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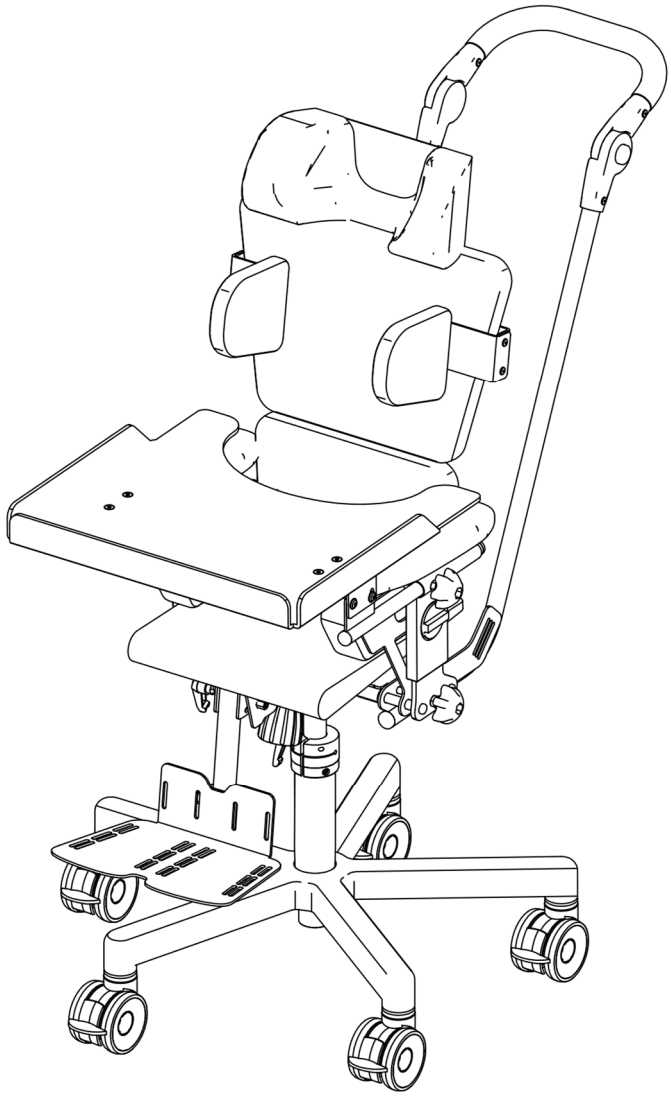
INSTRUCTIONS FOR USE

Baffin neoSIT BASIC



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NOTE! THERE IS A POSSIBLE RISK THAT A PART OF THE USER'S/AN ACCOMPANYING PERSON'S BODY MAY BE ENTRAPPED AND/OR SQUEEZED IN THE HOLES/GAPS BETWEEN INDIVIDUAL ELEMENTS WHEN USING THE PRODUCT, AS WELL AS WHEN ASSEMBLING AND ADJUSTING MECHANISMS OF THE PRODUCT. THESE PARTICULAR PROCEDURES SHOULD BE PERFORMED WITH PECULIAR CAUTION. WHEN ALL THE ADJUSTMENTS HAVE BEEN PERFORMED, IT IS CRUCIAL TO STABILISE THE POSITION BY PROPERLY TURNING THE NUTS / SCREWS.

NOTE! IT IS ESSENTIAL TO CAREFULLY READ THE INSTRUCTION MANUAL BEFORE USING THE DEVICE AND KEEP IT UNTIL THE END OF PRODUCT'S USE.

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Contents

1 Introduction

Thank you for purchasing the BAFFIN neoSIT Basic device from LIW Care Technology Sp. z o.o. We are confident that our innovative device, featuring advanced body adaptation functions, will enhance user comfort in the sitting position.

Developed by LIW Care Technology Sp. z o.o., the Baffin neoSIT Basic was designed to offer patients an alternative to ready-made seats with limited adjustment to the user's anatomical shapes and custom-made seats that perfectly replicate the body's anatomical curves but offer limited further correction possibilities.

We have made every effort to ensure that the device is as simple to operate as possible, while providing extensive adjustment options to anatomical shapes and correcting postural defects.

To ensure the maximum level of user safety and comfort, it is imperative to follow the recommendations in this manual. Before using the device, carefully read this manual and ensure that all the information, recommendations, and warnings contained therein are fully understood. In case of any doubts, it is essential to contact the seller or manufacturer before starting to use the device.

2 General safety conditions

Before using the device, it is necessary to read this manual. By following all the recommendations contained in the manual, you will avoid situations where you could damage the device and ensure complete safety and comfort of use throughout the entire period of product usage.

The primary concern of LIW Care Technology Sp. z o.o. is ensuring the safety of patients using our devices. To fully ensure the safety of Baffin neoSIT Basic users, the following recommendations must be strictly followed:

1. Before attempting to use the device, thoroughly read the contents of the user manual, and in case of any doubts, contact the seller or manufacturer.
2. Make sure that all information, recommendations, and warnings in these chapters are fully understood.
3. Do not leave a child in the device without adult supervision.
4. If a child is in the device, ensure that they are properly secured.
5. The Baffin neoSIT Basic product is designed for use by one person at a time.
6. Improper use of the Baffin neoSIT Basic device may be hazardous to health and cause bodily injury to the user.
7. When using and handling the Baffin neoSIT Basic device, and when adjusting its mechanisms, pay special attention to moving parts that pose a real safety risk, such as body pinching in openings or between components. After each adjustment, stabilize the position by thoroughly tightening nuts/screws and ensuring that elements are in a set and secured position.
8. It is forbidden to transport a child in the Baffin neoSIT Basic device while driving a car, meaning the Baffin neoSIT Basic seat is not a car seat. A child cannot stay in the Baffin neoSIT Basic device during car travel.
9. It is forbidden to move up and down stairs with the Baffin neoSIT Basic device, both with and without the patient.
10. It is forbidden to carry the Baffin neoSIT Basic device when the patient is using the device.
11. The device does not contain substances that may pose a threat to life or health.
12. The device does not cause interference in the electromagnetic field.

