MEDTEC | SCIENCE GMBH

VERSION 2.3

INSTRUCTION MANUAL

Zeus Defibrillation Simulator V1 and V2

This instruction manual is an essential part of the system, in accordance with EN 61010-1. Comply with it and keep it.

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1 | PRODUCT INFORMATION

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).

Zeus V1 enables defibrillator proof testing in accordance with IEC 60601-1, IEC 60601-2-25, IEC 60601-2-26, IEC 60601-2-27, among others.

Zeus V2 (25/400) is a test instrument for evidence of the **standards requirements** relating to the **energy reduction test** required during **defibrillation** in medical devices (e.g. the standards IEC 60601-1, IEC 60601-2-25, IEC 60601-2-27 and others).

Please note: To perform all defibrillator proof tests, you need **both** versions.

Zeus V1 features an features an integrated 10 Hz sine-wave generator (the output voltage corresponds to the requirements of the latest issues of the standards mentioned above).

Functions

Zeus provides the following functions:

- **The test voltage can be increased continuously 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 with adjustable voltage from 2.0 Vpp up to 20 Vpp (Zeus V1 only).**
- **Oscilloscope and test terminal connectors allow dynamic tests for limitation of energy at different parts of the device under test (Zeus V1 only).**
- **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 amplitude and the set polarity of the test voltage are shown in an LCD display.**
- **Zeus 25/400: BNC connector for measuring the energy drop on devices (Zeus V2 only).**

Safety

For your safety, 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. We direct your attention to the fact that a seal protects the enclosure. There is no guarantee in case of damaged seals.**
- **the user complies with this instruction manual when using the device.**

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 a discharge without building up any voltage. Discharging 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 Front panel

