regulations.

The following persons are authorised to conduct repairs and servicing and the safety check on the KaVo product:

- Technicians of KaVo branch offices after appropriate product training.
- Specifically KaVo-trained technicians of KaVo franchised dealers.

In Germany, operators, equipment managers and users are obliged to operate their equipment in accordance with the MPG regulations.
The services encompass all the test tasks required in accordance with § 6 of the medical devices operator ordinance (Medizinprodukte-Betreiberverordnung, MP-BetreibV).

Note
The product must be reprocessed and serviced according to instructions before and after extended period of time in which it is not used. Only use hygienic perfect products on the patient!

Note
Only accessories licensed for use with this machine may be used.

Note
All components contacting the patient's mucous membranes must be sterilised before the initial start-up.

2.2.2 Product-specific

The ARCUSevo / ARCUS facial bow records the position of the patient's maxilla. When creating a prosthesis, a working or tooth model can be correctly positioned in an articulator.
The facial bow is suitable for recording the Frankfurter horizontal and Camper's plane.

2.2.3 Disposal

Note
Any waste which is generated must be recycled or disposed of in strict compliance with all applicable national regulations in a manner which is safe both for people and the environment.
If you have any questions regarding proper disposal of the KaVo product, please contact the KaVo branch.

2.3 Safety Instructions

Note
All serious events occurring in relation to the product must be reported to the manufacturer and the competent authority of the member state, in which the user and/or patient resides.

NOTICE

Improper care.
Malfunction or property damage.
- Do not service the medical device with oil or maintenance spray.

NOTICE

Premature wear and malfunctions from improper servicing and care.
Reduced product life.
- The product does not need any special servicing to maintain its mechanical properties. Do not use oils or greases.

NOTICE

Product damage due to improper disinfection.
Malfunctions.
- Use the disinfectant according to the specifications of the manufacturer.
- No spray disinfection, perform wipe disinfection only.
- Do not immerse product or parts of the product in liquids.
- Mop up any spilled cleanser or disinfectant immediately.

⚠ WARNING

Injury or damage from damaged functional parts.
If functional parts are damaged, it can cause additional damage or personal injury.
- If functional parts are damaged: discontinue your work and have the damage repaired.
- Perform a visual inspection and a functional check before you use the device.

⚠ CAUTION

The reference pointer may touch the patient.

Eye injury, knock/startling

- When you place the facial bow, position the reference pointer in resting position away from the face. Move the reference pointer slowly and carefully towards the patient while avoiding any contact with the skin.

⚠ CAUTION

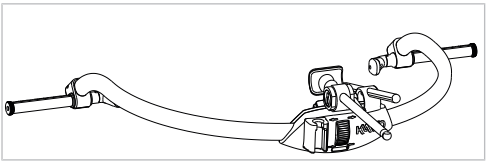
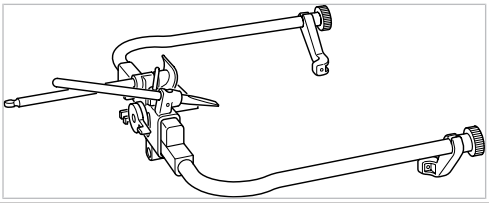
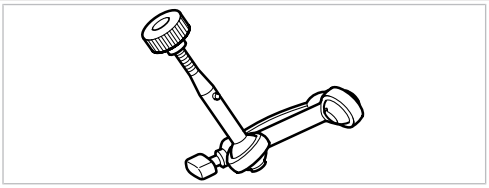
Bruising at the ear