Any modifications to the device made by the consumer that are not intended in the product's usage are prohibited and may result in the loss of warranty.

It is important to monitor the condition of the device. If any damage or signs of excessive wear occur, the device should be inspected, and if necessary, such occurrences should be reported to the distributor or manufacturer.

Any incidents related to the use of the device should be reported to the MANUFACTURER of the device and to the APPROPRIATE authorities depending on the location of the incident.

In the manuals of devices produced by LIW Care Technology Sp. z o.o., there is a section marked with the symbol NOTE! which is designed to draw particular attention to the content it contains. The meaning of the aforementioned symbol is as follows:

NOTE! This symbol is used to draw the reader's attention to the content marked with this symbol. FAILURE TO FOLLOW THE CONTENT UNDER THIS SYMBOL MAY ENDANGER THE USER'S LIFE OR HEALTH.

3 Indications and Contraindications for Use of the Product

The Baffin neoSIT Basic device is designed for individuals with a height of 85 to 130 cm and a weight not exceeding 60kg. The BAFFIN neoSIT Basic is suitable for people with postural defects and muscle dysfunction. It is particularly effective for children with cerebral palsy, muscular dystrophy, various forms of paralysis, tetraplegia, paraplegia, and children with postural abnormalities. The device can be used both therapeutically and prophylactically to prevent and correct existing postural defects and related improper body functions.

The Baffin neoSIT Basic is an orthopedic seat for children that stabilizes the back and head. Its primary function is the passive correction of a child's posture in a seated position. The device allows proper (optimal) positioning of the child's spine and pelvis, which improves the quality of life and the functioning of three key systems: respiratory, circulatory, and digestive. Using the device under the supervision of a physiotherapist after exercises increases the chances of returning the user to a proper position. The adjustment of the pelvis, which forms the body's base in a seated position, corrects the spine's alignment, thus correcting the entire body posture. An innovative feature of the device is that it "grows" with the child. It can be adjusted to the current position and height of the child.

The Baffin neoSIT Basic medical device is recommended for children diagnosed with:

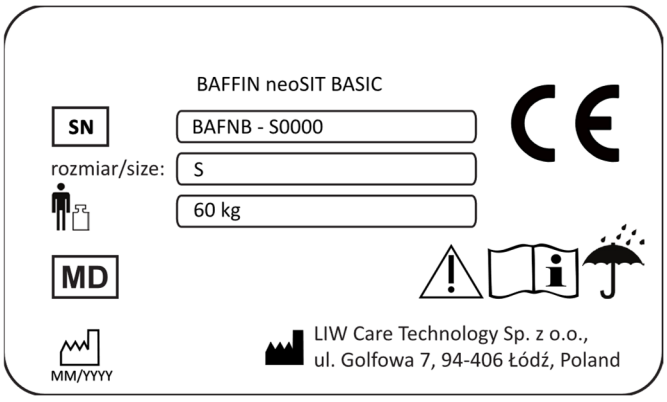
- Cerebral palsy (CP),
- Muscular dystrophies,
- Various forms of paralysis,
- Spina bifida,
- Meningomyelocele,
- Post-spinal injury conditions,
- Post-traumatic brain injury conditions,
- Post-stroke conditions,
- Other diseases accompanied by paresis, paralysis, or damage to the motor system that prevent independent movement.

The patient/user should not use the device when:

- The attending physician, in positioning recommendations, prohibits positioning the patient's body in positions indicated for normal product use,
- The condition does not allow the use of an orthopedic seat,
- Using the device could deteriorate the user's health condition.

If there is a contraindication for the patient to sit, the selection and adjustment of the device should be consulted with the attending physician or physiotherapist.

4 Identification plate



5 Identification of symbols

	Name of the manufacturer
	Date of production
	Serial number
	Permitted user's weight
	Follow the instructions for use
	Arrows indicating the direction of movement
	Conformity marking according to the Regulation 2017/745 of the European Parliament and of the Council (EU) dated from April 5th, 2017 on medical devices, Annex V.
	Medical device
	Avoid contact with water

6 Compliance with requirements concerning medical devices

Hereby we confirm that the Baffin neoSIT Basic meets requirements of the Regulation of the European Parliament and of the Council (EU) 2017/745 dated from April 5th, 2017 on medical devices.

The Baffin neoSIT Basic in accordance with Annex VIII of the Regulation of the European Parliament and of the Council (EU) 2017/745 dated from April 5th, 2017 on medical devices is a non-invasive, active class I medical device according to the rule 1.

Conformity declaration of the device can be obtained in the Commercial Department of the manufacturer.

The device meets the requirements of the ISO 21856:2023-01E standard.

7 The use of Baffin neoSIT BASIC

The Baffin neoSIT Basic is an orthopedic seat for children that stabilizes the back and head. It is designed for children with postural defects, muscle dysfunction, cerebral palsy, muscular dystrophy, various forms of paralysis, tetraplegia, paraplegia, and children with postural abnormalities. The device can be used both therapeutically and prophylactically to prevent and address existing postural defects and associated improper bodily functions.

NOTE! The device is anticipated to be used by one person at a time.

