ergo basic

Operating Manual

Art.-Nr.: 360 711 Ver.: b

mbnet engineering

Sales and Service Information:

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Contact your nearest **mbnet Engineering GmbH** subsidiary to obtain the address of your local distributor.

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Sales information can also be obtained from: **info@mbnet.de**

The basic bears the mark CE (IEC 60601-1, Class I, Type BF without defibrillation protection), indicating its compliance with the essential requirements regarding safety, functionality and labelling of Annex I of the Medical Device Directive 93/42/EEC.
The requirements apply to patients, users and third persons who come into contact with this device within the scope of its intended use.

Date of issue: 12.06.2020

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Art.-no.: 360 711 Ver.: b
Date of issue: 19.04.2024
Original

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1 Safety Notes

1.1 Responsibility of the User

- The device must be used only by qualified physicians or trained medical professionals.
- The responsibilities of the staff for operating and maintaining the device must be specified by the operator.
- Ensure that the staff have read and understood the user guide. This applies in particular to this section Safety notes.
- The device must not be stacked at any moment.
- Damaged or missing parts must be replaced immediately.
- The safety, reliability and performance of the device can only be guaranteed when the maintenance intervals as stated in Chapter 6: "Maintenance and Care" are observed.

Warning

- Do not modify this equipment without authorization of the manufacturer.

1.2 Organisational Measures

- Before using the device, ensure that a medical product representative has explained its functions as well as the safety requirements.
- Keep this user guide in an accessible place for reference purposes. Make sure that it is always complete and legible.
- Observe the operating and maintenance instructions.

1.3 Indications for Use

- The device is an ECG cable arm and is operated in combination with normal ECG devices. The device is suitable for both recording resting as well as exercise ECG and is used for patients of both genders as well as all ancestries and age groups (preferably as of the age of seven, also dependent on body size).
- The device is only to be operated in a professional healthcare environment.
- The device is suitable for use inside hospitals, cardiology centres, outpatient clinics and medical practices.
- The device can safely be used with pacemaker patients.
- Always operate the device in line with the technical data indicated.
- The device is not intended for sterile use or use outdoors.
- This is a device of type BF. It is not defibrillation protected. As a safety precaution, remove the electrodes before defibrillation!
- The device is intended for use only with power supply networks of 220–240 V AC. Use outside this range is not permitted. EMC compliance has been assessed for this voltage range.
- Use the device only in countries with mains voltages of 220–240 V AC. Use in other markets – especially in regions with 100 V AC – is excluded.

1.4 Contra-indication

- The device is not intended for sterile use.
- The device must not be used in potentially explosive areas or in the presence of flammable gases such as anaesthetic agents.
- The device is not for direct cardiac application.
- The device is not for use in an MRI suite.

1.5 Safety-conscious Operation

- Make sure that the staff have read and understood the operating instructions, in particular this section Safety Notes.
- Do not touch the housing of the device during defibrillation.
- To ensure patient safety, none of the electrodes, including the neutral electrode, nor the patient or any person with simultaneous patient contact, must come in contact with conductive parts, even when these are earthed.
- Immediately report any changes that impair safety (including operating behaviour) to the responsible person.
- Only use accessories and disposables recommended or supplied by **mbnet Engineering GmbH**. The use of accessories or disposables from other manufacturers may result in injury, inaccurate information and/or damage to the unit.

1.6 Safe Use with Electronics

- Operating the device with defective cables constitutes a danger to the life and limb of the patient. Therefore take note of the following:
  - Damaged cable connections and connectors must be replaced immediately.

1.7 Operation with other Devices

- If the device is part of a medical system, only the original ECG cables from **mbnet Engineering GmbH** must be connected to the device.
- Portable communication devices, HF radios and devices labelled with the symbol: (non-ionic electromagnetic radiation) can affect the operation of this device.