Injuries

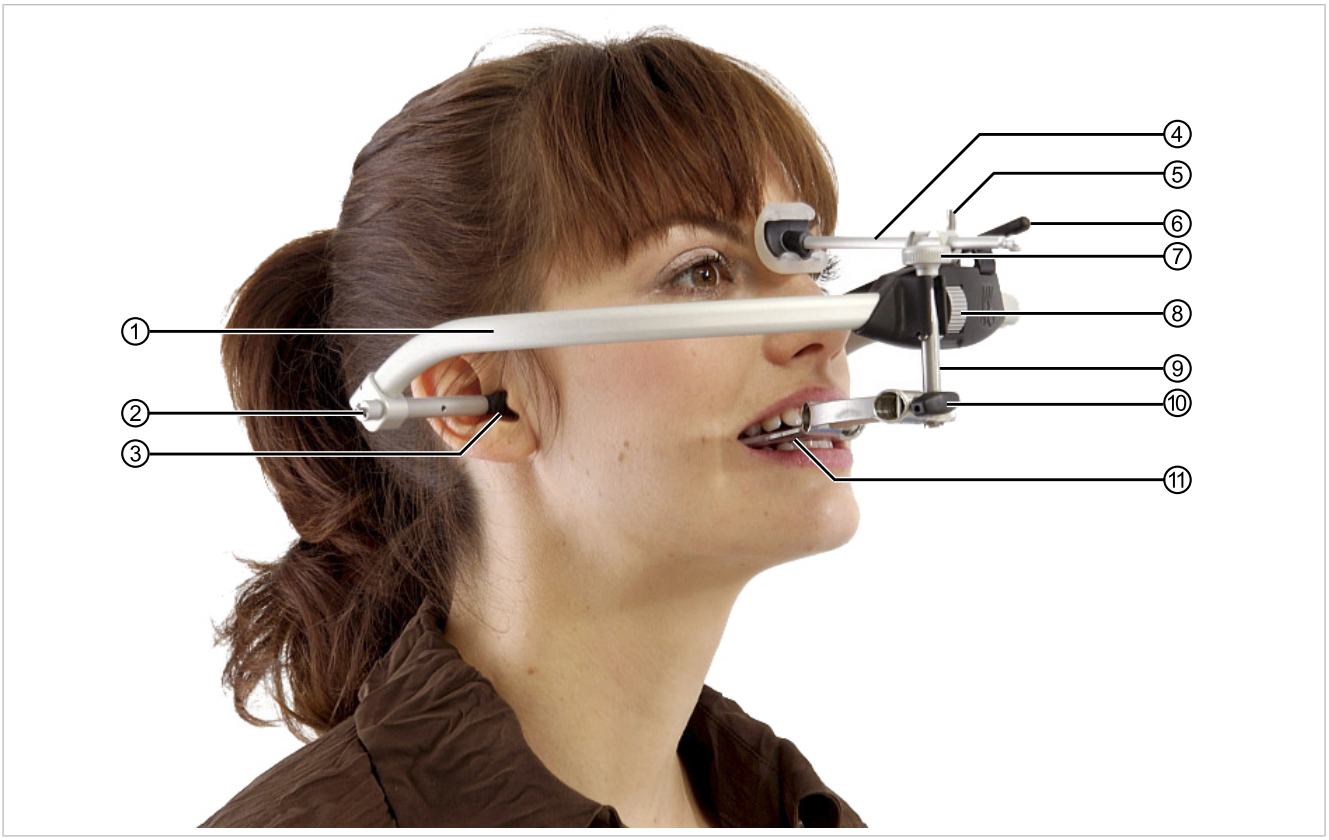
- Before you place the facial bow, set a sufficient distance considering the head size of the patient. Carefully place the earbuds in the auditory canals and fix them without injuring the patient. After completion of the measurement, return the earbuds to their starting position.

3 Product description

3.1 Scope of delivery

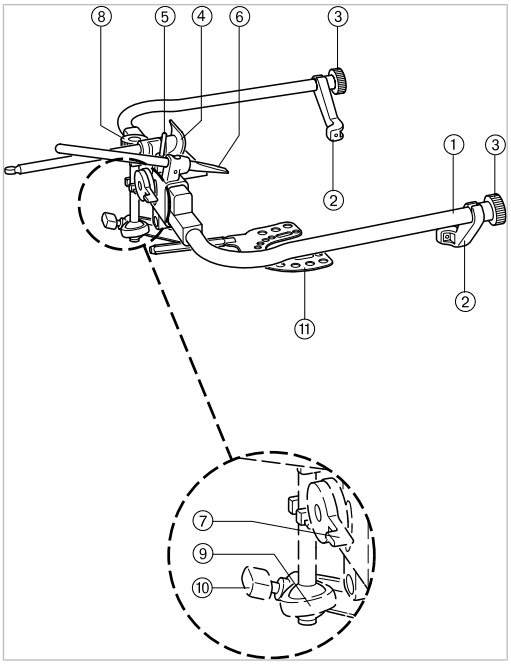
Figure	Name
 	Facial bow ARCUSevo / ARCUS incl. Earbuds Nose support Reference pointer
	Bite fork support
	Bite fork
	Instructions for use

3.2 ARCUSevo



① Bow
② Fastening nut for the earbud
③ Earbud
④ Nose support
⑤ Lock lever for the nose support
⑥ Reference pointer for the Frankfurter horizontal and Camper's plane
⑦ Fastening nut of the bite fork support
⑧ Adjustment wheel for adjusting the facial width
⑨ Bite fork support
⑩ Knurled screw of the bite fork support
⑪ Bite fork