NOTE! The device should be loaded only within the permitted load range, adding any objects, resting on the device, may cause the fall of the device.

NOTE! Extreme settings and unfavorable posture (leaning too far) increases the risk of falling.

NOTE! It is forbidden to lift the device with the user sitting in the device.

NOTE! The device is anticipated to move on flat and hardened surfaces. Overcoming obstacles such as thresholds, edges, is possible only when the seat is unoccupied, and the user is not sitting in the device.

NOTE! The Baffin neoSIT Basic device cannot be used as a restraining device for children in motor vehicles, nor is it approved for use on aircraft.

8 Technical data

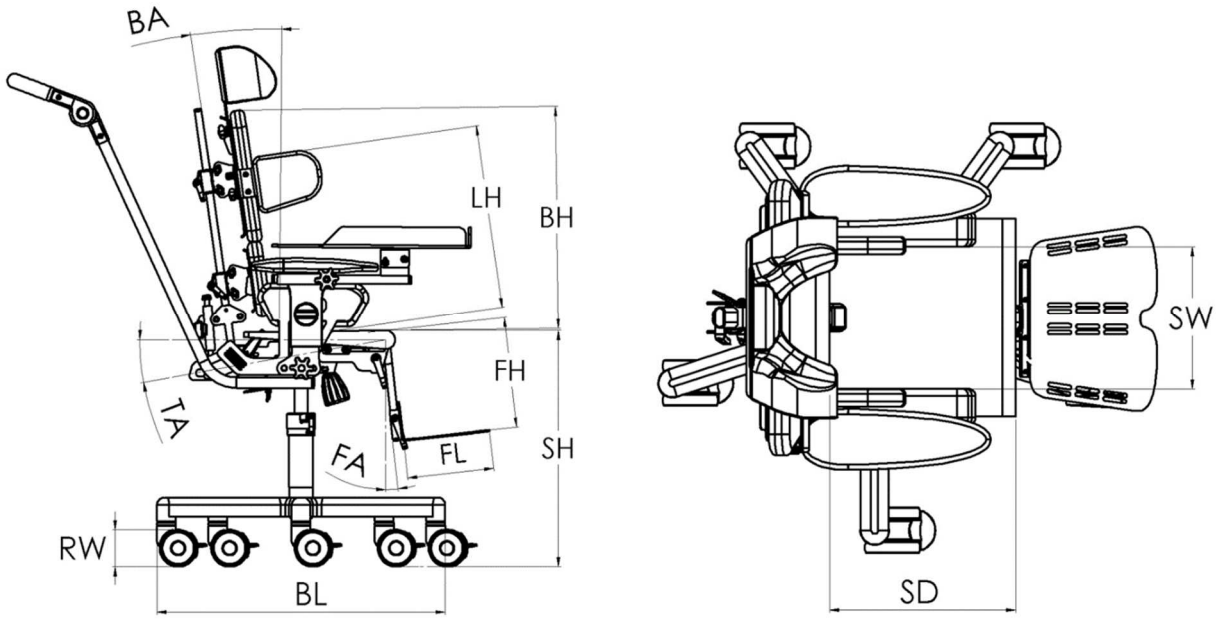
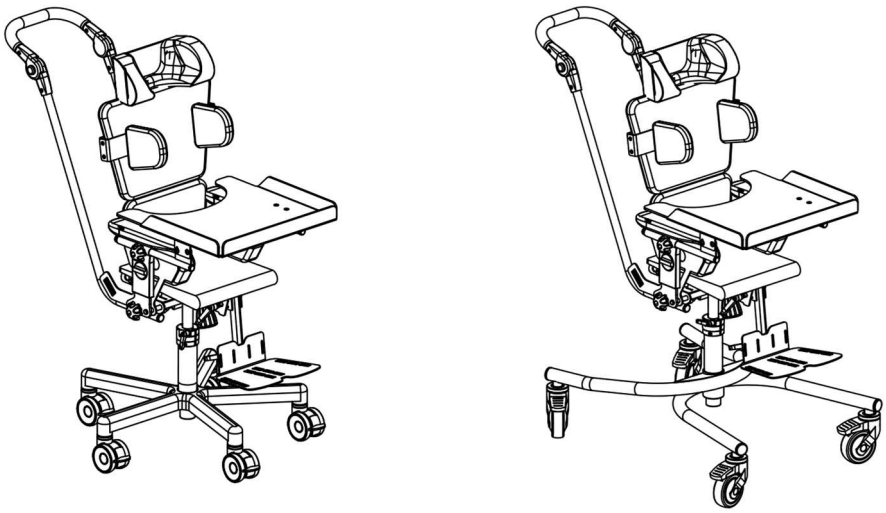


Fig. 1



STANDARD FRAME RS FRAME

Fig. 2

Fig. 2 shows two types of frame configurations on neoSIT Basic standard frame, on the right RS frame.

