medifa
the medical factory

Radiolucent arm rest

Art.-no. 81220

User manual

CE

Version: 1.0

we care.

Table of contents

1. Important information

1.1 Revision history

Version	Date	Reason for change to the publication
1.0	04/2020	First edition

1.2 CE marking

This product is a class 1 medical device according to the European Directive 93/42/ EEC on medical devices. This corresponds to the version of this directive valid at the time it was placed on the market.

1.3 Conformity

The manufacturer declares that this product complies with the main requirements according to MDD Appendix 1. The manufacturer also declares that a conformity assessment procedure, according to MDD Appendix 7, (and required for Class-1 products) was carried out and documented by a CE marking.

1.4 Manufacturer and distributor

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1.5 Copyright notice

2. Foreword

The company medifa thanks you for purchasing the product. The arm rest is a product that combines design, functionality and comfort with the highest quality associated with German manufacturing.

The medifa products are manufactured to have a long and trouble-free lifespan.
The development, design and production at medifa have been certified to comply with DIN EN ISO 9001 and DIN EN ISO 13485. These products comply with the requirements of the Medical Devices Act and bear the CE mark.

The product consists exclusively of high-quality materials with a high service life.
We are always available to help if you have any questions.

3. Understanding these operating instructions

ATTENTION

Please read and observe these operating instructions.
This operating instructions must have been read and understood fully by the operating personnel before initially commissioning the product, this applies particularly to the chapter Safety instructions and user obligations. If necessary, in-house training for technical qualifications may be carried out by a qualified person. The operating instructions must be closely followed and available at the place of use.

ATTENTION

This product is safe to use!
Any remaining residual hazards are indicated at the affected locations in the operating instructions.
Follow these instructions!

3.1 List of abbreviations

Abbreviation	Description
CE	European Community (from the French “Communauté Européenne”)
DIN	German Institute for Standardization
EN	European Standard
EEC	European Economic Community
MDD	Medical Device Directive
ISO	International Organization for Standardization
OP	Operations (surgery)

4. Symbols in use

These operating instructions use various warning, notice and safety symbols to highlight information of particular relevance.

Safety instructions

DANGER

DANGER indicates a hazardous situation which, if not avoided, will result in death or serious injury.

WARNING

WARNING indicates a hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

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

ATTENTION

Notice about a harmful situation; possible consequences: the device itself or surrounding objects could be damaged.

5. Safety instructions and user obligations

Keep these operating instructions close to the product so that the information can be accessed later! These operating instructions are an integral part of the product and must be transferred when the location or personnel changes. These operating instructions must also be easily accessible to all users of the product at all times.

5.1 General safety instructions

WARNING

Danger for the patient!
Do not change this medical product! The manufacturer assumes no liability resulting from changes made.

- All work with or on the product (installation, commissioning, operation, maintenance, decommissioning, transport or disposal) may only be carried out by trained medical or nursing staff.
- The product must only be used for the purposes specified in the Proper and intended usage!
- The values specified in Technical specifications must be complied with whenever the product is being used.
- The arm rest must be attached correctly according to the assembly instructions. Failure to follow the instructions may cause the system to become unstable, thus preventing the product from performing its protective function.
- The product may only be mounted on standard rails with the dimensions 10x25 mm.

5.2 Steps to take before each use in the OP

All mechanical components of the product must be checked for proper functionality and integrity before each use!
Do not use defective or damaged products!

5.3 Infection control

- Follow all regulations for cleaning and disinfection!
- Follow the cleaning and disinfection procedures described in these operating instructions!
- Only cleaned and disinfected devices and equipment may be handed over to a service technician or the manufacturer for repair work!

5.4 Maintenance and repair

The product is maintenance-free.
Wear caused by use as well as ageing can affect the safety relevant functions of the product. Check the condition of the product before each use. The product must no longer be used if damage has been identified.

