

CERTIFICATE

Management system as per

PN-EN ISO 13485:2016-04

Medical devices - Quality management systems - Requirements for regulatory purposes

In accordance with TÜV NORD Polska Sp. z o.o. procedures, it is hereby certified that



FAMED Żywiec Sp. z o.o.
ul. Fabryczna 1, PL / 34-300 Żywiec

applies a management system in line with the above standard for the following scope

Design, development, production, distribution and service of ICU beds, rehabilitation beds and hospital beds, delivery beds, baby cots, operating and treatment tables, gynecological and treatment chairs, patient transport trolleys, luminaires and relevant accessories.

Regardless of the fact that TÜV NORD Polska Sp. z o.o. is a notified body No. 2274 in the area of medical devices, this Certificate is not a Certificate of Conformity within the meaning of Directive 93/42/EEC and is not a basis for CE marking.

Certificate Registration No. **AC090 MD/1202/139/2016**

Audit Report No. PL139/2019

Valid from **07-10-2019**

Valid until **13-09-2022**

Initial certification: 23-09-2016



Manager of Certification Body
TÜV NORD Polska Sp. z o.o.

Katowice, 07-10-2019

This certification was conducted in accordance with the TÜV NORD Polska Sp. z o.o. auditing and certification procedures and is subject to regular surveillance audits.

TÜV NORD Polska Sp. z o.o.

ul. Mickiewicza 29

40-085 Katowice

www.tuv-nord.pl



AC 090
QMS

CERTIFICATE

Management system as per
PN-EN ISO 9001 : 2015

In accordance with TÜV NORD Polska Sp. z o.o. procedures, it is hereby certified that



FAMED Żywiec Sp. z o.o.
ul. Fabryczna 1, PL / 34-300 Żywiec

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AC 090
QMS

EU Declaration of Conformity
Deklaracja Zgodności UE
no/nr: 60/2021



FAMED ŻYWIEC sp. z o.o.

ul. Fabryczna 1
34-300 Żywiec, Poland
t: +48 33 866 62 00
www.famed.com.pl

SRN: PL-MF-000002794
GLN (GS1): 5904157200007

hereby declares under its sole responsibility that the
oświadcza na swoją wyłączną odpowiedzialność, że:

Medical Device Name: Nazwa wyrobu medycznego:	Operating table SU-03 Stół operacyjny SU-03
Alternative trade names: Inne nazwy handlowe:	
BASIC UDI-DI	59041572SU03PR
MD Class / Classification Rule Klasa wyrobu medycznego / reguła klasyfikacji	Class I / rule 13 Klasa I / reguła 13

meets the provisions of the EU Medical Device Regulation - MDR 2017/745.

The conformity assessment according to the Annex II and III of the above mentioned regulation has been followed. The device is marked with the **CE** mark.

This declaration is supported by the Quality System approval to ISO 13485:2016 issued by TÜV Nord Poland.

Any modifications of the medical device not authorized by Famed Żywiec sp. z o. o. will invalidate this declaration.

spełnia wymagania Rozporządzenia UE w sprawie wyrobów medycznych - MDR 2017/745.

Ocenę zgodności przeprowadzono zgodnie z załącznikami II i III wyżej wymienionego rozporządzenia. Wyrób jest oznaczony znakiem **CE**.

Deklaracja ta wsparta jest certyfikatem Systemu Zarządzania Jakością wg ISO 13485: 2016 wydanym przez TÜV Nord Polska.

Jakiegolwiek modyfikacje wyrobu medycznego nieautoryzowane przez Famed Żywiec sp. z o. o. unieważnią to oświadczenie.

Valid until/ważna do: **25.05.2024**

Dyrektor Rozwoju

.....**Patryk Gowin**.....
Person Responsible for Regulatory Compliance PRRC
Osoba odpowiedzialna za zgodność regulacyjną

President of the Board, CEO

Tomasz Rycak

Board President
Prezes Zarządu

Place and date of the issue:

Miejsce i data wydania: Żywiec, 26.05.2021 r.