There are three sizes of the Baffin neoSIT Basic. Size details are shown in the table below:

No.	Parameter	Symbol	Dimension [cm]		
			S	M	L
1	Seat height standard frame	SH	42÷55	42÷55	42÷55
	Seat height RS frame		46÷59	46÷59	46÷59
2	Back height	BH	37÷47	42÷58	48÷60
3	Back angle	BA	-5°÷25°	-5°÷25°	-5°÷25°
4	Standard Base length	BL	55	55	55
	RS Base dimension		83x55	83x55	83x55
5a	Foot platform height	FH	17÷27	17÷27	28÷38
5b	Foot platform height (longer version)		17÷33	17÷33	28÷44
5c	Separate footrest height		13÷24	13÷24	22÷35
6	Foot platform length	FL	18	18	21
7	Standard frame wheel diameter	RW	7,5	7,5	7,5
	RS frame wheel diameter		10	10	10
8	Seat depth	SD	16÷31	20÷31	29÷40
9	Seat width	SW	15÷30	15÷30	20÷32
10	Footplate angle	FA	-10°÷45°	-10°÷45°	-10°÷45°
11	Tilt angle	TA	20°	20°	20°
12	Lateral support height	LH	27÷42	28÷45	28÷50
13	Maximum user's weight		60kg	60kg	60kg
14	Device weight with the standard frame.		17kg	18kg	21kg
15	Device weight with the RS frame.		20kg	21kg	24kg

9 Basic design of the Baffin neoSIT BASIC

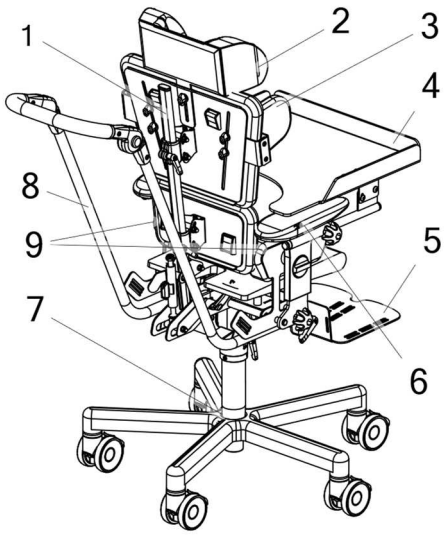


Fig. 3

1 Back support
2 Headrest
3 Lateral support
4 Tray
5 Footrest
6 Armrest
7 Frame with castor wheels
8 Push handle
9 Hip supports

10 Installation and Initial Setup

If the delivered product or packaging is damaged, notify the supplier and the manufacturer of the product. The packaging contains the Baffin neoSIT Basic device along with accessories, depending on the ordered version of the equipment. The Baffin neoSIT Basic device is delivered pre-assembled. After unpacking, adjust the parameters to fit the patient's dimensions. Adjustment methods are described later in this manual in the chapter "Adjustments and Settings." An area of about 2 m² is required for adjustment, operation, and maintenance of the device.

11 Adjustments and Settings

NOTE! After each adjusting procedure it is crucial to make sure that all regulated elements are properly mounted and secured.

11.1 Tools for Adjustment

For adjusting the device and accessories, the necessary tools are:
- Allen key H4
- Allen key H5
- Allen key H6

11.2 Push handle

To adjust the height of the push handle, press the buttons (1) as shown in Fig. 4, and then set the handle to the desired height.

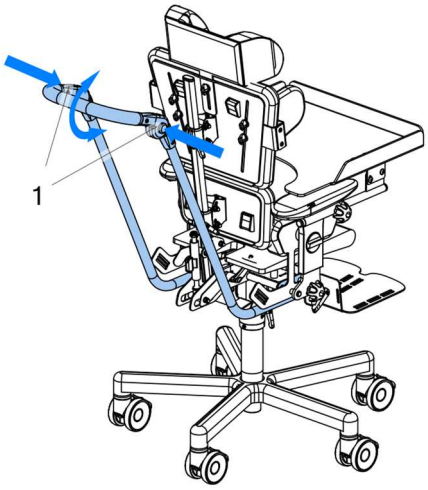


Fig. 4

NOTE! It is worth remembering that any additional object hanging on the push handle poses a significant influence on the stability of the device.

11.3 Parking brake

Basic regulation elements shown on Fig. 5

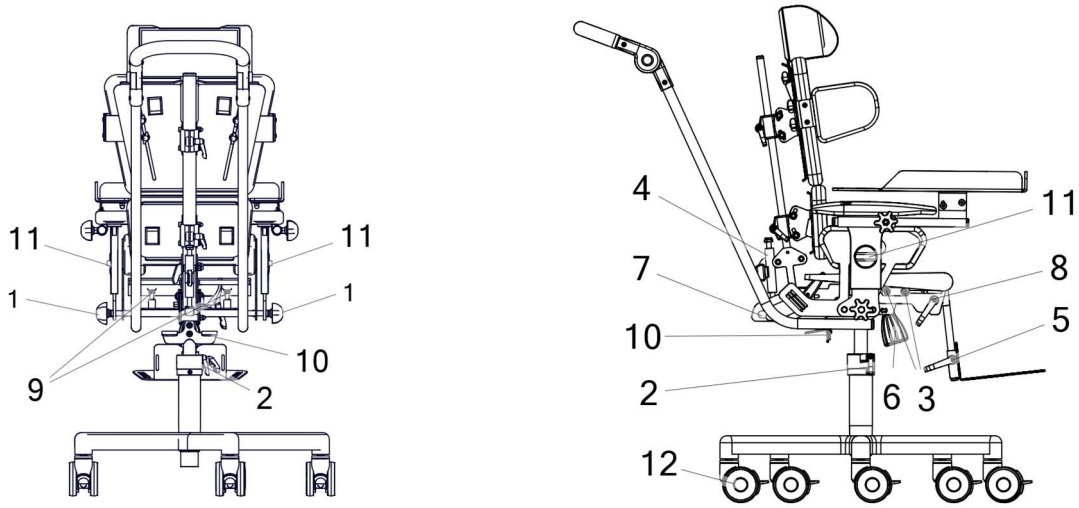


Fig. 5

The BAFFIN neoSIT Basic is equipped with wheel locks to prevent the base of the chair from moving uncontrollably. To lock the wheels, press the lock lever (12) located on each wheel. To unlock the wheels, lift the lock lever (12). During use by a child, all wheels should be locked.

