

INSTRUCTION MANUAL

Zeus Defibrillation Simulator

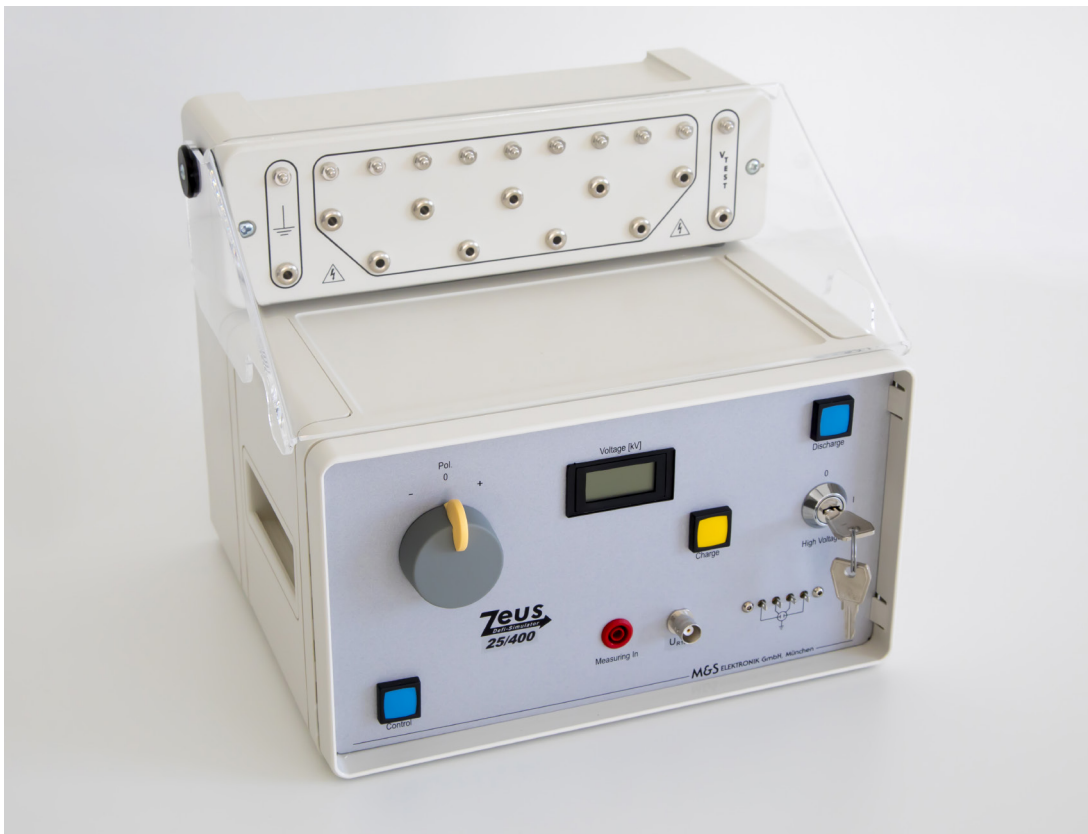


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1 | PRODUCT INFORMATION

The Zeus Defibrillation Simulator is a testing device used to measure the defibrillation protection of medical equipment (such as ECG recorders) and the accessories (such as patient cables, vacuum systems, electrodes).

Depending on the model variant (Zeus or Zeus 25/400) the Zeus allows the standardized testing of the defibrillation protection e.g. in accordance with the standards EN 60601-1, EN 60601-2-25, EN 60601-2-27 and EN 60601-2-49.

The device provides an integrated 10 Hz sine-wave generator (output voltage according to the latest issues of the standards mentioned above).

Functions

The Zeus provides the following functions:

- **The test voltage can be increased steplessly up to 5 kV.**
- **A 10-core patient cable with banana-type plugs or clips can be connected directly to the device.**
- **The device has an integrated 10-Hz sine-wave generator.**
- **Oscilloscope and test terminal connectors allow dynamic tests for limitation of energy at different parts of the device under test.**
- **The polarity selector switch is used to switch the polarity of the test voltage. This makes it easier to repeat every test with reversed polarity as required by the standards.**
- **The voltage and the selected polarity are shown in an LCD display**
- **Zeus 25/400: BNC socket for measuring the energy drop on devices**

Safety

For your safety, the Zeus provides the following safety equipment:

- **protective cover with safety switch for the electrode plugs**
- **connector for the red/green warning light (1,5 W/12 V)**
- **two-hand operation for charge and discharge**
- **high-voltage activation by a key switch**
- **automatic shutdown of the capacitor.**

2 | SAFETY PRECAUTIONS, CLEANING AND CALIBRATING

Proper use

- Check if the device is free of damage.
- Check if all cables and contacts of the experimental setup are free of damage.

