

17th July 2023
meeting
Tous Ergo
Rotating bed



Kleeberg

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Date : 10-07-2023
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Revisie A, 10-07-2023

Orbit



Kleeberg

Medical product

REGULATIONS

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 April 2017

on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

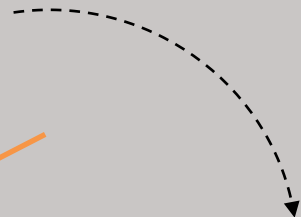
The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

(1) Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24).

MDR: Medical Device Regulation

- Safety



Medical product: standard

Nederlandse norm

NEN-EN-IEC 60601-2-52

(en)

Medical electrical equipment - Part 2-52:
Particular requirements for basic safety and
essential performance of medical beds (IEC
60601-2-52:2009,IDT)

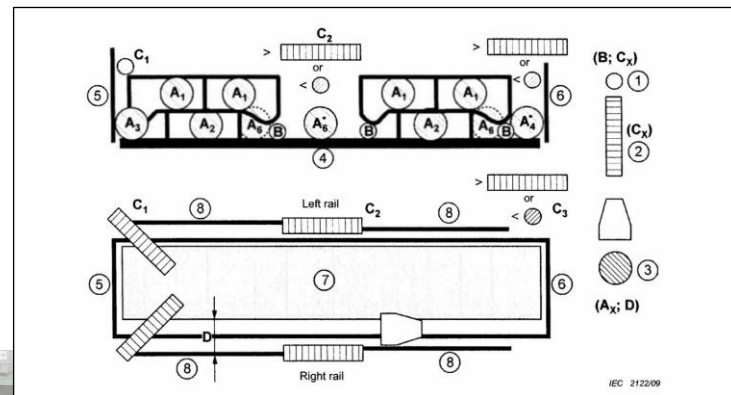
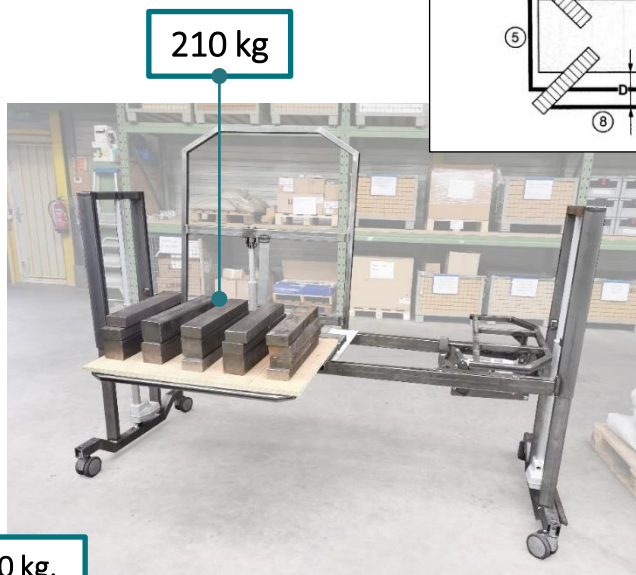
	
M&PRO T: +31 (0) 6 27 85 00 46 E: m.middelkoop@mpro.nl F: +31 24 588 634 G: 7504 AL NL W: www.mpro.nl BTW NL12083653801	
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Medical product

- Safety test EN 60601-2-52
- SWL = 235 kg: $2 \times 235 \text{ kg} = 470 \text{ kg}$
- Max patient = 200 kg



Total test weight= 480 kg.



Rules and regulation side rails

Bed in worst case position. Extra test, not required according by standard

Durability tests



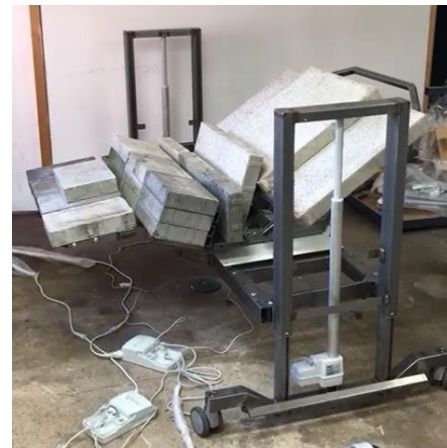
Back section
135 kg



Leg section
Upper leg: 100 kg
Lower leg: 50 kg



Rotation
310 kg



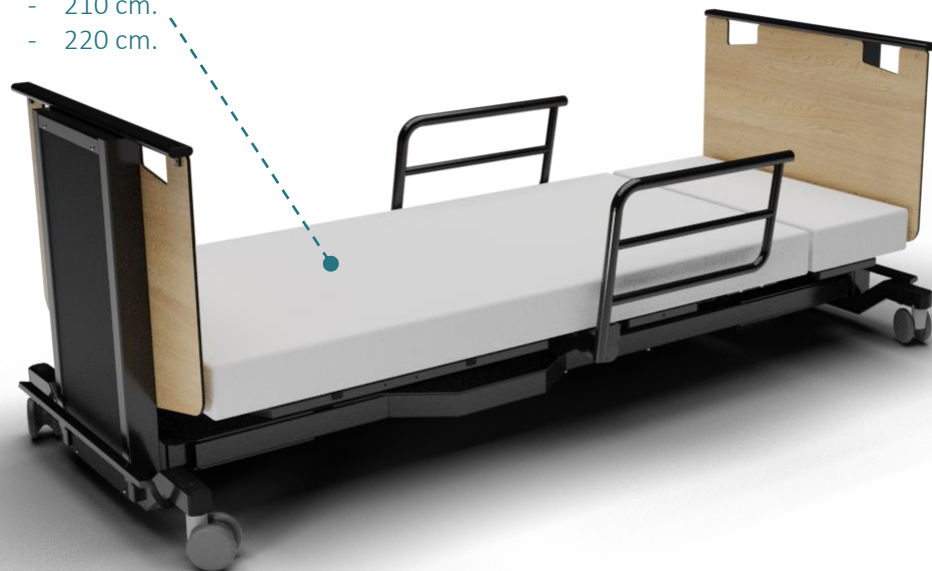
Height adjustment
310 kg

Functions

Bed lengths

Three bed lengths:

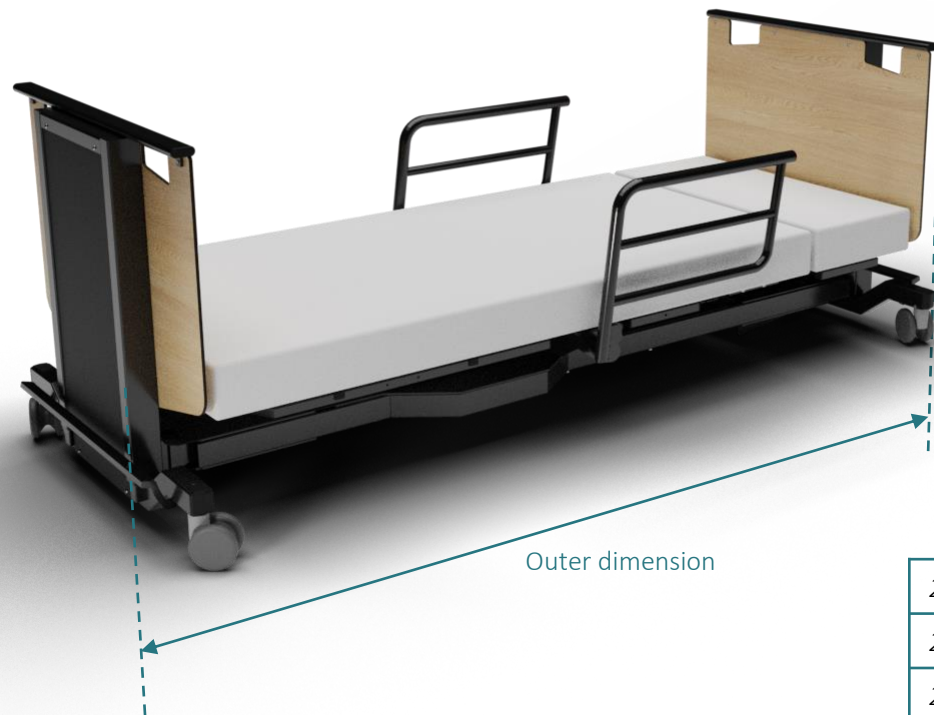
- 200 cm.
- 210 cm.
- 220 cm.



Bed lengths



Bed lengths

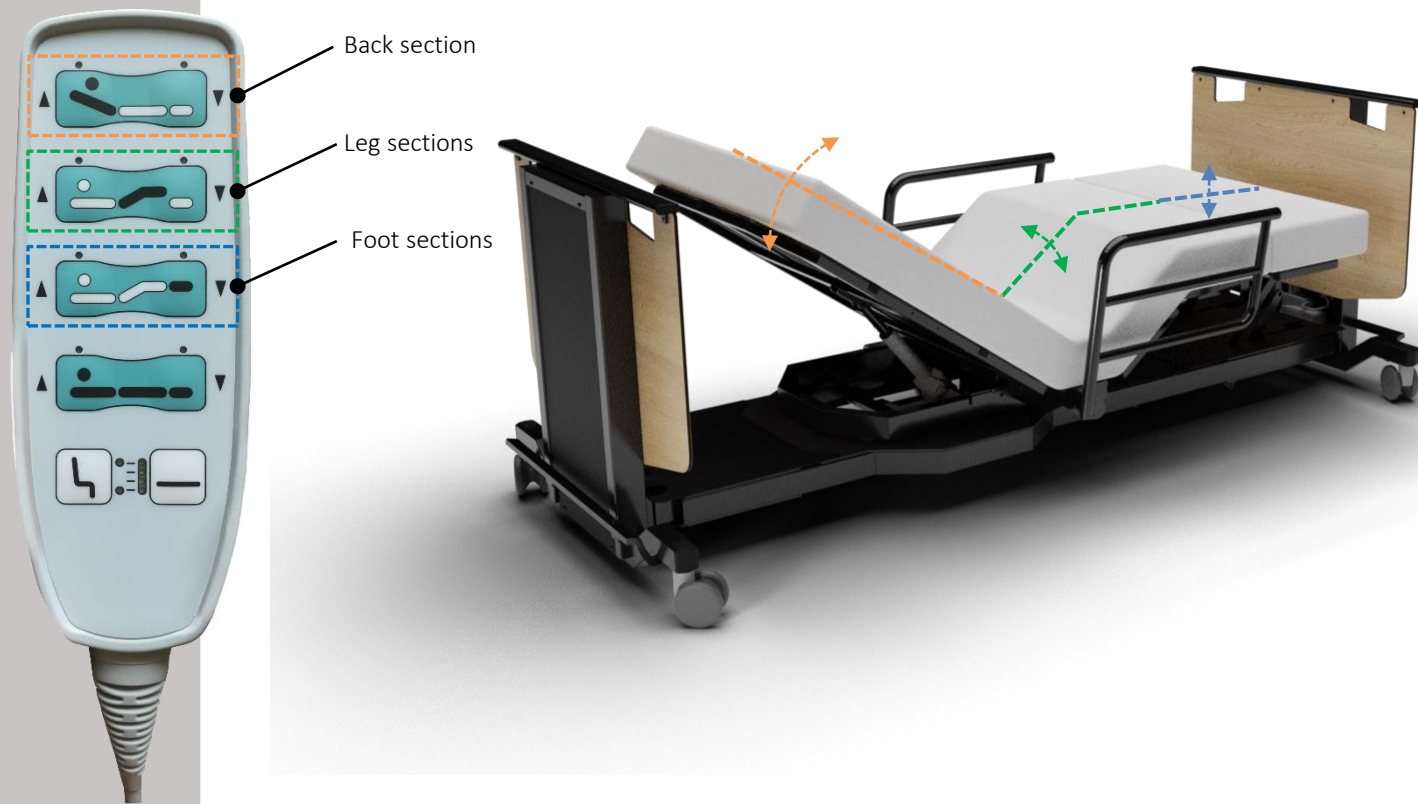


200 cm. Bed	220 cm.
210 cm. Bed	230 cm.
220 cm. Bed	240 cm.

