PRIMEDIC™

Instructions for use

Defi-N
Defi-B

CE 0123

Table of contents Page

1. Safety instructions

The following has to be considered in order to ensure safe and perfect function of the PRIMEDIC™ Defibrillators and to avoid risk to human beings and other material property:

1. Any use of the PRIMEDIC™ Defibrillators requires the knowledge and strict compliance of these instructions for use.

2. The PRIMEDIC™ Defibrillators are designed and suitable exclusively for the applications set out or described in this manual. Using the device for purposes any other than those mentioned in this manual may constitute a risk and has to be omitted.

3. Operation of the PRIMEDIC™ Defibrillators, as well as basically all other defibrillators, in areas subject to explosion hazards is not allowed.

4. The PRIMEDIC™ Defibrillators may only be used by trained and authorised personnel. Reading the instructions for use does not replace any training.

5. Any repair work, modifications, additions and installations of the PRIMEDIC™ Defibrillators may only be carried out by personnel authorised and trained by METRAX. The parts of the PRIMEDIC™ Defibrillators may not be repaired by the user.

6. The device may only be used with accessories, wearing parts and disposable parts the secure use of which is proofed by an inspection office authorised to tests of devices ready-to-use. Otherwise a safe and reliable function of PRIMEDIC™ Defibrillators is not guaranteed. The original PRIMEDIC™ accessories and wearing parts comply with this condition.

7. Before using the device the user has to check that the device is in a safe and reliable state. If e.g. the defibrillator cable is damaged the defibrillator may not be used.

8. The instructions and rules set out in appendix A1 have to be complied with when using the PRIMEDIC™ Defibrillators.

9. The unit must be under operating conditions before using.

10. The PRIMEDIC™ **Defi-N** is not suitable for use outdoors.

11. Do not use the PRIMEDIC™ Defibrillators near devices (e.g. measuring devices) sensible to magnetic fields or disturbing sources, which could interfere with the functions of PRIMEDIC™ Defibrillators. Keep sufficient distance.

12. Do not charge more than 15 times at maximum energy. The number of discharges should not exceed 3 per minute. Afterward, allow the unit to cool down for an extended period of time.

Additionaly the national regulations for the use of medical devices are applicable.

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2. Device Specification

The PRIMEDIC™ **Defi-N M100**

Fig.: 1General view of the PRIMEDIC™ **Defi-N**

1 Carrying handle
2 Release button
3 Paddle right (APEX)
4 Paddle cable
5 Defibrillator unit with operating elements
6 Mains plug
7 Paddle cable
8 Paddle left
9 Release button

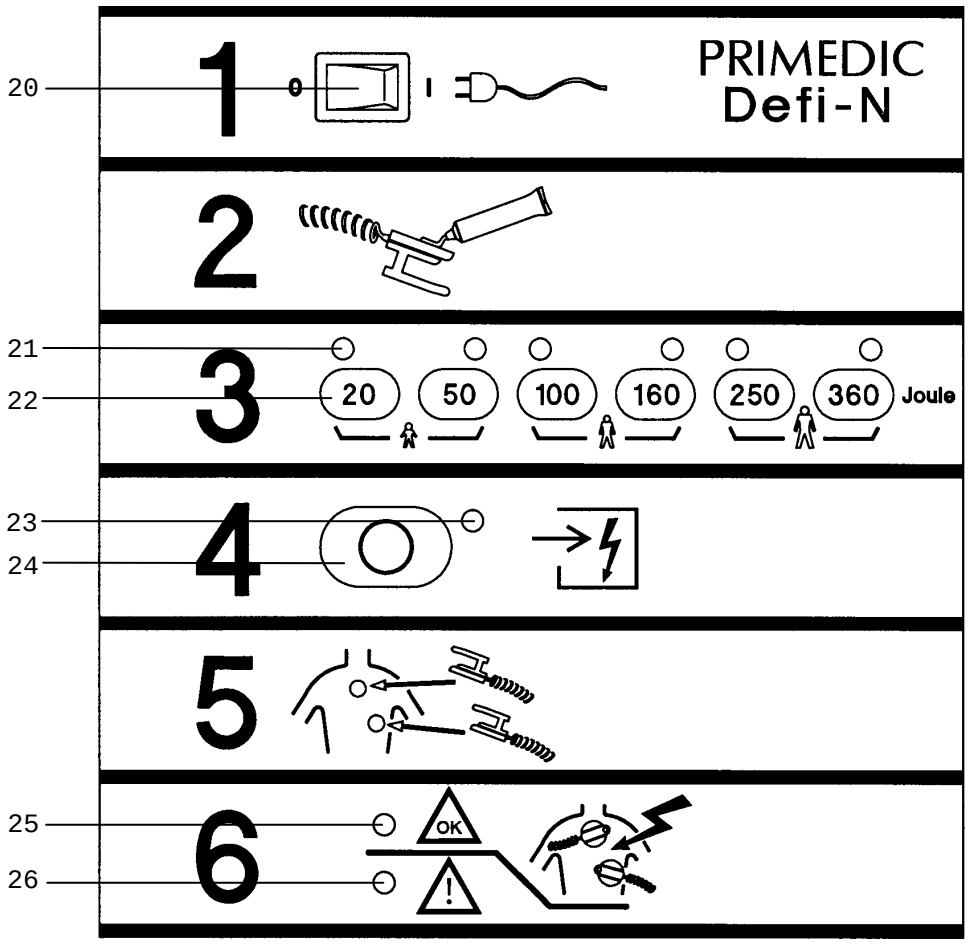


Fig.: 2Defibrillator unit with operating elements and displays

20	Power switch	To switch the device on or off
21	LED	To display the selected energy step
22	Energy key	To select the defibrillation energy
23	LED	To signal the charging of the defibrillation energy
24	Load key	To load energy for defibrillation
25	OK LED	To signal that selected energy is charged and available for the shock
26	Attention LED	To signal malfunction of the defibrillation unit