1.8 Maintenance

- Do not open the device! It contains no parts, which can be repaired by the user. Servicing must only be performed by qualified technicians authorised by **mbnet Engineering GmbH.**
- Do not use high-temperature sterilisation processes (such as autoclaving). Do not use e-beamor gamma radiation sterilisation.
- Do not use aggressive or abrasive cleaners.
- Do not, under any circumstances, immerse the device or cable assemblies in cleaning liquid.

1.9 Terms of Warranty

Your device is warranted against defects in material and manufacture, as stated in the Terms and Conditions. Excluded from this warranty is damage resulting from negligence or improper use. The warranty covers the free replacement of the defective part. Any liability for subsequent damage is excluded. The warranty is void if unauthorised or unqualified persons attempt to make repairs.

In case the device is defective, send it to your local **mbnet Engineering GmbH** representative or directly to the manufacturer. The manufacturer can only be held responsible for the safety, reliability and performance of the apparatus if:

- assembly operations, extensions, readjustments or repairs are carried out by persons authorized by the manufacturer, and
- the device and approved attached equipment is used in accordance with the manufacturer's instructions, and
- the maintenance intervals as stated in Chapter 6: "Maintenance and Care" have been complied with.

No further guarantees are assumed. **mbnet Engineering GmbH** makes no warranty of merchantability or fitness for a particular purpose with respect to the product or parts thereof.

1.10 Symbols and Pictograms

1.10.1 Symbols Used in this Document

The safety level is classified according to ISO 3864-2. The following overview shows the safety symbols and pictograms used in this user guide.

For general safety notes as listed in this section.

For electrical hazards, warnings or precautionary measures when dealing with electricity.

For possibly dangerous situations which could lead to damage to property or system failure.
Important or helpful user information.

Reference to other instructions.

DANGER

For a possibly dangerous situation which could lead to severe personal injury or to death.

Warning

For a direct danger which could lead to severe personal injury or to death.

Caution

For a possibly dangerous situation which could lead to slight personal injuries.
This symbol is also used to indicate possible damage to property.

1.10.2 Symbols Used on the Device

BF-symbol, no protection against defibrillation current

Dispose of as electronic waste

Manufacturer

Date of manufacture

CE label

Refer to instruction manual

Serial number

Lot number

Catalogue number

Medical Device

1.10.2 Symbols Used on the Device

BF-symbol, no protection against defibrillation current

Dispose of as electronic waste.

Attention: consult accompanying documents

Manufacturer

Date of manufacture

CE label

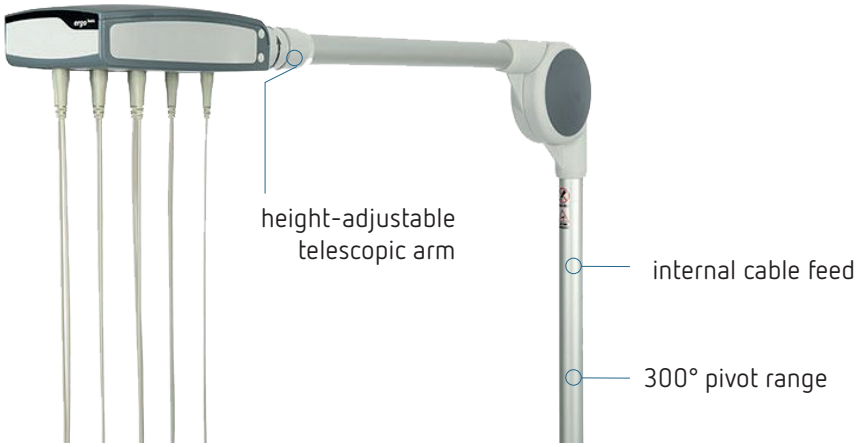
Follow the manufacturer's instructions

2 Introduction

The ergo basic is an ECG cable for recording heart potentials during resting and stress ECGs and sending the data to the ECG device.

