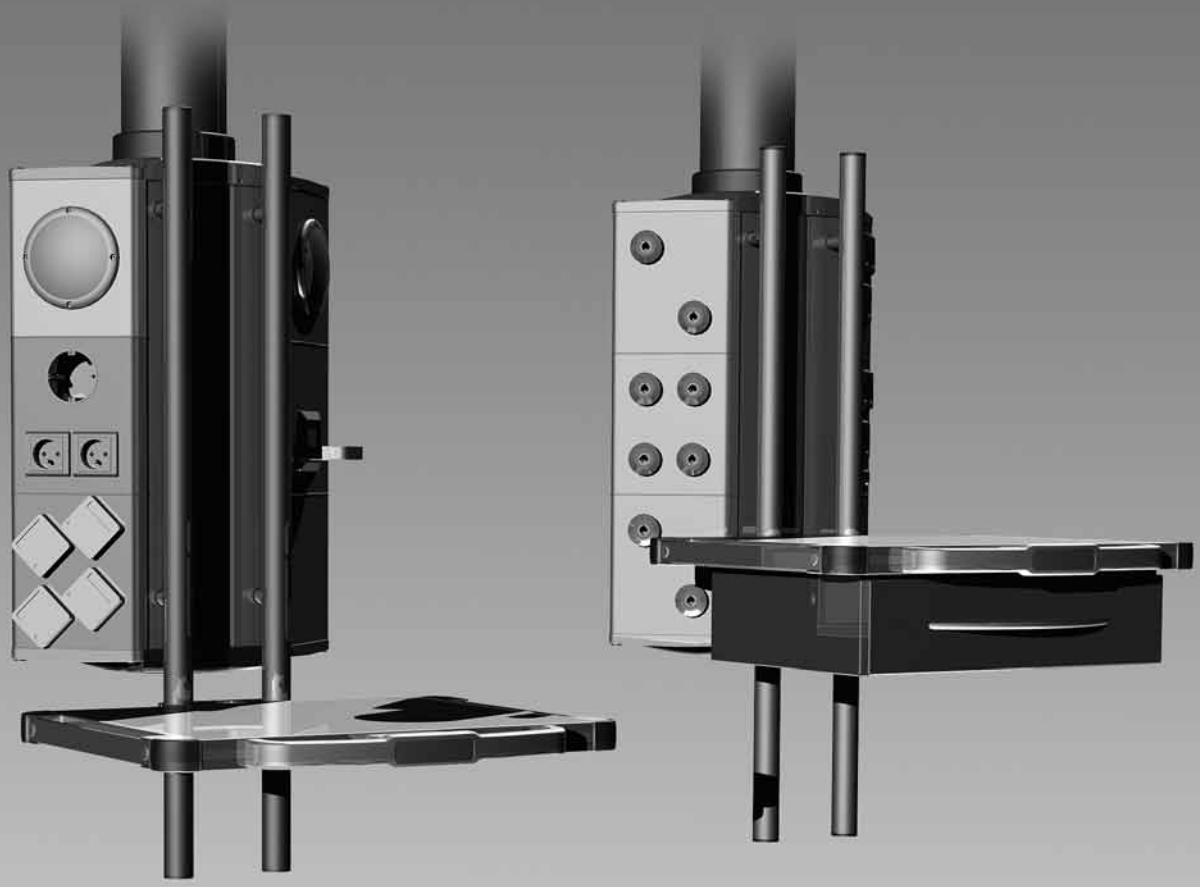


Operating Instructions [EN]

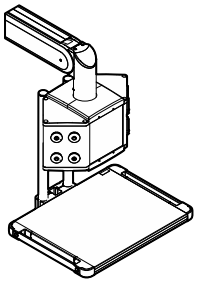
Navigator M6

A member of the
Medical Illumination International Group

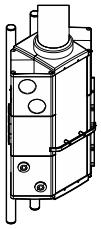
Configuration examples

The Navigator M6 in various equipment versions is combined with different Nuvo pendant systems depending on the medical discipline and individual space requirements.

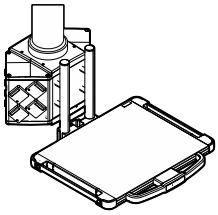
SpacePort®



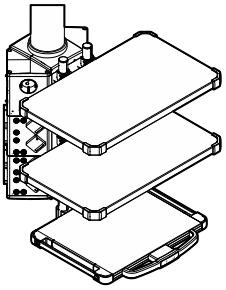
Navigator ™ OndaScope® 400 / 600



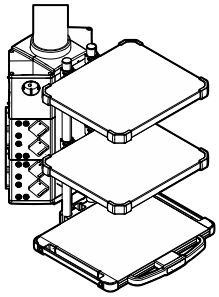
Navigator Lift ™ 150 / 180 / MMP 85 S / MMP 90



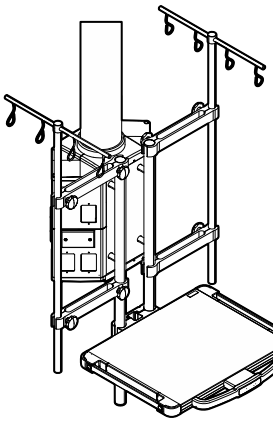
Navigator Lift ™ 250 / MMP 200



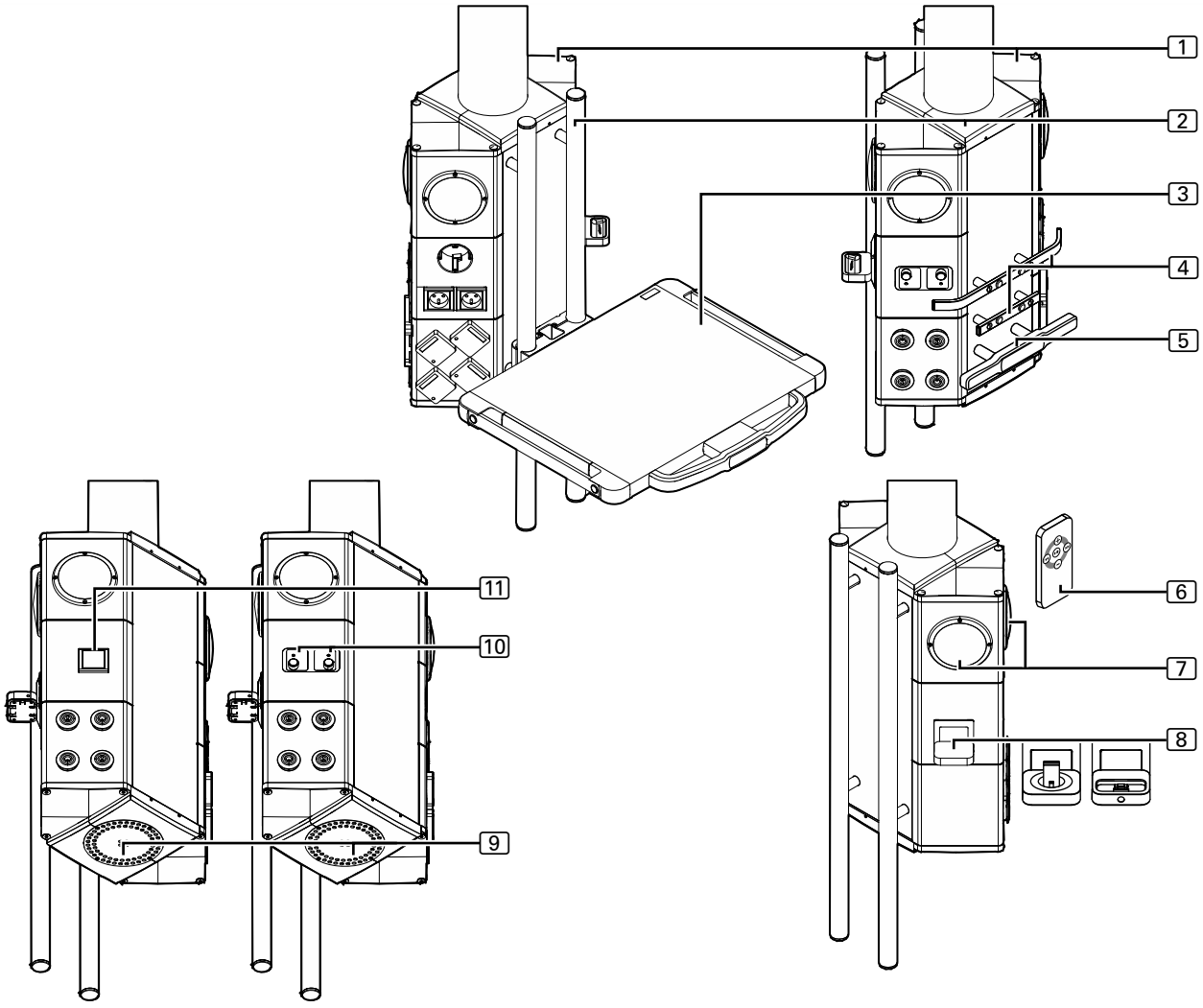
Navigator ™ OndaScope® 400 / 600



Navigator ™ OndaScope® 400 / 600



Parts and control elements



The Figure shows examples for the configuration of the Navigator M6 for various medical disciplines on the approved Nuvo pendant system.

[1] Navigator M6 (Standard or XL size) with optional
- gas outlet points for medical gases, vacuum and compressed air
- device sockets with equipotential bonding sockets
- phone, nurse call, computer data, etc.
- 1 UP/DOWN control button for the motor-powered height adjustment of the pendant systems MMP 90 / 200

[2] Optional Multi-Function Rack (MFR)
- for carrying optional accessories such as shelves, infusion holders, flat screen carriers, etc.

[3] Optional operating shelf with
- 2 control buttons for operating the electromagnetic brakes on the pendant systems Navigator ™ / Navigator Lift ™ or the pneumatic brakes on the pendant systems Navigator ™ / Navigator Lift ™ and OndaScope® 400 / 600
- 1 UP/DOWN control button for the motor-powered height adjustment of the pendant systems Navigator Lift ™ 150 / 250

[4] Standard rail (optional – Straight or Bent versions) with:
- 2 optional control buttons for operating the pneumatic brakes on the pendant system OndaScope® 400 / 600 and the MMP 90 / 200

[5] Optional operator handle with:
- 2 control buttons for operating the electromagnetic brakes on the pendant systems Navigator ™ / Navigator Lift ™
- 1 UP/DOWN control button for the motor-powered height adjustment of the pendant systems Navigator Lift ™ 150 / 250

Optional sound system

[6] Remote control unit for the version MediSound-System Interface

[7] 4 loudspeakers
- in the Navigator M6 or
- 1 spherical loudspeaker (optional), ceiling-mounted (not illustrated)

[8] Docking station for external digital media players
such as MP3 players, smartphones, Apple iPhones or Apple iPods (not included in the scope of delivery)
- Version MediSound-System Bluetooth with 3 interfaces or
- MediSound-System Interface with 2 interfaces, control button at the bottom and battery charging function

Optional lighting systems (only pendant systems Navigator ™ and Navigator Lift ™)

[9] Indirect Navigator M6 lighting (SurroundLED basic F)
- with air vents (must not be covered)

[10] 2 rotary dimmer switches with indicator lamps for
- controlling the indirect extension arm lighting and the indirect Navigator M6 lighting (SurroundLED advanced)

[11] ON/OFF switch for
- the indirect extension arm lighting (SurroundLED basic C, not illustrated) or the indirect Navigator M6 lighting (SurroundLED basic F)

Thank you very much for purchasing this Nuvo product. Please read these Operating Instructions very carefully, abide by the safety notices and observe all operating and cleaning requirements.