The PRIMEDIC™ **Defi-B M110**

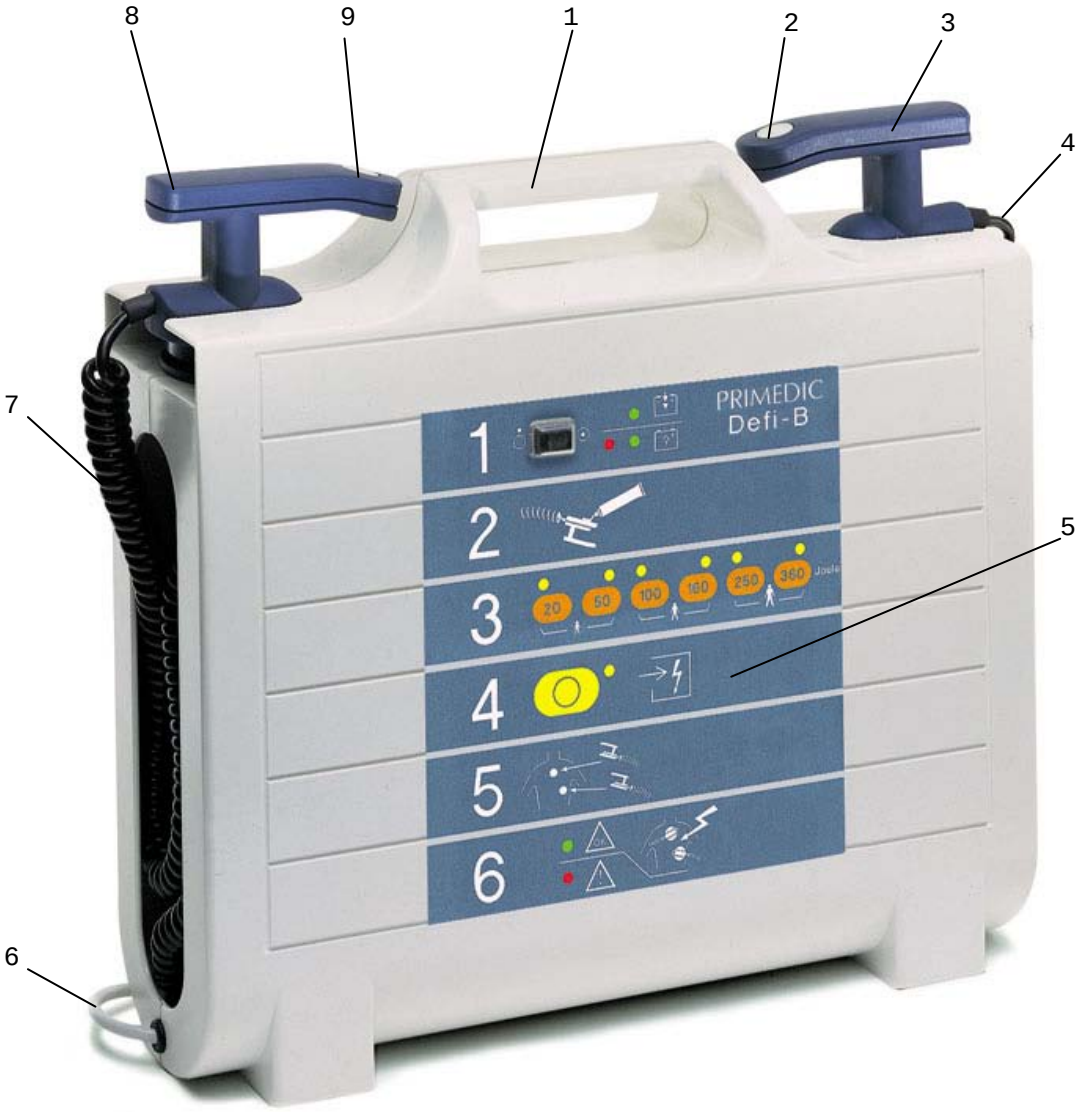


Fig.: 1 General view of the PRIMEDIC™ **Defi-B**

1 Carrying handle
2 Release button
3 Paddle right (APEX)
4 Paddle cable
5 Defibrillator unit with operating elements
6 Mains plug
7 Paddle cable
8 Paddle left
9 Release button

