INSTRUCTIONS FOR USE

HEKA Patient Chair

CE

KEEP THIS MANUAL WITH THE UNIT AT ALL TIMES
Manuals for OEM equipment is included in the shipping boxes.
Installation, Service, and Maintenance by authorized Heka Dental dealers only.

Note: With reservation of technical changes and colour changes. Images may be displayed with optional equipment. Images may be displayed without safety labels.

Introduction

Congratulations on your new HEKA Patient Chair.

We are delighted that you have chosen Heka Dental as your supplier for your practice.

Our goal is to be able to meet your needs and wishes by creating innovative solutions that help you in your daily work.

Our aim was to develop an ergonomically correct patient chair, with design, ergonomics, reliability, simple maintenance, and hygiene being essential considerations during the development of the product.

The **HEKA Patient Chair** was specially designed to suit our units.
Together, the HEKA Patient Chair and the unit make the perfect workstation; both convenient and a pleasure to use.

Heka Dental A/S has developed this patient chair with the aim of providing optimal functionality and comfort for both patient and dentist. The simple curves and stylish design result from our collaboration with dentists, the engineer and the designer.

As our equipment generally has a long lifetime and new options are added regularly, we have made it easy for you to update your Heka treatment unit in the future.

Heka features simple controls and innovative, high-quality solutions and designs that help and support you in your daily treatments.

These operating instructions are designed to help you before you begin treatment - and when you need information later.

We wish you all the best with your Heka.

Kind regards,

Your Heka Dental Team.

Heka Dental A/S is ISO 13485 certified.

Device Description

The HEKA Patient Chair is electrically controlled equipment for dental treatment.

The HEKA Patient Chair is intended for dental treatment performed by dental professionals. It is intended for use with a Heka Dental Delivery System.

This manual describes how to use and maintain the HEKA Patient Chair. Please read the manual in its entirety before using the unit. This manual is the primary source of information about the HEKA Patient Chair.

Please refer to the OEM documentation for information about OEM products.

Intended Purpose

Heka dental delivery systems are dental units. The system is intended for use in dental care treatments. The system is to be used by authorized professionals within the scope of his/her education, training, and experience. The system provides the dental practitioner a motorized patient chair, dental instruments, and optional suction system for removal of bodily fluids.

Indications for use

Dental care medical operations include evaluation, diagnosis, prevention and/or treatment of diseases, disorders and/or conditions of the oral cavity, maxillofacial area and/or the adjacent and associated structures and their impact on the human body.

Contraindications

There are no known contraindications for the use of this equipment.

Intended patient population

Age	3 years to geriatric
Weight	Less than or equal to 200 Kg / 440.9 lbs

Warnings & Precautions

Heka Dental assumes no responsibility for direct or indirect consequential damage resulting from improper use or arising through inadequate compliance with the operating instructions, or incorrect use and maintenance.

	Use only as intended. Inadequate compliance with the operating instructions could result in serious injury to the patient or user or irreparable damage to the equipment. Before using this product, please ensure that you have read and understood the operating instructions.
	Must be used by qualified and trained dental personnel only.
	Do not install the equipment in areas where there is a risk of explosion. HEKA Patient Chair is not intended for operation in oxygen rich environments or in the presence of flammable anaesthetics or gases.
	Please see the section on approved cleaning agents and methods for a detailed description of cleaning methods and maintenance for the HEKA Patient Chair. See enclosed OEM instructions for cleaning and maintenance of any OEM equipment and instruments.

	Electromagnetic Compatibility (EMC) Changes or modifications to this product not expressly approved by Heka Dental A/S may result in increased emissions or decreased immunity performance of the product and could cause EMC issues with other equipment. This product is designed and tested to comply with applicable regulation regarding EMC and shall be installed and put into service according to the EMC information stated below:
	Use of portable phones or other portable or mobile radio frequency (RF) emitting equipment near the product may cause unexpected or adverse operation such as dental light flickering or shut off.
	In the event of high-voltage emission ESD (8-15KV), the display on the handle for the suction tube holder can be turned off. The function keys will continue to work. The display will work again by turning the device off and on again.
	Portable RF communication equipment must be used only at a minimum distance of 40 cm (15 inches) from any part of the [ME EQUIPMENT or ME SYSTEM], including cables, as specified by manufacture.

	The use of accessories, transducers and cables and items other than those supplied with the equipment may result in increased emission and reduced immunity or performance of the product. HEKA Patient Chair must not be used next to or stacked with other equipment. If such use is necessary, the user will be responsible for testing that the configuration is safe for use during normal treatment. Detailed information about electromagnetic interference in relation to the HEKA Patient Chair starts in section EMC Information in these instructions. See EMC Information for recommended distances between the HEKA Patient Chair and other electronic devices.
	Do not let suction or handpieces, - including magnets, come near patients with implanted pacemakers.
	Do not touch the patient while you are handling the equipment in the service compartment or other internal parts of the dental unit.

Cautions

CAUTION	This equipment is only to be sold by or on the order of a dentist and only used in accordance with these operating instructions and exclusively by trained professional dental operators.
CAUTION	Position the equipment with sufficient area from walls or obstructions to easily operate the device. See the HEKA Patient Chair Installation Manual for the dimensions and space requirements of the equipment
CAUTION	Do not position or stack other equipment on the dental unit. See the HEKA Patient Chair Installation Manual for the dimensions and space requirements of the equipment
CAUTION	Always inspect the equipment components for damage before performing treatment. Damaged components must not be used and must be replaced before further use of the equipment.
CAUTION	Thoroughly read the documentation for the OEM products that are supplied with HEKA Patient Chair before they are connected and used.
CAUTION	The user is responsible for ensuring that the equipment is subjected to annual maintenance and must ensure that the functions of the equipment do not change over time.
CAUTION	The unit must be used only under the supervision of trained professional dental operators.
CAUTION	According to international standard: IEC 80601-2-60 Clause 201.4.3 Essential Performance: Dental equipment and hereby Heka Dentals dental equipment, does not have Essential Performance.

Additional Safety Information

The use of accessories that do not comply with the safety regulations for this type of equipment may compromise the safety of the entire system. Therefore, the following must be taken into consideration:

Use of accessories

Documentation of the safety certificates for accessories must be in accordance with the applicable international IEC 60601-1 and the current ISO 7494.

A complete list of standards that the unit treatment device complies with can be seen in the section “Compliance with regulatory standards” later in this instruction.

The HEKA Patient Chair device complies with all requirements set down in MDR: Medical device regulation 2017/745, RoHS, REACH and WEEE.

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IMPORTANT!
To ensure the safety, reliability, and functionality of this Equipment:

Use only qualified and authorized technicians for installation, calibration, modification, and repair of the HEKA Patient Chair.
Compliance with IEC 60364 for all electrical installations
Use of only authorized OEM accessories
Use this Equipment only in accordance with instructions provided in this manual.

DO NOT:

- Attempt to modify this equipment without authorization by Heka Dental A/S
- If modification is made, the equipment must be fully tested and inspected by a Certified Heka Dental technician prior to use, to ensure safety.

Regulatory classification

- Class I
- Type B Applied Parts
- Ordinary Protection

Not suitable for use in the presence of inflammable mixed aesthetic gases such as air, oxygen or laughing gas (nitrous oxide).

Online user registration for dentists

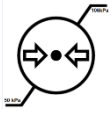
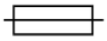
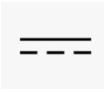
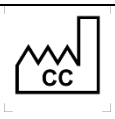
Register as a user of a Heka unit

Access special product information
Scan the QR code for online registration.

