

medifa 3000

Examination couches



User manual

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1. Important information

1.1 Revision history

| Version | Date | Reason or modification of publication |
|---------|---------|---------------------------------------|
| 1.0 | 02/2010 | Erstausgabe |
| 2.0 | 06/2020 | Layout |

1.2 CE label

This product is a Class 1 medical product according to the European Directive 93/42/EEC on medical products. It complies with the version of this Directive applicable at the time of being placed on the market.

1.3 Conformity

The manufacturer shall declare the conformity of this product with the essential requirements as per the Medical Device Directive (MDD) according to annex 1 as well as the execution of a conformity assessment procedure required for Class 1 products as per MDD according to annex 7 and shall document this through the CE label.

1.4 Manufacturer and distributor

medifa GmbH & Co. KG
Industriestraße 5
57413 Finnentrop
Germany
Telephone no. +49 2721 7177-0
Service Hotline: +49 2721 7177 410
Fax +49 2721 7177-255
info@medifa.com
www.medifa.com

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We are constantly working on the further development of our products. Please understand that we must reserve the right to change the scope of delivery in shape, equipment and technology at any time.

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All rights according to the copyright law are expressly reserved by medifa. medifa shall only be responsible for the safety-related properties of this device within the framework of the legal regulations if maintenance, servicing and changes to this device are carried out by medifa itself or a representative in accordance with instructions.

2. Foreword

medifa would like to thank you for purchasing the examination couche. With the examination couche, you have acquired a product that combines design, functionality and comfort in the highest possible quality „Made in Germany“.

medifa's products are manufactured for a long and trouble-free service life.
Development, design and production at medifa have been certified according to DIN EN ISO 9001 and DIN EN ISO 13485.
The products comply with the requirements of the German Medical Products Act (MPG) and bear the CE label.

The examination couche consists exclusively of high-quality materials with a long service life.
medifa offers a wide range of accessories to meet your requirements. Periodic maintenance by our trained service technicians also ensures that the table is always in perfect condition during the routine operation.

Should you have any further questions, please do not hesitate to contact us at any time.

3. Used symbols

Various information and safety symbols are used in these operating instructions to highlight particularly relevant information.

Safety instructions



HAZARD

HAZARD indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.



WARNING

WARNUNG verweist auf eine potenzielle Gefahrensituation die, wenn sie nicht vermieden wird, zum Tode oder zu schweren Verletzungen führen kann.



CAUTION

CAUTION indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury.

ATTENTION

Indication of harmful situation with the possible consequences: the device or something in its vicinity could be damaged.

4. Safety instructions



WARNING

Risk of injury!

The examination couch is designed for a maximum load of 225 kg. This safe working load must not be exceeded.



WARNING

Risk of injury!

Only accessories listed in the accessories list may be used.



WARNING

risk of tipping!

The examination couch must not be operated over an uneven floor!



CAUTION

Danger of personal injury by tilting the examination couch!

- When driving over thresholds, the examination couch can tip over.
- The crossing of thresholds must always be carried out with two persons.



CAUTION

Danger of collision!

Take special care when transporting the examination couch.

- Familiarize yourself with the handling features before transporting a patient for the first time.



CAUTION

Patient hazard!

It is forbidden to brake the examination couch while driving! Stop the examination couch first.

5. Intended use

The examination couch is intended exclusively for human medical purposes.

The examination couch in combination with the standard medifa accessories is intended for the following uses:

- The examination couch serves exclusively for short-term positioning of the patient during the examination and/or treatment.
- The storage has to be carried out in a lying position.

Due to the construction of the couch, the patient can lie on his stomach or on his back.

The patient ascent or patient placement must be laterally central. The adjustable segments of the couch are adjusted manually.

The positioning of the patient on the examination couch is done according to general practice and doctrine.

The examination couch must be covered with sterile material before use. The transport of objects, equipment or materials on the examination couch is prohibited. The product may only be used / operated by trained medical and nursing staff in a responsible and controlled manner.