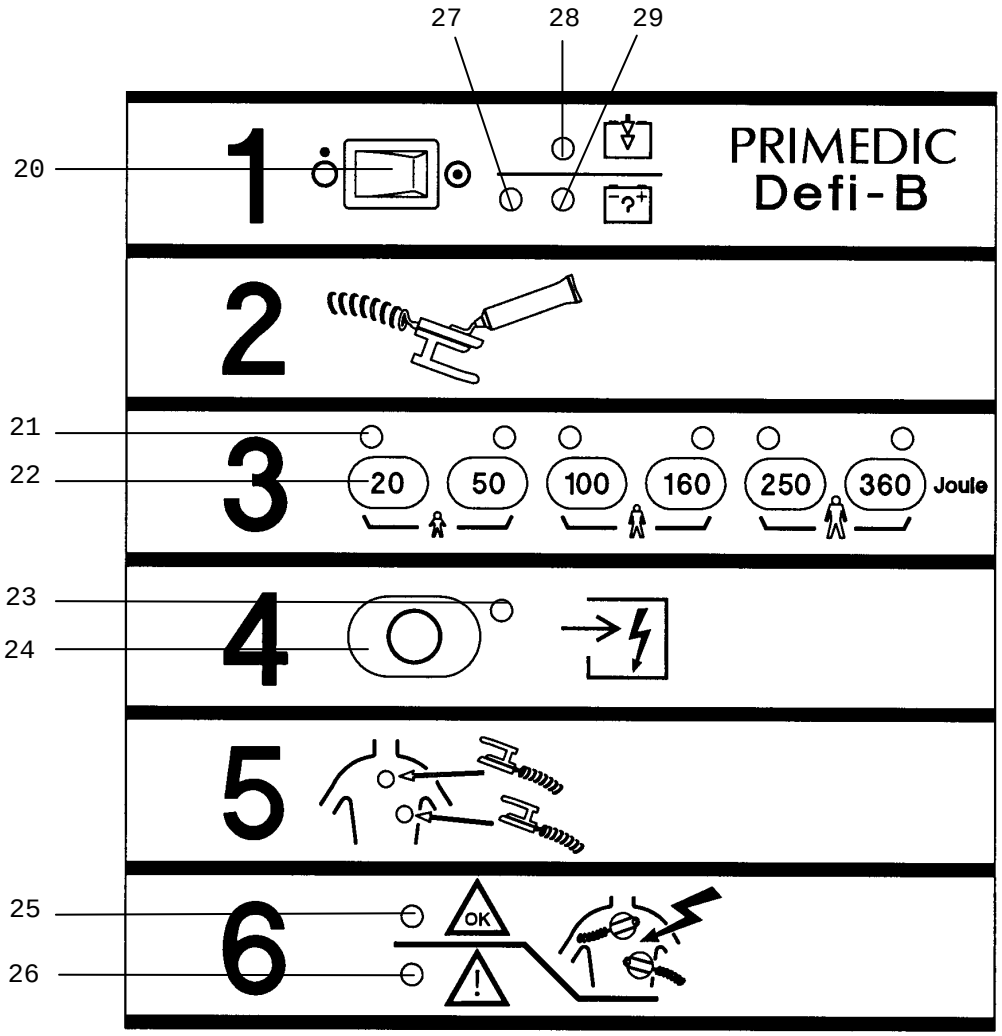


Fig.: 2 Defibrillator unit with operating elements and displays

20	Power switch	To switch the device on or off
21	LED	To display the selected energy step
22	Energy key	To select the defibrillation energy
23	LED	To signal the charging of the defibrillation energy
24	Charge key	To charge energy for defibrillation
25	OK LED	To signal that selected energy is charged and available for the shock
26	Attention LED	To signal malfunction of the defibrillation unit
27	Accumulator status LED red	
28	Charge LED	To signal that accumulator is being charged
29	Accumulator status LED green	Is illuminated when defibrillator is ready for use

3. Preliminary measures

The appliance can be kept on standby both in a horizontal and an upright position.
Defi-N: Insert mains plug in socket in the vicinity of ergometer. The mains cable has a length of 3 m, thereby permitting a corresponding operating radius emergiencies.
Defi-B: With the integrated rechargeable accumulator you are independent of a power source.

3.1 Loading the rechargeable batteries (only **Defi-B**)

To load the integral rechargeable batteries, connect the appliance to the electrical outlet with the power cord (6). The switch (20) should be in the „OFF“ Position. The green LED (28) next to the accumulator charge symbol indicates:

LED flashing or steady: The rechargeable batteries are charging or the appliance is in the „floating operation“ mode.

LED off: The rechargeable batteries are no longer being charged, because a limit value has been exceeded (e.g. temperature or end-of-charge voltage). As soon as the limit value exceeded status is cleared, the LED flashes again.

Caution:
The mains connection is only for charging batteries. Defibrillation cannot be triggered if the appliance to a power source when the batteries are empty. The charge time is appr. 3,5 hours. To guarantee full readiness for operation, the appliance must be connected to the mains at regular intervals (e.g. once a week). Should the unit not be used, Continuos mains connection is also possible, this will not damage the batteries.

Note:
In case that the defibrillators are operated from a timer (e.g. night disconnection) it may not be uninterruptedly connected to this socket. Otherwise the reconnecting of the power supply will cause a renewed charging procedure. This can cause damage to the battery due to over charging.

4. Operation of the defibrillator

4.1 Switching the defibrillator on and off / self-test

Switch on the PRIMEDIC™ defibrillator with the power switch (20).

When starting an internal self-test will be executed to check important functions and signal devices. The self-test is finished in approx. 20 seconds (**Defi-B**) resp. 11 seconds (**Defi-N**) and the appliance signals readiness for operation through a brief buzzing tone. The LED (21) corresponding to energy level “20 joules” flashes.

Caution:
During the internal self-test, a defective unit may discharge high tension via the paddle electrodes. Please always pay attention that the paddles are fixed in the according supports during this self-test, in order to avoid contact with the patient or the user!