2.1 Elements of the Suction Device

2.1.1 Overview



2.1.2 Scope of Delivery

Standard Model

- Banana plug or Clipcable

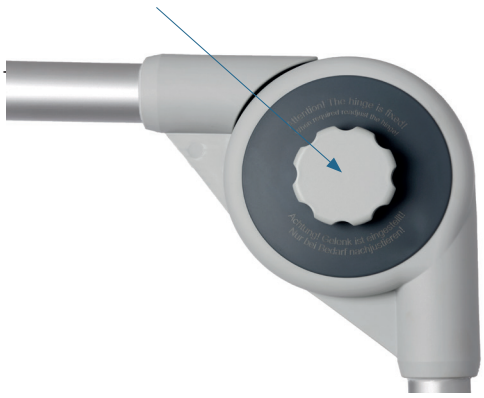
Options

- Trolley

2.2 Patient module

What makes the patient module stand out is its optimal user ergonomics.
The control panel is easy to clean.

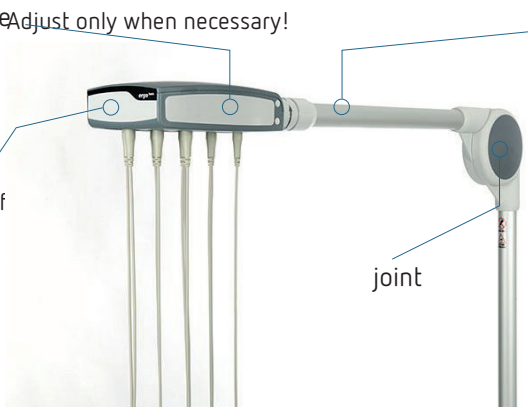
2.3 Joint



Caution The joint is set from factory! Adjust only when necessary!

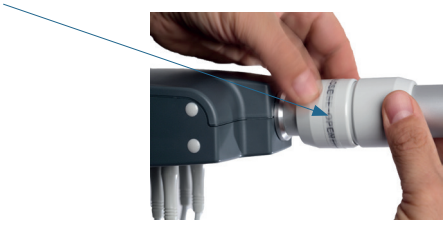
2.4 Cable Arm

The cable arm has a special f
horizontal telescopic arm.



Telescopic arm closure

Open and close to extend and retract of the telescopic arm.



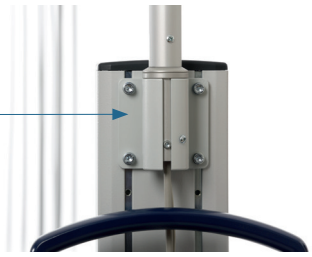
2.5 Leads

The tenshielded, interference-free electrode lines are trouble-free and standout by virtue of their low abrasion and high flexibility.

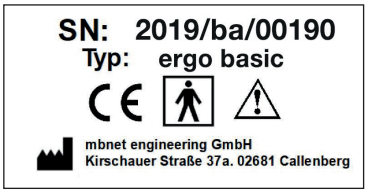
Caution Please pay attention on the careful handling of ECG-leads (see page 19, chapter 6.2)

2.6 Fixation of cable arm

Standard-Fixation ITD (accessory option, must be ordered separately).



2.7 Serial Number



2.8 Supplied accessories for ergo basic

- Cable arm with patient module
- Electrode suction hose (6 x 1 m / 4 x 1.30 m)
- Standard bracket
- Operation manual