For which devices do these Operating Instructions apply?

- Navigator M6 on the Nuvo pendant system

Customer service is at your disposal

if you have any questions about the device and its installation, and also in service or warranty cases.

Manufacturer and marketer

Nuvo Surgical • 1565 West 12th Street • Erie, PA 16501 • USA
Phone: +1 (800) 663-1152 (USA and CANADA)
Phone: +1 (814) 899-4220 (INTERNATIONAL)

1568917, Edition 2019-05, Version 0

Visit us on the Internet www.nuvosurgical.com
E-mail address sales@nuvosurgical.com

Supplier's address

Space for supplier’s stamp or label

Copyright and property rights

Copyright

- All rights reserved. These Operating Instructions are protected by copyright law.
- Any other use than that regulated by law must be approved in writing by Nuvo Surgical, hereinafter referred to as Nuvo.
- Nuvo does not take any liability for or in relation to the misuse of this information in the prohibited manner by any person or company.

Modifications and translations

Modifications to the device

- Nuvo products are subject to continuous further development. Nuvo reserves the right to modify the form, equipment and technology of the scope of supply without prior notice.

Modifications to the Operating Instructions

- The contents of these Operating Instructions are subject to change without prior notice.

Translations

- In case of translations into foreign languages, the German version of these Operating Instructions shall take precedence.

Trademarks

- All trademarks mentioned in these Operating Instructions are the sole and exclusive property of the corresponding manufacturer.

1.1 Information for identification of the device

- These Operating Instructions are intended solely for devices with the manufacturer's rating plate bearing the following information:

Device identification

  - Type designation: Navigator M6

1.2 How to identify the Operating Instructions

Make sure you are using the latest version

- To ensure that you always have the latest version of these Operating Instructions, every page bears a 7-digit identity number including the date of issue and the version number:

Identification of these Operating Instructions

  - Edition: 2019-03

- This identification is binding for the validity of the Operating Instructions and must not be removed, regardless of the type of publication (printed form, electronic form or excerpts).

1.3 Identification of target groups

The groups of persons described below are mentioned in these Operating Instructions.

1.3.1 Operator

The following natural persons or legal entities shall be considered as operators:

- All persons who use the device in a medical practice, hospital, etc. or hand over the device to third parties for use/application, and who have actual physical authority over the device during operation.
- The operator shall be liable for handing over a safe device and for instructing the user in its proper operation and normal use.

1.3.2 User

The following persons shall be considered as users:

- persons who, due to their professional qualification and instruction by the persons designated by the operator, are authorised to operate the device and to work with it.
- Users shall be fully responsible for the safe operation of the device in accordance with its intended purpose.

1.3.3 Qualified personnel

The following persons shall be considered as qualified personnel:

- persons who underwent special professional training in the field of medicine or medical engineering,
- persons who can assess their work and recognise the potential hazards involved on the basis of their professional experience and instruction in safety-relevant regulations.
- In States where the performance of tasks in the medical or medical engineering sector is subject to certification, qualified personnel must have obtained the corresponding certificate.

1.4 Notes for the operator

- Although the device has been designed according to the state of the art and is safe to operate, it must be considered a potential source of danger, in particular when operated by insufficiently trained personnel or used improperly and not as prescribed.
- The device may only be operated, cleaned and disinfected by trained qualified personnel.
- All the mounting, dismounting and adjustment work described in these Operating Instructions may only be carried out by qualified personnel who have been authorised and instructed by the operator.
- For safety reasons, any operator actions or interventions exceeding this scope may only be carried out by Nuvo or companies authorised by Nuvo. As a prerequisite for the authorisation of a company, its service technicians must have successfully participated in technical training organised by Nuvo. This authorisation is granted for a limited period.
- All lengths (mm) and angles (degrees) are approximate values and subject to production-related tolerances.

1.4.1 Initial commissioning

Validity

- These Operating Instructions only apply after initial commissioning has been properly carried out.
- Prior to initial use, the device must be thoroughly cleaned and disinfected.
- The instruction for the proper installation of the device is included in the Installation Instructions applicable for the device.

1.4.2 Availability of these Operating Instructions

Duty to inform

- Since these Operating Instructions are an integral part of the device, they must always be kept near the device in order to be able to look up safety instructions and important information on use at any time.
- Do not pass on the device to any third party without valid Operating Instructions. Based on the ID and version numbers, make sure that you hand over an up-to-date and valid version of the Operating Instructions together with the device.

1.4.3 Warranty

The warranty of Nuvo for the safety and operational reliability of the device is subject to the following conditions:

- The device is used exclusively as prescribed and operated as stipulated in these Operating Instructions.
- Only genuine spare parts or accessories and those defined and approved by Nuvo are used. The use of other parts may involve unknown risks and must be avoided in all cases.
- No structural alterations are made to the device. Unauthorised modifications or conversions to the device are not permitted for safety reasons.
- Inspections and maintenance are carried out at the specified time intervals.
- Initial commissioning has been carried out and the device has been released for operation by means of a declaration of acceptance.

1.4.4 Essential performance features

- There are no essential performance features.

1.5 Notes for the user

- All the steps described in these Operating Instructions may only be carried out by qualified personnel who have been authorised and instructed by the operator.

1.5.1 Instruction on the device

Instruction

- The instruction must be carried out on the device directly by Nuvo, by a company authorised by Nuvo or by a person designated by the operator.
- On completion of the instruction, a certificate must be created and signed in order to document that the user has understood the special operator control actions required for normal use.

1.5.2 Duty to inform and inspect

Duty to inform and inspect

- Read these Operating Instructions carefully before using the device for the first time. This ensures that you benefit from all the advantages of the device and prevents any risk of injury or damage to property.
- Prior to any use or transfer for use, the functional reliability and proper condition of the device must be inspected by the user.

Troubleshooting

- In case of special problems which are not sufficiently described in detail in these Operating Instructions, contact your supplier for your own safety.

1.5.3 Marking

CE mark: Nuvo declares that the products comply with the relevant regulations set forth in the applicable European Directives.

CE mark with the ID number of the conformity assessment body indicated: Nuvo declares that the assessment of conformity in accordance with 93/42 EEC (Medical Device Directive) has been performed by the body indicated.

This symbol marks the product as a component approved by a "Nationally Recognized Testing Laboratory" which complies with both Canadian and US deviations from applicable standards.

1.5.4 Standards and directives

The device complies with the safety requirements of the following standards, laws and directives:

- Medical Devices Act (MPG)
- 93/42 EEC (Medical Device Directive)
- IEC 60601-1 – Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- DIN EN ISO 11197 – Medical Supply Units

1.6 Intended purpose

- The Navigator M6 on the Nuvo pendant system is individually equipped; depending on the version and equipment, it serves for:
– carrying and positioning medical devices in OR or intensive care rooms and medical environments;
- the conveying and extraction of fluids:
– medical gases, vacuum and compressed air,
– electricity and data.

- The Navigator M6 is suitable for continuous operation.

Qualified personnel

- The Navigator M6 may only be operated by instructed, qualified medical personnel.
- The Navigator M6 may only be cleaned and disinfected by instructed hygiene specialists.
- Maintenance work on the Navigator M6 must be carried out by the operator's technical specialist personnel in accordance with the applicable instruction document.

1.6.1 Incorrect use

- The maximum loading capacity of the Navigator M6 and its components as specified in Chapter 16, "Technical Data", on Page 49 must not be exceeded.
- Independently of the maximum loading capacity (payload) the optional components may only be loaded with the maximum weight specified in Chapter 18, "Approved Nuvo Products", on Page 57.

Duty cycle of the height adjustment mechanism (only pendant systems MMP 90 / 200 and Navigator Lift ™ 150 / 250)

- The maximum duty cycle of the height adjustment mechanism on the motor arm (only pendant systems MMP 90 / 200 and Navigator Lift ™ 150 / 250) must not exceed 3 minutes:
– If the height adjustment mechanism is actuated over a longer period of time, the electric motor of the motor arm may switch off automatically as a protection measure against overheating.
– In order to prevent an overload of the electric motor, make sure you wait at least 30 minutes after actuating the height adjustment mechanism before putting the height adjustment mechanism back into operation. Afterwards the height adjustment mechanism can be operated once again for 3 minutes.

Duty cycle of the electromagnetic brakes (only for pendant systems with electromagnetic brakes)

- The maximum duty cycle of the electromagnetic brakes (only for pendant systems with electromagnetic brakes) must not exceed 1 minute:
– If the electromagnetic brakes are actuated over a longer period of time, the power pack may switch off automatically as a protection measure against overheating.
– Once the power pack has switched off, it must cool down for 10 minutes and then be disconnected from the mains for 10 seconds before being switched back on again. Normal system operation may only be resumed afterwards. To prevent safety cut-offs, the maximum duty cycle should not be exceeded.

1.6.2 Contraindications

- The Navigator M6 must not be used close to strong magnetic fields.
- No BF or CF application parts in accordance with IEC 60601-1 may be directly connected to the Navigator M6.

1.7 Ambient conditions

1.7.1 Ambient conditions for storage and transport

The following conditions apply to storage:

- Ambient temperature: -25 °C to 60 °C
- Relative humidity: 10 % to 75 %
- Atmospheric pressure: 500 hPa to 1,060 hPa

1.7.2 Ambient conditions for operation

- Ambient temperature: 10 °C to 40 °C
- Relative humidity: 30 % to 75 %
- Atmospheric pressure: 700 hPa to 1,060 hPa
  (This corresponds to a maximum operating altitude of 3,000 m).

1.8 Approved Nuvo products

The following Nuvo products are approved for installation on the Navigator M6:

- Nuvo products as described in Chapter 18, "Approved Nuvo Products", on Page 57:
  – The components have been adapted to each other and are safe to operate. Any other type of installation, and in particular the use of components from third-party manufacturers, is strictly prohibited because these components can be potential sources of danger.
  – The combination of any other Nuvo product with the Navigator M6 must be approved by Nuvo Surgical. If applicable, the conformity assessment must be repeated.