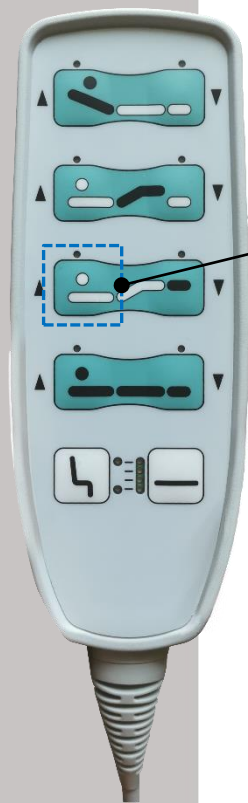
Comfort position



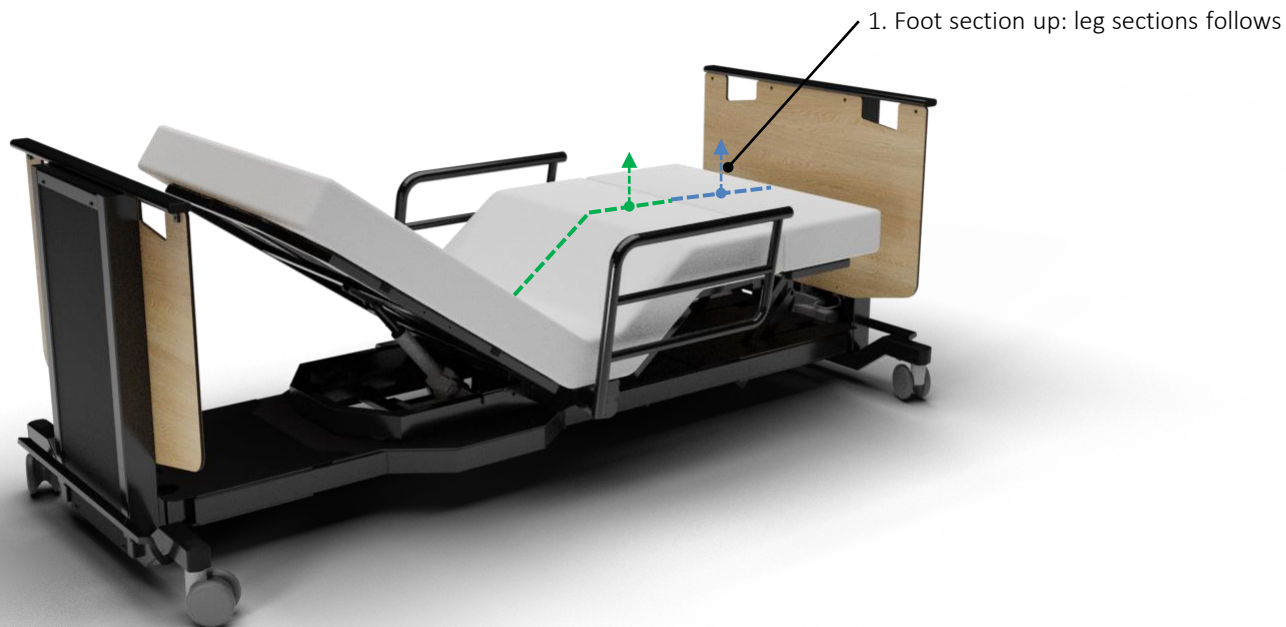
Comfort position



Foot up



Foot sections

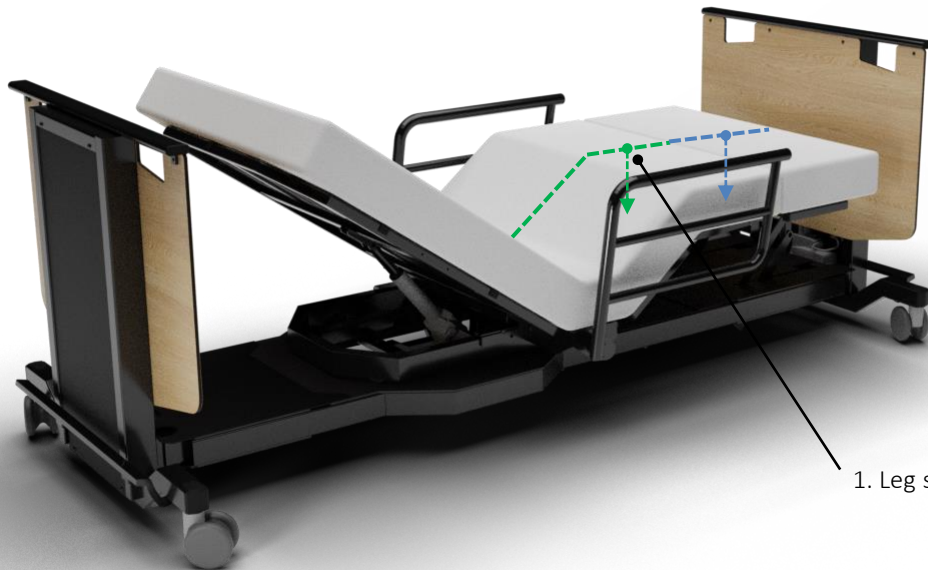


1. Foot section up: leg sections follows

Leg sections down

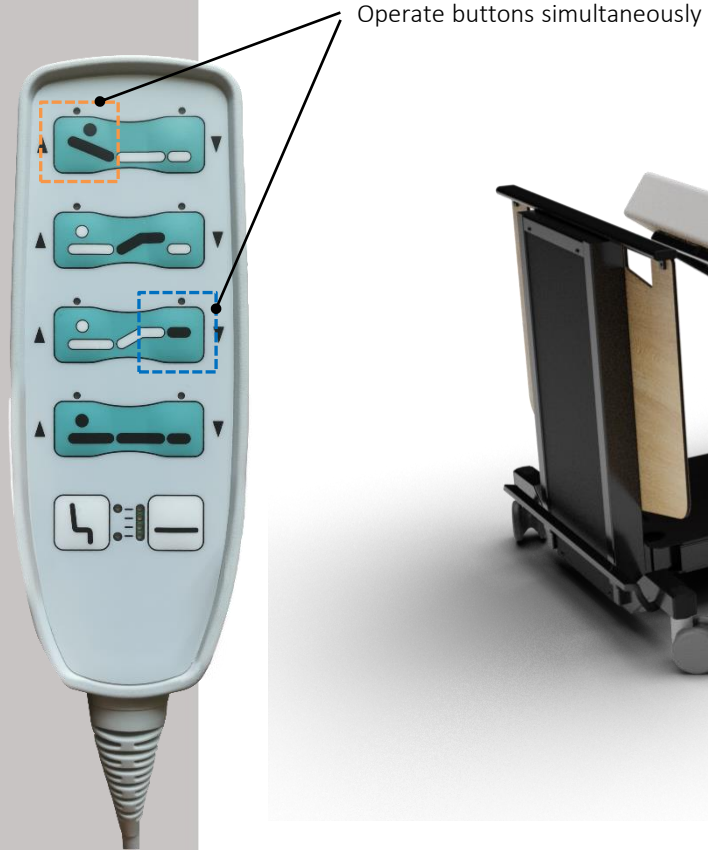


Leg sections

