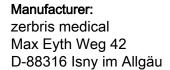
Operating Instruction ARCUSdigma II USB, SD, wireless



Always be on the safe side.







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1 User instructions | 1.1 User guide

1 User instructions

1.1 User guide

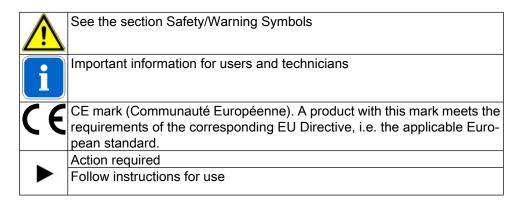
Requirement

Read these instructions before the initial startup to prevent misuse and damage.

1.1.1 Abbreviations

Short form	Explanation
GA	Instructions for use
PA	Care instructions
MA	Assembly instructions
TA	Technician's instructions
STK	Safety check
IEC	International Electrotechnical Commission
RA	Repair instructions
EMC	Electromagnetic compatibility

1.1.2 Symbols



1.1.3 Target group

This document is for dentists and office personnel as well as employees who work with the KaVo ARCUSdigma II SD, USB or wireless.

1 User instructions | 1.2 Service

1.2 Service



Service hotline: +49 7351 56-1600 Service.Zahntechnik@kavo.com Please indicate the product serial number in all requests. Additional information can be obtained at: www.kavo.com 1 User instructions | 1.3 Warranty provisions

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 data of invoice, subject to the following conditions:

In case of justified complaints, KaVo will honour its warranty with a repair or free replacement. Other claims of any nature 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 cannot be held liable for defects and their consequences that are or may be due to natural wear, improper handling, cleaning or maintenance, non-compliance with operating or connection instructions, calcination or corrosion, contaminated air or water supplies or chemical or electrical factors deemed abnormal or impermissible in accordance with KaVo's instructions for use or other manufacturer specifications. The warranty does not usually cover lamps, light conductors made of glass and glass fibres, glassware, rubber parts and the colourfastness of plastic parts. Defects or their consequences that can be attributed to interventions on or changes made to the product by the customer or a third party not authorised by KaVo are excluded from the warranty.

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, unit number or type and serial number must be clearly visible on this document.

1.4 Transportation and storage

1.4.1 Currently valid packaging ordinance



Note

Only applicable for the Federal Republic of Germany.

KaVo transport packaging must be disposed of and recycled by local disposal service providers and recycling companies in accordance with Dual System requirements.

For more information about disposal and recycling, and an up-to-date list of local disposal service providers and recycling companies, please visit the following Internet sites:

http://www.umweltdatenbank.de

http://www.quality.de

KaVo will bring KaVo transport packaging returned by the customer at the customer's own cost to the appropriate recycling companies without reimbursement...

1.4.2 Damage in transit

In Germany

If external damage to the packaging is visible upon delivery, follow the procedure below:

- 1. The recipient must record the loss or damage in the notice of delivery. The recipient and employee of the transportation firm must sign the notice of delivery.
- 2. Leave the product and packaging unchanged.
- 3. Do not use the product.
- 4. Report damage to the shipping company.
- 5. Report damage to KaVo.
- 6. A damaged product cannot be returned before talking with KaVo.
- 7. Send the signed notice of delivery to KaVo.

If the product is damaged and there is no discernable damage to the packaging upon delivery, proceed as follows:

- 1. Report damage immediately or at least 7 days after the delivery to the delivery company.
- 2. Report damage to KaVo.
- 3. Leave the product and packaging unchanged.
- 4. Do not use a damaged product.



Note

If the recipient does not follow one of the above instructions, the damage will be held to have occurred after the delivery (according to ADSp. Art. 28)..

1 User instructions | 1.4 Transportation and storage

Outside of Germany



Note

KaVo is not liable for damage arising from transportation. Immediately inspect the delivery after receipt!

If external damage to the packaging is visible upon delivery, follow the procedure below:

- The recipient must record the loss or damage in the notice of delivery. The recipient and employee of the transportation firm must sign the notice of delivery.
 The recipient can only assert damages against the transportation company based on these records.
- 2. Leave the product and packaging unchanged.
- 3. Do not use the product.

If the product is damaged and there is no discernable damage to the packaging upon delivery, proceed as follows:

- 1. Report the damage immediately or at least 7 days after the delivery to the delivery company.
- 2. Leave the product and packaging unchanged.
- 3. Do not use a damaged product.



Note

If the recipient does not follow one of the above instructions, the damage will be held to have occurred after the delivery (according to . CMR law , section 5, Art. 30).

1 User instructions | 1.4 Transportation and storage

1.4.3 Information on the packaging: Storage and transport



Note

Keep the packaging for returning the product for service or repairs .

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

<u>11</u>	Transport upright with the arrows pointing upwards
Y	Fragile - protect against knocks
	Keep dry
kg max	Maximum permitted stacking load
, C	Temperature range
	Humidity
hPa	Air pressure

2 Safety | 2.1 Description of safety instructions

2 Safety

2.1 Description of safety instructions

2.1.1 Warning symbol



Warning symbol

2.1.2 Structure



The introduction describes the type and source of the hazard.

This section describes the potential consequences of non-observance.

▶ The optional step contains necessary measures for avoiding hazards.

2.1.3 Description of danger levels

Safety instructions with three hazard levels are used in this document for avoiding personal and property damage.



CAUTION

indicates a hazardous situation that can lead to property damage or minor to moderate injury.



WARNING

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



DANGER

indicates a maximum hazardous situation that can directly cause serious injury or death.

2.2 Proper use

2.2.1 General information

The user must ensure that that the device works properly and is in a satisfactory condition before each use.

The KaVo ARCUSdigma is a medical device according to relevant national statutory regulations.

This KaVo product is intended only for use in the field of dentistry. It is impermissible to use the product for a purpose for which it was not intended.

"Proper use" includes following all the instructions for use and ensuring that all inspections and service tasks are performed.

Apply and meet the overarching guidelines and/or national laws, national regulations and the rules of technology for medical devices applicable for startup and use of the KaVo product for the intended purpose.

Responsibility is accepted for the safety, reliability and performance of the components supplied by KaVo provided:

- installation, upgrades, adjustments, changes or repairs are carried out by technicians trained by KaVo or third parties authorised by KaVo, or by the personnel of authorised distributors.
- The unit is operated in accordance with the instructions for use, care and installation.
- The IT components supplied by the operator meet the technical requirements in these instruction for use for hardware and software, and they are installed and set up according to the descriptions of these components.
- If it is repaired, the requirements of VDE 0751-1 "Repeat tests and tests before start-up of electrical items of medical equipment and systems - general regulations" must be met in full.

The user must observe the following:

- only use properly operating equipment.
- protect himself or herself and third parties from danger.
- avoid contamination from the product.

During use, national legal regulations must be observed, in particular:

- the applicable health and safety regulations.
- the applicable accident prevention regulations.

Authorised to repair and service the KaVo product:

- Technicians from the KaVo branches who are trained to deal with the product.
- the technicians of the KaVo franchised dealers specifically trained by KaVo.

In Germany, the operator, person responsible for the device and user must operate their devices in accordance with the provisions of the Medical Device Law.

2 Safety | 2.2 Proper use

These service tasks include all testing tasks that are stipulated in the Operator Ordinance (MPBetreiber V) § 6.



Note

Only those accessories may be used that are approved for the device.

Information on electromagnetic compatibility



Note

Based on EN 60601-1-2 concerning the electromagnetic compatibility of electromedical devices, we need to point out that:

- Medical electrical devices are subject to special measures regarding electromagnetic compatibility and must be operated in accordance with KaVo assembly instructions.
- Portable and mobile high-frequency communications devices can influence medical electronics.

See also: 8 Data on electromagnetic compatibility according to DIN EN 60601-1-2, Page 138



Note

KaVo cannot guarantee that accessories, lines and transformers not delivered by KaVo will correspond with EMC requirements of EN 60601-1-2.

Disposal



Note

The waste that arises must be recycled or disposed of in a manner safe for humans and the environment. Observe the applicable national regulations.

Please direct all questions regarding the proper disposal of KaVo products to the nearest KaVo branch.

Disposal of electronics



Note

According to EC directive 2002/96 concerning used electrical and electronic devices, this product is subject to the cited directive and must be disposed of accordingly within Europe.

Before disassembling / disposing of the product, it must be completely processed (disinfected, sterilized) according to the section "Preparation methods" Additional information can be obtained from KaVo (www.kavo.com) or your dental supplier.



Note

Batteries may not be disposed of with household garbage. In the interest of environmental protection, the end consumer is legally bound by the battery ordnance to return old and used batteries. Used batteries can be returned at municipal collection facilities or wherever batteries of the relevant kind are sold. No refund is provided for the returned batteries.

2.2.2 Product-specific

Determining findings

The KaVo ARCUSdigma is an electronic recording system based on 3D ultrasound measurement. The ARCUSdigma measures the individual movements of the patient's mandible. It measures the individual patient data that are required for programming the articulator and for fabricating functional restorations.

The 3-D representation of the dynamic behaviour of the kinematic, arbitrary, or terminal axes provides important information on the movement of the temporomandibular joint.

Therapy

From the measured mandibular movements, the ARCUSdigma calculates all of the necessary settings for the articulator for designing a functional restoration.

Articulators

All of the measured data can be reproduced with the KaVo PROTARdigma (Mat. no. 1.002.9564).

Alternatively, the PROTAR 7 (**Mat. no. 1.002.3321**) and the optional shift angle inserts (**Mat. no. 0.622.1111**) can be used to reproduce all of the measured data. In addition, the fully adjustable incisal table (**Mat. no. 1.003.7600**) is required when using the PROTAR 7 for anterior and canine guidance.

Settings from the following articulators by different manufacturers can also be calculated using the ARCUSdigma USB/wireless:

- SAM
- Artex AR (Girrbach/Amann)
- Referenz SL (Girrbach/Amann)
- Stratos 300 (Ivoclar)
- Panadent
- Denar Mark II (in preparation)

2.3 Safety instructions

2.3.1 General information



Premature weary and malfunctions from improper servicing and care.

Reduced production time.

Perform regular proper care and maintenance.



Injury or damage from damaged functional parts.

When functional parts are damaged, it can cause additional damage or personal injury.

- ▶ When operating parts are damaged: Stop working and eliminatethe damage, or notify a service technician.
- ▶ Check the electrode lines and accessories for damage to the insulation.

2.3.2 Product-specific



Hazardous external effects.

Injury or product damage.

Liquids that penetrate the device can cause fire, electric shock or other serious injury.

- ▶ The device is a high precision device. Do not drop it or and bump it.
- ▶ Do not place the device on an unstable base.
- ► Never place the device where there is moisture, or at a location where it could be sprayed with liquid.
- Never pour liquid on the system or its components.
- Never use the device outdoors.
- ▶ Do not leave the device in hot locations such as in a parked car, next to a heater, etc.).
- Do not insert objects into the device or in other system components.
- Only service the system as described in these instructions for use.
- ▶ Never open the device or alter it.



Note

Contact the manufacturer in the following situations:

- When liquid has been poured over the devices or other system components.
- The system does not work properly even when the instructions for use have been maintained.
- The device or other system components are worn, or the housing is damaged.

2 Safety | 2.3 Safety instructions



The use of damaged or incorrect rechargeable batteries can damage the device.

- ► Only use approved rechargeable batteries! The following are permitted: Battery type: Mignon button AA HR6 1.5 V.
- Do not short the rechargeable batteries, take them apart or alter them!
- ▶ Do not insert the rechargeable batteries with reversed polarity (+/-).
- ▶ Do not use new and old rechargeable batteries at the same time or different types of batteries.
- Only use leak-proof rechargeable batteries.
- ▶ Remove the rechargeable batteries when the device is not used for a long time.
- Properly dispose of used rechargeable batteries.
- Do no use non-rechargeable batteries.



Electrical storm

Electrical shock

- Only use the product with the provided power supply.
- Do not use a defective power supply.
- ▶ Do not use damaged accessory parts, especially plugs and cables.
- Send damaged accessory parts, especially plugs and cables, to the manufacturer for a safety check.
- Contact the manufacturer in case of malfunctions or if you are unsure of anything.



Note

The operation of the measuring system should be regularly checked.



Simultaneous use of a high-frequency surgical device.

The simultaneous use of the ARCUSdigma with a high-frequency surgical device can burn the skin under the EMG electrodes or potentially damage the input amplifier.

▶ Never used the ARCUSdigma together with a high-frequency surgical device.

Observe the following points when measuring with the ARCUSdigma:

- Patient and measuring data may only be copied, moved or deleted using the database function provided by the KaVo application programs. If the data is intentionally changed without the database functions, the user is solely responsible for any associated risk.
- Only trained personnel may use and operate the system or evaluate and interpret measuring data. The manufacturer is not liable for personal or property damage and data loss arising from the improper use of software, the device or its accessory parts.
- The measuring results may be distorted when a shortwave or microwave therapy device is used close to the ARCUS digma. This should therefore always be avoided.
- All of the measuring results should be checked for their relevance. In case of
 invasive surgery, the measuring system may only be used as an additional observation tool. Invasive surgery are measures that may harm the patient cannot
 and should not be based solely on the measuring results.

2 Safety | 2.3 Safety instructions

Special instructions on the ultrasound motion analysis system



Risks of mutual malfunctions from ultrasonic devices

Unnoticed distortion of the measured values.

- ► To prevent mutual malfunctions, two ultrasonic motion analysis systems should not be used together unless they are synchronized.
- Never use the system close to other devices that are using ultrasound, or close to sources of sound interference. The same holds true when these devices meet the applicable transmission requirements according to CISPR.

3 Product description | 3.1 Product variations

3 Product description

3.1 Product variations

The following product variations are obtainable:

- KaVo ARCUSdigma SD (Mat. no. 1.005.2300)
- KaVo ARCUSdigma USB (Mat. no. 1.005.2301)
- KaVo ARCUSdigma Wireless (Mat. no. 1.005.2302)



Note

The ARCUSdigma SD can be expanded at the factory to:

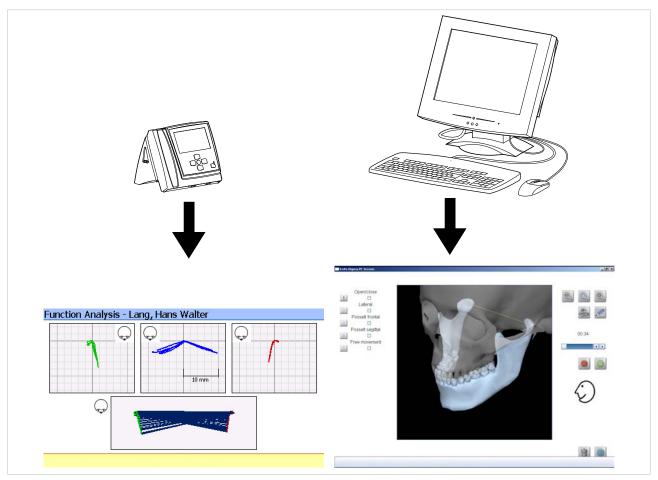
- ARCUSdigma USB (with SD USB upgrade, Mat. no. 1.005.4117)
- ARCUSdigma wireless (with SD wireless upgrade, **Mat. no. 1.005.4118**) The ARCUSdigma USB can be expanded at the factory to:
- ARCUSdigma wireless (with USB wireless upgrade, Mat. no. 1.005.4119)

All three product variations are described in these instructions for use. If a section is only relevant for a particular product variation, it is noted in the respective section.

If a computer has a USB or wireless connection to the basic unit, the display is simultaneous on the screen of the basic unit and screen of computer. Both screen views are depicted in these instructions for use.

3 Product description | 3.1 Product variations

The images on the computer screen are irrelevant to the operation of the ARCUS-digma SD.



Example: left: Basic unit screen, right: Computer screen (irrelevant for the ARCUSdigma SD)

3 Product description | 3.1 Product variations

The following table shows the available functions and software modules in the individual production variations:

Operation	ARCUSdigma SD	ARCUSdigma USB	ARCUSdigma Wireless
	Mat. no. 1.005.2300	Mat. no. 1.005.2301	Mat. no. 1.005.2302
Data transmission	Via SD cards to a compu-	Via USB cable online to a	Via KaVo radio module to
	ter	computer	a computer
Selectable	 KaVo Transfer System 		1
Reference axes	 Kinematic axis 	 Kinematic axis 	 Kinematic axis
	 Arbitrary axis 	 Arbitrary axis 	 Arbitrary axis
	 Individual centric axis 	 Individual centric axis 	 Individual centric axis
Software module	 Articulator programm- ing 	 Articulator programm- ing 	 Articulator programm- ing
	 Manually-guided cent- 	 Manually-guided cent- 	 Manually-guided cent-
	ric	ric	ric
	Mandibular movement		
	analysis	the "Adduction field"	the "Adduction field"
	 EPA - Electronic position analysis of the 	 Centric determined via the "Gothic arch" 	 Centric determined via the "Gothic arch"
	mandibular position	Mandibular movement	Mandibular movement
		analysis	analysis
		Mandibular positioning	
		after the movement	after the movement
		analysis	analysis
		EPA - Electronic posi-	EPA - Electronic posi-
		tion analysis of the	tion analysis of the
O discord		mandibular position	mandibular position
Optional	-	EAEF module by Prof. A Burnary for data wait	1
Software module		A. Bumann for determi-	A. Bumann for determi-
		ning painful mandibu- lar positions and for	ning painful mandibu- lar positions and for
		designing dynamic	designing dynamic
		splints	splints
		(Mat. no. 1.005.4122)	(Mat. no. 1.005.4122)
		• EMG analysis – 2	• EMG analysis – 2
		channel EMG to deter-	channel EMG to deter-
		mine muscular activity	mine muscular activity
		(Mat. no. 1.005.4123)	(Mat. no. 1.005.4123)
Compatible articulators	KaVo PROTAR/evo	KaVo PROTAR/evo	 KaVo PROTAR/evo
	articulators	• SAM	• SAM
		 Girrbach 	 Girrbach
		 Stratos 	 Stratos
		 Panadent 	 Panadent
		 Denar 	 Denar

3.2 Scope of delivery: ARCUSdigma SD/USB/wireless



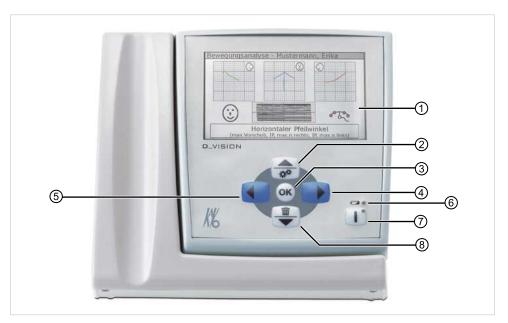
- ① Power supply with country adapter
- ② Bite fork support
- ③ ARCUSdigma foot
- 4 ARCUSdigma basic unit
- ⑤ Footswitch
- 6 Axial pin
- ⑦ ARCUSevo face bow

- ARCUSdigma receiver
- Reference pointer for the Frankfurter horizontal and Camper's plane
- Mandibular attachment
- 1 KTS bite fork
- Normal bite fork
- ARCUSdigma transmitter
- Reference pointer

The measuring bow consists of:

- 1 ARCUSevo facial bow
- 2 axial pin
- 1 ARCUSdigma receiver
- Head supports for securing to the head

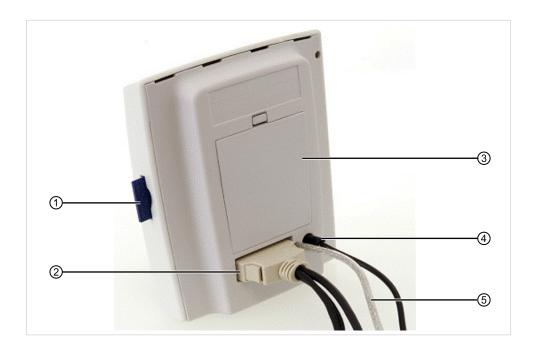
3.2.1 Basic unit



Control panel

- ① Touchscreen
- ② "High/menu" key
- ③ "OK" key
- 4 "Forwards" key

- ⑤ "Back" key
- ® "Battery charging display" key green: Battery charged, yellow: Immediately plug in power supply
- ⑦ "On/off" key
- ® "Delete/down" key



3 Product description | 3.2 Scope of delivery: ARCUSdigma SD/USB/wireless

Rear

- ① SD card reader
- 2 Sensor plug
- 3 Battery compartment
- ② Connection for charging the battery or mains operation
- ⑤ USB connection

3 Product description | 3.3 Technical data

3.3 Technical data

3.3.1 Technical data on the ARCUSdigma

Dimensions and weights of the basic unit

Width	144 mm
Depth	130 mm
Height	35 mm
Weight	approx. 330 g (without batteries)

Dimensions and weights of the ARCUSevo facial bow (with sensors)

Max. width	345 mm (345 mm)
Depth	300 mm (300 mm)
Height	100 mm (100)
Weight	250 g (340 g)
Weight of bite fork/bite fork support	100 g

Environmental conditions

Permissible operating temperature	10 °C to 40°C
Relative humidity	30 % to 80 %
Storage temperature	5 °C to 70°C

Device classification

EC Directive 93/42/EEC	Class 1 with measuring function
ICE 601-1: Mode	continuous operation duty type
ICE 601-1: Type of protection agains electrical shock	Device of protection class II
ICE 601-1: Degree of protection agains electrical shock	Application part type BF
ICE 601-1: Mode	continuous operation duty type

Electrical supply - variation with nominal voltage of 230 V

Alternating voltage	230 to 240 V; ± 10%
Nominal frequency	50/60 Hz
max. current	840 mA
permissible impedance	0.5 Ω

3 Product description | 3.3 Technical data

Cross-section of the power line	Up to a max. length of 16 m: 1.5 mm ² (or AWG14), any more and the diameter must be thicker
Power line design	Nominal voltage 250 V, corresponding to applicable regulations

Electrical supply - variation with nominal voltage of 110 V

Alternating voltage	100 to 110 to 130 V; ± 10%
Nominal frequency	50/60 Hz
max. current	840 mA
permissible impedance	0,2 Ω
Cross-section of the power line	Up to a max. length of 8 m: 1.5 mm ² (or AWG14), any more and the diameter must be thicker
Power line design	Nominal voltage 110 V corresponding to applicable regulations (ANSI/NFPA and UL for USA)

Measuring precision

EPA test	± 0.1 mm
Calculation of the articulator settings	± 2,0°

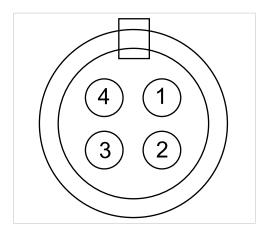
Transportation and storage condtions in the original packaging

temperature	-20 °C to 50°C
Humidity	5% to 90%
Air pressure	750 hPa to 1050 h Pa

The measuring system should only be stored and transported in the provided original packaging.