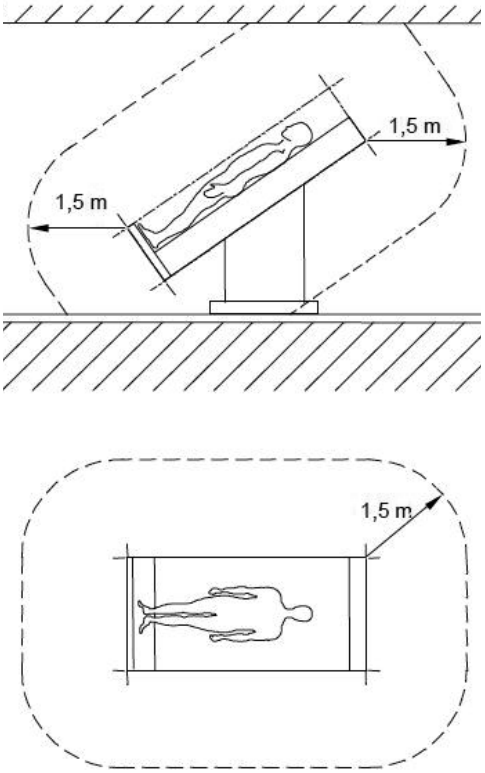
1.9 Combination with products of other manufacturers

Read the Operating Instructions for combined medical products

- The Navigator M6 is combined with products of other manufacturers as described in Chapter 19, "Approved Third-Party Products", on Page 57.
  To prevent dangerous overload, which can damage or lead to a collapse of the pendant system and the Navigator M6, the maximum loading capacities specified must be adhered to.
  – The party placing the device into operation is responsible for the validation of the overall system. A conformity assessment procedure shall be executed if required and a declaration in accordance with Article 12 of 93/42/EEC (Medical Device Directive, MDD) shall be provided.
  – Read the Operating Instructions provided by the third-party manufacturer to obtain the information required for the operation of the end device.
- Power packs intended for the supply of end devices must ensure electrical isolation and provide two protective measures in accordance with IEC 60601-1.

1.10 Patient environment

Figure 1: Patient environment, illustration A.9 from IEC 60601-1:



(See „Figure 1“)

- Medical electrical devices which contain tangible parts and are attached to the Navigator M6 and positioned within the patient environment must provide 2 Means Of Patient Protection (MOPP) in accordance with EN 60601-1.
- If tangible parts are positioned outside the patient environment, 2 Means Of Operator Protection (MOOP) in accordance with EN 60601-1 must be provided.
- The dimensions in the Figure illustrate the minimum extension of the patient environment in an unrestricted area.

2.1 Structure of the safety instructions

2.1.1 Warnings of risk of injury

Important notes in this document are marked with graphic symbols and signal words. Signal words such as DANGER, WARNING or CAUTION describe the degree of risk of injury. The triangle symbols visually emphasise the degree of hazard.

⚠ DANGER

DANGER refers to a potential hazard with a high degree of risk which, if not avoided, will lead to death or severe injury.

⚠ WARNING

WARNING refers to a potential hazard with a medium degree of risk which, if not avoided, can lead to death or severe injury.

⚠ CAUTION

CAUTION refers to a potential hazard with a low degree of risk which, if not avoided, can lead to minor or moderate injury.

2.1.2 Warnings of damage to property

NOTICE

NOTICE refers to a potential hazard, which, if not avoided, will lead to damage to property.

2.1.3 Indication of additional information

NOTE

A NOTE provides additional information and useful tips for the safe and efficient use of the device.

2.2 Supplementary symbols used in the safety instructions

Explosion hazard: warns of the improper use of oxygen (see Chapter 2.4.2, "Proper use of oxygen", on Page 18).

Danger of fire: warns of the improper use of oxygen (see Chapter 2.4.2, "Proper use of oxygen", on Page 18).

Electric shock hazard: warns of electric shock which can lead to severe injury or even death.

Risk of the Navigator M6 dropping: warns of the risk of the Navigator M6 suddenly dropping because the maximum loading capacity has been exceeded.

Risk of parts falling off: warns of parts falling off while carrying out mounting or dismantling work underneath the pendant system.

Battery disposal: Batteries contain toxic substances. Never dispose of batteries as normal household waste; return them to the collection points provided by shops or dispose of them at waste management facilities under public law. For transport or disposal, cover the battery connectors with insulating tape in order to prevent accidental short circuits.

2.3 Graphic symbols on the device and/or on the packaging

Observe the Operating Instructions: Read these Operating Instructions carefully before using the Navigator M6 for the first time. This ensures that you benefit from all the advantages of the Navigator M6 and prevents any risk of injury or material damage.

Observe the maximum load bearing capacity or maximum loading capacity (payload): warns of the risk of the Navigator M6 suddenly dropping because the maximum load bearing capacity or maximum loading capacity (payload) has been exceeded. The maximum value is indicated in kg or Nm.

General note reminding the user to handle the Navigator M6 with care.

Environmentally friendly disposal: warns of damage to the environment caused by improper disposal of the Navigator M6 (must not be disposed of as normal household waste).

ESD component: warns of a high current pulse caused e.g. through frictional electricity which, when coming into contact with the docking station, triggers an electrostatic discharge that can damage microelectrical components.

Non-ionising electromagnetic radiation: warns that the high-frequency electromagnetic radiation generated by mobile phone base stations and radio transmitters interferes with medical devices and electronic implants.

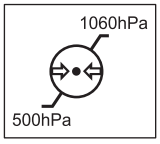
Equipotential bonding: marks the equipotential bonding connections to be used for earthing end devices (e.g. flat screen, etc.).

Do not loosen the screws: warns of the Navigator M6 suddenly dropping because the screws indicated have been loosened.

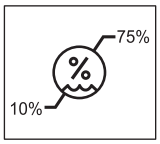
CE mark: Nuvo declares that the products comply with the relevant regulations set forth in the applicable European Directives.

CE mark with the ID number of the conformity assessment body indicated: Nuvo declares that the assessment of conformity in accordance with 93/42 EEC (Medical Device Directive) has been performed by the body indicated.

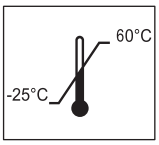
This symbol marks the product as a component approved by a "Nationally Recognized Testing Laboratory" which complies with both Canadian and US deviations from applicable standards.



Atmospheric pressure: indicates the permissible atmospheric pressure values in a range from 500 hPa to 1060 hPa for transport and storage.



Relative humidity: indicates the permissible humidity values in a range from 10 % to 75 % for transport and storage.



Ambient temperature: indicates the permissible ambient temperature values in a range from -25 °C to 60 °C for transport and storage.

2.4 Overview of the most important safety instructions

The safety instructions in the following chapters must be adhered to.

2.4.1 Operation

⚠ DANGER

The pendant system and the Navigator M6 can drop if the maximum loading capacity (payload) is exceeded

If the maximum permissible loading capacity (maximum payload) has been exceeded, there is a risk that the pendant system, the Navigator M6 or components of the pendant system may disengage from the fastening device and drop:

- The total weight of the fixedly attached or placed end devices, accessories, etc. must not exceed the maximum permissible loading capacity (payload) indicated on the Navigator M6.
- Independently of the maximum loading capacity (payload) on the Navigator M6, optional accessories may only be loaded with the maximum weight specified in Chapter 18, "Approved Nuvo Products", on Page 57.

If you cannot clearly determine the maximum loading capacity (payload), contact Nuvo in order to prevent damage to persons or property.

- Phone: +1 (800) 663-1152 (USA and CANADA)
- Phone: +1 (814) 899-4220 (INTERNATIONAL)

⚠ WARNING

Risk of injury when lowering the Navigator M6 close to the patient:

When lowering the Navigator M6 above or close to the patient, there is a risk of the patient suffering bruises or severe injury by the Navigator M6 or accessories mounted onto it:

- When lowering the Navigator M6, make sure that the Navigator M6 and any accessories mounted onto it (e.g. infusion poles mounted on the side)) do not cause bruising to the patient.
- Keep a safety distance of at least 50cm between the Navigator M6 and accessories mounted to it and the patient.

⚠WARNING

Risk of injury when swivelling the Navigator M6 close to the patient:

If the Navigator M6 is swivelled close to the patient, there is a risk of end devices or accessories dropping and hurting the patient:

- Do not swivel the Navigator M6 and any accessories mounted onto the Navigator M6 above or close to the patient.

Risk of patient supply cables tearing off

When swivelling the Navigator M6 and adjusting its height, patient supply cables can tear off on the patient or medical device side and important patient care systems can fail:

- Before swivelling the Navigator M6 and adjusting its height, check the length of the supply cables on the patient and on medical devices.
- Check the swivel range and vertical lift for obstacles.
- Make sure you swivel the Navigator M6 slowly and adjust its height with care in the area of the supply lines connected to the patient.

Collision damage

In case of collision with other devices, walls or ceilings, the Navigator M6 or components of the pendant system can be damaged and important patient care systems can fail:

- After a collision, the Navigator M6 and the pendant system must be inspected for damage.
- In case of doubt, contact your supplier.

2.4.2 Proper use of oxygen

⚠ DANGER

Oxygen explosion

Oxygen becomes explosive when in contact with oil, grease and lubricants. Compressed oxygen presents an explosion hazard:

- Make sure that the oxygen and gas outlet points are free from oily, greasy and lubricating materials!
- Do not use any cleaning agents containing oil, grease or lubricants.

Danger of fire

Escaping oxygen is combustible:

- Open fires, red hot objects and naked flames are not permitted when working with oxygen!
- Do not smoke!

2.4.3 Ventilation at the bottom of the Navigator M6

⚠ DANGER

Danger of fire

Escaping oxygen is combustible: If the air vents [9] at the bottom of the Navigator M6 are covered, there is a risk of oxygen enrichment in the Navigator M6 in case of failure of optional oxygen hoses:

- Make sure the air vents are not covered.
- Attachments to the bottom of the Navigator M6 must be installed at a minimum distance of 50 mm from the ventilation slots.

2.4.4 Cleaning and disinfection

Cleaning

⚠WARNING

Risk of contamination and infection of the patient

Parts of the pendant system and the Navigator M6 are made of plastic. Solvents can dissolve plastic materials. Strong acids, bases and agents with an alcoholic strength of more than 60 % can lead to the plastic materials becoming brittle. Detached particles can fall into open wounds. If liquid cleaning agents are allowed to penetrate the pendant system and the Navigator M6, excess cleaning liquid may drip into open wounds.

Disinfection

⚠WARNING

Health hazard

Disinfectants can contain substances hazardous to health which, when in contact with the skin and eyes, can cause injuries or affect the respiratory organs when inhaled. Observe the protective measures:

- Observe the hygiene regulations.
- Adhere to the disinfectant manufacturer's instructions.
- Perform surface disinfection every working day and in case of contamination.

2.4.5 Maintenance work

⚠WARNING

Electric shock hazard

Power cables are laid in the pendant system and the Navigator M6. Contact with energized components presents a danger to life from electric shock. Prior to any installation/dismantling and setting up work, the pendant system must be disconnected from the mains:

- Disconnect all the poles from the mains and prevent the device from being switched back on again.
- Make sure that all the devices connected via the Navigator M6 are de-energised.

⚠WARNING

Maintenance work

- The pendant system and the Navigator M6 must be inspected as specified in Chapter 21, "Inspection Plan".
- In case of failure or damage, please contact your supplier.