EU Declaration of Conformity
Deklaracja Zgodności UE
no/nr: 60/2021



Standards applied / Zastosowane standardy:

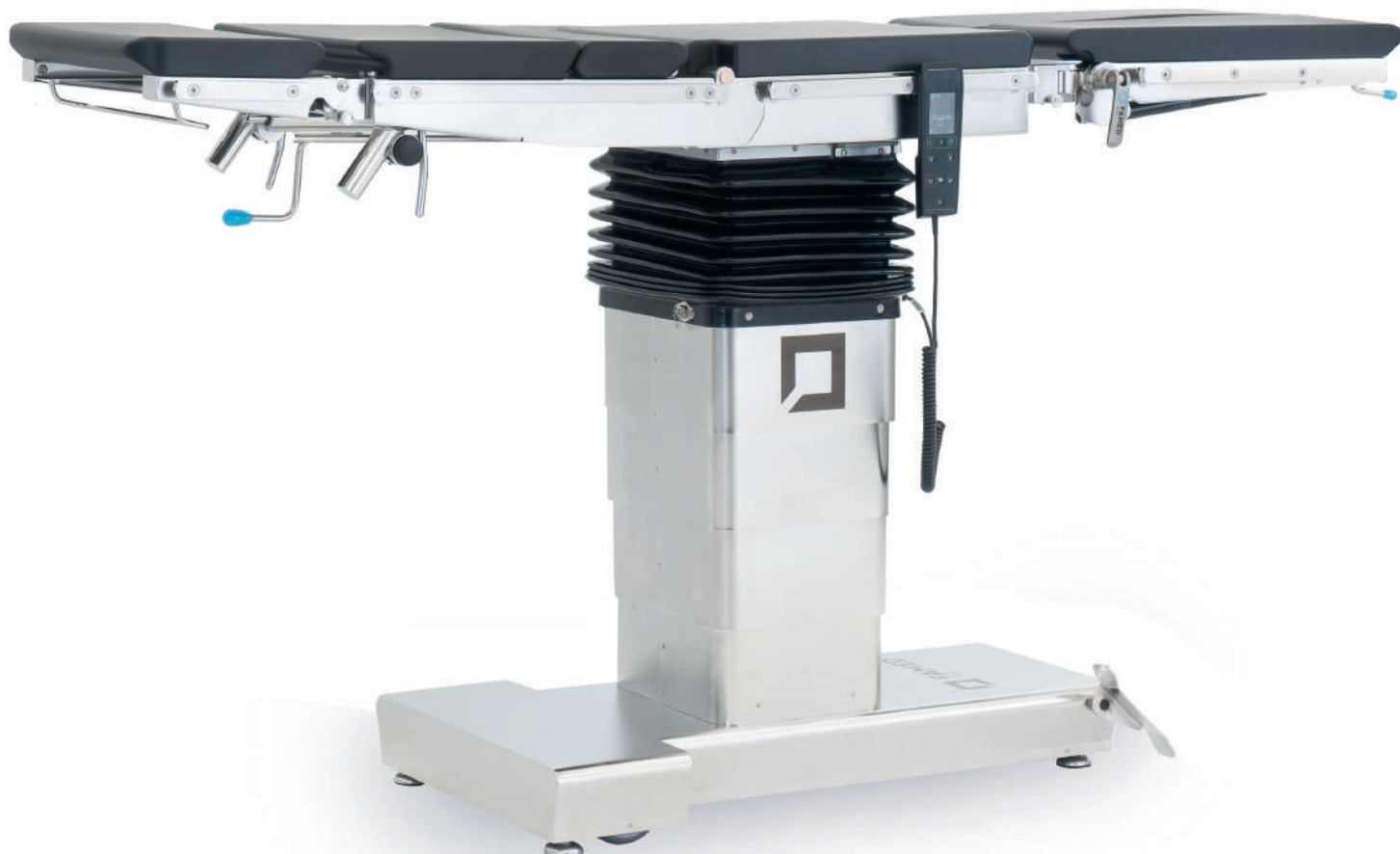
Standard ID	Description / Opis
PN-EN ISO 13485	<i>Medical devices. Quality management systems. Requirements for regulatory purposes/</i> Wyroby medyczne. Systemy zarządzania jakością. Wymagania dla celów przepisów prawnych.
PN-EN ISO 14971	<i>Medical devices. Application of risk management to medical devices/</i> Wyroby medyczne Zastosowanie zarządzania ryzykiem do wyrobów medycznych.
PN-EN 60601-1	<i>Medical electrical equipment - Part 1: General requirements for basic safety and essential performance/</i> Medyczne urządzenia elektryczne. Część 1. Wymagania ogólne dotyczące bezpieczeństwa podstawowego i oraz funkcjonowania zasadniczego
PN-EN 60601-1-2	<i>Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests/</i> Medyczne urządzenia elektryczne -- Część 1-2: Wymagania ogólne dotyczące bezpieczeństwa podstawowego oraz funkcjonowania zasadniczego -- Norma uzupełniająca: Zakłócenia elektromagnetyczne -- Wymagania i badania
PN-EN 60601-1-6	<i>Medical electrical equipment –Part 1-6: General requirements for basic safety and essential performance –Collateral standard: Usability/</i> Medyczne urządzenia elektryczne Część 1-6: Wymagania ogólne dotyczące bezpieczeństwa podstawowego oraz funkcjonowania zasadniczego – Norma uzupełniająca: Użyteczność