Registered users have access to special software, user guides, quick guides, user guides videos, tips & tricks, product news, etc. We are constantly expanding the possibilities for registered users of Heka units.

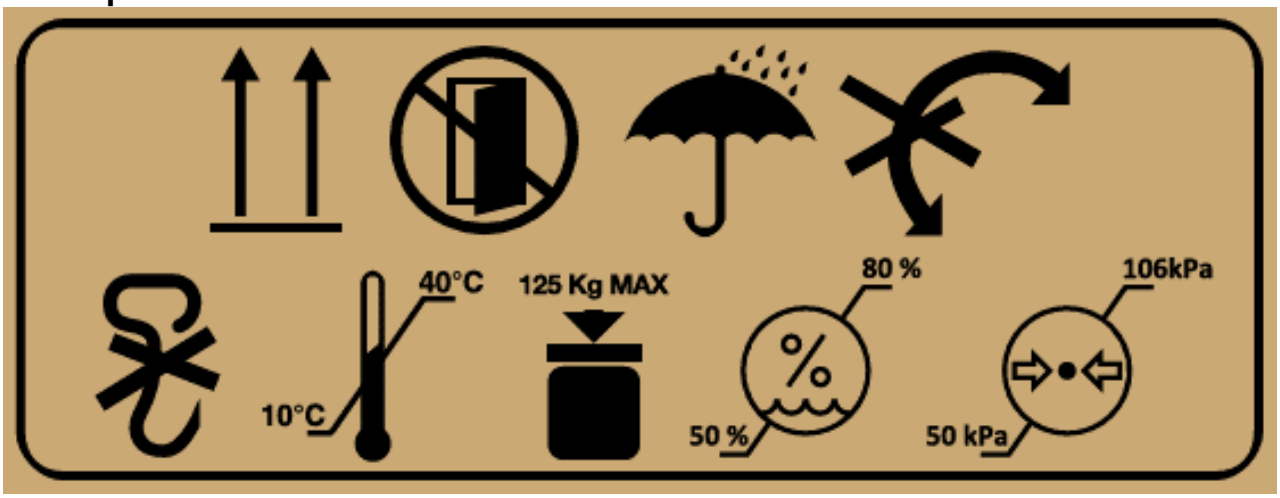
Symbols

Symbols	Description
	Type B Equipment
	Alternating Current
	General CAUTION! (Standard ISO 7010) See enclosed documents and/or catalogues
	Protective earth
	Follow instructions for use
	Foot control
	Separate collection of electrical and electronic equipment in accordance with Directive 2002/96/EEC (WEEE).
	Temperature Limitations
	Keep dry

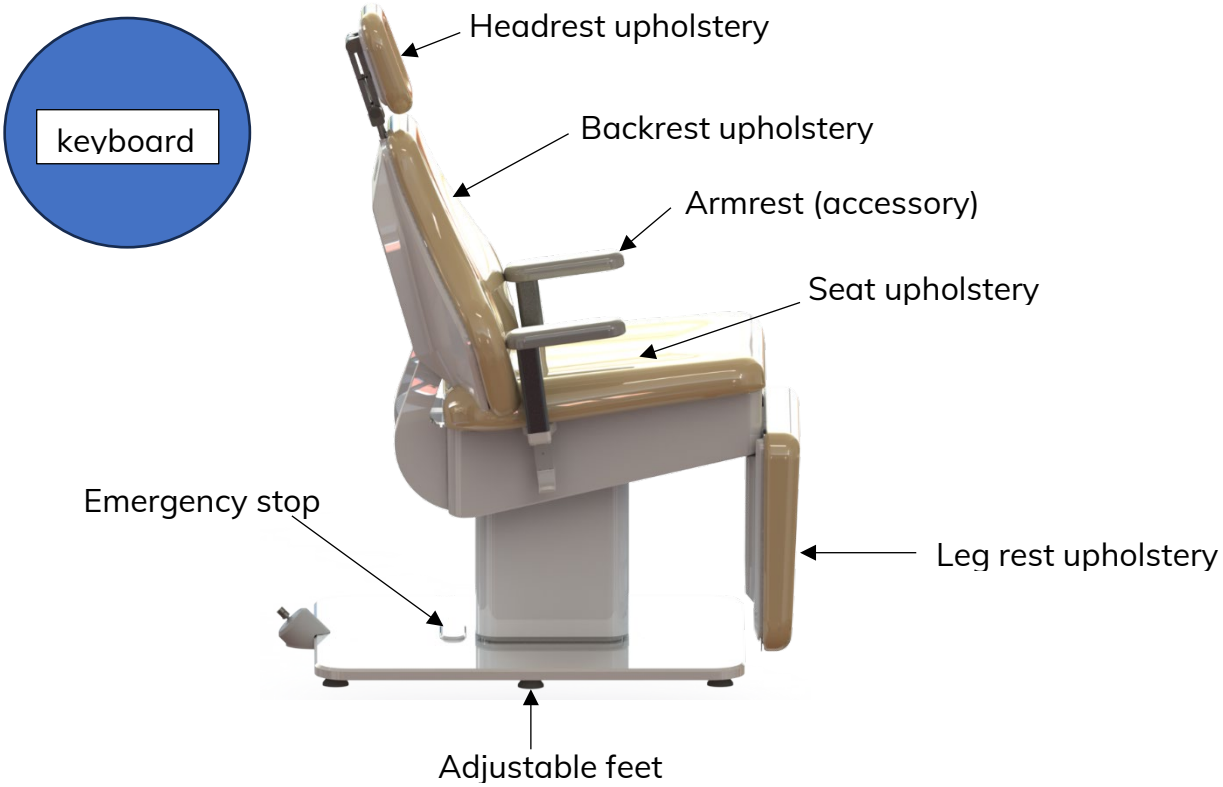
	This side up
	Do not use hand hooks
	Fragile
	No rotation
	Stacking limitations
	Limitations on Relative Humidity
	Limitations on Pressure
	Fuse
	Direct Current
	Do not open
	Operating Instructions
	In house use
	Manufacturer
	Country of manufacturer

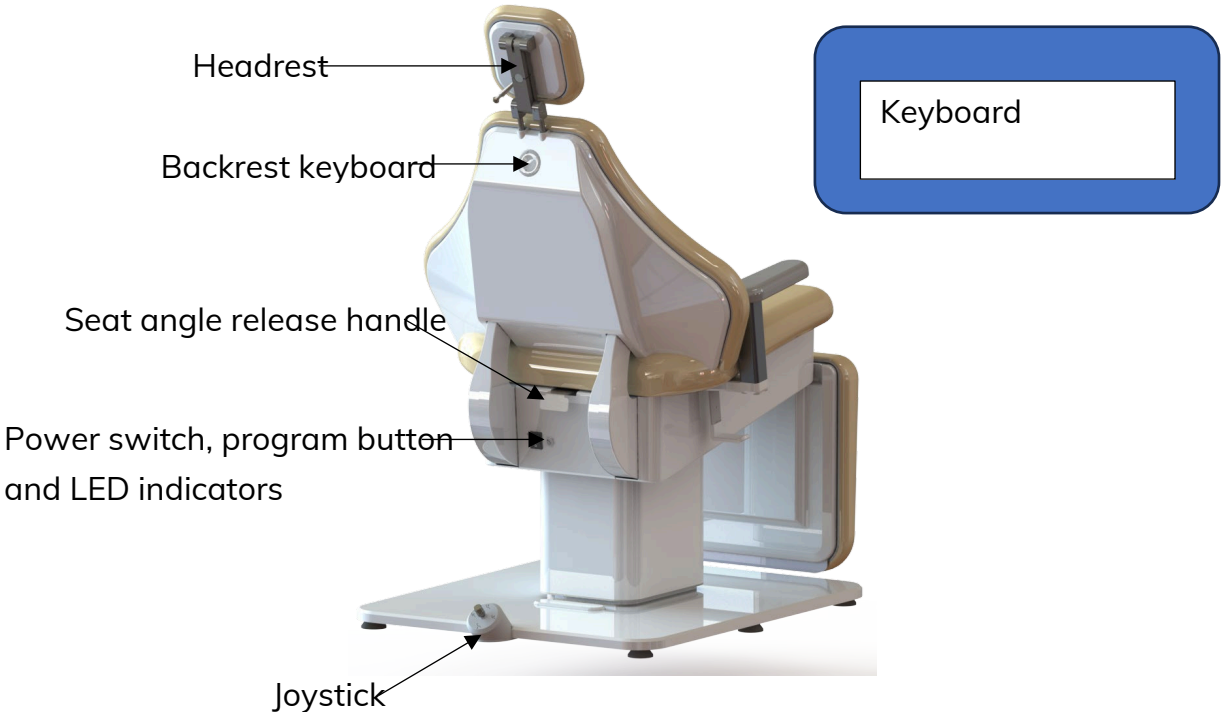
MD	Medical device
UDI	Unique device identifier