3.3 ARCUS



① Arch
② Earbuds
③ Fastening nuts for earbuds
④ Nose support
⑤ Lock lever for the nose support
⑥ Reference pointer for FH + CP
⑦ Clamping lever for adjustment of the facial width
⑧ Fastening nut of the bite fork support on the ARCUS
⑨ Bite fork support
⑩ Toggle screw of the bite fork support
⑪ Bite fork

3.4 Technical data

Dimensions and weights of the ARCUSevo

Facial width	100 mm to 185 mm
Weight	250 g
Weight of bite fork/bite fork support	100 g

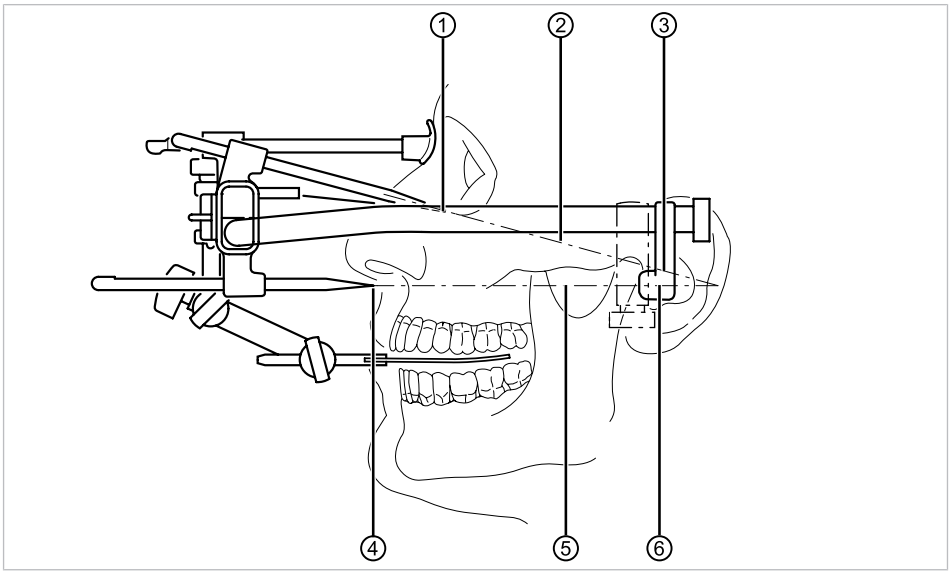
Dimensions and weights of the ARCUS

Facial width	106 mm to 186 mm
Weight	200 g
Weight of bite fork/bite fork support	100 g

Ambient conditions

Permissible operating temperature	10 °C to 40 °C
Relative Humidity	5% to 95% (non-condensing)
Storage temperature	-20 °C to 55 °C

Information on the planes and reference points



Frankfurter horizontal ② (FH):
Connection between the infraorbital point ① and porion ③

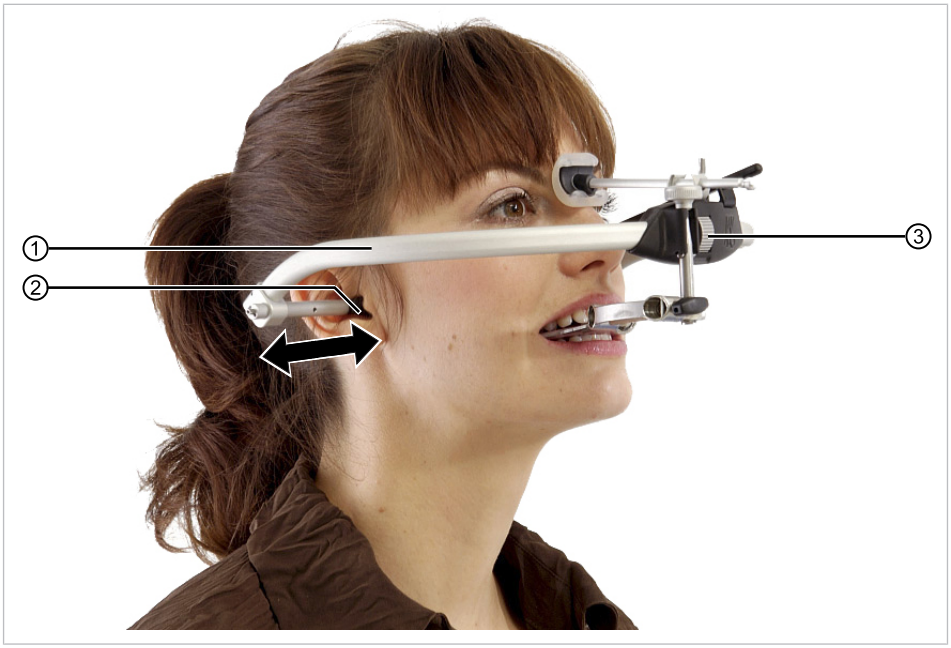
Camper's plane ⑤ (CP):
Connection between the subnasal point ④ and Targus medialis ⑥

The angle difference between the FH and CP is 15°.