Liability exclusion in case of improper use



NOTE

In case of improper use or maintenance, MedTec-Science GmbH will not be liable!

The manufacturer is only responsible for the security and reliability of the device if:

- **all changes, enhancements, repairs and any other work on the device is performed by a person authorized by MedTec-Science GmbH, e.g. a distribution partner or service technician of MedTec-Science GmbH and**
- **the user complies with this instruction manual when using the device.**

We direct your attention to the fact that a seal protects the enclosure. There is no guarantee in case of damaged seals.

Safety precautions



WARNING

We direct your attention to the following safety precautions.

- **Check the function of the safety switch of the protective cover for the electrode plugs regularly: Activate the discharge without building up any voltage. The discharge must not be possible if the protective cover is open. Otherwise please contact the manufacturer!**
- **In case of a mechanical damage or a fall do not use the device any longer. Please send the device to the manufacturer for an inspection.**

- **Do not keep or use the device near strong electrical fields (e.g. near X-ray or diathermy machines).**
- **Do not spill liquids on the device.**
- **Avoid direct solar radiation.**
- **Do not expose the device to extreme heat or cold (e.g. sauna, refrigerator or freezer).**

Cleaning



NOTE

Unplug the power plug before you clean the device!

Clean the device only with a soft, lint-free cloth and a common cleaner for plastics. The cloth should be moist, not dripping wet. Do not spray the cleaner directly onto the device.

Do not use spray cleaners, solvents, benzenes, spirits or similar agents.

Calibrating



NOTE

It is recommended to check the capacitor capacity after approx. 5.000 discharges. This value corresponds to approx. 250 tested devices (at an average 20 discharges per device under test) or after an operating time of about two years. Please send the device to the manufacturer for maintenance.

3 | ENCLOSURE, OPERATING ELEMENTS AND ACCESSORIES

3.1 Enclosure front

The following figure shows the enclosure front of the Zeus:

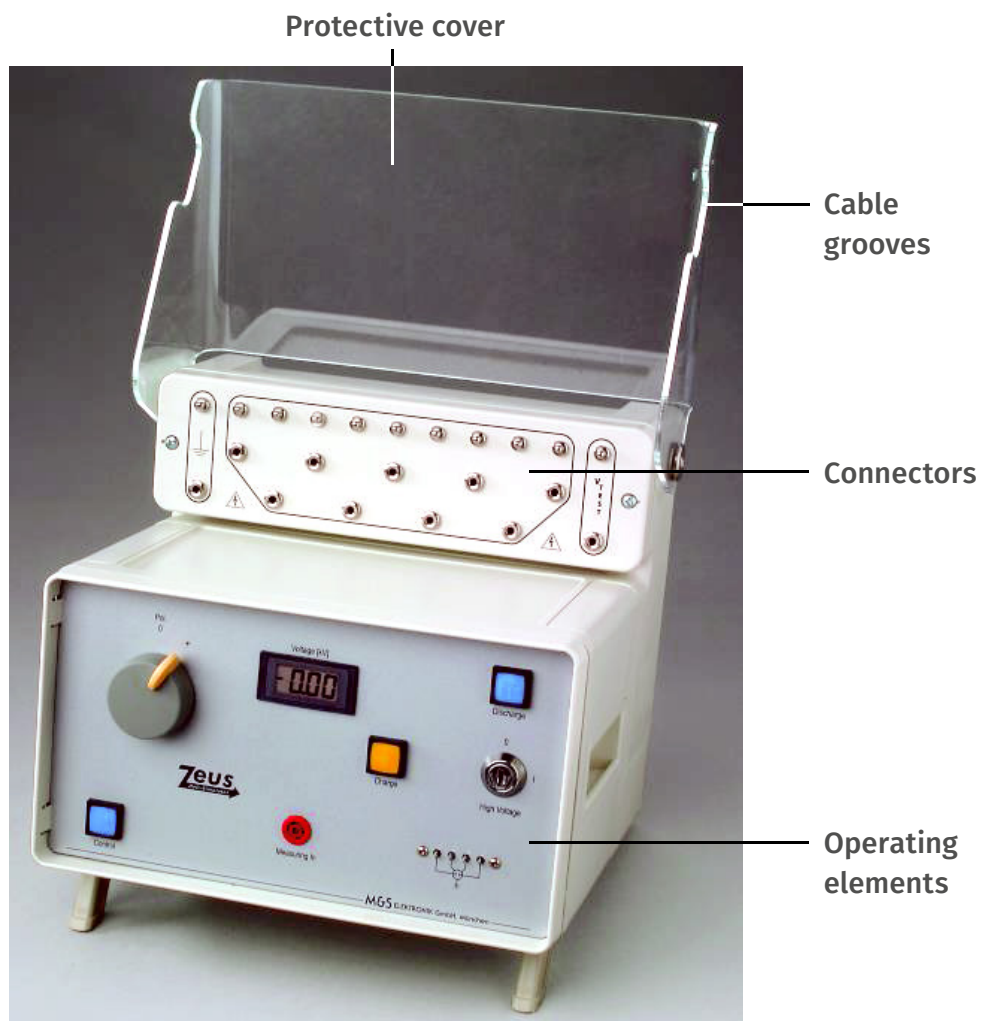


Figure 3-1: Enclosure front of the Zeus

Protective cover

The protective cover prevents undesired contact of the user with the electrode contacts.