Transport and stock conditions



HEKA Patient Chair Overview





Components

The following components of the unit are manufactured by Heka Dental:

HEKA Patient Chair
Upholstery
Armrest (Accessory)

Operation, maintenance, and cleaning information can be found in this manual for the items listed above.

Optional accessories

Optional accessories for use with the HEKA Patient Chair can be purchased separately.

If you purchased any of the optional accessories for use with your HEKA Patient Chair , please refer to the OEM documentation included with your shipment for information on installation, operation, maintenance, and cleaning of those items.

Accessories:

Armrest
Ergo suction (Requires a HEKA Dental S+ or derived hardware unit to function)
Telescopic arm (Requires a HEKA Dental S+ or derived hardware unit to function)
Additional joysticks
Hanger for foot control
Autonomous suction

Safety instructions

The HEKA Patient Chair should only be placed on and fixated to a floor of concrete, ceramic tile or other non-flammable material in accordance with the mounting instructions.

CAUTION: The HEKA Patient Chair is EN/ISO 6875 approved to 200Kg/440.9lbs

To protect the operator, patient, and chair against injury and damage, the HEKA Patient Chair may only be operated by, or under supervision of dental professionals.

To avoid injuries to the operator and patient, ensure the patient is seated correctly in the HEKA Patient Chair before moving it.

Maintain a clear view of patient and chair, to ensure the best ergonomic position possible during treatment.

Before moving the HEKA Patient Chair into a different position, check that the area is clear of any obstructions.

Position of the operator

The intended positioning of the operator for the HEKA Patient Chair is next to the headrest, facing the
chair and patient for optimal overview. This allows the operator to guide the patient into the correct position before moving the chair to the next position.

Position of the patient

The intended positioning of the patient with their hands resting on their abdomen or on the armrest, if these are installed, especially during chair movement to minimize any risk of pinching or collision.

Warning signals and emergency stop

The HEKA Patient Chair is equipped with safety systems in the backrest and on the leg rest, to protect against injuries and mechanical damage.

Stopping chair movement

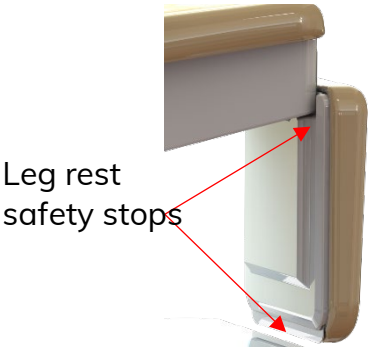
Chair movement to a programmed position can be stopped by activating the joystick in any of the four directions.

Safety stop: Backrest

A safety stop is implemented in the bottom of the backrest to preventing the backrest to move towards the seat in case of a collision. The backrest can be moved away from the seat manually using the backrest keyboard.
The chair can be operated normally again when the backrest is cleared of collision, but the movement curve is affected by the adjustment of the backrest.

Safety stops: Leg rest

Two safety stops are implemented in the leg rest to preventing the leg rest to move towards the seat and floor in case of a collision. The leg rest can be moved away from the seat and floor manually using the joystick. The chair can be operated normally again when the leg rest is cleared of collision.



Limit stops

The HEKA Patient Chair is equipped with a limit stops to prevent excessive strain on the chair's mechanical components. When the limit stop is reached, the motor cuts out and the chair can be moved in the opposite direction.

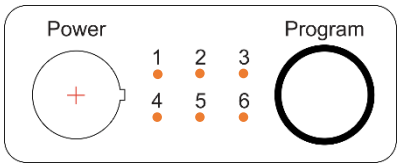
Starting up the HEKA Patient Chair

Toggle the main power switch at the back of the chair seat to switch the chair on and off.
The chair will play a tune if is in stand-alone mode.

Calibration

The first time the chair is powered on, it should run a calibration of the limit positions, this is normally done during installation and should only be done again in case of service or maintenance.
To calibrate the HEKA Patient Chair, remove the seat upholstery and ensure the seat is in the approximated Trendelenburg position (angled), then power the chair on while holding the program button.
The program button can be released when the chair starts to move.

If the seat is in the horizontal position, the chair cannot calibrate, and all 6 LEDs will light orange for 1 second.
Use the seat release handle at the back of the seat to move it into the angled position and retry calibration.



Operating introductions

If the equipment does not start as described below
- contact an authorized Heka Dental dealer immediately.

HEKA Patient Chair functionality

The HEKA Patient Chair is designed to comfortably support the patient during every step of a procedure and to assist practitioners in their work.
The chair consists of a seat on a height adjustable column with a reclinable back support and leg rest to support the patient's body from a sitting- to supine position. The angles of back- and leg rests are mechanically coupled and permits the chair to become a flat surface.
The default seating position is tilted back at a 7,5° angle and the back reclining range permits an approximated Trendelenburg position. A manual seat angle release handle permits a horizontal positioning of the supine patient intended for surgical procedures.
The backrest includes an automatic, motorised height adjustment to accommodate every patient height and includes a user operated fine adjustment option.
The three default patient heights programmed in the backrest keyboard are 160cm (5'3"), 178cm (5'10") and 190cm (6' 3") the movement curve will adapt to any adjustments made to the height of the backrest keeping the rotational point as reference.

The headrest can be adjusted to a height, depth, and angle to provide access for a wide range of procedures.
Height is adjusted by sliding the headrest in or out, depth and angle by loosening the locking lever while supporting the patient's head, adjusting to desired position and returning the locking lever firmly to the locked position.

The optional armrests provide support for the patient during entry and exit of the chair and reassurance during the procedure. The armrests can be rotated away for easier chair access.

Surfaces supporting the patient are made from biocompatible artificial leather (brand etc.?) built on a sturdy and durable steel & aluminium frame with protective plastic covers. Armrests are closed-cell PUR foam over a steel & aluminium structure.

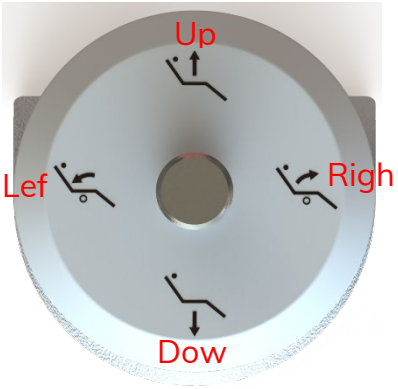
Installed as part of a complete Heka dental delivery system

For the chair to work properly with the HEKA unit, the unit's firmware version must be 1.5.1 or later.
Chair positions are stored in the Heka dental delivery system and the chair can be controlled from both the joystick on the chair base as well as remotely from the Heka dental delivery system.
As default, chair movement will be blocked when an instrument is selected, or the spittoon rotated out, until all instruments and the spittoon have been returned to their resting positions.