4 Operation

4.1 ARCUSevo

4.1.1 Adapting the facial bow



ARCUSevo

- ▸ Turn the adjustment wheel ③.

⇨ The earbuds ② move further apart. The bow ① can be placed on the patient.

4.1.2 Mount the facial bow

The facial bow is mounted with reference to the Frankfurter plane and the Camper's plane.

⚠ CAUTION

Non-approved registration materials

Hazard for the patient

- ▸ Use approved registration materials only!

⚠ CAUTION

The reference pointer may touch the patient.

Eye injury, knock/startling

- ▸ When you place the facial bow, position the reference pointer in resting position away from the face. Move the reference pointer slowly and carefully towards the patient while avoiding any contact with the skin.

⚠ WARNING

Hazard from contaminated products.

Contaminated products are associated with an infection hazard.

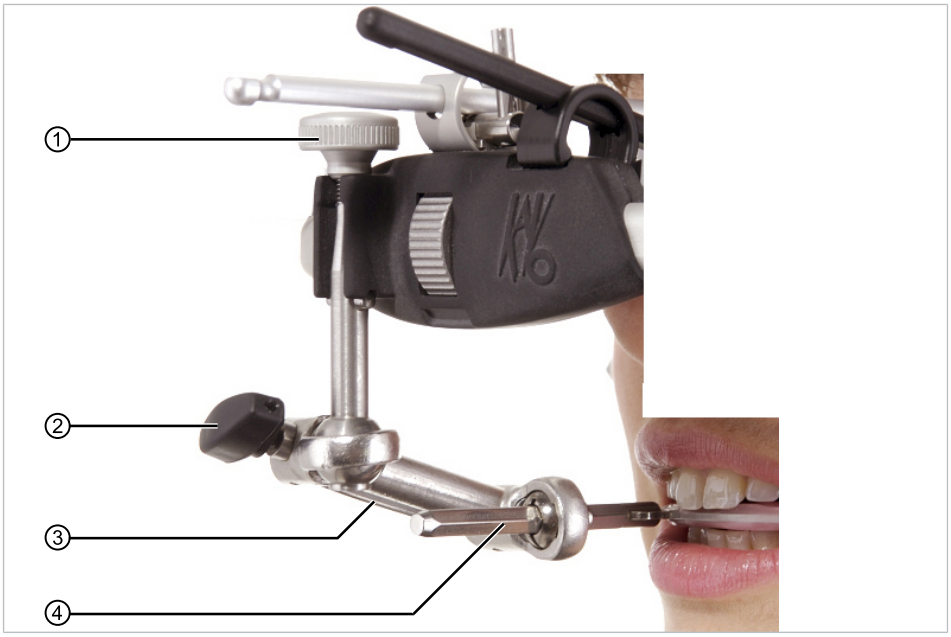
- ▸ Take suitable personal protective measures.

- Place the prepared bite fork in the patient's mouth. The fastening pin must be situated on the side of the right upper jaw.

- Adapt the bow ⑥ to the width of the patient's face.
- Insert the earbuds ⑦ into the outer auditory channel of the patient.
- Align the facial bow with the desired reference point (infraorbital point for the Frankfurter horizontal or the subnasal point for the Camper's plane).
- Affix the nose support ① with the the lock lever ②.