PN-EN 60601-2-46	<i>Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables/</i> Medyczne urządzenia elektryczne – Część 2-46: Szczegółowe wymagania bezpieczeństwa stołów operacyjnych.
PN-EN ISO 10993-1	<i>Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process/</i> Biologiczna ocena wyrobów medycznych Część 1: Badanie i ocena w procesie zarządzania ryzykiem
PN-EN 1041	<i>Information supplied by the manufacturer of medical devices/</i> Informacje dostarczane przez producenta wraz z wyrobem medycznym.
PN-EN 62366-1	<i>Medical devices -- Part 1: Application of usability engineering to medical devices/</i> Urządzenia medyczne - Zastosowanie inżynierii użyteczności do urządzeń medycznych.
PN-EN ISO 19054	<i>Rail systems for supporting medical equipment/</i> Systemy szynowe do podtrzymywania wyposażenia medycznego.
PN-EN 15223-1	<i>Medical devices – Symbols to be used with medical devices labels, labelling and information to be supplied – Part 1: General requirements/</i> Wyroby medyczne - Symbole do stosowania na etykietach wyrobów medycznych, w ich oznakowaniu i w dostarczanych z nimi informacjach Część I: Wymagania ogólne.
PN-EN 60529	<i>Degrees of Protection Provided by Enclosures/</i> Stopnie ochrony zapewniane przez obudowy (Kod IP).