The discharge can only be activated if the protective cover is closed.

Cable grooves

Push the connected cables through the cable grooves on both sides of the protective cover:

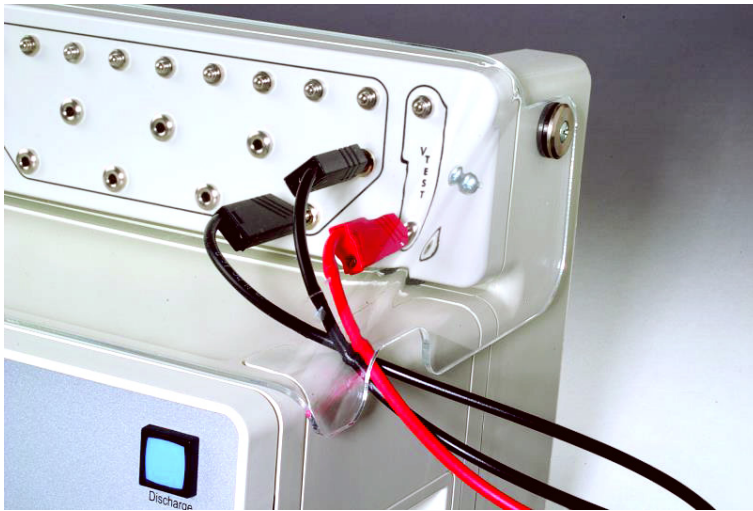



Figure 3-2: Cable routing

Connectors

The Zeus provides connectors for 10-core patient cables and testing cables. Banana plugs or clips can be used.

Furthermore, the following connectors are available:

- V_{TEST} **connector for test voltage**
-  **connector for ground terminal**

3.2 Operating elements

The following figure shows the operating elements of the Zeus:

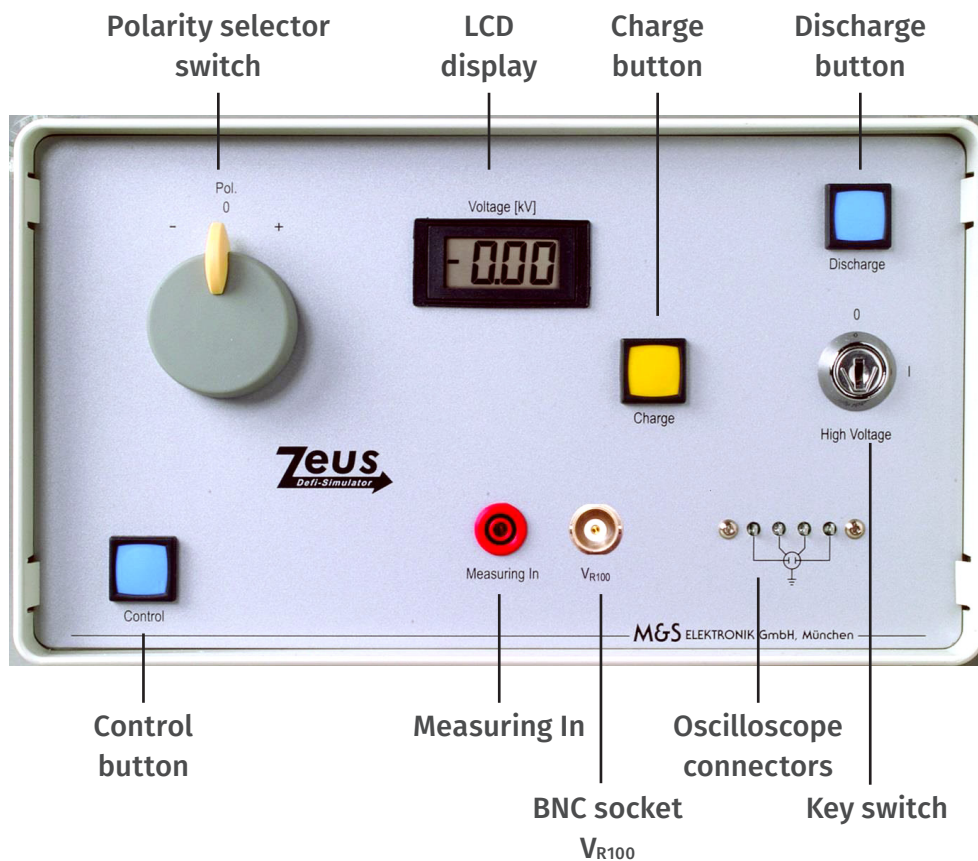


Figure 3-3: Operating elements of the Zeus

Polarity selector switch

In accordance to EN 60601-1, all tests have to be repeated with reversed polarity. The polarity selector switch allows polarity reversal without connecting the electrodes again.