If, during self-testing, an error or internal malfunction has been discovered, then this will be indicated by the red warning LED (26) and cyclical beeping sound.

Now, by pressing the load key (24), the system can be instructed to correct the error. The LED’s of the power levels (21) run cyclically as „running light“. After pressing the load key (24) again, and assuming the correction of malfunction was successful, the Defibrillator is again ready for use. If the malfunction or error mode is resumed, then Service should be informed. There is a defect.

Diminished Readiness to operate
The system-test determines that a least 20 shocks with 360 joules are stored. This is indicated by a red steady-burning accumulator-status LED (27). (Only Defi-B)

Conditionally ready to operate
If the system-test discovers that there are 10 or less shocks with 360 joules stored in the accumulator, then the readiness for operation will be indicated by the blinking of the red light (27) at the symbol accumulator status. (only **Defi-B**)

Rechargeable batteries are empty
It the accumulators are already upon switching the device upon, the this is indicated by the blinking of the red light (27) at the symbol for accumulator status as well as by pulsating beeping sounds. The device is not operable. Please connect the unit to the mains as soon as possible in order to guarantee the readiness for use. (only **Defi-B**)

4.2 Energy selection

Press one of keys (22) to select the energy. LED (21) located directly above the key pressed lights up to acknowledge the energy setting.

Note:
The energy step required for the defibrillation depends on the patient, its body height and weight and its condition. For information please refer to appendix A1.

Advice:
If a wrong energy step was chosen, you may change it by pressing the right button with the new energy step. However, it will only work if the load key has not been activated in the meanwhile.

If the load key was already pressed, a correction is only possible :

by switching the unit off and turning it on again,

wait until the 15 seconds have exceeded and the energy was discharged internally

4.3 Energy charging

The selected energy can be charged by pressing the load key (24) and thus made available for the shock.

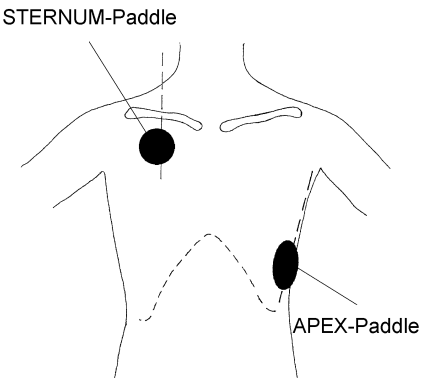
LED (23) flashing indicates the charging procedure. The charging time depends on the selected energy step. With full accumulators, a charging time of approx. 7 seconds for **Defi-B** resp. 9 seconds for Defi-N is required to attain the maximum energy of 360 joules.

After the charging the energy will be available for 15 seconds which is signalled by a permanent signal and the lighting up of the OK signal (25). If there is no defibrillation during this time, an internal safety discharge will be executed. Afterwards the defibrillator is immediately ready to use.

Should an error occur during energy charging, an intermittent warning signal and the Attention LED (26) will be on.

Attention:
If the Attention LED (26) lights up the function of the defibrillator can be tested by switching-off and then on again with the help of a self-test. When the signal goes out, the defibrillator is ready-to-use.

Attention:
If the Attention LED (26) is still on after switching off and on again, the malfunction must be eliminated immediately.



4.4 Positioning of paddles

Grasp the paddles (3 and 8) on the grips and remove them from their support by pulling to the right resp. to the left.

The paddles must be positioned along the cardiac axis. The APEX-paddle has to be positioned in the left chest area, on the axillary line above the apex of the heart. The second paddle has to be positioned in the right chest area, below the clavicle.

Attention:
To avoid skin burns, it is extremely important to apply a sufficient quantity of gel to the electrode surface.

Attention:
Both paddles have to be pressed on the thorax by applying a pressure of approx. 10 kg in order to ensure safe energy transmission and to avoid damaging the skin under the paddles.

Attention:
Please insure that there is no contact or conducting gel between the paddles.

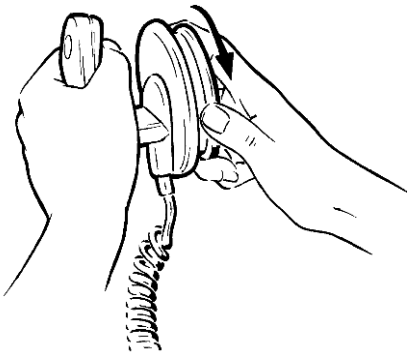
4.5 Discharging of energy

Press release buttons (2) and (9) at the paddles simultaneously to discharge the energy. The energy will be discharged immediately after simultaneous depression of buttons.

After defibrillation, the LED (21) corresponding to the energy level previously selected flashes. This allows you to check whether defibrillation has actually taken place.

Attention:
Before and during the discharging of energy all persons attending to the resuscitation have to step back and any contact with patients or conducting parts (e. g. stretcher) has to be avoided. Remove all connected devices without defibrillation protection from the patient before energy is discharged.

Attention:
Absolutely avoid a destroying of the energy in the equipment (by simultaneous pressing of the release keys). In this case a strong magnetic field develops, whereby the equipment can take damage. An energy discharged may only over a patient, or by an independent internal safety discharging after 15 seconds take place.



4.6 Paediatric paddles

Electrodes with smaller electrode surface have to be used for the defibrillation of children. The paediatric paddles are integrated in the paddles for adults. Remove the large electrodes from both paddles by turning counterclockwise.