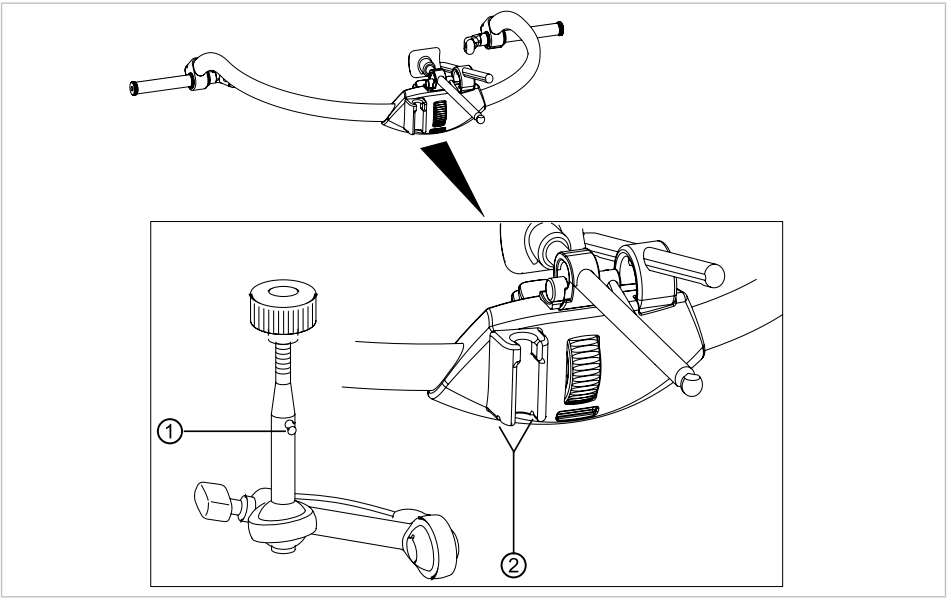
Note

If the Frankfurter horizontal is used, the reference pointer must be inserted with the pointer guide at position ④ as in the picture.
If the Camper plane is used, the reference pointer must be moved with the pointer guide below the adjustment wheel at position ⑤.



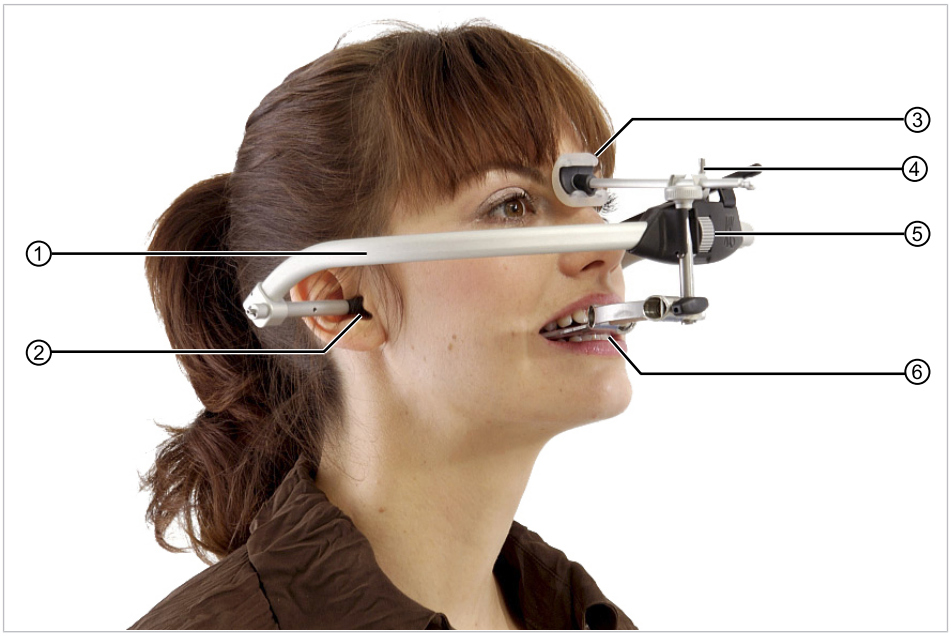
- Remove the knurled screw ②.
- Shove the bite fork support ③ onto the bite fork ④.

- Suspend the bite fork support ③ on the facial bow and tighten it with the fastening nut ①. Make sure that the guide pins of the bite fork support ③ engage in the guide groove of the facial bow.
  See also: following picture.
- Tighten the knurled screw ② to affix the bite fork ④.



① Guide pins of the bite fork support ② Guide groove of the facial bow

4.1.3 Removing the facial bow

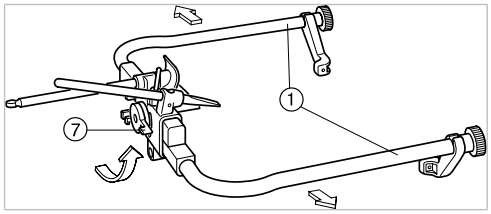


- Open the lock lever ④ of the nose support ③, push back the nose support ③ and fix.
- Turn the setting wheel ⑤ to remove the earbuds ② of the facial bow ① from the ears.
- Completely remove the facial bow from the patient with bite fork ⑥ fixed in the correct position.

For information on the transfer into the articulator, see the instructions for use of the KaVo PROTAR Articulator.

4.2 ARCUS

4.2.1 Adapting the facial bow



ARCUS

- Open the clamping lever ⑦ and open up the bow ①.

⇨ The bow ① can be placed on the patient.

4.2.2 Placing the facial bow

The facial bow is mounted with reference to the Frankfurter plane and the Camper's plane.

⚠ CAUTION

Non-approved registration materials

Hazard for the patient

- Use approved registration materials only!

⚠ CAUTION

The reference pointer may touch the patient.