2.4.6 Mounting / dismantling

⚠WARNING

Electric shock hazard

To prevent the risk of electric shock, the pendant system and the Navigator M6 may only be connected to a supply network equipped with a protective conductor:

- The pendant system and the Navigator M6 must be connected in such a way that they can be disconnected from the mains at all poles and at the same time.

Electric shock hazard

Power cables are laid in the pendant system and the Navigator M6. Contact with energized components presents a danger to life from electric shock. Prior to any installation/dismantling and setting up work, the pendant system and the Navigator M6 must be disconnected from the mains:

- Disconnect all the poles from the mains and prevent the device from being switched back on again.
- Make sure that all the devices connected via the Navigator M6 are de-energised.

⚠WARNING

Risk of parts falling off

During all uninstallation and installation work, it must be ensured that no person is in the area underneath the pendant system.

2.5 Warranty

⚠WARNING

Pendant system dropping

The pendant system and the Navigator M6 are an adapted system with regard to the maximum load bearing capacity and maximum loading capacity (payload).
Alterations to the pendant system can result in exceeding the permissible, total or maximum loading capacity (system load) of the individual components. In this case, there is a risk of the pendant system or components thereof disengaging from the fastening device and dropping.
Nuvo warrants the functional reliability of the pendant system only under the condition that:

- No structural alterations are made to the pendant system and the Navigator M6. Unauthorised modifications or conversions to the pendant system and the Navigator M6 are not permitted for safety reasons.
- Only genuine spare parts or accessories and those defined and approved by Nuvo are used. The use of other parts may involve unknown risks and must be avoided in all cases.
- Inspections and maintenance are carried out at the specified time intervals.
- Related documents for dismantling, mounting and adjustment work to be carried out on the pendant system and the Navigator M6 are available from Nuvo on request.
- The party placing the device into operation is responsible for the validation of the overall system. A conformity assessment procedure shall be executed if required and a declaration in accordance with Article 12 of 93/42/EEC (Medical Device Directive, MDD) shall be provided.

2.6 Electromagnetic interference

Medical electrical devices are subject to special precautionary measures with regard to electromagnetic compatibility (EMC) and must be installed and put into operation in accordance with the instructions below.
The instructions in Chapter 17, "Electromagnetic Compatibility (EMC) Information", on Page 52 must also be observed.

⚠WARNING

Failure of medical devices

Portable and mobile high-frequency communication devices (e.g. MP3 players, Apple iPods and iPhones) can interfere with medical electrical devices or their displays and put essential patient supply measures at risk:

- Do not operate MP3 players, Apple iPods and iPhones immediately next to or together with medical electrical devices.
- If the devices mentioned above must be operated next to or together with medical electrical devices, the medical electrical device should be observed in order to ensure its proper operation.

Do not use third-party accessories

The use of other accessories, including converters, adapters or cables, than those approved – except for the spare parts provided by the manufacturer for internal components – can result in increased emitted interference from the MP3 player, Apple iPod or iPhone. This interference can impact medical electrical devices and put important patient supply measures at risk:

- Use approved accessories (adapters, plugs, etc.) or accessories specified in Chapter 10.1, "General safety instructions", on Page 38 only.

Keep a distance from other electrical devices

The Navigator M6 can be influenced by the electromagnetic radiation of other electrical devices even if these comply with the emission requirements specified by the CISPR (International Special Committee on Radio Interference):

- Do not operate the Navigator M6 immediately next to or together with other electrical devices.
- If operation next to or together with other electrical devices is required, the Navigator M6 should be observed in order to ensure its proper operation.

2.7 Electromagnetic discharge

NOTICE

Do not touch plugs

Do not touch the pins of plugs marked with the ESD symbol with your fingers or handheld tools. Electrostatic discharge can cause the operator to suffer an electric shock or damage or even destroy microelectrical components.

Take the following protection measures:

- Do not touch the pins of the plugs in the docking station with your fingers or handheld tools.
- To earth your body, touch the Multi-Function Rack (MFR) or a metal part of the Navigator M6 once.
- Minimise the electrostatic discharge hazard through preventive measures (e.g. air conditioning, air humidification, conductive floor covering or non-synthetic clothes).

Train personnel

The operator should train all staff members exposed to the hazards mentioned above:

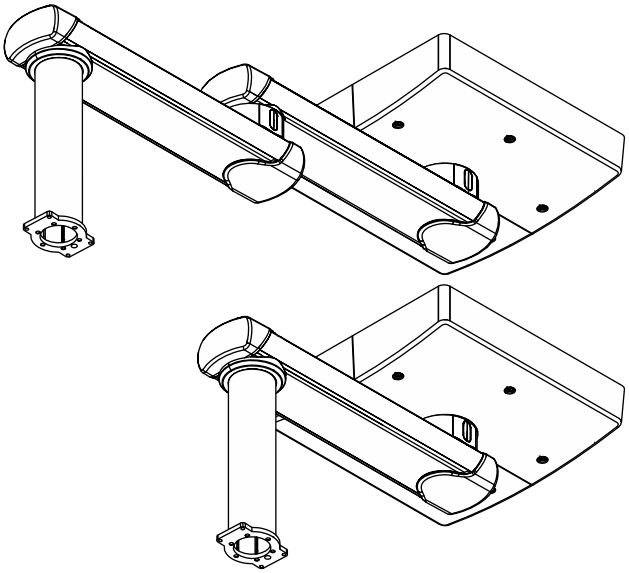
- Explain the ESD symbol;
- Explain potential electrostatic discharges and the potential destruction of microelectrical components by touching electrostatically charged operators;
- Explain the necessity of discharging one's own body prior to touching medical electrical devices;
- Explain and train ESD protective measures to avoid electrostatic discharge.

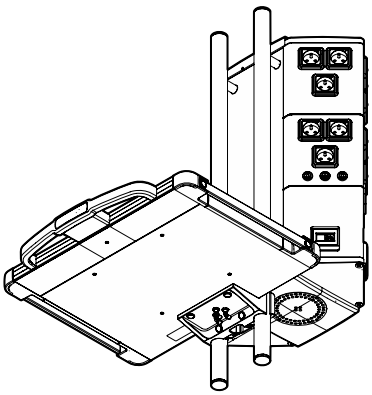
2.8 Disposal

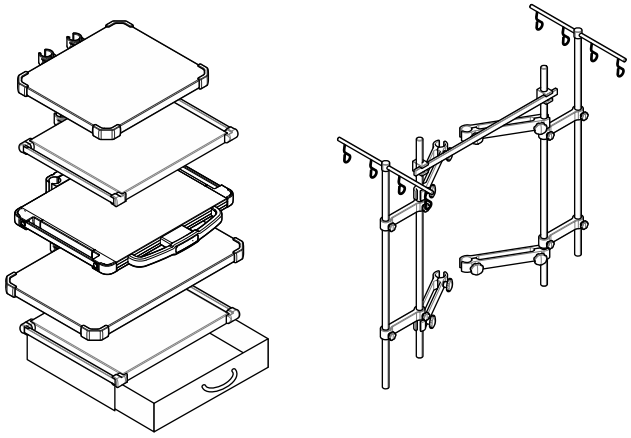
RoHS conformity

- The pendant system and the Navigator M6 comply with the requirements of the 2011/65/EC RoHS Directive (on the restricted use of certain hazardous substances in electrical and electronic equipment).
- To prevent environmental damage and personal injury, we therefore request you to contact us or your authorised service partner if you intend to take the pendant system and the Navigator M6 definitively out of operation for the purpose of disposal.
- The pendant system and the Navigator M6 must be disposed of at a suitable collection point for recyclable waste in accordance with country-specific regulations.

Figure 2: Overview of the structure of the Operating Instructions







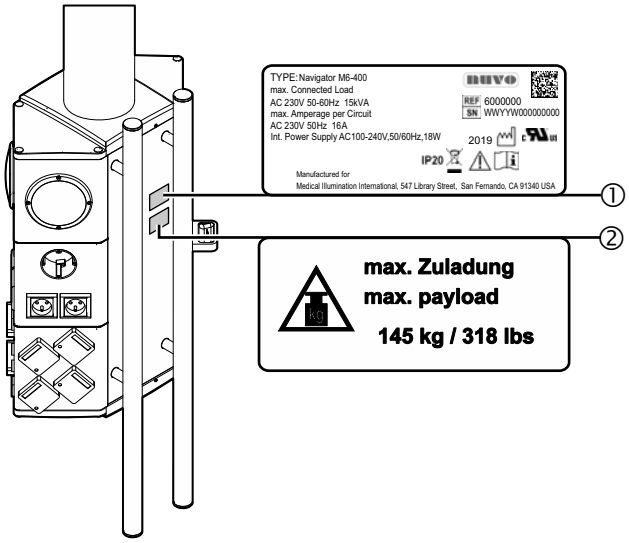
The Operating Instructions for the entire pendant system consist of separate documents. For this reason these Operating Instructions are only valid and complete if all the documents are available at the place of installation.
The following parts must be available:

Part 01: Pendant system (example of Navigator ™)

Part 02: Navigator M6
(Observe the Operating Instructions of the gas outlets installed – these Operating Instructions are included in the scope of delivery)

Part 03: Accessories approved for the Navigator M6

Figure 3: Position of the rating plate and the label



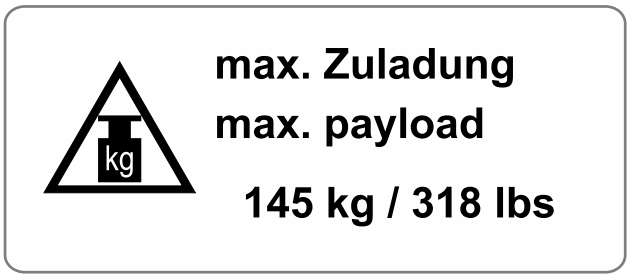
4.1 Position of the rating plate and the label

(See „Figure 3“)

- The Navigator M6 is provided with a label ② under the rating plate ① :

– The label ② indicates the maximum loading capacity (payload) approved for the specific Nuvo pendant system (see Chapter 4.2 on Page 24).

