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1. Safety instructions

Your PRIMEDIC™ Defi-Monitor was designed in accordance with the high requirements of the use in emergency situations. Modern technology based on the many years of experience in the development and production of defibrillators together with new shock absorbing materials and new ideas offer the necessary support when every second counts.

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

1. Any use of the PRIMEDIC™ Defi-Monitor requires the knowledge and strict compliance of these instructions for use.
2. The PRIMEDIC™ Defi-Monitor is 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™ Defi-Monitor, as well as basically all other defibrillators, in areas subject to explosion hazards is not allowed.
4. The PRIMEDIC™ Defi-Monitor may only be used by trained and authorised personnel. Reading the instructions for use does not replace any training.
5. Improper use or excessive operating duration of the SpO_2 sensor can cause tissue damages.
6. Strong light, movements and certain physical conditions of the patient, intravascular dye, incorrect attaching of the SpO_2 sensor could also result in wrong indications of oxygen saturation. Do not use the SpO_2 measure as single method to monitor the vital functions.

   The instructions for the use of pulsoximeters have to be complied with (appendix A3).
7. Any repair work, modifications, additions and installations of the PRIMEDIC™ Defi-Monitor may only be carried out by personnel authorised and trained by METRAX. The parts of the PRIMEDIC™ Defi-Monitor may not be repaired by the user.
8. 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™ Defi-Monitor is not guaranteed. The original PRIMEDIC™ accessories and wearing parts comply with this condition.
9. Before using the device the user has to check that the device is in a safe and reliable state.

   If e.g. the pacer / defibrillator cable is damaged the defibrillator / pacer may not be used.
10. The instructions and rules set out in appendix A1, A2 and A3 have to be complied with when using the PRIMEDIC™ Defi-Monitor.
11. The unit must be under operating conditions before using. This is e.g. essential when storing the defibrillator in an ambulance car during winter.
12. Do not use the PRIMEDIC™ Defi-Monitor near devices (e.g. measuring devices) sensible to magnetic fields or disturbing sources, which could interfere with the functions of PRIMEDIC™ Defi-Monitor. Keep sufficient distance.

For the other states of the European Union the national regulations for the use of medical devices are applicable.

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Rheinwaldstraße 22
D-78628 Rottweil
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2. Device specification

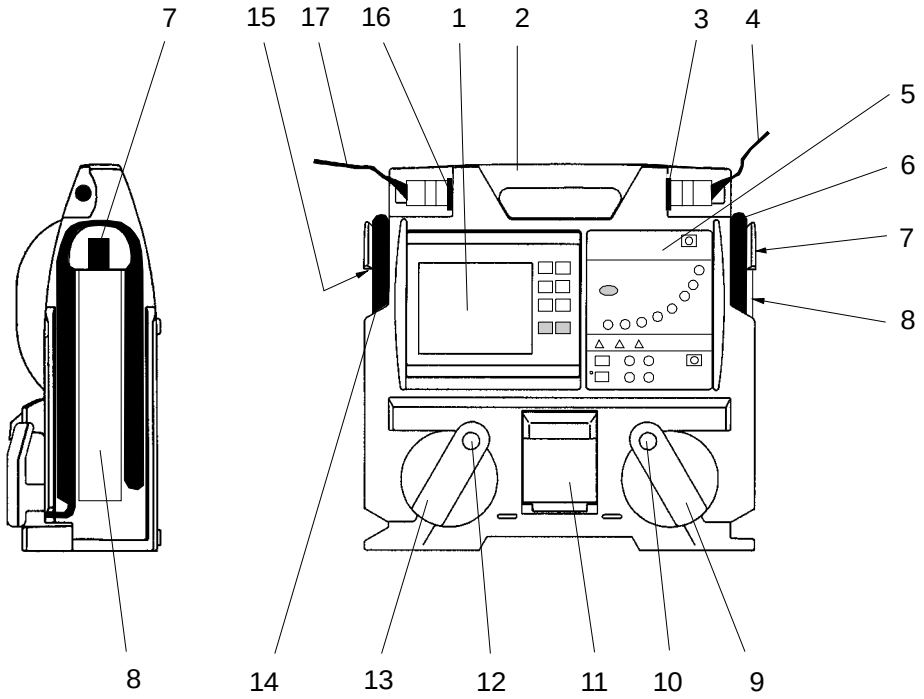


Fig.: 1 General view of the PRIMEDIC™ Defi-Monitor

1 ECG-unit with monitor and operating elements
2 Carrying handle
3 Input socket for ECG patient cable
4 ECG patient cable for recording the ECG
5 Defibrillator unit with operating elements
6 Paddle cable for APEX paddle
7 Release button for accumulator
8 Changeable accumulator
9 Paddle for APEX position
10 Release button
11 Printer with cover and compartment for paper reel
12 Release button
13 Paddle for STERNUM position
14 Paddle cable for sternum paddle
15 PRIMEDIC™ modular plug to connect modules as e.g. pacer module, I/D module for internal defibrillation (only models DM 10 and DM 30)
16 Input socket for SpO_2 patient cable (only model DM 3)
17 SpO_2 patient cable to connect NELLCOR® sensors (connector plug) (only model DM 3)

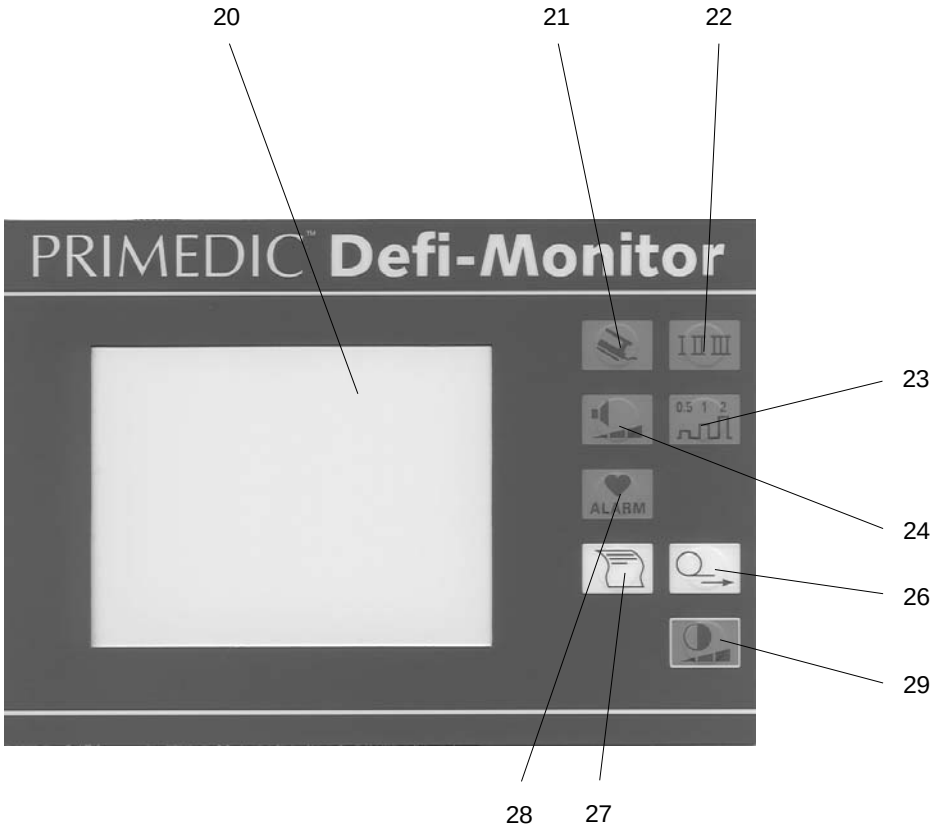


Fig.: 2 ECG-unit with operating elements and monitor ECO 1

20	ECG monitor	high resolution EL monitor to show ECG signals and important device parameters.
21	Key PADDLE LEAD	To select the ECG signal of paddles.
22	Key LEAD SELECTION	To select standard leads.
23	Key SIGNAL AMPLIFICATION	To set the amplification factors for the ECG signal.
24	Key VOLUME	To control the volume of the systole beep.
25	Key ALARM(SpO_2)	To activate alarm limits for low and high SpO_2 values, presettable in the set-up menu.
26	Key PAPER FEEDInsertion of printing paper	
27	Key PRINTER ON / OFF	Switching ON / OFF the ECG on-line printing
28	Key ALARM (heartrate)	To activate alarm limits for low and high heartrates, presettable in the set-up menu.
29	Key CONTRAST	To change the monitor contrast, to adapt light and temperature

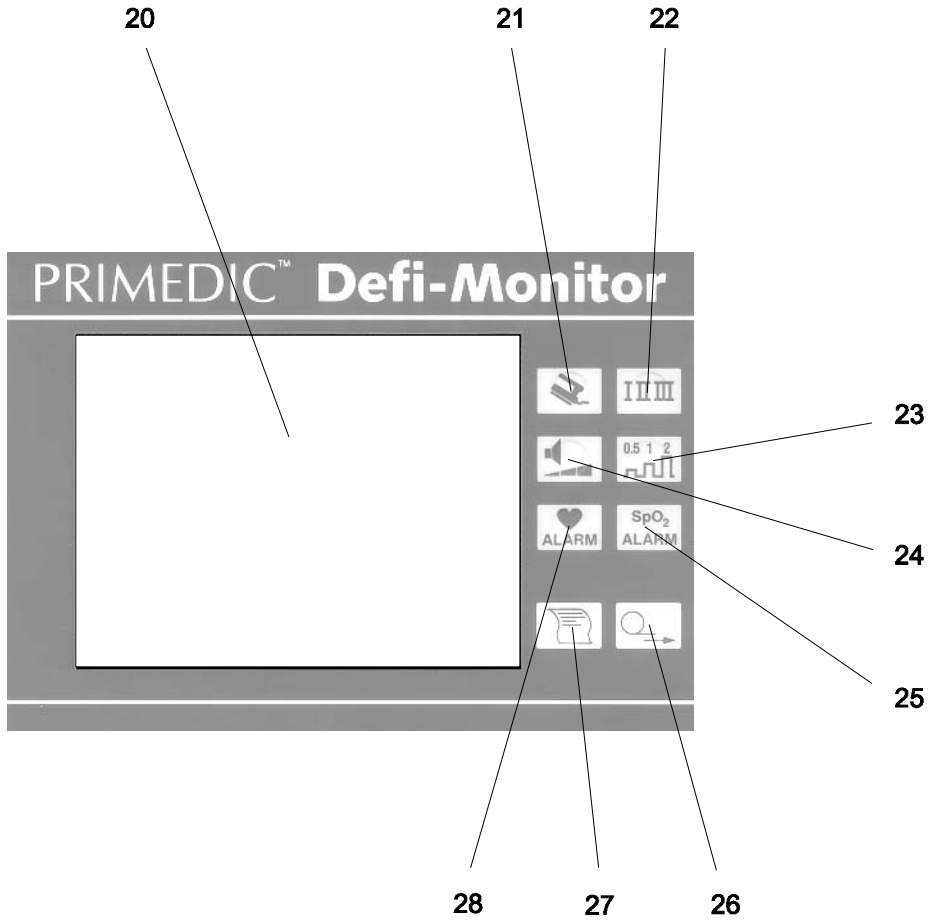


Fig.: 3 ECG-unit with operating elements and monitor DM 1 / DM 3

20	ECG monitor	high resolution EL monitor to show ECG signals and important device parameters.
21	Key PADDLE LEAD	To select the ECG signal of paddles.
22	Key LEAD SELECTION	To select standard leads.
23	Key SIGNAL AMPLIFICATION	To set the amplification factors for the ECG signal.
24	Key VOLUME	To control the volume of the systole beep.
25	Key ALARM(SpO_2)	To activate alarm limits for low and high SpO_2 values, presettable in the set-up menu.
26	Key PAPER FEED	Insertion of printing paper
27	Key PRINTER ON / OFF	Switching ON / OFF the ECG on-line printing
28	Key ALARM (heartrate)	To activate alarm limits for low and high heartrates, presettable in the set-up menu.