See the user manual for the individual dental delivery systems for details on remote chair controls.

The LED indicators on the back of the seat is used for error codes, which will be shown in red.

Programming chair positions in unit mode
As the chair positions are stored in the dental delivery system, the programming of the chair is done using the Heka One Connect or by pressing the programming button while tapping the joystick to the position you want to save the chair's position in.
To store the new positions, press icon on the instrument table display.



Loss of communication

In case of loss of communication between dental delivery system and patient chair, the chair will only allow the seat to be lowered by pressing and holding the program button while pressing and holding the joystick in the down position.

Stand-alone

A total of 6 operator profiles can be stored in the chair each with up to four pre-programmed chair positions.
Pressing the program button on the back of the seat toggles between operator profiles.
A blue light in the LED indicators will tell which profile is currently active.

Programming chair positions in stand-alone mode
Programming the chair in stand-alone mode is done by manually moving the chair into the position, then press and hold the program button while tapping the joystick to the position you want to save the current chair position in.

Up to four chair positions can be stored for each of the six user profiles depending on the setup. Last position will take up a program position.

The LED indicators on the back of the seat are also used for error codes, which will be shown in red.

Description of the joystick

The joystick is used to activate chair movement.
To move the chair manually, press and hold the joystick in the direction you want the chair to move.

To move the chair to a pre-programmed position, tap the joystick to the position required, and the chair will move automatically to the stored position.

The chair can be equipped with up to 3 joysticks to make adjustments easier.
For example, the backrest and seat can be activated simultaneously.

Elevating the seat

Pressing the joystick upwards will cause the seat to be elevated, to stop the movement, release the joystick.
The chair will stop automatically if the limit is reached.

Lowering the seat

Pressing the joystick downwards will cause the seat to be lowered, to stop the movement, release the joystick.
The chair will stop automatically if the limit is reached.

Declining the backrest

Pressing the joystick to the left will cause the backrest to recline, to stop the movement, release the joystick.
The chair will stop automatically if the limit is reached.

Inclining the backrest

Pressing the joystick to the right will cause the backrest to incline, to stop the movement, release the joystick.
The chair will stop automatically if the limit is reached.

Moving to a pre-programmed position

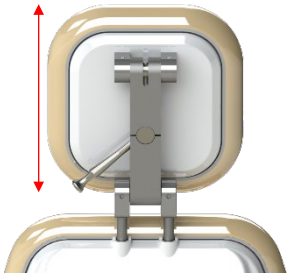
The chair can be programmed with up to four positions for each user profile or treatment, in addition to rinse position if installed with a Heka Dental Delivery System.

To move the chair to one of the pre-programmed positions, tap the joystick to the required program position. To stop the chair from moving, tap the joystick in any of the four directions.

The chair is pre-programmed with four positions from the factory. Once installed, the programs can be modified to suite the operator's needs at any given time.

Adjusting the height of the headrest

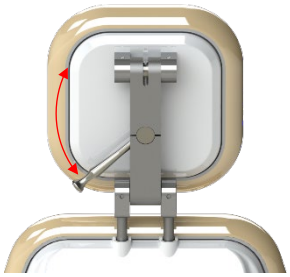
The height of the headrest can be adjusted manually by pulling or pushing it to the required height.



Caution! Fingers may get caught between the headrest and the backrest.

Adjusting the position of the headrest

The position of the headrest can be adjusted by pulling the handle away from the backrest.

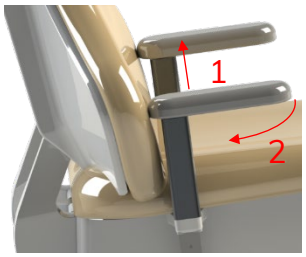


After the headrest has been adjusted, it must be locked into position by pushing the handle towards the backrest.

Caution! Fingers may get caught between the headrest plate and the neck clamp.

Operating the armrest

The armrest on the HEKA Patient Chair is an accessory which can be installed at any given time. The armrest can be swivelled away from the chair by lifting it upwards and rotating the handle, to make it easier for the patient to get in and out of the chair.



Adjusting the angle of the seat

The angle of the seat can be adjusted by pulling the seat angle release handle on the back the seat. Applying pressure on the seat with the handle pulled, will allow the seat to be set in a horizontal position. if the chair seat is within 50mm of the bottom of the movement range for the angled seat position, the seat will be elevated an additional 50 mm.

The horizontal position may be an advantage when treating children.

Pulling the seat angle release handle without pressure on the seat, will allow it to move into the angled position. If the chair seat is at the bottom of the movement range for the surgical seat position, the seat will be lowered an additional 50 mm.

Ergo suction stop

Suction stops can be placed in the same positions as the Joystick.

The Ergo Suction Stop makes it easy to switch the suction on or off during the treatment by means of a foot control, which is mounted on the base plate of the chair.
The suction is interrupted while pressure is applied.

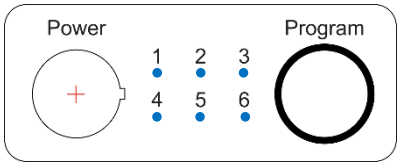
Status, warnings and error indications

The LEDs on the back of the seat are also used for status and error indications.

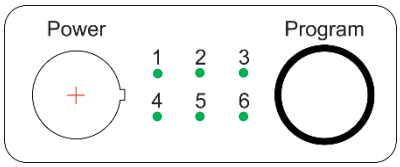
The below list shows the status and errors the chair can show.

Status indications

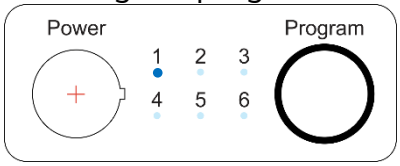
Unit mode: Unit is ON
All six LEDs are illuminated blue.
The chair is connected to a dental delivery system, which is switched on.



Unit mode: Unit is OFF
All six LEDs are illuminated green.
The chair is connected to a dental delivery system, which is switched off.



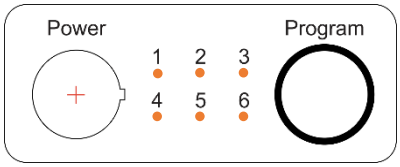
When the chair is in stand-alone mode, it can store chair positions for up to 6 operators.
The LED is illuminated blue to show which operator profile (1 – 6) is currently active.
Pressing the program button allows for switching between operator profiles.



Seat angle “not correct” for calibration

If the seat is in the horizontal position, the chair cannot calibrate, and all 6 LEDs will light orange for 1 second.

Use the seat release handle at the back of the seat to move it into the angled position and retry calibration.

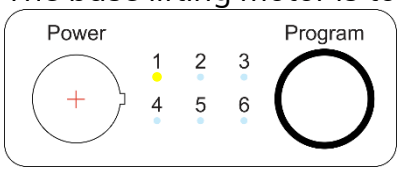


Warning indications

Base motor driver overtemperature

LED 1 is illuminated yellow.

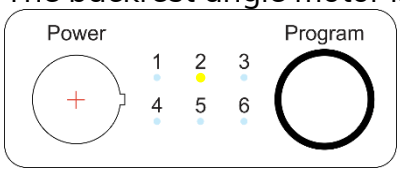
The base lifting motor is too warm and need time to cool down.