Figure 4: Label indicating the maximum loading capacity (payload)

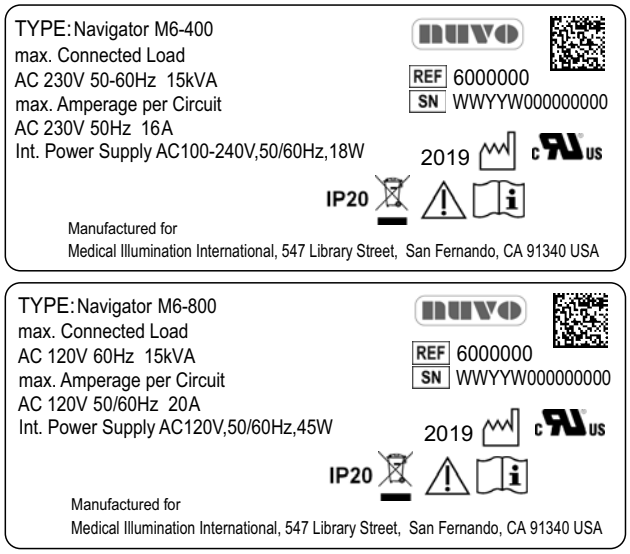


4.2 Label indicating the maximum loading capacity (payload) of the Navigator M6

(See „Figure 4“)

- The label shows the example of the Navigator M6 with a maximum loading capacity (payload) of 145 kg / 318 lbs
- If a Multi-Function Rack (MFR), an operator handle or a standard rail is mounted onto the Navigator M6, the dead weight of these components is already included.
  If accessories such as an operating shelf are mounted onto the Multi-Function Rack (MFR), the dead weight must be subtracted from the maximum loading capacity (payload), see Chapter 6.3, "Checking the maximum loading capacity (payload)", on Page 29.
- The information and illustrations serve as examples.

Figure 5: Rating plate with serial number and indication of the supply voltage



4.3 Information on the rating plate

(See „Figure 5“)

The rating plate is attached:

- to the front side of the Navigator M6.

Serial number

- The rating plate indicates the serial number (SN) of the Navigator M6.

Power supply

- The rating plate provides information on the power supply of the Navigator M6.

Date of manufacture

- The digits 1 to 4 of the serial number (SN) indicate the date of manufacture.
  - The first two digits indicate the week of manufacture, e.g. 15 = calendar week 15.
  - The following two digits indicate the year of manufacture, e.g. 14 = 2014.
  - The letter in the 5th position indicates the factory, e.g. H = Hünfeld.
  - The digits following the letter indicate the serial number.
- The information and illustrations serve as examples.
- The information and illustrations on the rating plate can vary. Rating plates without a file number under the UL symbol are approved for IEC 60601-1, second and / or third edition.

5.1 Device description

5.1.1 Positioning

Device description of the pendant system

The device description of the pendant system to which the Navigator M6 [1] is installed is part of the Operating Instructions included in the scope of delivery.

5.1.2 Multi-Function Rack (MFR), operating shelf and standard rail (optional)

Multi-Function Rack or standard rail side

An operating shelf [3] with control buttons and further accessories such as keyboard trays, drawers, desk tops, etc. can be installed on the Multi-Function Rack (MFR) [2] (Ø 38mm) (for a list of accessories approved for installation on the Navigator M6 [1] refer to Chapter 20, "Optional Accessories", on Page 58).

Standard rail

Additional accessories such as a holding clamp, hooks, etc. for attaching further medical devices can be mounted onto the standard rail [4] with control buttons (for a list of accessories approved for installation on the Navigator M6 [1] refer to Chapter 20, "Optional Accessories", on Page 58).

5.1.3 Power supply and gas outlets (optional)

Medical gas outlets and device sockets

The Navigator M6 [1] can be fitted with gas outlets, device sockets, equipotential bonding devices and other functions such as nurse call, computer interfaces, etc.

5.1.4 Sound system (optional)

Sound system

The sound system consists of the docking station [8] for external digital media players such as MP3 players, smartphones, Apple iPhones or Apple iPods, 4 loudspeakers [7] in the Navigator M6 [1] or 1 spherical ceiling loudspeaker (not illustrated).
It is operated via the software of the external media player, via the remote control unit [6] or directly via the docking station [8].

5.1.5 Lighting (optional)

Lighting system

The lighting system is available in 3 versions:

Indirect extension arm lighting (SurroundLED basic C, not illustrated) on the top extension arm (only pendant systems Navigator™ and Navigator Lift™).

The indirect Navigator M6 lighting [9] (SurroundLED basic F) at the bottom of the Navigator M6 [1] (only pendant systems Navigator™ and Navigator Lift™).

The combination of indirect extension arm and Navigator M6 lighting (SurroundLED advanced) (only pendant systems Navigator™ and Navigator Lift™).

5.1.6 Swivelling the pendant system and adjusting its height

Operating the pendant system

The pendant system is operated via the control buttons on the operating shelf [3], on the standard rail [4], on the operator handle [5] or directly on the Navigator M6 [1].

5.2 Functional description

5.2.1 Positioning

Functional description of the pendant system

The functional description of the pendant system to which the Navigator M6 [1] is installed is part of the Operating Instructions included in the scope of delivery.

5.2.2 Multi-Function Rack (MFR) and operating shelf (optional)

Multi-Function Rack (MFR)

The Multi-Function Rack (MFR) [2], the operating shelf [3] and the standard rail [4] serve for the connection of optional accessories.

Operating shelf

No medical end device (e.g. flat screen, etc.) can be installed on the operating shelf [3].

5.2.3 Power supply and gas outlets (optional)

Medical gas outlets and device sockets

The gas outlets serve for extracting medical gases. The device sockets serve for the power supply of medical end devices (e.g. flat screen, etc.) (see Chapter 9.5 on Page 37).

Nurse call, computer interfaces, etc.

For more detailed information on the functions and operation of additional accessories, e.g. nurse call, computer interfaces, etc., refer to the Operating Instructions of the corresponding manufacturer.

5.2.4 Sound system (optional)

External digital media players

External digital media players such as MP3 players, iPods or iPhones are connected to the docking station [8]. The music playing functions are operated directly via the docking station [8] or the remote control unit [6] (see Chapter 10.1 on Page 38).

5.2.5 Lighting (optional)

Lighting system

Depending on the variant, the lighting system is operated via the rotary dimmer switch with luminous display [10] or the ON/OFF switch [11]:

The indirect extension arm lighting (SurroundLED basic C, not illustrated) is switched ON and OFF via the ON/OFF switch [11].

The indirect Navigator M6 lighting [9] (SurroundLED basic F, not illustrated) is switched ON and OFF via the ON/OFF switch [11].

If the 2 systems (SurroundLED advanced) are combined, the lighting is controlled via 1 rotary dimmer switch with luminous display [10] each per variant.

Indicator lamps on the luminous display

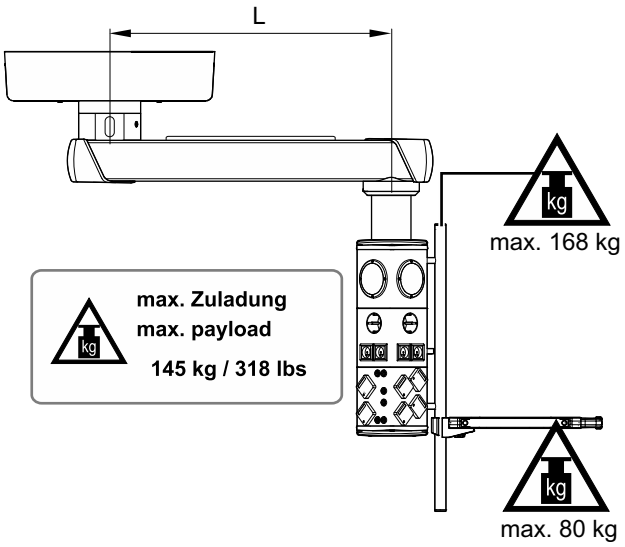
Whilst the lighting is switched on, the corresponding lamp for the extension arm lighting, the Navigator M6 lighting [9] or both indicator lamps light up on the rotary dimmer switch with luminous display [10] (see Chapter Figure 20: on Page 42).

5.2.6 Swivelling the pendant system and adjusting its height

Control buttons for operating the pendant system

2 brake buttons for operating the pneumatic or electromagnetic brakes on the pendant system (see Chapter 9.2 on Page 33) and 1 UP/DOWN button for the motor-powered height adjustment of the pendant systems Navigator Lift ™ 150 / 250 and MMP 90 / 200 (see Chapter 9.3 on Page 35) are located on the operating shelf [3], the standard rail [4], the operator handle [5] or directly on the Navigator M6 [1].

Figure 6: What is the maximum loading capacity (payload)?



6.1 What is the maximum loading capacity (payload)?

(See „Figure 6“)

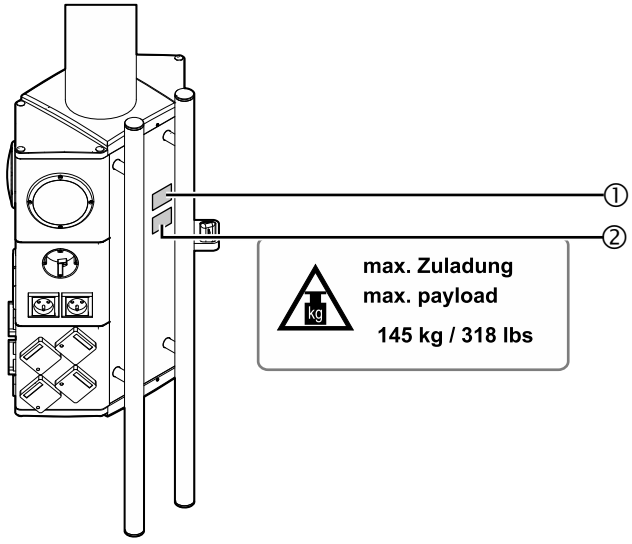
The maximum loading capacity (payload) corresponds to the total weight of all end devices, accessories, etc. which you have fixedly attached or placed onto the Navigator M6 (e.g.: operating shelf, shelf, flat screen, infusions, etc.). A sample calculation is available in Chapter 6.3 on Page 29.

The maximum permissible load bearing capacity on the extension arm differs for the various extension arm lengths "L" of the pendant system. This is why the maximum loading capacity (payload) indicated on the Navigator M6 is specifically adapted to the pendant system to which the Navigator M6 is installed.
In this example, the maximum loading capacity (payload) is 145kg / 318lbs.

The maximum loading capacity (payload) indicated on the Navigator M6 includes the dead weight of the basic equipment (e.g. Drop tube, Navigator M6 and pre-assembled Multi-Function Rack (MFR), the operator handle and the standard rail).

Independently of the maximum loading capacity (payload) indicated on the label, optional accessories may only be loaded with the maximum weight specified in Chapter 20, "Optional Accessories", on Page 58.

Figure 7: Reading and checking the maximum loading capacity (payload)



6.2 Reading the maximum loading capacity (payload)

(See „Figure 7“)

The label ② indicating the maximum loading capacity is attached below the rating plate ① on the Navigator M6.