Attach the paddles for adults to the paediatric electrodes by turning clockwise.

Note:
Clean the paediatric paddles after use before attaching the paddles for adults.

Attention:
Attach the paddles for adults firmly to ensure safe contact of the paddles for adults.

5. Maintenance and care

Ensure that the appliance has been switched off and pluged out.

Normal domestic cleaning agents can be used for tending the defibrillator. Always use a clean cloth.

Use a commercial disinfectant (e. g. Gigasept FF) for disinfection of the paddle electrodes.

Attention:
Do not use soaking wet clothes for cleaning. Do not pour any liquids over the device and do not plunge it into water.

Regardless of the use of the device, we recommend visual inspections / maintenance of the PRIMEDIC™ **Defi-B** and the accessory parts to be carried out by the user.

Pay attention to the following:

1. Check whether the parts of the casing are damaged
2. Check whether the insulation of the paddle cable is damaged.
3. Remove remaining gel and impurities from the paddle electrodes in order to ensure safe contact between children's paddles and paddles for adults and to prevent sparking voltage.

Only valid for **Defi-B:**

In order to guarantee a perfect functioning of the unit, the unit bust be equipped with a accumulator in working order. The unit must enable 15 shocks with a full accumulator - should this not be the case, METRAX recommends to get the accumulator changed through the service department.

The user may check the accumulator capacity by charging the unit completely and by discharging the requested 15 shocks (please see point 6 of the technical safety controls).

Attention:
Damaged parts of the casing and isolations have to be repaired immediately.

Advice:
Please find enclosed (annexe A3) supplementary information concerning the regular intervals of the technical security controls according to the guideline „Medizinprodukte-Betreiberverordnung“ (MPBetreibV).

5.1 Maintenance of the accumulator (only for **Defi-B**)

In order to reach a long durability of the accumulator it is necessary to use the greater part of accumulator capacity. If you use only part of the capacity, the so-called memory effect will occur. This may cause a defect of the accumulator.

Please consider the following advices in order to prevent this procedure:

- Charge accumulator / unit (minimum 4 hours at the public supply).
- Pull out mains plug.
- Use the unit until the red Accumulator-status-LED (27) will lighten (reserve of 15 shots with 360 J).
- Put the unit then again to the public supply and recharge it (the unit must be turned out).
- After charging please disconnect the unit from public supply then.

If you charge the accumulator prematurely (that means when the Accumulator-status-LED (29) is still lightening green) you will risk to damage the accumulator on a long-term basis.

6. Waste treatment

At the end of its useful life, the unit must be recycled in accordance with the relevant local regulations. In case of doubt, please request details from the local recycling company.

7. Technical data, accessories, symbols

7.1 Technical data PRIMEDIC™ **Defi-N**

Defibrillation:	
Operating mode:	asynchronous, external defibrillation
Energy steps:	20, 50, 100, 160, 250, 360 joule (50 Ω)
Charging time:	approx. 9 s (360 Joule) with 230 V / 50 Hz
Paddle:	Paddle for children integrated

Safety Classification: Protection type II, Type BF, Medical device class 2b

CE 0123

Regulatory affairs: The product is a medical device according to EC guideline 93/42/EEC.

Other data:	
Nominal main circuit:	see rating plate
Operating conditions:	0 ... 40 °C, 30 ... 95 % rel. humidity, but without condensation
	700 hPa ... 1060 hPa
Storage environment:	-20 ... 70 °C, 20 ... 95 % rel. humidity, but without condensation
	500 hPa ... 1060 hPa
Dimensions:	40 x 48 x 12 cm (w x d x h)
Weight:	8,5 kg

Subject to alterations.

Delivery specification:

		Part no.
1	PRIMEDIC™ **Defi-N**	90426
	consists of:	
1	Conductive gel, 60 g	13026
1	Medical device protocol	13084
1	Instructions for use	19621
1	Briefing protocol	18514

Accessories

	Part no.
Bag with two transparent storage compartments	14467
Conductive gel, 60 g	13026

7.2 Technical data PRIMEDIC™ **Defi-B**

Defibrillation:

Operating mode:	asynchronous, external defibrillation
Energy steps:	20, 50, 100, 160, 250, 360 joule (50 Ω)
Charging time:	approx. 7 s (360 Joule)
Paddle:	Paddle for children integrated

Safety Classification: Protection type II, Type BF, Medical device class 2b

CE 0123

Regulatory affairs: The product is a medical device according to EC guideline 93/42/EEC.

Other data:

Power supply:	by accumulator 14,4 V / 1,5 Ah
Nominal voltage:	see rating plate
Charging time:	3,5 hours (100 %)
Accumulator capacity:	35 shocks + 10 in reserve (360 Joule)
Operating conditions:	0 ... 40 °C, 30 ... 95 % rel. humidity, but without condensation 700 hPa ... 1060 hPa
Storage environment:	-20 ... 70 °C, 20 ... 95 % rel. humidity, but without condensation 500 hPa ... 1060 hPa
Dimensions:	40 x 48 x 12 cm (w x d x h)
Weight:	9 kg

Subject to alterations.