EU Declaration of Conformity
Deklaracja Zgodności UE
 no/nr: 60/2021



Available versions of the product / Dostępne wersje produktu:

BASIC UDI-DI:	
UDI-DI (GTIN)	VERSION DESCRIPTION / OPIS WERSJI
5904157201004	Operating Table SU-03, 4-section table top, "T" base/ Stół operacyjny SU-03, 4-sekcyjny, podstawa "T"
5904157201011	Operating Table SU-03, 5-section table top, "T" base/ Stół operacyjny SU-03, 5-sekcyjny, podstawa "T"
5904157201028	Operating Table SU-03, 6-section table top, "T" base/ Stół operacyjny SU-03, 6-sekcyjny, podstawa "T"
5904157201035	Operating Table SU-03, "T" base with orthopedic table top/ Stół operacyjny SU-03, podstawa „T” z blatem ortopedycznym
5904157201042	Operating Table SU-03, 5-section table top, "T" base, electric back section/ Stół operacyjny SU-03, 5-sekcyjny, podstawa "T", elektryczne oparcie pleców
5904157201059	Operating Table SU-03, 5-section table top, "T" base, one piece leg rest/ Stół operacyjny SU-03, 5-sekcyjny, podstawa "T", podnóżek jednoczęściowy
5904157201066	Operating Table SU-03, 4-section table top, "T" base, one piece leg rest/ Stół operacyjny SU-03, 4-sekcyjny, podstawa "T", podnóżek jednoczęściowy
5904157201073	Operating Table SU-03, 4-section table top, "T" base, electric back section/ Stół operacyjny SU-03, 4-sekcyjny, podstawa "T", elektryczne oparcie pleców
5904157201080	Operating Table SU-03, 4-section table top, large wheels base/ Stół operacyjny SU-03, 4-sekcyjny, podstawa supermobil
5904157201097	Operating Table SU-03, 4-section table top, large wheels base with alternative drive/ Stół operacyjny SU-03, 4-sekcyjny, podstawa supermobil z alternatywnym napędem
5904157201103	Operating Table SU-03, 5-section table top, large wheels base/ Stół operacyjny SU-03, 5-sekcyjny, podstawa supermobil
5904157201110	Operating Table SU-03, 5-section table top, large wheels base with alternative drive/ Stół operacyjny SU-03, 5-sekcyjny, podstawa supermobil z alternatywnym napędem
5904157201127	Operating Table SU-03, 6-section table top, large wheels base/ Stół operacyjny SU-03, 6-sekcyjny, podstawa supermobil
5904157201134	Operating Table SU-03, 6-section table top, large wheels base with alternative drive/ Stół operacyjny SU-03, 6-sekcyjny, podstawa supermobil z alternatywnym napędem
5904157201141	Operating Table SU-03, 4-section table top, large wheels base, electric back section/ Stół operacyjny SU-03, 4-sekcyjny, podstawa supermobil, elektryczne oparcie pleców
5904157201158	Operating Table SU-03, 5-section table top, large wheels base, electric back section/ Stół operacyjny SU-03, 5-sekcyjny, podstawa supermobil, elektryczne oparcie pleców
5904157201165	Operating Table SU-03, 5-section table top, large wheels base, electric back section, with alternative drive/ Stół operacyjny SU-03, 5-sekcyjny, podstawa supermobil, elektryczne oparcie pleców z alternatywnym napędem
5904157201172	Operating Table SU-03, large wheels base with orthopedic table top/ Stół operacyjny SU-03, podstawa supermobil z blatem ortopedycznym