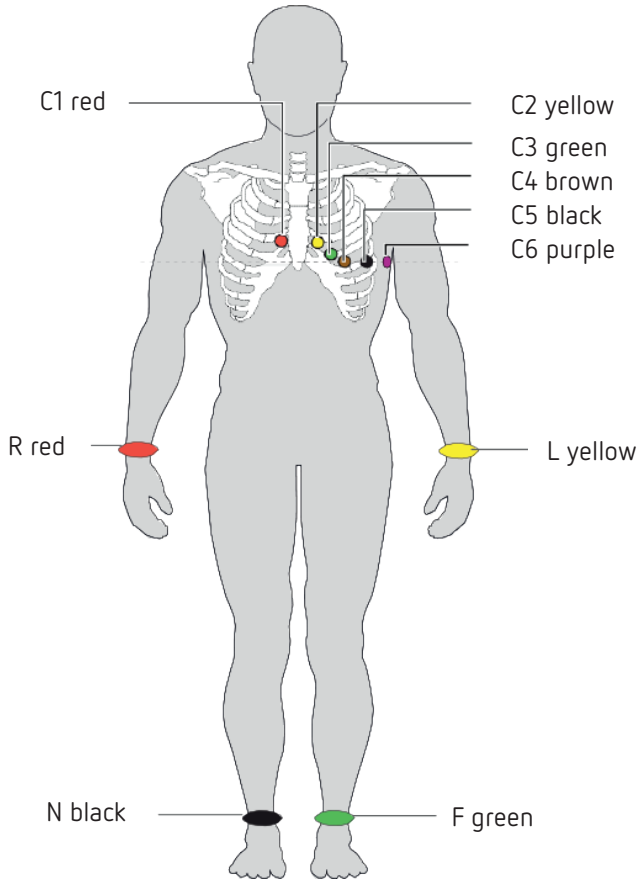
3 Operation

3.1 Getting Started

DANGER **The device must not be used if it is suspected to be damaged.**

Location

- The device must not be stored or operated in a wet, humid or dusty area. It must also not be exposed to direct sunlight or heat from other sources.
- The device must not come into contact with acids or acidic fumes.
- The device should not be placed in the vicinity of X-ray, hf surgical equipment, diathermy units, large transformers or electric motors.



4 ECG Recording

Warning

- Ensure that neither the patient nor the leading

parts of the patient connection nor the electrodes
(including the neutral electrodes) come in contact with other persons or conductive objects
(even when these are earthed).

4.1 Placement of Electrodes

Careful application of the electrodes and good electrode contact is important for a good recording (see electrode positioning on page 14, chapter 4.4).

A minimal resistance between skin and electrode is required to obtain the best ECG signal and ensure the highest quality ECG recording. Therefore, please note the following points:

1 Only use electrodes that are recommended by **mbnet Engineering GmbH**.

2 To increase the electrode's conductivity and adherence:

- Shave the areas where the electrodes are to be placed, if necessary.
- Thoroughly clean the areas with alcohol or soapy water (skin cream is often applied above all during the winter as this will increase electrode resistance enormously(!) – Always COMPLETELY remove skin cream at the application sites!).
- Let the skin dry thoroughly before you apply the electrodes.

3 Check the electrode resistance.

4 If the electrode contact is higher than the acceptable level:

- Remove the electrode and use an abrasive cleaning pad or abrasive cleaning gel to remove the uppermost layer of epidermis.
- Apply the electrode.

5 Ensure that the patient is warm and relaxed before you start the recording.

6 After the recording, remove the electrodes.

* Dedicated abrasive cleaning gel gives very good results in reducing the skin-electrode resistance.

4.2 Possible Sources of Errors with the ECG Recording

4.2.1 Preparation

With adhesive electrodes, observe their shelf-life - They should not beexpired!
Should you use suction bulbs and clams, always check wether they are cleaned before usage.

4.2.2 Application of Electrodes

The areas of skin to which the electrodes will be applied must be clean and dry.
Use an electrolyte ECG spray, which contains soluble chloride.

- Do not use ECG gel! Only ECG spray!
- Remove any skin cream!

4.2.3 Before the Recording

Inform the patient about the procedure so that they are not frightened.

The patient must:

- be lying down relaxed (attention: hands must be on the couch, not in the air)!
- not be cold (above all for resting ECG recordings)!

No powerful devices must be in operation close by at the same time.

The couch should not be touching the walls!