3 Product description | 3.3 Technical data

3.3.2 Technical data on the analogue inputs of the EMG adapter (optional accessories)



Pin	Operation	Dynamics	Permissible maximum or
			load
Pin 1: +5 V	Power supply	-	10 mA
Pin 2: Signal	Signal input	see table	± 60 V
Pin 3: GND	Power supply	-	-
Pin 4: -5 V	Power supply	-	10 mA

Input impedence of the signal input (EMG): 146 $\mbox{K}\Omega$ according to GND

3.3.3 Technical data on differential electrode cables (optional accessory)



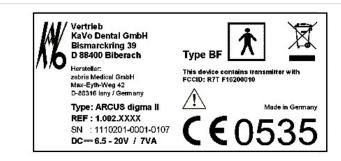
Electrical data

Supply voltage	±5 V to ± 15 V
Input resistance	10 E + 12 Ω
CMRR	110 dB
Noise referred to input	0.28 μV pp
Voltage amplification	1000
Bandwidth	7 Hz to 500 Hz
Output voltage	Voltage supply minus 1 V

Mechanical data

Dimensions	30 x 23 x 9 mm (L x W X H)
Cable length	1.45 m

3.4 type plate



Type	ARCUSdigma
SN	Year of manufacture - serial number
REF	Material number
	Disposal instructions see also: Proper use
•	Classification
1	Type BF application parts
$\overline{\mathbb{V}}$	Follow instructions for use!
C€ 0535	CE mark according to EC Directive 93/42 for medical devices
	Appointed institution 0535: EUROCAT, Institute for Certification and Tes-
	ting, Darmstadt, Germany

4 First use

4.1 Installation of the KiD/ARCUSdigma PC software

4.1.1 General information

The PC software for the KiD/ARUCSdigma saves and portrays the ARCUSdigma measurements on the computer.

See also: Instructions for use of the KiD - KaVo Integrated Desktop

KiD - KaVo Integrated Desktop

KiD is the central database that saves all measured values of the ARCUSdigmas on the computer. If additional measuring systems are available that provide digital information such as the oral camera, digital x-ray systems, etc., these data are also saved in the database. The care provider can tell at a glance which measuring data are available for which patient.

All of the measurements can be portrayed or printed out from this database. Complete data records can be sent to other KiD/ARCUSdigma users (for example to obtain expert opinions).

The patient's master data are transferred from the available practice software. A separate input window is also available for the patient master data.

ARCUSdigma and computer software

The computer software for the ARCUSdigma displays the data on the computer screen during measurement. Additional measuring steps can be added to the measuring program by means of the computer keyboard. If comments are required for specific measurements, they can also be entered using the computer keyboard.

4.1.2 System requirements



Note

The system technical data must be checked before installation.



Note

To display 3-D movement, a graphics card is recommended with OpenGL 3-D integrated hardware acceleration. This includes for example cards from the Radeon X13xx Series by ATI, or the GeForce 62xx series by Nvidia. Most computers made within the last two years support OpenGL.

The following system requirements are necessary:

- Computer with min. 1GHz processor
- 256 MB RAM for single-user station or workstation
- 512 MB RAM for SQL database server
- 50 MB free hard disk space on system drive
- Depending on data volume, 5 to 50 GB hard disk space on the data drive (may tally with system drive)
- Min. screen resolution 1024x768, min. colour depth 24 bits 24 Bit

 Operating system: Microsoft Windows 2000 as of service pack 4, Microsoft Windows XP as of service pack 2

4.1.3 Start the installation routine

Insert the provided installation KiD CD into the drive. The installation routine automatically starts (autostart), and the installation assistant appears.

The KiD version to be installed is cited on the entry page.



Accept the license contract of KiD to continue the installation routine.



Set a target directory.





Note

The program files are saved in the target directory. The target directory must be on a local hard disk. It is recommendable to use the suggested directory path (C: \Programs\KaVo\KiD). A target directory on a network drive can cause malfunctions.

4.1.4 Installing a single-user or system

Deactivate the checkbox when KiD should only be operated on individual computer.



Set the program symbol.



Confirm the installation settings.



Conclude installation.



4.1.5 Installing a multiple-user system

When KiD is installed on a network, several workstations on which KiD is installed can access a common database.

A computer in the network must be configured as the database server in this case. This computer must always be started before all the other computers and turned off after all the other computers are turned off (for example in evening if it is turned off at all).



Note

If you plan a network installation of KiD, KiD must first be installed on a database server.



Note

In a multi-user system, all the associated workstations must access the same database server, the same database and the same document path; otherwise inconsistencies in the data can arise.

▶ Check the checkbox when the KiD is to be operated in a multi-user system.



▶ Install a database server when no database server is found on this computer.



KiD must first be installed on the database server in a multi-user system. Microsoft SQL Server 2005 Express only has to be installed on this computer. The checkbox must be deactivated at all other workstations.



Note

If Microsoft SQL Server is already installed on this computer, this version can be used. The user account used for installation must have administrator rights.

Select the database server when the database server is not installed on this computer.



When installing the workstations in the network, the installed database server is found and can be selected (several database servers can exist in a network).

Requirement

Expert mode is set.

Manually enter the name of the database server.

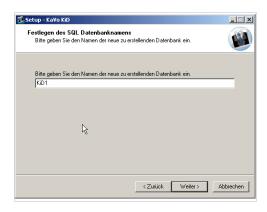


 Select the database when the database server is not installed on this computer, or several KiD databases exist on the selected database server.



In a second installation on the database server, a second KiD database can be created.

▶ When a new database is created on an existing database server, specify the name for the new database.



▶ When installing the database server or if the server release is not found, select a document directory.



The document directory will later contain individual files that are assigned to the patients. The files have a KaVo-specific format and a unique name. When a server is installed, this directory is released in the network. The generated release is "\ \Computername>\\<DatenbankName>Data\$". Normally, the name of the database is "KiD".



Note

When installing the workplaces, the normal release name is searched on the server. If the release name is not found, the path for each workstation must be correctly set during installation.

4 First use | 4.1 Installation of the KiD/ARCUSdigma PC software

Confirm the installation settings.



Various submodules are installed during KiD installation. These can vary depending on the installed version of Windows:

- Microsoft Windows Installer 3.1
 This package is a part of Microsoft Windows XP updates. If the operating system has not been updated for a long time, it is installed. This can take up to 10 minutes
- Microsoft .NET 2.0 Runtime
 This package contains a license agreement from Microsoft that has to be accepted for installation. It is a part of the optional update from Microsoft.
- Microsoft SQL Server Express

 This package is only installed for a new database server installation. This can take up to 10 minutes.

Release document directory

Conclude installation.



4.1.6 Troubleshooting during installation

Malfunction	Cause	Remedy
The installation of the Microsoft	Parts of the program are already in-	Search for the parts of the SQL
SQL Server Express does not work.	stalled.	Server installation with the sys-
		tem control software (for exam-
		ple Microsoft SQL native client)
		and then install them.

4 First use | 4.1 Installation of the KiD/ARCUSdigma PC software

Malfunction	Cause	Remedy
The database cannot be found.	The server name, catalog name, database name or document directory are set incorrectly.	 Check and correct if necessary the database settings using the program options.
The automatic patient data transfer does not work.	The plug-in was not correctly initialized.	 Using the program options, open the options of the plug-in patient data transfer, confirm with OK, and restart the KiD pro- gram.
The media catalog is empty and not- hing can be added.	The primary directory of the media catalog is not correctly configured.	Using the program options, open the options of the plug-in media and enter a valid, descri- bable directory path as the first entry.

4.2 Start up the ARCUSdigma basic unit

4.2.1 Electrical connection

The basic unit may only be operated using the medically approved power supply (EN 60601) or batteries.



The use of damaged or incorrect rechargeable batteries can damage the device.

- Only use approved rechargeable batteries! The following are permitted: Battery type: Mignon button AA HR6 1.5 V.
- ▶ Do not short the rechargeable batteries, take them apart or alter them!
- ▶ Do not insert the rechargeable batteries with reversed polarity (+/-).
- ▶ Do not use new and old rechargeable batteries at the same time or different types of batteries.
- Only use leak-proof rechargeable batteries.
- ▶ Remove the rechargeable batteries when the device is not used for a long time.
- Properly dispose of used rechargeable batteries.
- Do no use non-rechargeable batteries.

Battery operation is advantageous when the basic unit is used at different locations in the practice. A full set of batteries is sufficient for approximately 1.5 hours of measuring, and they will last for approximately 6 hours in standby mode.

If the basic unit has a fixed location in the treatment unit or if the measuring times will be longer, it is advantageous to operate the basic unit using the provided power supply.

▶ Plug in the power supply plug into the connection for the basic unit power supply.

4.2.2 Connect the sensors, foot switch and EMG to the distributor box

- Fasten the distributor box to the belt on the patient.
- Connect the sensors, foot switch and EMG (optional accessory) as shown in the graphic.

4 First use | 4.2 Start up the ARCUSdigma basic unit



- 1) Distributor box
- ② Connection for the receiver on the facial blow
- ③ Transmitter connection (mandible)
- 4 Footswitch
- **⑤** Connection to channel 2 EMG
- Line to the ARCUSdigma basic unit

4.2.3 Connection options for the ARCUSdigma USB

Connection to the practice computer or a laptop

The ARCUSdigma can be directly connected to the practice computer or a laptop using a USB cable.



Note

The USB cable may only be extended with an "active USB cable."

Connection to the KaVo multimedia unit

If the KaVo multimedia screen is used to display the ARCUSdigma , the following device requirements are necessary:

- USB connection to the behind-the-head computer.
- VGA cable (max.10 m) for the treatment unit.
- ERGOcom light for operating the screen on the treatment units is installed.

Connection to the E80 treatment unit

If the ARCUSdigma is to be connected to the US interfaces with the E80 treatment unit or the assistant element of the E80, the following device requirements are necessary:

- The ERGOcom 4 must be installed (deliverable starting 2008)
- The ethernet line to be behind-the-head computer for data input is available.

4 First use | 4.3 Mount the ARCUSdigma measuring bone

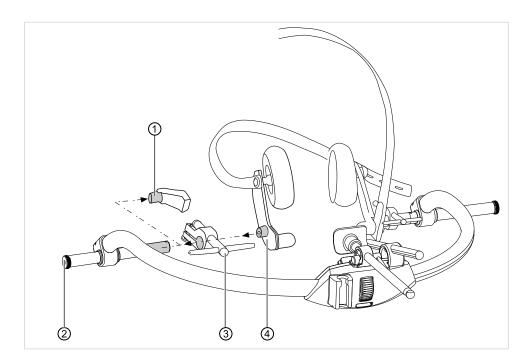
4.3 Mount the ARCUSdigma measuring bone

The measuring bow consists of:

- 1 ARCUSevo facial bow
- 2 axial pin
- 1 ARCUSdigma receiver
- Head supports for securing to the head

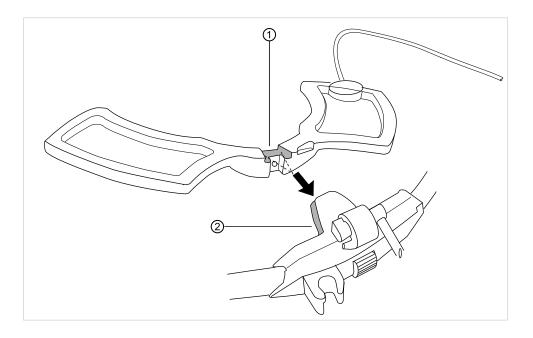
When the ARCUSdigma is delivered, teh parts of the head attachment are already mounted.

4.3.1 Mount the head attachment to the facial bow



- ▶ Remove the fastening nut ②.
- ► Remove the earbuds ① from the facial blow.
- ▶ Push the axial pin ③ (Mat. no. 1.004.7640) onto the mobile axes.
- Screw the head supports (4) tight with fastening nuts.

4.3.2 Mount the ARCUSdigma receiver on the facial bow



▶ Push the ARCUSdigma receiver ① onto the conical tab of the facial bow ②.

5 Operation

5.1 General use

5.1.1 Turn the ARCUSdigma basic device on and off



- ► Press the "On/off" key for 1 second to turn the device on.
- Press the "On/off" key for 3 seconds to turn the device off.

Before measurement, make sure that the battery is sufficiently charged. The power supply may have to be connected while working.



The battery charge display is green:

The measurement can be made without the power being connected.

The battery charge display is yellow:

The power supply must be connected for measurement.

5.1.2 Configuring the ARCUSdigma

When the basic unit is first turned on, the national language for the basic unit and the used articulator must be selected.

Open the configuration menu



Simultaneously press the "OK" button and "Up"/menu". The configuration menu opens.

Set the country language

- ► Touch the "Language" button.
- ► Touch the button for the desired language.
- Press the "Save" button to accept the settings.



Press the "OK" button to return to the last screen.

Select the articulator

► Touch the "Select articulator" button.

An overview screen appears with all the articulators that can be calculated.

5 Operation | 5.1 General use

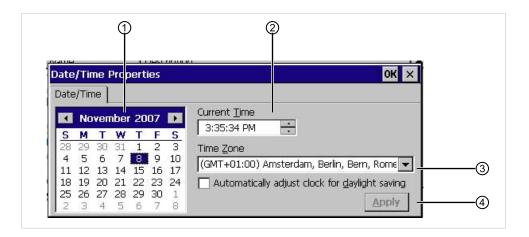


- Select the desired articulator.
 The selected articulator is provided for all additional measurements.
- Press the "Save" button to accept the settings.



▶ Press the "OK" button to return to the last screen.

Set the time and date



- Set the date with the calendar ①.
- Set the time using the "Current Time" field ②.
- ► Set the time zone using the "Time Zone" field ③.
- ► Confirm the entry with the "Apply" button ④.

Restore defaults

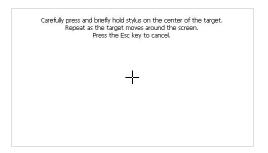
- ► Touch the "Defaults" button.
- ► Touch the "Yes" button to reset all configurations to their defaults.

Calibrate the touchscreen

The touchscreen needs to be recalibrated after the power to the basic unit completely fails.

5 Operation | 5.1 General use

► Confirm the centre of the circle with a pin.



5.1.3 Functions of the keys on the membrane keypad of the basic unit

Key	Designation	Operation
	On	Press for 1 second to turn on the basic unit.
	Off	Press for 5 seconds to turn off the basic unit.
ОК	ОК	Press once to confirm or end measurements. Return to program interface.
	Forward	Press once to go to the next step or start continuous measurement.
	Measurement	Hold down to record the jaw position.
	Right	Press as many times as you want or hold down to navigate to the right. The function is described on the screen.
	Back	Press once to go back to the next step or repeat the step.
	Left	Press as many times as you want or hold down to navigate to the left. The function is described on the screen.
OK + ♣	Configuration menu	Pressed simultaneously to open the configuration menu.
***	Up	Press as many times as you want or hold down to navigate up. The program indicates that the button has a navigation function.
ОК + <u>ш</u>	Delete	Press simultaneously to delete the selection.
	Down	Press as many times as you want or hold down to navigate down. The program indicates that the button has a navigation function.

5.1.4 Functions of the buttons of the KiD/ARCUSdigma computer software

Button	Name/function
	Delete
	End
8	Menu
(C)	Program
	Practise
	Save
Sha.	Select the patient
4	Create new patient
	Process patient data
	Delete patient data
Sha.	Log off
	Open replay function
	Back to patient selection
	Select data

5 Operation | 5.1 General use

Button	Name/function
	Reset everything to default
	Print preview of report
	Measurement of articulator settings
	Guided centric determination
	Adduction field (centric determination)
	Gothic arch (centric determination)
EAEF	EAEF
	EPA electronic position analysis
	Movement analysis
	Mandibular positioning according to movement analysis
	EMG
	Play recording
	Stop the recording
	Zoom in
	Zoom out

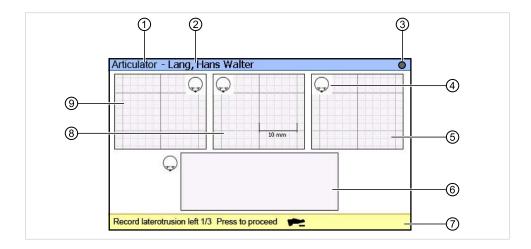
5 Operation | 5.1 General use

Button	Name/function
	Rerun the measurement in replay mode
Internal	Measurement: Measure length and angle
	Insert comment
5	Data import
	Data export

5.1.5 Colour-coding of lines/"+" signs/circles on the screen

Colour coding	Meaning
Green lines	Right temporomandibular joint
Red lines	Left temporomandibular joint
Black lines	Selected reference axis in the temporomandibular joint
Red "+" sign	Current mandible position
Black "+" sign	Accepted average mandible position
Green "+" sign	Accepted point for centric determination

5.1.6 Layout of the ARCUSdigma screen



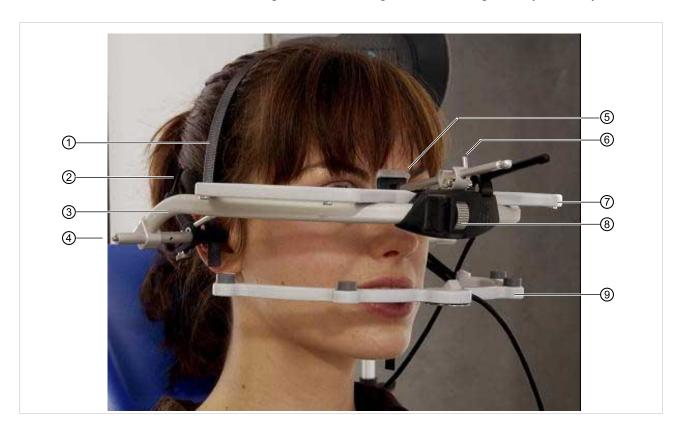
- ① Active measuring program
- 2 Patient name
- ③ Device diagnosis green: Device OK, red: Device is defective
- ④ Button for switching to other views
- (5) Top view of left joint

- Top view of both temporomandibular joints
- ⑦ Command line
- 8 Front view of incisal point
- Top view of right joint

The ARCUSdigma has a touchscreen. Functions can be actuated by touching the buttons on the screen.

5.2 Creating the ARCUSdigma sensor system

5.2.1 Creating the ARCUSdigma measuring arch (receiver)



- ① Headband
- ② Rubber band
- 3 ARCUSevo face bow
- 4 Moveable axis
- ⑤ Nose support

- 6 Lock lever for the nose support
- ARCUSdigma receiver
- Adjustment wheel for adjusting the facial width
- ARCUSdigma transmitter

The ultrasonic receiver is fastened to the patient's head using the ARCUSdigma measuring bow. If the arbitrary axis is used for transferring the mandibular model, the measuring bow simultaneously serves as a facial bow.