SU-03

**Economical table with
electro-hydraulic control**



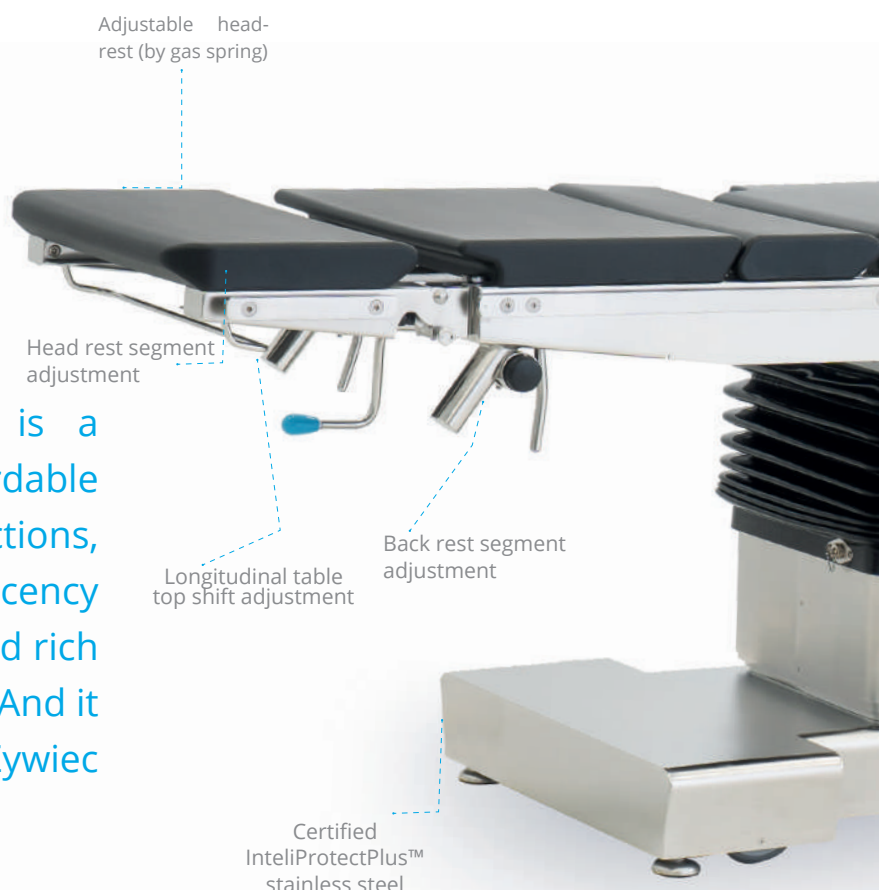
The product was made of materials with
antimicrobial/antibacterial properties.

SU-03

Economical table with electro-hydraulic control

Famed SU-03 operating table is a universal product with a very affordable price. SU-03 offers numerous functions, high load capacity, good radiolucency parameters, longitudinal travel and rich choice of compatible accessories. And it has the legendary quality of the Żywiec plant production.

The entire offer of additional equipment is presented in the "Equipment for operating tables" catalogue.