Zeus V1

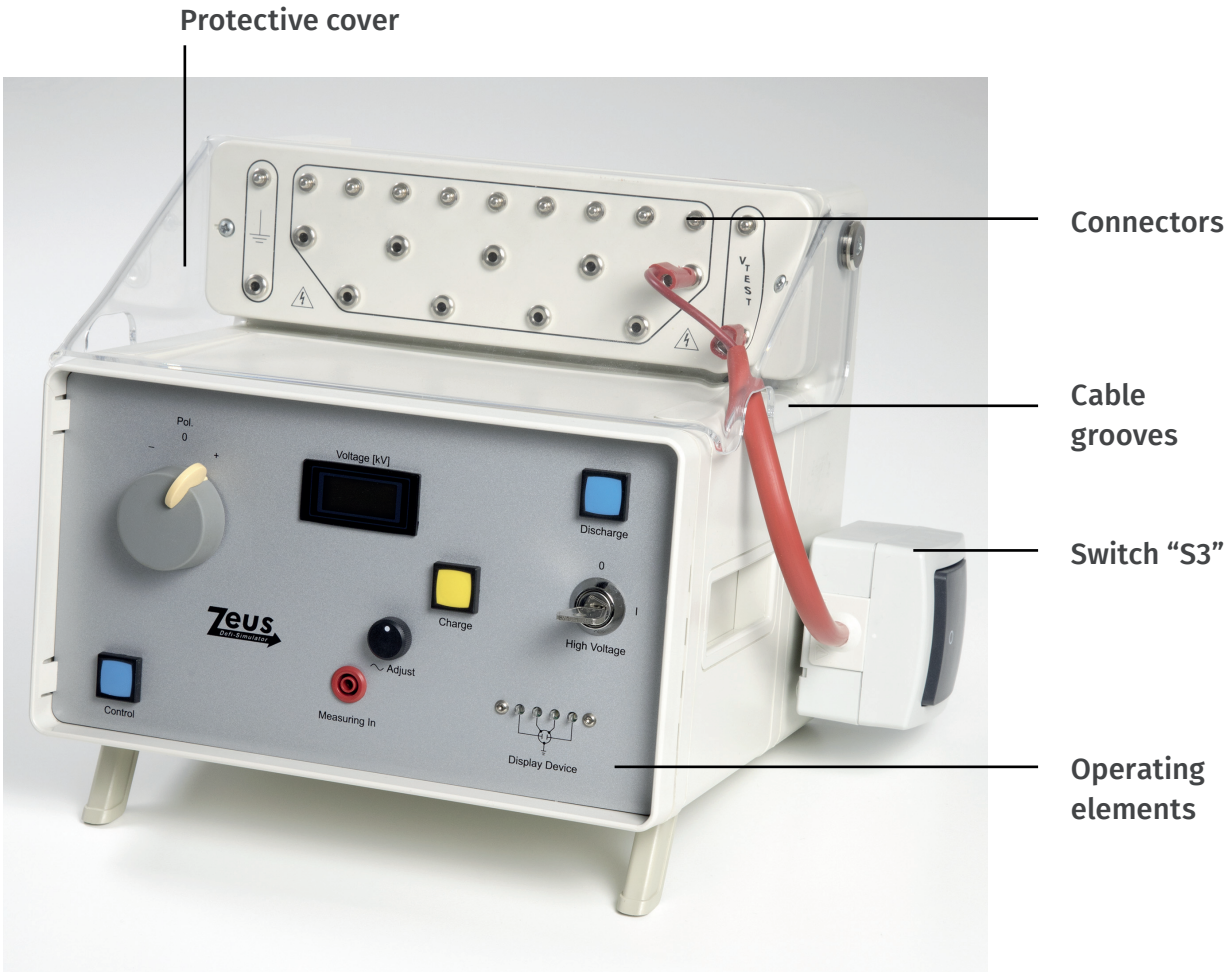


Figure 3-1: Front panel of Zeus V1

Zeus V2

Abbildung 3-2: Front panel of Zeus V2

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:

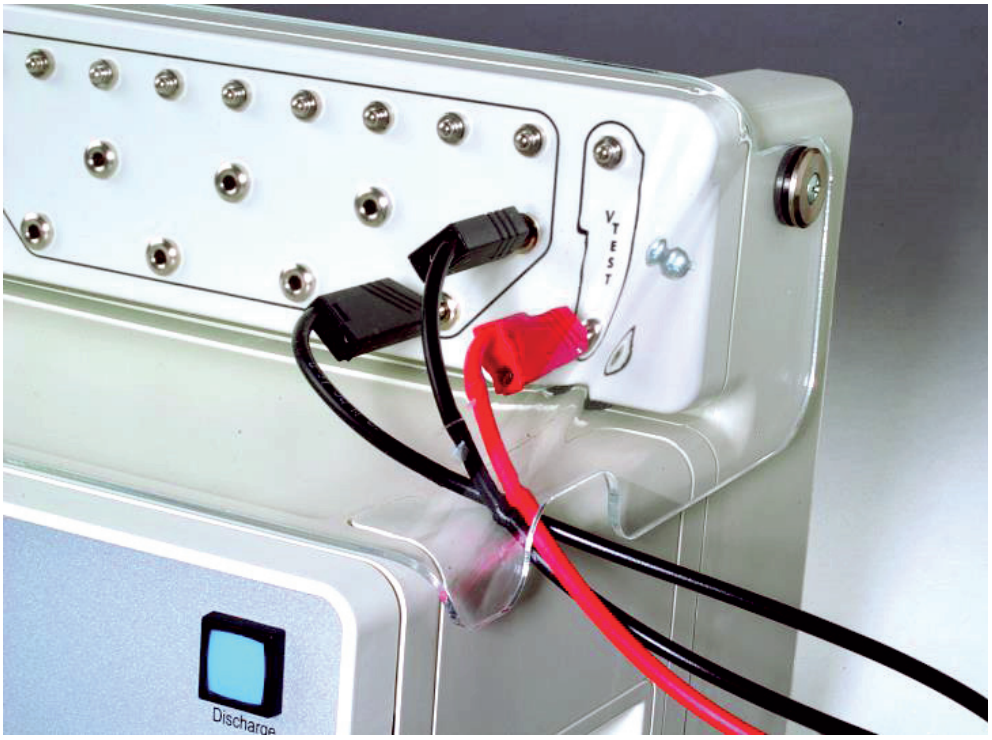


Figure 3-3: Cable routing

Connectors

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}	**Output for test voltage pulse (0 to 5 kV) and 10 Hz sinusoidal voltage (0.5 - 5 mVpp)**
⏚	**Grounding**