- Move the patient to an upright sitting position.
- ► Move the nose support ⑤ so that the moveable axes ④ lie approximately above the outer ear canals.
- ► With the adjustment wheel ⑧, move the two sides of the facial bow ③ toward the patient's head.
- Lock the rear rubber band ②.
- ▶ If necessary, fix the facial bow ③ using the head band ①.
- ► Position the nose support ⑤ and fix with the the lock lever ⑥.
- ► Ensure that the measuring bow is comfortable and well-seated over the entire measurement.

5.2.2 Create an ARCUSdigma distributor box

 Fasten the ARCUSdigma distributor box to the patient's head using teh provided neck band.

5.2.3 Fasten the ARCUSdigma transmitter to the mandibular arch

The ARCUSdigma transmitter is affixed to the mandibular arch using the mandibular attachment.

The mandibular attachment is rigidly affixed in a paraocclusal manner to the labial surfaces of the mandibular anterior teeth.

The mandibular attachment can be a fixed in the following ways:

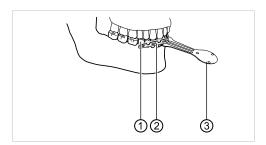
- By being adhered to the labial surfaces of the bottom anterior teeth
- by a individually fabricated plastic mounting tool made by a lab technician

Adhere the ARCUSdigma transmitter directly to the bottom anterior teeth

The ARCUSdigma transmitter can be adhered directly to the labial surfaces of the bottom anterior teeth if only one measurement is required, and the bite situation permits this.

The following adhesives can be used:

- Structure 2 SC (VOCO)
- Protemp (3M/Espe)
 or acrylate adhesive such as Histacryl (Braun) can be used
- Pattern Resin (GC)
- Futar D (Kettenbach) or acrylate adhesive such as Histacryl (Braun) can be used



- Anterior mandibular teeth
- ② Mandibular attachment
- ③ ARCUSdigma transmitter
- Adapt the mandibular attachment ② by shaping to the anterior contour of the anterior teeth.
- ► Adhere the mandibular attachment ② to the labial surfaces of the anterior mandible ①.

Fasten the ARCUSdigma transmitter using a mounting tool

The following conditions require the use of a mounting tool:

- The measurement should be repeated several times on the same patient.
- The patient has a large overbite.
- The patient has a closed bite or overbite.

The following items are helpful for producing a mounting tool:

- Triad (Firma Dentsply)
- Various prosthetic plastics such as plastics for the creation of individual trays

The mounting tool is directly affixed to the ARCUSdigma transmitter.

Create the mounting tool

- ▶ Move the situation models (mandible and maxilla) into static occlusion.
- Sufficiently insulate the plastic model so that the plastic can be easily removed after it hardens without damaging the model.
- ► Determine the path and dimension of the plastic paraocclusal attachment and indicate with a pin.
- Create the mounting tool.
- If the attachment to natural vestibular tooth surface is insufficient, extend the plastic part into the premolar/molar area of the vestibular tooth surface.
- ▶ Block out overlapping zones in the area of the vestibular tooth surfaces.

Fasten the mounting tool in the patient's mouth

- Check if the mounting tool is correctly and properly seated in the patient's mouth, and remove any problematic areas.
- Dry natural vestibular tooth surfaces with cotton rolls.
- Place dots of acrylate adhesive such as Histacryl on the plastic surfaces of the mounting tool that correspond to the tooth surfaces.
 Use a small amount of acrylic adhesive and make sure that the acrylate adhesive does not contact the gingiva or oral mucosa.
- ► Fasten the mandibular attachment with the mounting tool to vestibular tooth surfaces.
- Ask the patient to assume the necessary mandibular starting position, and press the plastic part onto the vestibular tooth surfaces for a few minutes.

5.2.4 Remove the ARCUSdigma transmitter from the mandibular arch

- Ask the patient to assume static occlusion during the removal process.
- ► Remove the mandibular attachment with small, vertical loosening movements on the attachment.
- ► Remove residual acrylate adhesive on the surface of the teeth using a curette or scaler.

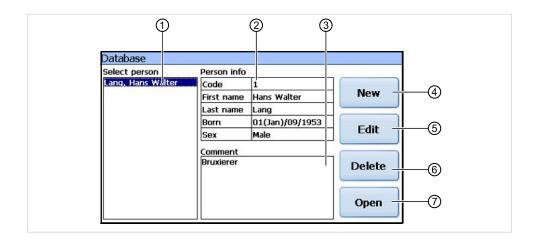
5.3 Prepare for patient measurement with the ARCUSdigma SD

The ARCUSdigma SD variation does not have an online connection with the computer. All measured values are saved on the chip card.

After the device is turned on, the user is asked to insert a suitable chip card into the device (SD 512 MB).

5.3.1 Retrieve the patient master data

- Turn on the ARCUSdigma SD.
- Insert the chip card.
 The database for patient administration is opened.



- ① "Select person" selection list
- 2 Patient master data
- ③ Comments on the patient
- 4 "NEW" key

- ⑤ "Edit" key
- @ "Delete" key
- ⑦ "Open" key

The "Select Person" ① selection list contains saved patient master data.

- ▶ Press the "NEW" button to add a new patient in the database.
- Touch the "Edit" button to change the patient entries.
- Press teh "Delete" button to delete all patient data.

5.3.2 Start measuring

- Press the "Open" button to start patient measurement.
- ► Perform the measurement.

See also: 5.7 Select the measuring program, Page 63

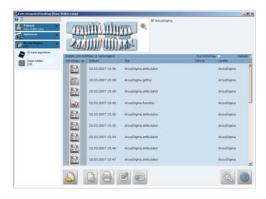
5 Operation | 5.3 Prepare for patient measurement with the ARCUSdigma SD

5.3.3 Save the measured data in the KiD/ARUCSdigma computer software

The values saved on the memory cards can be imported into the database using the accompanying SD card reader.



Click the "Import SD card" button to transfer the data from the SD card to the computer.



The data are available for further processing with the KiD/ARCUSdigma software.

5.4 Prepare for patient measurement with the ARCUSdigma USB

5.4.1 Establish a USB connection

- ► Use the USB cable to connect the basic unit with a computer. See also: 4.2.3 Connection options for the ARCUSdigma USB, Page 38
- ► Turn on the ARCUSdigma basic unit.

 See also: 5.1.1 Turn the ARCUSdigma basic device on and off, Page 41
- Start the KiD software on the computer.

5.4.2 Administer patient master data

The KiD software is a central database. Office programs that have a VDDS interface can directly correspond with the ARCUSdigma. The patient's master data can therefore be transferred from the practice software. If the practice software does not have a suitable interface (such as a VDDS), the patient's master data cannot be automatically transferred. In this case, the data is entered through its own window.





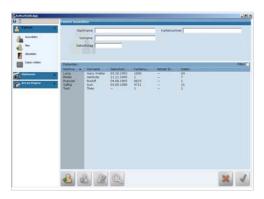




Click the "Select" button to open available patient master data.



Click the "New" button to enter new patient master data. The window for entering the patient's master data opens. 5 Operation | 5.4 Prepare for patient measurement with the ARCUSdigma USB



5.4.3 Start measuring

Requirement

The ARCUSdigma basic unit is turned on, and there is a USB connection.



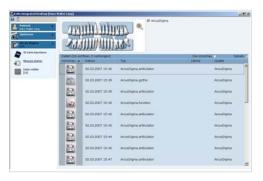
- Click the "Select" button to open available patient master data.
- Double-click on the patient to open the data.



► Click the "Arcus Digma" button to open the Arcus Digma menu.



Click the "Start measuring" button.





Note

The "Start measuring" button only appears when the basic unit is connected to the computer.

▶ Perform the measurement.

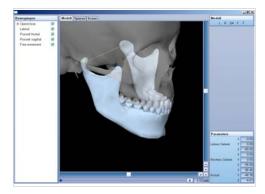
5.4.4 Adjust the screen view on the computer

The following views can be selected using the four tabs on the top edge of the screen:

- Model (3D)
- Movement tracks

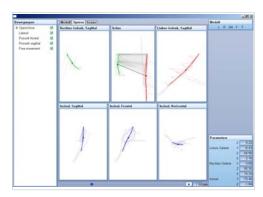
5 Operation | 5.4 Prepare for patient measurement with the ARCUSdigma USB

Scene

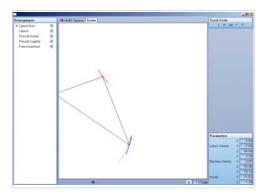


Model view

The view of the skull can be aligned with the bottom and left scrollbars.



Movement path view



Scene view

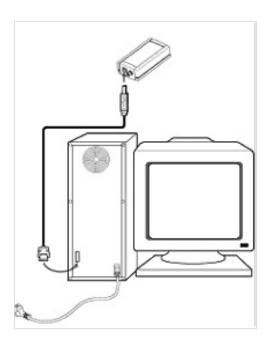
5.5 Prepare for patient measurement with the ARCUSdigma Wireless

The radio link designed for the ARCUSdigma works reliably within a room. Structural factors in the building can strongly restrict the transmission paths.

5.5.1 Activate the ARCUSdigma radio link

► Insert the USB cable into the USB port of the computer and the KaVo wlink. The device drivers automatically install themselves after the device is connected when the computer is started.

When the device is connected, the device drivers automatically install before the computer is started when the operating system boots.





Note

No additional device drivers are required to install KaVo wlink. These are provided by the operating system.

KaVo wlink is configured and operated with the Tool wlink Control. **See also:** Instructions for use for KaVo wlink (**Mat. no. 1.003.8891**)

5.5.2 Turn the radio link on or off

The radio link must be configured once when setting up the system.



Start the synchronization with KaVo wlink by pressing the Login button of the basic unit.

The activation of synchronization is shown on the display. Synchronization remains active for 30 seconds. If no radio partner is identified after 30 seconds, then the ARCUSdigma is started without having set up the radio link.

5 Operation | 5.5 Prepare for patient measurement with the ARCUSdigma Wireless

By using the tool "wlink Controls", you can also start synchronization on the computer. You can also select the channel. It prevents malfunctions when simultaneously using several devices.

The software "wlink Control" displays the successful synchronization of the AR-CUSdigma and KaVo wlink. The display is on the screen of the ARCUSdigma.



Note

Each ARCUSdigma and KaVo wlink have their own unique addresses that are exchanged during synchronization. This ensures unambiguous assignment.

5.6 Working with the KiD/ARCUSdigma software

The KiD/ARCUSdigma software takes over the administration and display of the measurements. A few functions will be described in greater detail below. **See also:** KiD instructions for use

5.6.1 Import and export measurement data



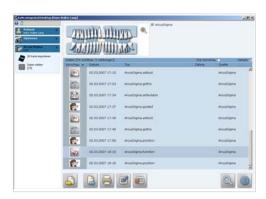
Measurement data from other ARCUSdigma users or measurement data from the ARCUSdigma I can be imported by pressing the "Data import" button. The measurement data must be saved in a file.



If all the measurement data is to be exported to another ARCUSdigma user, it can be exported by selecting the measurement and pressing the "Data export" button. The data are saved in a file that can be exported by e-mail.

5.6.2 Run recording and replay mode

All patient measurements can be dynamically replayed as frequently as desired.



Select measurement



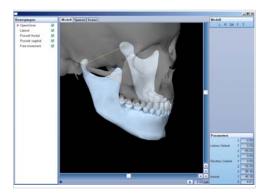
Press the "Replay mode" button to start the replay mode

Three different views are available in replay mode that can be activated by the tab on the top edge of the screen.

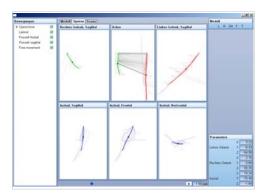
In the "Model" view, the mandibular movement is clearly and understandably depicted.

The views "Paths" and "Scene" are informative for the analysis of a movement recording.

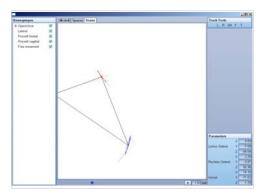
5 Operation | 5.6 Working with the KiD/ARCUSdigma software



Model view



Movement path view

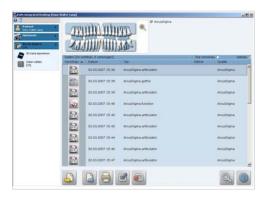


Scene view

5.6.3 Document recordings

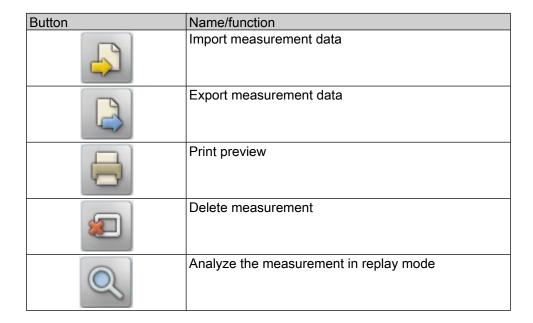
At the end, a document is available that was saved in the KiD database.

5 Operation | 5.6 Working with the KiD/ARCUSdigma software



Open a document from the KiD database

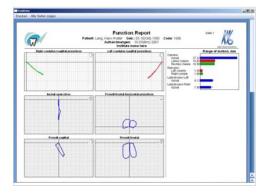
The following functions are available for documentation:



Print the analysis



Press the "Print" button to show a print preview.



5 Operation | 5.6 Working with the KiD/ARCUSdigma software

The print preview can be printed on a standard printer.

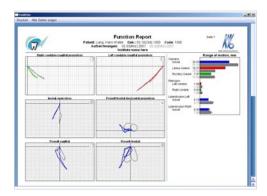
Overlap records

If a treatment is to be documented, up to three measurements can be overlapped.

► In the KiD database, select the corresponding measurements using the "Ctrl" and the left mouse button.



► Click the "Print" button.

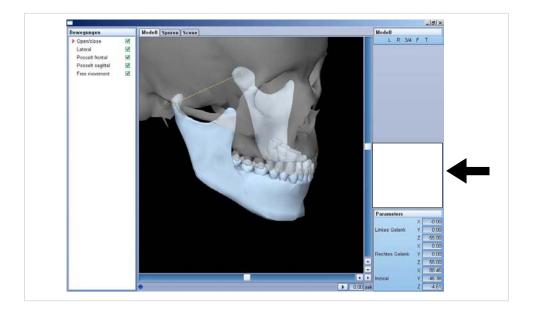


The second measurement is grey.

Inserting comments

Comments can be entered during or after an analysis using the computer keyboard.

- ► Click the "Note" window (the "Note" window is on the bottom right of the screen).
- Enter notes.



5 Operation | 5.7 Select the measuring program

5.7 Select the measuring program

The desired measuring program can be selected using the touchscreen of the basic unit. The grey buttons represent the measuring programs.

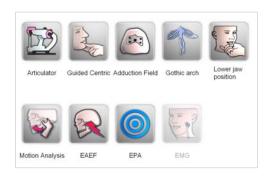
Depending on the product type, optional measuring programs are available.

See also: 3.1 Product variations, Page 17



5.8 Perform articulator calculations for the KaVo PROTAR articulator

Open the "Measuring programs" window.





▶ Press the button for the "Articulator" measuring program.

Articulators from other manufacturers can be selected in the configuration menu.

See also:

5.1.2 Select the articulator, Page 41

5.9 Run the articulator calculations for a third-party articulator, Page 88

5.8.1 Select the reference axis system

The dentist can select different axis systems that each have different advantages.

Selectable reference axis systems:

- KaVo Transfer System (KTS)
- Arbitrary axis
- Individual centric axis

If the bite is raised only slightly or not at all in a prosthesis (less than 2 mm), KaVo recommends using the KaVo Transfer System.

If the patient's bite is to be raised more than 2 mm, the arbitrary or individual centric access can be used.

If the patient is unable to generate any rotation while opening their mandible (nearly all patients), the individual centric axis cannot be used. Use the arbitrary access in this case.



Note

The ARCUSdigma suggests the most suitable axis system for all measuring programs. This system is surrounded with a red frame. Axis systems that are unsuitable cannot be activated in certain measuring programs.

The last selected axis is saved.

5.8.2 KaVo Transfer System (KTS)



Note

The KaVo Transfer System (KTS) it is only suitable for the KaVo PROTAR articulator.

See also: Instructions for use KaVo PROTAR Artikulator



The KaVo Transfer System offers numerous advantages as an axial system:

- A special transfer status allows models to be quickly transferred to the KaVo PROTAR articulator. This largely prevents transmission errors.
- The articulator axis of the PROTAR is used as the axis system. For the articulator calculation, the bite fork stands in a known relationship with the articulator joints whose settings are calculated. The axis therefore does not need to be determined.



Press the foot switch or the "KaVo Transfer System" to activate the selected axis system.

Recording the articulator settings

The articulator settings are recorded in seven steps:

Step 1: Create the maxillary bike fork

► Place hard silicone or wax on the maxillary bite fork. Make sure that the numbers 1 and 2 are visible on the top of the bite fork.



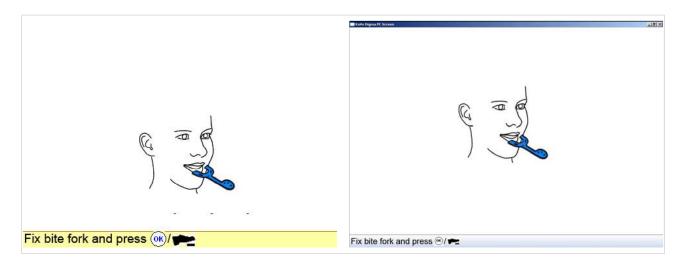


Note

For holding impressions of the maxillary arch, the preferred materials have been hard silicones such as Registrado x-Tra (by VOCO) or waxes.

Position the maxillary bite fork in the patient's mouth. Make sure that the numbers 1 and 2 are visible on the top of the bite fork.

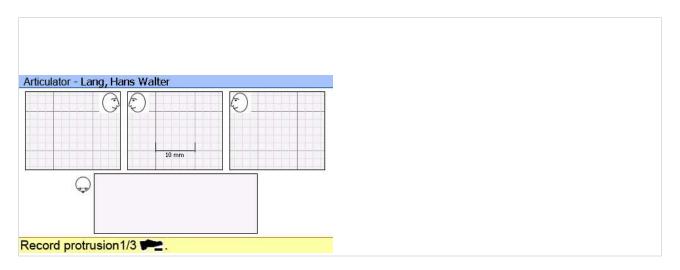
Step 2: Record the maxillary position



Snap the ARCUSdigma transmitter on to the maxillary bite fork (magnetic).



Press the footswitch.The measuring screen is displayed.



Remove the maxillary bite fork with the ARCUSdigma transmitter from the patient's mouth.

Step 3: Fasten the ARCUSdigma transmitter to the mandibular arch

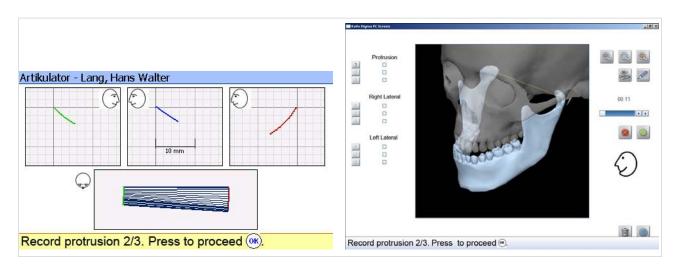
► Fasten the mandibular attachment to the mandibular arch, and snap the AR-CUSdigma transmitter onto the mandibular attachment (magnetic).

See also: 5.2.3 Fasten the ARCUSdigma transmitter to the mandibular arch, Page 50

Step 4: Detecting the protrusion

Three protrusions should be recorded to provide a precise analysis of the joint path.

- Ask the patient to assume intercuspation.
- Press the foot switch, and ask the patient to protrude their teeth to the maximum amount while maintaining maintaining tooth contact.
- ▶ Release the foot switch once maximum protrusion is achieved.
- Ask the patient to return to maximum intercuspation.
- Perform measurements 2 and 3 in the same manner.





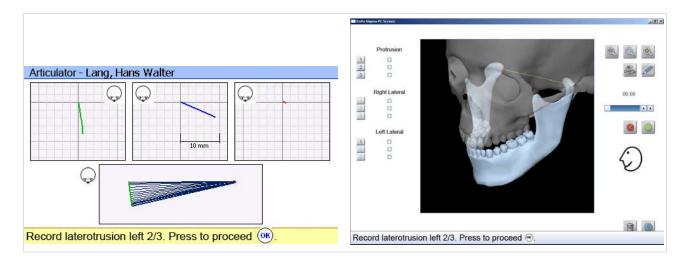
Note

If you prese the "OK" button after the first or second measurement, only these measurements will be selected.

Step 5: Record left laterotrusion

The measuring routine is the same as when recording protrusion. Record three left laterotrusions.