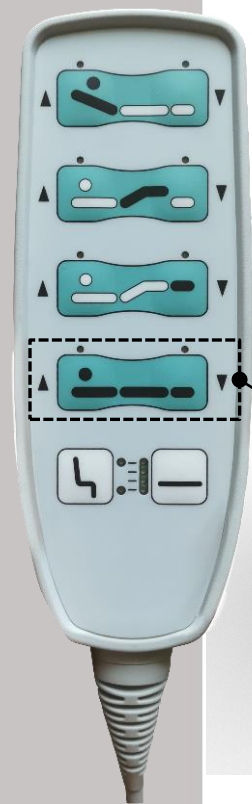


1. Leg sections down: foot section follows

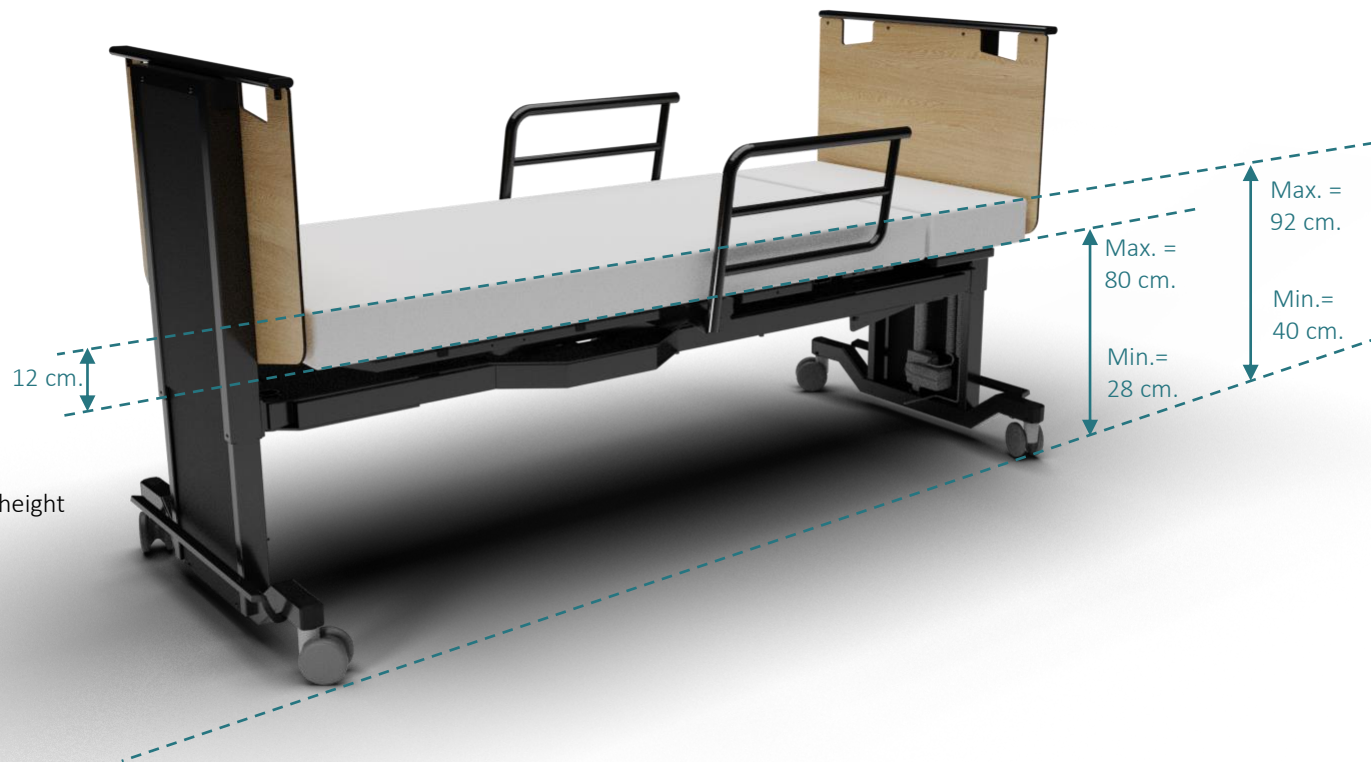
Operate buttons simultaneously



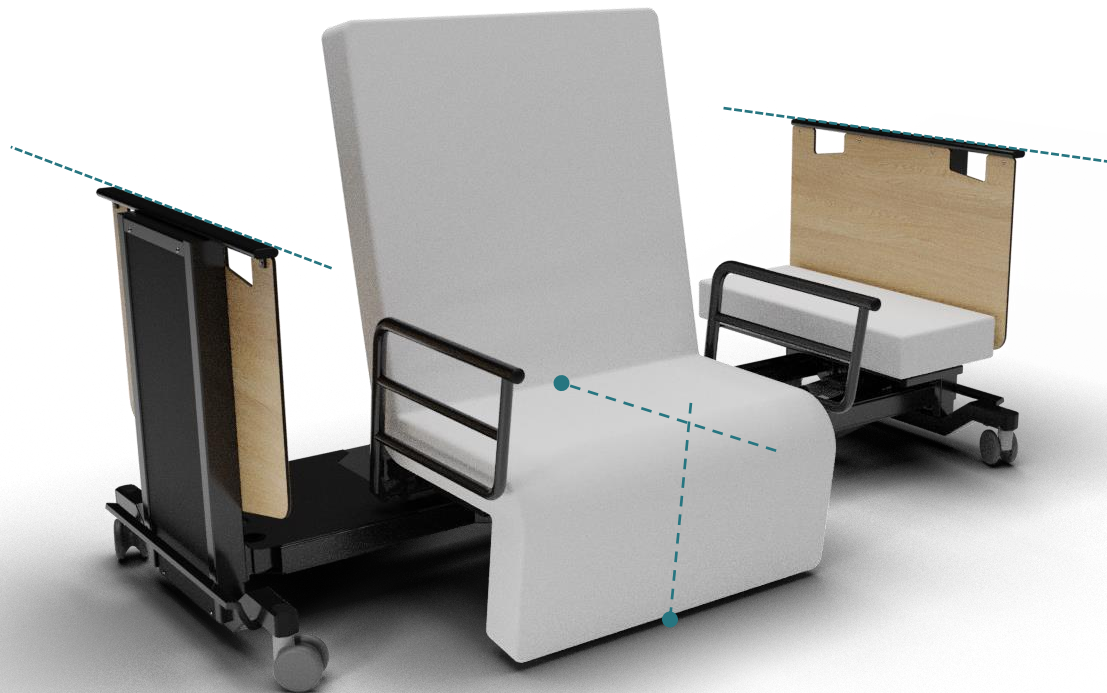
Nursing height



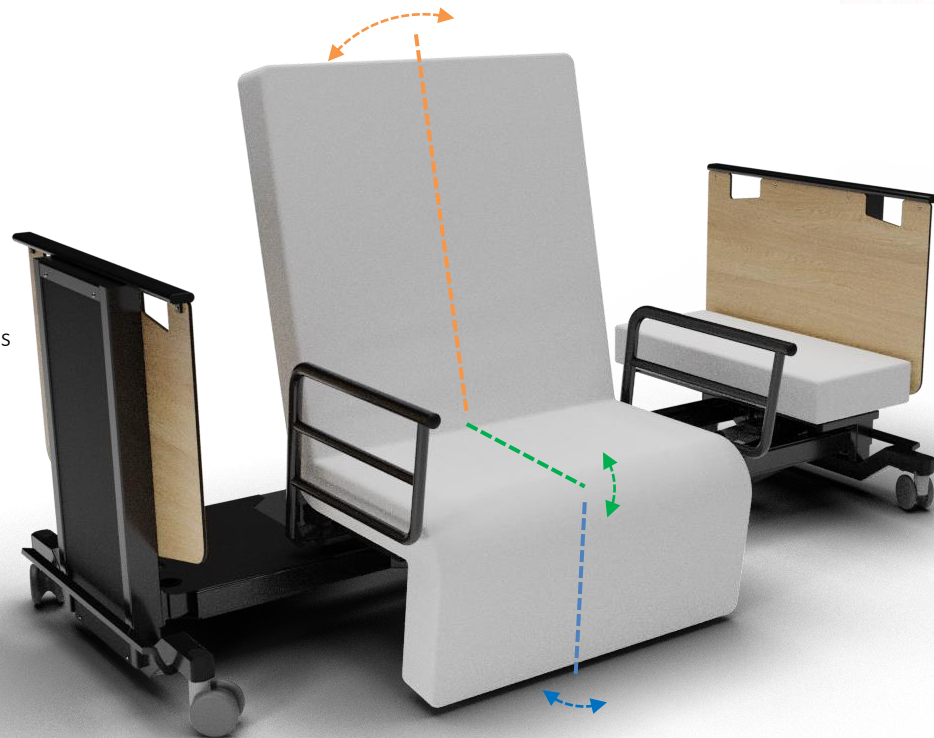
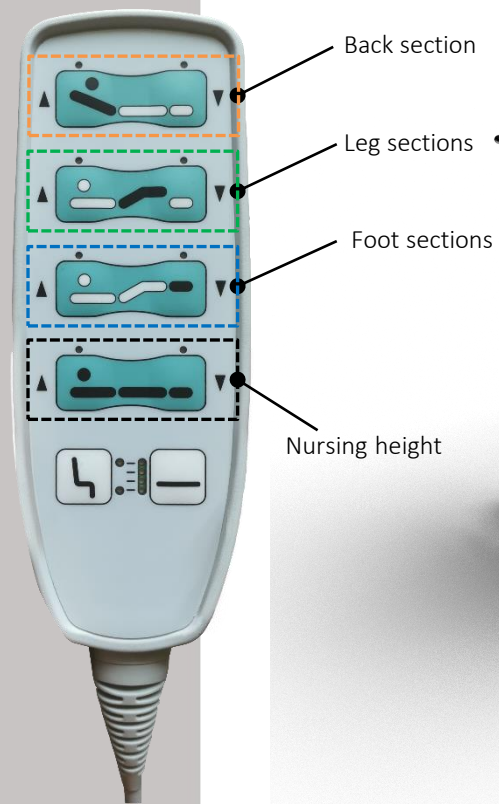
Nursing height