Repairs
Repairs may only be carried out by the medifa technical support or by personnel who have been authorized, trained and certified by medifa.The company medifa is not liable for any damages due to neglected inspections, inadequate repair, improper maintenance or changes made to the product!
For servicing work, please contact the medifa technical support department.

6. Proper and intended usage

This product is an arm rest. It is an accessory of the medifa 8000.
The medifa 8000 and the standard accessories are intended exclusively for human medical purposes.
The product is intended for supporting and positioning the patient's arm immediately before, during and after performing surgery as well as for examination and treatment.

The product may only be used and operated responsibly and in a controlled manner by trained medical and nursing staff. The manufacturer of other persons authorised by the manufacturer shall carry out the training for the operating and care personnel.

In order to ensure proper and intended usage of the product, these operating instructions for the arm rest and the X-ray table must be followed! Any other usage is considered improper and unintended! The supplier/manufacturer is not liable for personal injury or property damage as a result of improper operations or usage.

7. Rating plate

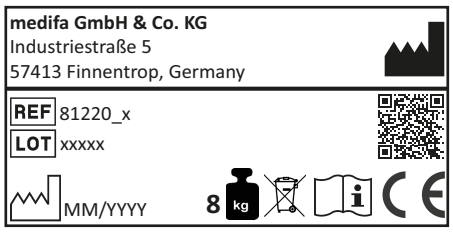


Fig. 1: Ratings plate 81220_x

Elements / symbols	Description
	Manufacturer specifications and contact information
REF	Article number
LOT	Batch number
	QR code
	Date of manufacture
kg	Max. load
	Read the operating instructions.
	Follow the instructions for disposal
CE	This product is declared to be compliant with Directive 93/42/EEC.

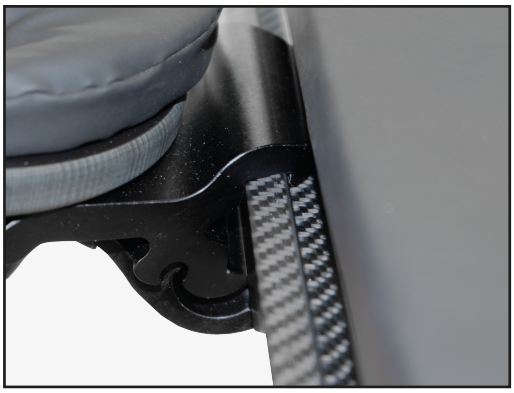
8. Assembly and adjustment

8.1 Inspection of the product for damage

Make sure that all parts of the product are mechanically in order. The plastic parts must not have sharp edges or any kind of damage.