LCD display (Voltage (kV))

The LCD display shows the selected polarity and the current voltage

Control button

For safety reasons, you need two hands to work with the Zeus. For charge and discharge of the capacitor you have to press the Control button and the Charge or Discharge button simultaneously.

Charge button

If you press the Charge button and the Control button simultaneously the capacitor is charged.

Discharge button

If you press the Discharge button and the Control button simultaneously the capacitor is discharged.

High voltage – key switch

High voltage can only be activated if the key switch is set to I. The protection with the key switch prevents unauthorized access to the high voltage.

Measuring In (test terminal connector)

The measuring-in connector is the input for the dynamic test of the energy limitation of the device under test. A cable is fixed at the connector and connected to different parts of the test under device (see 3.4 Accessories).



NOTE

The connector is only intended for measurements in accordance to EN 60601-1, point 17 h.

VR100

The BNC socket labelled VR100 is only installed on the Zeus 25/400! It is used to connect an oscilloscope or voltmeter for testing the energy drop of the specimen.

Oscilloscope connectors

The Zeus provides connectors for an oscilloscope.



NOTE

Observe the instructions of the oscilloscope manufacturer for the measurement of high voltage and the necessary safeguards.

Connect the oscilloscope as indicated in the block diagram (see 7 Block diagram).

3.3 Enclosure back

The following figure shows the enclosure back of the Zeus:

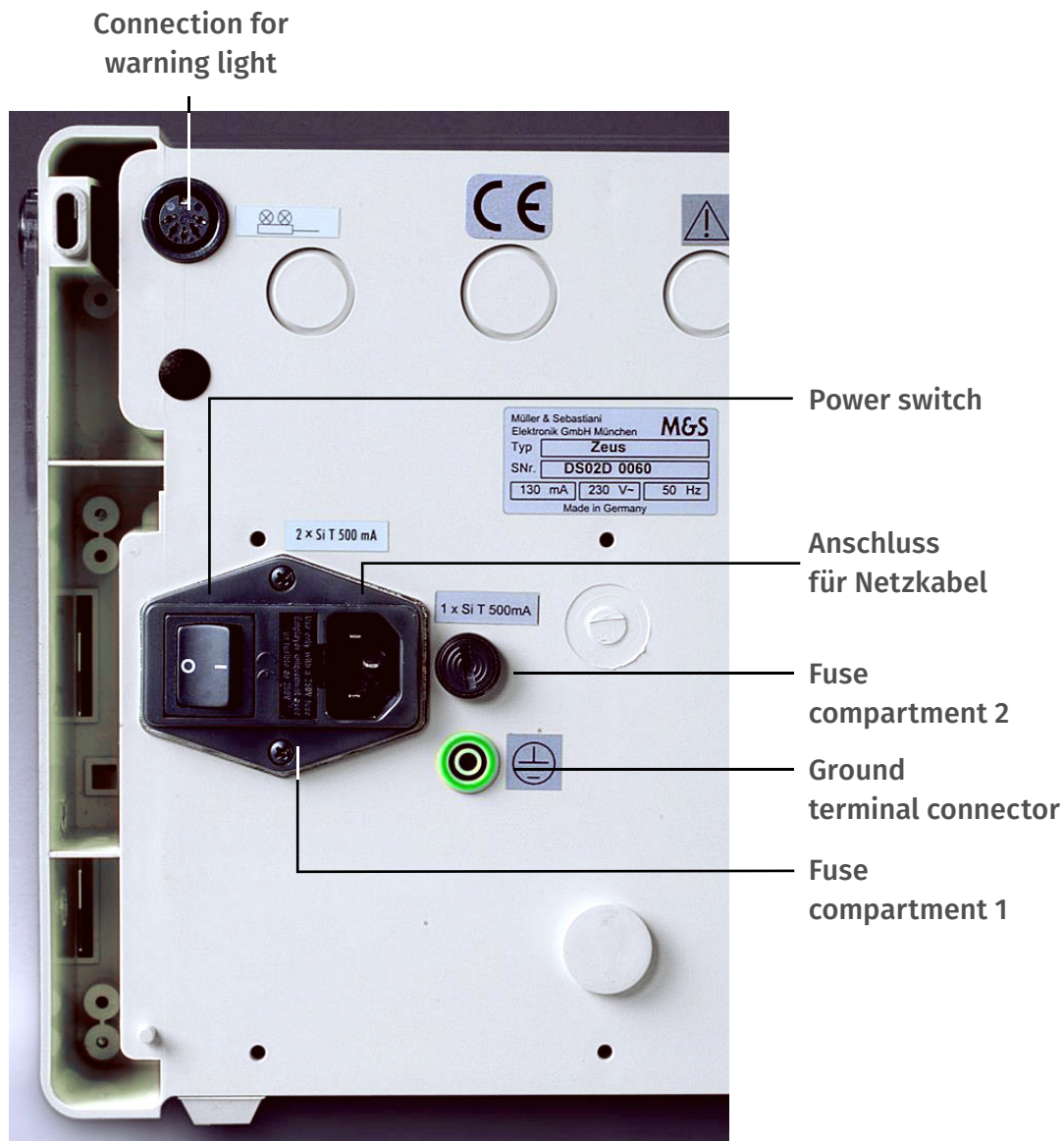



Figure 3-4: The Zeus enclosure back

Connection of a red/green warning light (1,5W / 12V)

The warning light is available as an accessory (see 3.4 Accessories).

The light is connected at the back of the Zeus (symbol ).

It indicates if high voltage is on or not:

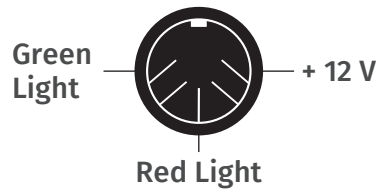
red means: "Attention: High Voltage!".

The red warning light flashes at a capacitor voltage of approx. 500 V.

Using other warning lights

The connector is a three-way connector in accordance with DIN 41524. The pins are assigned as follows:

- 1 + 12 V
- 2 red
- 3 green



Fuse compartment 1 and 2

For the function and the replacement of the fuses see **5 Replacing the fuses**.

Ground terminal

For a standard-compliant measurement one of the poles of the capacitor has to be grounded. The protective ground terminal of the Zeus ensures this. The ground terminal connector at the back of the Zeus is intended to produce another defined grounding in addition to the protective ground terminal.

3.4 Accessories

The following accessories are available:

- **red/green warning light (order number 46.710)**
- **for testing recovery times: sponge, pan, electrode clips (order number 46.712) Note: Due to changes in the new versions of IEC 60601-2-25 und IEC 60601-2-27 some accessories (sponge, electrode clips...) have been removed from the accessories list.**
- **test terminal connector (order number 46.711).**

4 | PERFORMING A TEST

4.1 Tests in accordance with the standards

The tests of the defibrillation protection of ECG devices and their accessories aim at:

- preventing the generation of dangerous energies at enclosure parts, signal inputs and outputs during a defibrillation
- testing the recovery of the normal device function after a defibrillation within a defined recovery period.

In detail the standards specify the following tests:

- EN 60601-1 voltage pulse tests: individual and composite test
- EN 60601-2-25 dynamic test of energy limitation at various parts of the device under test, measuring the recovery time of the device in response to defibrillation discharge.

The following figure shows the experimental setup for measuring the recovery time of the device in response to defibrillation discharge:



Figure 4-1: Testing the recovery time in response to defibrillation discharge

4.2 Instructions for the experimental setup



NOTE

For the correct experimental setup (block diagrams and instructions) see the standards EN 60601-1 and EN 60601-2-25.

Furthermore, note the following instructions:

- **V**Before starting the test, the Zeus has to be in the testing room for at least two hours to adapt to the surroundings (temperature, air humidity).
- Testing the recovery time in response to defibrillation discharge: sponge, pan and electrode clips can be ordered as an accessory (see 3.4 Accessories).
- Dynamic test of energy limitation at various parts of the device under test: for this test a test terminal connector (see 3.4 Accessories) is connected at the Measuring In-connector (see Figure 3-3).
- Measuring the energy drop of the specimen during a defibrillation. The voltage at the internal 100 Ω discharge resistor (see block diagram) is output via a voltage divider 1:1000 (output voltage range: 0 – 5 V, accuracy ± 2 %), at the BNC socket labelled V_{R100} . A discharger protects the output against voltages exceeding 100V. The formula:

$$E = \int_0^{t1} 1/R \cdot u^2(t) dt \quad \text{mit } R = 100 \Omega$$

can be used to calculate the energy drop at the specimen via the output voltage. For practical implementation, it is recommended to record the voltage curve with a storage oscilloscope and evaluate the curve using a maths software program or numeric integration according to the formula:

$$E = \Delta t \cdot \sum_{k=0}^{k=t/\Delta t} 1/R \cdot u^2(k\Delta t)$$

with

$R = 100 \text{ Ohm}$,

$u^2(k\Delta t)$ = voltage level of the corresponding interval,

Δt = length of the selected interval

t = length of the recorded voltage impulse

For the discharge curve shown in Figure 4-2, $\Delta t = 0.2 \text{ ms}$ was selected for a recorded voltage impulse length of $t = 8 \text{ ms}$. This means that $k = 8 \text{ ms} / 0.2 \text{ ms} = 40$. The voltage levels must be read out in the corresponding intervals (e.g. $u(\Delta t_1) = 2.0 \text{ kV}$, $u(\Delta t_2) = 3.2 \text{ kV}$, $u(\Delta t_3) = 4.0 \text{ kV}$, $u(\Delta t_4) = 4.05 \text{ kV}$,... $u(\Delta t_{40}) = 0.45 \text{ kV}$). In this case, the energy output at the internal resistor $R = 100 \Omega$ (without specimen) equals $E \approx 366 \text{ Ws}$. In a test with specimen, the energy at the 100Ω resistor is reduced according to the resulting voltage divider.

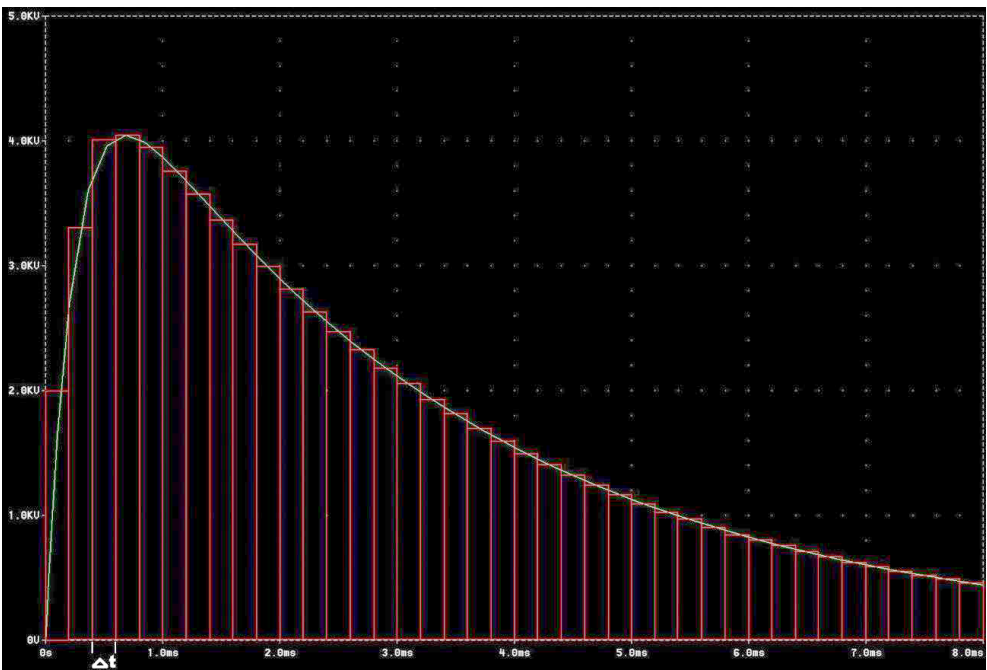



Figure 4-2: Discharge curve over internal 100Ω resistor

Please refer to the relevant standards (e.g. EN 60601-1) for a detailed description of the implementation of the test.

- Depending on the test requirements, one of the connectors in the middle has to be connected to the V_{TEST} connector or . A testing cord is provided.

4.3 Instructions for the user safety



We direct your attention to the following safety precautions:

WARNING

- Only one person may operate the device.
- Comply to the safety standards for a high voltage test equipment (DIN VDE 0104):

- The workplace and the experimental setup must be closed off by belts.
- A warning light to indicate dangerous voltage should always be connected.
- Closing off the experimental setup, it must be guaranteed that no other person except the tester can contact with any parts of the experimental setup.
- Prior of each test, check if all cables and contacts of the experimental setup are free of damage.
- The cables and electrode connections must be arranged in a way that they cannot come into contact with the tester or any other person.
- The protective cover for the electrode contacts must always be closed when a discharge is activated. The cover protects against high voltage as well as against injuries due to a possible destruction of electrode contacts.

Note that a discharge is only possible if the protective cover is closed. If you charge the capacitor when the protective cover is open, the capacitor will be discharged automatically.

- The test under device and the connection cables should be placed in an adequate distance from the tester. This protects the tester against injuries due to possible damages at the device.
- After having finished the tests it is mandatory to turn the key switch to 0 and to remove the key. This way you prevent the device from unauthorized use.