11.4 Regulations and adjustments

11.4.1 Width adjustment

To adjust the side hip supports turn knob (1) Fig. 5 right or left until the required dimensions are obtained. The adjustment elements are situated on the left and right, allowing for symmetrical and asymmetrical positioning of the user's pelvis.

11.4.2 Armrest height adjustment

Turn knob (11) Fig. 5 until the required height is set. The knobs are located on the left and right side. They operate independently from each other, making it possible to adjust the armrest height asymmetrically.

11.4.3 Depth adjustment

To unlock, loosen bolts (3) Fig. 5 located on each side. After unlocking the screws, set the depth by pushing or pulling the front part of the device. To lock, tighten bolts (3). If the adjustment range provided by the bolts (3) is not sufficient, additional adjustment may be obtained by loosening bolts (7) and pulling or pushing the backrest. After completing the adjustment procedure, make sure the bolts (7) are tightened.

11.4.4 Footrest adjustment

In order to adjust the height of the footrest loosen knob (1) Fig. 6, move the footrest to the desired height, then tighten the knob (1). In order to set the correct angle of the footrest, loosen the knob (2), set the desired angle, then tighten the knob (2).

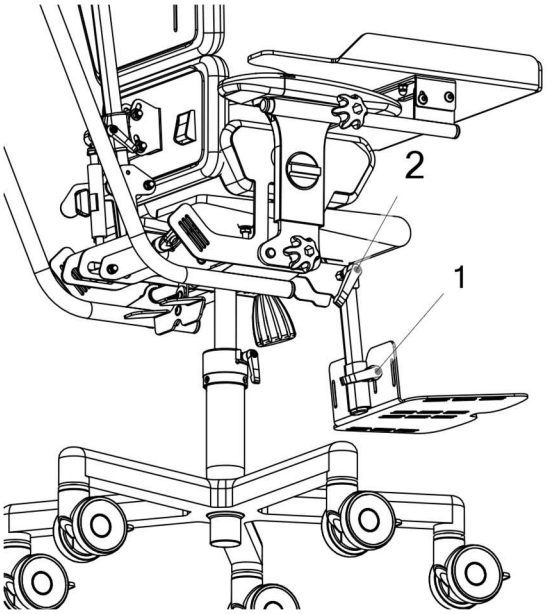


Fig. 6

11.4.5 Separate footplates

In order to adjust the proper height of the foot platform loosen both knobs (1) Fig. 7, slide the platforms to the desired height and tighten the knobs (1). They operate independently from each other, making it possible to adjust the platform height asymmetrically. In order to set the proper angle of the foot platform loosen the angle knob (2), set the desired angle and tighten the knob (2).

To precisely set the position of each platform, loosen the screws (3), set the desired position of the platform, then tighten the screws (3). This adjustment allows you to set the exact tilt angle, rotation angle, and extension position for each platform independently.

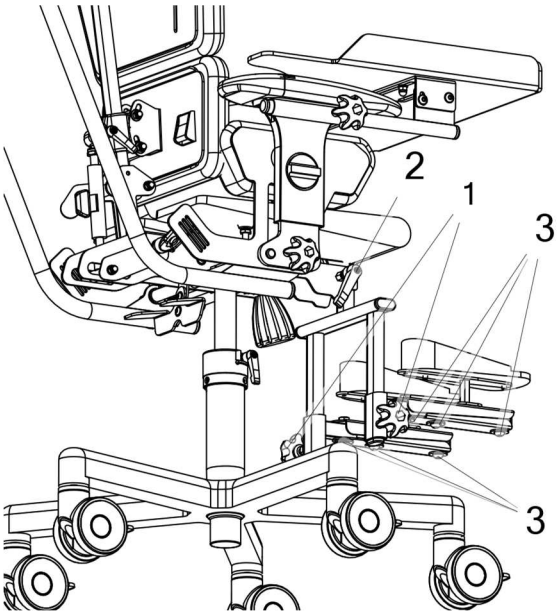


Fig. 7

11.4.6 Seat angle adjustment

In order to adjust seat angle, turn knob (6) Fig. 5 until the required angle of sitting position is obtained.

11.4.7 Seat height adjustment

To increase the height of the seat in relation to the floor, first, loosen the knob (2) Fig. 5 and press the releasing mechanism lever (10) (towards the front of the device). The gas-operated spring automatically raises the seat. After adjustment, re-tighten the rotation lock.

To decrease the seat height, loosen knob (2) of the rotation lock and press lever (10), simultaneously applying load on the seat. Set the required height and release the lever (10) to lock in position. Finally, re-tighten the rotation lock.

11.4.8 Buttock support height adjustment

In order to adjust buttock support height, turn screw (9) Fig. 5 until the required height is obtained.

NOTE! Screws (9) are located on the left and right side of the device and are independent from each other, to ensure asymmetrical adjustment of the buttock supports. In order to facilitate adjustments, it is possible to remove the upholstery from the seat to expose the buttock supports.

11.4.9 Backrest angle adjustment

To change the angle of the backrest, the lever (4) Fig. 8 should be turned and hold, the required angle position should be adjusted manually, and then the lever should be released.