Delivery specification

		Part no.
1	PRIMEDIC™ **Defi-B**	90427
	consists of:	
1	Conductive gel, 60 g	13026
1	Medical device protocol	13084
1	Instructions for use	19621
1	Briefing protocol	18514

Accessories

	Part no.
Bag with two transparent storage compartments	14467
Conductive gel, 60 g	13026

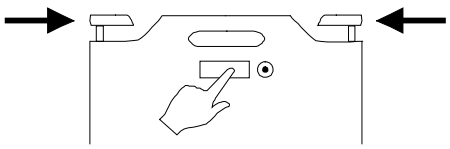
7.3 Symbols

The following symbols are used on the device:

Rating plate:

	Protection type II
IPX1	Drip-proof (**Defi-N)**
IPX4	Splash-proof, (**Defi-B)**
	Comply with instructions for use!
	Degree of protection BF

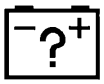
Paddle / Casing:

	Hazardous electric voltage (high voltage)
	Danger
	Fix paddles within fitting before switching on

Operating elements:

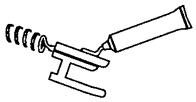
Defi-N: Connect mains cable,
Switch unit on

only **Defi-B**: Accumulator
charge symbol



only **Defi-B**: Accumulator status symbol

Apply conductive gel to paddle electrodes



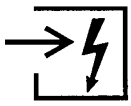
Select energy step according to

20 / 50 Joule 10 - 30 kg body weight

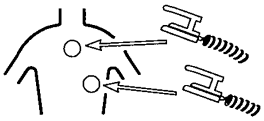
100 / 160 Joule 30 - 50 kg body weigh

250 / 360 Joule as of 50 kg body weig

Charge energy



Place paddles



Discharge energy
Give shock

System error!
Defibrillation
impossible!

8. Conditions of Guarantee

As the manufacturer, METRAX grants a guarantee on this device for 2 years starting with the date of purchase. During this period, METRAX will eliminate any defects in the device, resulting from material faults or manufacturing faults, free-of-charge. Elimination of defects is made by METRAX either by repair or by replacement. Any repair carried out during the guarantee period shall not extend the original guarantee period.

The right to claim under guarantee and damage claims provided by law do not apply in case of only immaterial impairment of usefulness, natural wear or damages, produced after liability transfer to the buyer, as a result of wrong or negligent use, excessive stress or caused by extreme external influences not covered by the terms of agreement. The same applies if the buyer or third parties perform modifications or repair work in an unprofessional manner.

Further contractual and non-contractual claims against METRAX are excluded unless such claims are based on intent or on severe negligence or on compelling liability regulations provided by law.

Claims for damages by the buyer against the seller (trader) remain unaffected by this guarantee.

In case of claims under guarantee, you are asked to send the device including a buyer’s certificate (e.g. a bill), stating your name and address, to your dealer or to METRAX.

The METRAX-customer service will be glad to assist you even after the guarantee period has expired !

9. Appendix

A1 General instructions and rules for the handling of defibrillators

What is a defibrillator ?
During defibrillation current is delivered to the heart muscle. The contraction caused and the depolarization of the heart muscle eliminate dangerous cardiac irregularity.

Cardiac irregularity means uncoordinated electric and mechanical activities of the heart muscle.

Dysrhythmia	possible measures
partly uncoordinated activities of the heart muscle (e. g. atrial fibrillation)	synchronized defibrillation (cardioversion)
completely uncoordinated activities of the heart muscle (ventricular flutter)	Unsynchronised defibrillation

The a. m. table shows two general groups of cardiac irregularity and the possible counter-measures. PRIMEDIC™ defibrillators **Defi-N** and **Defi-B** are designed for assynchronious defibrillation, therefore synchronious cardioversions are not possible.

The procedure of the two cardioversions are different and described in the following:

1. Unsynchronized defibrillation:

With this procedure energy is released immediately as soon as the keys for "shock release" are pressed. This procedure requires the clear and definite establishment of the diagnosis "ventricular flutter or pulse missing".

Asynchronous supply of energy to the cardiac rhythm by the defibrillator can cause damages to the heart. If the energy is supplied to the heart muscle during the ventricular refractory period (approx. first half of the T-wave) the heart is susceptible to ventricular fibrillation.

2. Synchronized defibrillation (not with **Defi-N** and **Defi-B**):

For the application of this procedure it is essential that the patient has got a discernible heart rhythm. A clear QRS complex in the ECG is required for the synchronous shock release. Controlled by the synchronous mechanism of the ECG unit, the shock is released a few milliseconds (about 10-60 ms) after detection of the R-peak.

The ECG unit marks the detected QRS complex with a "SYNC" marker serving as aid for the doctor in charge.

The best "care" of the doctor releasing the shock is indispensable during this procedure. He has to watch the ECG signal on the monitor continuously and ensure that every QRS complex is detected and no artefacts or pacemaker pulses are synchronized.

Procedure for defibrillation (unsynchronized):

The steps for defibrillation described in the following apply for the handling of the defibrillator only. The area of the mechanical, cardiopulomary or pharmacological resuscitation is not described.

The procedure of the unsynchronized cardioversion must only be applied in case of ventricular fibrillation, i. e. P-, QRS- or T-peaks missing in the ECG of the patient.