4.4 Testing procedure

To perform a test, execute the following steps:

1. Build up the experimental setup in accordance to the standards: block diagrams and instructions of the standards EN 60601-1, EN 60601-2-25.
2. Exclude all sources of danger for the tester. For example, be careful at the safety distances and prevent the contact between the tester and parts of the experimental setup. See **4.3 Instructions for the user safety**.
3. Protect the experimental setup against the surroundings.
See **4.3 Instructions for the user safety**.
4. Switch on the Zeus (power switch at the enclosure back).
5. Activate the high voltage: Push the key all the way into the key switch and turn it to I.
6. Select the desired polarity.
7. Push the connected cables through the cable grooves on both sides of the protective cover.
8. Close the protective cover.
9. Charge the capacitor: press the Charge button and the Control button simultaneously until the desired voltage is reached.



NOTE

Observe the display during charging. The current voltage and the selected polarity are displayed.

The red warning light will flash at a capacitor voltage of approx. 500 V.

The Zeus provides an automatic charge shutdown. If the voltage exceeds 5.5 kV nevertheless, stop the charging process immediately. Please send the device to the manufacturer for an inspection.

Short-time voltage fluctuations can be ignored.



NOTE

Keep pressing the Control button even after reaching the desired voltage!

When you release the Control button, the automatic discharge of the capacitor starts (internal resistor of 10 kΩ).

10. Discharge the capacitor to the device under test: press the Discharge button and the Control button simultaneously. The discharge relay is closed for 200 ms (+/-50 %). If the Discharge and the Control button are pressed for more than six seconds, the discharge relay will be closed again.
11. Repeat the test with reversed polarity.

5 | REPLACING THE FUSES

The Zeus provides two fuse compartments:

- **Fuse compartment 1 with 2 x 500 mAT fuses** The fuses in fuse compartment 1 are blown, if there is no more display and no more functions can be executed with the Zeus.
- **Fuse compartment 2 with 1 x 500 mAT fuse** The fuses in fuse compartment 2 are blown, if no high voltage can be activated.



Use exclusively fuses of type 500 mAT.

NOTE

Fuse compartment 1

- Remove the cover from the fuse compartment: pull out the complete compartment at the strap on the right side.
- Remove the fuses and put in the new ones.
- Close the fuse compartment.