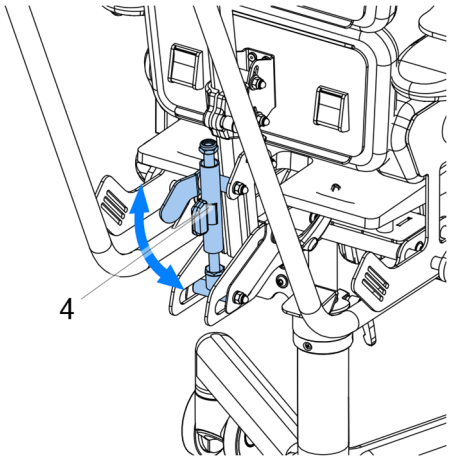


Fig. 8

NOTE! While the patient is leaning against the backrest, releasing the backrest lever will cause the backrest to drop suddenly. Always support the falling backrest with your hand!

11.4.10 Tray adjustment

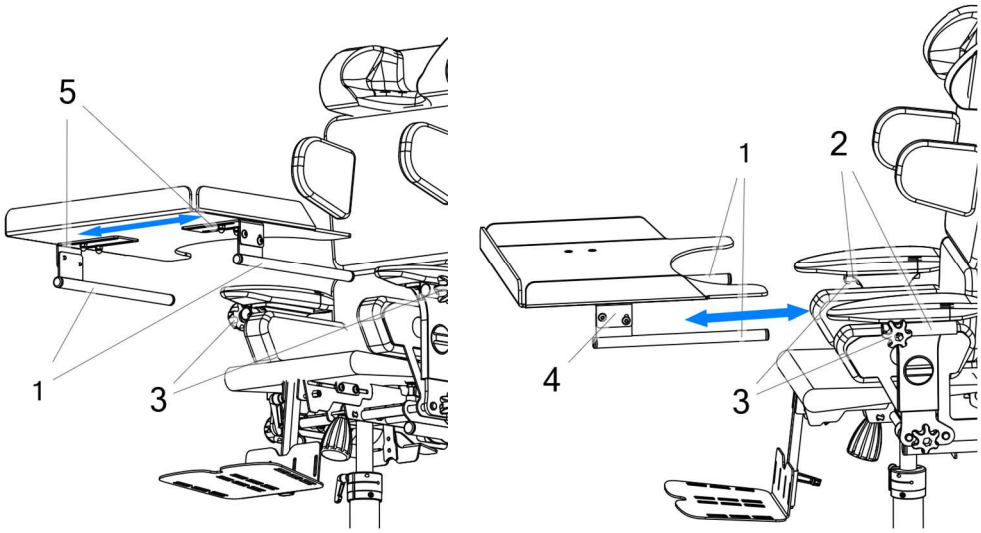


Fig. 9

To adjust the spacing of the tray handles (1) Fig. 9 to the spacing of the tray sockets (2) located in the armrests, loosen the bolts (5), which can be found on the tray handles under the tray top. Join or draw the handles apart adjusting them to the spacing of the sockets and tighten the tray handles screws.

To fit the tray, loosen the locking knobs (3) and slide the tray handles (1) into the sockets located under the armrests (2). After inserting the tray to the proper depth, re-tighten the locking knobs (3).

To adjust the tray angle, loosen both handle bolts (4) located over the tray handles (1), below the tray top. After setting the required tilt angle, re-tighten the handle bolts (4).

12 Additional features

12.1 Anatomic Headrest

Headrest assembly Fig. 10:
- take off the adjustment wing nut (15),
- insert the headrest fixing bracket (13) into the backrest profile (14),
- tighten the adjustment wing nut (15).

Headrest height adjustment:
- loosen the adjustment wing nut (15),
- set the headrest in the correct height,
- tighten the adjustment wing nut (15).

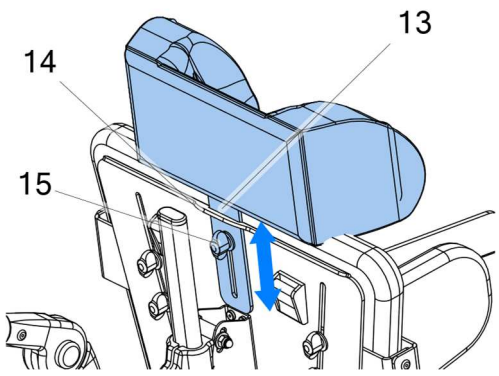


Fig. 10

12.2 Headrest

Headrest assembly (1) Fig. 11:
- loosen the knob (2),
- insert the headrest fixing bracket (3) onto the backrest profile (5),
- tighten the knob (2).

Headrest height adjustment (1):
- loosen the knobs (4),
- set the headrest in the correct height and position,
- tighten the knobs (4).

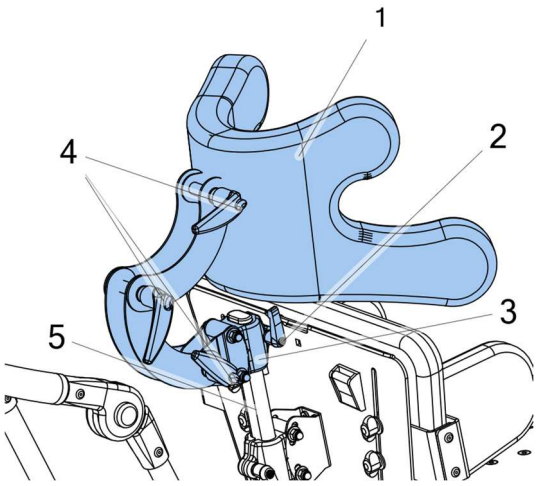


Fig. 11

12.3 Lateral supports

Assembly of lateral supports Fig. 12:
- insert the arm support fixing bracket (16) onto the backrest with fixing bolts to the sliding slots (17),
- tighten the fixing bolts with wing nuts (18).