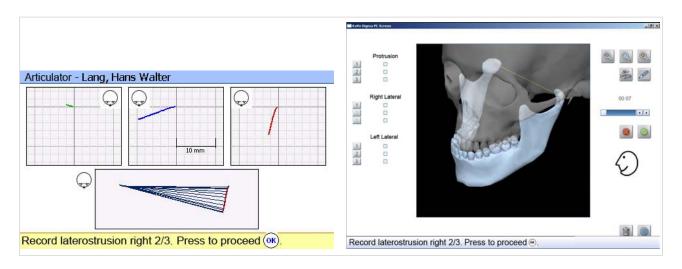
See also: 5.8.2 Step 4: Detecting the protrusion, Page 67



Step 6: Record right laterotrusion

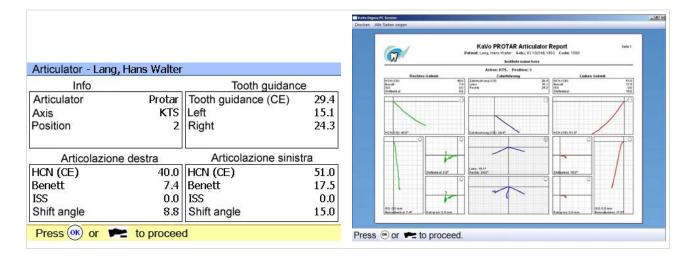
The measuring routine is the same as when recording protrusion. Record three right laterotrusions.

See also: 5.8.2 Step 4: Detecting the protrusion, Page 67



Step 7: Adjust the articulator

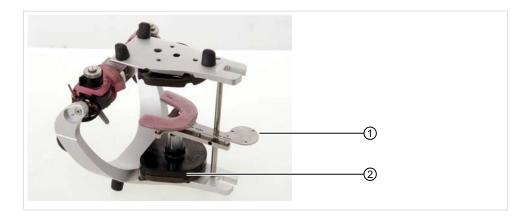
After all three measurements are performed that are requested in the command line, the device automatically generates all of teh articulator settings.



Transfer the articulator settings to the articulator.

Place the maxillary model in the articulator

Remove the incisal pin and incisal table.

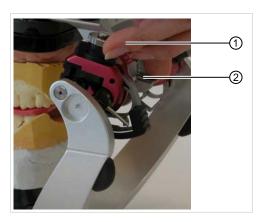


- Insert the ARCUSdigma bite fork holder ②.
- ▶ Place the ARCUSdigma bite fork ①in position 2 or 1 corresponding to the articulator report.
- Place the maxillary model in the impressions of the bite fork.
- ▶ Place the maxilla in the articulator.
- ► Insert the incisal pin and incisal table.

Transfer the articulator settings to the articulator

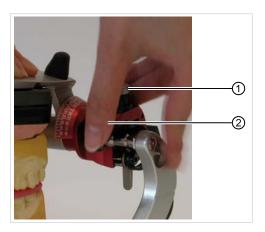
After the maxilla is mounted in the articulator, the articulator settings from the articulator report can be transferred to the articulator.

Adjust the joint path angle (HCN)



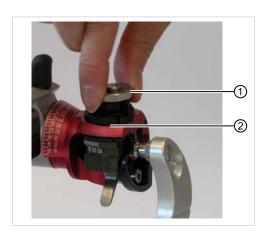
- Undo the backwards lock ② for the articulator boxes.
- ► Adjust the articulator boxes ① according to the articulator report.
- Lock the backwards lock ② for the articulator boxes.

Adjust the Benett angle



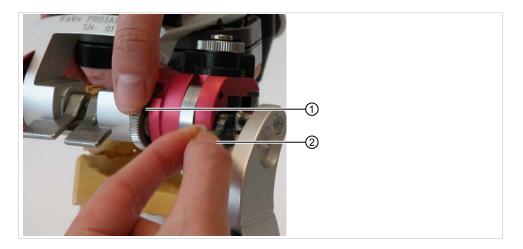
- ► Remove the knurled screw ①.
- ► Adjust the Bennett angle ②.
- ► Tighten the knurled screw ①.

Adjust the lateral mobility ISS



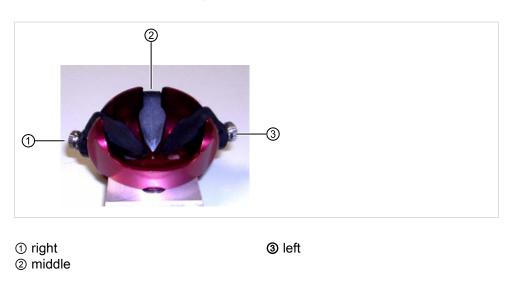
- ► Remove the knurled screw ①.
- ► Adjust the lateral mobility (ISS) ②.
- ► Tighten the knurled screw ①.

Set the shift angle



- ► Remove the knurled screw ②.
- ► Adjust the shift angle ①.
- ► Tighten the knurled screw ②.

Adjust the anterior canine guidance

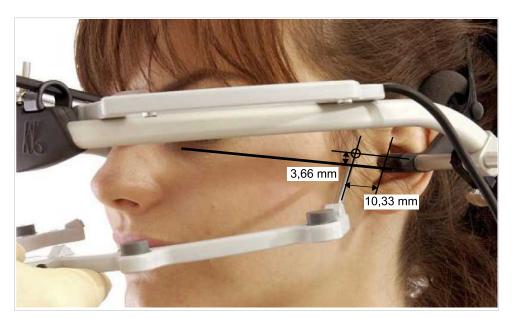


Adjust the anterior canine guidance plate corresponding to the articulator report.

5.8.3 Arbitrary axis

The arbitrary axis points can be found by palpation or from the information in the literature.

According to Reiber/Dickbertel, the arbitrary axis points are 10.33 mm before the Tragus medialis and 3.66 mm above the connecting line between the Tragus medialis and infraorbital point.



Determining the axis according to Reiber/Dickbertel



▶ Press the "Arbitrary axis" button to select the axis system.

Recording the articulator settings

The articulator settings are recorded in 9 steps:

Step 1: Create the maxillary bike fork

Place hard silicone or wax on the maxillary bite fork.





Note

For holding impressions of the maxillary arch, the preferred materials have been hard silicones such as Registrado x-Tra (by VOCO) or waxes.

Step 2: Fasten the maxillary bite fork in the patient's mouth

The position of the maxilla is required for mounting in the articulator.



- Push the bite fork joint on the hexagon ③ of the bite fork.
- Use the knurled screw ① to tighten the bite fork joint at the black centre of the facial bow.
- ▶ Use the black knurled screw ② to fix the bite fork joint with the bite fork.
- ▶ Position the bite fork so that all maxillary teeth leave impressions on the bite fork.
- ► Loosen the knurled screw ① and remove the bite fork support with the fixed bite fork from the patient's mouth.

Step 3: Perform the calibration

This measuring step is for calibration. The mandible position does not matter; however, the jaw must be closed (tooth contact). The mandible may not move during calibration.



Step 4: Enter the left arbitrary axis point

- ► Insert the axis pointer ① into position 1 of the ARCUSdigma transmitter.
- ► Guide the ARCUSdigma transmitter manually for the following measurements.
- ► Hold the axis pointer tip ① on the left arbitrary axis point on the patient's skin, and press the footswitch.
- Mark the selected arbitrary axis point with a pin on the skin.



Note

The dot is removed later with the axis pointer and is required for transferring the model to the articulator.



Step 5: Enter the right arbitrary axis point

- ▶ Push the axis pointer all the way into position 2 on the ARCUSdigma transmitter.
- Guide the ARCUSdigma transmitter manually for the following measurements.
- ► Hold the axis pointer tip on the right arbitrary point and press the footswitch.

Mark the selected arbitrary axis point with a pin on the skin.



Note

The dot is removed later with the axis pointer and is required for transferring the model to the articulator.



Step 6: Enter the infraorbital point

The lowest point of the bony eye socket serves as a reference for the infraorbital point (palpate).

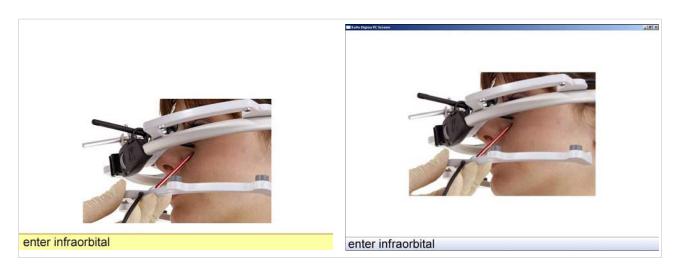
- ▶ Push the axis pointer all the way into position 3 on the ARCUSdigma transmitter.
- Palpate the lowest point of the bony eye socket.
- Align the axis pointer tip with the selected reference point.
- Press the footswitch to save the infraorbital point.

The three reference points describe the reference plane against which all the angles are calculated.

The axis pins of the facial bow must be aligned with the two reference points on the skin.

See also:

5.8.3 Step 7: Align the right axis pin, Page 77 5.8.3 Step 8: Align the left axis pin, Page 77



Step 7: Align the right axis pin



Step 8: Align the left axis pin

▶ Use the same procedure as in section 6.

Step 9: Record protrusions and laterotrusions

The protrusion and laterotrusion are recorded for the arbitrary axis in the same manner as in the KaVo Transfer System.

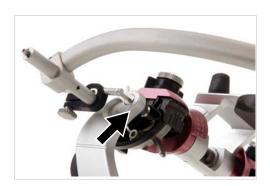
► Perform steps 3 to 6 as described in section on the KTS. **See also:** 5.8.2 Step 3: Fasten the ARCUSdigma transmitter to the mandibular arch, Page 67

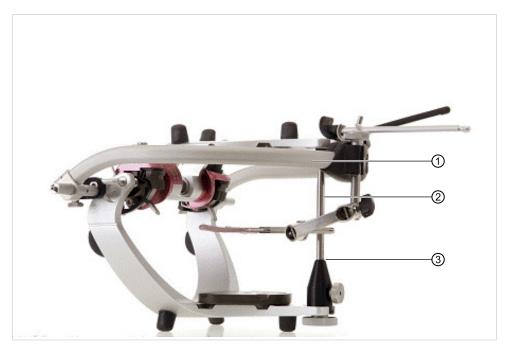
Place the maxillary model in the articulator

When the arbitrary axis is used, the axial pins were aligned with the arbitrary axis points. The facial bow is fastened in the articulator using these axial pins.

Loosen the fastening nut of the facial bow and remove the head supports.

► Fix the axial pins in the recess of the articulator axis.





- ▶ Place the facial bow ① on the articulator support pin ②.
- ► Set the articulator support pin ② to zero ③.

Transfer the articulator settings to the articulator

► Use the same procedure as in the KTS section.

See also: 5.8.2 Transfer the articulator settings to the articulator, Page 70

5.8.4 Individual centric axis

The individual centric axis represents the rotational centre in the temporomandibular joint. It should be noted that the patient generally cannot execute a true rotational movement without manipulation. This movement is actually more of an overlap of rotation and forwards gliding.

Since however it is frequently desired to place the module in the articulator with reference to the individual centric axis, especially with comprehensive prosthetic restorations that have an altered vertical dimension, a measuring program is available for this.



► Press the "Individual centric" button to select the axis system.

The articulator settings are recorded in 9 steps:

Step 1: Create the maxillary bike fork

Place hard silicone or wax on the maxillary bite fork.





Note

For holding impressions of the maxillary arch, the preferred materials have been hard silicones such as Registrado x-Tra (by VOCO) or waxes.

Step 2: Fasten the maxillary bite fork in the patient's mouth

The position of the maxilla is required for mounting in the articulator.



► Push the bite fork joint on the hexagon ③ of the bite fork.

- Use the knurled screw ① to tighten the bite fork joint at the black centre of the facial bow.
- ▶ Use the black knurled screw ② to fix the bite fork joint with the bite fork.
- Position the bite fork so that all maxillary teeth leave impressions on the bite fork.
- ► Loosen the knurled screw ① and remove the bite fork support with the fixed bite fork from the patient's mouth.

Step 3: Perform the calibration

This measuring step is for calibration. The mandible position does not matter; however, the jaw must be closed (tooth contact). The mandible may not move during calibration.



Step 4: Enter the infraorbital point

The lowest point of the bony eye socket serves as a reference for the infraorbital point (palpate).

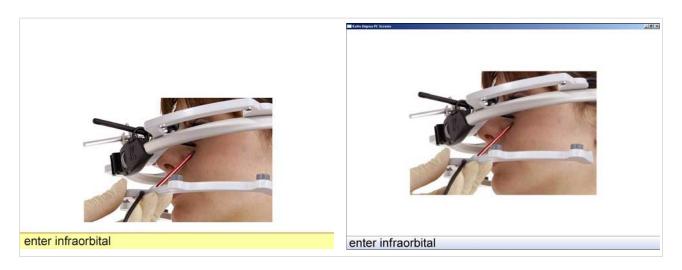
- ▶ Push the axis pointer all the way into position 3 on the ARCUSdigma transmitter.
- Palpate the lowest point of the bony eye socket.
- ► Align the axis pointer tip with the selected reference point.
- Press the footswitch to save the infraorbital point.

The three reference points describe the reference plane against which all the angles are calculated.

The axis pins of the facial bow must be aligned with the two reference points on the skin.

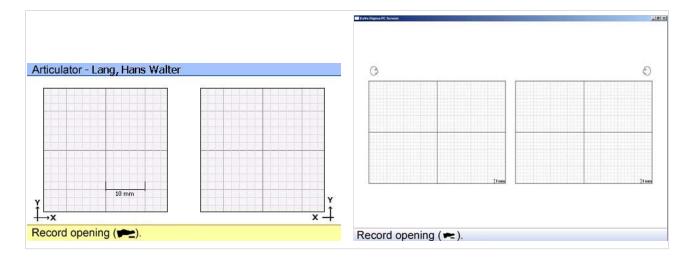
See also:

5.8.3 Step 7: Align the right axis pin, Page 77 5.8.3 Step 8: Align the left axis pin, Page 77



Step 5: Locate the axis

After the infraorbital point has been saved, two measuring windows are displayed on the screen of the ARCUSdigma for locating the axis.

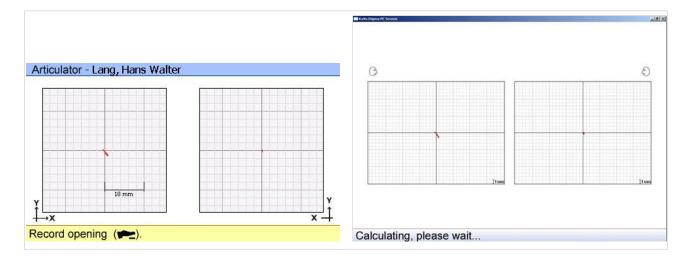


The patient must open their mandible in a guided manner corresponding to the request in the command line.

The technique shown below with a small mouth opening (maximum of 5 mm) is required for this type of axis location.



Press the footswitch and slightly force the mandibular opening.



If a therapeutically relevant individual centric axis was determined, the following image is portrayed on the screen for both temporomandibular joints.

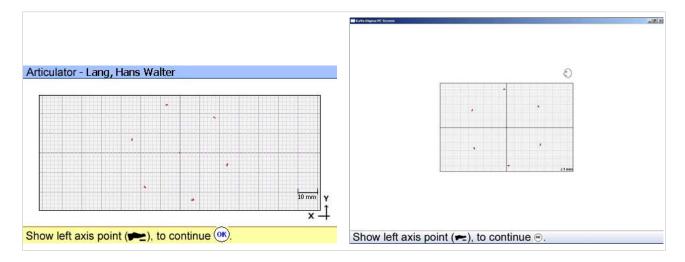
If a rotational centre was could not be found due to insufficient rotation, the unit displays the following information:

"The axis point cannot be used for movement analysis and articulator programming; please use the arbitrary axis points."



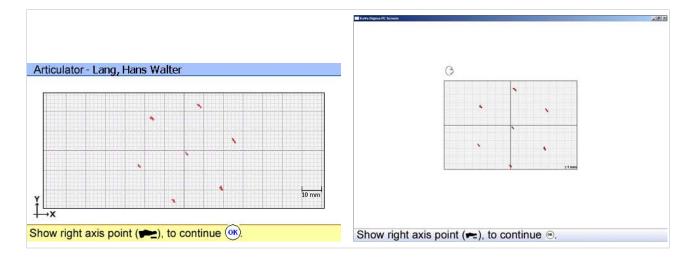


- ▶ Remove the ARCUSdigma transmitter from the mandibular attachment.
- ▶ Push the left axial pin all the way into position 1 on the ARCUSdigma transmitter.
- ► Press the foot switch, and guide the ARCUSdigma transmitter manually for the following measurements.
- Guide the pointer tip over the skin to create a black + on the screen in the centre of the measuring grid. A signal can be heard whose frequency and pitch rises as the tip of the axial pin approaches the analyzed access point. Now the axis pointer tip is precisely over the located rotational centre.
- Mark this point on the skin.



The point of the individual centric axis transferred to the surface of the skin serve to precisely align the axis pointer of the facial bow.

▶ Do the same measuring routine with the right axis point.



Step 7: Align the right axis pin



Step 8: Align the left axis pin

Use the same procedure as in section 6.

Step 9: Record protrusion and laterotrusion

The protrusion and laterotrusion are recorded for the arbitrary axis in the same manner as in the KaVo Transfer System.

► Perform steps 3 to 6 as described in section on the KTS. **See also:** 5.8.2 Step 3: Fasten the ARCUSdigma transmitter to the mandibular arch, Page 67

Place the maxillary model in the articulator

See also: 5.8.3 Place the maxillary model in the articulator, Page 77

▶ Use the same procedure as in the "Arbitrary axis" section.

Transfer the articulator settings to the articulator

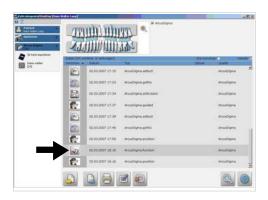
► Use the same procedure as in the KTS section.

See also: 5.8.2 Transfer the articulator settings to the articulator, Page 70

5.8.5 Document articulator settings

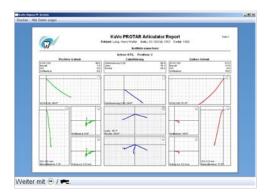
The articulator report serves to document the analyzed articulator settings. In addition, all measured values are portrayed and saved in the articulator report.

► Select the desire articulated measurement with the left mouse button.

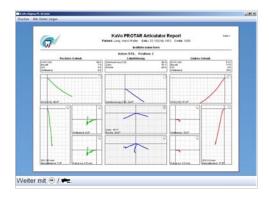




► Click the "Print" key to retrieve the articulator report.



Configure the articulate a report



The articulator report is clearly laid out.

The user can configure it in several instances ((such as inserting the practice logo and data).

Run the configuration once for the first report.

Insert practice logo:

The practice logo can be inserted in the header of the report.

- Open (or create) a new logo in a drawing program such as Paint (CTRL + C).
- Click the ARCUSdigma logo and insert a new logo (CTRL + V).

Insert the dentist and practice data:

- Click on the empty field, "Dentist, practice".
- ► Insert practice data.

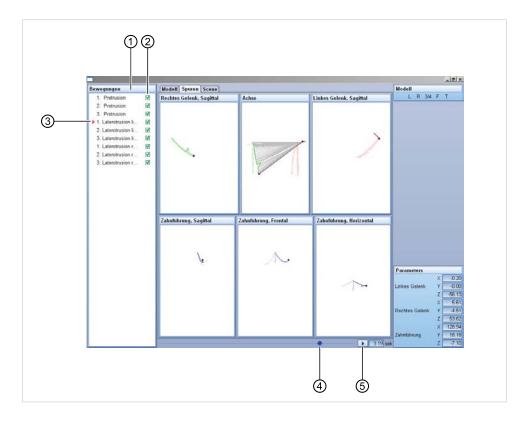


Note

The patient data are automatically transferred from the database.

Overlap records

In the "Paths" display mode, records can be overlapped after measurement.



All the available measurements are listed in the "Movement" window ①. Here you can select which measurements are to be overlapped and which measurement is to be placed in the foreground.

- Check the checkboxes ② when this measurement is to be overlapped.
- Click the number before the measurement ③ to place the measurement in the foreground.
 - A red arrow is appears before the measurement that is in the foreground.
- ► Move the slider ④ to the left or right to interactively play the recording in the foreground (here the 1st left laterotrusion).

Press the "Replay" button to play the record in the foreground without interruption.

Inserting comments

Records can be provided with comments and any time.

5 Operation | 5.9 Run the articulator calculations for a third-party articulator

5.9 Run the articulator calculations for a third-party articulator

Settings from the following articulators by different manufacturers can also be calculated using the ARCUSdigma USB/wireless:

- SAM
- Artex AR (Girrbach/Amann)
- Referenz SL (Girrbach/Amann)
- Stratos 300 (Ivoclar)
- Panadent
- Denar Mark II (in preparation)

5.9.1 Select the third-party articulator

Select the articulator in the configuration menu.

See also: 5.1.2 Select the articulator, Page 41

5.9.2 Working with third-party articulators

The method used for recording mandibular movements is the same for all articulators and occurs in the same manner as for the KaVo PROTAR.