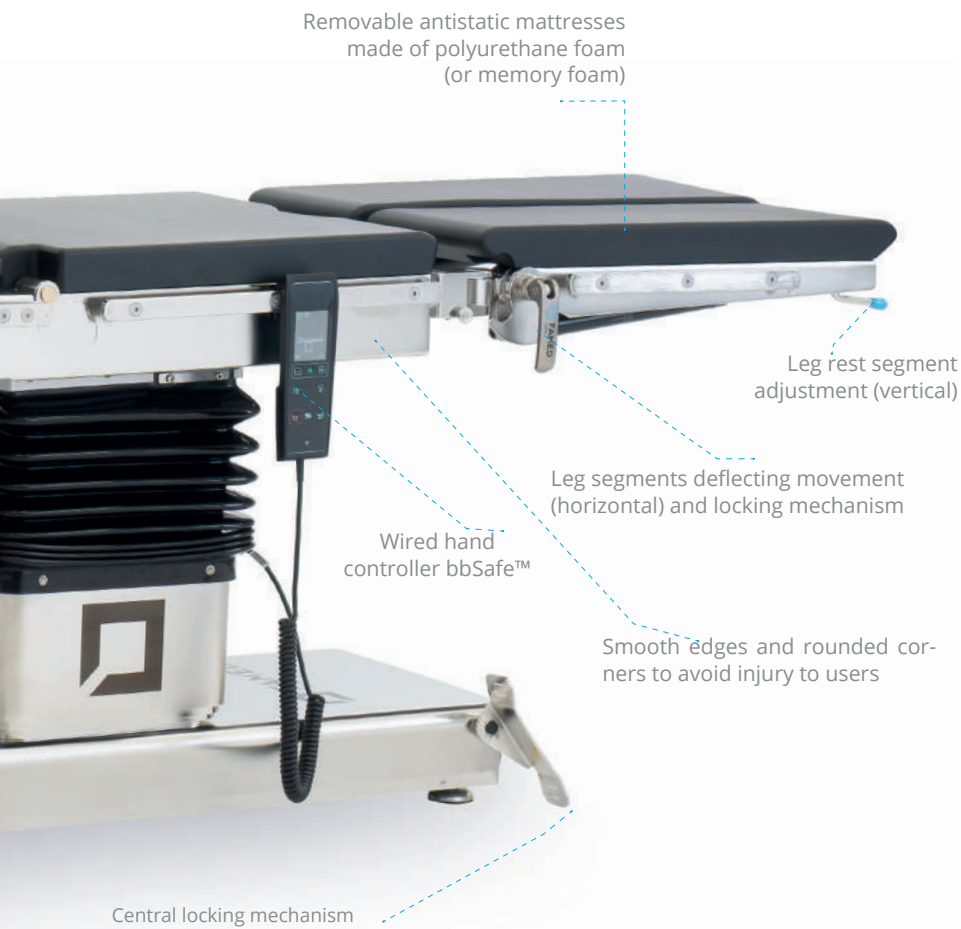


Standard structure

- All steel components are made of high-alloy, corrosion-resistant stainless steel AISI 316L that subjected to electropolishing process - **IntelliProtectPlus™** technology, resistant to disinfecting agents.
- Mobile base is equipped with central locking system activated by a foot lever (T-shaped base: mechanical-hydraulic foldable pods; H-shaped base (large wheels): central lock with directional lock).
- Mattresses are easy removable from the table top segments.
- Surfaces of the tables are easy to be kept clean and are resistant to disinfecting agents.
- The table top is X-ray translucent. It enables taking X-ray pictures and monitoring the patient with a C-arm.

Functions and drives

- Table top height adjustment, lateral tilt adjustment, Trendelenburg and reverse-Trendelenburg adjustment, table top leveling are executed with the use of a remote controller with the use of electro-hydraulic motors and 24V **fCharge™** power supply. Hand controller is equipped with battery charge level indicator.
- Back rest and leg rest segment (single section) and head rest segment angle adjustment are supported by gas springs equipped with locking mechanism.
- Electro-hydraulic back rest segment (option in SU-03; standard in SU-03.91).
- Divided leg rest segments are being set up with the use of gas springs.
- Kidney elevator height adjustment at 5 and 6 segments table top is manually executed with the use of the gear transmission located at head rest segment side.
- Table top stepless longitudinal shift is executed manually.
- Leg rest segments are deflected horizontally manually.



Gynaecological and urological position



Proctologic position

Proctology attachment WS-30.5



Trendelenburg position



Lateral tilt



Beach chair position



Raised kidney bench



STANDARD FUNCTIONS AND SOLUTIONS

Cooperation with C arm

Longitudinal table top shift, asymmetric table column location allow you to use the C arm during interventions required continues patient monitoring. Table top is fully translucent (with certificate), all inner crossbars for strengthening the construction are made from carbon fibre and will not affect the pictures.



Range of X-ray permeability (remember, you can always switch the leg and head segments).