Width and height adjustment of lateral supports:
- loosen the fixing bolts (18),
- slide the arm supports until the required width and height is obtained,
- tighten the fixing bolts (18).

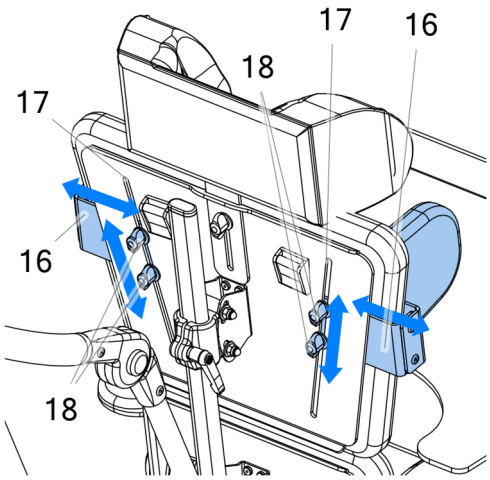


Fig. 12

12.4 Additional angle and height of upper and lower back support panels

Back support panels adjustment Fig. 13:
- loosen the knob (20),
- slide back support section up or down until correct height is obtain,
- tighten the knob (20),
- loosen the nuts and bolts (19),
- change the angle of upper back support until correct angle is obtain,
- tighten the nuts and bolts (19).

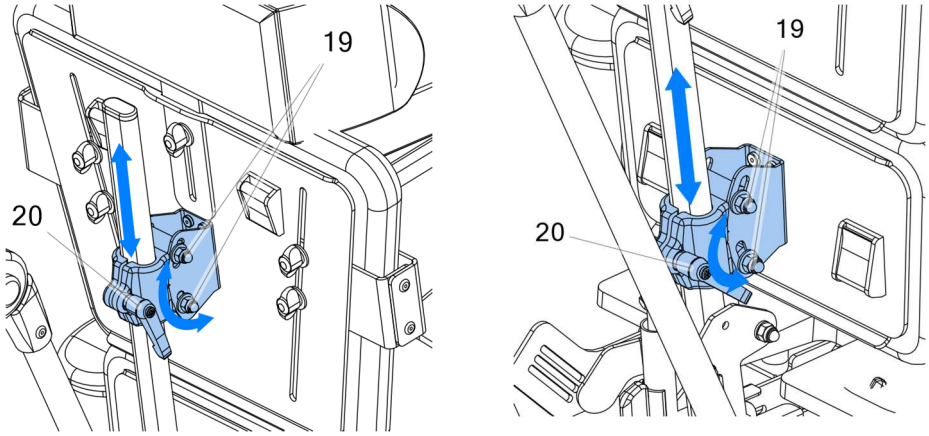


Fig. 13

In the case of children with particularly short height, only the upper part can be used.

NOTE! A prerequisite for starting the rehabilitation process using the BAFFIN neoSIT Basic device is prior consultation with the physician overseeing the patient's care. The adjustment of back support can only be made according to the recommendations of a doctor or physiotherapist.

12.5 Fixing and adjusting the vest, legs abduction belts and pelvic belts

The device is equipped with a vest and pelvic stabilization belts designed to secure the user's proper position. The vest and pelvic stabilization belts are attached to the device using straps. To properly attach the vest, thread the fastening straps through the buckles located at the back of the backrest. The vest's fastening buckles are located at the top and bottom of the backrest (21 and 22) in Fig. 14. The length of the vest's fastening straps can be adjusted by threading the straps through the fastening buckles on the backrest or through the buckles fastening the straps to the vest. The pelvic stabilization belts are attached to the loops located behind the armrests (23). The length of the belts is adjusted by threading the fastening straps (loosening or tightening) through the fastening buckles or loops.

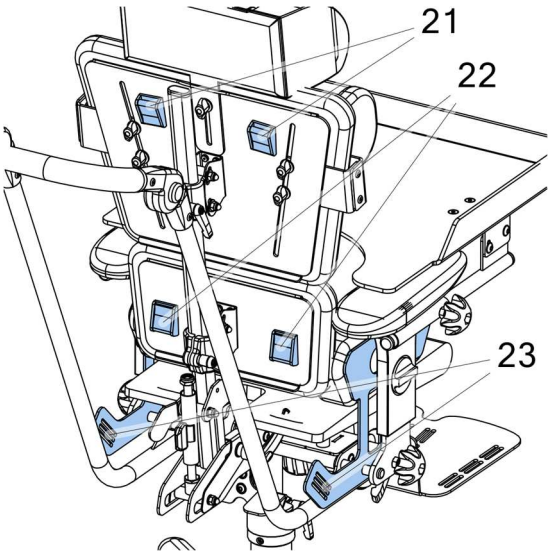


Fig. 14

NOTE! Check precisely that the adjustment is correct:
1. No element exerts excessive pressure on the user's body.
2. There is not too much space between the user and the device.
3. All adjustment screws and knobs are re-tightened after the adjustment process is completed.

13 Spare Parts and Consumables

The manufacturer does not foresee the replacement of parts by the end customer. Repairs and replacement of parts should be carried out by persons with technical knowledge, so as not to damage the equipment during replacement and not to create a risk to life or health. The device does not foresee the use of consumables in the sense of parts replaceable by the end customer. To replace parts, contact the distributor or the manufacturer's customer service department. Contact information can be found in the warranty and service chapter.

14 Troubleshooting

Before each use, check the proper fastening and tightening of all adjustment elements. Adjustments are described in the adjustments and settings section. If the wheels do not rotate, check whether the parking brake is engaged.