See also: 5.8 Perform articulator calculations for the KaVo PROTAR articulator, Page 64



Note

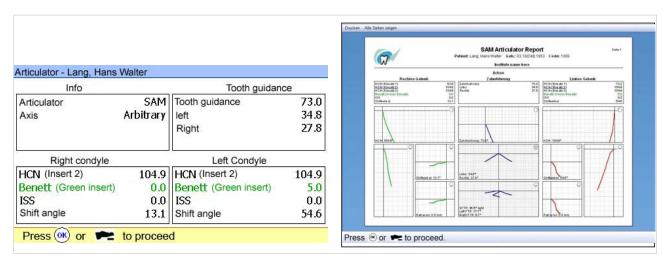
Due to the limited transmission possibilities, only the arbitrary axis can be used with third-party articulator's.

- Record mandibular movements using the arbitrary axis.
- Place the maxilla model in the articulator as usual using the available facial bow. Observe the instructions for use for the articulator and facial blow.

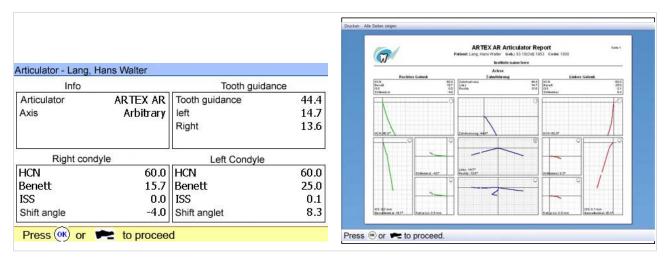
The ARCUSdigma identifies the position of the facial bow or the type of scaling of the articulator boxes of the articulator.

After measuring the mandibular movements, a special articulator report is prepared for this articulator.

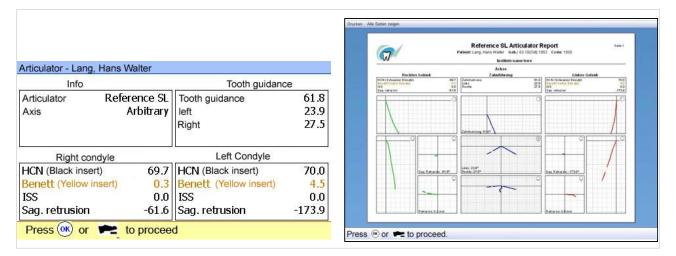
5 Operation | 5.9 Run the articulator calculations for a third-party articulator



Example: Articulator report for SAM

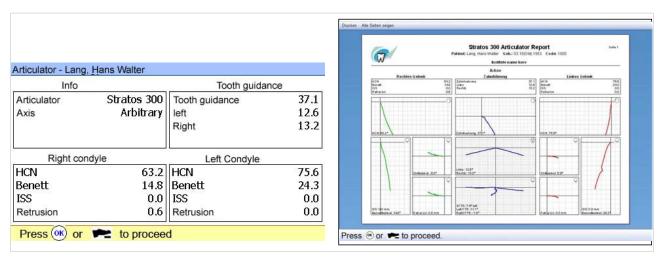


Example: Articulator report for Artex AR (Grirrbach/Amann)

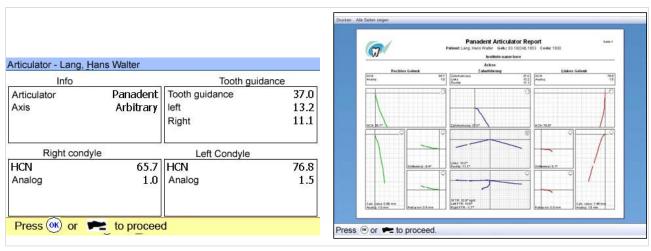


Example: Articulator report for Referenz SL (Grirrbach/Amann)

5 Operation | 5.9 Run the articulator calculations for a third-party articulator



Example: Articulator report for Stratos 300 (Ivoclar)



Example: Articulator report for Pandent

5.10 Determining centrics



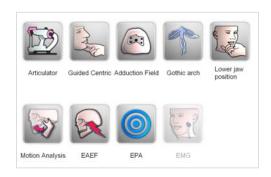
Note

For the ARCUSdigma, you can integrate the 2 channel EMG by KaVo (optional accessories). If the EMG is integrated, this signal is available as additional information in centric determination.

See also: 5.15 EMG - relaxation measurement using electromyography , Page 129

5.10.1 Manually-guided centric

Open the "Measuring programs" window.





Press the button for the "Guided centric" measuring program.

In addition to determining the articulator settings (dynamic occlusion), the centric position (static occlusion) of the mandible is required to mount the mandible model. The ARCUSdigma (SD/USB/Wireless) helps the dentist transfer the desired centric mandibular position to a registration.

Select the axis system

The following axis systems can be selected.

- KTS System
- Arbitrary axis
- Individual centric axis

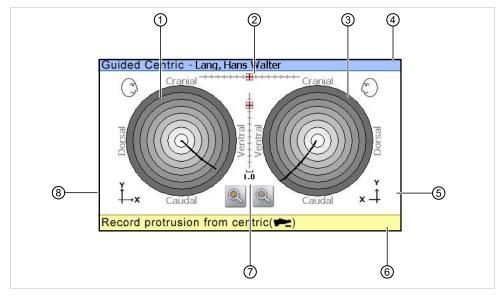
See also: 5.8.1 Select the reference axis system, Page 64

Press the button for the desired axis system.

Run the "Guided centric" measuring program

This method of determining the centric is the most conventional methods. The dentist is provided with a visualization of a guided centric in relation to an unguided protrusion path. This information illustrates the degree to which the mandible was for example guided in a cranial and the dorsal direction for the desired centric po-

sition. In a final measurement, this dental position is shown on the screen and transferred to a registration.

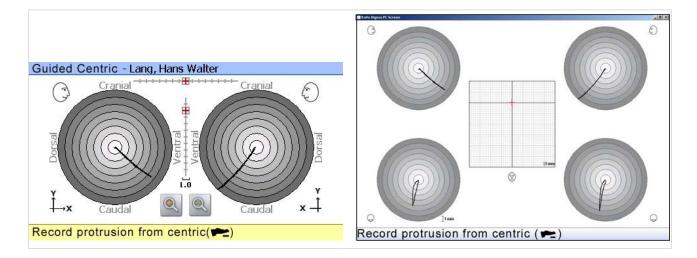


"Guided centric" measurement screen

- View of right joint
- ② Anterior view of the incisal point
- ③ View of left joint
- ④ Type of measurement patient name
- ⑤ Left EMG signal
- 6 Command line
- Anterior view of the incisal point
- 8 Right EMG signal

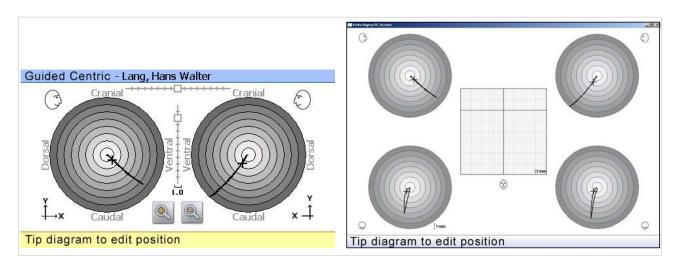
Step1: Recording protrusion

- Press the footswitch.
- ► Mask the patience to execute a protrusion movement without manipulation.
- Release the foot switch after the protrusion movement.



Step 2: Guide the patient to the desired centric position

Press the footswitch. The black X's show the respective position of the selected axis in the guided centric position.



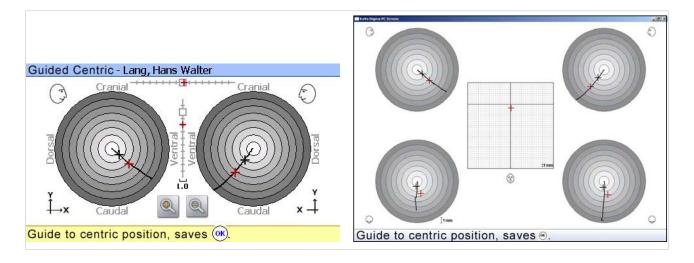
Step 3: Move the guided centric position

If the dentist wants to compensate the guided position to match the protrusion path (perhaps the temporomandibular joint was compressed excessively and the black + is above the protrusion path), it can be changed.

- ► Touch the grey circle.

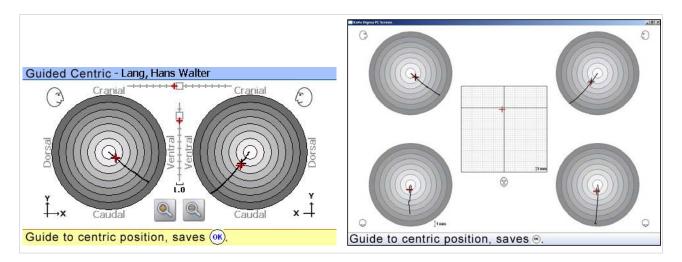
 The black + changes to red.
- ▶ Use the arrow keys to move the + wherever you want on the control panel.
- ► Touch the grey circle again.

 The new position of the + is fixed. The + changes back to black.



Step 4: Creating a centric registration

- Place suitable registration material (such as Futar D, Futar super fast) on the dental arches.
- Press the footswitch.
 Two red X's show the current position of the temporomandibular joint.
- Carefully move the patient's mandible until the red and black X's overlap.
- ► Keep the patient in this position until the compound has hardened.
- ► Hold down the footswitch during the hardening phase. This tells you if the patient stays in the desired position.





Note

The EMG signal is portrayed by the outer bar diagrams in the product types AR-CUSdigma USB or Wireless when the 2 channel EMG is connected. The two EMG signals should supply approximately the same display values when in the desired centric position.

The encoded position (registration position) is saved as screen content and can be shown on the screen by printing it with the KiD software.

5.10.2 Determining the centric via the adduction field



Note

This software module is only available with the ARCUSdigma USB and Wireless variations.

Open the "Measuring programs" window.





► Press the button for the "Adduction field" measuring program.

Select the axis system

The following axis systems can be selected.

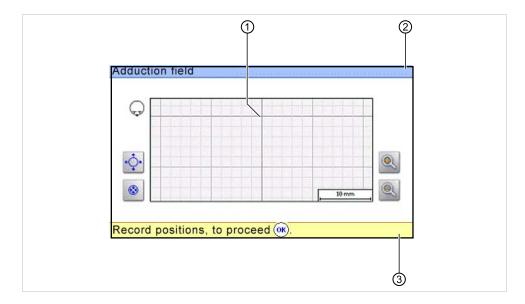
- KTS System
- Arbitrary axis
- Individual centric axis

See also: 5.8.1 Select the reference axis system, Page 64

Press the button for the desired axis system.

Running the "Adduction field" measuring program

The method of determining the centric is done without manipulating the patient. A patient with full or partial detention executes any number of opening and closing movements. Each mandible position with tooth contact represents a measurement. From all the positions, The ARCUSdigma calculates the mathematical centre that is used to position the mandible.



"Adduction field" measurement screen

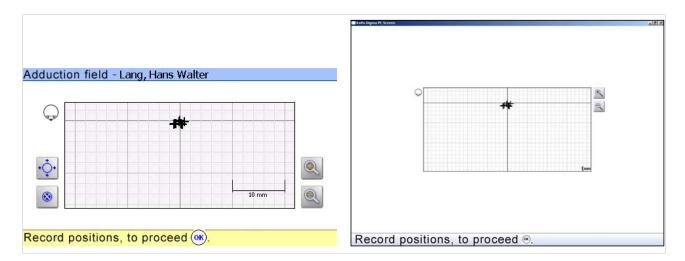
Measurement grid

- ③ Command line
- 2 Type of measurement patient name

The displayed measuring grid ① lies in the horizontal projection of the oral cavity. The intersection is 80 mm behind the centre of the sensor picture. This position can be approximately compared with a support pin position.

Step 1: Measure the addition point

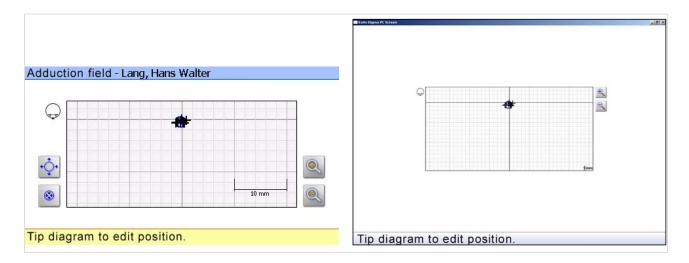
- ► Ask the patient to execute opening and closing movements.
- Press the footswitch when there is tooth contact. The position is indicated by the X.
- Repeat the process as frequently as required. Each position is indicated by an X.



Step 2: Evaluate the measured values

Press the "OK" button.

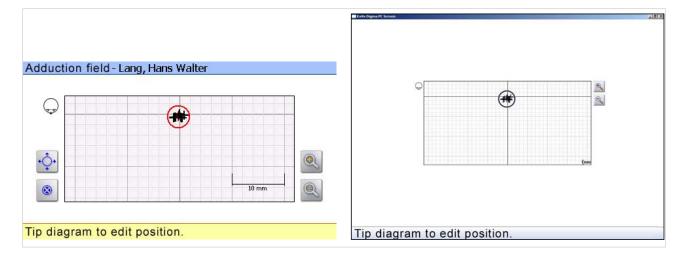
The measured values are sent for evaluation. A blue circle indicates the measured values provided for evaluation. All X's outside are not included in the evaluation.



The size of the evaluation circle can be changed.

► Touch the evaluation circle.

The evaluation circle changes to red.

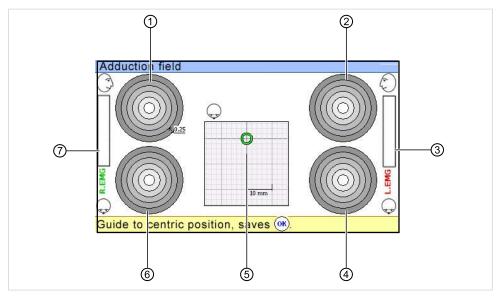


- ► Change the evaluation circle with the "Large" key.
- ► Touch the evaluation circle again.

 The evaluation circle changes back to blue.

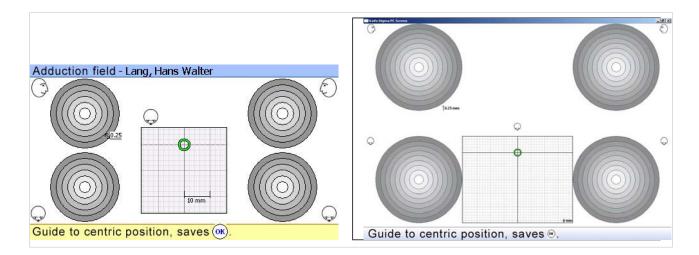
Step 3: Creating a centric registration

Press the footswitch "OK" button.The screen appears for registration creation.

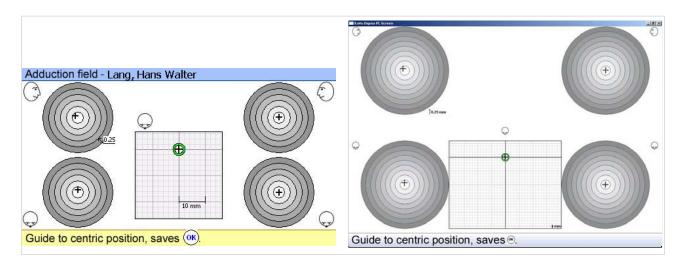


"Create registration" screen.

- ① Saggital view of the right joint
- ② Sagittal view of the left joint
- 3 Left EMG signal
- 4 Horizontal view of the left joint
- ⑤ Calculated centric position in the centre of the green circle
- 6 Horizontal view of the right joint
- Right EMG signal



- ▶ Place suitable registration material between the dental arches.
- Press and hold down the footswitch.
- ► Carefully move the patient's mandible until the black X is in the centre of the green circle.

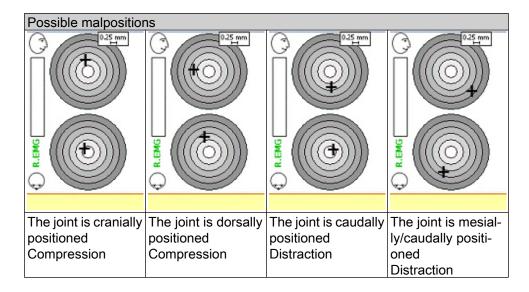


- ► Keep the patient in this position until the compound has hardened.
- Hold down the footswitch during the hardening phase. This tells you if the patient stays in the desired position.



Note

The EMG signal is portrayed by the outer bar diagrams in the product types AR-CUSdigma USB or Wireless when the 2 channel EMG is connected. The two EMG signals should supply approximately the same display values when in the desired centric position.



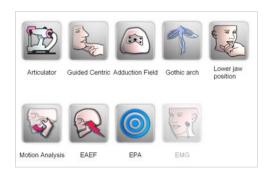
5.10.3 Centric determined via the Gothic arch



Note

This software module is only available with the ARCUSdigma USB and Wireless variations.

▶ Open the "Measuring programs" window.





▶ Press the button for the "Gothic arch" measuring program.

Select the axis system

The following axis systems can be selected.

- KTS System
- Arbitrary axis
- Individual centric axis

See also: 5.8.1 Select the reference axis system, Page 64

Press the button for the desired axis system.

Run the "Gothic arch" measuring program

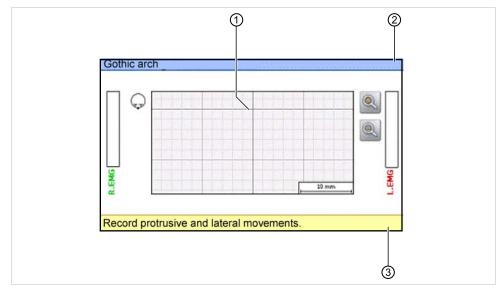
The method of determining the centric is done without manipulating the patient. This method is primarily used for edentulous patients or those with malfunctions.

Mount a support pin registration in the patient's mouth. Make sure that only a minimum bite lock occurs in patients with a full set of teeth.



The patient makes a number of mandibular movements. Both protrusive and retrusive movements are required as well as lateral movements. From all the move-

ments, the ARCUSdigma calculates the intersection of forward movements and lateral movements.



[&]quot;Gothic arch" measuring screen

Measurement grid

- 3 Command line
- ② Type of measurement patient name

The displayed measuring grid ① lies in the horizontal projection of the oral cavity. The intersection is 80 mm behind the centre of the sensor picture. This position can be approximately compared with a support pin position.

Step 1: Measure the gothic arch

- Press the footswitch and hold it during the measurement (long measurement).
- Ask the patient to execute the following mandibular movements with support pin contact:
 - Project
 - Retract
 - Right
 - Left

The so-called "Gothic arch" is drawn on the measuring screen.

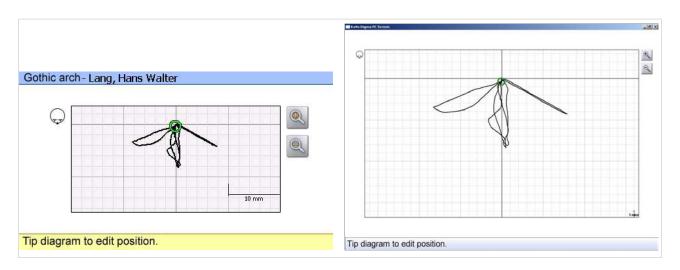
Then have the patient execute this type of movement any number of times.

Step 2: Evaluate the measured values

Once a number of these complete movements are available, release the footswitch.

The ARCUSdigma calculates the intersection of all movements.

This intersection is depicted with the aid of a green circle.



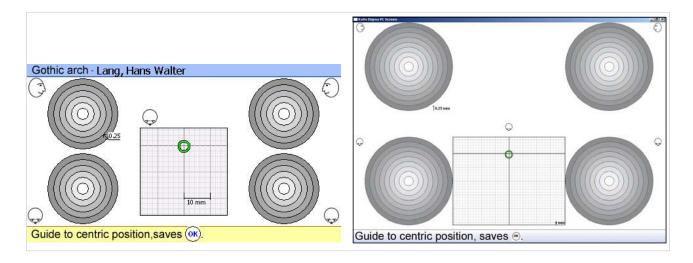


Note

If the intersection is not found, the suggested intersection is accepted with "OK".

The analysis of the centric position can be changed by the care provider. Especially with edentulous patients, the determined position is preferably shifted a slight amount in a retral direction (0.5 mm).