The instruction of the operating and nursing personnel is carried out by the manufacturer or by other persons appointed by the Manufacturer authorized persons.

For the intended use of the examination couch this instruction manual must be observed!

Any other use of the couch is considered as not in accordance with the intended purpose!

The supplier/manufacturer is not liable for personal injury or damage to property as a result of improper operation or use.

6. medifa 3000 examination couches

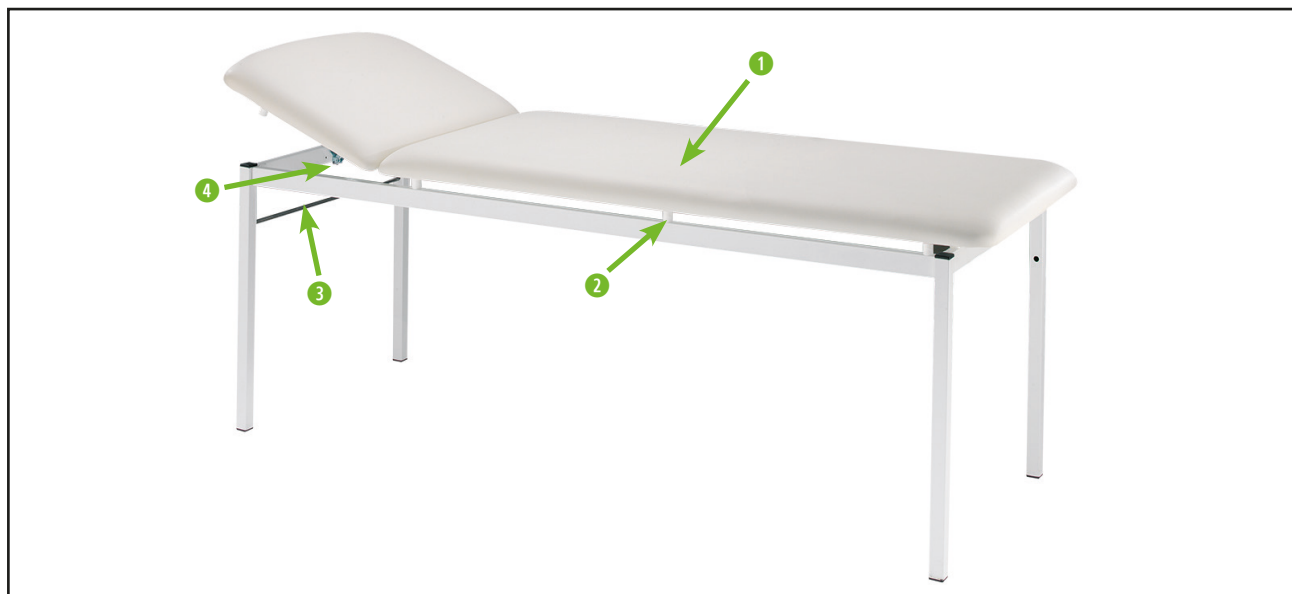


Fig. 1: Model 111419/111519

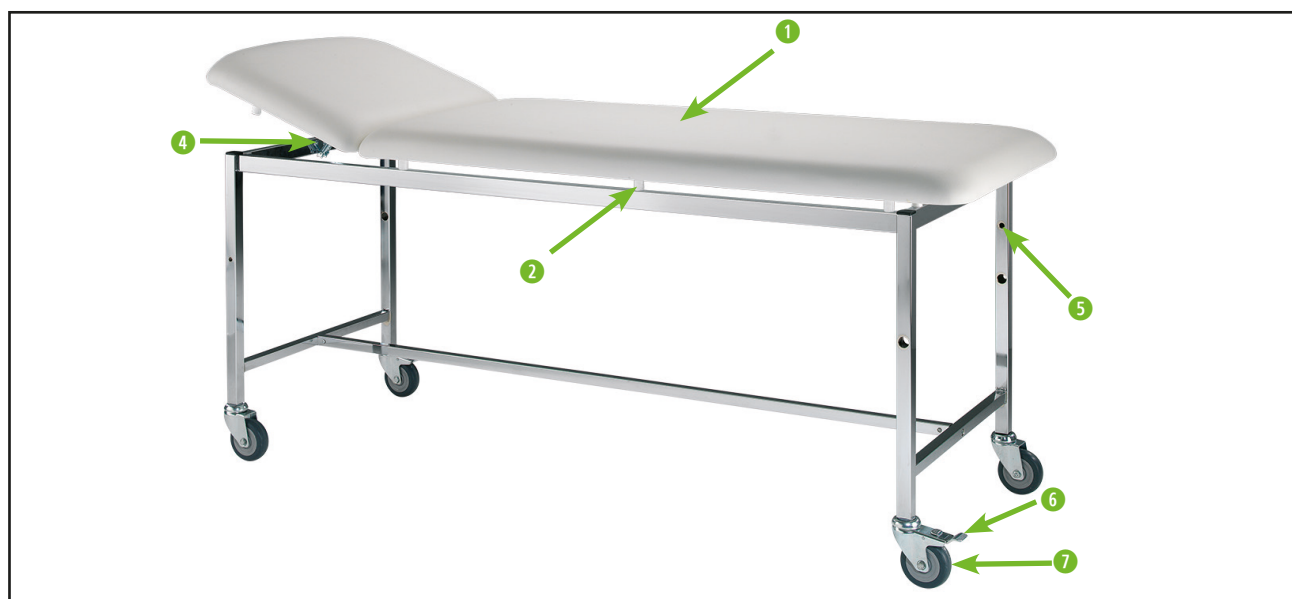


Fig. 2: Model 111519/171519F

| No. | Description |
|-----|-------------------------------------|
| 1 | Upholstery |
| 2 | Safety spacer |
| 3 | Paper roll holder stick |
| 4 | Adjustable latch on the headrest |
| 5 | Holder for paper roll holding stick |
| 6 | Rocker switch for parking brake |
| 7 | Castor |