15 Cleaning

The Baffin neoSIT Basic product is a mechanical device with a structure made of aluminum and steel coated with a powder paint finish. None of the coatings cause skin irritation. Foam inserts are attached to the metal structure of the device. The foam is covered with breathable textile covers. They have Oeko-Tex Standard 100 certification, confirming their total safety for use, including by children. The fabrics used for the upholstery are free from harmful substances, including pesticides, chlorophenols, formaldehyde, allergenic dyes, prohibited azo dyes, and extractable heavy metals. The Oeko-Tex Standard 100 label is awarded only to textiles whose all components have been tested and received positive results. This product, like any medical device, should be kept clean and used according to the manufacturer's recommendations.

- Cleaning should be performed whenever the device is excessively dirty. The device should be cleaned frequently enough to ensure that the upholstered parts, frame, and other parts do not pose a health risk.
- Painted surfaces and plastic parts should be cleaned with a cloth dampened with water. Mild cleaning agents are permitted. Vacuum mechanically or use a brush with soft bristles.
- Foam inserts can be cleaned with a cloth dampened with water and a mild, neutral chemical agent or one intended for foam and sponge inserts. After this, the insert should be thoroughly dried at room temperature.

- Before washing, remove the foam inserts from the covers.
- Wash the covers by hand or in a washing machine (drum type) at a temperature not exceeding 40°C.
- Use detergents with certification intended for delicate items in the quantities indicated on the packaging.
- For children with allergies, use gray soap or special chemical agents.
- Do not wring; brief spinning is allowed.
- Dry in a hanging position at room temperature.
- Regularly maintain the frame, removing dirt and mud from moving parts.
- Do not use aggressive cleaning agents. This may cause corrosion or damage to the paint coatings.
- If the device is used by different people (e.g., in a rehabilitation center), disinfectants should be used. For manual disinfection of the product, Incidin Plus in a concentration of 0.25% to 0.5% or a similar disinfectant is recommended. Follow the application instructions provided by the manufacturer of the disinfectant.
- Before disinfecting, clean the upholstery and handles.
- Avoid prolonged exposure to sunlight and check the temperature of the seat before use.

NOTE! When washing upholstery covers, special attention should be paid to Velcro fastenings. To avoid damaging the upholstery, make sure that the Velcro is unfastened during washing and does not come into contact with the surface of the upholstery. Do not wash foam inserts.

NOTE! Before reusing, the upholstery should be dry.

16 Maintenance

The Baffin neoSIT Basic device should undergo regular inspections and maintenance activities listed in the table below to ensure long-lasting and trouble-free operation. If the user is unable to perform the following activities independently, they should seek assistance from a specialized medical equipment service center or contact the manufacturer's service directly. These activities are not covered under the current warranty and are performed at a cost.

Activity	Every day	Every week	Every month
Check the proper functioning of the wheel brakes	X		
Check the fastening of the vest, abduction belts, and pelvic belts	X		
Visual inspection of structural elements (damage, cracks)	X		
Check screw connections (eliminate any looseness)		X	
Inspect the fastening of the footrest		X	
Visual inspection of the wheels			X
Check the proper functioning of the tilt adjustment mechanism			X
Check the proper functioning of the back angle adjustment mechanism			X

17 Conditions of Use, Storage, and Transport

The dimensions and weight of the device can be found in the technical data section. For safety reasons, the Baffin neoSIT Basic device should be carried according to the method shown in Fig. 15.

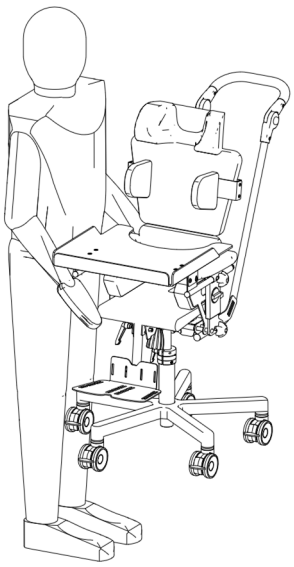


Fig. 15

NOTE! It is forbidden to carry the device with the patient sitting in it.

The product is intended for indoor use.

Do not transport persons in the device in vehicles such as cars, ships, or airplanes.

The manufacturer does not foresee repackaging the product except in service cases. The device should be packed in such a way that no additional damage occurs during transport.

NOTE! The device can be stored, transported, and used at temperatures from -20°C to +40°C and relative humidity from 10% to 90%; however, it is recommended that the device be stored or transported at room temperature and humidity.

If the device has been stored or transported at high ambient temperatures or exposed to direct sunlight, ensure that the device has a safe operating temperature, i.e., the caregiver should check that the temperature of the device is not too high before the user has any contact with the device.

18 Warranty/ service

In case when any defects or damages should occur, cease to use the device immediately and contact the seller or the manufacturer. Secure the damaged device in order to prevent further extension of the damage. Do not undertake any attempts to individually repair the device. Do not replace any original parts with spare parts developed individually or obtained from any source other than the one recommended by the manufacturer.

- When the user abandons the future use of the device, then he is obliged to utilize the device according to the applicable environmental regulations.
- The manufacturer determines the product life to be 5 years. After this period, the device should undergo an inspection by the manufacturer to determine whether it is suitable for further use.
- The post -warranty service of the device is performed by the manufacturer.

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Contact details of the service department:
LIW Care Technology Sp. z o.o.
Golfowa 7, 94-406 Łódź.
www.liwcare.pl
email: service@liwcare.pl

- Current address details can be obtained on the following website: www.liwcare.pl.
- Warranty conditions have been determined in the warranty car

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