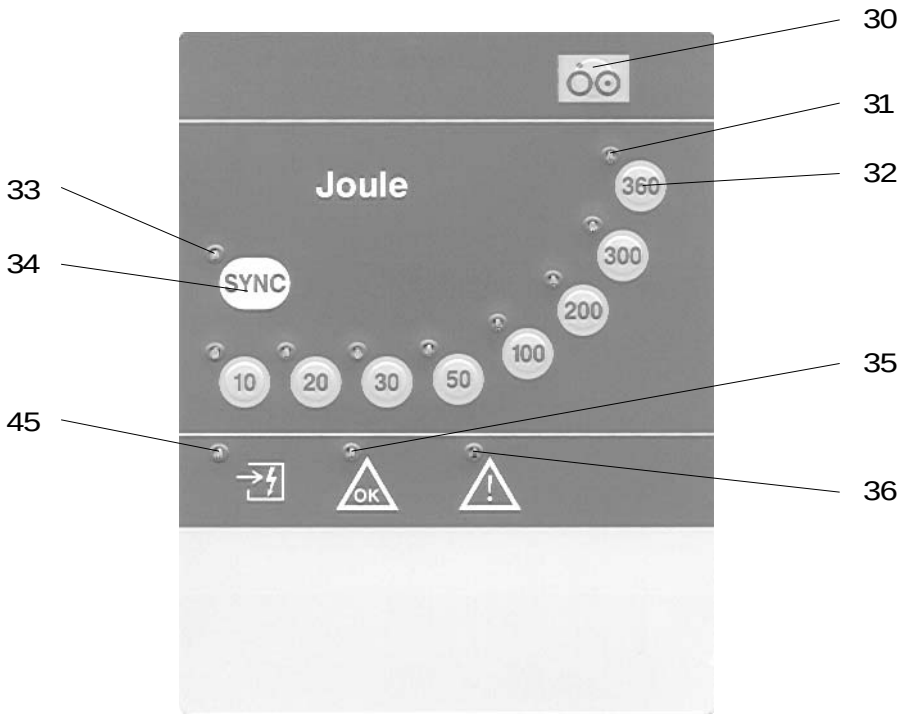


Fig.: 4 Defibrillator unit with operating elements and displays ECO 1

30	Key ON / STAND-BY	To switch the complete device on or to stand-by mode
31	LED	To display the selected energy step
32	Key ENERGY	To select the defibrillation energy
33	SYNC LED	To indicate synchronous operating mode
34	Key SYNC	To switch to synchronous operating mode
35	OK LED	To signal that selected energy is charged and available for the shock (defibrillation / cardioversion).
36	Attention LED	To signal malfunction of the defibrillation unit
45	LED	To signal the charging of the defibrillation energy

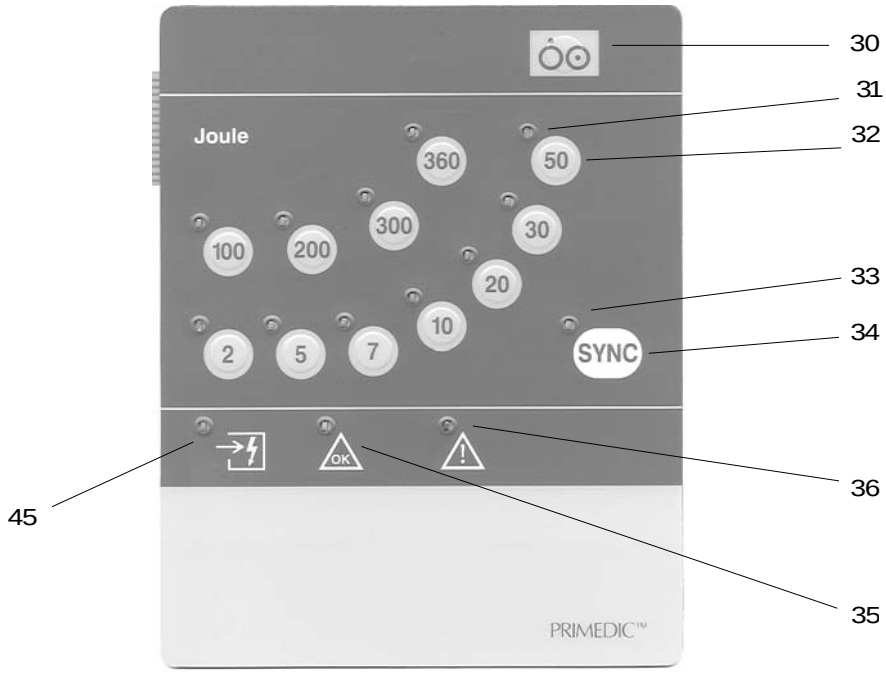


Fig.: 5 Defibrillator unit with operating elements and displays DM 1 / DM 3

30	Key ON / STAND-BY	To switch the complete device on or to stand-by mode
31	LED	To display the selected energy step
32	Key ENERGY	To select the defibrillation energy
33	SYNC LED	To indicate synchronous operating mode
34	Key SYNC	To switch to synchronous operating mode
35	OK LED	To signal that selected energy is charged and available for the shock (defibrillation / cardioversion).
36	Attention LED	To signal malfunction of the defibrillation unit
45	LED	To signal the charging of the defibrillation energy

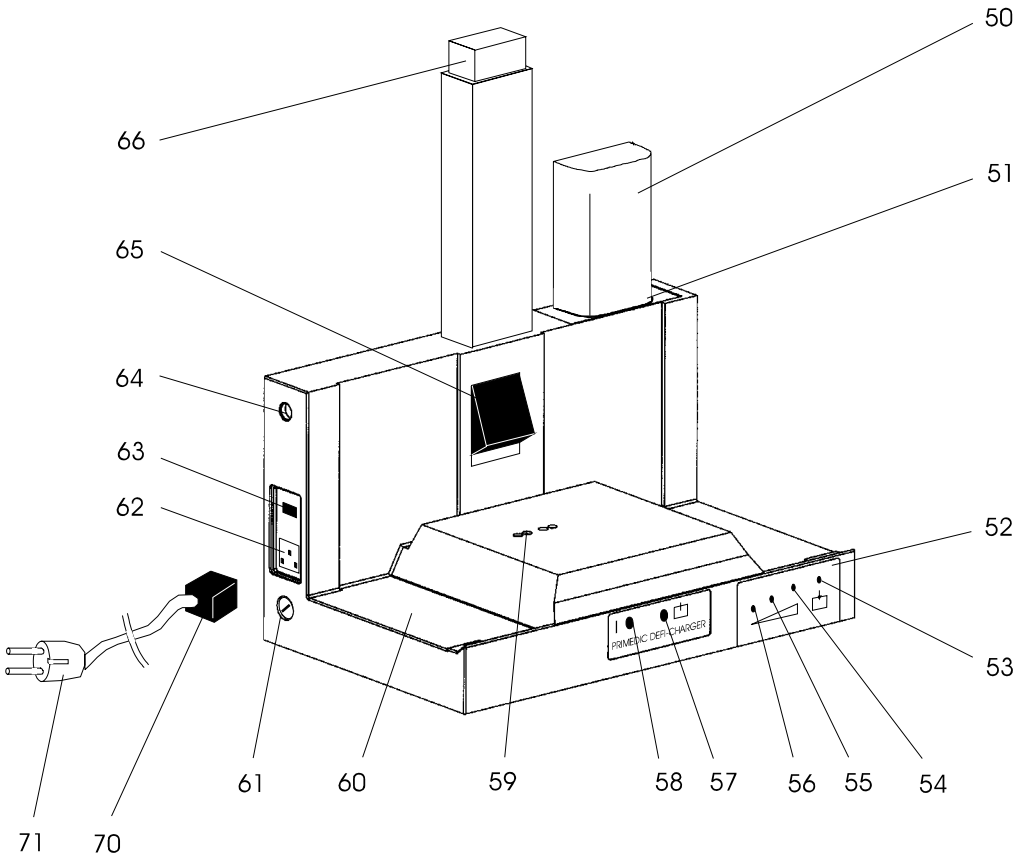


Fig.: 6 PRIMEDIC™ Defi-Charger Charging unit with connections and indicators

50	Changeable	Inserted in the charging shaft accumulator (optional)
51	Shaft	To charge or to keep a second PRIMEDIC™ Accu
52	Charging module (option)	To charge a second accumulator
53	LED green	To signal that standby accumulator is being charged
54	LED green	To signal accumulator capacity 90 - 100 %
55	LED yellow	To signal accumulator capacity 50 - 90 %
56	LED red	To signal accumulator capacity 10 - 50 % or a accumulator fault while flashing
57	LED yellow	To signal that the accumulator is being charged at the defibrillator
58	LED green	To signal availability of energy to charge the defibrillator or the optional standby accumulator
59	Contacts	To transmit the charging current to the defibrillator
60	Charging base	To insert the defibrillator
61	Fuse	Circuit protection for 12 / 24 V on-board voltage
62	Universal socket	To connect to the mains
63	Voltage selector	To set voltage range 100 - 120 V or 200 - 240 V
64	Lead through housing	To connect 12 / 24 V on-board voltage
65	Locking (optional)	To lock the defibrillator in the charging unit
66	Release button (optional)	One-hand release of the defibrillator
70	Plug	To connect to universal socket (62) at the charging unit
71	Mains plug	To connect to the mains socket

The PRIMEDIC™ Defi-Monitor is an external defibrillator with integrated ECG monitor and on-line printer. The defibrillator can be synchronized with the ECG enabling synchronous cardioversions.

The device series is organised modularly. Several models are available:

PRIMEDIC™	Defi-Monitor
ECO 1	low cost model
DM 1	basic model
DM 3	with pulsoximeter
DM 10	with module slot
DM 30	with pulsoximeter and module slot

The modules Pacer, I/D (internal defibrillation) and R/D (free-handed defibrillation) can be connected to the module slots of DM 10 and DM 30.

The design of the PRIMEDIC™ Defi-Monitor allows quick and safe use in cases of emergency. All function units and operating elements are based on the following features:

- clear structure of the function units
- reduction to the essential functions
- logical user guidance
- clear, self-explaining operating elements
- ergonomical design
- retrofitable functions, due to the modular design

At the models DM 1, DM 3, DM 10 and DM 30 the ECG monitor has a high resolution graphic EL display ensuring clear screen contrast even under problematic lighting conditions.

The ECG monitor can be moved upwards and downwards allowing a perfect viewing angle towards the ECG shown, e.g.:

- in lying position outdoors
- in upright position with deep installation places in ambulances.

As for the device versions DM 3 and DM 30 a continuous non-invasive measure of the functional oxygen saturation of arterial haemoglobin (SpO_2) is possible. The PRIMEDIC™ monitor is provided with a high-quality measuring module from NELLCOR PURITAN BENNETT Inc.

Together with the in Capter 6.2 (Selection of correct SpO_2 sensor) adviced sensors, a continuous monitoring of adult or paediatric patients is possible. Parallel to the measurement in % a continuous pulse curve is displayed in the monitor. This can be documented by the use of the high resolution printer.

During the measurement of the oxygen saturation, alarm thresholds can be activated to indicate changes in the patient's condition.

The printer can be used to document the monitoring as well as to record the emergency situation (the 5 s before and 5 s after every shock).

The defibrillator allows safe and extremely quick use:

- Charging time for 100 joule approx. 1 s (*)
- Charging time for 360 joule approx. 5 s (*)

(*) = when accumulator capacity is 90 % of nominal value.

A module slot is provided at the sides of models DM 10 and DM 30, where e.g. a pacer module may be inserted, which is particularly operator-friendly. In contrast to common pacers the paddle does not have to be removed in order to connect the pacer- / defibrillation cable. With PRIMEDIC™ pacers the pacer- / defibrillation cable is simply attached to the module. If the pacer- / defibrillation cables are connected, the paddle electrodes are switched-off.