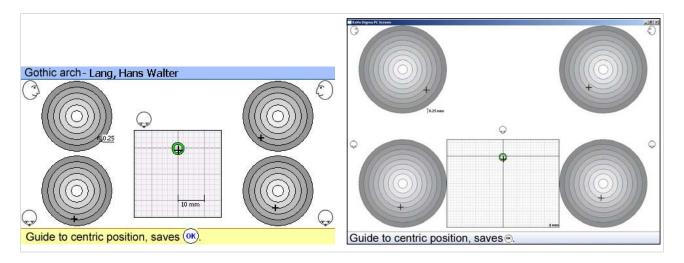
- Touch the circle.The circle changes to red.
- ► Move the circle on the control panel with the "Up" or "Down" keys.
- Touch the circle again. The circle is fixed, and it changes to green.



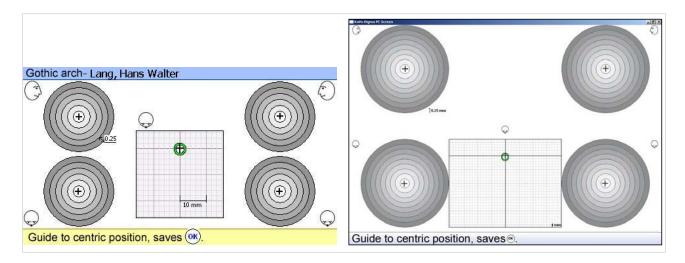
Step 3: Creating a centric registration

Place suitable registration material between the support pin and the dental arches.

► Carefully move the patient's mandible until the black X is in the centre of the green circle. The black +'s in the 4 circles show the dentist how the temporomandibular joints are positioned.



- ▶ Keep the patient in this position until the compound has hardened.
- Hold down the footswitch during the hardening phase. This tells you if the patient stays in the desired position.





Note

The EMG signal is portrayed by the outer bar diagrams in the product types AR-CUSdigma USB or Wireless when the 2 channel EMG is connected. The two EMG signals should supply approximately the same display values when in the desired centric position.

5 Operation | 5.11 Movement analysis

5.11 Movement analysis

A clinical functional analysis and electronic movement analysis help determine the necessity of a functional pretreatment of restorative measures so that nothing is overlooked.

The ARCUSdigma documents the 3-D mandibular movement in easy to understand reports, and saves all the relevant data.

Information on restricted movement, discoordination and hypermobility can be obtained by portraying condylar and incisal movements in the three dimensions and by simultaneously considering condylar movement in the right and left sides in the form of the kinematic axis. Potential causes in the arthogenic, myogenic and occlusal areas can then be considered.

► Open the "Measuring programs" window.





Press the button for the "Movement analysis" measuring program.

5.11.1 Select the axis system

The following axis systems can be selected:

- Kinematic axis
- Arbitrary axis
- Individual centric axis

The kinematic axis represents the preferred axis system for movement analysis. Dentists place great demands on measuring systems that analyze movement. In addition to tooth-guided mandibular movements, information is also required on non-manipulated opening movements. Major translation movements arise in the temporomandibular joint from the patient's opening movements. Rotational movements tend to be the exception. It is very advantageous to determine the kinematic axis.



Press the "Kinematic axis" button to select the axis system.

Movement can be analyzed with the "arbitrary axis" or the "individual centric axis."

5 Operation | 5.11 Movement analysis

See also:

5.8.3 Arbitrary axis, Page 725.8.4 Individual centric axis, Page 78

Determining the kinematic axis

KaVo recommends using the kinematic axis for movement analysis.

Step1: Perform the calibration

This measuring step is for calibration. The mandible position does not matter; however, the jaw must be closed (tooth contact). The mandible may not move during calibration.

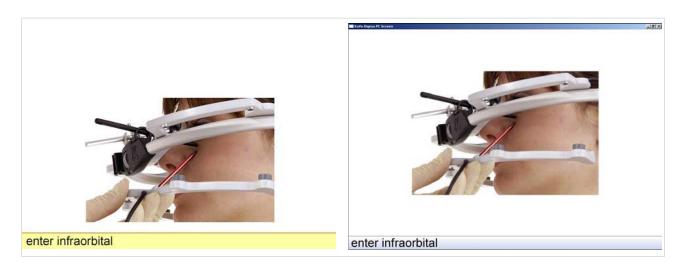


Step 2: Enter the infraorbital point

The lowest point of the bony eye socket serves as a reference for the infraorbital point (palpate).

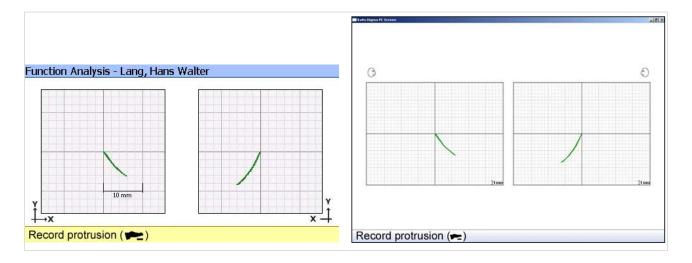
- ▶ Push the axis pointer all the way into position 3 on the ARCUSdigma receiver.
- ► Align the axis pointer tip with the selected infraorbital point.

5 Operation | 5.11 Movement analysis



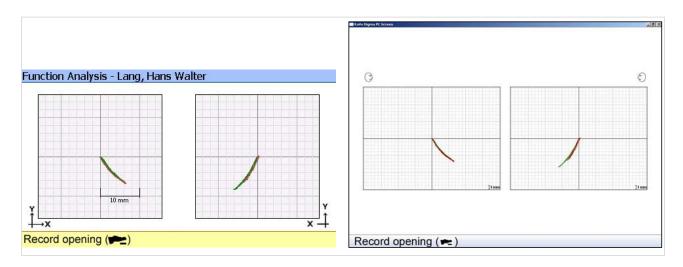
Step 3: Recording protrusion

- Press and hold down the footswitch.
- Ask the patient to assume maximum protrusion.
- ► Release the foot switch.
- Ask the patient to resume intercuspation.



Step 4: Record the opening in

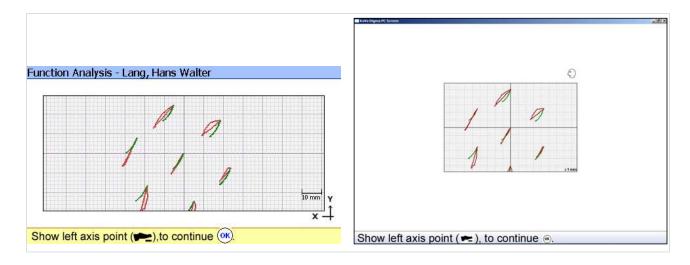
- Press and hold down the footswitch.
- ► Ask the patient to open their jaw as much as possible.
- ► Release the foot switch.
- Ask the patient to resume intercuspation.



Step 5: Calculate the kinematic axis

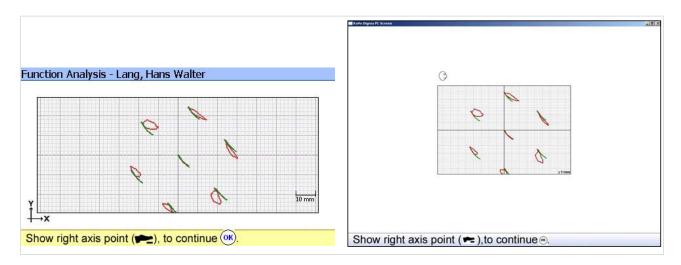
The kinematic axis is automatically calculated. The calculated kinematic axis point is shown in the middle of the screen.

The kinematic axis point shows nearly identical movement paths both for protrusion (green) and for the opening movement (red).



- ► Touch the "OK" button Additional axis points are also shown for information, but not included in the evaluation.
- Press the footswitch to display the position of the kinematic axis with the axis pointer of the mandible transmitter on the skin.

See also: 5.8.4 Individual centric axis, Page 78



► Click the "OK" button.

5.11.2 Running the "Movement analysis" measuring program

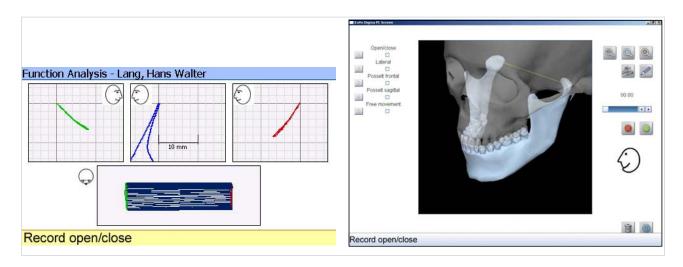
A proven measuring routine is integrated for the movement analysis. The ARCUS-digma can create a report on this measuring routine. The specified measuring routine provides information on the mobility of the mandible (temporomandibular joints and incisal point). Furthermore, the movement paths of the selected axis are shown and documented.

If additional measurements are to be taken, they can be recorded with the "NEW" key in the measuring program. Unfortunately, it is not possible to create an expanded report.

Step 1: Record the mouth opening analysis

- Ask the patient to assume intercuspation (guide the patient if necessary).
- Press the footswitch.
- ▶ Ask the patient to open their mandible as much as possible and then close it.

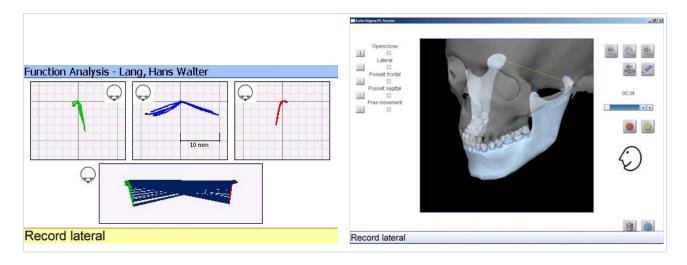
As long as the foot switch remains pressed, this recording can be repeated as often as desired. All measurements are sent for evaluation.



Step 2: Record the analysis of the mandible movement to the side

- Ask the patient to assume intercuspation (guide the patient if necessary).
- ► Press the footswitch.
- Ask the patient to move their mandible as far as possible to the right and left while maintaining tooth contact.

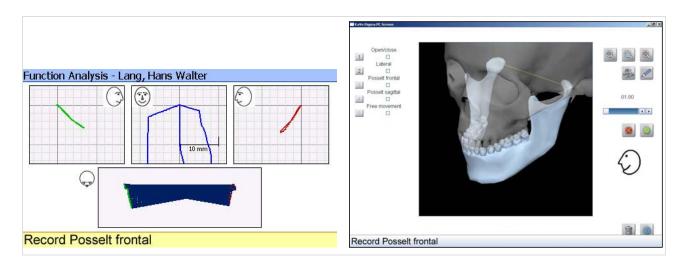
As long as the foot switch remains pressed, this recording can be repeated as often as desired. All measurements are sent for evaluation.



Step 3: Record a Prosselt diagram from the front

- Ask the patient to assume intercuspation (guide the patient if necessary).
- Press the footswitch and hold it during the following measurement.
- ► Ask the patient to execute the following sequential movements:
 - move the mandible to the right as far as possible while maintaining tooth contact
 - Open the mandible as far as possible and close it assuming intercuspation.
 - Move the mandible to the left as far as possible while maintaining tooth contact.
 - Open the mandible as far as possible and close it assuming intercuspation.

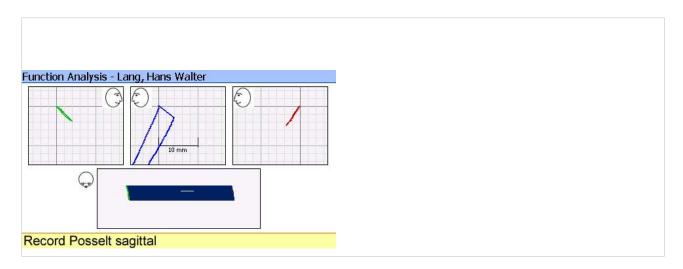
As long as the foot switch remains pressed, this recording can be repeated as often as desired. All measurements are sent for evaluation.



Step 4: Record a Prosselt diagram from the sagittal direction

- Ask the patient to assume intercuspation (guide the patient if necessary).
- Press the footswitch and hold it during the following measurement.
- Ask the patient to execute the following sequential movements:
 - Move the mandible to the front as far as possible while maintaining tooth contact
 - Open the mandible as far as possible and close it assuming intercuspation.

As long as the foot switch remains pressed, this recording can be repeated as often as desired. All measurements are sent for evaluation.



Step 5: Record the Gothic arch

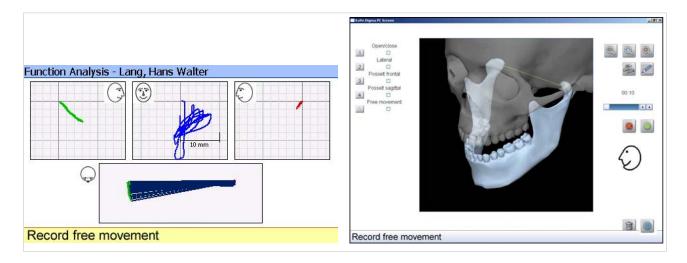
- Ask the patient to assume intercuspation (guide the patient if necessary).
- Press the footswitch and hold it during the following measurement.

- ► Ask the patient to execute the following sequential movements:
 - Move the mandible to the front as far as possible and back while maintaining tooth contact
 - Move the mandible to the right and left as far as possible
 - Return the mandible to intercuspation

As long as the foot switch remains pressed, this recording can be repeated as often as desired. All measurements are sent for evaluation.

Step 6: Record your own defined movement

► If you want to make additional recordings, they can be entered after pressing the "New" button on the computer or the basic unit.



5.11.3 Run the recordings of the movement analysis in replay mode and document them

At the end of the movement analysis, all the recordings are available in the KiD software.

All of the movements can be reviewed in replay mode.

See also:

5.6.2 Run recording and replay mode, Page 59

5.6.3 Document recordings, Page 60

5 Operation | 5.12 Mandibular positioning according to movement analysis

5.12 Mandibular positioning according to movement analysis



Note

This software module is only available with the ARCUSdigma USB and Wireless variations.

If the movement analysis reveals that a new therapeutic position is required, this software module can be used for example to create a splint position (registration).

► Open the "Measuring programs" window.





► Touch the button for the "Mandibular positioning" measuring program.

5.12.1 Select the axis system

The same axis system must be used that was used for the movement analysis.



► Touch the "Last used" icon to select the axis system.

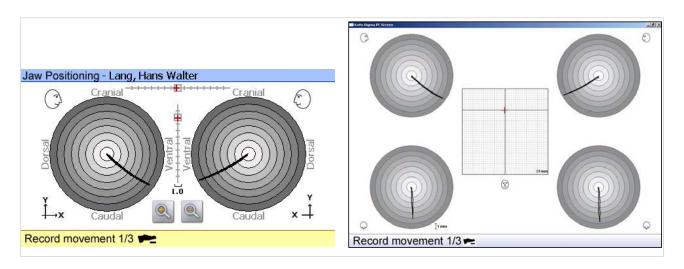
5.12.2 Determining dysfunctional mandibular movement

To determine a new therapeutic position, three recordings of movement are required.

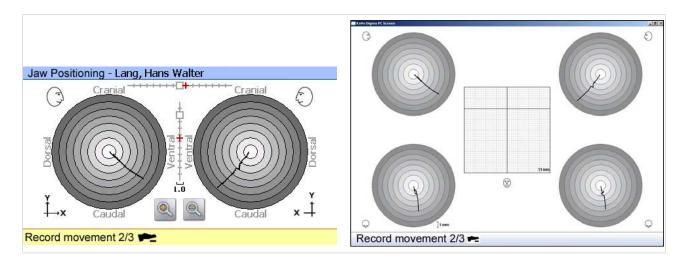
These three recordings should tell the dentist the position in which for example a splint should be created.

5 Operation | 5.12 Mandibular positioning according to movement analysis

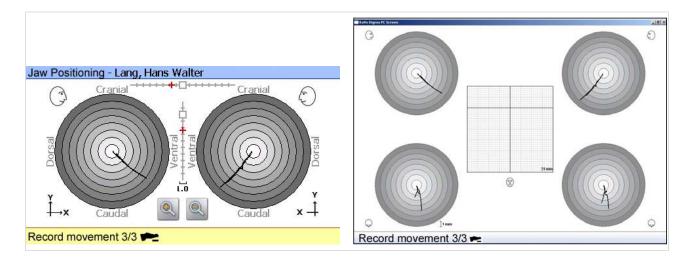
Step 1: Record movement 1



Step 2: Record movement 2



Step 3: Record movement 3



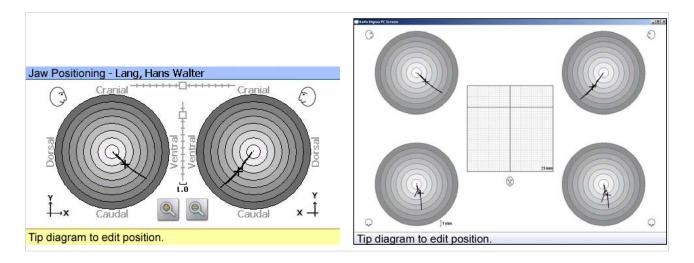
5 Operation | 5.12 Mandibular positioning according to movement analysis

The screen shows all three movements overlapped.

The position that should be avoided is clearly represented. For example, a displacement of a disc can cause a jump in the movement path.

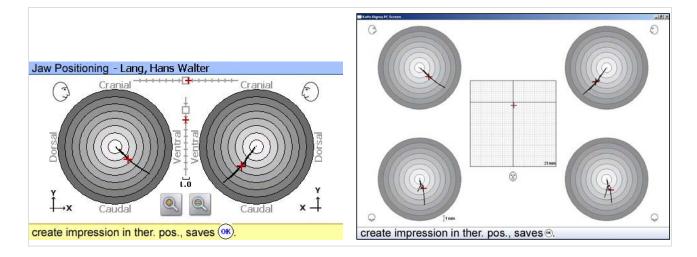
Step 4: Guide the patient into the new therapeutic position

- ► Guide the mandible by manipulation into a position that for example lies before the position to be avoided.
- ► If necessary, adapt the new position using the navigation keys. Touch the respective side, and move the "+" using the navigation keys.
- ► Press the "OK" button.



Step 5: Transfer the new therapeutic position to the registration

- ► Apply a suitable registration material (such as Futar D, Futar Fast, Registrator, etc.) between the dental arches.
- Press the footswitch and hold it during the following measurement.
- Guide the mandible until the red "+" sign overlaps with the black "+" signs.



The registration serves as the basis for a new splint, for example.

5.13 EAEF - Electronic Analysis of Etiological Factors

The manual structure analysis can detect and record painful temporomandibular joint positions using passive examination techniques. The subsequent electronic analysis can distinguish the individual causes of the malfunction. A specific splint can then be created taking into account the documented findings.



Note

The software module EAEF (**Mat. no. 1.005.4122**) is not included in the installed ARCUSdigma software. To use the EAEF software, you must participate in a practical course with Dr. A. Bumann (www.viz.de).

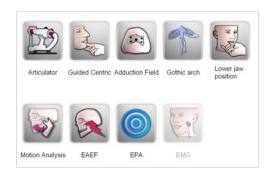


Note

In order to use the EAEF software, you need the ARCUSdigma USB or Wireless versions.

The articulator calculation for producing splints using the EAEF can only be offered for the KaVo PROTAR (**Mat. no. 1.005.4121**) since the required controlled laterotrusive movements can only be executed with this articulator.

Open the "Measuring programs" window.





► Press the button for the "EAEF" measuring program.

5.13.1 Select the axis system

The following axis systems can be selected.

- KTS System
- Arbitrary axis
- Individual centric axis

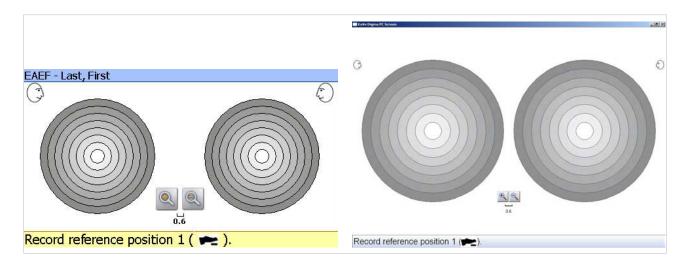
See also: 5.8.1 Select the reference axis system, Page 64

Press the button for the desired axis system.

5.13.2 Run the "EAEF" measuring program

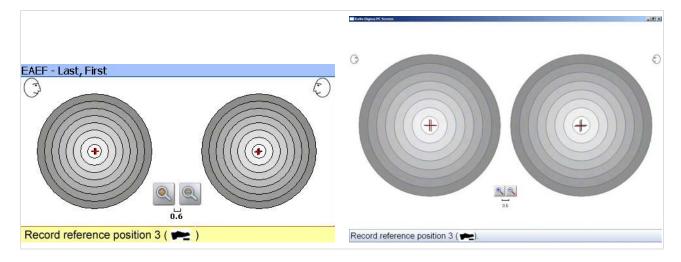
A reference point is first required as the starting point for all measurements.

Preparation: Record the reference position



The reference point can for example be centric occlusion. The measurement can be repeated as freely as desired. Generally, three measurements are sufficient.