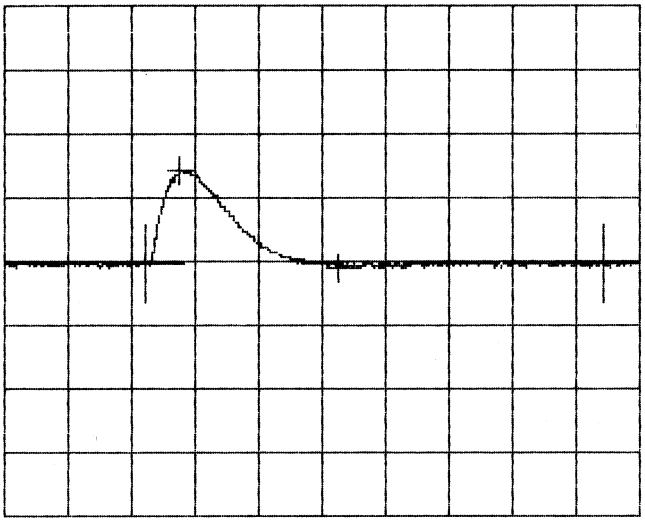
1. Switch on defibrillator.
2. Apply electrode gel to paddle electrodes.
   Apply sufficient electrode gel on the paddle electrodes to limit the contact resistance so that the energy can be released completely to the patient. Insufficient contact gel may cause that the skin under the electrodes gets burnt.
   Do not spread the electrode gel on the handles of the paddles, otherwise energy may flash over to the doctor in charge of the defibrillation.
3. Select energy.
   The energy to be released depends on the patient's body height and weight. The following rule of thumb applies: 2 - 3 joule per kg body weight. The most suitable energy is based on experience and depends on the emergency situation.
4. Positioning of the paddles.
   Stick the paddles firmly to the bare chest of the patient by applying a pressure of approx. 10 kg to ensure perfect energy transfer. Applying not enough pressure may cause that the skin under the electrodes gets burnt. Applying correct pressure should be trained on devices provided for that purpose.
   The position of the paddles decides on the success of the resuscitation. The flow of current between the paddles through the chest has to flow through a large part of the tissue of the heart muscle. The chance to eliminate the ventricular fibrillation only exists when the "critical mass" of about 80 % of the heart is perfused sufficiently.
   In case of incorrect paddle position most of the current misses the heart and is thus ineffective.
   Position of the first paddle (Sternum): - right chest area
   - right close to sternum
   - below the clavicle
   Position of the other paddle (Apex): - left, lower chest area
   - above apex of the heart
   - midaxillary line
   Make sure that no electrode gel has been spread between the paddles on the patient's chest. Otherwise the current flows on the surface between the paddles. Do not spread the electrode gel on the handles of the paddles, otherwise energy may flash over to the doctor in charge.
5. Energy charging
   After charging the energy remains available for a limited time, i. e. 15 seconds with the PRIMEDIC™ **defibrillators**. If no shock is released during this time the energy is discharged internally for safety reasons and has to be recharged afterwards.
6. Protection against electric shock.
   Before defibrillating the doctor releasing the shock has to ask all persons attending to the resuscitation clearly and unmistakably to step back from the treatment location and to touch neither the patient nor the bed nor the connected devices. Remove any devices without defibrillation protection from the patient before releasing the shock. Otherwise energy may flash over to persons in unfavourable situations.
7. Discharge energy (shock).
   Discharge the defibrillator by pressing both release buttons on the paddles simultaneously.
8. Check the result.
   Check the condition of the patient and the ECG monitor after defibrillation. Depending on the result of the defibrillation, further defibrillations in quick succession might be necessary (repeat steps 3-8). The emergency physician may ask for accompanying manual or pharmacological measures.

9. Keep the defibrillator ready for use.
   Clean the paddles, cable and electrodes at the end of the resuscitation to ensure availability of the defibrillator for the next application. Functional disorders or faults have to be checked or if required rectified immediately by an authorized service technician.

A2 Voltage - time graphs

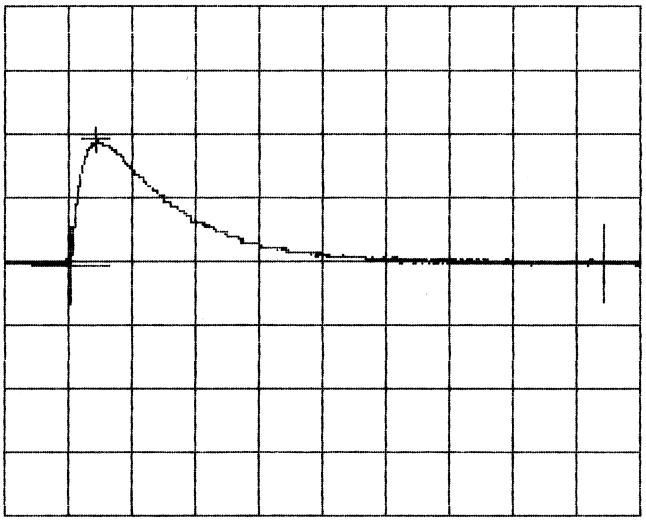
Please find in the following the graph shapes of the defibrillation pulses depending on the terminal resistance.