If during the pacer process a defibrillation is necessary, a shock may be released via cushion electrodes. The release buttons of the module control the charging of energy and the release of a shock. Also without the pacer being active free-handed defibrillation may be carried out with the cushion electrodes.

If the pacer is not needed and the user does not wish to apply the energy via paddle, the R/D module may be used. To this module the cushion electrodes for the free-handed defibrillation are connected.

By means of the I/D module for internal defibrillation the internal electrodes can be connected via a sterilised patient cable. In case of working at an open thorax a wide range of internal electrodes is available.

The power supply of the PRIMEDIC™ Defi-Monitor is provided by changeable accumulators with NiCd cells. The applied charging electronics corresponds to the latest technology thus assuring a maximum service life of the accumulators used.

In rest position the PRIMEDIC™ Defi-Monitor can be inserted into a charging unit. Wall mounting or mounting into a vehicle is possible by means of various adapters (optional). In an emergency case the PRIMEDIC™ Defi-Monitor can be released easily and quickly with one hand.

The electric connections (mains voltage or DC on-board voltage) are fitted in the charging unit. The charging unit also supplies the power for the accumulator charging.

A comfort version of the unit is available as option allowing to charge a second changeable accumulator. When using the comfort version with Accu-Care function the accumulator receives best maintenance which prevents the problematic memory effect. Retrofitting of all standard charging units with the Accu-Care option is possible. The PRIMEDIC™ Defi-Monitor can also be operated while sitting on the charging unit. For safety reasons the accumulator has to be connected during operation to avoid removing the defibrillator from the charging unit without accumulator in case of emergency.

A variety of accessories are available.

3. Preliminary measures

3.1 Accumulator charging

The changeable accumulator has to be charged before first use of the PRIMEDIC™ Defi-Monitor.

Lock the changeable accumulator at the provided and marked location from the side in its position (see also section 9.1).

Then insert the PRIMEDIC™ Defi-Monitor into the PRIMEDIC™ Defi-Charger. The green LED (58) lights up to indicate that power is supplied to the charging unit (mains or on-board voltage).

When the accumulator needs to be charged the charging electronics starts the charging process, this indicated by the charging LED (57) of the charging unit. At the end of the charging procedure the charging LED (57) goes off.

Caution:
A completely discharged battery has to be recharged for at least 45 minutes. A too short charging duration may lead to a wrong interpretation of the battery charge by the device due to the nature of the battery. The battery charge monitor in the display will falsely indicate a full battery. A safe operation of the device under certain circumstances will not be guarantied.

3.2 Configuration of the defibrillator / ECG monitor (set-up menu)

The PRIMEDIC™ Defi-Monitor was configured at the factory. Certain parameters can be changed in the set-up menu in order to realize individual settings. This configuration remains until it is changed regardless whether the defibrillator is switched off or the accumulator is changed.

The set-up menu is partitioned on two pages. On page 1 the following parameters can be changed.

The underlined parameters represent the factory setting.

1.	Filter	Off / <u>50 Hz</u> / 60 Hz
2.	Date	DD.MM.JJ
3.	Time	hh.mm.ss
4.	Language	<u>deutsch</u> / english / français / espanol / portugesh
5.	Automatic printing	On / <u>Off</u>
6.	Print	<u>1-lead</u> / 3-lead *
7.	Print	<u>25 mm</u> / 50 mm *
8.	Memo-Print	activate

*= with installed software option.
*=only for DM 1 and DM 3 eligible.

The second page allows the following settings:

1.	♥ Alarm 1	<u>30</u> / <u>90</u>
2.	♥ Alarm 2	<u>40</u> / <u>130</u>
3.	♥ Alarm 3	<u>50</u> / <u>180</u>
4.	SpO_2 Alarm 1	<u>95</u> / <u>100</u>**
5.	SpO_2 Alarm 2	<u>90</u> / <u>100</u>**
6	SpO_2 Alarm 3	<u>80</u> / <u>100</u>**

*= only for DM 3 eligible

Press PADDLE-LEAD (21) and LEAD SELECTION (22) simultaneously during operation in order to start the set-up menu. The set-up menu is displayed.

During the configuration keys (21), (24) and (28) have special functions of which the symbols are displayed on the monitor.

Key (21)	UP	(σ)
Key (24)	DOWN	(τ)
Key (28)	OK	(↵)

Use these keys to control the configuration.

When calling up the set-up menu the first menu item is marked. To change e. g. the time move the cursor downwards by actuating DOWN (24) one or several times until the menu item time is marked. Select the menu item time by actuating OK (28). Then the cursor moves to the hour which is changed by actuating UP (21) or DOWN (24). Confirm the correct setting with OK (28). The cursor then moves to the minutes which can be changed in the same way as described. When confirming with OK (28) the cursor returns to the menu item time. Now you can realize further changes in the same way as described in the example time.

To quit the set-up menu move the cursor to the menu item END by means of UP (21) or DOWN (24) and confirm with OK (28).
Then the PRIMEDIC™ Defi-Monitor returns to monitoring operation.

Note:
If during the setting of the menu parameters the defibrillator has to be used immediately because of an emergency the set-up menu can be terminated immediately by pressing ENERGY (32).

4. Operation of the defibrillator

4.1 Switching the defibrillator on and off / self-test

Press ON / STAND-BY (30) shortly to switch on the PRIMEDIC™ Defi-Monitor.

To switch off, press ON / STAND-BY (30) for approx. 2 secs. During switch off procedure an acoustic signal is given. This time was chosen to prevent the device from being switched off accidentally. Energy that possibly has been charged for the defibrillation will automatically be discharged internally.

Note:
The complete device is switched on and off with ON/ STAND-BY (30). Thus the functions of all components can be used without loosing time.

When starting an internal self-test will be executed to check important functions and signal devices. All LEDs of the defibrillator light up for approx. 2 seconds. Be sure that all LEDs are active. During this time a warning buzzer has to be on as well. It is important that the buzzer functions.

Attention:
If one or several LEDs or the warning buzzer do not function, the defect has to be eliminated immediately.

4.2 Synchronous and asynchronous operation

When switching on the PRIMEDIC™ Defi-Monitor the defibrillator is automatically in asynchronous operation.

Press SYNC (34) to select synchronous operation of the defibrillator (cardioversion) if required by the emergency situation.

LED (33) signals the synchronous operation. In addition, the note "SYNC" is displayed on the ECG monitor.

After a synchronous discharge (cardioversion) the defibrillator switches back to asynchronous operation.

Note:
During synchronous operation ECG markings are shown on the monitor. For safe synchronous operation these cardioversion markers must appear in every QRS complex with a R-peak. A clear, artefactfree ECG signal with sufficient amplitude is essential.

If there are no markings shown on the ECG monitor, the amplitude probably has to be changed by means of SIGNAL AMPLIFICATION or a lead with improved signal quality has to be selected.

Note:
Do not use the paddles but the external ECG patient electrodes for the ECG recording during synchronous operation. Otherwise artefacts can be caused when moving the paddles which leads to faulty synchronization.

Note:
The delay time between the recognition of a QRS complex (synchronous pulse) and energy discharge is less than 60 ms.

Attention:
Before releasing the cardioversion check on the monitor whether the cardioversion markers are clearly related to the R-peaks and do not react e. g. to pacemaker pulses or artefacts.

4.3 Energy selection

Press one of keys (32) to select the energy. LED (31) located directly above the key pressed lights up to acknowledge the energy setting. In addition the selected energy step is indicated on the monitor.

Note:
The energy step required for the defibrillation / cardioversion depends on the patient, its body height and weight and its condition. For information please refer to appendix A2.

An energy step selected by mistake can be changed by pressing the correct key with the required energy step. This is also possible if energy has already been charged for defibrillation. When increasing the energy step the missing energy is added. When decreasing the energy step the excessive energy is discharged in small steps.

4.4 Energy charging

The selected energy can be charged by pressing one of the release buttons (10) or (12) and thus made available for the shock.

Then the energy will be charged quickly. LED (45) flashing indicates the charging procedure. The charging time depends on the selected energy step and the available accumulator capacity. Charging the defibrillator up to 100 joule takes approx. 1 second, charging up to 360 joule takes about 5 second. In case of a partly discharged accumulator the charging time may slightly be longer. See also technical data.

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 (35). The remaining time is simultaneously indicated on the monitor. If there is no defibrillation during this time, an internal safety discharge will be executed.

During this time the energy charged can be changed again if required (see section 4.3). After the change, the energy is available for another 15 seconds for defibrillation.

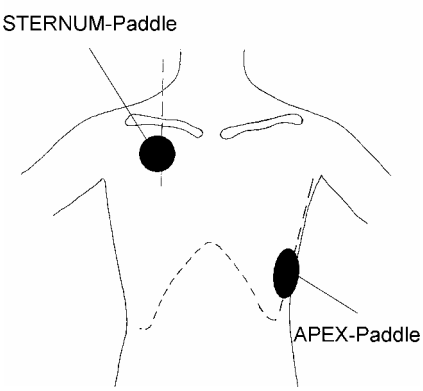
Should an error occur during energy charging, an intermittent warning signal and the Attention LED (36) will be on.

Attention:
If the message „load accumulator“ appears at least 5 discharges with maximum energy are available, in this case the Defi-Monitor should be placed again as fast as possible on the charging unit.

Attention:
If the ATTENTION LED (36) 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 (36) is still on after switching off and on again, the malfunction must be eliminated immediately.

4.5 Positioning of paddles



The paddles must be positioned along the cardiac axis.

APEX paddle (9) hast to be positioned in the left chest area, on the axillary line above the apex of the heart.

STERNUM paddle (13) hat to be positioned in the right chest area, below the clavicle.

4.6 Discharging of energy (shock)

Press release buttons (10) and (12) at the paddles simultaneously to discharge the energy.

In case of asynchronous operation energy will be discharged immediately after simultaneous depression of buttons.

In case of synchronous operation both release buttons (10) and (12) have to be pressed down simultaneously until the moment for the cardioversion is reached. During this time an intermittent signal will be on.

No cardioversion will be released, if during discharging the release buttons are let go off.

The energy is discharged internally if no synchronization takes place within 3 seconds while keeping the release buttons pressed down. Thereafter, the PRIMEDIC™ Defi-Monitor returns to asynchronous mode.

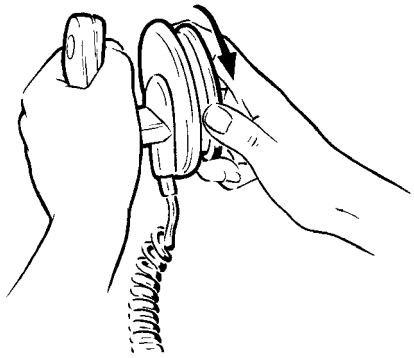
During the shock the ECG input will generally be overloaded for a short time. The PRIMEDIC™ Defi-Monitor will supply a stable ECG baseline already after approx. 1 second after the shock so that the defibrillation success can be seen immediately.

Attention:
Before releasing the cardioversion check on the monitor whether the cardioversion markers on the monitor are clearly related to the R-peaks and do not react e. g. to pacemaker pulses or artefacts.

Attention:
Both paddles have to be pressed on the thorax by applying a pressure of approx. 100 N 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.

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.



4.7 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. Operation of the ECG monitor

5.1 Selection of ECG leads

The ECG graph can be realized in two ways:

1. via paddles
2. via external ECG patient cables.

The paddle lead is automatically active after switching on the PRIMEDIC™ Defi-Monitor which is indicated by a paddle symbol on the monitor.

The monitor cannot be switched to the standard leads if no external ECG patient cable is connected.

The standard leads can be used if an ECG patient cable is connected. Press LEAD SELECTION (22). Lead II is immediately active. Press LEAD SELECTION (22) to switch between the possible leads I, II, III, aVR*, aVL* or aVF*. The selected lead is shown on the monitor.