3.2 Operating elements

Zeus V1

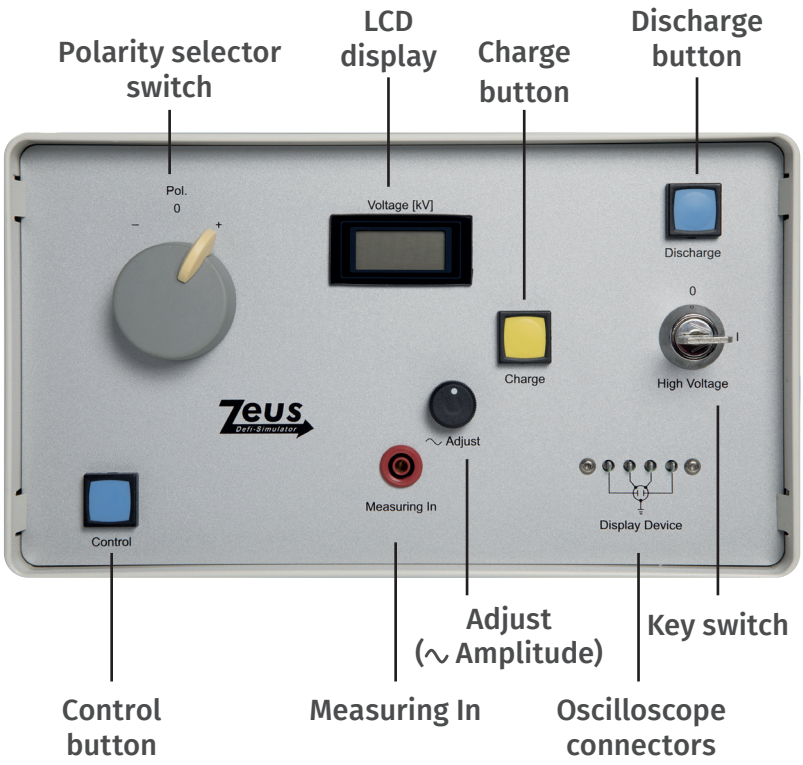


Figure 3-4: Operating elements of Zeus V1

Zeus V2

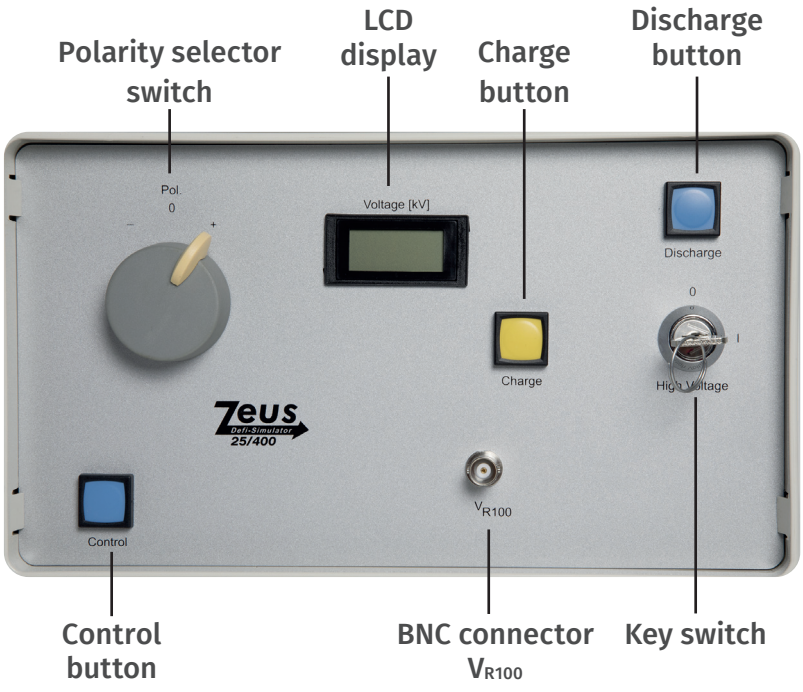


Figure 3-5: Operating elements of Zeus V2

Polarity selector switch

In accordance to IEC 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 Zeus. For charge and discharge of the capacitor you have to press the Control button and the Charge or Discharge button simultaneously.

NOTE

Please note: Pressing the Control button disconnects the internal sine-wave generator (version 1 only) from the high voltage supply immediately! The connection is re-established only after releasing the Control button and the sinusoidal signal is again applied to the connectors!

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, Zeus V1 only)

The Measuring In connector serves as measuring input when measuring potentially hazardous electrical energy in the device under test that may occur during a defibrillation. A test terminal connector (included) is plugged in the measuring connector and connected to different parts of the device under test.

WARNING

ATTENTION! The Measuring In socket is ONLY used for the purpose described in the relevant standards (e.g. IEC 60601-1, Figure 9, see also block diagram on page 23 of this manual) to scan various points on the housing. The Measuring In socket must NOT be connected to the discharge pulse at VTest! The measuring circuit can be destroyed by this!

Rotary knob ∿ Adjust (Zeus V1 only)

Use the ∿ Adjust knob to individually set the level of the sinusoidal voltage required in the standards (internal generator voltage 2 - 20 Vpp, results in a display of 0.5 - 5 mVpp on the device unter test). Turn until the required amplitude is shown on the display of your device under test.

V_{R100} (Zeus V2 only)

The BNC connector labelled V_{R100} is only installed on Zeus 25/400! It is used to connect an oscilloscope or voltmeter for testing the energy drop of the specimen.

Oscilloscope connectors (Zeus V1 only)

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). We recommend using a differential probe.

3.3 Rear panel

The following figure shows the rear panel of Zeus:

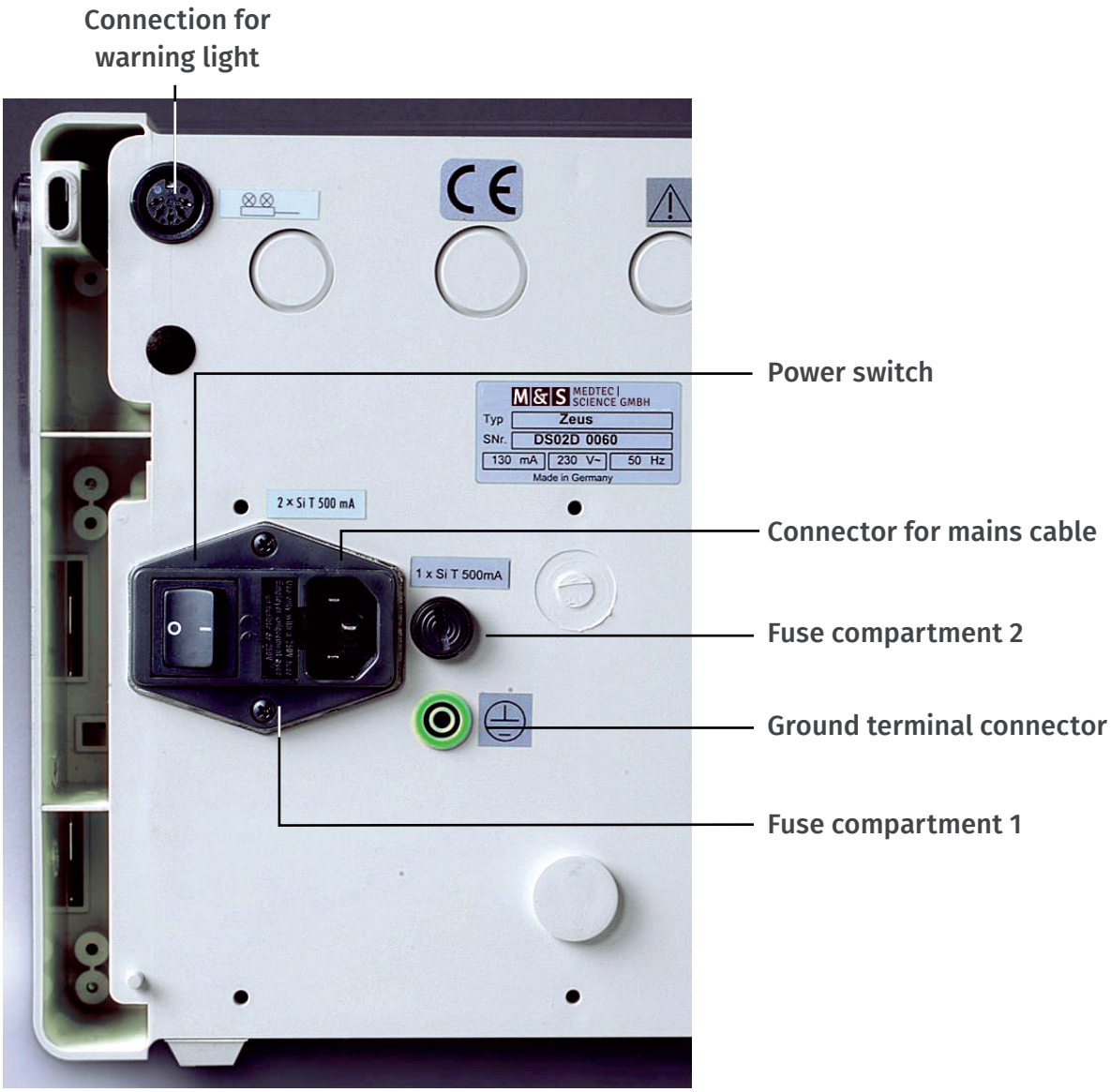


Figure 3-6: Zeus rear panel

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 Zeus (symbol ⊗⊗——).
It indicates if high voltage is on or not:

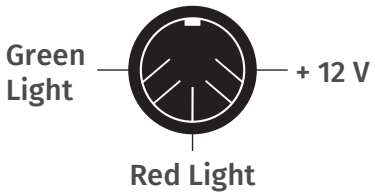
red means: “Attention: High Voltage!”.

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 Zeus ensures this.

The ground terminal connector at the back of 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)**
- **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.**
- **Test of the energy reduction in the device under test during defibrillation.**

4.2 Instructions for the experimental setup

NOTE

For details regarding the setup and the performance of the respective tests refer to the applicable standards.

Furthermore, note the following instructions:

- **Before starting the test, Zeus has to be in the testing room for at least two hours to adapt to the surroundings (temperature, air humidity).**
- **Dynamic test of energy limitation at various parts of the device under test: for this test a test terminal connector (inculded) 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 connector 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 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, Δt = 0.2 ms was selected for a recorded voltage impulse length of t = 8 ms. This means that k = 8 ms/ 0.2 ms = 40. The voltage levels must be read out in the corresponding intervals (e.g. $u(\Delta t_1)$ = 2.0kV, $u(\Delta t_2)$ = 3.2kV, $u(\Delta t_3)$ = 4.0kV, $u(\Delta t_4)$ = 4.05kV,... u(Δt40) = 0.45kV). In this case, the energy output at the internal resistor R = 100 Ω (without specimen) equals E ≈ 366 Ws. In a test with specimen, the energy at the 100 Ω resistor is reduced according to the resulting voltage divider.