Rotate out



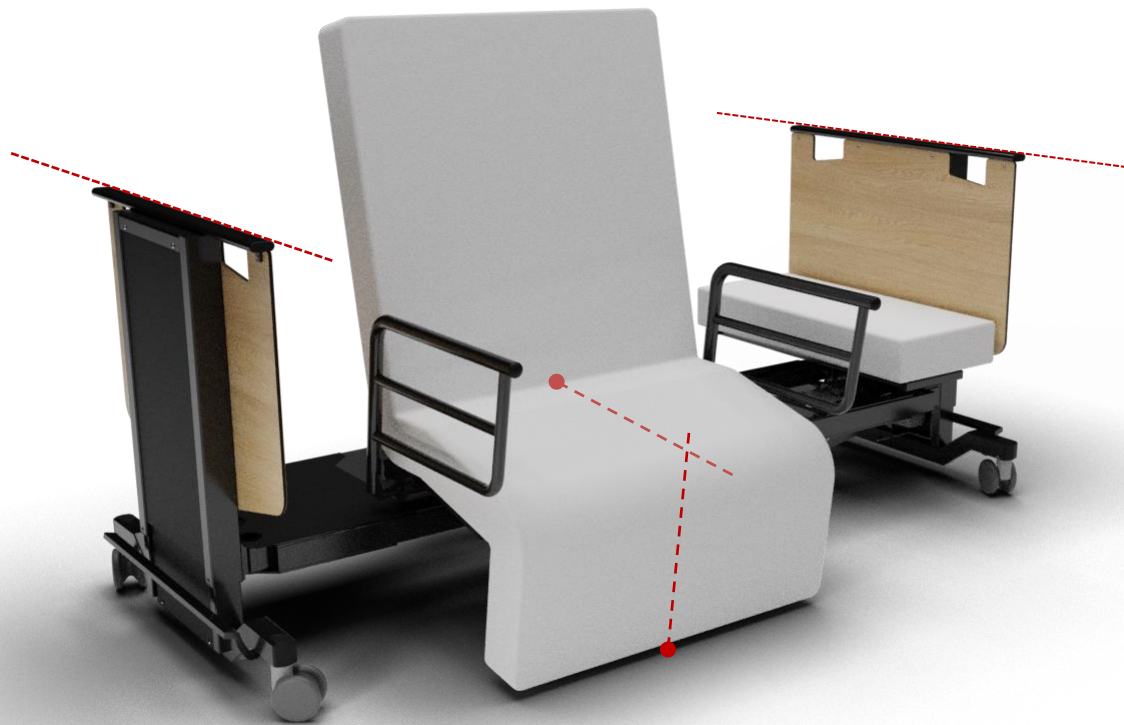
Rotate out



Stand up



Repress





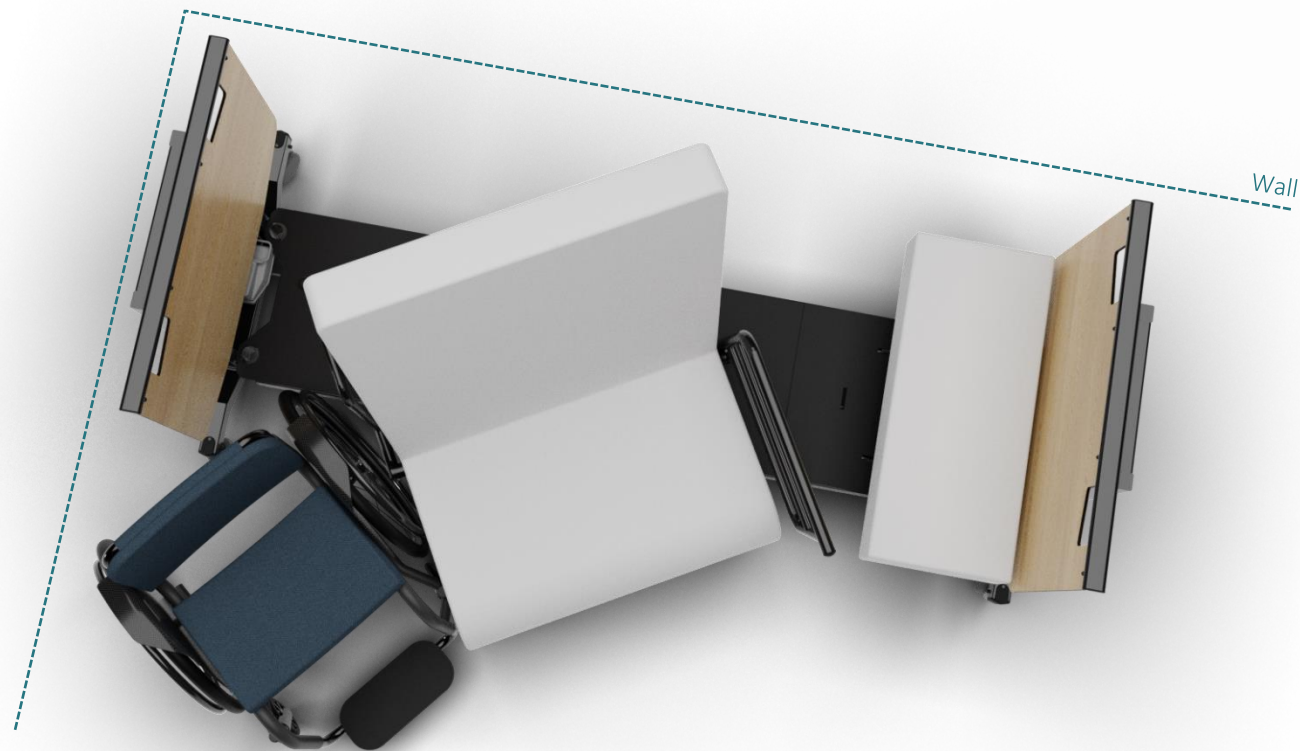
60 degrees rotation



60 degrees rotation



Wheelchair



Transfer from wheelchair



Transfer to wheelchair

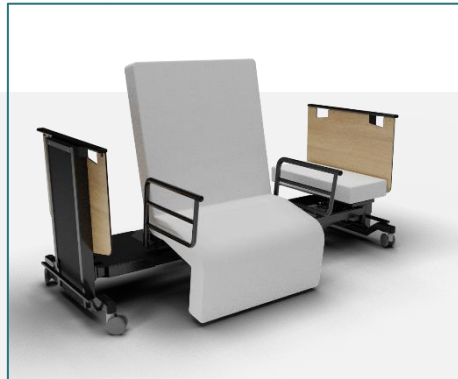


Unique selling points

Nursing height



Stand-up function



Wheelchair



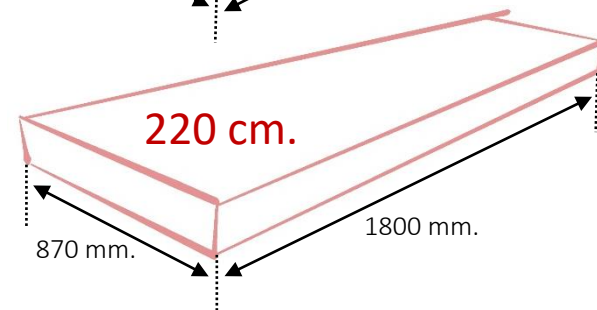
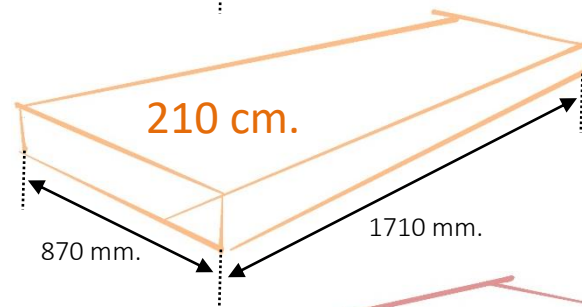
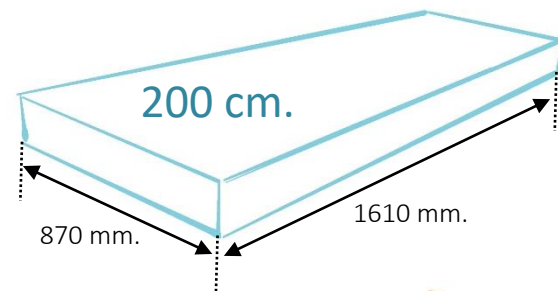
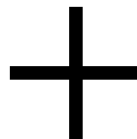
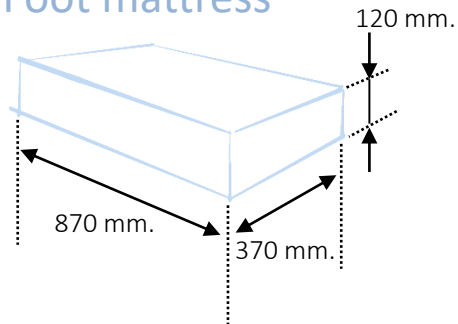
Bed lengths (200, 210 and 220 cm.)

Mattress



Mattress dimensions

Foot mattress

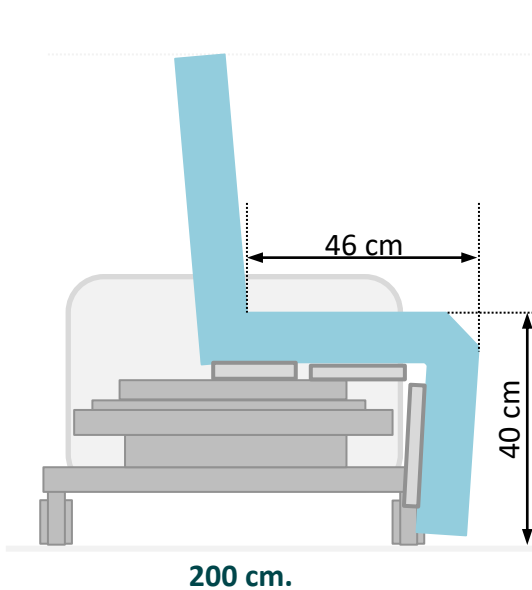


Mattress dimensions

200 cm.

Seat height
A = 400 mm.

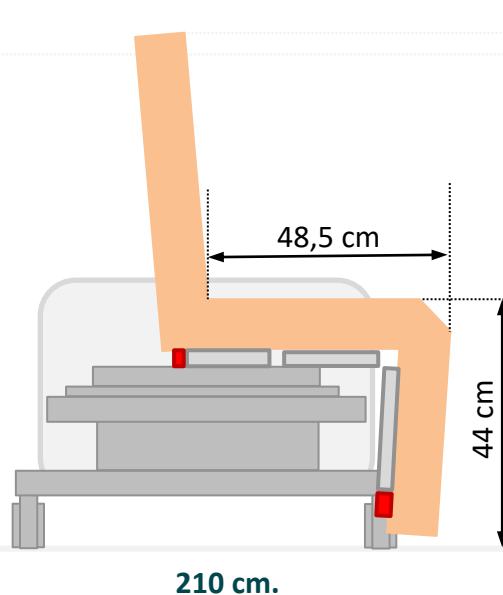
Seat depth
B = 460 mm.



210 cm.

Seat height
A = 440 mm.

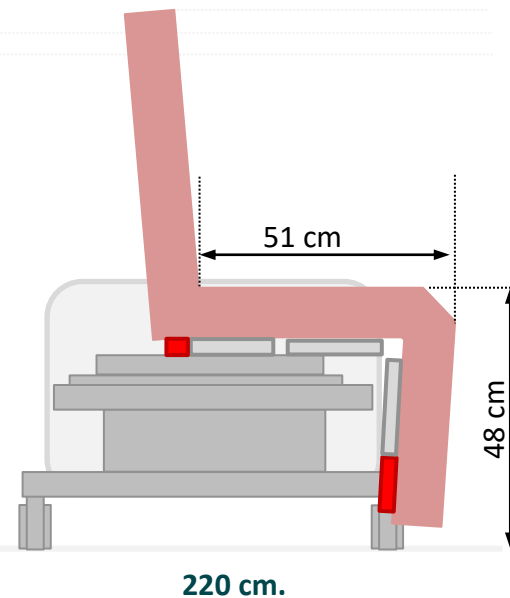
Seat depth
B = 485 mm.



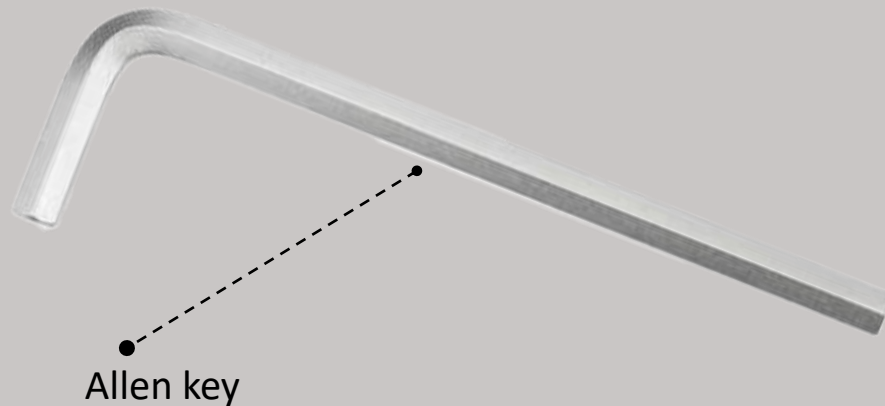
220 cm.