To switch back to lead via paddle electrodes press PADDLE-LEAD (21) regardless whether ECG signals are available via the external patient cable.

The monitor automatically switches to paddle lead when pulling out the ECG patient cable from the input socket of the PRIMEDIC™ Defi-Monitor during the monitoring.

Note:
The PRIMEDIC™ Defi-Monitor switches off automatically when no ECG is shown or no key is pressed for 15 minutes while the device is switched on. Approx. 30 seconds before switching off an acoustic signal is given. By pressing any key, the switching off routine is interrupted.

Note:
If the paddle lead is selected and the paddles are not attached to the patient, an intermitting line with the message „Electrodes open“ will be displayed in the monitor. As soon as the paddles are attached to the patient, the recorded ECG signal will be displayed in the monitor.

= only for DM 1 and DM 3 with installed software option.

5.2 Setting of signal amplification

Five signal amplification steps are available:

1. 0.5 cm/mV
2. 0.8 cm/mV
3. 1.0 cm/mV
4. 1.5 cm/mV
5 2.0 cm/mV

Amplification step 1 cm/mV is automatically active after switching on the PRIMEDIC™ Defi-Monitor. Press SIGNAL AMPLIFICATION (23) to switch between the amplification steps in ring counting method. The 1mV reference is constantly shown on the left of the monitor border. After switching to a different value the reference marking is shown for about 5 seconds in lower status line.

5.3 Volume of systole beep

Three volume steps are available for the systole beep: off, low, high.

After switching on the volume step off is automatically active. The volume symbol is shown on the monitor.

Press VOLUME (24) to switch between the three volume steps. Each depression on key (24) causes the continuation by one step.

5.4 Activation of heartrate alarms

Four steps are available:

1. – – –
2. ♥ ALARM 1 30 / 90
3. ♥ ALARM 2 40 / 130
4. ♥ ALARM 3 50 / 180

The above mentioned alarm limits are preset at delivery. The values of the second and fourth alarm step can be changed by means of the set-up menu (see section 3.2).

The alarm is not active after switching on the PRIMEDIC™ Defi-Monitor which is indicated on the monitor. Press ALARM (28) for activation. Every depression of this key causes the continuation by one alarm step.

The value indicated on the monitor (e. g. ♥ ALARM 30 / 90, SpO_2 90 / 100) means that a pulsating acoustic alarm will be released when exceeding the heartrate of 90 beats/ minute or remaining under 30 beats / minute. You can acknowledge (switch off) the alarm by pressing ALARM (28) shortly. The acoustic alarm is switched off for about 1 minute whereas the alarm limits remain. To change the alarm limits or to switch off the alarm press ALARM (28) until the desired selection (e. g. ♥ ALARM — — —) is shown on the monitor.

After the defibrillation the heart alarms are set OFF automatically.

Note:
Test possibility for alarm circuit.
Select alarm limits with no patient connected. The optical and acoustical alarm has to be released immediately. After acknowledging ALARM (press button 28) the acoustical alarm is suppressed for about 1 minute. The optical alarm has to remain active (intermittent alarm signal).

5.5 Contrast-Settings (only for ECO 1)

Five different contrast settings are available. Depending on the ambient temperature or brightness it may be useful to change the contrast for high-contrast monitoring. The most suitable contrast step can be determined by repeated actuation of CONTRAST (29). After switching off the PRIMEDIC™ Defi - Monitor the current contrast setting is saved and active again when switching on.

5.6 Filter

The monitoring has the possibility to use high-quality line filter with 50 or 60 Hz. This can be adjusted in set-up menu (see section 3.2). It is recommendable to activate the 50 Hz filter.

5.7 Positioning of ECG electrodes

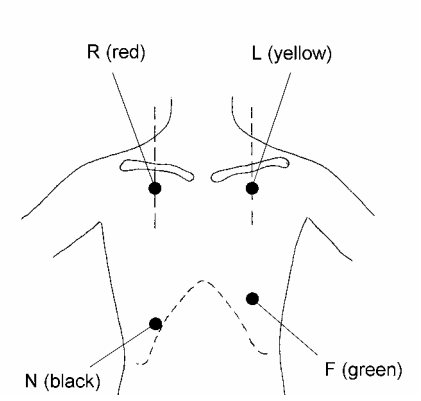
The quality of the indicated ECG signal depends among others on the safe contact and correct positioning of the ECG electrodes.

Position the electrodes carefully in order to minimize the movement artefacts.

Positioning of disposable electrodes:

1. Connect the plug of the patient cable (4) to the ECG plug-in connection (3) so that it engages audibly.
2. Attach the patient electrode cable firmly to the electrode by means of the clip connection.
3. Pull the lamination sheet off the electrodes.
4. Make sure that there is no electrolyte gel on the adherent surface.
5. Stick the electrodes to the skin of the patient by pressing the adherent surface firmly against the skin. Positioning according to the table.

Positioning of electrodes with four-wire cable (with neutral electrode):



Electrode	Position
Red (R)	directly below the right medioclavicle
Yellow (L)	directly below the left medioclavicle
Green (F)	directly below the left pectoral muscle on the medioclavicle line
Black (N)	right side of the body, e. g. lowest rib on the medioclavicle line

After use remove the disposable electrodes by pressing together the electrode bracket. Do not apply used disposable electrodes!

Note:
Use silver / silver chloride electrodes (Ag / AgCl) in order to minimize a polarization of the electrodes during defibrillation.

Attention:
Only use the original- PRIMEDIC™ patient cable. This patient cable has an integrated defibrillation protection protecting the ECG monitor from dangerous high voltage. The use of another patient cable may cause the destruction of the ECG unit and may be hazardous to the user.

Attention:
The black ECG electrode (N) always has to be connected, to guarantee the function of the identification of electrodes open.

6. Operation of SpO_2 monitor (only model DM 3)

6.1 Connection of SpO_2 sensor

The PRIMEDIC™ Defi-Monitor with integrated NELLCOR ® pulsoximeter module is provided with a blue input socket (16) at the upper left of the casing for the SpO_2 patient cable.

Proceed as follows:

1. Insert into slot (16) the blue plug (17) of the patient cable (about 1,4 m).
2. Plug the NELLCOR® sensor into the other end of the SpO_2 patient cable until the traction relief engages.
3. Test the perfect mechanical locking of the plug-in-connection.

To dismount the NELLCOR ® sensor from the SpO_2 patient cable, push the release of the plug-in-connection and take out the sensor without applying force.

If the NELLCOR ® sensor is positioned on a patient, after about 5 seconds of measuring time the value in % and the pulse curve are shown on the monitor. A rhythmically oscillating signal bar at the right fringe of the pulse curve indicates when the module recognizes an evaluable oxygen saturation value.

Note:
Do not kink sensor or patient cable to avoid defects or malfunctions.

Note:
Reusable sensors may remain at one measuring point for 4 h maximally, provided that state of the skin, the correct and secure positioning of the sensor at the measuring point are controlled regularly. As the tolerance towards sensors at the measuring point depends upon the individual condition of the skin, it may be necessary to change the points of measure with some patients.

Note:
Before using the sensor read the instructions for use.

Attention:
Do not use damaged sensors or sensors with unprotected optical components.

Attention:
Only use original NELLCOR® sensors for SpO_2 measures. Other sensores could cause measuring errors or damage the SpO_2 module.

Attention:
Always use original SpO_2 patient cables which guarantee the perfect connection of NELLCOR® sensors to the Defi-Monitor.

Attention:
Avoid tensile load at the NELLCOR® sensor or the SpO_2 patient cable.

6.2 Selection of correct SpO_2 sensor

In order to select the correct sensor for the respective application it is necessary taking into account the following facts:

- weight of the patient
- activity of the patient
- duration of the measure
- blood circulation of the limbs

Also observe the instructions for the use of pulsoximeters in appendix A3.

The following table summarizes the most important NELLCOR® sensors with appropriate fields of applications for the PRIMEDIC™ Defi-Monitor.

NELLCOR®-Sensors	Weight of the patient	special features
DS-100 A	> 40 kg	operator-friendly, reusable
D-YS	> 1 kg	universal sensor, reusable, applicable with ear clip
RS-10	> 40 kg	reflecting sensor, attachable at forehead or temple, especially for patients with reduced peripheral circulation, reusable
OXI-A/N	< 3 or > 40 kg	reusable, insteril disposable adherend
OXI-P/I	3 - 40 kg	reusable, insteril disposable adherend

More NELLCORE® sensors are available. Please ask for our detailed documentation.

Note:
Operating instructions for the above mentioned sensores are provided in the instructions for use.

Attention:
Only use the sensores according to their determined purpose (weight of the patient, measuring point .....). Exact notes and instructions for the correct use can be seen in the instructions for use of the corresponding sensors.

6.3 Setting of alarms for SpO_2

Four steps are available:

1. — — —
2. SpO_2 alarm 1 95 / 100
3. SpO_2 alarm 2 90 / 100
4. SpO_2 alarm 3 80 / 100

The above mentioned alarm limits are preset at delivery. The values of alarm step 2 to 4 can be changed by means of the set-up menu (see chapter 3.2). The setting range for the lower alarm limit lies between 80 - 99 %, for the upper alarm limit between 90 - 100 %.

After switching on the PRIMEDIC™ Defi-Monitor the alarm is not active. This is shown on the monitor. The alarm can be activated by pressing the SpO_2 ALARM (25). The SpO_2 ALARM (25) operates in ring counting method, i.e. every depression of the key causes a continuation by one alarm step.

The message displayed on the monitor (e.g. SpO_2 ALARM 80 / 90) means that a rhythmic alarm is released when a SpO_2 value is falling below 80 % or passing 90%.
The alarm bell flashes. If the alarm is released it can be acknowledged (switched off) by shortly pressing SpO_2 ALARM (25). The alarm audio signal is switched off for about a minute. The alarm bell symbol is crossed out during muting. If you want to change the alarm limits or switch of the alarm, press SpO_2 ALARM (25) until the desired message e.g. SpO_2 ALARM — — —is displayed on the monitor.

After a defibrillation the SpO_2 ALARMs are automatically set OFF.

Note:
Test possibility for alarm circuit.
Select alarm limits with no patient connected. The optical and acoustical alarm has to be released immediately. After acknowledging ALARM (press button 28) the acoustical alarm is suppressed for about 1 minute. The optical alarm has to remain active (intermittent alarm signal).

Note:
If no SpO_2 value is displayed, this can mean that:
- no sensor or SpO_2 patient cable is connected
- sensor damaged

The alarm will be released in any of the above mentioned cases with alarm limits activated.

7. Operation of printer

7.1 Protocol of the ECG signal

The PRIMEDIC™ Defi-Monitor has a printer with high resolution. ECG prints of 3 channels at a time are possible, at printing speeds of 25 and 50 mm/s*.

To protocol the ECG graph during monitoring the on-line printing has to be started by pressing PRINTER ON/OFF (27).

Repeated actuation of PRINTER ON/OFF (27) stops the printing of the protocol. Printing is with 2 seconds delay. The ECG is printed with the parameters chosen in the set-up menu. The following set-up possibilities are available:

1-channel-print	prints the ECG channel displayed on the monitor. With SpO_2 measure active the SpO_2 pulse curve is displayed additionally.
3-channel-print *	prints channel I, II, III or aVR, aVL, aVF simultaneously, depending upon the lead displayed on the monitor.
25 mm/s -printing speed*	The information is printed at 25 mm/s.
50 mm/s - printing speed*	The information is printed at 50 mm/s.

As for device version DM 3 it is possible to print the SpO_2 in protocol printing quality, but only in the 1-channel-mode.

Printing is started 3 seconds after some information is displayed on the monitor, i.e. events that happened before the activation of the print can be represented.

The cutting edge integrated in the printer cover (11) allows to cut off the ECG protocol tape. Cut off the tape by pulling sideways to the top.