7. Rating plate

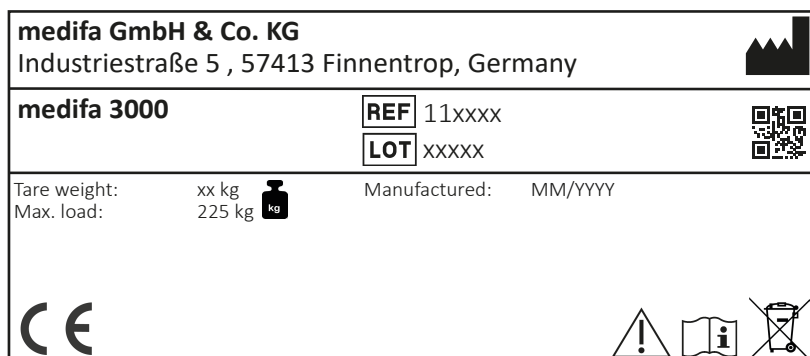









Fig. 3: Rating plate

| Elements / symbols | Description |
|---|---|
|  | Manufacturer details and contact information |
| REF | Product name / type |
| LOT | Batch number |
|  | QR Code |
| Manufactured | Production period |
|  | Details of unladen weight and maximum additional load |
| Tare weight | Unladen weight |
| Max. Load | Maximum weight including accessories and patient |
|  | Observe the safety instructions in the accompanying documents |
|  | Read the user manual |
|  | Observe instructions for disposal |
|  | Device is declared compliant with Directive 93/42/EEC |

8. Commissioning

8.1 Headrest adjustment

To adjust the angle of the headrest [1], it only needs to be lifted. To lower the head section, it must first be raised to the stop. This disengages the adjustment grid [2] and the head section can be lowered without difficulty.