Backrest angle motor driver overtemperature

LED 2 is illuminated yellow.

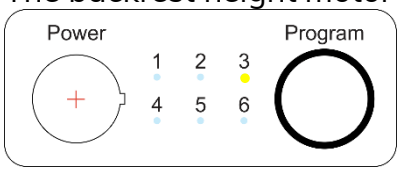
The backrest angle motor is too warm and need time to cool down.



Backrest height motor driver overtemperature

LED 3 is illuminated yellow.

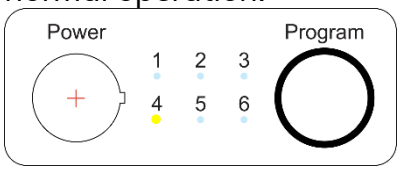
The backrest height motor is too warm and need time to cool down.



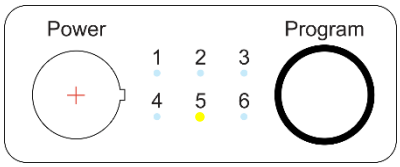
Safety stop active

LED 4 is illuminated yellow.

One of the three safety stops have been activated, remove any obstacles to continue normal operation.

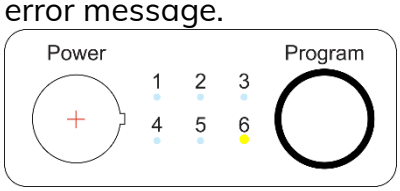


Emergency “stop” active
LED 5 is illuminated yellow.
The emergency stop has been activated, remove the obstacle and power the chair off and on to continue normal operation.



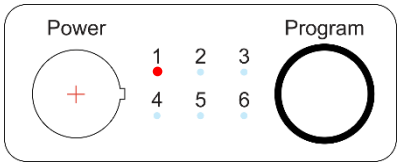
Emergency movement active
The chair movements are disables when the chair loses communications to a dental delivery system to reduce risk of collision with for example a rinsing bowl.

The seat can be lowered with an emergency movement which is activated by pressing the joystick downwards for 5 seconds. The seat motor will continue to move downwards until the joystick is released or the seat reaches the lowest possible position.
NOTE: it is the operators’ responsibility to ensure that the chair does not collide with any obstructions during the emergency movement.
During the emergency movement LED 6 will be illuminated yellow. Once the emergency movement is stopped, the chair will display the previous status, warning or error message.

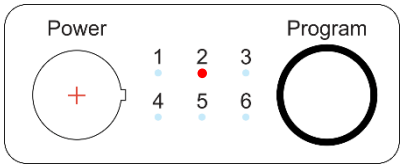


Error indications
When an error is shown, please contact a certified Heka technician.

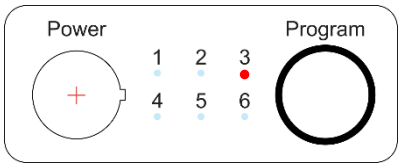
Base motor driver fault
LED 1 is illuminated red.



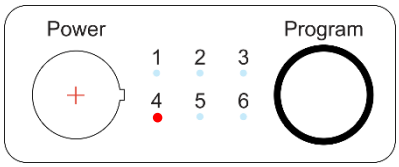
Backrest angle motor driver fault
LED 2 is illuminated red.



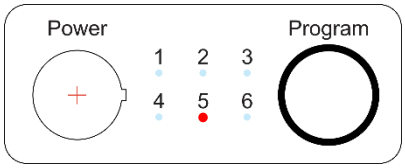
Backrest height motor driver fault
LED 3 is illuminated red.



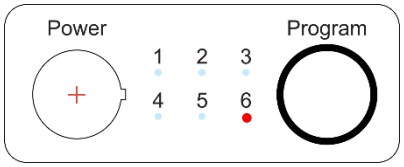
DIP setting (bad DIP setting/detecting unexpected connection compared to DIP setting)
LED 4 is illuminated red.



Communication error (protocol/HW peripheral)
LED 5 is illuminated red.



Other faults (from on-board ICs, i.e., 5V out, 5V telescope, LED driver, etc.)
LED 6 is illuminated red.



Cleaning & Disinfection

This section contains information about how to clean and disinfect the HEKA Patient Chair.
For detailed information about cleaning, disinfection and sterilization of OEM equipment and instruments purchased for use with HEKA Patient Chair, please refer to the OEM documentation.

The Centre for Disease Control and Prevention (CDC) recommends the use of an EPA-registered chemical antibacterial hospital disinfectant, intended for use on tuberculocidal activity surfaces contaminated by patient materials.
In accordance with these guidelines, we recommend disinfection between patients. Dürr FD333, Sani-Cloth AF3 or similar may be used. It is important to follow the manufacturer's instructions to ensure effective disinfection.

Cleaning & Disinfection of external clinical contact surfaces

The following is a list of external clinical contact surfaces:

- Base
- Column
- Backrest
- Seat
- Leg rest
- Joystick
- Suction stop
- Telescopic Suction Arm
- Suction hose Holder
- Suction Hoses

External surfaces of the device should be cleaned and then disinfected.

FIRST, CLEAN
Wipe using a soft cloth moistened with mild detergent or disinfecting solution at the beginning and end of each workday and if visibly soiled. Take Care to avoid running water and splashing during cleaning of the unit surfaces.

SECOND, DISINFECT
After cleaning, disinfect between patients using Sani-Cloth AF3, Dürr FD366 or Clinell Universal wipes.
ALWAYS follow the manufacturer instructions for use.

Cleaning & Disinfection of the chair upholstery and armrests

Do not use the detergents included in the following list as these could damage the device components:

- Acetone
- Ethanol
- Disinfectants containing halogens
- Perchloroethylene
- Powder cleaning
- Sulphuric detergents
- Tetrachloroethylene
- Trichloroethylene
- Wax polishing agents

Cleaning:
Wipe all surfaces using a Sani-Cloth AF3, Dürr FD 366 cloth or Clinell Universal wipes at the beginning and end of each workday, and between patients. Inspect and repeat this process if any visible impurity or residue is present. Discard the Sani-Cloth used for cleaning. For stains, alcohol-based cleaners such as Dürr FD 360, Fantastik® and Formula 409® can be used. To sanitize, use a 1:5 solution of bleach and water. Rinse with clean water to remove cleaning solution residue. Allow to air dry.

Disinfection:
Disinfect after cleaning using a fresh Sani-Cloth AF3, Dürr FD 366 or Clinell Universal wipes. Ensure the surfaces remain wet for the full three minutes. It is crucial that the Sani-Cloth AF, Dürr FD 366 or Clinell Universal wipes manufacturer instructions are followed to ensure effectiveness.

Annual service

To ensure continues high reliability and functionality in accordance with the specifications, the equipment must be checked annually by an authorised service technician.
Furthermore, this is a prerequisite for the factory warranty.

No parts of the Dental delivery system should be serviced or maintained while in use with a PATIENT!

Printed and electronic information

The information is delivered with the equipment and is also available to authorized Heka Dental service technicians.

Please contact our technical department for further information or an authorized Heka Dental dealer.