Note:
Well-thought and short-time printing saves energy and paper and increases the mains-independent operating time of the device, especially in case of printing at a speed of 50 mm

*= as for DM 1 only with installed software package.
* = only for DM 1 and DM 3.

7.2 Automatic printout after every shock (auto print)

With the PRIMEDIC™ Defi-Monitor it is possible to protocol automatically the event after every shock (defibrillation / cardioversion). The 5 seconds before and 5 seconds after every shock are documented. All important parameters are printed in the beginning:

- Date, time
- Energy (joule)
- Synchronous / asynchronous operation
- Lead
- Heartrate
- Filter
- Signal intensification
- Lines for additional notes
- SpO_2 value (only model DM 3)
- Speed

The auto print function can be switched on and off in the set-up menu. The function is switched off at delivery.

Use the cutting edge integrated in the printer cover (11) to cut off the ECG protocol tape. Cut off the tape by pulling sideways to the top.

Note:
The auto print function switched on in the set-up menu remains active even after switching off the defibrillator or changing the accumulator. The device configuration has to be changed in the set-up menu in order to deactivate this function.

7.3 Printing of the event memory

The PRIMEDIC™ Defi-Monitor saves the last 10 shocks (defibrillations/cardioversions) automatically in an event memory. The 5 seconds before and 5 seconds after every shock, as well as all important parameters are saved:

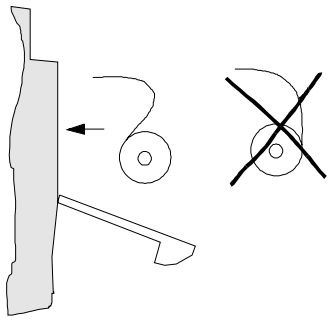
- Date, time
- Energy (joule)
- Synchronous / asynchronous operation
- Lead
- Heartrate
- Filter
- Signal intensification
- Lines for additional notes
- SpO_2 value (only with model DM 3)
- Speed

Every new event pushes the oldest event out of the memory.
With the set-up menu the memory contents beginning with the last event are printed, by using the just actual signal intensification.

Call the set-up menu and move with cursor key to item “Memo-Print“, acknowledge “activate“. The memo print starts. To stop the printout press PRINTER ON / OFF (27). The print speed is 25 mm/s.

Use the cutting edge integrated in the printer cover (11) to cut off the ECG protocol tape. Cut off the tape by pulling sideways to the top.

Note:
After printing the data remains in the event memory. The data can be printed as often as necessary.



7.4 Insertion of printing paper

Fold down the printer cover (11) to the front to insert the printing paper (paper reel). Prepare the paper reel provided (remove the adhesive strip, uncoil approx. 10 cm of paper). Insert the paper reel into the printer shaft so that the paper runs as per the opposite drawing. Otherwise the paper would be printed on the reverse. Hold the end of the paper against the rubber cylinder and press PAPER FEED (26). The paper now takes its starting position.

Close the cover (11) and press again PAPER FEED (26). The paper will be fed automatically through the cover shaft up to the cutting edge.

Note:
The cover is designed in such a way that it jumps out of its position without being damaged when applying stronger external pressure. Replace the cover by pushing back the snap lockings by means of a screw driver until the cover engages.

8. Handling of the charging unit

After every use the PRIMEDIC™ Defi-Monitor should be inserted into the charging unit in order to recharge the accumulator. Otherwise a second charged PRIMEDIC™ Accu has to be available or the accumulator has to be charged with the external charging/regenerating table unit in order to be prepared for a case of emergency.

When inserting the defibrillator into the charging unit the springs have contact and the accumulator can be charged.

The fixing parts for wall mounting or mounting into a vehicle ensure a safe position of the PRIMEDIC™ Defi-Monitor when inserting into the charging unit. Hold the handle of the defibrillator and press down release button (66) with your index to remove the PRIMEDIC™ Defi-Monitor from the charging unit. Now the defibrillator can be removed or tilted downwards in order to reach the second accumulator.

Note:
After insertion check whether the defibrillator is locked firmly.

Caution:
A completely discharged battery has to be recharged for at least 45 minutes. A too short charging duration may lead to a wrong interpretation of the battery charge by the device due to the nature of the battery. The battery charge monitor in the display will falsely indicate a full battery. A safe operation of the device under certain circumstances will not be guarantied.

9. Handling of the changeable accumulator

The changeable accumulator (PRIMEDIC™ Accu) is charged automatically when inserting the defibrillator into the charging unit. In case of permanent use of the PRIMEDIC™ Defi-Monitor one or more charged accumulators have to be kept available for use in case of emergency. The comfort version (optional) of the charging unit (see section 9.2) allows the charging of an additional accumulator.

All accumulators based on NiCd technics have to be discharged completely before recharging in order to avoid a "memory" effect (see appendix A1).

The comfort version of the charging unit ensures best accumulator care. For the charging of a second accumulator it is equipped with the so-called Accu-Care function that checks the inserted accumulator and discharges it completely before charging the maximum capacity.

The "memory" effect can be avoided effectively by regular exchange of the accumulator connected to the PRIMEDIC™ Defi-Monitor for the second accumulator of the charging unit (approx. every second week).

Note:
Accumulators are subject to wear. Even best care does not avoid a derating of capacity in the long run. Stop using the accumulator if after approx. 2 years the accumulator capacity only allows few shocks with maximum energy.

Note:
Accumulators have to be disposed of professionally. Return the used PRIMEDIC™ Accus to us or to the dealer. Do not dispose of the accumulators in the household garbage!

Note:
Insertion of the defibrillator with discharged accumulator into the charging unit allows monitoring operation immediately after switching on.

Attention:
To operate the PRIMEDIC™ Defi-Monitor the accumulator has to be connected to the right side of the casing. This is also necessary for safety reasons for the operation of the defibrillator when it is inserted into the charging unit.

9.1 Changing of the accumulators

Connect the PRIMEDIC™ Accu to the defibrillator as follows:

1. Remove the right paddle cable (apex) from its rest position to facilitate locking of the accumulator.
2. Take the PRIMEDIC™ Accu with the connection contacts showing to the top.
3. Put the accumulator in the guide provided from the side. Ensure that it sits close to the defibrillator side and is perfectly aligned in its lowest position.
4. Move the accumulator upwards until it engages audibly.

Note:
The PRIMEDIC™ Accu must sit close to the defibrillator casing while moving upwards until it engages. Oblique insertion of the accumulator is not possible.

Remove the PRIMEDIC™ Accu from the defibrillator as follows:

1. Remove the right paddle cable (apex) from its rest position to facilitate changing of the accumulator.
2. Press down the marking on the release button (7) and keep the button pressed down.
5. Move the accumulator downwards while it is sitting closely to the defibrillator until it disengages audibly.
4. Release the release button (7).

9.2 Parallel accumulator charging in the charging unit

Charging of a second PRIMEDIC™ Accu is only possible with the comfort version of the charging unit.

Insert the PRIMEDIC™ Accu into shaft (51) of the charging unit with the contacts showing downwards. Insert from top to the bottom.

If the charging unit is mounted e. g. at the wall and the defibrillator is inserted, you can still insert or remove the second accumulator. To do so press release button (66) and tilt the defibrillator to the front until access to the shaft is possible.

After insertion the accumulator capacity is indicated. All three Accumulator LEDs (54-56) in the charging base (52) light up. Then the accumulator is completely discharged which is indicated by the flashing of LEDs (54-56).

At the end of the discharging the accumulator is charged completely. LED (53) flashes to indicate the charging. When charging of the PRIMEDIC™ Accu is finished LED (53) goes off and the 100 % LED (54) lights up. Remove the accumulator. The charged capacity remains should the accumulator sit on the charging unit for a longer period.

Note:
Do not remove the accumulator from the shaft during charging or discharging.

10. Maintenance and care

For maintenance of the PRIMEDIC™ Defi-Monitor, all accessory parts such as ECG patient cable and the charging unit PRIMEDIC™ Defi-Charger we recommend a commercial domestic cleaner. Use a wet, clean cloth for cleaning.

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-Monitor 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 (defibrillator, charging unit, accumulator).
2. Check whether the insulation of the ECG patient cable and 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.
4. Remove dirt accumulated in the shaft.

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

11. 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.

12. Technical data, accessories, symbols

12.1 Technical data PRIMEDIC™ Defi-Monitor ECO 1 / DM 1 / DM 3

Defibrillation / cardioversion:

Operating modes:	synchronous or asynchronous, external defibrillation
Energy steps:	10, 20, 30, 50, 100, 200, 300, 360 joule (50 Ω)
Discharges:	60 with 360 joule at 20 °C, 30 with 360 joule at 0 °C
Charging time, accumulator charged:	1 s (100 joule), 5 s (360 joule)
Charging time after 15 shocks:	1.5 s (100 joule), 5.5 s (360 joule)
Delay time:	< 60 ms between synchronization pulse and energy discharge

EKG-Monitoring Modell ECO 1:

Construction:	ECG monitor movable by ± 30° for easy reading of ECG
Monitor type	high resolution graphic EL monitor (electro-luminescence)
Monitor size:	120 x 90 mm (diagonal 5,7" or145 mm)
Resolution:	320 x 240 pixel (pixel size 0.36 x 0.36 mm)
Filter:	connectable, 50 or 60 Hz
Functions:	signal amplification, systole beep, heartrate, paddle lead, energy step, accumulator capacity, heartalarm limits,
Alarm:	variable for high and low heartrates

EKG-Monitoring DM 1 / DM 3:

Construction:	ECG monitor movable by ± 30° for easy reading of ECG
Monitor type	high resolution graphic EL monitor (electro-luminescence)
Monitor size:	115 x 86 mm (diagonal 143 mm)
Resolution:	320 x 240 pixel (pixel size 0.36 x 0.36 mm)
Filter:	connectable 50 or 60 Hz
Functions:	signal amplification, heartrate, lead, energy step, accumulator capacity, heartalarm limits, SpO_2 value, SpO_2 alarm limits (SpO_2 only with DM 3)
Alarm:	variable for high and low heartrates or SpO_2 (SpO_2 only with DM 3)

NELLCOR®-pulsoximetry-module:

Indication range:	100 ... 0 %		
Calibration range:	100 ... 50 %		
Measurement precision:	SpO_2		
	Adults	100 ... 70 %	+/- 2 digits
		69 ... 50 %	+/- 3 digits
		50 ... 0 %	not specified
	New-born	95 ... 70 %	+/- 3 digits
	For information about test procedures for the calibration ask manufacturer.		
Wavelength:	Red: 660 nm		
	Infrared: 920 nm		
Light density:	0,5 lumen/cm^2		
Operating mode:	continuous		
Actualisation time:	< 2 sec.		

Information related with toxicity of the materials getting into contact with the patients 18565 Fingersensor DS.100A for pulsoximeter EN10993-10, ISO 10993-5

Printer:

Printer type:	thermal transfer head, 1-channel
Resolution:	8 bit / 200dpi
Paper width:	58 mm
Operating modes:	auto print (protocol printing showing the events of the 5 s before and 5 s after defibrillation)
	ECG print (EKG on-line protocol printing)
	MEMO-print (printing of the saved events of the last 10 defibrillations with 5 s before and 5 s after defibrillation)
	1/3-canal print
	*only model DM1 and DM3

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 changeable accumulator (PRIMEDIC™ Accu)
Changeable accumulator:	14.4 V / 1.5 Ah / NiCd
Operating conditions:	0 ... 50 °C, 30 ... 95 % rel. humidity, but without condensation 700 hPa ... 5000 hPa for 1 h, 700 hPa ... 1060 hPa continuous service
Storage environment:	-20 ... 70 °C, 20 ... 95 % rel. humidity, but without condensation 500 hPa ... 1060 hPa
Dimensions:	42 x 12 x 42 cm (w x d x h)
Weight:	8 kg

Subject to alterations.