Mattresses

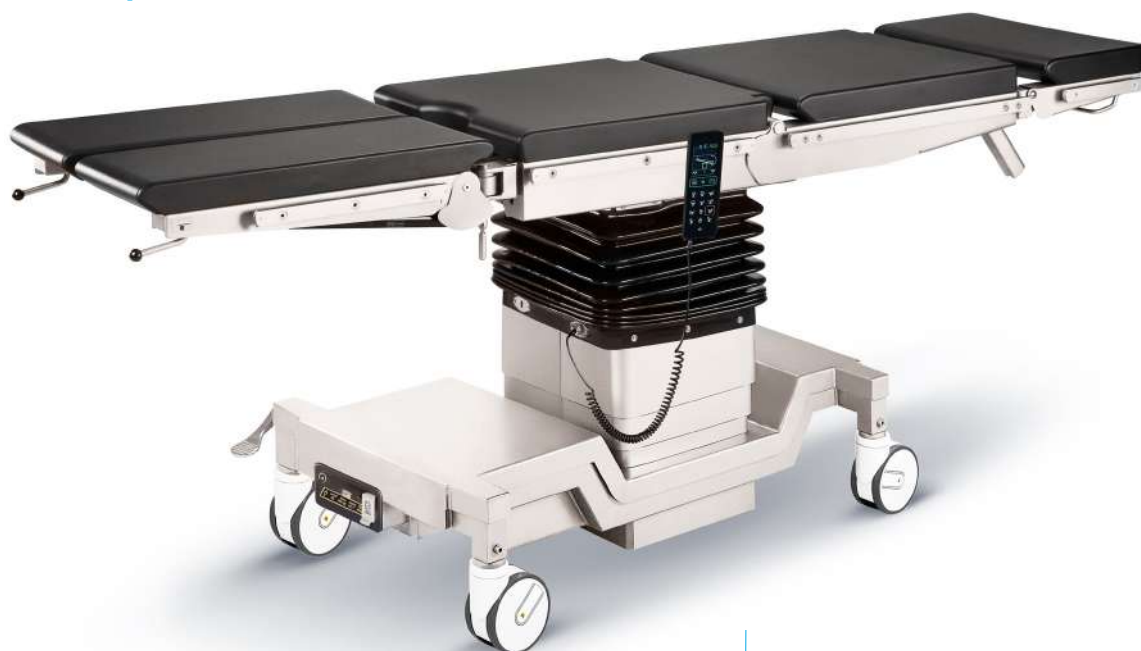


Table is equipped with removable, seamless, molded polyurethane pads 50 mm thick. All mattresses are antistatic, waterproof and X-ray translucent. They can be easily detached from the table top (they are mounted on with the use of special pegs, which secures them in place and prevents from moving during the table adjustments). The homogenous surface of the mattress is easy to clean and resistant to disinfecting agents.

Every mattress is made inside Famed facility, undergoes thorough several quality tests to ensure long-lasting, trouble-free use.

Quick and easy way to remove the mattresses

Available base options



Mobile base
H-shaped base equipped with large 125 mm wheels

TABLE TOPS OPTIONS



Total length:

- 4-segments table top 2060 mm
- 5-segments table top 2060 mm
- 6-segments table top 2160 mm

Total width:

- 4-segments table top 550 mm
- 5-segments table top 550 mm
- 6-segments table top 550 mm

Leg segment length:

- 4-segments table top 655 mm
- 5-segments table top 655 mm
- 6-segments table top 765 mm

Table top BL-20.0 technical data (without the head rest segment):

- Total table top length 1735 mm
- Total table top width 545 mm
- Back rest adjustment -25° to +80°



4-segments table top



5-segments table top



6-segments table top



Possibility removal of the table top segments

TECHNOLOGIES AND ACCESSORIES

InteliProtect™



This technology is primarily based on the use of new, better-grade stainless steel (according to the international standard EN 10088) and modernization of the production process, which reduced the number of contaminants generated on the table surface. In addition, **InteliProtect™** technology means that we are using a richer chemical bath that better protects our products. Additionally, places particularly exposed to contamination and corrosion, are covered with a protective layer of a zinc-based agent.

bbSafe™



Wired remote control with 2.8" screen in IPS technology, which enables quick and precise change of position and real-time preview of setting values. For patient safety, we have designed the **bbSafe™** system – triple protection against accidental change of position and a warning about high energy consumption. Following an adjustable idle time, the remote control automatically switches to standby mode. In addition, there is a two-step process of changing the bed's position – the operator first presses a button corresponding to the category of movement, and then, in the next step, enters information about its direction. Moreover, the **bbSafe™** system warns the user when the movement of the table puts a heavy load on the battery cells – this allows you to predict the power consumption and plan battery charging accordingly. The remote control meets the IP67 standard.