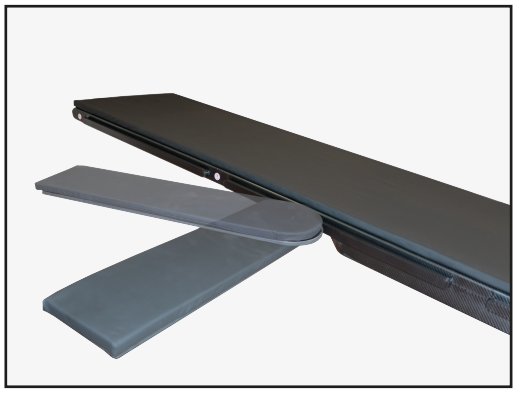
8.2 Attaching the arm rest

1. Press the clip-on retainer together and hook it (from top to bottom) into the carbon rail at the desired position.

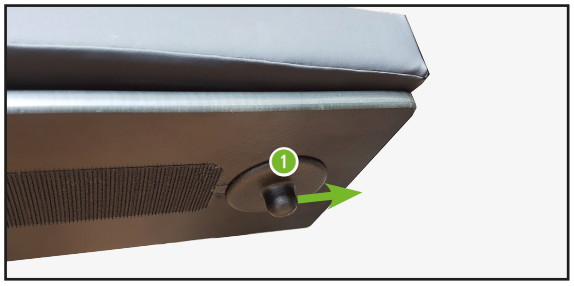


2. Release the clip-on retainer The arm rest is now firmly clamped in at the desired position.

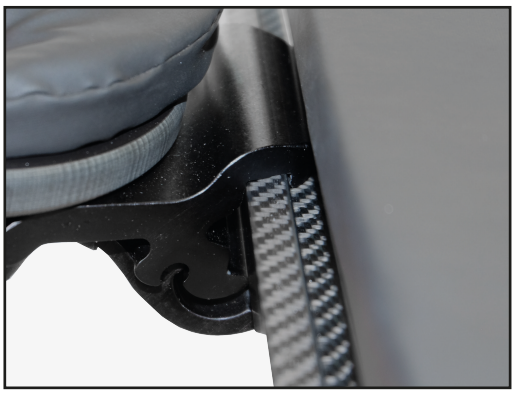
8.3 Adjusting the arm rest



1. Pull the release ball[1] in the direction of the arrow. Then turn the armrest to the desired position (it is adjustable up to 180 degrees).



8.4 Removing the arm rest



1. Press the clip-on retainer together.

2. Remove the arm rest upwards.

9. Care instructions

CAUTION

Risk of personal injury!
Only cleaned and disinfected products and devices may be handed over to a service technician for maintenance and repair work!

ATTENTION

Danger: incorrect care may damage property!
- Improper cleaning products can damage the surface!
- When cleaning the product, do not use scouring cleansers or detergents and disinfectants containing halide or peracetic acid.
- For the plastic parts, do not use alcoholic or solvent-based (flammable) cleaning/disinfecting agents!

The cleaning products for the cleaning and disinfection must comply with the applicable national regulations for the medical sector and/or be listed by the German Society for Hygiene and Microbiology / Association for Applied Hygiene.
Clean contaminated products immediately! The cleaning/disinfection is limited to a regular wiping (not dipping!) using the appropriate substance.

9.1 Cleaning

For cleaning the plastic parts, use a pH-neutral or slightly alkaline all-purpose cleaner with surfactants for cleaning-active components. If parts are heavily contaminated, use concentrated cleaner and then wipe with clear water.

9.2 Disinfecting

For disinfecting, follow the instructions of the disinfectant manufacturer!
Surface disinfectants based on alcohol or aldehyde are suitable for disinfecting the stainless steel parts. For the plastic parts, only use aldehyde-based surface disinfectants. Alcohol-based agents can damage the surface.

9.3 Drying

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

9.4 Disposal

Dispose of all cleaning and disinfectant residues in a proper and environmentally friendly manner!

10. Technical specifications

10.1 Dimensions, weights and load limits

Dimension	Length: 690 mm
	Wide: 155 mm
Upholstery height	Art.-no. 81220_1: 20 mm
	Art.-no. 81220_2: 40 mm
	Art.-no. 81220_3: 60 mm
Tare weight	Art.-no. 81220_1: 2 kg
	Art.-no. 81220_2: 2,2 kg
	Art.-no. 81220_3: 2,4 kg
Max. load	8 kg

10.2 Classification

Medical device class	I

11. Pictograms on the transport packaging

There are several handling symbols on the transport packaging.

Elements / symbols	Description
	Protect the transport packaging against moisture.
	Read the operating instructions.
	Protect from sunlight.
	Date of manufacture
	Follow the instructions for disposal.
	QR code

ATTENTION

Danger of damage to property
The packaging is not weatherproof! Please observe the storage instructions.

12. Disposal

The arm rest and packaging must be recycled in an environmentally friendly manner. The disposal of individual parts must also be carried out in an environmentally friendly manner (i.e. according to the relevant legal regulations)!

For more information about the proper disposal of used products, please contact medifa Technical Support, your local dealer or the appropriate national authority.

The company medifa will take back old products, defective devices, or products no longer in use.
Contact medifa Technical Support for more details.

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we care.

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