- Ask the patient to assume centric occlusion (guide the patient if necessary).
- Press the footswitch.
- Repeat this measurement three times. Based on the deviations, the dentist can identify the reproducibility of centric occlusion.



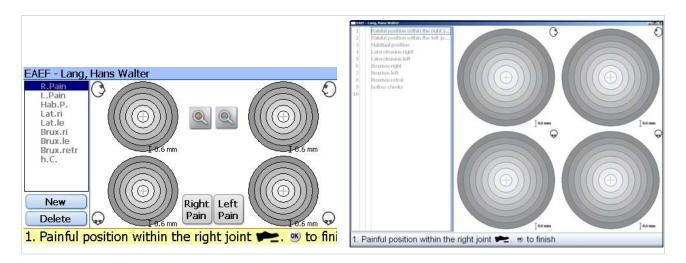
The average of all three measurements is calculated. A + in the middle of the circles indicates this point. All additional measurements are in relation to this measurement.

Step 2: Locate the pain position in the right joint

- ▶ Press and hold down the footswitch.
- ► The dentist manipulates the patient's mandible using the clinically positive examination technique (primary load vector).

As soon as the patient indicates that the current mandibular position is causing pain in the right temporomandibular joint, release the foot switch.

The current position is saved and displayed on the screen as a second black +.



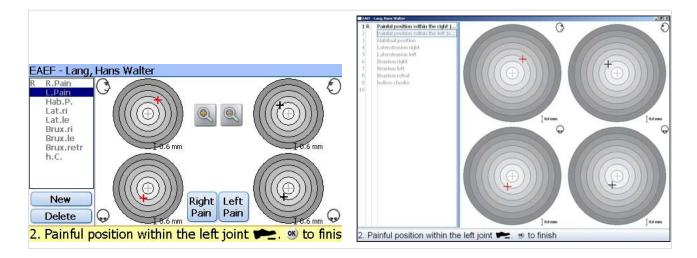
Press the "Pain" button to clearly identify this position. The "+" changes to red.

Painful positions are also characterized in other measurements by pressing the "Pain" key.

Step 3: Locate the pain position in the left joint

- Press and hold down the footswitch.
- ► The dentist manipulates the patient's mandible using the clinically positive examination technique (primary load vector).

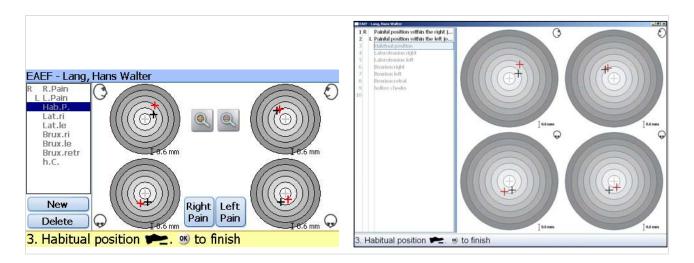
The movement of the condyl is displayed on line on the screen.



Step 4: Record the habitual position

Press and hold down the footswitch.

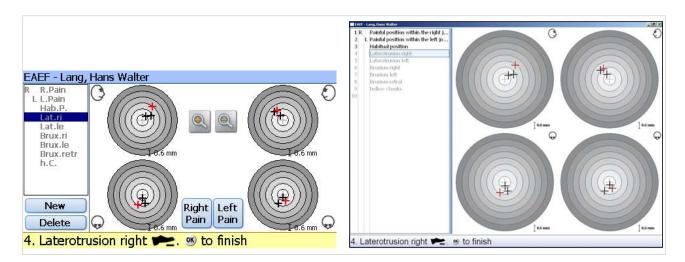
The dentist manipulates the patient's mandible using the clinically positive examination technique (primary load vector).
The movement of the condyl is displayed on line on the screen.



Step 5: Record the right laterotrusion position

- Press and hold down the footswitch.
- ► The dentist manipulates the patient's mandible using the clinically positive examination technique (primary load vector).

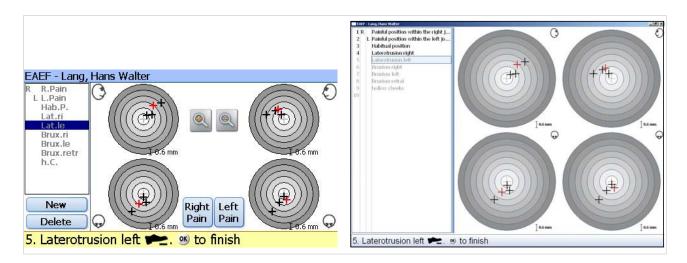
 The movement of the condyl is displayed on line on the screen.
- Ask the patient to move his mandible to the right (canine/canine) while maintaining tooth contact.



Step 6: Record left laterotrusion position

- ▶ Press and hold down the footswitch.
- ► The dentist manipulates the patient's mandible using the clinically positive examination technique (primary load vector).

Ask the patient to move his mandible to the left (canine/canine) while maintaining tooth contact.

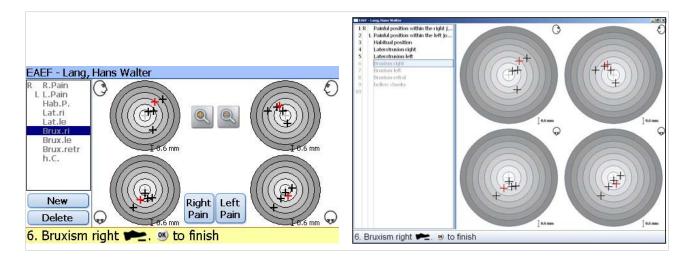


Step 7: Record the right bruxism position

- Press and hold down the footswitch.
- ► The dentist manipulates the patient's mandible using the clinically positive examination technique (primary load vector).

The movement of the condyl is displayed on line on the screen.

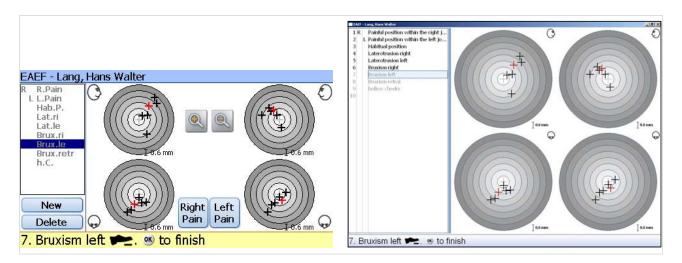
Ask the patient to grind their teeth to the right in their facets (lock-and-key principle).



Step 8: Record the left bruxism position

- Press and hold down the footswitch.
- ► The dentist manipulates the patient's mandible using the clinically positive examination technique (primary load vector).

Ask the patient to grind their teeth to the left in their facets (lock-and-key principle).

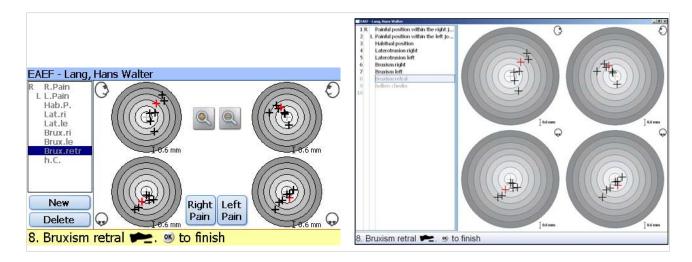


Step 9: Record retral bruxism position

- Press and hold down the footswitch.
- ► The dentist manipulates the patient's mandible using the clinically positive examination technique (primary load vector).

The movement of the condyl is displayed on line on the screen.

Ask the patient to grind their teeth to the right in their facets (lock-and-key principle).



Step 10: Record the mandible position when the cheeks are sucked in

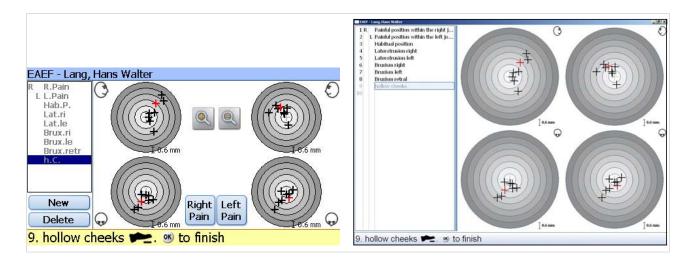
- Press and hold down the footswitch.
- ► The dentist manipulates the patient's mandible using the clinically positive examination technique (primary load vector).

Ask the patients to forcefully suck in their cheeks.

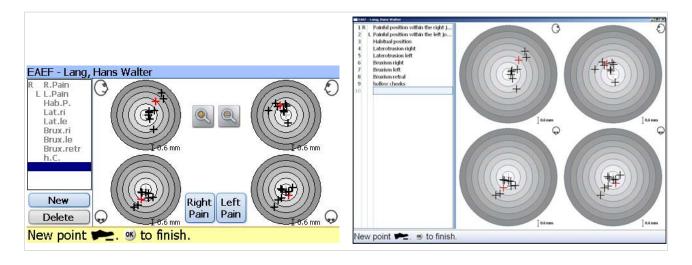


Note

The measuring routine defined by Dr. A. Bumann can be expanded as desired. After pressing the "New" key, the title of the desired measurements can be entered on the computer.



Step 11: Evaluate EAEF



All the measurements are shown on the screen in relation to each other as black "+" signs. Painful positions are red "+" signs.

► Touch the individual steps on the left side to view the mandibular positions in relation to each other.

The clicked position is identified by a yellow position.

This type of representation is useful for explaining to patients which of their actions causes the mandible to assume a painful position.

This pain position analysis report is saved and can be printed out for the patient. It serves as the basis for calculating the splint design.

5.13.3 Run the "Splint" measuring program

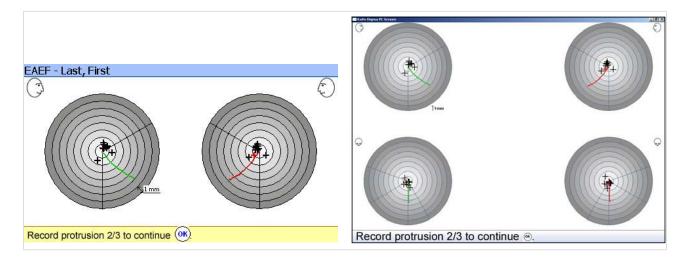
If the EAEF was performed correctly, the ARCUSdigma can be used to calculate a therapeutic splint design.

The location and representation of the pain position on the computer screen allows the dentist to specifically guide the mandible (generally lateroprotrusive) to relieve the painful regions. The goal is to create a splint with mandibular movements that relieve the patient.

Step 1: Recording protrusions

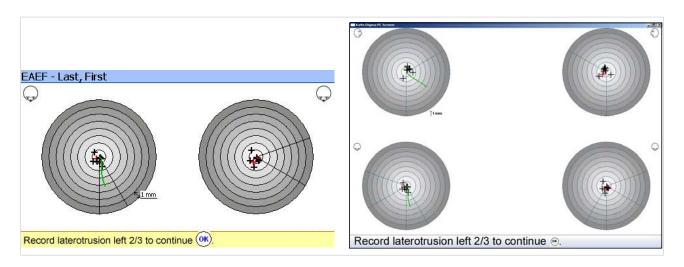
The located pain positions are represented on the screen by the red "+" signs in the two circles. The two black lines are limitations. Within these limits, three protrusions are required for calculating the splints.

- Ask the patient to assume intercuspation (guide the patient if necessary).
- Press the footswitch.
- Ask the patient to protruded their mandible as far as possible.
- Repeat this process three times.
- If the pain position was touched during this recording, please use the arrow keys to delete the measurement and repeat it.



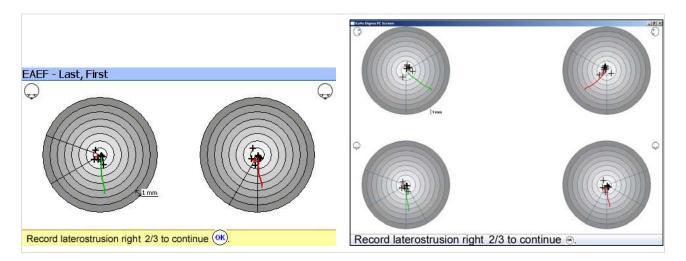
Step 2: Record left laterotrusion

- Ask the patient to assume intercuspation (guide the patient if necessary).
- Press the footswitch.
- Guide the patients intentionally past any pain positions in a left lateroprotrusive movement.
- Repeat this process three times.
- ► If the pain position was touched during this recording, please use the arrow keys to delete the measurement and repeat it.

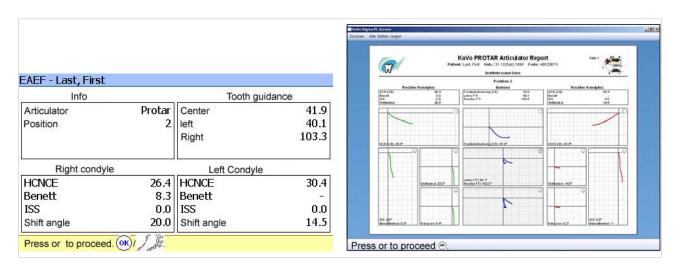


Step 3: Record the right laterotrusion

- ► Ask the patient to assume intercuspation (guide the patient if necessary).
- Press the footswitch.
- Guide the patients intentionally past any pain positions in a right lateroprotrusive movement.
- Repeat this process three times.
- ► If the pain position was touched during this recording, please use the arrow keys to delete the measurement and repeat it.



Step 4: Calculation of the articulator settings



Adjust the displayed articulator values in the KaVo PROTARdigma. Adjust the maxilla and mandible in the articulator.

Step 5: Create splint with therapeutic static and dynamic occlusion

The patient can execute mandibular movements under the influence of the splint and relieve the clinically diagnosed painful position.

5.14 EPA - Electronic position analysis of the mandibular position

Mandibular positions can be compared relative to each other using electronic position analysis (EPA).

► Open the "Measuring programs" window.





Press the button for the "EPA" measuring program.

5.14.1 Select the axis system

Press the button for the desired axis system.

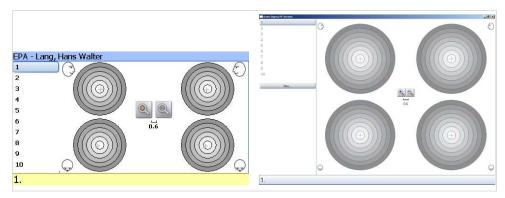
See also: 5.8.1 Select the reference axis system, Page 64

5.14.2 Run the "EPA" measuring program

Concentric circles appear on the screen.

The axial points of the selected axis are displayed corresponding to the selected spell axis.

The different bite positions of the patient are displayed by different points in the circle segments (such as (1) a habitual position, (2) maximum intercuspation, (3) maximum masticatory pressure, etc.).



EPA measuring screen

The dentist can create an examination routine with the EPA. By clicking the fields on the left side, you can save the desired text. After pressing the footswitch, the

position is displayed, and the next measuring step is opened. Any number of measurements are possible.

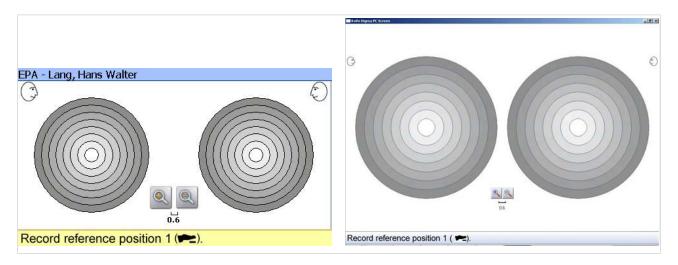
By touching specific individual fields on the left side the base unit, any number of defined fields can be jumped.

Step 1: Determine the reference position

A reference position is determined in the first step. All additional measurements are in relation to this reference position.

To ensure that the selected reference position is also reproducible, it can be displayed as frequently as desired by the Digma. An average is then formed from all of the measurements.

- ► Touch position 1.
- ► Have the patient assume the desired reference position.



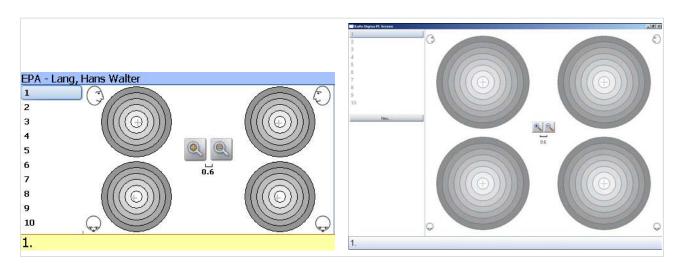
- Press the foot switch to record the reference position.
- Repeat the process as frequently as required.



If for example after the third measurement you press the "OK" key and not the footswitch, the ARCUSdigma calculates the average of all three measurements.

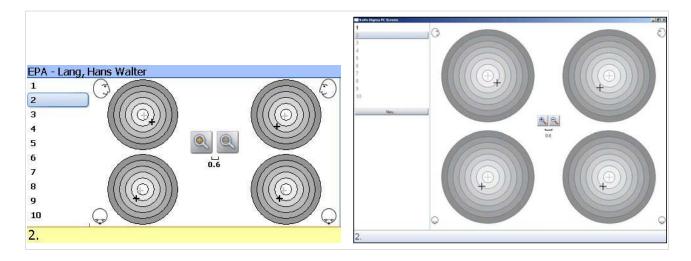
Step 2: Measure the first position

The calculated reference position is these centre in each circle but it is not showed. As soon as position 1 is measured, it is displayed.



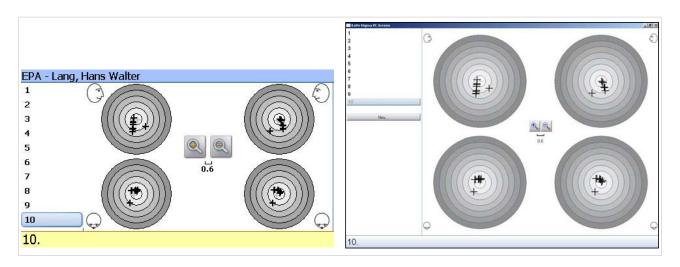
Step 3: Measure the second position

As soon as position 2 is measured, positions 1 and 2 are displayed.



Steps 4 to 10: Measure additional positions

Another measuring point is displayed with each new measurement.



Step 11: End the measurement

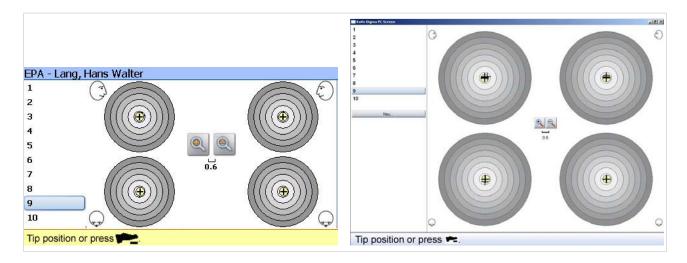


Once a sufficient number of measurements have been taken, press the "OK" key.

The EPA measurement is ended.

Step 12: Display the measured positions

Touch the desired position.
 The desired position is marked by a yellow circle.



5.15 EMG - relaxation measurement using electromyography

Before certain diagnostic and therapeutic measures, the patient is required to tense their masculatory muscles. Electromyography is suitable for testing muscle tone.

5.15.1 EMG functions

The KaVo EMG measuring system records teh action potential using skin surface electrodes. The process is similar to recording the action potential of the heart muscle by ECG.

By connecting to the KaVo ARCUSDigma USB/Wireless measuring system, the muscle action potential can be directly measured from the movement data. The measurement results are shown in real time on the computer and automatically analyzed in the report

The EMG differential electrode cable contains an active electronic circuit that ensures a high signal-to-noise ratio. in No cable artifacts can arise. The EMG activity of small and large muscles can be precisely and reliably detected.

5.15.2 Prepare the patient

Instructions and recommendations for the electrode system



Note

The validity and reproducibility of the EMG measurement primarily depends on the quality of the electrode application. You therefore need to ensure that only the specified EMG electrodes are used with the system.

Prepare the skin before applying the electrodes.

See also: 5.15.2 Prepare the skin, Page 129

- Make sure that the EMG amplifier provides signals without noise. The EMG amplifier provides noise-free signals when the skin impedance is between 1 and 50 kOhm (measured between the pair of electrodes).
- ► Check the impedance with a conventional multimeter to get a feeling for the quality of the measurements (this applies particularly for beginners).

Prepare the skin

Recommendations for skin preparation:

Recommendations for skin preparation:	
Clean with alcohol	Use alcohol as teh standard cleaning method (alcohol content: 70%).
	Rub the skin firmly to thoroughly clean and degrease it.
	This may slightly redden teh skin.
Hair removal	Removing hair improves the adhesion of the electrodes.
	The hair should be removed of patients who tend to sweat.