Delivery specification:		Part no.
PRIMEDIC™ Defi-Monitor ECO 1		96017
1	PRIMEDIC™ Accu, 14,4 V / 1,5 Ah, NiCd	72264
1	ECG patient cable, 4-lead, neutral electrode (3+N)	72303
30	ECG-electrodes Ag/AgCl Ø 55 mm, with push button, single use	18155
1	conductive gel, 60 g	13026
1	Printer paper, 58 mm, 25 m	18122
1	Medical device protocol	13084
1	Instructions for use	19094
1	Briefing protocol	18514
PRIMEDIC™ Defi-Monitor DM 1		96088
see ECO 1		
PRIMEDIC™ Defi-Monitor DM 3		90067
see DM 1, but additional		
1	SpO_2 fingersensor DS-100 A (NELLCOR ®)	18565
1	SpO_2 patient cable (2.4m)	18783

12.2 Accessories

	Part no.
Bag with three transparent storage compartments	72310
Shoulder strap with fixation kits incl. shoulder pad	18578
conductive gel, 60 g	13026
ECG patient cable, 4-lead, neutral electrode (3+N)	72303
ECG-electrodes Ag/AgCl Ø 55 mm, with push button, single use	18155
PRIMEDIC™ Accu, 14.4 V / 1.5 Ah, NiCd	72264

More accessories see separate accessories / price list.

12.3 Symbols

The following symbols are used on the device:

Rating plate:

Protection type

IPX1

Splash-proof

Comply with instructions for use!

Paddle:

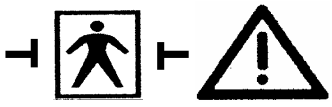
Degree of protection BF,
input with defibrillation protection

Hazardous electric voltage
(high voltage)

ECG input socket:

Degree of protection CF,
input with defibrillation protection

SP02 input socket:
(only model DM 3)



Degree of protection BF; input with defibrillation protection. Comply with instructions for use!

13. 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 !

14. Appendix

A1 General instructions and rules for the use of accumulators

What is an accumulator?

Accumulators are used for storing electric energy. During the charging procedure the charge current is stored in the accumulator by a chemical process. When the accumulator is discharged (during operation) the chemical energy is converted back into electric energy. This charging and discharging process can be repeated several times.

Lead-acid or NiCd-accumulator?

Various accumulator designs with different and typical features proved in practice.

1. Lead-acid accumulator
2. NiCd-accumulator (nickel-cadmium)
3. metal-hybrid accumulator

The development of the PRIMEDIC™ Defi-Monitor is based on the NiCd-accumulator since practice revealed advantages over other constructions.

The lead-acid accumulator, one of the first accumulator types, converts the energy to hazardous oxyhydrogen gas (explosion hazard) when the charge is too strong. Compared to the lead-acid accumulator the NiCd-accumulator has got a considerably higher energy density. This means that the PRIMEDIC™ Accu of the same size can release far more shocks (i. e. has a longer monitoring time) than a comparable lead-acid accumulator.

The metal-hybrid accumulator has even got a higher energy density than the NiCd-accumulator but the current level delivered by this accumulator is too low. This would cause a too long supply time of energy required for the shock which contradicts the requirements of today's defibrillators.

The handling of the NiCd-accumulator is easy. State-of-the-art microprocessor-controlled charging circuits, also used in the PRIMEDIC™ Defi-Monitor allow to realize very short charging times and a longer service life of the accumulator.

Partial discharging and recharging of the NiCd-accumulator over a longer period lead to the typical phenomenon, the "memory" effect. Due to the "memory" effect the accumulator operates like a small accumulator with low capacity although it has got a nominally large accumulator capacity.

Example:

An accumulator has a capacity of 60 shocks with 360 joule each. Energy for 5 shocks will be released and the accumulator recharged. This procedure, if continued over a longer period, can cause the "memory" effect. This means that the accumulator capacity will be reduced to 5 to 6 shocks since the accumulator is "trained" on 5 shocks.

It is very difficult to eliminate the "memory" effect, i. e. to get back to the full capacity, if the "remaining capacity" remains under a practicable value.

How to avoid the "memory" effect?

The "memory" effect can be avoided by discharging the accumulator completely from time to time so that a complete charging can be carried out. There are various possibilities for the practice:

1. Do not immediately recharge the accumulator if it has only been discharged slightly. In most cases sufficient energy is available for later applications. The PRIMEDIC™ Defi-Monitor does not always recharge the accumulator immediately. The accumulator is recharged only after falling below a limit.

2. Before charging the accumulator use the remaining capacity for e. g. several shocks with high energy or for monitoring. This is not necessary every time before charging but only from time to time (every week or month, depending on the use).

3. Best accumulator care is obtained by means of the fully automatic discharging / charging unit which carries out a defined discharging before every charging procedure. For safety reasons, this charging process is not used with accumulators being charged directly in the defibrillator. The worst case could be that the defibrillator is required just when the accumulator is completely discharged. .

   The fully automatic discharging / charging, i. e. the Accu-Care function is integrated in the charging unit of the PRIMEDIC™ Defi-Monitor. This option (retrofitting possible) allows to charge a second PRIMEDIC™ Accu and to avoid efficiently the "memory" effect by means of the Accu-Care function.

Further effects of accumulators?

In daily practice, accumulators have two further features:

1. Self-discharge
2. Aging after a longer period of use.

In practice self-discharge means that a full accumulator is subject to a slow but continuous loss of charge. After approx. 4 weeks 90 % of the capacity are available. This effect, however, is only important if several charged accumulators are kept "on stock".

The PRIMEDIC™ Defi-Monitor is equipped with a circuit for conservation of the charge.

Even best maintenance of the accumulator does not avoid an aging after approx. 2-3 years (depending on the use). After approx. 500-1000 charging cycles (depending on the type) it is impossible for the accumulator to transfer the electric energy charged to the chemical storage. Thus the accumulator becomes unusable and has to be replaced for a new one.

A2 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 cardioversion
completely uncoordinated activities of the heart muscle (ventricular flutter)	unsynchronized cardioversion (defibrillation)

The a. m. table shows two general groups of cardiac irregularity and the possible counter-measures.

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

1. Unsynchronized cardioversion (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 cardioversion:

   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 10-30 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 cardioversion):

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- and T-waves as well as QRS-copmlexe missing in the ECG of the patient.

1. Switch on defibrillator and ECG unit.
   With the PRIMEDIC™ Defi-Monitor the ECG unit is also switched on automatically.

2. Make sure that the defibrillator is not in synchronous mode.
   With the PRIMEDIC™ Defi-Monitor the defibrillator always starts in asynchronous mode. Even after release of a shock in synchronous mode it switches back to asynchronous mode.

3. 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.

4. Select energy.
   The energy to be released depends on the patient's body height and weight. The following rule of thumb applies: 2 joule per kg body weight. The most suitable energy is based on experience and depends on the emergency situation.

5. Positioning of the paddles.
   Stick the paddles firmly to the bare chest of the patient by applying a pressure of approx. 100 N 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 sternum paddle:
   - right chest area
   - right close to sternum
   - below the clavicle

   Position of the apex paddle:
   - 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.

6. Energy charging.
   After charging the energy remains available for a limited time, i. e. 15 seconds with the PRIMEDIC™ Defi-Monitor. This time is also shown on the monitor and counted down in steps of seconds. If no shock is released during this time the energy is discharged internally for safety reasons and has to be recharged afterwards.

7. 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.

8. Discharge energy (shock).
   Discharge the defibrillator by pressing both release buttons on the paddles simultaneously.

9. 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 4 - 9).
   The emergency physician may ask for accompanying manual or pharmacological measures.

10. 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. Insert the defibrillator into the charging unit to charge the accumulator in order to ensure that sufficient energy is available for the next use.
    Functional disorders or faults have to be checked or if required rectified immediately by an authorized service technician.

Procedure for synchronized cardioversion

The steps described in the following apply for the handling of the defibrillator only. Alternative or supporting treatments are not described.

The synchronized cardioversion must only be applied if a clear QRS complex is available. The synchronized cardioversion can be applied for treatments of cardiac irregularity such as atrial fibrillation / atrial flutter, ventricular tachycardia with pulse or supraventricular tachycardia.

1. Prepare the patient for synchronous cardioversion.
   For most cardioversions sufficient time is available (selective treatment) which allows to prepare the patient for the treatment:

   a) ask the patient for written consent (and inform the patient),
   b) no food intake (6-10 hours before beginning with the treatment),
   c) light sedation of the patient (preparing for anesthesia),
   d) sedation of the patient, perhaps intubation (controlled by an anesthetist)

   Exception: The emergency cardioversion (e. g. supraventricular tachycardia) requires only the sedation of the patient.

2. Switch on defibrillator and ECG unit.
With the PRIMEDIC™ Defi-Monitor the ECG unit is also switched on automatically.

3. Connect the ECG electrode cable, carry out the ECG.
Connect the external ECG electrode cable to the ECG defibrillator / unit and position the patient's electrodes safely at the respective lead positions. Select the corresponding standard leads at the monitor. Check whether "usable" signals from all standard leads are shown on the monitor in order to verify the correct contact of all electrodes.

The most suitable lead for synchronized cardioversion is in most cases the standard lead II. Any other lead showing a clear R-peak can be used as well.

A clear R-peak is important for a reliable synchronization. Watch the monitor and "optimize" the ECG graph if required by changing the signal amplification. A weak ECG signal can generate a good synchronous signal by amplifying it (e. g. 2 cm/mV). An overloaded ECG signal can reduce the reliability, i. e. weaken the signal if required (o.5 cm/mV.

Use another lead if required or change the position of the patient's ECG electrodes slightly. Never select the paddle lead since slight movements (artefacts) can misroute the synchronous signal.

4. Switch the defibrillator to synchronous mode.
During synchronized cardioversion the defibrillator must work in synchronous mode. Asynchronous operation may be life-threatening for the patient.

Verify several times that synchronous mode is activated by watching the monitor (plain text display: "SYNC" and SYNC markings on the ECG) as well as the lighting up of the LED located above the SYNC key (with PRIMEDIC™ Defi-Monitor). Consider that the defibrillator switches back to asynchronous mode after every synchronized cardioversion, i. e. that it definitely switches on the SYNC mode before any further synchronous cardioversion.

5. Check ECG signals.
Every R-peak must supply a synchronous signal in order to obtain a reliable synchronized cardioversion. Artefacts and pacemaker pulses must not show synchronous markings. Check the ECG signal permanently and make sure that every R-peak shows a SYNC marker.

If not, change the amplification as described under item 3, select another lead or change the position of the ECG electrodes.

In case of intensive tachycardia it is possible that only every second R-peak shows a SYNC marker. That is no reason to be alarmed since not every R-peak must be marked but every SYNC marker must be related to a R-peak. .

6. 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.

7. Select energy.
The energies required for synchronized cardioversion are in most cases lower than for defibrillation (unsynchronized cardioversion) as it is not necessary to depolarize all heart muscles.

The energy depends roughly on the patient's body height and weight. The indications, however, determine the energy, i. e. the following empirical values are applicable:

Ventricular tachycardia with unstable pulse: 50 joule, further cardioversions to be increased by approx. 50 joule each (100 j, 160 j, 200 j, ...)

Supraventricular tachycardia:	50-100 joule
Atrial flutter:	20-50 joule
Atrial fibrillation:	100 joule

If ventricular fibrillation arises from the treatment immediate defibrillation in asynchronous mode at adjusted and higher energy is necessary.

8. Positioning of the paddles.
Stick the paddles firmly to the bare chest of the patient by applying a pressure of approx. 100 N to ensure perfect energy transfer. Applying not enough pressure may cause that the skin under the electrodes gets burnt.

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 change 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 sternum paddle:	- right chest area - right close to sternum - below the clavicle
Position of the apex paddle:	- 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.

9. Energy charging
After charging the energy remains available for a certain time, i. e. 15 seconds with the PRIMEDIC™ Defi-Monitor. This time is also shown on the monitor and counted down in steps of seconds. If no shock is released during this time the energy is discharged internally for safety reasons and has to be recharged afterwards.