Heka Dental A/S, Litauen Alle 4, DK-2630 Høje Taastrup.
Tel.: +45 43320990, Fax: +45 43320980, heka-dental.com

Technical guidelines – only for authorized technicians

Technical data

Voltage	230V or 115V
Rated frequency	50 or 60 Hz
Power consumption	4 or 8 Ampere
Protective level	Type B applied parts
Classification	Class I (protectively earthed equipment)
IP classification	IP20
Operating mode	Continuous operating with intermittent load
Intermittent use, motor	30 sec. ON/ 270 secs. OFF
Fuse	230V : T5A H250VAC 5x20mm
Max load capacity	440.9 lbs / 200 kg
Mass of patient chair	209 lbs / 95 kg
Temperature and humidity: During operation Storage/transport condition	During operation: 10° C to 35° C, non-condensing air humidity from 20 to 75%, pressure 800 hPa to 1060 hPa. Max height: up to 2000m 10° C to 40° C, non-condensing air humidity from 50 to 80%, pressure 500 hPa to 1060 hPa.
Accessories	Armrest (one or two can be installed). Type B applied part. Upholstery. Type B applied part. Telescopic arm Autonomous suction Ergo suction Joystick Hanger for foot control

Components & Performance Specifications

Components:	Chair Controller PCB Motors (Backrest, Seat) Emergency stop Safety Stop (Backrest, leg rest) Chair Base Headrest Backrest Armrest
Materials:	Structured steel, aluminium and plastic Continental Skai® Evida orToronto
Dimensions: Chair Length Chair Height Base Length Base Width	 69.5” – 75,4”/1765mm – 1915mm 20” – 40.1”/510mm – 1010mm 27.2”/690mm 19.3”/490mm
Performance Specifications: Weight Load: Range of vertical motion: Backrest to Seat: Seat Angle: Headrest Tilt: Programming Capabilities: Safety Stops: Emergency Stop:	 200 Kg/440.9 lbs Approximated Trendelenburg :410/+500 mm Horizontal seat: 460/+500 mm Minimum 105°/Maximum 180° 7.5˚/0˚ Minimum 180°/Maximum 270° Four preprogrammed positions Backrest: Upon touching obstruction on bottom Leg rest: Upon touching obstructions on back and bottom Plate on top of base plate

Possibility of contact with parts occurring

Part	**Operators contact duration**	**Patient contact duration**	**Comment**
Chair Upholstery (applied part)	N/A	10 min =< t 43	Can be in patient contact during treatment, max 43°C
Chair Enclosure, metal	1 s =< t < 10 s 56	T < 1 min 51	Is touched by the operator for moving the table in position, max 51°C

DIP switch settings

Switch	ON	OFF
1	CAN termination ON	CAN termination OFF
2	Reserved	Reserved
3	Connected to Heka+	Standalone mode
4	Last Position ENABLED	Last Position DISABLED
5	Last Position UP	Last Position DOWN
6	Reserved	Reserved

CAN bus termination
Only in case both CAN bus connectors are used switch 1 is OFF, else switch 1 must be ON.

UNIT/Stand-alone mode
If the HEKA Patient Chair is connected to a Heka S+ or G+, switch 3 must be ON. If the HEKA Patient Chair is used as stand-alone, this switch must be OFF.

Last position in stand-alone mode
If the chair is used in stand-alone mode, the Last Position feature is enabled when switch 4 is ON. If the chair is not in stand-alone mode, then switch 4 is ignored.

Last position joystick direction in stand-alone mode
If the chair is used in stand-alone mode and switch 4 is ON, Last position can be reached by pressing the joystick short UP is the switch 5 is ON, or short DOWN is the switch 5 is OFF. If the chair is not in stand-alone mode or switch 4 is OFF, then switch 5 is ignored.

Reserved switches
Reserved switches must be OFF.

Calibration sequence
Whenever a component is replaced, or the software updated, it is important to make a calibration of the motion range of the chair.
The calibration updates the limit positions and thus ensures that chair positions are accurate.

Ensure the seat is in the approximated Trendelenburg (angled) position before starting the sequence.

The calibration is initiated by holding the program button while powering the chair on.

During the calibration, the chair will move to all limit positions.

The chair will then recalibrate the system settings. After completing the calibration, the chair will return to the normal function.

Installation requirements

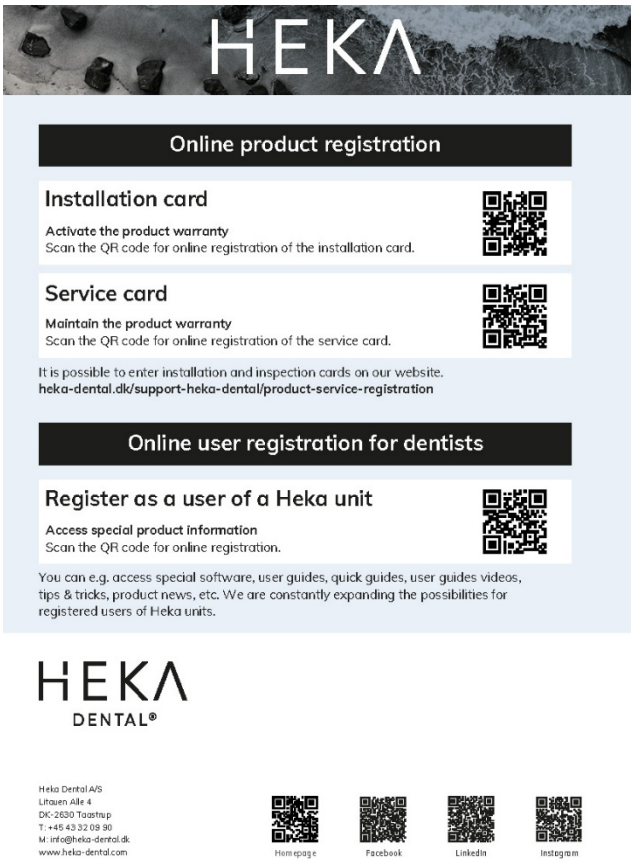
For positioning of the patient chair, please refer to the ground plan in the installation manual.

1. 230 Volt/115 Volt +/- 10%, 50/60 Hz, with earth. Branch fuse 4A/8A.
2. Place for installation of the patient chair should be concrete, ceramic tile or other non-flammable material.
3. Temperature and humidity:
   During operation: 10° C to 35° C, non-condensing air humidity from 20-75%, pressure 800 hPa - 1060 hPa.
   Storage/transport condition: 10° C to +40° C, non-condensing air humidity from 50-80%, pressure 500 hPa - 1060 hPa.

Warning! To avoid electric shock, the patient chair must only be connected to a mains supply with protective earth.

Installation/Service card

A physical version of the installation/service card is included with the manuals.



<u>Attention:</u>

Warranty is only valid if the Dental Delivery System is serviced annually with recommended service kits and the installation/service cards and service-kit serial-numbers are submitted to Heka Dental A/S.