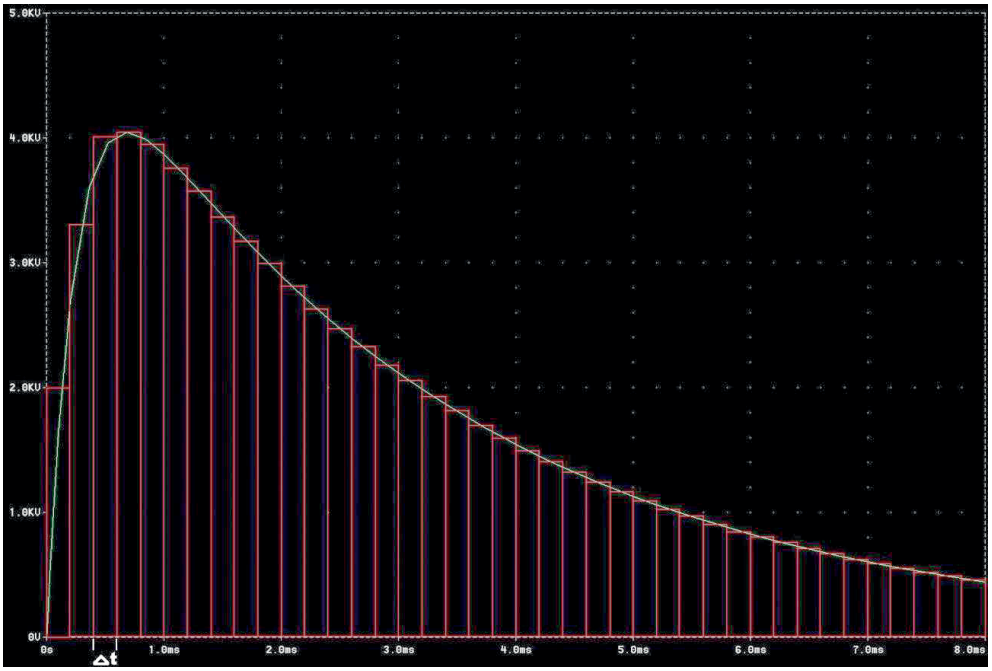


Figure 4-2: Discharge curve over internal 100 Ω resistor

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 ⏚.**

For the test “Test of protection against the effects of defibrillation (common mode)“ according to figure 201.103 of IEC 60601-2-25 the switch “S3” (S3 mentioned in the standard above, implemented using the accessory part no. 48.249, see figure 3-1 (page 7)) must be connected between V_{TEST} and one of the centre connectors. The switch is operated as described in the standard!

Please note that the sine-wave (Zeus V1 only) cannot be seen when switch S3 is in closed position (position I)!

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 (EN 50191):**
  - **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 capacitor will be internally discharged immediately after charging if the protective cover is open!
- **The device under test (DUT) 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 IEC 60601-1, IEC 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 Zeus (power switch at the rear panel).
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

During charging, observe the LCD display, which shows the current voltage and polarity.

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

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 energy to the device under test: press the “Discharge” button while holding down the Control button.

NOTE

After discharge immediately release the Control button to ensure that the sinusoidal signal (version 1 only) is applied to the connectors again.

11. Repeat the test with reversed polarity.

5 | REPLACING THE FUSES

Zeus provides two fuse compartments:

- **Fuse compartment 1 with 2 x 500 mAT fuses. The fuses in fuse compartment 1 are blown, if the LCD display remains dark and no functions can be carried out with 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.**

NOTE

Use exclusively fuses of type 500 mAT.