Seat height
A = 480 mm.

Seat depth
B = 510 mm.

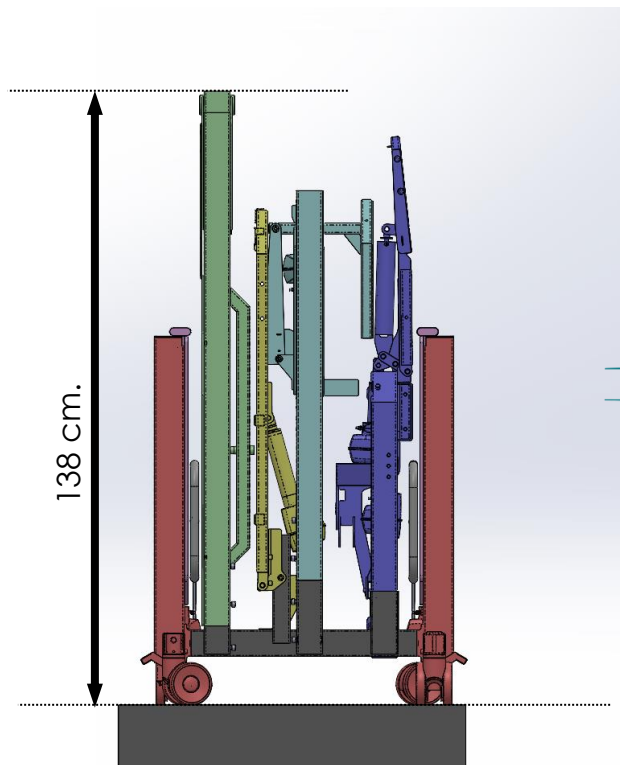


Installation

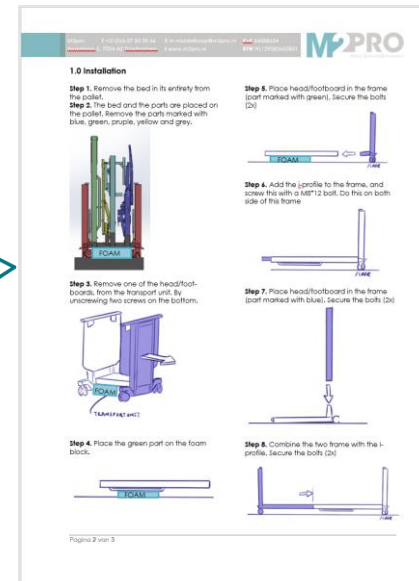


Installation

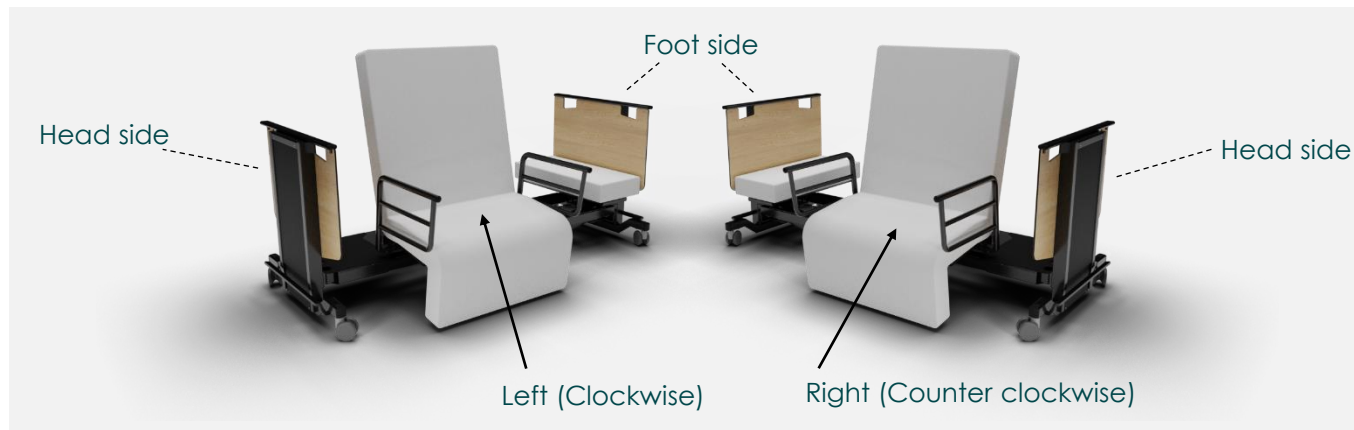
- Total weight:
150 kg
- Max. part weight:
25 kg
- Assembly:
one person
- Assemble time:
20 min.



Installation manual



Change rotation direction



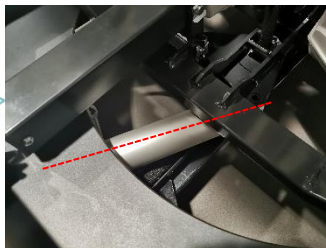
Change rotation direction

Step 1, rotate bed in
(without mattress)



Step 2, putt the actuator in the correct hole

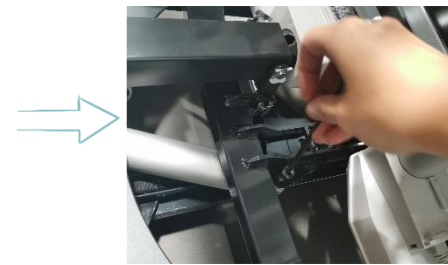
Left (CCW)



Right (CW)



Step 3, screw in the bolt



Adjustments (back section)

200 cm.



210 cm.



220 cm.



Adjustments (foot side)

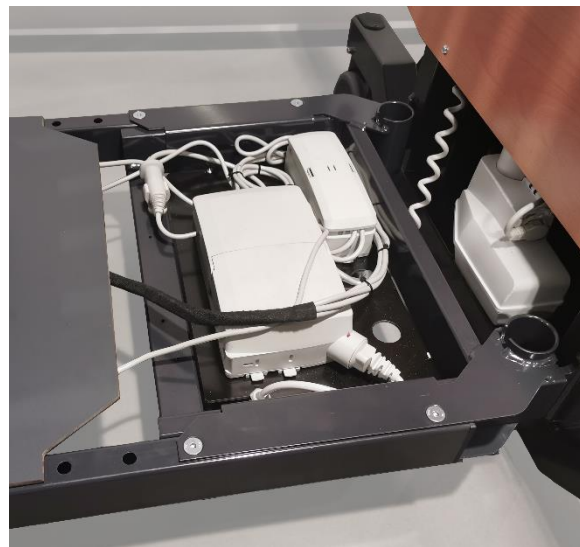
200 cm.



210 cm.



220 cm.



Adjustments (back section)

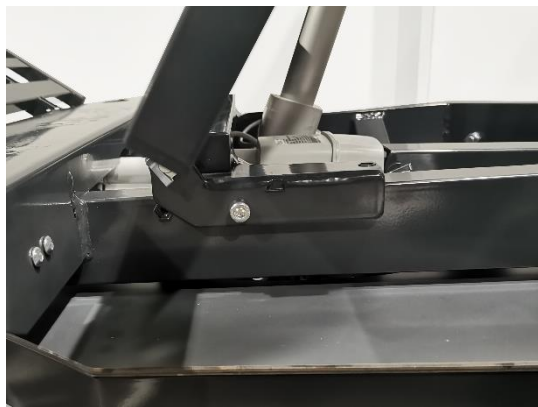
200 cm.



210 cm.



220 cm.



Adjustments (lower leg section)

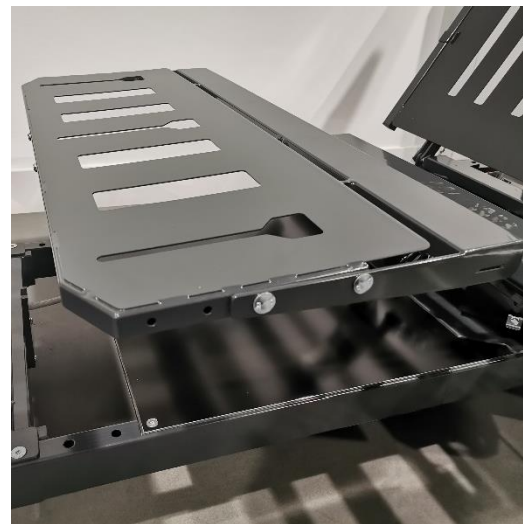
200 cm.



210 cm.

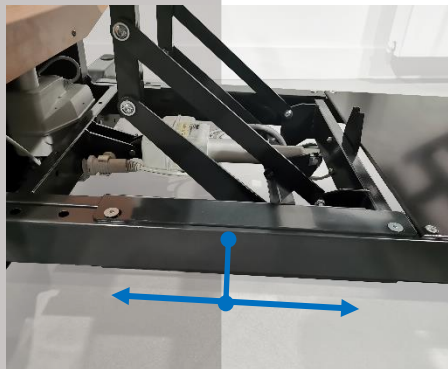


220 cm.



Adjustments (overview)