Eye injury, knock/startling

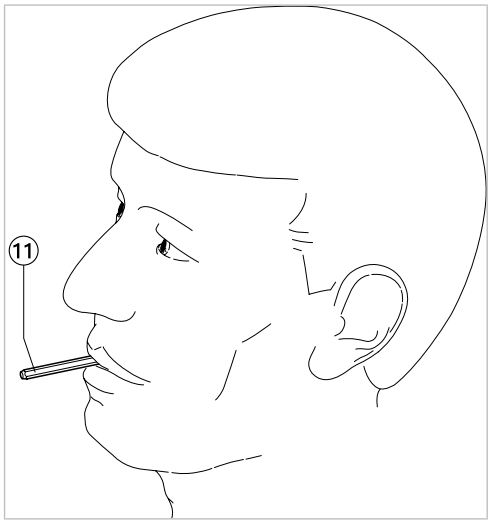
- When you place the facial bow, position the reference pointer in resting position away from the face. Move the reference pointer slowly and carefully towards the patient while avoiding any contact with the skin.

⚠ WARNING

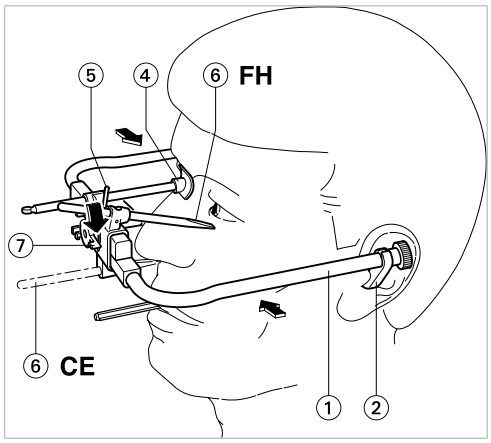
Hazard from contaminated products.

Contaminated products are associated with an infection hazard.

- Take suitable personal protective measures.

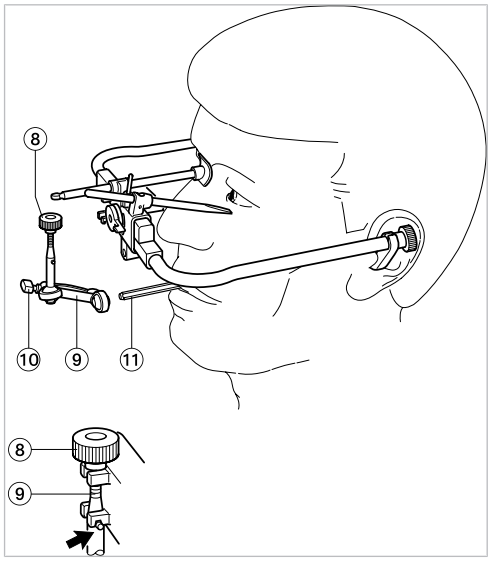


- Place the prepared bite fork ⑪ in the patient's mouth.

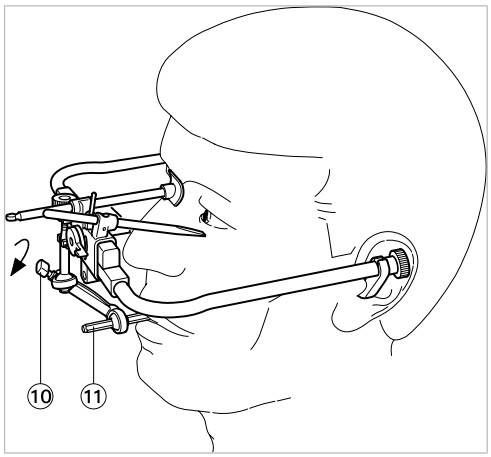


- Slide together the bow ① to the facial width of the patient and insert the earbuds ② of the bow ① in the outer auditory canal of the patient. Close the clamping lever ⑦ again.
- Affix the nose support ④ with the lock lever ⑤.
- Measure the reference points on the patient, infraorbital point for the Frankfurter plane or the subnasal point for Camper's plane, using the reference pointer ⑥. Carefully move the pointer towards the patient.
- If Camper's plane is to be used, the reference pointer ⑥ must be re-positioned.

Note
Never work with both planes simultaneously!