Roughen the skin	Use fine sandpaper for example.
	Apply a slight amount of pressure to roughen the skin
	and remove the cells of the corneal stratum.
Cleaning and roughening	Use abrasive conductive paste.
in one step	

Select electrodes

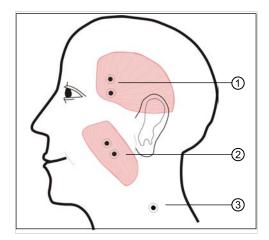
The best lead results are obtained with we gel electrodes. Adhesive gel electrodes can also be used, but their tap impedance is higher.

The additional effort required for cleaning the reusable electrodes must be taken into account. Note that small electrodes increase the selectivity of the measurement, but the impedance is higher and the measuring conditions are more difficult. Bipolar disposable wet gel electrodes with a diameter of approximately 0.5 to 1 cm are most frequently used. KaVo recommends their general use.

5.15.3 Affix the electrodes

- Place the electrodes centrally on the muscle belly parallel to the muscle fibre approximately 2 cm apart.
- First press on the bipolar electrodes in the middle and then on the edge to retain the polarity.

The following arrangement is suggested as a standard:



- ① Temporalis anterior
- ② Masseter

3 Neutral electrode

Masseter (bilateral)

The fibre direction runs between the angle of the mandible and the pupil.

Insert cotton rolls if necessary for palpation.

► Insert the electrodes so that the largest muscle belly lies between the electrodes.

Temporalis anterior (bilateral)

The fibre direction extends in a star shape in relation to the coronoid process.

Adhere the bottom electrode above the zygomatic bone and the top electrode under the temporal bone crest. Make sure that the electrodes do not stick to the temple hairs and are distant from the eye.

Neutral electrode

- Affix the neutral electrode to the side of the patient's neck at the transition between the neck and shoulder in a muscle-free zone. The muscle-free zone is a soft spot without any palpable resistance from the muscle approximately 1-1/2 hand widths from the ear.
- ► To prevent the electrode cable from accumulating a static charge, always first connect to the electrode cable to an EMG basic unit and only then to the patient electrode.
- Use two fingers to press together the two pressure points of the "easy snap" electrode contact, and place it on the pushbutton of the electrode.
 If applicable, offset the two neighbouring contacts at an angle to each other.



- Rotate the contacts so that the cables hang downward. Make sure that no voltage is transmitted to the adhesive electrode and that the electrodes are not lifted off.
- Loosely affix the cable to the patients close with a clip.

Ensure the quality of the measurements

- If measurements are taken under dynamic conditions, test the shift of the muscle belly (in relation to the electrodes) over the entire movement.
- After connecting the electrodes, start the relaxation test to check the quality and stability of the signal.

Artifact influences can be identified when the signal does not return to the zero line after a movement, and/or the baseline has too much noise. Given the high sensitivity of the system, small amplitude fluctuations may arise on the zero line; however, this should not exceed 10 to 15 μ Volts.

5.15.4 Determine the muscle tone (relaxation test)

Before certain diagnostic and therapeutic measures, the patient is required to tense their masculatory muscles. Electromyography is especially suitable in this instance.

Record the muscle tone of the two masseter muscles over 2 to 5 minutes.

5.15.5 Overlapping measurements

The signal reports of two sessions can be overlapped and displayed in a diagram.

In the KiD database, click on the two desired EPA measurements. Hold down the Ctrl key and press the left mouse button. The signal reports of two sessions are overlapped and displayed in a program. 6 Preparation methods DIN EN ISO 17664 | 6.1 Cleaning

6 Preparation methods DIN EN ISO 17664



Note

Each time the ARCUSdigma is used, it needs to be set up in accordance with DIN EN ISO 17664.



Note

All of the components that contact the patient's mucous membrane must be sterilized after use.

The following components must be sterilized:

- Normal bite fork (Mat. no. 0.622.0911)
- KTS bite fork (Mat. no. 1.000.8518)
- Mandible attachment (Mat. no. 1.000.9291)

6.1 Cleaning

6.1.1 Manual cleaning

- Before sterilization, clean the bite fork and mandible attachment under flowing water (tap water quality, 30°C ± 5°C, flow rate: 2 litre/min) 30 seconds with a medium-hard toothbrush.
- ► Sterilise directly before cleaning.

6.1.2 Machine cleaning

Not applicable.

6 Preparation methods DIN EN ISO 17664 | 6.2 Disinfection

6.2 Disinfection

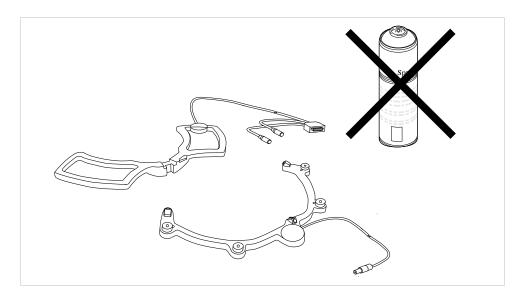
6.2.1 Manual disinfection



Do not spray disinfect.

Spray disinfection destroys the highly precise measuring sensors.

- ► Do not spray disinfect.
- Only disinfect by wiping.



Allowed disinfectants

- Microcide liquid (Schülke & Mayr)
- Wipe-disinfect all components.

6.2.2 Automated disinfection

Not applicable.

6 Preparation methods DIN EN ISO 17664 | 6.3 Sterilisation

6.3 Sterilisation



Note

sterilisation should directly follow cleaning.

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

7 Accessories | 7.1 Accessories for the ARCUSdigma SD

7 Accessories

7.1 Accessories for the ARCUSdigma SD

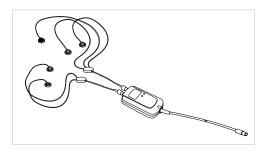
Figure	Name/description	Material number
	PROTAR/evo Digma	1.005.4121
	Adaptation to KaVo E 80 treatment unit Screwed on to the E 80 assistant element	1.005.4127

7.2 Accessories for the ARCUSdigma USB/Wireless

Figure	Name/description	Material number
	PROTAR/evo Digma	1.005.4121
	EAEF module for locating painful positions in the temporomandibular joint	1.005.4122
	EMG analysis – 2 channel EMG to determine muscular activity	1.005.4123
	EMG dual electrodes Type NORAXON Dual Electrodes Product 272 Four dual electrodes	1.005.8012
0 00 00 00 00 00 00 00 00 00 00 00 00 0	Adaptation to KaVo E 80 treatment unit Screwed on to the E 80 assistant element	1.005.4127

2 channel EMG

The ARCUSdigma USB/Wireless has an interface for the KaVo 2 channel EMG. The two-channel EMG with four measuring electrodes and 1 basic electrode is a valuable supplement especially when determining the centric position and relaxing the patient.





Using electrodes that are not specified by KaVo

Biological incompatibility.

Only use the electrodes provided by KaVo.

8 Data on electromagnetic compatibility according to DIN EN 60601-1-2 | 8.1 Electromagnetic Transmissions

8 Data on electromagnetic compatibility according to DIN EN 60601-1-2

8.1 Electromagnetic Transmissions

The ARCUSdigma movement analysis system is for use in an environment like the one cited below.

The customer or user of the ARCUSdigma should ensure that it is used in the correct environment.



Note

Although the ARCUSdigma meets all the requirements of DIN EN 60601-1-2 (Medical Electrical Devices parts 1-2: General specifications regarding safety -- supplementary standard: Electromagnetic compatibility -- requirements and tests) of October 2002, portable and mobile high frequency communications devices may nonetheless influence the ARCUSdigma movement analysis system. Such devices should not be used near the ARCUSdigma movement analysis system when measurements are being taken.



Note

The use of accessories, especially computer connecting cables that are not provided by KaVo for the ARCUSdigma or are expressly recommended for use with the device can reduce the noise immunity of the ARCUSdigma movement analysis system.

Measuring noise transmission	Conformance	Electromagnetic environment - gui- delines
HF transmission according to CISPR 11	Group 1	The ARCUSdigma II movement analysis system uses HF energy only for its internal operation. Its HF transmission is therefore very low, and it is improbable that neighbouring electronic devices will be disturbed.
HF transmission according to CISPR 11	Class B	The ARCUSdigma movement analysis system is for use in all facilities including residential ones, and facilities that are directly connected to a public power supply that also supplies residential buildings.

8 Data on electromagnetic compatibility according to DIN EN 60601-1-2 | 8.1 Electromagnetic Transmissions

Measuring noise transmission	Conformance	Electromagnetic environment - gui- delines
Harmonics in accordance with IEC 61000-3-2	Class B	The ARCUSdigma movement analysis system is for use in all facilities including residential ones, and facilities that are directly connected to a public power supply that also supplies residential buildings.
Transmissions of voltage fluctuations or flicker according to IEC 61000-3-3	fulfilled	The ARCUSdigma movement analysis system is for use in all facilities including residential ones, and facilities that are directly connected to a public power supply that also supplies residential buildings.



Note

The ARCUSdigma movement analysis system may not be used directly next to or stacked on other devices. If the unit has to be used next to or stacked on other devices, the unit must be monitored to ensure that it operates properly in this arrangement.

8 Data on electromagnetic compatibility according to DIN EN 60601-1-2 | 8.2 Resistance to electromagnetic interference

8.2 Resistance to electromagnetic interference

The ARCUSdigma movement analysis system is for use in an environment like the one cited below.

The customer or user of the ARCUSdigma should ensure that it is used in the correct environment.

Immunity tests	IEC 60601 test level	Conformance level	Electromagnetic environ- ment - guidelines
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV atmospheric di- scharge	± 6 kV contact discharge ± 8 kV atmospheric di- scharge	Floors should be made of wood or concrete or have ceramic tiles. When the floor is made of synthetic material, the relative humidity must be at least 30%.
Fast transient electrical disturbances/ Bursts according to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines	± 2 kV for power lines ± 1 kV for input and output lines	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surges according to IEC 61000-4-5	± 1 kV Push-pull voltage ± 2 kV common mode vol- tage	± 1 kV normal mode volta- ge ± 2 kV common mode vol- tage	voltage should correspond to that of a typical business or hospital envi- ronment.
Voltage interruptions, short-term interruptions and fluctuations of the supply voltage according to IEC 61000-4-11	< 5% U_T (> 95% interruption of the U_T) for 1/2 period 40% U_T (60% interruption of the U_T) for 5 periods 70% U_T (30% interruption of the U_T) for 25 periods < 5% U_T (> 95% interruption of the U_T) for 5 s	< 5% U_T (> 95% interruption of the U_T) for 1/2 period 40% U_T (60% interruption of the U_T) for 5 periods 70% U_T (30% interruption of the U_T) for 25 periods < 5% U_T (> 95% interruption of the U_T) for 5 s	The quality of the supply voltage should correspond to that of a typical business or hospital environment. When the user of the ARCUSdigma movement analysis system needs continued operation even when the power supply is interrupted, it is recommended to supply the ARCUSdigma movement analysis system from an uninterrupted power supply or a battery.
Magnetic field with a supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	Not tested since the device cannot be influenced within the specified test level. (see comment B)	Magnetic fields at the mains frequency should correspond to typical values in a business and hospital environment.

Comment1: V_t is the alternating mains voltage before the test level is used.

Comment 2: Influence of low-frequency magnetic alternating fields:

To estimate influences, the maximum possible voltage induced by the magnetic field on the printed conductors is calculated and tested for any disturbing influences. The

8 Data on electromagnetic compatibility according to DIN EN 60601-1-2 | 8.2 Resistance to electromagnetic interference

field strength used in during testing is H=3 A/m, and the flux density B = μ 0*H = 3 A / m * 1.26 * 10E-6 Vs/Am = ~ 4 * 10 E-6 Vs/m² = 4 μ T.

An alternating field at frequency f and flux density B induces a voltage U = $B^*A^*2^*pi^*f^*sin(2^*pi^*f^*t)$ on a square loop with area A. The peak voltage Us = $B^*A^*2^*pi^*f$. Based on the size of the PCB (<2 dm²) and the fact that no printed conductors are in spirals, the maximum possible induced voltage on a printed conductor is Us = 4^*10 E-6 Vs/m2 * 0.02 m² * 2^* pi *60 1/s = 30 μ V. This value cannot cause interference with the digital part (permissible noise ratio > 0.5V).

The influence on the analogue part is also negligible since the amplifier is capacitively coupled and therefore manifests highpass behaviour. 30 μ V directly coupled in at the input of the ADC with a conversion voltage of approximately 3 V has a content of 10E-5. With an 8-bit resolution, the change in voltage for a digit is approximately 10 mV, and the maximum anticipated interference is lower than the converter resolution limit by a factor of 300. The induction voltage therefore does not influence the connected cable since there are no ground loops and no current can flow.

8 Data on electromagnetic compatibility according to DIN EN 60601-1-2 | 8.3 Resistance to electromagnetic interference

8.3 Resistance to electromagnetic interference

The ARCUSdigma movement analysis system is for use in an environment like the one cited below.

The customer or user of the ARCUSdigma should ensure that it is used in the correct environment.

Immunity test	IEC 60601 test level	Conformance level	Electromagnetic environment - gui- delines
Conducted HF disturbances according to IEC 61000-4-6 Radiated HF disturbances according to IEC 61000-4-3	3 V _{eff} 150 MHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V _{eff} 3 V/m	Portable and mobile radio devices including the wires should not be used closer to the ARCUSdigma movement analysis system than the recommenced safe distance calculated using the equation for the transmission frequency. Recommended safe distance: $d=1,2^{\sqrt{P}}$ de = 1,2 $^{\sqrt{P}}$ for 80 MHz to 800 MHz de = 2.3 $^{\sqrt{P}}$ for 800 MHz to 2.5 GHz with P as the rated power of the transmitter in Watts (W) according to the transmitter manufacturer, and d as the recommended safe distance in meters (m). The field strength of stationary radio transmitters is less than the conformance level at all frequencies in an on-site check ^a . Disturbances are possible close to devices that have the following symbol. ((a))

Comment 1: At 80 MHz and 800 MHz, the higher value applies. Comment 2: These guidelines may not be applicable in all situations. The spread

of electromagnetic waves is absorbed and reflected by buildings, objects and people.

^aThe field strength of stationary transmitters such as base stations of mobile telephones and land radio devices, amateur radio stations, AM and FM, radio and television broadcasters cannot be theoretically predetermined. To determine the electromagnetic environment resulting from stationary high frequency transmitters, the location should be investigated. When the calculated field strength at the location of the ARCUSdigma movement analysis system exceeds the above cited conformance level, the ARCUSdigma movement analysis system should be monitored to see if it is operating normally. If unusual performance is observed, it may be necessary to undertake additional measures such as reorienting or moving the AR-CUSdigma movement analysis system.

^bThe field strength is less than 3 V/m over the frequency range of 150 kHz to 80 MHz.

8 Data on electromagnetic compatibility according to DIN EN 60601-1-2 | 8.4 Recommended safe distances

8.4 Recommended safe distances

Recommended safe distance between portable and mobile HF telecommunications equipment and the ARCUSdigma movements analysis system.

The ARCUSdigma movement analysis system is intended for use in an electromagnetic environment in which transmitted HF disturbances are controlled. The customer or user of the ARCUSdigma movement analysis system can help prevent electromagnetic interference by maintaining minimum distances between portable and mobile high-frequency communication devices (transmitters) and the ARCUSdigma movement analysis system as recommended below corresponding to the maximum output of the communication device.

Safe distance according to the transmission frequency

Rated power of the trans-		80 MHz to 800 MHz	800 MHz to 2.5 GHz
mitter	$d = 1.2 \sqrt{P} m$	$d = 1.2 \sqrt{P} \text{ m}$	$d = 2.3 \sqrt{P} m$
W			
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters whose maximum rated power is not in the above table, the distance can be calculated using the equation for the respective gap, where P is the maximum rated power of the transmitter in Watts (W) according to the manufacturer's information.

Comment 1: To calculate the recommended safe distance from transmitters with a frequency range of 80 MHz to 2.5 GHz, an additional factor of 10/3 was used to reduce the probability that a mobile unintentionally brought into the patient area would cause malfunction.

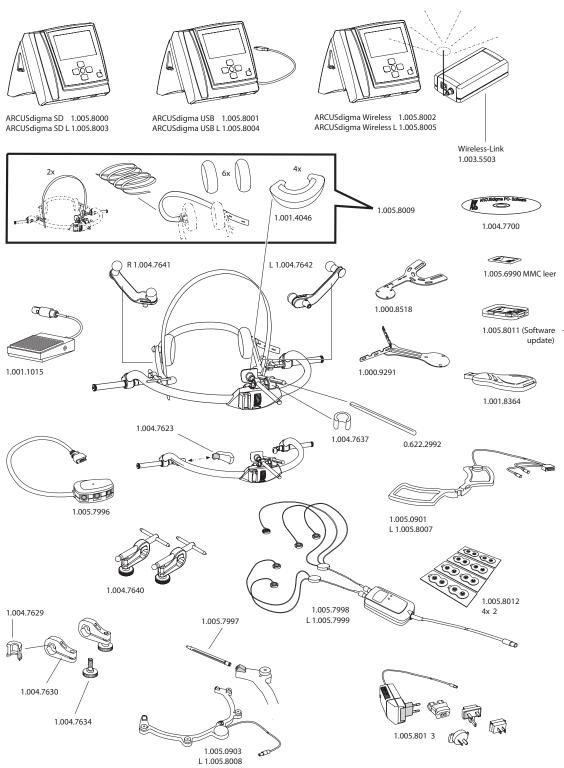
Comment 2: These guidelines may not be applicable in all situations. The spread of electromagnetic waves is absorbed and reflected by buildings, objects and people.

9 Replacement parts

Verk.-Nr . ARCUSdigma SD / USB / Wireless



11/2007 09.28

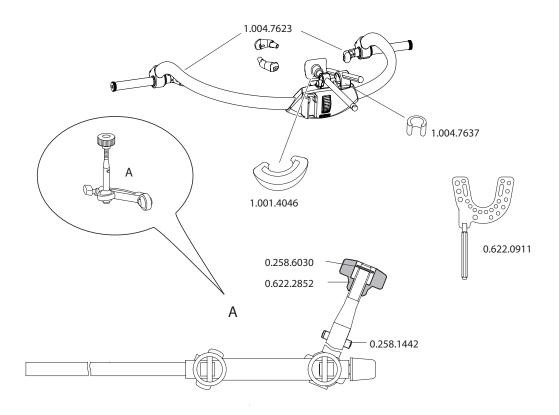


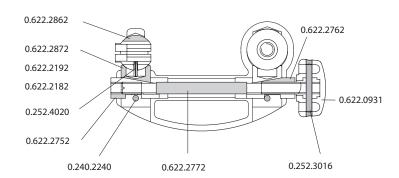
9 Replacement parts

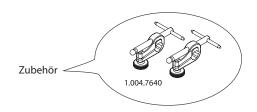
Ve rk.-Nr . Gesichtsbogen ARCUSevo



11/2007 09.30







10 Declaration of conformity

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EG - KONFORMITÄTSERKLÄRUNG

EC - DECLARATION OF CONFORMITY

Für das nachstehend bezeichnete Medizinprodukt / For the following named medical device

Produktname / Name of product: Pantograph / Pantographs

Modell/Typ / Model/Type: ARCUS digma II

UMDNS Code: 15-720
Produktklasse / Product Class: Im
Regel / Rule: 12

Hersteller / Manufacturer: zebris Medical GmbH

Anschrift / Address: Max-Eyth Weg 42

88316 Isny Germany

Angewandte Normen / Applied Standards:

DIN EN 980:2003 DIN EN 1041:1998 DIN EN 10993-1:2003 DIN EN 14791:2000 DIN EN 60601-1:1996 DIN EN 60601-1-2:2002 DIN EN 60601-1-4:2001

DIN EN 60601-2-40:1998

Hiermit erklären wir die Übereinstimmung für das oben genannte Medizinprodukt in seinen beschriebenen Ausbaustufen mit den grundlegenden Anforderungen des Anhanges I der Richtlinie 93/42/EWG über Medizinprodukte und übernehmen die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung.

Diese Erklärung beruht auf der Genehmigung des Konformitätsbewertungsverfahren gemäß des Anhanges V durch eine benannte Stelle und gilt in Zusammenhang mit der finalen serialnummerbezogenen Freigabe im ERP-System der zebris Medical GmbH.

We herewith declare that the above mentioned medical device with its extensions as described complies with the essential requirements of appendix I of directive 93/42/EEC concerning medical devices and take sole responsibility for the provision of this declaration of conformity.

This declaration is based upon the approval of the procedure for the evaluation of conformity by an appointed authority according to appendix V and is valid in interrelation with the final product inspection related to the serial number, documented within the ERP-System of zebris Medical GmbH.

Isny, den 05.03.2007

Wolfgang Brunner
Geschäftsführer / Managing Director

Benannte Stelle / Notified Body: EUROCAT Institute for Certification and Testing GmbH D-64295 Darmstadt

C C 0535

10 Declaration of conformity