1. Graph shape with 25 Ω



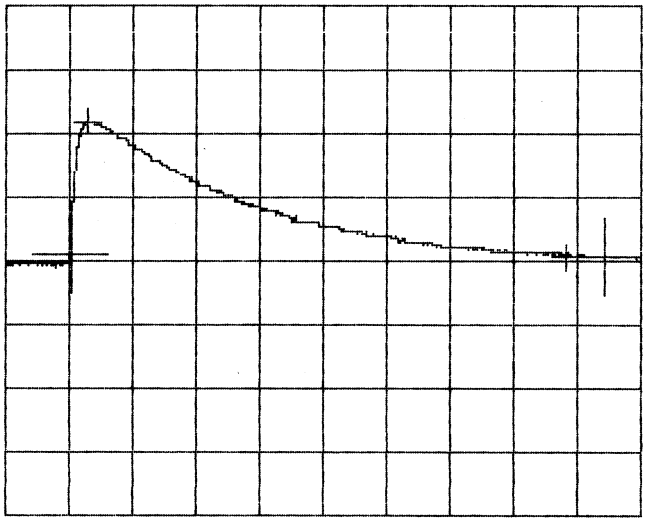
U = 2.280 V 2 ms / div.

2. Graph shape with 50 Ω



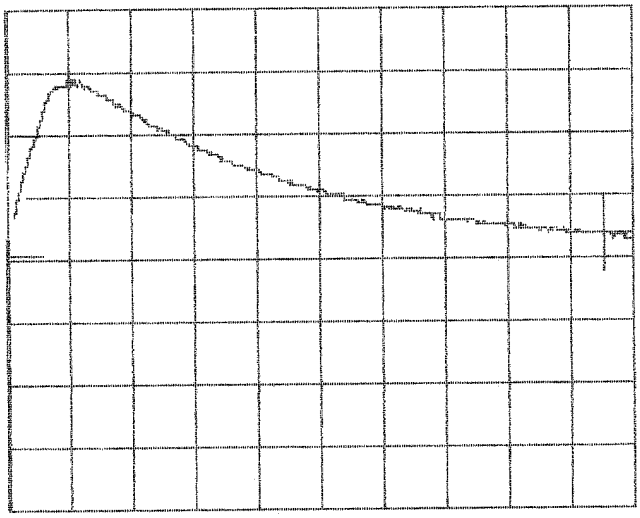
U = 2.940 V 2 ms / div.

3. Graph shape with 100 Ω



U = 3.180 V 2 ms / div.

4. Graph shape with 125 Ω



U = 2.800 V 2 ms / div.

A3 Safety control

According to Medizinprodukte Betreiberverordnung (MPBetreibV) § 6 (safety controls) users of defibrillators are obliged to have the devices controlled. According to MPBetreibV § 6 METRAX has prescribed controls in 12 month cycles.

The safety controls must be carried out only by persons qualified by their training, their knowledge and experience gained in practice to execute controls professionally and not receiving any instructions for the controls. They also must dispose of the appropriate measure- and test instruments.

If the safety control reveals any defect that represents a hazard for patients, employees or third parties, the responsible authority has to be informed immediately by the user according to MPBetreibV § 3.

In accordance with MPBetreibV § 7 the following data has to be entered in the medical device protocol accompanying the device:

- Time when the work was carried out
- Name of the person or company who/which carried out the work and
- the work carried out.

METRAX can be held responsible for the contents of the operating manual only. This especially applies to new settings, commissioning and modifications to the device.

In the rotational control the following work and checks have to be undertaken by a service technician:

1. Check whether the device shows external damages
   - Casing deformed?
   - Paddle cable damaged?
   - Mains plug damaged
   - Paddle damaged?
   - Paddle for adults available and attached?
   - Rating plate on the back of the device legible?
2. Check whether operating elements are damaged
   - Release buttons damaged?
   - Mains switch dust-cover damaged?
   - Mains switch and rocker are in order?
   - Membrane keyboard legible?
   - Membrane keyboard damaged?

3.1 Display Elements **Defi-N**

- Check the LEDs in the membrane keyboard:
  - The LED allocated to the selected energy step lights up (check all energy steps once).
  - After pressing the load key (24), the according LED (23) must illiuminate.
- Check the acoustic warning signals.

3.2 Display Elements **Defi-B**

- One of the LED’s on the accumulator status display must light up when unit is turned on.
- Check the LED’s in the membrane keyboard for proper function:
  - The LED allocated to the selected energy step lights up (check all energy steps once).
  - After pressing the load key (24), the according LED (23) must illuminate.
- Check the acoustic warning signals.

4.1 Measure the charging time **Defi-N**

- Switch off device - and switch it on again.
- Press the key 360 Joule (22).
- Press the load key (24) while concurrently switching on the stop-watch.

At 230 V / 50 Hz supply voltage the charging time should not exceed 9 seconds.
At 200 V / 50 Hz supply voltage the charging time should not exceed 14 seconds.

4.2 Measure the charging time **Defi-B**

- Switch off device - and switch it on again.
- Press the key 360 Joule (22).
- Press the load key (24) while concurrently switching on the stop-watch.
- With the accumulator fully charged, the charging time may not exceed 7 seconds.
- After 15 defibrillations with 360 joules, loading takes only slightly longer.

5. Measuring the power output
When checking the defibrillation energy at a 50 Ohm load the following deviations are permissible:

- 20 Joule ± 4 Joule
- 50 – 360 Joule ± 15 %

All energy levels between 20 joules and 360 joules are measured. During the measuring process, make sure that the discharge sequence of 3 times per minute is not exceeded. Faster sequences will not destroy the device, but it is possible that the thermostatic switch will operate in the high-voltage transformer.

6. Replacing the batteries (only **Defi-B**)
If 15 discharges are no longer possible in the text mention under item 4 then the batteries should be replaced. (It is required, however, that accumulator was fully charged during the test).

7. Measuring of the patient's lead current according to EN 60601-1.