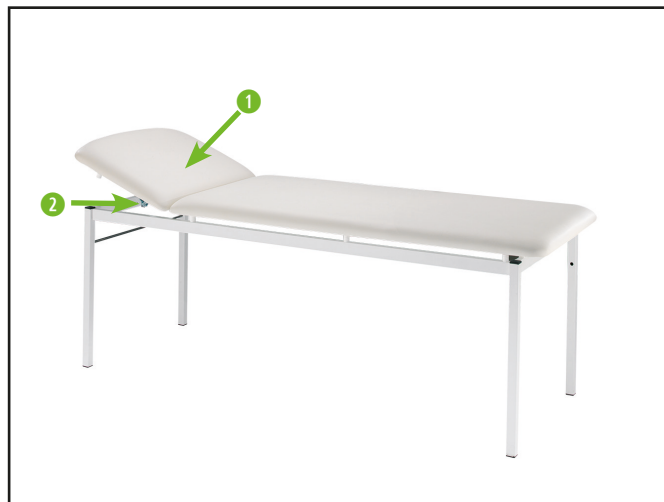


Fig. 4: Headrest adjustment

8.2 Mobility (111519F / 171519F)

The examination couch is equipped with four castors instead of the feet. There are two castors [1] diagonally to each other, which can be locked. If the rocker switch of the castor is operated, the castor is locked. Furthermore, the examination couch is equipped with a castor [2] which is directionally stable. If the rocker switch is actuated via this castor, the castor no longer changes direction and is therefore stable to move. The last castor [3] on the examination couch is free-running.



Fig. 5: Castors 111519F / 171519

8.3 Floor leveling screws (111519 / 171519)

The examination couch is additionally equipped with ground levelling screws [1] to avoid the danger of tipping over on an uneven surface. If necessary, turn the corresponding compensating screws a little into or out of the foot of the examination couch.

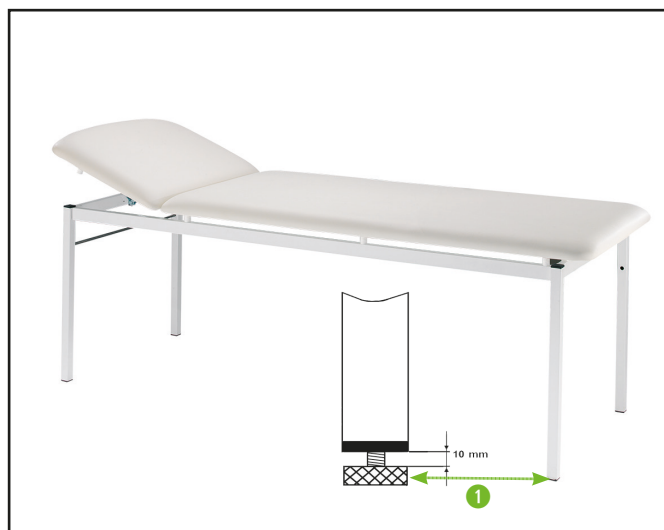


Fig. 6: Floor leveling screws 111519 / 171519

8.4 Attaching a paper roll

To attach a paper roll, take the supplied paper roll holder stick [1] and push it through the paper roll.

Afterwards the roll can easily be hooked in between the pair of legs at the head end or foot end with the stick in the middle. To do this, drill holes are provided on both sides in the examination couch feet available.



Fig. 7: Mounting the paper roll

8.5 Upholstery

The upholstery [1] of the examination couches consist of a stable carrier plate glued with foam. This is seamlessly covered with a hard-wearing, tear-resistant artificial leather suitable for medical use.