rCover™



The wireless remote control for the operating table is an option for the facilities which require maximum convenience and usability. This controller offers all the features of a wired remote control, a powerful battery pack and a docking station with a wireless charger. It is equipped in **bbSafe™** and **rCover™** technology – built-in protection against interference with other wireless devices that work in the vicinity of the operating room. Part of the system is also a special table and the remote-control pairing procedure and appropriately calculated signal power limit.

pDetach™



Optional control of the operating table located on the column. This additional control module is a removable panel that can be detached from the column and operated like a traditional remote control. It provides full functionality in setting the table position. The panel has a convenient **pDetach™**, magnetic mechanism, which protects it against getting accidentally brought down, while providing a simple and quick disassembly.

AlterSafe™



The alternative drive ensures operation of all electric table adjustment options in the event of control circuit failure or essential power supply failure. Tables with the alternative **AlterSafe™** technology drive have two independently operating drive systems: electro-hydraulic and mechanical-hydraulic. The alternative mechanical-hydraulic **AlterSafe™** system allows for the operation of all functions available through the electrical system. Individual table functions are selected using a lever placed in the table base and are carried out using a foot pump.



Wired **bbSafe™** hand controller



Wireless **rCover™** controller with wireless charger (option)



Column-mounted **pDetach™** control panel (option)



Wired foot controller type WS-36.6 (option)



SU-03 **AlterSafe™** alternative drive (H-base)

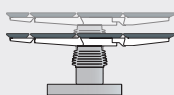


SU-03

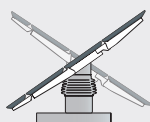


Operating table functions
executed with use of the
hand controller

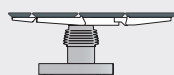
680 to 1080 mm



40° 40°



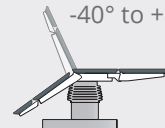
"0"



30°



-40° to +80° (optional)



220°
Flex (optional)

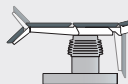


100°
Reflex (optional)

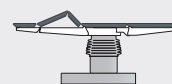


Operating table functions
executed manually

-50° to +55°

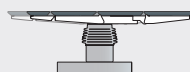


-90° to +25°



150 mm *

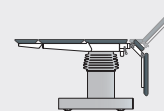
340 mm



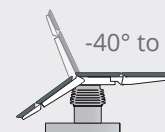
180°



-90° to +45° **



-40° to +85° (standard)



* in 5 or 6 segment table top

** in 6 segment table top

Technical data	SU-03
Total table top length (with head rest)	2060 mm
Table top width	500 mm
Total table top width	550 mm
Table top height adjustment (without the mattresses)	680 to 1080 mm
Trendelenburg / reverse-Trendelenburg	40°
Lateral tilt	±30°
Back rest segment adjustment	-40° to +85°
Head rest segment adjustment	-50° to +55°
Kidney elevator height adjustment	150 mm
Kidney elevator adjustment angle	110°
Leg rest segment inclination adjustment (4,5 - section)	-90° to +25°
Leg rest segment inclination adjustment (6 - section)	-90° to +45°
Maximum leg rest segment inclination	180°
Table top longitudinal shift	340 mm
fCharge™ battery power	24 V DC
Maximum permissible load static/dynamic (standard)	350 kg / 200 kg
Maximum permissible load static/dynamic (optional)	350 kg / 250 kg
Total table weight	250 kg
Class of protection against electric shock	I
Type part of the application	B
Protection grade (IP Code in IEC standard 60529)	IP-X4



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 www.famed.com.pl



The product meets the requirements of the European Directive
 MDD 93/42/EEC concerning safety of medical devices

Edition 173/2020/08/1. Famed Żywiec reserves the right to make modification in the products in the course of technical progress. All illustrations and photos, used in the material, are for illustration and may not accurately depict the actual product. Actual product may vary / differ from what is indicated herein and are subject to change.