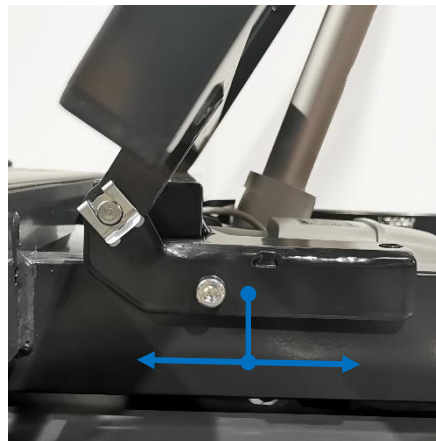
Footside



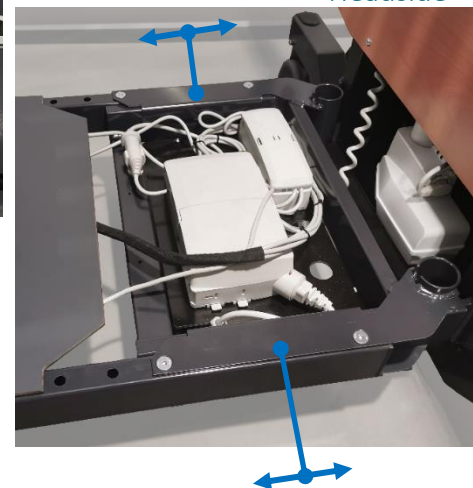
Lower leg section



Back section



Headside



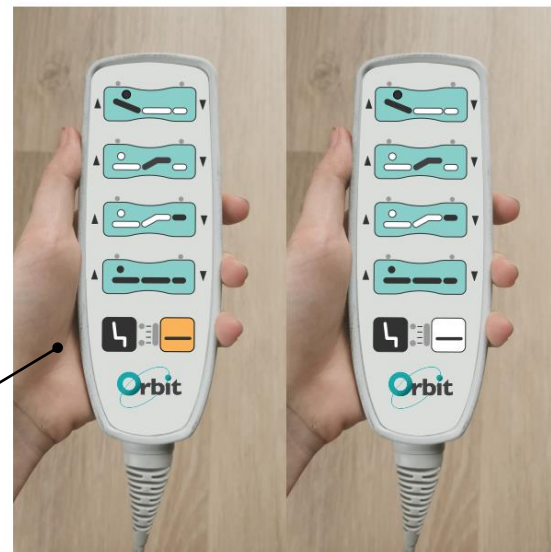
Software adjustment

Handset design

Current design



Possible
location
for logo



5 colors

1. Dark grey, 2. Light grey, 3. White, 4. Blue & 5. Orange

4 colors

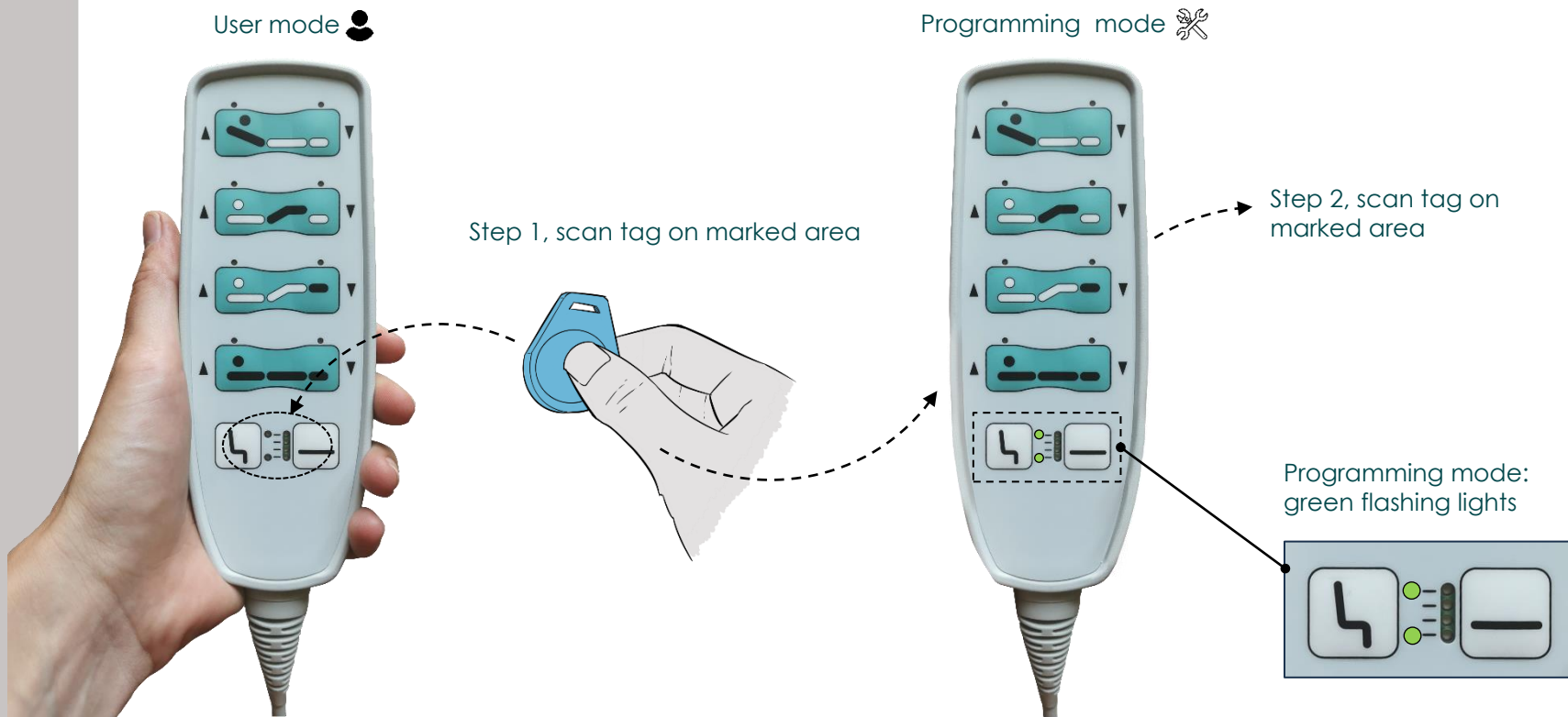
1. Dark grey, 2. light grey, 3. white & 4. Blue

Software programming

User mode Programming mode 

Step 1, scan tag on marked area

Step 2, scan tag on marked area

Programming mode:
green flashing lights

Software programming

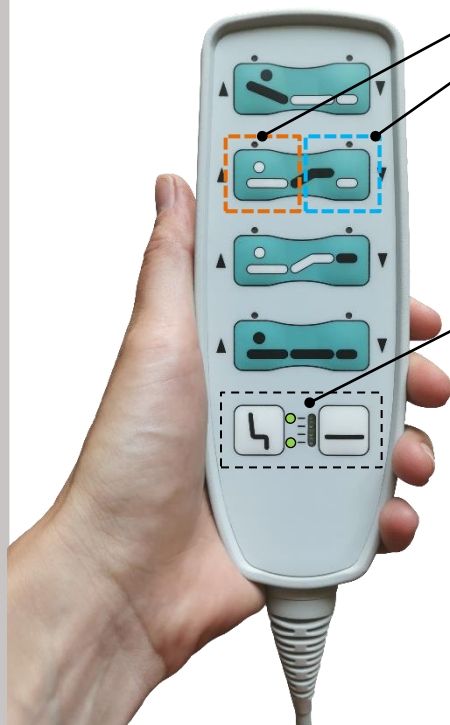
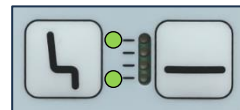


Bed length

Step 1, go to programming mode

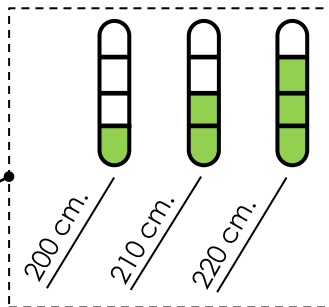


Programming mode:
green flashing lights



Step 2, press and hold orange

Step 3, press blue to toggle



Step 4, wait 30 seconds or scan the tag to go to user mode

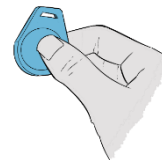


Software programming

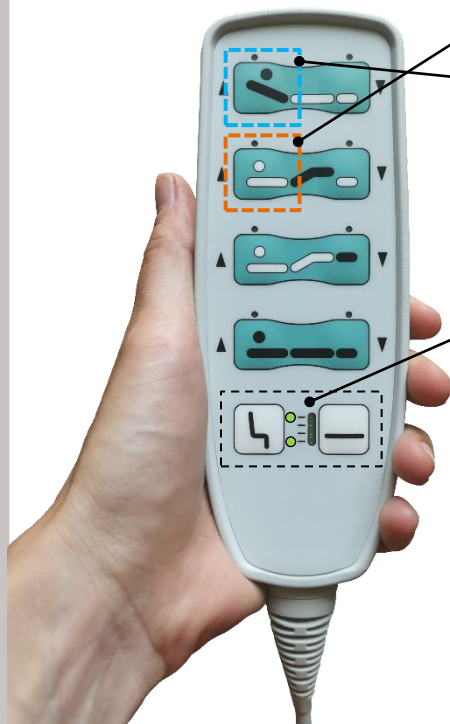


60-degree (Wheelchair)

Step 1, go to programming mode

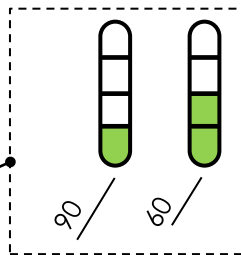


Programming mode:
green flashing lights



Step 2, press and hold orange

Step 3, press blue to toggle



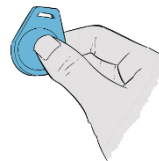
Step 4, wait 30 seconds or scan
the tag to go to user mode



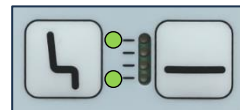
Software programming

Rotation

Step 1, go to programming mode

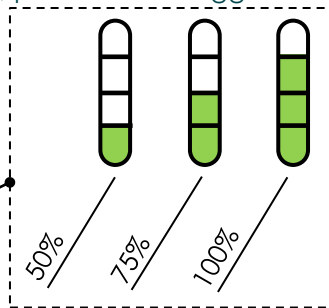
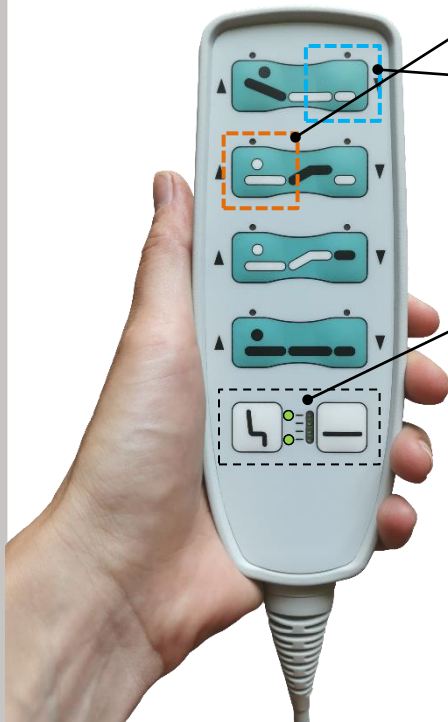