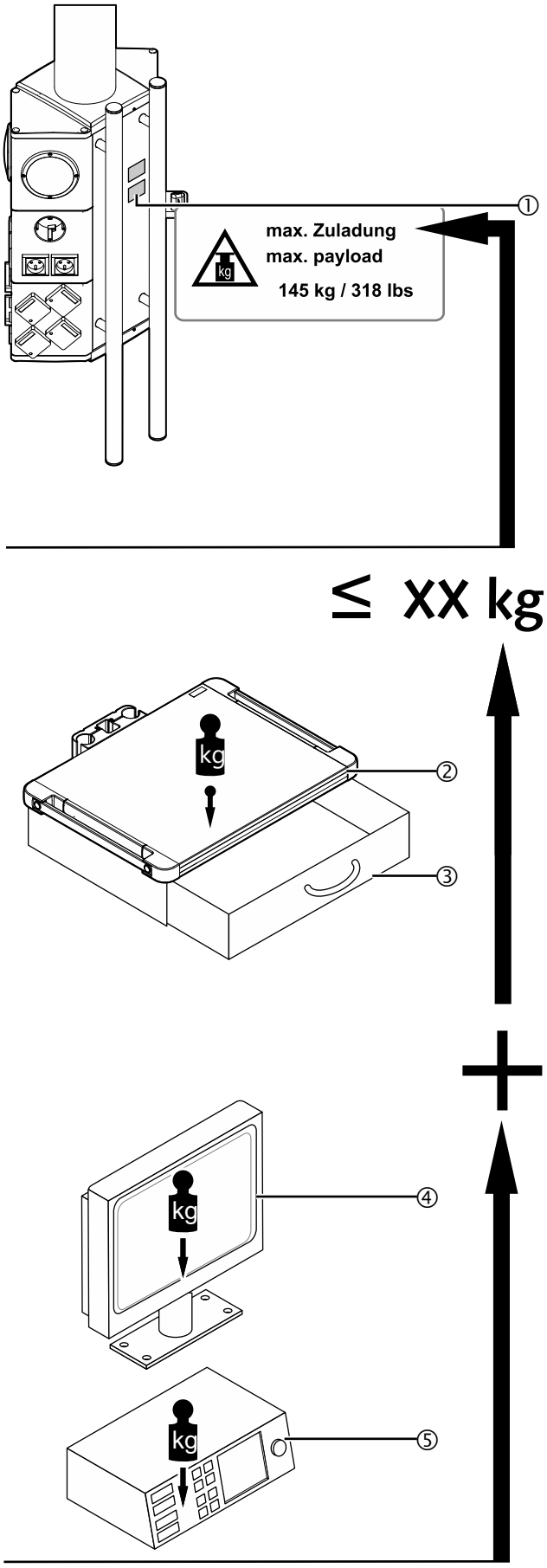
⚠WARNING

The pendant system and the Navigator M6 can drop if the maximum loading capacity (payload) is exceeded

If the maximum permissible loading capacity (maximum payload) has been exceeded, there is a risk that the pendant system, the Navigator M6 or components of the pendant system may disengage from the fastening device and drop:

- The total weight of the fixedly attached or placed end devices, accessories, etc. must not exceed the maximum permissible loading capacity (payload) indicated on the label ②.
- If additional accessories are installed, such as a shelf, the dead weight of the shelf (see Chapter 20, "Optional Accessories", on Page 58) must be subtracted from the maximum loading capacity (payload).
- Check the maximum loading capacity (payload) specified in Chapter 6.3 on Page 29.

Figure 8: Checking the maximum loading capacity (payload)



6.3 Checking the maximum loading capacity (payload)

(See „Figure 8“)

The Figure shows the example of the Navigator M6 with a pre-assembled Multi-Function Rack (MFR).
The label ① indicates a maximum loading capacity (payload) of 145kg for this configuration. If additional accessory components are mounted, their weight must not exceed the weight indicated on the label ①. Check this by means of the following sample calculation:

1. Add the weight of all the accessories (e.g. shelf) and end devices (e.g. flat screen, etc.), other accessory components, etc. installed by you.
- The dead weight of the optional accessories is indicated in Chapter 20, "Optional Accessories", on Page 58.

2. Compare the sums of the weights with the maximum loading capacity (payload) indicated on the label ①.

å The total weight of the fixedly attached or placed end devices, accessories, etc. must not exceed the maximum permissible loading capacity (payload) indicated on the label ①.

6.3.1 Configuration example

(See „Figure 8“)

- For this example the maximum loading capacity (payload) indicated on the label ① is 145kg / 318lbs.
- Dead weight of the additional standard shelf, 520mm large, with standard rail and drawer ② = 9.5kg
- Dead weight of the drawer, Single ③ = 10.9kg
- Dead weight of the flat screen ④ = 12.5kg
- Dead weight of the medical device ⑤ = 34.5kg

6.3.2 Calculation of the maximum loading capacity

(See „Figure 8“)

- Maximum loading capacity (payload) = 145kg – (9.5kg + 10.9kg + 12.5kg + 34.5kg) = 77.6kg (residual loading capacity).

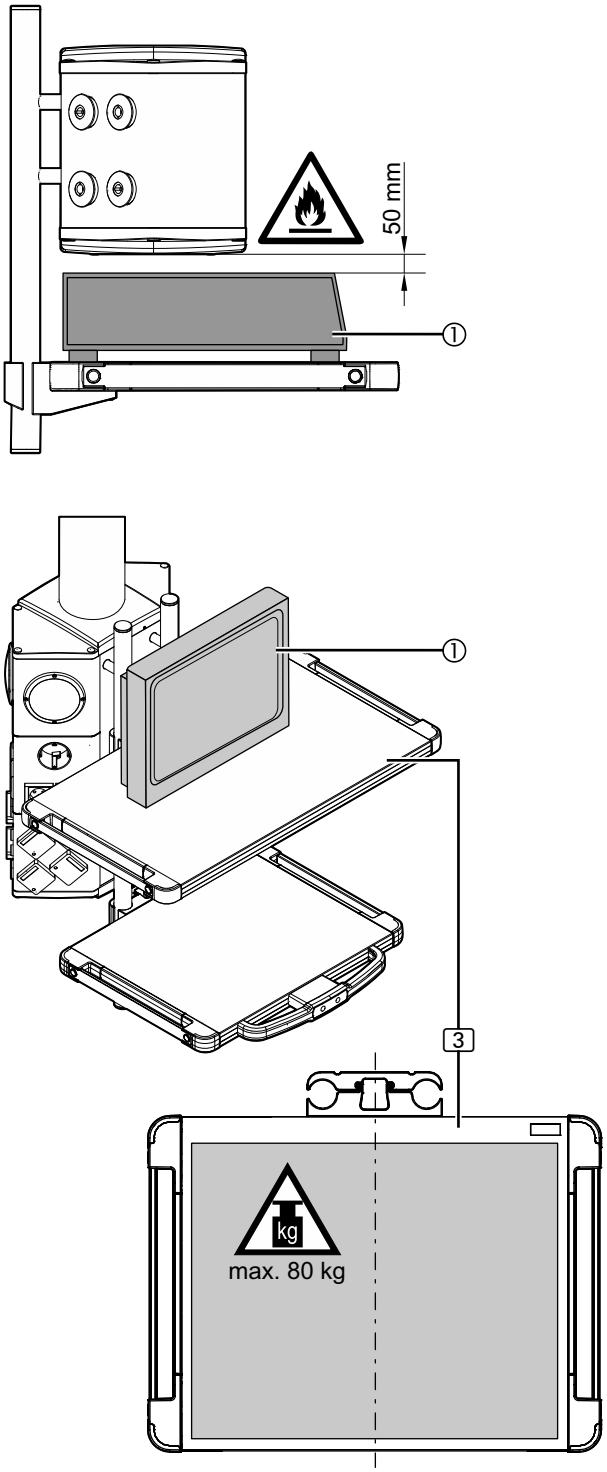
6.3.3 Evaluation

- The maximum loading capacity (payload) indicated on the Navigator M6 is 145kg.
- The calculated weight of the additionally installed components is 67.4kg.
- The maximum loading capacity (payload) of 145kg is observed.

6.3.4 Observing the maximum loading capacity (payload) of individual components

- Independently of the maximum loading capacity (payload) indicated on the label, optional accessories may only be loaded with the maximum weight specified in Chapter 20, "Optional Accessories", on Page 58.

Figure 9: Installing Optional End Devices onto the Shelf



(See „Figure 9“)

NOTE – Qualified personnel required

An end device may only be mounted by a qualified hospital technician or the operator's specialist personnel with equivalent qualification.

⚠WARNING

Danger of fire

Escaping oxygen is combustible. If the air vents at the bottom of the Navigator M6 are covered, there is a risk of oxygen enrichment in the Navigator M6 in case of failure of optional oxygen hoses:

- Make sure the air vents are not covered.
- Attachments to the bottom of the Navigator M6 must be installed at a minimum distance of 50 mm from the ventilation slots.

⚠WARNING

Risk of the shelf dropping because the maximum loading capacity (payload) has been exceeded

If the shelf is loaded with more than 80 kg, it can drop and cause injury:

- The maximum loading capacity (payload) of 80 kg must be observed.

1. Make sure you only drill holes for the end device (e.g. flat screen, etc.) ① into the shelf [3] in the area highlighted in grey in the Figure.
2. Screw in the fastening screws to securely fasten the end device (e.g. flat screen, etc.) ① on the shelf [3] in such a way that it cannot fall off.

Initial commissioning

1. The Navigator M6 must be properly installed. Instructions for installation are included in the scope of delivery of the product.
2. For start-up following installation, proper initial commissioning must be carried out for the entire pendant system and the Navigator M6.

Functional test

Prior to using the pendant system and the Navigator M6 on a patient for the first time, a functional test must be performed at the installation site. This functional test must be carried out by the operator or a person authorised by the operator, and the persons authorised by the operator must be duly instructed.
This requirement is considered fulfilled if:

1. The functional reliability of the pendant system and the Navigator M6 has been ensured.
2. The maximum permissible loading capacity (payload) has been safely determined and is indicated on a label attached to the Navigator M6.
3. The proper functioning of the device has been approved by the operator during initial commissioning and documented by signing a test report in accordance with Appendix G DIN EN 62353.

The following points must be observed during handover to the operator:

1. The pendant system and the Navigator M6 must not be handed over to the operator until they have been tested.
2. Handover must be documented in writing including confirmation by the operator.
3. On handover, the operator must be instructed in the functioning and effect of the maximum loading capacity (payload).
4. In addition, the operator must be instructed in the functioning, operation, cleaning and disinfection of the pendant system and the Navigator M6.
5. Furthermore, on handover, the operator must be instructed in the adjustments permitted according to the Operating Instructions included in the scope of delivery.
6. On completion of the instruction, an instruction certificate must be created and signed in order to document that the operator/user has understood the special operator control actions required for normal use.

9.1 General safety instructions

⚠WARNING

Risk of injury when lowering the Navigator M6 close to the patient:

When lowering the Navigator M6 above or close to the patient, there is a risk of the patient suffering bruises or severe injury by the Navigator M6 or accessories mounted onto it:

- When lowering the Navigator M6, make sure that the Navigator M6 and any accessories mounted onto it (e.g. infusion poles mounted on the side) do not cause bruising to the patient.
- Keep a safety distance of at least 50cm between the Navigator M6 and accessories mounted to it and the patient.

Risk of injury when swivelling the Navigator M6 close to the patient:

If the Navigator M6 is swivelled close to the patient, there is a risk of end devices or accessories dropping and hurting the patient:

- Do not swivel the Navigator M6 and any accessories mounted onto the Navigator M6 above or close to the patient.