Regulatory Standards Compliance

Standard:	Title:
IEC 60601-1 :2006 IEC 60601-1/ corr.1 :2008 IEC 60601-1/corr.2 : 2008 IEC 60601-1/A1 :2012 DS/EN 60601-1/AC :2013 DS/EN 60601-1/A1 :2013 DS/EN 60601-1/A12 :2014 DS/EN 60601-1:2006/A2:2021	Medical electrical equipment General safety w. corrections A1
DS/EN 55011:2016 DSF/EN 55011:2016/prAB DSF/prEN IEC 55011:2023	Industrial, scientific and medical equipment – Radio frequency disturbance characteristic.
DS/EN ISO 20417 :2021	Information supplied by the manufacturer of medical devices
DS/EN 1640:2009	Dentistry – Medical device for dentistry - equipment
S/EN ISO 14971:2019 DS/EN ISO 14971:2019/A11:2021	Medical device – application of risk management to medical devices
DS/EN ISO 7493	Dentistry Chairs
DS/EN ISO 7494-1:2018	Dentistry Dental units and Patient Chairs Part 1: General requirements.
DS/EN ISO 7494-2:2022	Dentistry Dental units Part 2: Air, Water, Suction and waste system
DS/EN ISO 1942:2020	Dentistry - Terms
DS/EN ISO 9687:2015 + A1:2018	Dentistry Graphical symbols
DS/ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
DS/ISO 10993-5:2018	Biological evaluation of medical devices - Part 5: Test for in vitro cytotoxicity
DS/ISO 10993-10:2018	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
DS/EN 60601-1-2: 2015 + A1:2021	Medical electrical equipment- Part 1-2: EMC

EN 62304 EN 62304_2006_A1_2015	Medical device software – software life cycle + A1
EN ISO 15223-1:2021	Medical equipment, Symbols to be used with medical device labels
IEC 60601-1-6 :2010 DS/EN 60601-1 :2010/A1 :2015 DS/EN 60601-1 :2010/A2 :2021	Medical electrical equipment – Part 1-6: General Requirements for basic safety and essential performance – Collateral standard: Usability
IEC 62366-1 :2015 DS/EN 62366-1 :2015/AC :2015 DS/EN 62366-1 :2015/AC :2016 DS/EN 62366-1:2015/A1:2020 DS/IEC TR 62366-2:2016	Application of usability engineering to medical device
EN ISO 21530:2004	Dentistry – Materials used for dental equipment surfaces – Determination of resistance to chemical disinfectants

Warranty Terms & Conditions

Warranty applicable to HEKA dental delivery systems and patient chairs.

- The equipment is covered by a 24-month warranty (from the installation date) on the conditions that the equipment has been installed by an authorized Heka Dental dealer/technician and an annual service check is performed 12 months after installation.
- Annual service checks must be performed by an authorized Heka Dental technician using an original Heka Service Kit
- The installation registration constitutes important documentation that the dentist has been properly instructed in the basics of the new equipment which decreases the risk of incorrect usage and unnecessary reporting of errors.
- The installation registration must be submitted within 15 days of the installation date. This is done online or using the attached registration card.
- The warranty is cancelled if the installation registration or service registration are not submitted to Heka Dental in due time.

Option to extend the warranty:

- Heka Dental offers the option to purchase a warranty extension of up to 7 years from installation date.
- A service agreement covering annual service checks by an authorized Heka Dental technician using original Heka Dental Service Kits is a prerequisite for the warranty extension.
- The warranty extension must be purchased no later than 24 months after the original installation date.
- The extension is valid from registration of the 24-month service at Heka Dental
- All warranty repairs must be performed by an authorized Heka Dental technician.
- The service registrations must be received by Heka Dental within 15 days from the day the annual service check is performed.

The following general terms apply to the warranty:

- Heka Dental does not cover the authorized dealer’s working hours, travel, and lodging expenses on warranty repairs.
- Heka Dental cannot be held liable for defects and consequential damage in the event of failure to use the equipment correctly.
- Heka Dental cannot be held liable for defects and consequential damage caused by wear and tear, incorrect cleaning or maintenance, lack of compliance with operating, maintenance and connection manuals, calcium build-up, corrosion, contaminated air, water supply or chemical and/or electrical factors that are regarded as abnormal or do not accord with the manufacturer’s specifications and instructions.
- The warranty does not cover electrical bulbs/LEDs, glass, rubber parts, instrument hoses, O-rings, chair upholstery or other wearing parts or discoloration of plastic parts.

- OEM products (instruments, instrument accessories, handpieces, suction systems (separator, separator drain pump, central suction, tubing system, etc.), amalgam separators, separators, water purification systems etc.) which are not proprietary Heka Dental products are covered by the manufacturer's 12- or 24-month warranty – please see the individual manufacturers websites for information on warranty terms.
- Defects and consequential damage that can be attributed to the Heka Dental authorized dealer or modifications made to the product by third parties are not covered by warranty.

Exchangeable parts

To provide our customers with a fast and efficient service after the end of the warranty period, Heka Dental offers several exchangeable parts at a fixed repair price outside the warranty. These only apply to equipment being serviced (standard service and annual service) by an authorized Heka Dental dealer. Original Heka Dental parts must be used for both standard services and annual services.

IFUs and Label Language Requirements

Country	IFUs and Label Language Requirements	
	Used by trained professionals	Used by non-professionals
Austria	German	German
Belgium	Dutch German French	Dutch German French Note: All three must be used for patient instructions.
Bulgaria	English and Bulgarian	Bulgarian
Croatia	Croatian	Croatian
Cyprus	English and Greek	Greek
Czech Republic	Instructions for use must be in Czech language for public use; for the professional use information required for the safe use of the product must be in the Czech language, all other parts of the User Manuals can be in English (for all MD). User Interface can be in English, provided that the information required for the safe use of the product is included in Czech language into User Manual (or into another document available for the user.)	
Denmark	Danish	Danish
Estonia	Estonian	Estonian
Finland	English Finnish Swedish	Finnish Swedish
France	French	French
Germany	German	German
Greece	Greek	Greek
Hungary	Hungarian	Hungarian
Iceland	Icelandic Note: For the professional user other languages are accepted (e.g., Swedish, Danish, Norwegian, German, English).	Icelandic
Ireland	English	English
Italy	Italian	Italian
Netherlands	Dutch	Dutch
Norway	Norwegian	Norwegian
Poland	Polish	Polish

EMC Information

Guidance and manufacturer's declaration – electromagnetic emissions
The Dental Delivery System is intended for use in the electromagnetic environment specified below. The customer or the user of the Dental Delivery System should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	Dental Delivery System uses HF energy only for its internal function. Therefore, its HF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Dental Delivery System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic emissions
The unit is intended for use in the electromagnetic environment specified below. The customer or the user of the unit should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment- guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	± 2/4/6 kV contact discharge ±2/4/8 kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge According to IEC 61000-4-5	± 1 kV push-pull voltage ± 2 kV common mode voltage	± 1 kV push-pull voltage ± 2 kV common mode voltage	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines. IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s (250 periods)	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s (250 periods)	Mains power quality should be that of a typical commercial or hospital environment. If the user of Dental Delivery System requires continued operation during power mains interruptions, it is recommended that the Dental Delivery System be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	NA	NA	The product has not been tested for susceptibility to magnetic fields since the product does not contain components which are sensitive to such fields.
Proximity Magnetic fields	IEC 61000-4-39	9kHz to 13,56 MHz	
NOTE: U_T is the a.c. mains voltage prior to application of the test level			

Guidance and manufacturer's declaration – electromagnetic emissions			
The unit is intended for use in the electromagnetic environment specified below. The customer or the user of the unit should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment- guidance**
Wire-based HF interference according to EN 61000-4-6 Wireless HF interference according to EN 61000-4-3	3 Veff 150 kHz to 80 MHz outside the ISM bandsa 3 V/m 80 MHz to 2.5 GHz	3 Veff 3 V/m	Handheld and mobile wireless devices should not be used at a shorter distance from the unit including cables than the recommended safe clearance calculated using the appropriate equation for the emission frequency. Recommended safe distance: d = 1.17 P d= 1.17 P for 80 MHz to 800 MHz d= 2.33 P for 800 MHz to 2.5 GHz where P is the maximal nominal power of the transmitter in watts (W) as specified by the transmitter manufacturer and d is the recommended safe clearance in metres(m). bThe field strength of stationary wireless radio transmitters as measured locally should be lower than the conformance level at all frequencies. dInterference is possible in the vicinity of devices bearing the following icon. 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and refection from structures, objects and people.			
A The ISM frequency bands (for industrial, scientific, and medical applications) between 150 kHZ and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to13.567 MHz; 26.957 MHz to 27.283 MHz, and 40.66 MHz to 40.70 MHz. b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range from 80 MHz to 2.5 GHz are intended to reduce the probability of mobile/handheld communications facilities causing interference when they are inadvertently introduced into the patient area. For this reason, the additional factor of 10/3 is applied in the calculation of the recommended safe clearances in these ranges of frequencies. c The field strength of stationary transmitters, such as, e.g., base stations of mobile phones and mobile terrestrial radio devices, amateur radio stations, AM and FM radio and television transmitters, cannot be determined exactly based on theoretical considerations. A site study should be considered to determine the electromagnetic environment in terms of stationary transmitters. If the measured field strength at the site, at which the unit is used, exceeds the compliance levels shown above, the unit should be monitored to demonstrate proper function. If any uncommon performance characteristics are observed, additional measures may be required, such as, e.g., changing the orientation or using a different location for the unit. d In the frequency range of 150 kHz to 80 MHz, the field strength should be less than 3V eff V/m.			