Programming mode:
green flashing lights

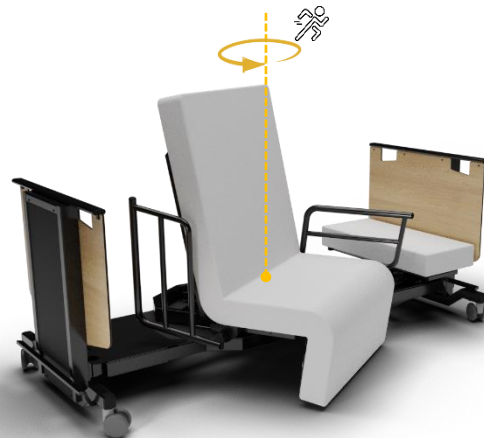


Step 2, press and hold orange

Step 3, press blue to toggle



Step 4, wait 30 seconds or scan
the tag to go to user mode

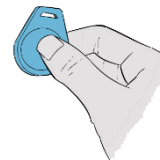


Software programming

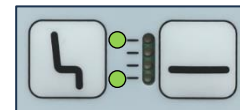


Stand up

Step 1, go to programming mode

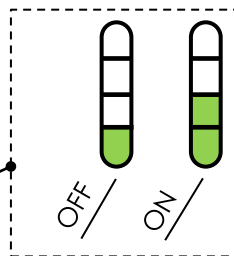


Programming mode:
green flashing lights

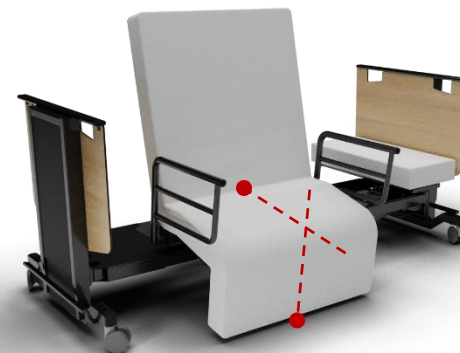
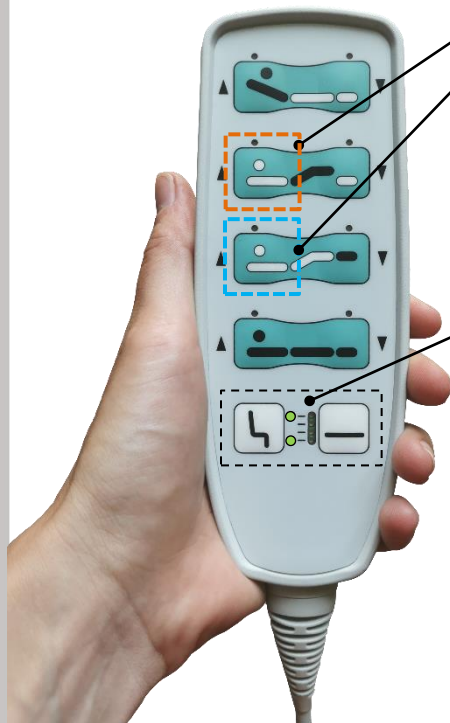


Step 2, press and hold orange

Step 3, press blue to toggle

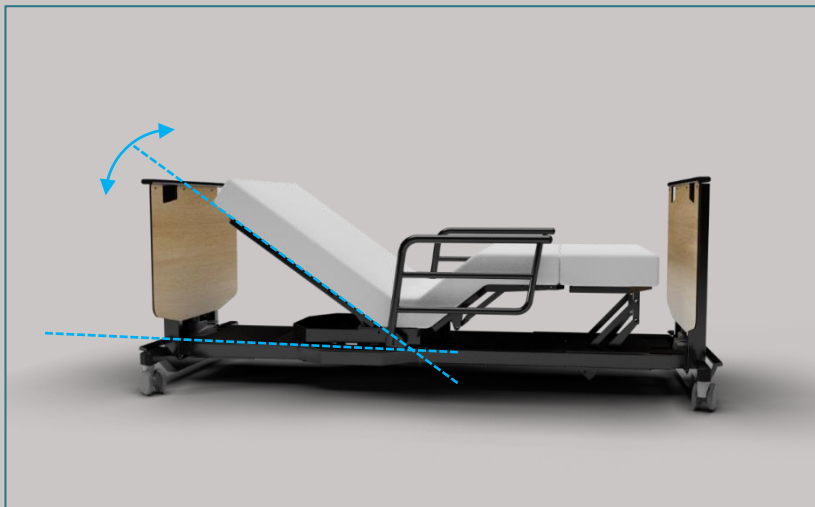


Step 4, wait 30 seconds or scan
the tag to go to user mode

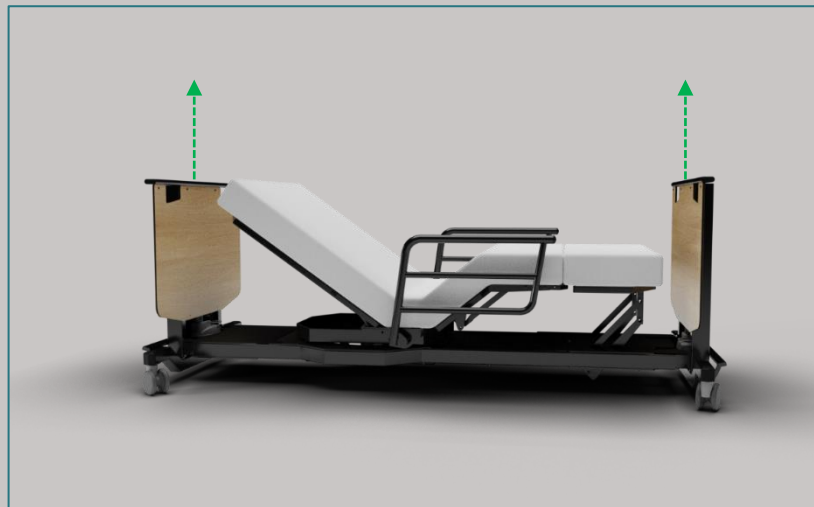


Rotation variables

Back segment



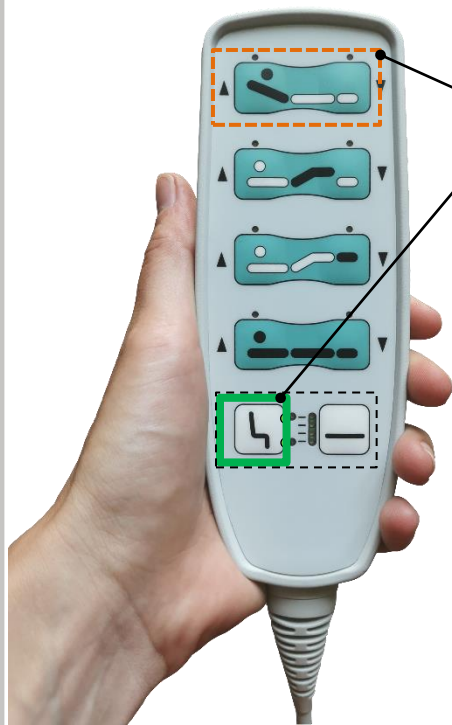
Height segment



Software programming



Back angle (during rotation)

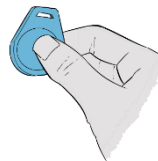


Step 1, go to programming mode

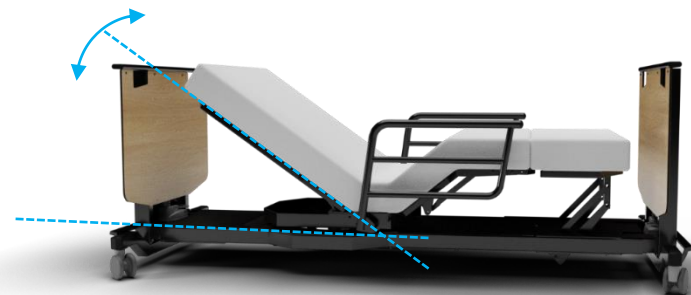
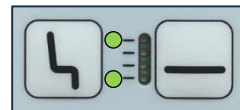
Step 2, put the backrest on the wanted angle, but using the orange buttons

Step 3, use button marked with green to save the back angle position

Step 4, wait 30 seconds or scan the tag to go to user mode



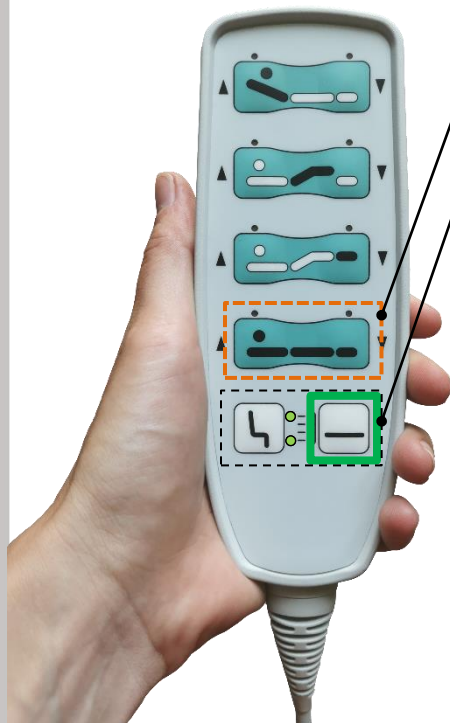
Programming mode:
green flashing lights



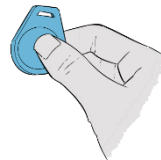
Software programming



Seat height



Step 1, go to programming mode



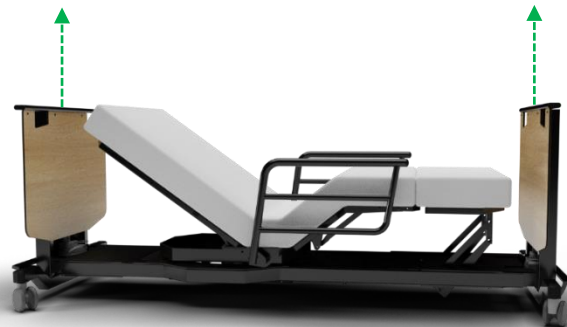
Programming mode:
green flashing lights



Step 2, put the bed on the wanted height, but using the orange buttons

Step 3, use button marked with green to save the height

Step 4, wait 30 seconds or scan
the tag to go to user mode

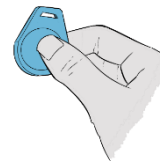


Software programming

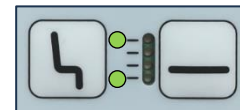


Factory default

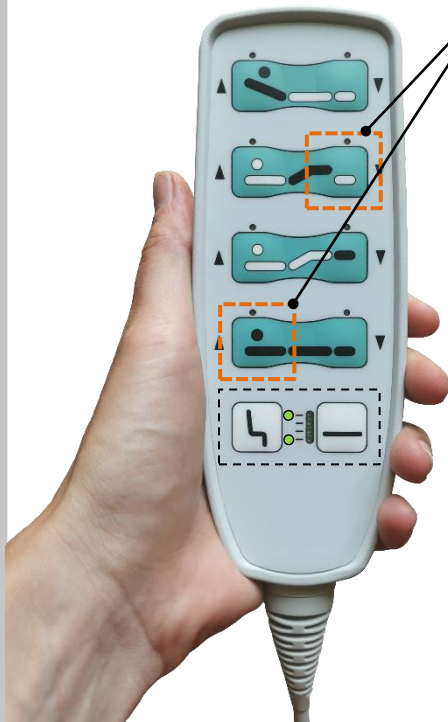
Step 1, go to programming mode



Programming mode:
green flashing lights



Step 2, press orange buttons



Factory setting includes:

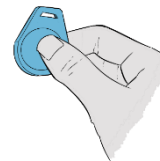
- Back angle during rotation is not able to touch the wall when the bed is placed directly to the wall
- 210 cm. bed length
- 90 degrees
- Rotation speed 75 %
- Stand up function off

Software programming

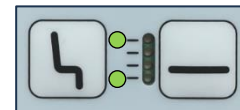


Factory default

Step 1, go to programming mode

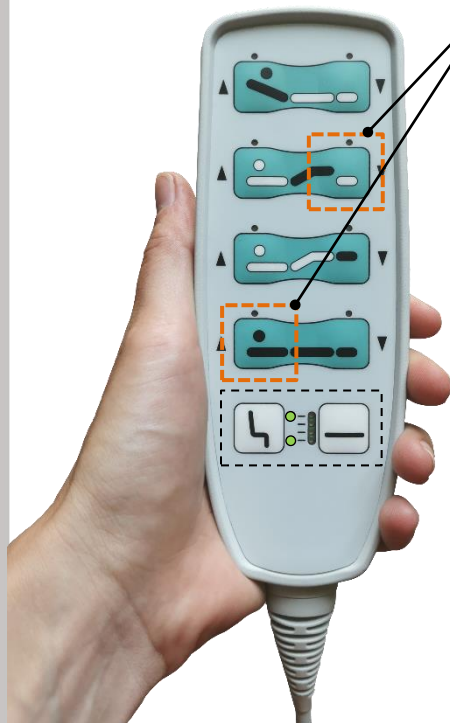


Programming mode:
green flashing lights



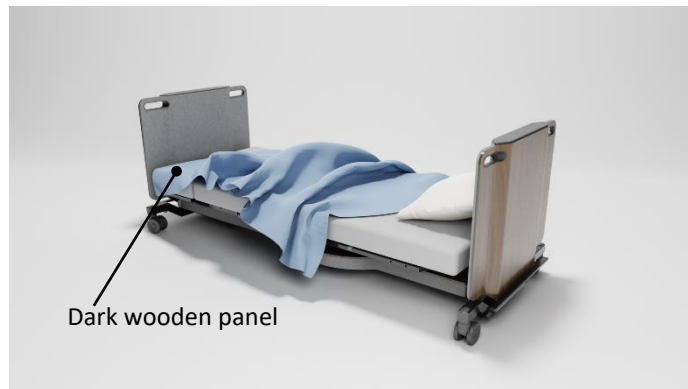
Step 2, press orange buttons

Step 3, wait 30 seconds or scan
the tag to go to user mode



Options

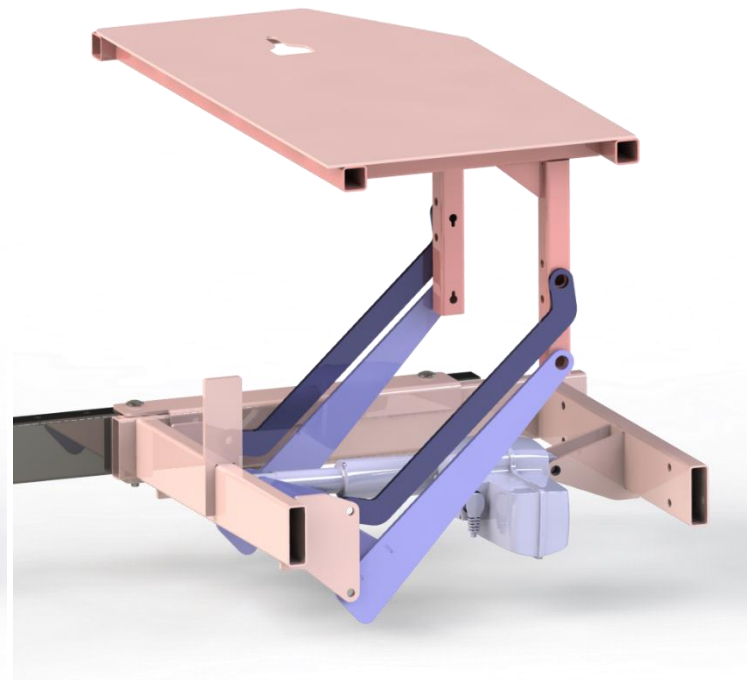
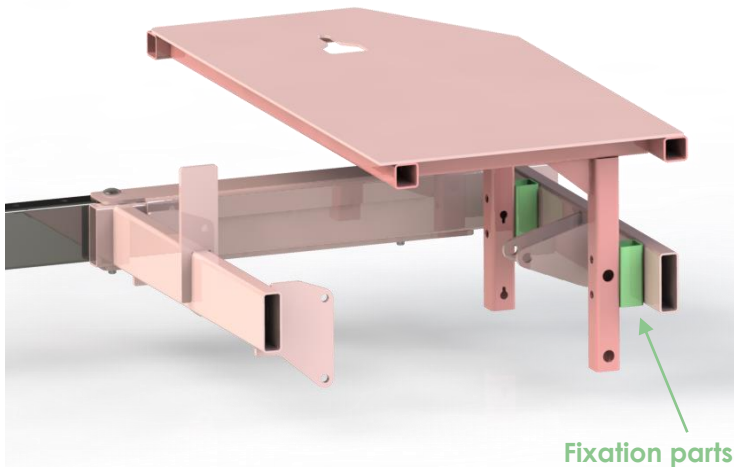
Design options



Options

Upgrade feet section

- Red: standard parts
- Blue: rising mechanic parts
- Green: fixed parts



Options

Wheels

No wheels



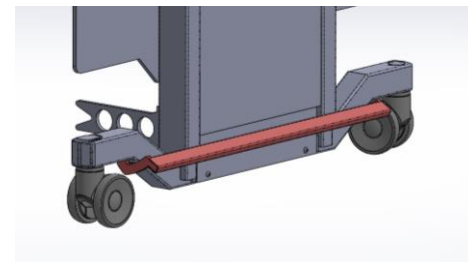
Single-roll



Dubble-roll



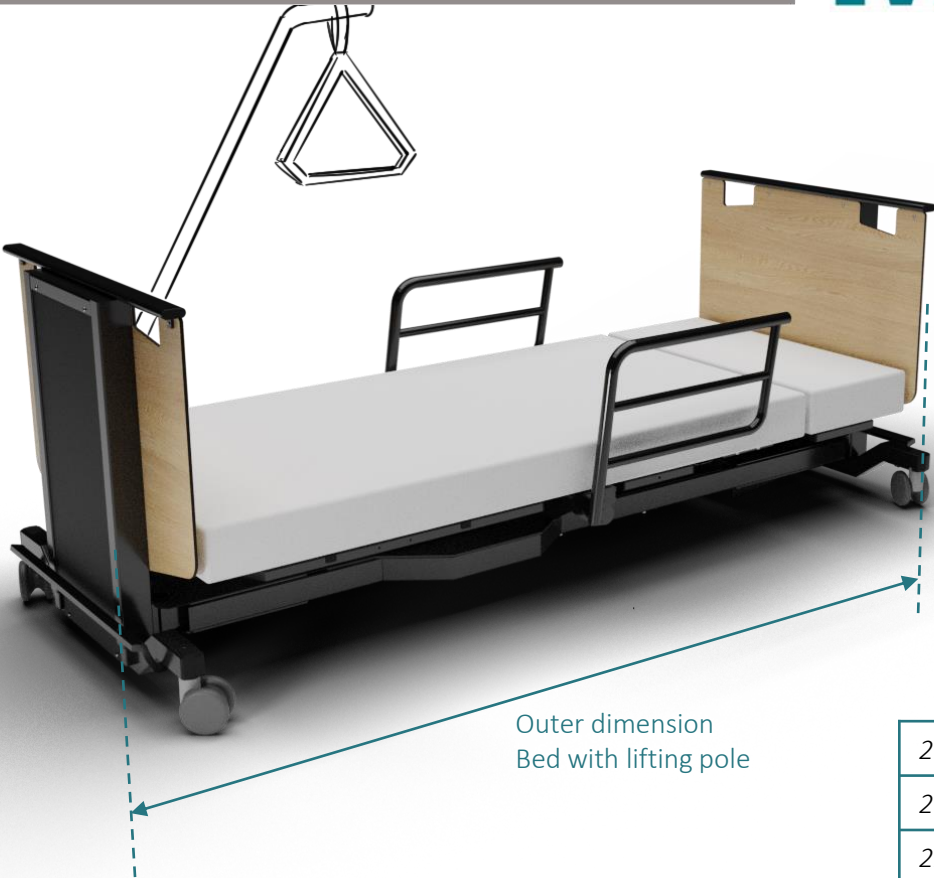
Central brake



Options



Lifting pole



Outer dimension
Bed with lifting pole

200 cm.	225 cm.
210 cm.	235 cm.
220 cm.	240 cm.

Options (overview)

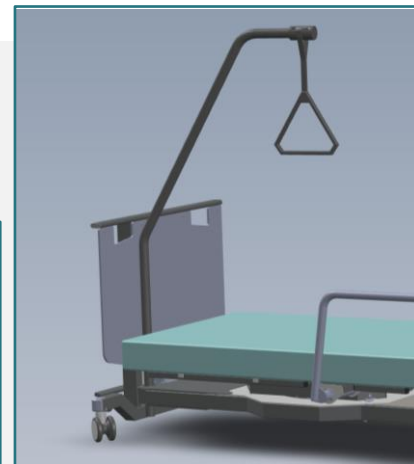
Rising feet-section



Brakes



Lifting pole



Unique selling points

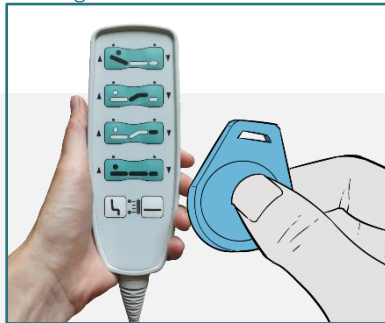
1. Nursing height



2. Stand-up function



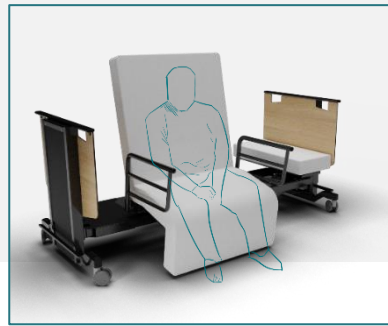
3. Programmable software



4. Wheelchair mode



5. Bed lengths (200, 210 and 220 cm.)



6. Customizable for end-user

Zenith Multi Move