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

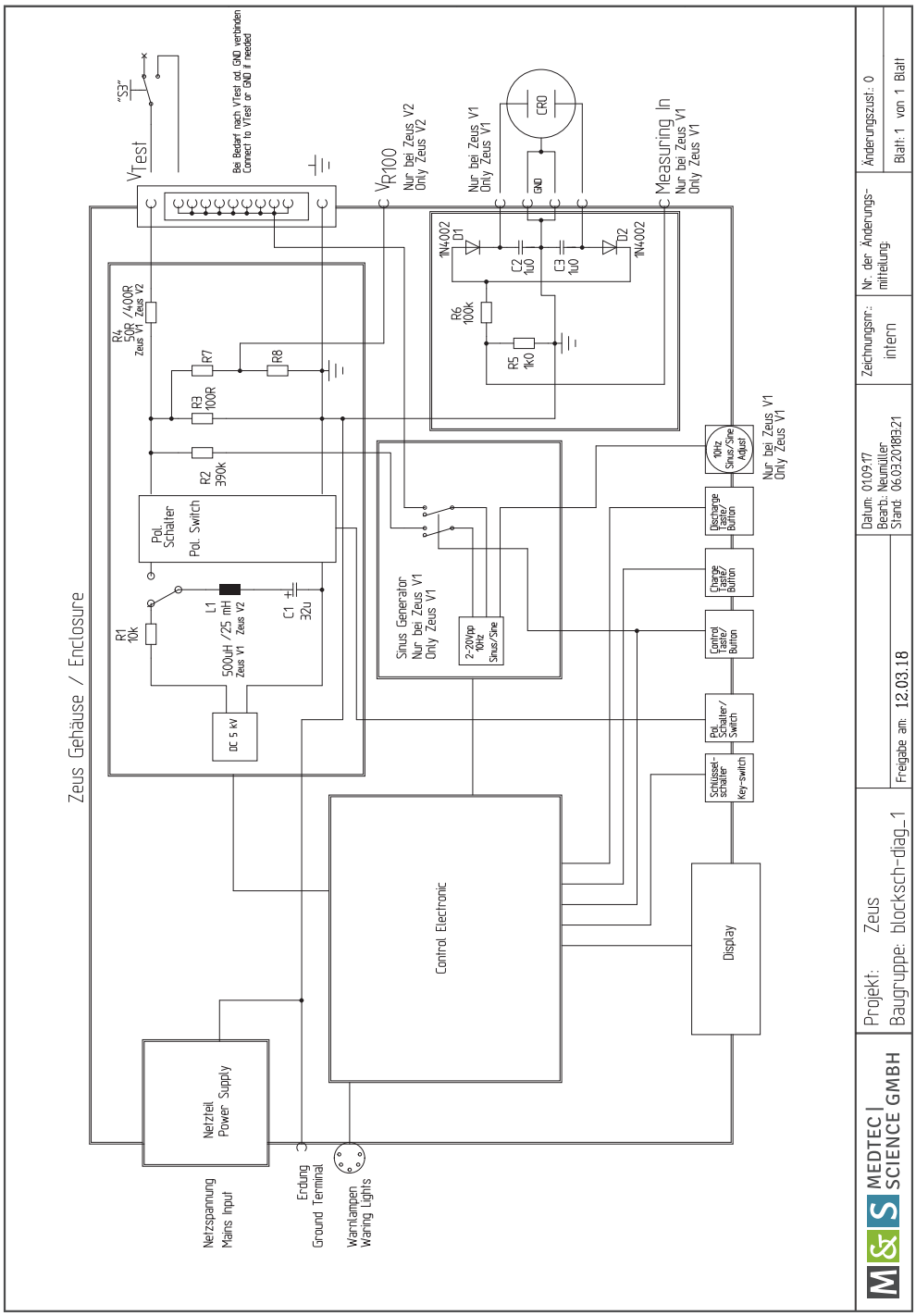
- **Open the bayonet socket: insert a coin and turn the socket anticlockwise approx. ¼.**
- **Remove the fuse and put in the new one.**
- **Close the bayonet socket.**