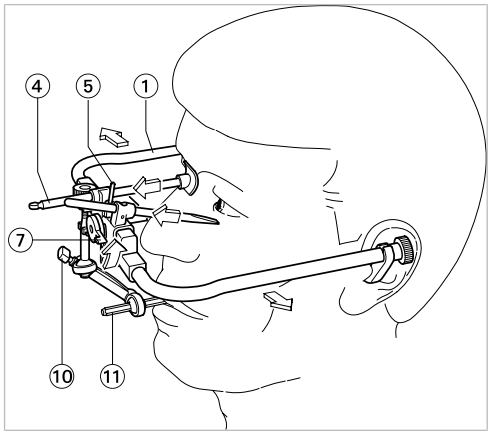


- Remove the knurled screw ⑩. Slide the bite fork support ⑨ onto the bite fork ⑪.
- Suspend the bite fork support ⑨ on the facial bow and tighten it with the fastening nut ⑧. Make sure that the guide pins of the bite fork support ⑨ engage the guide groove of the facial bow.



- Fix the bite fork ⑪ in place by tightening the knurled screw ⑩.

4.2.3 Removing the facial bow



- Open the lock lever ⑤ of the nose support, push back the nose support ④ and fix it in place.
- Use your thumb to open the clamping lever ⑦ on the facial bow and pull apart the bow ①.
- Completely remove the facial bow from the patient with bite fork ⑪ fixed in the correct position.

For information on the transfer into the articulator, see the instructions for use of the KaVo PROTAR Articulator.

5 Reprocessing steps in accordance with DIN EN ISO 17664

NOTICE

Cleaning with solvents or aggressive chemicals.

Damage to the product.

- Do not use solvents or aggressive chemicals for cleaning.

NOTICE

Never reprocess the device in an ultrasonic cleaner.

Malfunction and material damage.

NOTICE

Do not disinfect the product with chloride-containing products.

Malfunction and material damage.

Note

The reprocessing instructions have been validated by the manufacturer. Any departure from the instructions provided must be checked by the reprocessing entity for efficacy and possible detrimental consequences.

Note

All components contacting the patient's mucous membranes must be sterilised after use.

Note

Carry out the reprocessing steps as described in dedicated premises using suitable personal protective equipment.

Note

Carry out the reprocessing steps as described ahead of the first use as well. Only use perfectly hygienic and intact products on the patient.

Overview of reprocessing of ARCUS / ARCUSevo

Reprocessing items/medical devices	Cleaning manual	Cleaning automatic	Disinfection manual	Disinfection automatic	Sterilisation automatic
Contact components					
Earbuds	X		X		
Nose support	X		X		
Nose support, cushion	X		X		
Bite fork, complete	X		X	X	X

5.1 Cleaning

5.1.1 Preparations at the site of use

- Remove any soiling on the surface right after use.

- KaVo recommends to carry out the reprocessing as soon as possible after use.

5.1.2 Machine cleaning

Not applicable.

5.1.3 Manual cleaning

- Clean the bite forks under running water (tap water quality, 30 °C ± 5°C, flow rate: 2 litres/min) for 30 seconds using a medium-hard toothbrush.

5.2 Disinfection

⚠ WARNING

Incomplete disinfection.

Infection hazard.

- Only use disinfection procedures that are verified to be bactericidal, fungicidal and virucidal.
- If the disinfectants used do not meet these requirements, the process must be concluded by disinfection of the unit(s) without packaging using a steam steriliser.

5.2.1 Manual disinfection

Approved disinfectants:

- KaVo Wipes, CaviWipes and CaviCide made by Metrex
- Mikrozid AF made by Schülke & Mayr (liquid or cloths)
- FD 322 made by Dürr

- Disinfect the following components by wipe disinfection:
  Bite fork, complete
  Nose support
  Earbuds
  Pointer
  GB nasal support pad

5.2.2 Automated disinfection

KaVo recommends washer disinfectors from Miele in accordance with EN ISO 15883-1 that are operated with alkaline cleaning agents.
The validations were conducted with the VARIO-TD programme, the cleaning agent neodisher® MediClean and the neutralisation agent neodisher® Z.

- The program settings, cleaners and disinfectants that must be used can be found in the instructions for use of the thermodisinfector.

Drying

- Allow all disinfected and and sterilised parts to dry fully on room air before using them again.

The drying procedure is normally part of the cleaning program of the thermodisinfector.

5.3 Inspection and testing after reprocessing

- Testing for cleanliness, lack of wear, care.
- Testing the technical-functional safety (function check).

5.4 Packaging

Note

The sterile goods package must be large enough for the product so that the packaging is not stretched.

The quality and use of the packaging of the items to be sterilised must satisfy the applicable standards and be appropriate for the sterilisation process!

5.5 Sterilisation in a steam steriliser (autoclave) in accordance with EN 13060 / EN ISO 17665-1

NOTICE

Contact corrosion due to moisture.

Damage to product.

- Immediately remove the product from the steam steriliser after the sterilisation cycle.