4.2.4 During the Recording

Suction hoses must under no circumstances pull/tear/stretch the electrodes, but must hang freely!

Wait with the recording of the ECG until you can see a good ECG recording on the screen.
Under no circumstances press the recording button beforehand!

Under no circumstances must the electrodes be applied on the patient's skin for longer than 25 minutes (risk of blisters forming)!

4.2.5 Removal of Electrodes from the Skin

Do not pull on the electrode cables.

4.3 Electrode Identification and Colour Code

The electrode colour codes in this section correspond to Code 1 (IEC).
Below you will find the corresponding colour codes in accordance with Code 2 (AHA).

	IEC		AHA	
	IEC label	Colour	AHA label	Colour
Extremity	R L F	red yellow green	RA LA LL	white black red
Chest according to Wilson	C1 C2 C3 C4 C5 C6	white/red white/yellow white/green white/brown white/black white/purple	V1 V2 V3 V4 V5 V6	brown/red brown/yellow brown/green brown/brown brown/black brown/purple
Neutral	N	black	RL	green

4.4 Resting ECG with 10-lead Patient Cable Electrode Placement for Standard Leads

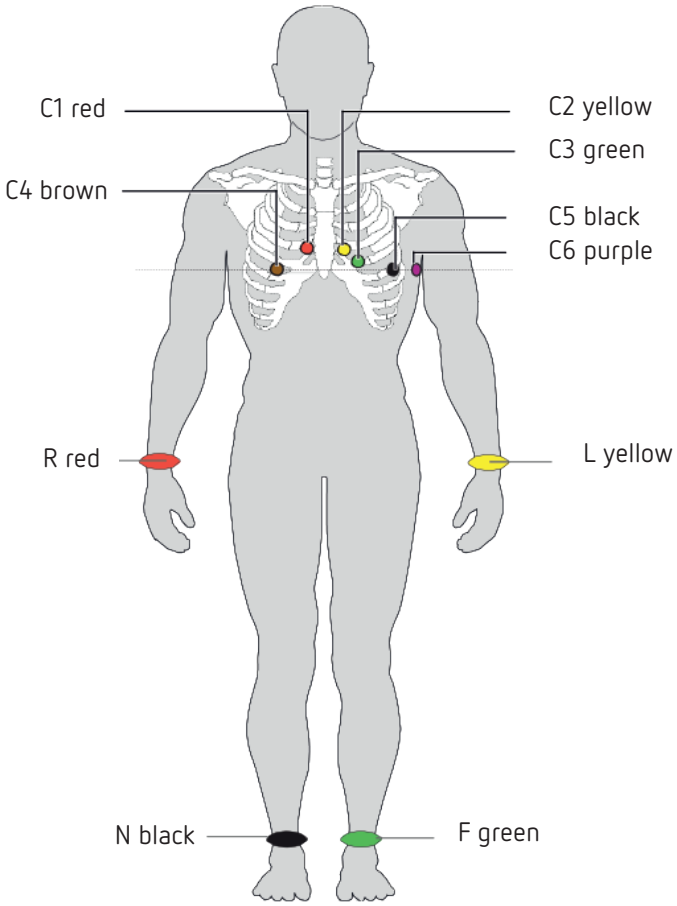
programmed to V4r.n.

IEC label	AHA label	Connecting the ECG patient cable
C1, red	V1, red	Fourth intercostal space at the right sternal border
C2, yellow	V2, yellow	Fourth intercostal space at the left sternal border
C3, green	V3, green	Midway between C2 and C4
C4, brown	V4, blue	Fifth intercostal space on the mid-clavicular line
C5, black	V5, orange	Anterior axillary line on the same horizontal level as C4
C6, purple	V6, purple	Mid-axillary line on the same horizontal level as C4
L, yellow	LA, black	Left arm (resting ECG)
R, rot	RA, white	Right arm (resting ECG)
F, green	LL, red	Left foot (resting ECG)
N, black	RL, green	Right foot (resting ECG)

It is sometimes difficult with a child to apply all the electrodes. In this case electrode C4 can be placed on the right side of the chest and the setting "Recording display"

4.5 Right Precordial (C4r)

The ACC/AHA guidelines recommend that in all patients with myocardial infarction with inferior ST elevation, an investigation into a possible RV ischemia or a RV infarction is carried out; this investigation is undertaken with a right precordial C4r recording.