10. Check ECG signal. See item 5.

11. 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.

12. Discharge energy (shock).
Prepare the defibrillator for the shock by pressing the release buttons on the paddles simultaneously. Keep the buttons pressed down. The shock is released by the ECG as soon as the next R-peak is recognized. In case of quick pulse the shock may follow shortly after pressing the release buttons simultaneously. A slow pulse may cause an evident delay in time. In this case do not reduce the pressure of the paddles on the patient's chest. Keep the release buttons pressed down and check the ECG. If no shock follows after several seconds, release the release buttons before taking the paddles off the chest.

With the PRIMEDIC™ Defi-Monitor an internal safety discharge is carried out when keeping the release buttons pressed down for more than three seconds and no shock is released during this time (no R-peak available / detected). After the internal safety discharge the PRIMEDIC™ Defi-Monitor is available for the next defibrillation in asynchronous mode.

13. Check the result.
Check the patient's heart rhythm, breathing and condition after the synchronous cardioversion. Check the ECG and decide whether a further trial is necessary. If yes, repeat steps 4 to 13.

Please consider that nearly all defibrillators on the market (PRIMEDIC™ Defi-Monitor included) switch back to asynchronous mode automatically after a synchronous shock has been released.

Control the heart rhythm over a certain time after successful cardioversion.

14. 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. Insert the defibrillator into the charging unit to charge the accumulator in order to ensure that sufficient energy is available for the next use.

In case of malfunctions or faults have the defibrillator checked immediately and if necessary repaired by an authorized service technician.

A3 General instructions for the use of pulsoximeters

What is pulsoximetry?

A pulsoximeter determines the SpO_2 value (oxygen saturation) by optical measuring methods. This method is based on the penetration of light of different wavelengths through tissues and vessel.

The components of blood important for the SpO_2 measuring, are oxygenated (oxygen-enriched) or deoxygenated (without oxygen) haemoglobin, i.e. exactly the components necessary for oxygen supply of the organism.

The tissues and vessels are “penetrated by light“ with the help of transmitter-receiver elements. Depending upon the oxygen saturation of the blood the quantity of light arriving on the receiver side of the transmitter changes. Thanks to the application of precise modules and calibrated sensores, highly exact SpO_2 measures are possible.

Usual measure points for the sensors are

- finger tips
- tows
- earlobes
- heel

Why are there different sensors?

As described in, among others, chapter 6.2 (selection of the correct SpO_2 sensor) different sensors have to be used for different patients to guarantee reliable and exact measures.

The following factors have to be taken into account:

- weight of the patient
- activity of the patient
- duration of the measure
- blood circulation in the limbs
- possible measuring point
- physical condition of the patient
- sterile measure necessary?

Evidently no single sensor can meet all the, to some extent contradictory, requirements. The different SpO_2 sensors are designed for specific purposes.

As an example may serve the sensor DS-100 A or the D-YS respectively from NELLCOR®. DS-100 A allows rapid handling and it is simple to be slipped on fingers of different thickness thanks to its sophisticated mechanism. But it is not suitable for children because of its geometry. Using this sensor for patients who move a lot is also not possible, as, due to the design of the casing the sensor might slip off the patients finger. As the D-SY has no casing this sensor D-SY may be applied for higher weight classes, moreover it might be positioned with more flexibility and can fixed with an adherent strip, which reduces the rapid positioning of this sensor.

Which factors influence the SpO2 measure?

As the measuring of the oxygen saturation is an optical method, the following influencing factors might affect the results:

- direct sun light
- strong artificial light (e.g. operating room lighting)
- infrared lamps
- ultraviolet lamps (bilirubin lamps)

The influence of the above mentioned factors can be reduced positioning the sensor correctly and using covers of the sensors.

More influencing factors are:

- dirty measuring point
- incorrect cleaning of the sensor
- opaqueness or colour distortion at the measuring point e.g. by nail-varnish
- highly active patient
- injected contrast media, (e.g. indiocyanide green or methylene blue)
- high proportions of dysfunctional haemoglobin (carboxy haemoglobin)
- wrong point of positioning (e.g. point with venous pulse)
- use of the pulsoximeter close to strong source of energy like e.g. nuclear spin tomograph
- sensor applied too rigidly
- arterial occlusion close to the sensor
- blood congestion e.g. by artery catheter or by sphygmomanometer

Some of these factors are easy to recognize (e.g. nail-varnish) and are removable; a repeatable result can be obtained at a different measuring point.

Other factors (e.g. contrast media or blood serum disorder) are not as easy to be determined.

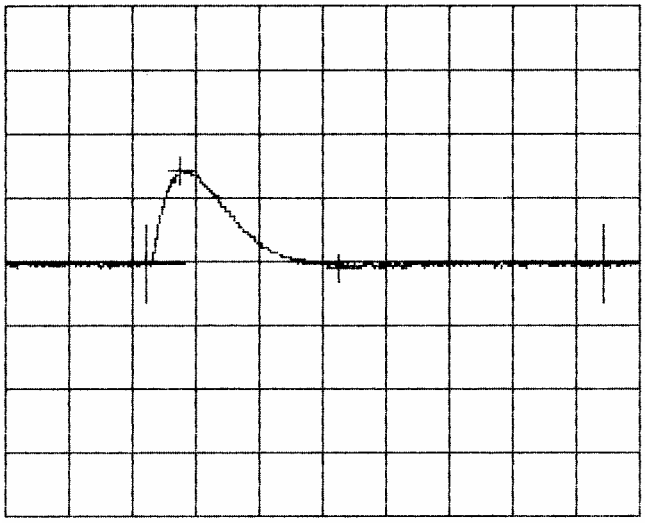
The SpO_2 measure should not be the only method applied to monitor the vital functions due to this multitude of influencing factors. More parameters must always be monitored (e.g. ECG, blood pressure, respiration ...).

The SpO_2 measure can be an important instrument for the diagnosis of patients, when the sensor is used correctly, the specific warnings and hints on the use of the sensor are observed and the clinical symptoms are taken into consideration.

A4 Voltage - time graphs

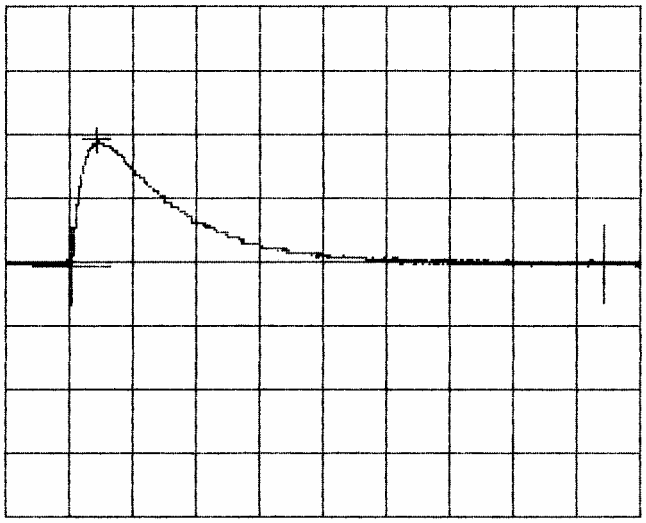
Please find in the following the graph shapes of the defibrillation pulses depending on the terminal resistance.

1. Graph shape with 25 Ω



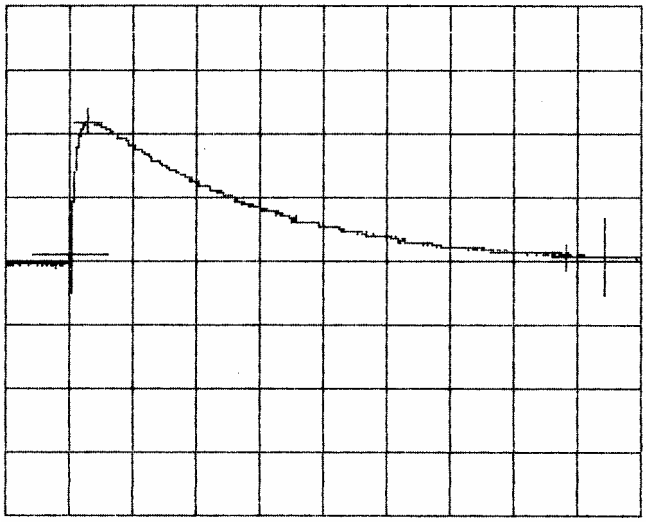
U = 2.280 V 2 ms / div.

2. Graph shape with 50 Ω



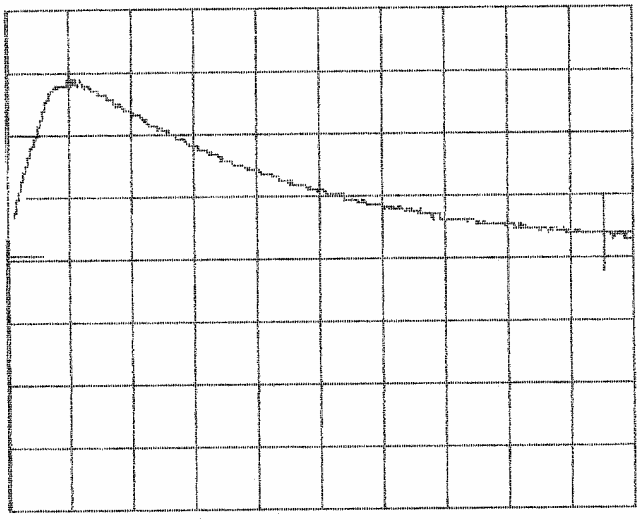
U = 2.940 V 2 ms / div.

3. Graph shape with 100 Ω



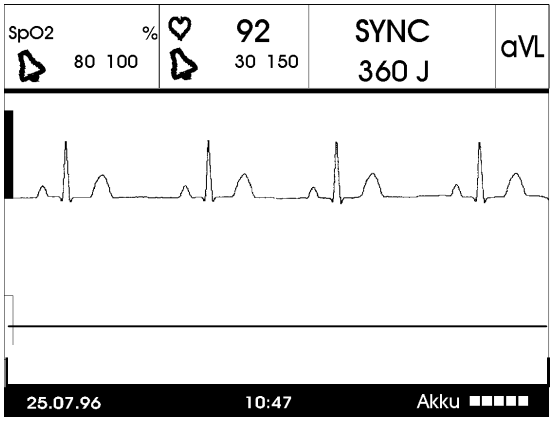
U = 3.180 V 2 ms / div.

4. Graph shape with 125 Ω



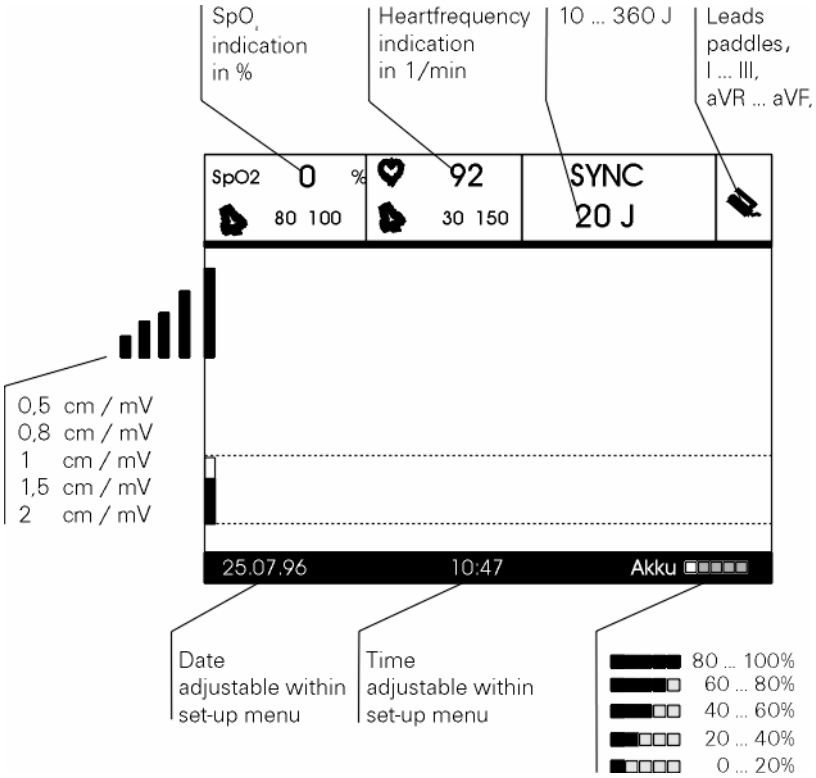
U = 2.800 V 2 ms / div.