Recommended separation distances between Portable and mobile HF communications equipment and unit			
The unit is intended for use in an electromagnetic environment in which radiated HF disturbances are controlled. The customer or the user of unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile HF communications equipment (transmitters) and the unit as recommended below, according to the maximum output power of the communications equipment. Safe distance depending on the transmission frequency:			
Rated power P of the transmitter in W	**Safe distance depending on the transmission frequency in m**		
	150 kHz to 80 MHz d=1.17 P	**80 MHz to 800 MHz d=1.20 P**	**800 MHz to 2.5 GHz d=2.3 P**
0.01	0.12	0.12	0.23
0.1	0.37	0.38	0.73
1	1.17	1.20	2.3
10	3.69	3.79	7.27
100	11.7	12	23

Data on electromagnetic compatibility according to EN 60601-1-2 | 10.4 Immunity to electromagnetic interference.			
Rated power P of the transmitter in W	**Safe distance depending on the transmission frequency in m**		
	150 kHz to 80 MHz d=1.17 P	**80 MHz to 800 MHz d=1.20 P**	**800 MHz to 2.5 GHz d=2.3 P**
U1 = Compliance level according to 4-6: 3 Veff E1 = Compliance level according to 4-3: 3 V/m			
Factor	[3.5/U1]	[12/E1]	[23/E1]

For transmitters whose maximum rated power is not in the above table, the re- commended safe distance d in meters (m) 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.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

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

Disposal of the unit

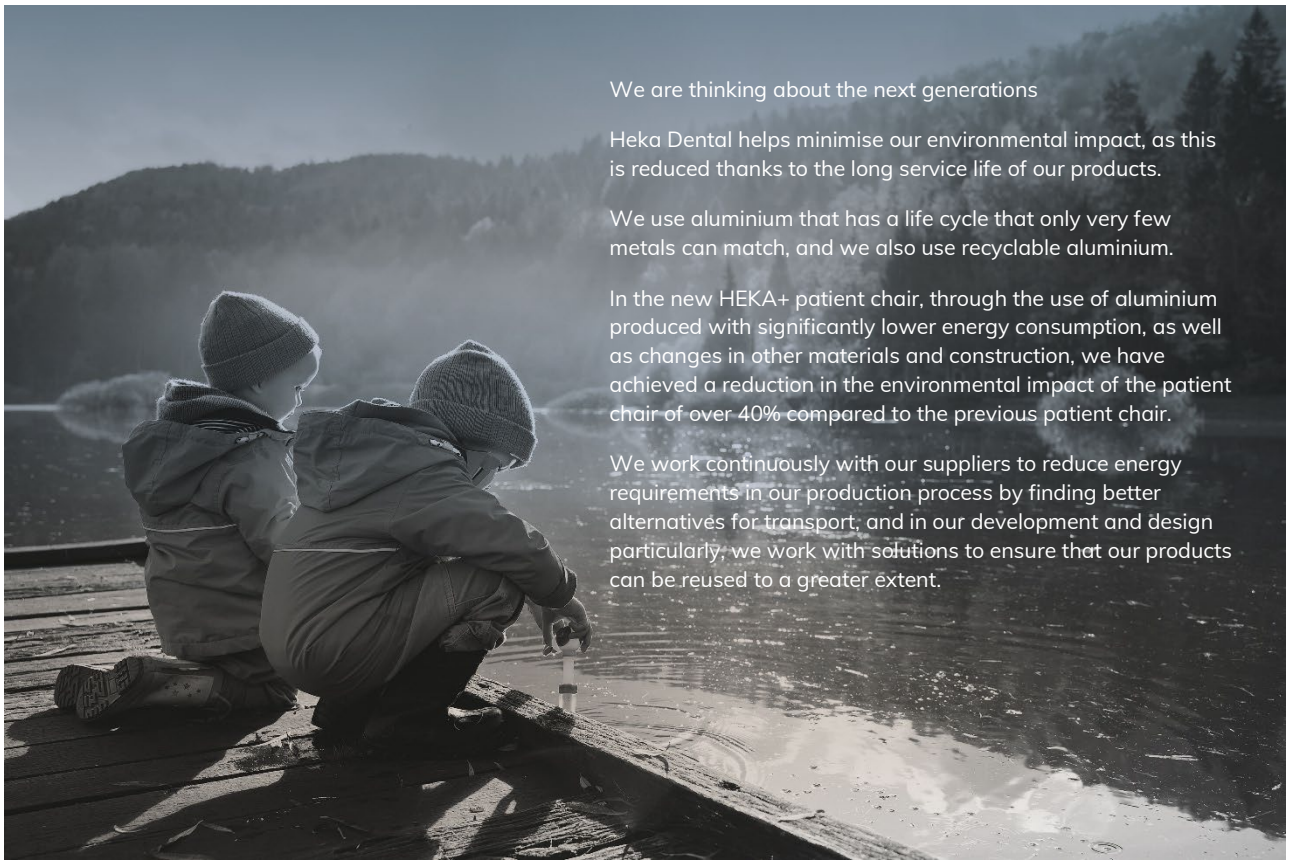
To reduce the environmental impact of the product throughout its lifetime, the device is designed to be as safe as possible to manufacture, use and dispose of. Components suitable for recycling should always be sent to a recycling centre once all hazardous materials have been removed. Obsolete units are disposed of at the owner's own responsibility and risk.
All components and parts containing hazardous materials must be disposed of in compliance with current legislation and the guidelines issued by the environmental authorities. Risks must be considered, and the necessary precautionary measures must be taken when handling waste products.

Part	Primary materials for disposal	Recyclable materials	Environment controlled burning	Landfill waste disposal site	Hazardous waste (separate collection)
Frame and screening					
- Metal	Aluminium				
	Stainless steel	X			
	AISI303/304/316	X			
	Steel	X			
	Galvanized steel	X			
- Plastic					
	ABS / ASA	X			
	PVC	X			
	PE		X		
	(Powder coating)		X		
	PU		X		
	(Powder coating)	X			
	TPE				X
	PUR		X		
	PTFE				X
	Other plastic			X	
	Silicone	X			
Motor		(X)			
Component board		(X)			
Cables, transformers	Copper	X			
	Steel	X			
Packaging	Wood	X			
	Cardboard	X			
	Paper	X			
Other parts				X	

Designed and manufactured in our own factory in Denmark, the HEKA+ Patient Chair reflects our commitment to innovation, craftsmanship, and quality.

Take a behind-the-scenes look at our modern facilities and discover how we are shaping the future of dental units with solutions tailored to your needs.

HEKA
Factory Tour



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