Risk of patient supply cables tearing off

When swivelling the Navigator M6 and adjusting its height, patient supply cables can tear off on the patient or medical device side and important patient care systems can fail:

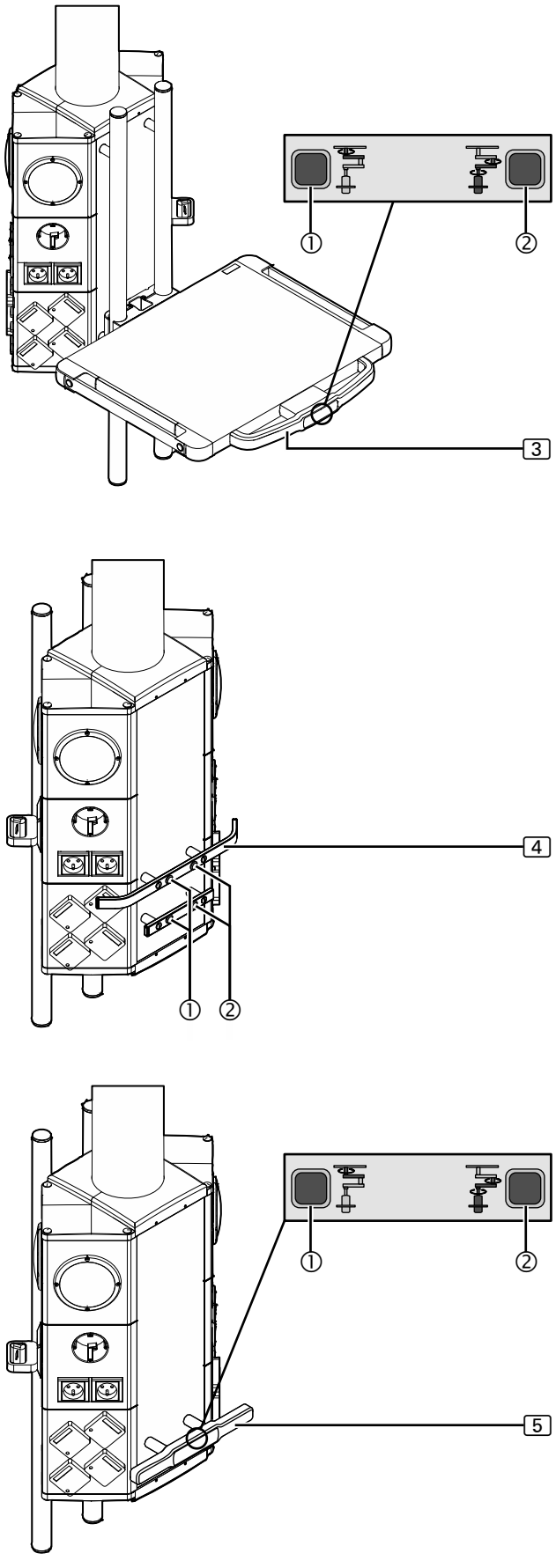
- Before swivelling the Navigator M6 and adjusting its height, check the length of the supply cables on the patient and on medical devices.
- Check the swivel range and vertical lift for obstacles.
- Make sure you swivel the Navigator M6 slowly and adjust its height with care in the area of the supply lines connected to the patient.

Collision damage

In case of collision with other devices, walls or ceilings, the Navigator M6 or components of the pendant system can be damaged and important patient care systems can fail:

- After a collision, the Navigator M6 and the pendant system must be inspected for damage.
- In case of doubt, contact your supplier.

Figure 10: Releasing the brakes and swivelling the Navigator M6



9.2 Releasing the brakes and swivelling the Navigator M6

(See „Figure 10“)

The optional brake buttons ① / ② are located on the operating shelf [3], the standard rail [4], the operator handle [5] or directly on the Navigator M6.

The brake buttons ① / ② are highlighted with different colours. To release the pneumatic or electromagnetic brakes on the pendant system, press the corresponding brake button ① / ②:

- Brake ① = Green brake button for the upper bearing/rotating point,
- Brake(s) ② = Blue brake button for the lower bearing/rotating point and optionally for the Navigator M6.

9.2.1 Releasing the pneumatic or electromagnetic brakes

(See „Figure 10“)

NOTICE

Damage to the pendant system

To prevent damage to the pendant system:

- Prior to swivelling, release the brakes on the pendant system.
- Do not hit the end stops of the pendant system hard.
- Avoid collisions of the pendant system with other components.

Damage to the electromagnetic brakes

Duty cycle of the electromagnetic brakes

- The maximum duty cycle of the electromagnetic brakes must not exceed 1 minute.
- If the electromagnetic brakes are actuated over a longer period of time, the power pack may switch off automatically as a protection measure against overheating.

NOTE – How to proceed after the power pack has switched off

Once the power pack has switched off, it must cool down for 10 minutes and then be disconnected from the mains for 10 seconds before being switched back on again. Normal system operation can only be resumed afterwards.
To prevent a safety cutoff, the maximum duty cycle should not be exceeded.

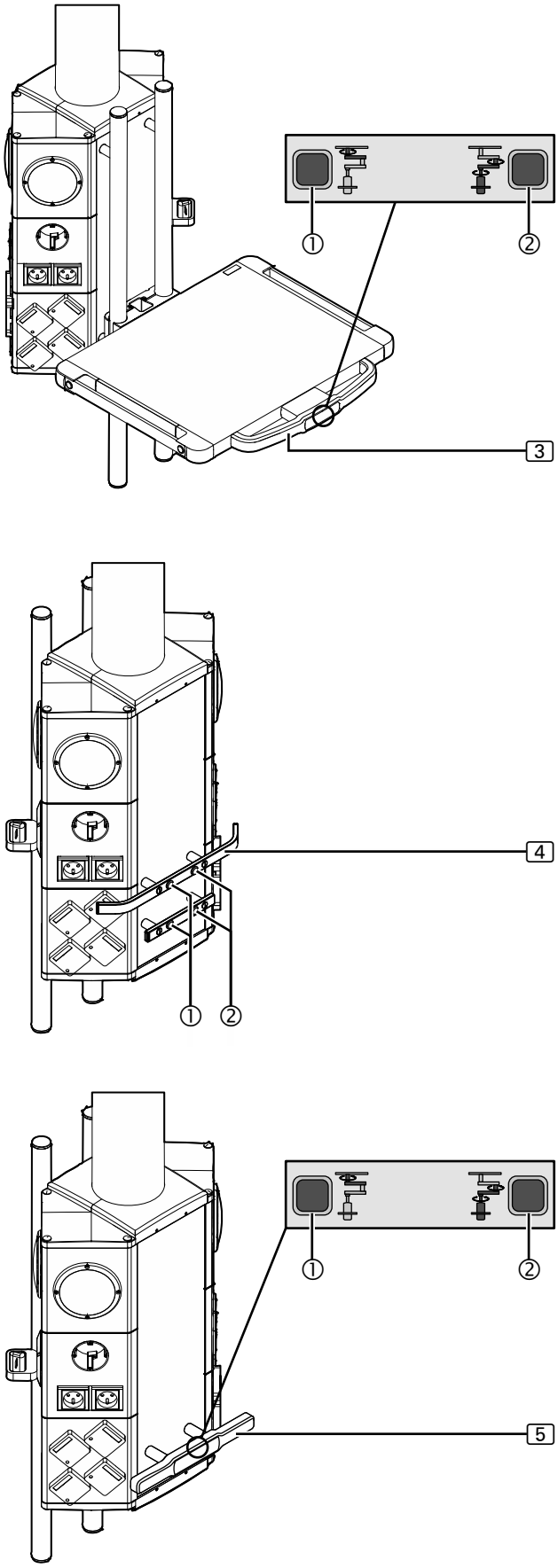
1. To release the pneumatic or electromagnetic brakes, press the brake buttons ① / ②.

å A hissing noise can be heard when the pneumatic brakes on the pendant system are released.

å A single click can be heard when the electromagnetic brake is released and an optical feedback takes place on the bearing points (optional).

Continuation on the next page.

Abbildung 10: Releasing the brakes and swivelling the Navigator M6



9.2.2 Swivelling the Navigator M6

(See „Figure 10“)

1. Follow the safety instructions in Chapter 9.1 on Page 32.

2. Be careful when swivelling the Navigator M6.

å The swivel range ends at the internal end stops of the pendant system.

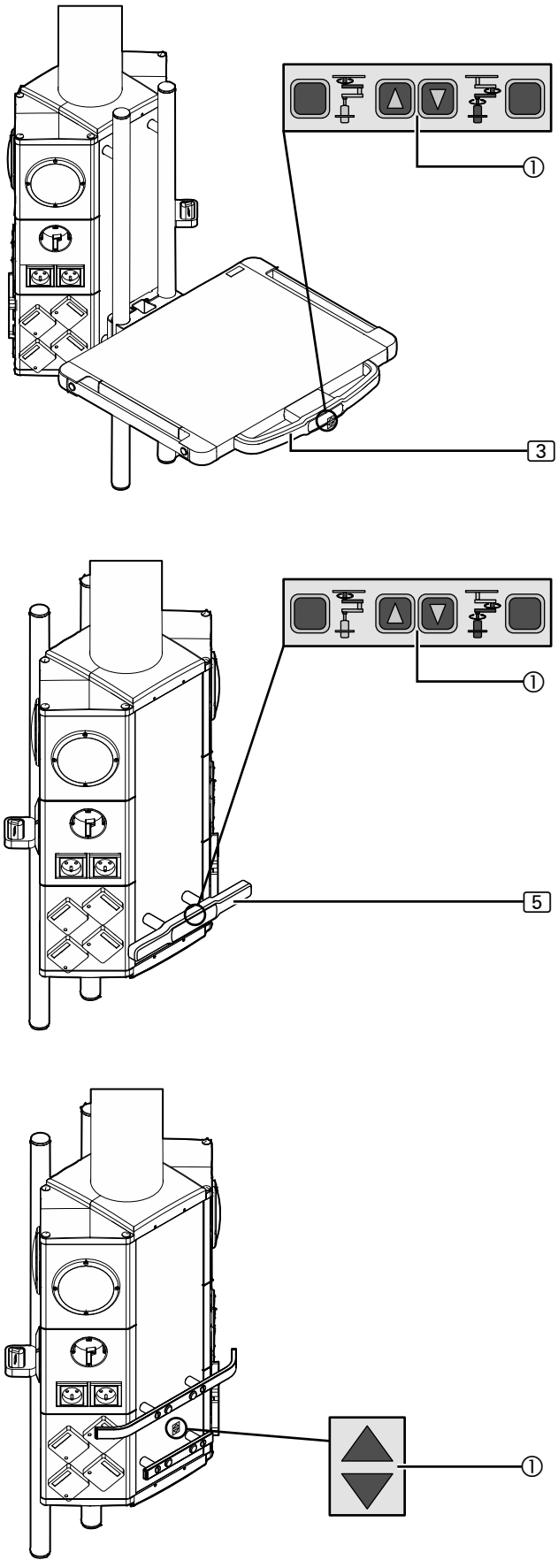
9.2.3 Engaging the pneumatic or electromagnetic brakes

(See „Figure 10“)

- Release the brake buttons ① / ② as soon as the Navigator M6 [1] has been swivelled to the desired position.