4.5 Right Precordial (C4r)

HF source Wireless communicationsdevices	Transmitter frequency (MHz)	Testing-frequency [MHz]	max. power P (W)	Distance d (m)
Various radio services (TETRA 400)	380 – 390	385	1.8	0.3
Walkie-talkie (FRS) Rescue service, police, fire brigade, servicing (GMRS)	430 – 470	450	2	0.3
LTE Band 13/17	704 – 707	710/745/780	0.2	0.3
GSM800 / 900 LTE band 5 Radio telephone (micro cellular) T1+, CT2,CT3	800 – 960	810/870/930	2	0.3
GSM1800/1900 DECT (radio telephone) LTE band 1/3/4/25 UMTS	1700 – 1990	1720/1845 /1970	2	0.3
Bluetooth, WLAN 802.11b/g/n LTE band 7 RFID2450 (active and passive transponders and readingdevices)	2400 – 2570	2450	2	0.3
WLAN 802.11a/n	5100 – 5800	5240/5500/5785	2	0.3

7.3 Warranty

mbnet Engineering GmbH will assume the statutory warranty in accordance with its Terms and Conditions of Sale, Delivery and Payment. Wear and tear parts and disposables are excluded from the warranty.

The warranty will lapse in the following cases:

- Damage resulting from incorrect operation and incorrect use.
- In the event of defective installation, intervention by unauthorised persons or the use of accessories, disposables or spare parts, which are not original parts of **mbnet Engineering GmbH**.
- If changes, extensions, repairs or other work was carried out by persons who are not authorized by the manufacturer.
- If the electrical facility in the room in which the device is connected, does not comply with the requirements of VDE 0100-710.
- If the instructions for use were not observed when the device was used.

7.4 Accessories and Disposables

Warning

Always use **mbnet Engineering GmbH** spare parts and disposables or products approved by **mbnet Engineering GmbH**. Failure to do so may endanger life and/or invalidate the warranty.

Your local representative stocks all the disposables and accessories available for the device. A comprehensive list of all **mbnet Engineering GmbH** representatives can be found on the **mbnet Engineering GmbH** website. In case of difficulty, contact our head office directly. Our staff will be pleased to help with your concerns and any questions you may have.

8 Technical Data

8.1. Device

Ambient conditions	
Operating temperature	10 to 50 °C, storage 10 to 40 °C
Relative humidity Air	30 to 75 % (non-condensing)
Pressure during use	700 to 1060 hPa

8.2 System Cable

System cable length	1.9 m
ECG connection	15-channel in accordance with IEC Standard Norm
Control cable	1.5 m

8.3 Cable Arm

Length	800 to 1100 mm
Range of height adjustment	1000 to 2000 mm
Pivot range	300°

8.4 Safety Standards

Safety standard	IEC/EN60601-1
Classification	CE/I in accordance with EC Directive 93/42/EWG
Protection	This device is not intended for outdoor use (IPX0)

Declation of Conformity

EC Declaration of Conformity

Directive 93/42/EEC Annex VII

Directive 2007/47/EEC Annex VII

The manufacturer

mbnet Engineering GmbH

Kirschauer Straße 37a

OT Callenberg

D-02681 Callenberg

hereby declares that the product

ergo basic (Class I)

is in compliance with the following:

Directive 93/42/EEC

Directive 2007/47/EEC

Applied Standards IEC 60601-1

Manuel Bucher
(Management))

Callenberg, 12.06.2020

(* Signature omitted for security reasons)