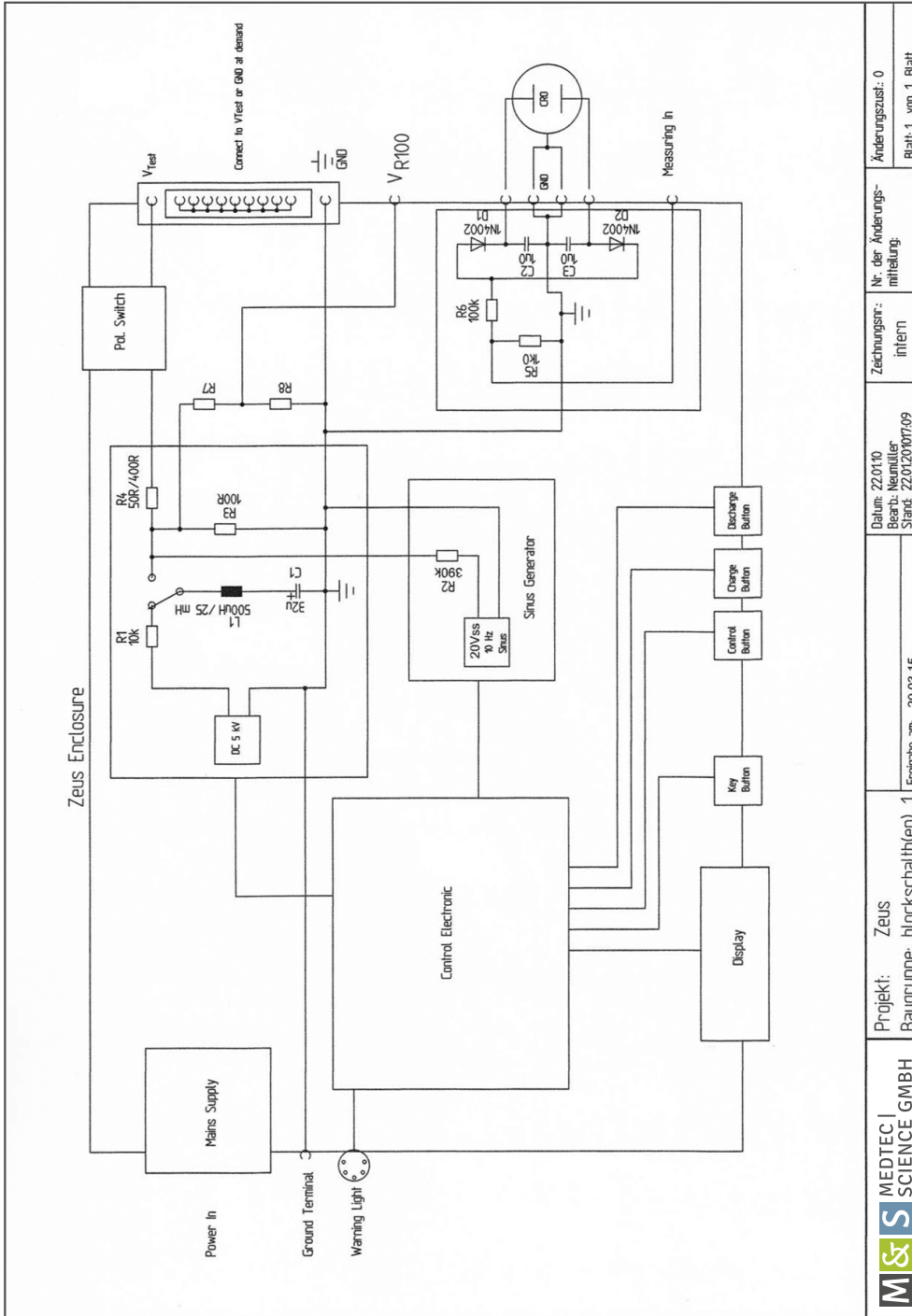
Fuse compartment 2

- Open the bayonet socket: insert a coin and turn the socket anticlockwise approx. $\frac{1}{4}$.
- Remove the fuse and put in the new one.
- Close the bayonet socket.

6 | SPECIFICATION

Enclosure material	solid plastic, front panel made of aluminium
Dimensions (D x W x H)	approx. 24 x 27 x 24 cm
Weight	approx. 7.0 kg
LCD display	3.5 digit liquid-crystal display
Electronics	<p>supply voltage: 230 V / 250 mA</p> <p>test voltage can be increased steplessly up to 5 kV</p> <p>automatic discharge at 5.2 kV</p> <p>experimental setup in accordance to EN 60601-1</p> <p>integrated 10 Hz sine-wave generator</p> <p>integrated measuring circuit for the connection of an oscilloscope and a test clip (dynamic testing)</p> <p>internal discharge for interruption of the supply voltage and test interruption</p> <p>maximum number of capacitor discharges: 10.000</p> <p>maximum discharge frequency of the capacitor: 2 discharges/min</p>
Discharge circuit	<p>Zeus: L = 500 uH, R = 50 ohm</p> <p>Zeus 25/400: L = 25 mH, R = 400 ohm (see block diagram)</p>
Surroundings	<p>temperature: 10 – 40 °C</p> <p>air humidity: 10 – 75% noncondensing</p> <p>atmospheric pressure: 75 kPa – 106 kPa</p>

7 | BLOCK DIAGRAM



	Projekt: Zeus Baugruppe: blockschalt(en)_1	Datum: 22.01.10 Bearb: Neumüller Stand: 22.01.2007:09	Zeichnungsnr.: intern	Nr. der Änderungs- mittelung:	Änderungszust.: 0 Blatt: 1 von 1 Blatt
	Freigabe am: 20.03.15				

8 | TROUBLESHOOTING AND ERROR CORRECTION

Note the following instructions to troubleshooting and error correction:

- **If the display is dark check the fuses in fuse compartment 1.**
 - If no high voltage can be activated:
 - check the fuses in fuse compartment 2.
- **make sure that a polarity is selected (not 0).**
- **If no discharge can be activated, make sure that the protective cover is closed.**

9 | DECLARATION OF CONFORMITY

We hereby declare under our sole responsibility that the products

Type	Description	Part number
ECG Simulator	Phantom 320	59.009
ECG Simulator	MS 410	59.022
Defibrillation Simulator	Zeus V1	59.101
Defibrillation Simulator	Zeus V2	59.102

to which this declaration relates are in conformity with the basic requirements of the following **EC regulations**:

2006/95/EC	EC Low Voltage Directive, according to Annex III B.
2004/108/EC	Electromagnetic Compatibility
2011/65/EC	Restriction of the use of certain hazardous substances (RoHS II)

Applied harmonized standards:

DIN EN 61010-1	Safety requirements for electrical equipment for measurement, control and laboratory use
DIN EN 61326-1	Electrical equipment for measurement, control and laboratory use – EMC requirements
DIN EN 50581	Documentation for the assessment of electrical and electronic products

Ottobrunn, 15.11.2014

Peter Müller

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