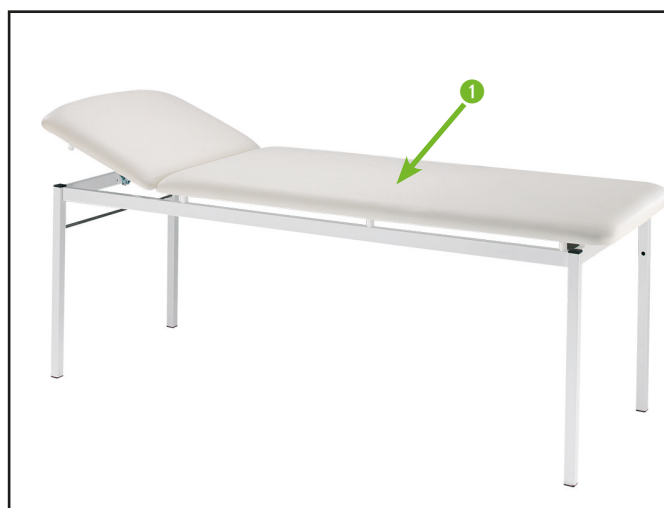


Fig. 8: Upholstery

9. Care instructions



CAUTION

Danger of personal injury.

- Only hand over cleaned and disinfected devices / equipment to a service technician for maintenance and repair work.
- Replace padding that no longer meets the hygiene and infection prevention requirements.

WARNING

Risk of damage to property due to incorrect care.

The product is not suitable for a mechanical cleaning process.

Avoid excessive distribution / application of water on the surfaces of the product.

Incorrect care products damage the surface.

For the care of the product, do not generally use abrasive cleaning and disinfecting agents containing halide and peracetic acid. For plastic parts and padding, do not use any alcoholic and solvent-based (flammable) cleaning and disinfecting agents.

The care products for cleaning and disinfection must comply with the nationally valid regulations for the medical sector and/or be included in the list of the German Society for Hygiene and Microbiology / Verbund für Angewandte Hygiene e.V. (Association for Applied Hygiene).

Clean contaminated products immediately. Cleaning / disinfection is limited to regular wiping (not immersing) with suitable agents.

9.1 Cleaning

For cleaning stainless steel and plastic parts, use a pH-neutral or slightly alkaline all-purpose cleaner with surfactants as active cleaning components.

In case of heavy contamination, use the cleaner in concentrated form and subsequently wipe it off with clear water.

9.2 Disinfection

For disinfection, follow the application instructions of the disinfectant manufacturer.

Alcohol- or aldehyde-based surface disinfectants are suitable for disinfecting the stainless steel parts. Only use aldehyde-based surface disinfectants for plastic parts and padding, as alcohol-based agents can damage the surface.

9.3 Drying

After cleaning and disinfection, remove excess moisture with a dry cloth.

9.4 Disposal

Dispose of all cleaning and disinfectant residues or remnants in a harmless and environmentally friendly manner.

10. Technical data

10.1 Dimensions and adjustment ranges

| Model | Length [mm] | Width [mm] | Height [mm] | Headrest adjustment | Upholstery thickness [mm] | Weight [kg] | Maximum load | Castors |
|---------|-------------|------------|-------------|---------------------|---------------------------|-------------|--------------|---------|
| 111419 | 1950 | 650 | 650 | + 35° | 50 | 35 | 225 kg | No |
| 111519 | 1950 | 650 | 650 | + 35° | 70 | 35 | 225 kg | No |
| 111519F | 1950 | 650 | 650 | + 35° | 70 | 38 | 225 kg | Yes |
| 171519 | 1950 | 650 | 650 | + 35° | 70 | 35 | 225 kg | No |
| 171519F | 1950 | 650 | 650 | + 35° | 70 | 38 | 225 kg | Yes |

11. Disposal

Examination couche, accessories and packaging must be recycled in an environmentally friendly manner. The disposal, even of individual parts, must always be carried out in an environmentally friendly manner, i.e. in accordance with the valid legal regulations.

For proper disposal of old devices, please contact medifa's Technical customer service department, your local dealer or the appropriate national authority.

The medifa company takes back old devices, defective or no longer used products. For detailed information, please contact medifa's technical customer service department.



medifa GmbH & Co. KG

Industriestraße 5
57413 Finnentrop
Germany
fon +49 2721 7177-0
fax +49 2721 7177-255
info@medifa.com