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
Display	3.5 digit liquid-crystal display (LCD)
Electronics	supply voltage: 230 V ± 10 % / 250 mA test voltage can be increased steplessly up to 5 kV automatic charge stop at 5.2 kV internal test setup in accordance to EN 60601-1 integrated 10 Hz (± 2 Hz) sine-wave generator integrated measuring circuit for the connection of an oscilloscope and a test clip (dynamic testing) internal discharge at interruption of the supply voltage and test interruption maximum number of capacitor discharges: 10,000 maximum discharge frequency of the capacitor: 2 discharges/min
Discharge circuit	Zeus V1: L = 500 µH, R = 50 Ohm Zeus V2 (25/400): L = 25 mH, R = 400 Ohm (see block diagram)
Environmental conditions	temperature: 10 – 40 °C air humidity: 10 – 75 % noncondensing atmospheric pressure: 75 kPa – 106 kPa

Values of the output voltages and their tolerance can be found in the enclosed calibration report.

7 | BLOCK DIAGRAM



8 | TROUBLESHOOTING AND ERROR CORRECTION

Note the following instructions to troubleshooting and error correction:

- **If the LCD display is dark check the fuses in fuse compartment 1.**
- **If no high voltage can be activated:**
  - check the fuses in fuse compartment 2.
  - check the polarity switch (if at position 0).
- **If no discharge can be activated, make sure that the protective cover is closed.**
  The protective cover must be completely closed, as shown on page 9 Fig. 3-3. Otherwise, the capacitor will be discharged again when the “Charge” button is released.
- **Please refer to the FAQ section on our home page.**
- **The device is rated for a voltage supply of 230 V ± 10 %. If the voltage is lower than that, the capacitor might not be charged to 5 kV.**

9 | DECLARATION OF CONFORMITY

MEDTEC|SCIENCE GMBH

EU-Konformitätserklärung
EU-Declaration of Conformity

Hersteller / manufacturer: MedTec & Science GmbH | Maria-Merian-Str. 6 | 85521 Ottobrunn, Germany

Wir erklären hiermit in alleiniger Verantwortung, dass das Produkt/ die Produkte
We hereby declare under our sole responsibility that the product/ the products

Typ / *type*	Bezeichnung / *description*	Artikelnummer / *part number*
EKG-Simulator ECG-Simulator	**Phantom 320 Code1**	59.009
EKG-Simulator ECG-Simulator	**Phantom 320 Code2**	59.010
EKG-Simulator ECG-Simulator	**MS 410**	59.022
Defibrillations-Simulator Defibrillation-Simulator	**Zeus V1**	59.101
Defibrillations-Simulator Defibrillation-Simulator	**Zeus V2**	59.102

den Bestimmungen der nachstehenden EG/EU-Richtlinie(n)/Verordnung(en) entspricht/entsprechen:
is/are in conformity with the following EG/EU-Directive(s)/Regulation(s):

2014/35/EU	EU-Niederspannungs-Richtlinie Electrical Equipment designed for use within certain voltage limits
2014/30/EU	Elektromagnetische Verträglichkeit Electromagnetic Compatibility
2011/65/EU (inkl. (EU) 2015/863)	Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten (ROHS II und Änderungsrichtlinie 2015) Restriction of the use of certain hazardous substances in electrical and electronic equipment with amendment 2015

Angewandte (harmonisierte) Normen / *Applied (harmonised) standards:*

EN IEC 61010-1	Sicherheitsbestimmungen für elektrische Mess-, Steuer-, Regel-, und Laborgeräte Safety requirements for electrical equipment for measurement, control, and laboratory use
EN IEC 61326-1	Elektrische Mess-, Steuer-, Regel-, und Laborgeräte – EMV Anforderungen Electrical equipment for measurement, control and laboratory use – EMC requirements
EN IEC 63000	Technische Dokumentation zur Beurteilung von Elektro- und Elektronikgeräten hinsichtlich der Beschränkung gefährlicher Stoffe Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Ottobrunn, 2021-04-28

Michael Ecker
Geschäftsführer / Director

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