- Sterilise the bite fork in a fractionated initial vacuum at 134°C ± 1°C, 3.04 bar for 4 minutes (sterilisable up to max. 138°C).

5.6 Storage

Prepared products must be stored, protected from germs (as far as possible) and dust, in a dry, dark, cool room.

Note

Observe the shelf life of the sterile item.

6 Accessories

Hinge axis pointer (ARCUSevo only) **Mat. no. 1.004.7640**

7 Spare parts sheet

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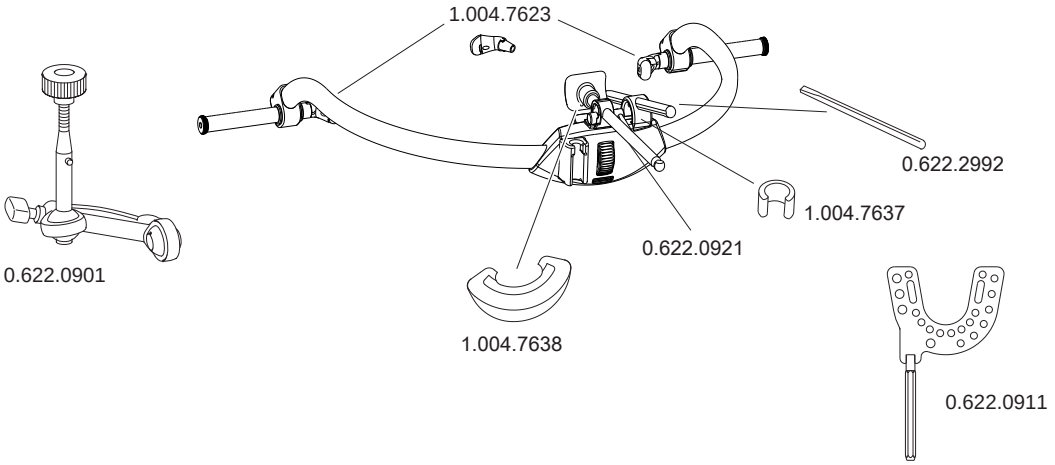

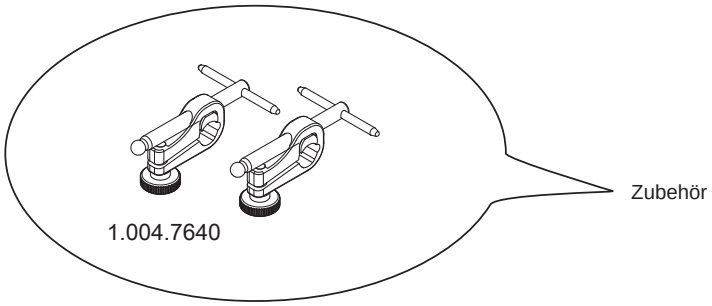

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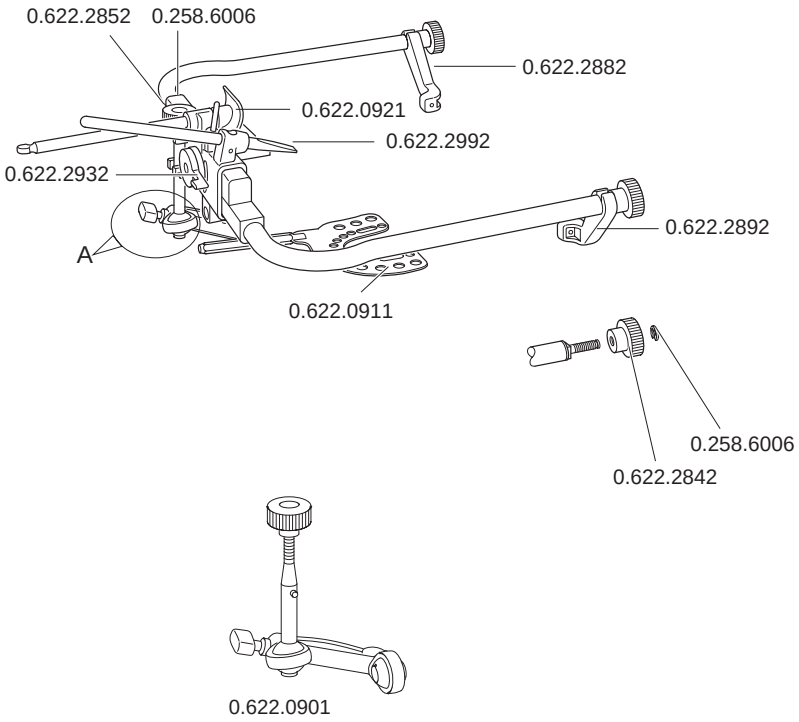

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