A5 Description of monitor screen and printouts

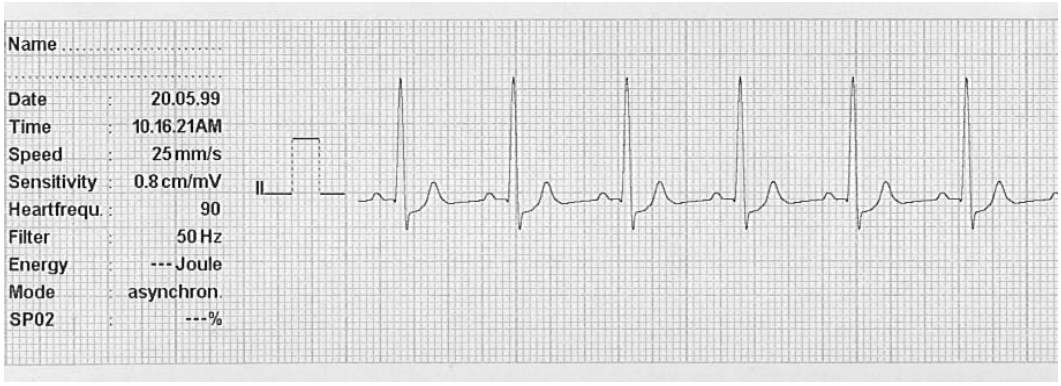


Reference:

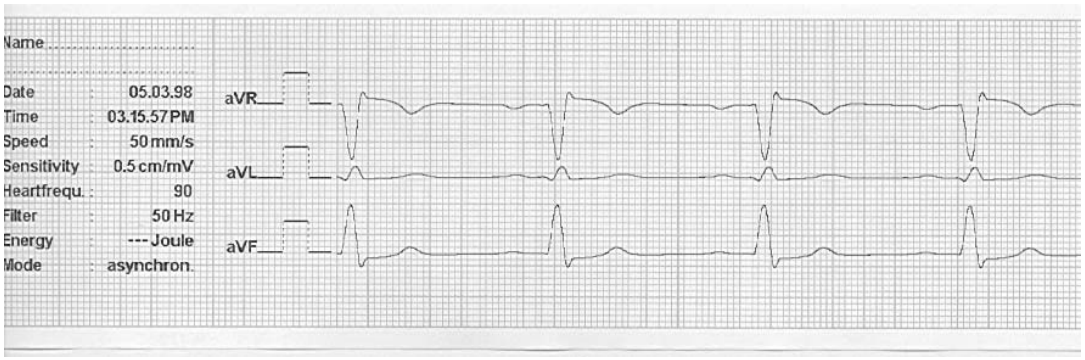
operating mode:	synchronous
lead:	aVL
selected energy:	360 joule
heartrate:	92 / min
upper alarm limit:	150 / min
lower alarm limit:	30 / min
upper SpO_2 alarm	100 %
lower SpO_2 alarm	80 %
signal amplification:	2 cm/mV
accumulator capacity:	80 - 100 %



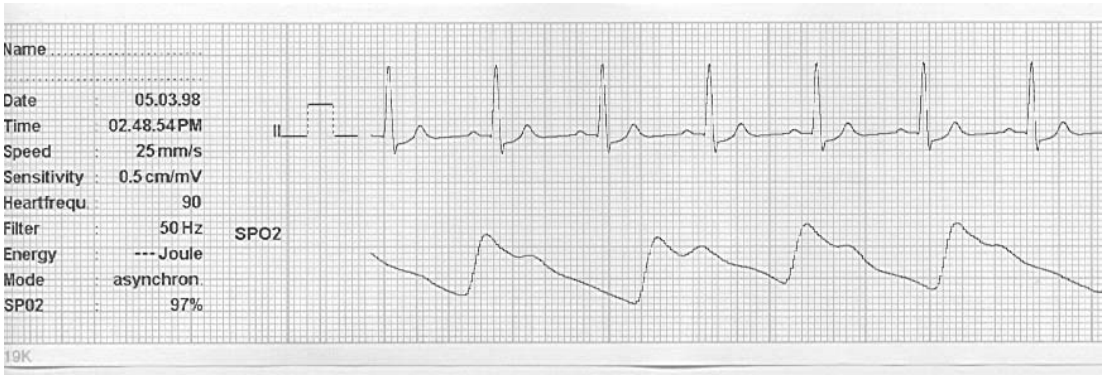
Printout of the ECG in synchronous mode with synchronous markers, 1-channel, 25 mm/s printing speed



Printout of the ECG in asynchronous mode, 3-channel, 50 mm/s printing speed

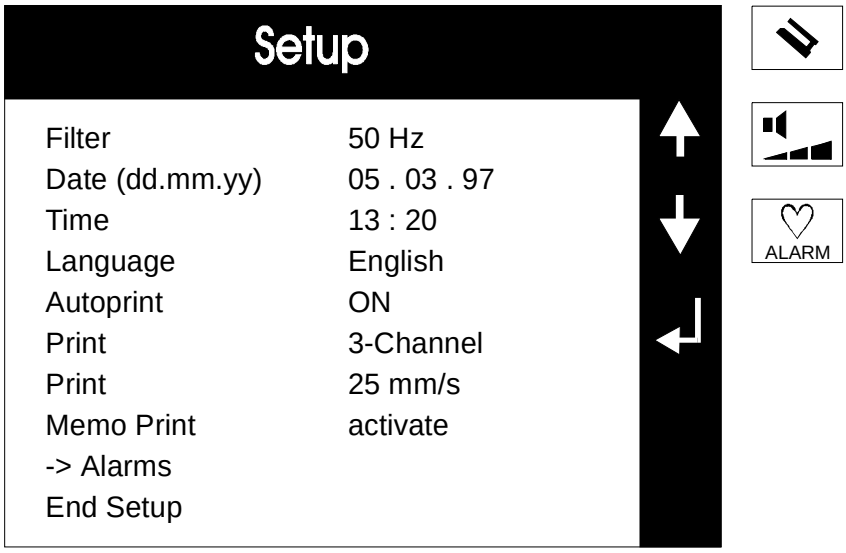


Printout of the ECG, 1-channel, 25 mm/s printing speed, with SpO_2

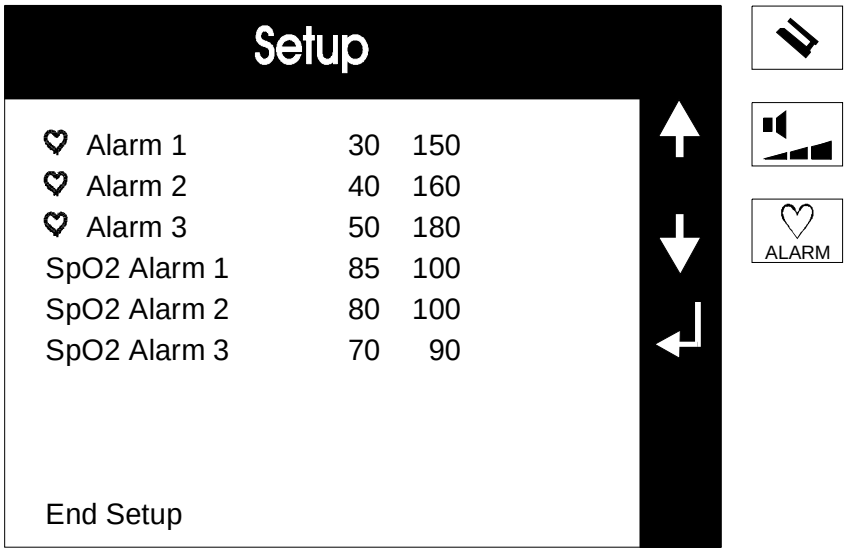


Monitor screen during set-up with example settings

1. Page



2. Page



A6 Safety control

According to Medizinprodukte Betreiberverordnung (MPBetreibV) § 6 (safety controls) and § 11 (measurement controls) users of defibrillators are obliged to have the devices controlled. According to MPBetreibV § 6 METRAX has prescribed controls in 12 months 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.

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 devices 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, ECG patient cable, SpO_2 patient cable (*) damaged?
   - ECG input socket, SpO_2 input socket (*) 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
   - Membrane keyboard legible?
   - Membrane keyboard damaged?
3. Check the indicating elements
   - all LEDs are active for approx. 2 second after switching on the defibrillator?
   - the LED allocated to the selected energy step lights up (check all energy steps once)
   - LED (33) lights up after pressing "SYNC" (34)?
   - the warning buzzer goes on for approx. 2 second after switching on the defibrillator?
4. Measure the charging time.
   - Charging time for 360 joule when the accumulator is full less than 7 seconds?

   Procedure for the test:
   1. Press key for 360 joule.
   2. Press paddle release (10) or (12).
   3. Start stop watch simultaneously.
   4. Energy charging finished when the green OK LED (41) lights up.

5. Measure the output power.
the checking of the defibrillation energy with 50 Ω the following tolerances are allowed:
   - at 20 joule ± 4 joule
   - at 50 to 360 joule ± 15 %

   All energy steps from 10 to 360 joule are measured.

6. Functioning of the ECG monitor.
   - Is the selected energy displayed on the monitor?
     Press one or several joule keys (32).
   - Is the synchronous operation displayed on the monitor? Press SYNC (34).
   - Is the SpO_2 value displayed? (*) Insert the NELLCORE™ sensor and the SpO_2 patient cable into socket (16).

   Feed an ECG signal with known frequency coming from the ECG simulator via the patient cable.
   - Systole beep can be switched on and off (key 24)?
   - Heartrate indicated with a tolerance of ± 10 %?
   - All leads can be selected and are displayed (key 22)?
   - ECG signal can be represented with 0.5 cm/mV or 2 cm/mV (key 23)?
   - After pressing SYNC (34) synchronous markers related to the R-peaks appear?

   Activate one of the three heartrate alarms (key 28) and switch off the ECG simulator.
   - Heartrate alarm goes on?
   - After acknowledgement of the alarm (pressing of ALARM (28)) heartrate alarm goes on once more for about 60 seconds?

7. Functioning of the pulsoximeter (*)
   Insert NELLXOR sensor DS-100 A and SpO_2 patient cable into the socket (16). To control the function put index finger into the sensor or connect a SpO_2 test advice to the SpO_2 patient cable.
   - Is a SpO_2 value displayed?
   - Is the pulse curve displayed?
   - Is an error message displayed when the SpO_2 patient cable is pulled off?

8. Functioning of the printer.
   Feed an ECG signal coming from the ECG simulator via the patient cable.
   - On-line printing follows after pressing PRINTER ON / OFF (39).
   - Choose a different printing speed in the set-up menu (except DM 1), check if the printing speed is identical with the preset speed?

9. Functioning of the accumulator / charging unit.
   Charging LED (57) flashes for at least 1minute after inserting the defibrillator into the charging unit.

10. Measuring of the patient's lead current according to IEC 601-1.
    1. Paddle lead selected (key 21) and measurements for type BF performed
    2. Standard lead selected (key 22) and measurements for type CF performed

(*) = only if the corresponding option is installed in the device. Pulsoximeter is integrated in model DM 3.