å The brakes on the pendant system hold the system in the selected position.

Figure 11: Adjusting the height of the Navigator M6



9.3 Adjusting the height of the Navigator M6

(See „Figure 11“)

The optional UP/DOWN button ① is located on the operating shelf [3], on the operator handle [5] or directly on the Navigator M6.

1. Follow the safety instructions in Chapter 9.1 on Page 32.

NOTICE

Damage to the pendant system (types Navigator Lift ™ 150 / 250 and MMP 90 / 200 only)

The maximum duty cycle of the height adjustment mechanism must not exceed 3 minutes. If the height adjustment mechanism is actuated over a longer period of time, the electric motor may switch off automatically as a protection measure against overheating.

- The maximum duty cycle of 3 minutes must not be exceeded.
- In order to prevent an overload of the electric motor, make sure you wait at least 30 minutes after actuating the height adjustment mechanism before putting the height adjustment mechanism back into operation.
- Afterwards the height adjustment mechanism can be operated once again for 3 minutes.

Operating the pendant systems Navigator Lift ™ 150 / 250 and MMP 90 / 200

2. Press the UP/DOWN button ① to gently adjust the height of the Navigator M6.

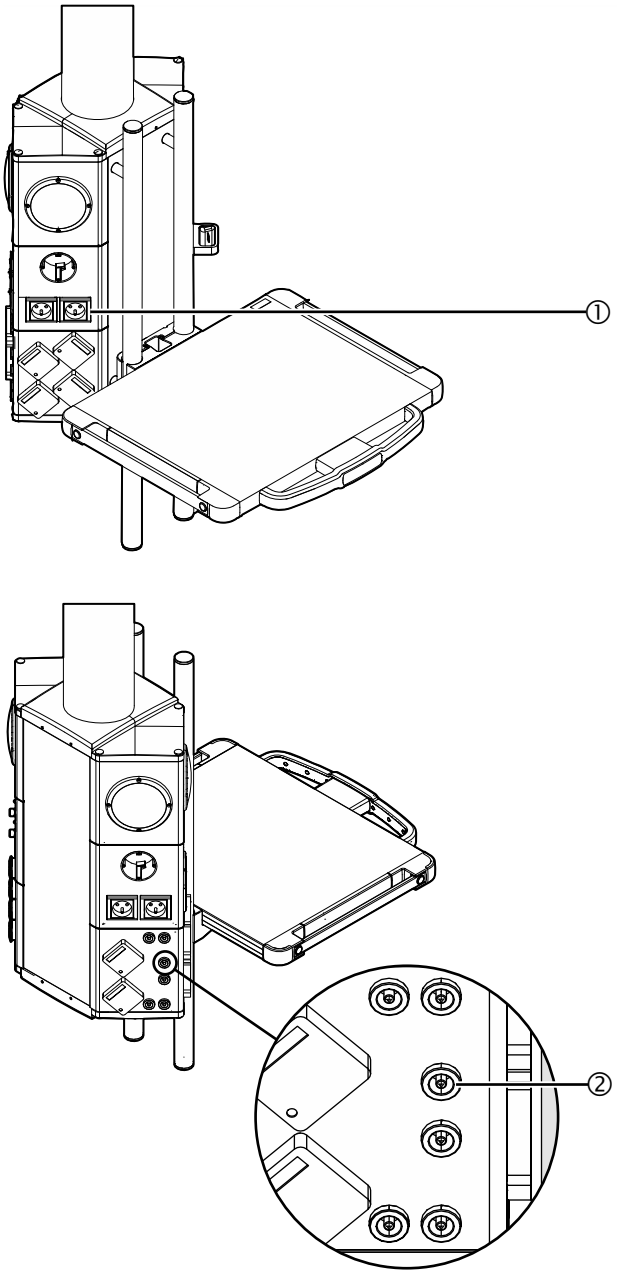
å The height adjustment ends at the internal end stops of the pendant system.

Operation on the spring-operated Navigator Lift ™ 180, MMP 85 S and on the spring arm SpacePort®

3. Gently adjust the height of the Navigator M6 manually.

å The height adjustment ends at the internal end stops of the pendant system.

Figure 12: Connecting the power supply of medical end devices



9.4 Connecting/disconnecting the power supply of medical end devices

(See „Figure 12“)

The Navigator M6 can be equipped with power sockets for the supply of medical electrical devices.
The Figure illustrates an example of the Navigator M6 equipped with sockets.

9.4.1 Mains connection

(See „Figure 12“)

NOTE – Emergency power supply

The sockets ① on the Navigator M6 are assigned to separately fused electric circuits:

- The assignment of a socket ① to an electric circuit is indicated on the interior of the socket ① lid. The electric circuits are marked with 1, 2, etc.
- In case of failure of an electric circuit, the other electric circuits remain functional if they are connected to the mains; the mains supply can be re-established by plugging the plugs into the corresponding socket ①.

⚠WARNING

Power supply failure when using multiple socket outlets

The use of multiple socket outlets can result in an overload and disconnection of an electric circuit:

- To ensure the failure safety of the power supply, multiple socket outlets must not be used.

1. Open the socket lid ① and read the electric circuit marking 1, 2, etc.
2. Insert the mains plug of the end device (e.g. flat screen, etc.) into the socket ①.

⚠WARNING

Electric shock due to missing earthing

A non-earthed end device (e.g. flat screen, etc.) can, if defective, expose a patient / operator to a risk of danger to life from electric shock.

- Make sure you always earth the end device (e.g. flat screen, etc.) on an equipotential bonding socket ② of the Navigator M6.

1. Connect the equipotential bonding socket of the end device (e.g. flat screen, etc.) to an equipotential bonding socket ② of the Navigator M6 using the equipotential bonding cable.
2. Check that the assembly connection is securely in place.

Continuation on the next page.

Figure 13: Disconnecting the power supply of medical end devices

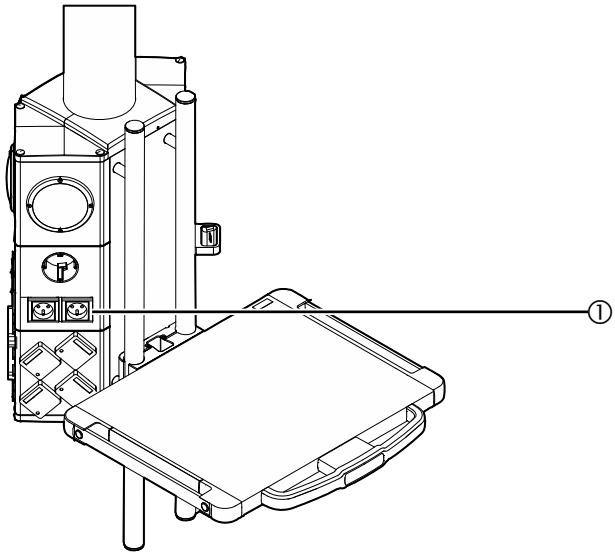
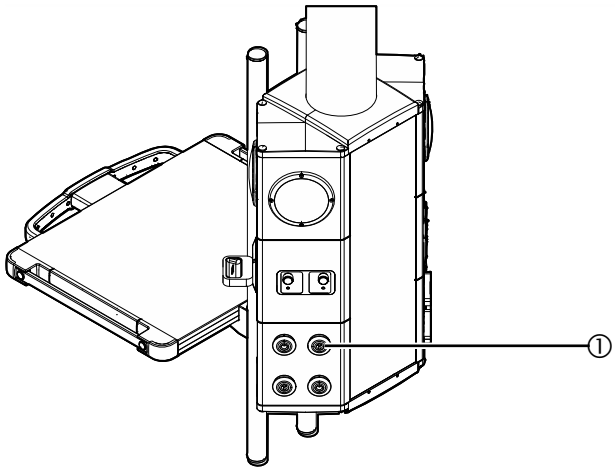


Figure 14: Connecting / disconnecting the gas supply



9.4.2 Disconnecting the power supply

(See „Figure 13“)

The Figure illustrates an example of the Navigator M6 equipped with sockets.

NOTICE

Damage to the mains plug and the mains cable

Do not pull the mains cable to withdraw the mains plug of the end device (e.g. flat screen, etc.) from the socket ① :

- Hold your hand against the socket ① and then pull out the mains plug.

1. Hold your hand against the socket ①.
2. Hold the mains plug to pull it out of the socket ①.

9.5 Connecting / disconnecting the gas supply

(See „Figure 14“)

The Navigator M6 can be equipped with gas sockets for the supply of medical electrical devices. The Figure illustrates an example of the Navigator M6 equipped with gas outlet sockets.

⚠ DANGER

Oxygen explosion

Oxygen becomes explosive when in contact with oil, grease and lubricants. Compressed oxygen presents an explosion hazard:

- Make sure that the oxygen and gas outlet points are free from oily, greasy and lubricating materials!
- Do not use any cleaning agents containing oil, grease or lubricants.

Danger of fire

Escaping oxygen is combustible:

- Open fires, red hot objects and naked flames are not permitted when working with oxygen!
- Do not smoke!

NOTE – Observe the separate Operating Instructions

For the operation of the gas outlets ① and the anaesthetic gas suction device, read the Operating Instructions provided by the corresponding third-party manufacturer.

10.1 General safety instructions

⚠WARNING

Failure of medical devices

Portable and mobile high-frequency communication devices (e.g. MP3 players, Apple iPods and iPhones) can interfere with medical electrical devices or their displays and put essential patient supply measures at risk:

- Do not operate MP3 players, Apple iPods and iPhones immediately next to or together with medical electrical devices.
- If the devices mentioned above must be operated next to or together with medical electrical devices, the medical electrical device should be observed in order to ensure its proper operation.

Do not use third-party accessories

The use of other accessories, including converters, adapters or cables, than those approved – except for the spare parts provided by the manufacturer for internal components – can result in increased emitted interference from the MP3 player, Apple iPod or iPhone. This interference can impact medical electrical devices and put important patient supply measures at risk:

- Use approved accessories (adapters, plugs, etc.) or accessories specified in Chapter 10.1, "General safety instructions", on Page 38 only.

Keep a distance from other electrical devices

The Navigator M6 can be influenced by the electromagnetic radiation of other electrical devices even if these comply with the emission requirements specified by the CISPR (International Special Committee on Radio Interference):

- Do not operate the Navigator M6 immediately next to or together with other electrical devices.
- If operation next to or together with other electrical devices is required, the Navigator M6 should be observed in order to ensure its proper operation.

Do not touch plugs

Do not touch the pins of plugs marked with the ESD symbol with your fingers or handheld tools. Electric discharge can cause the operator to suffer an electric shock or damage or even destroy microelectrical components. Take the following protection measures:

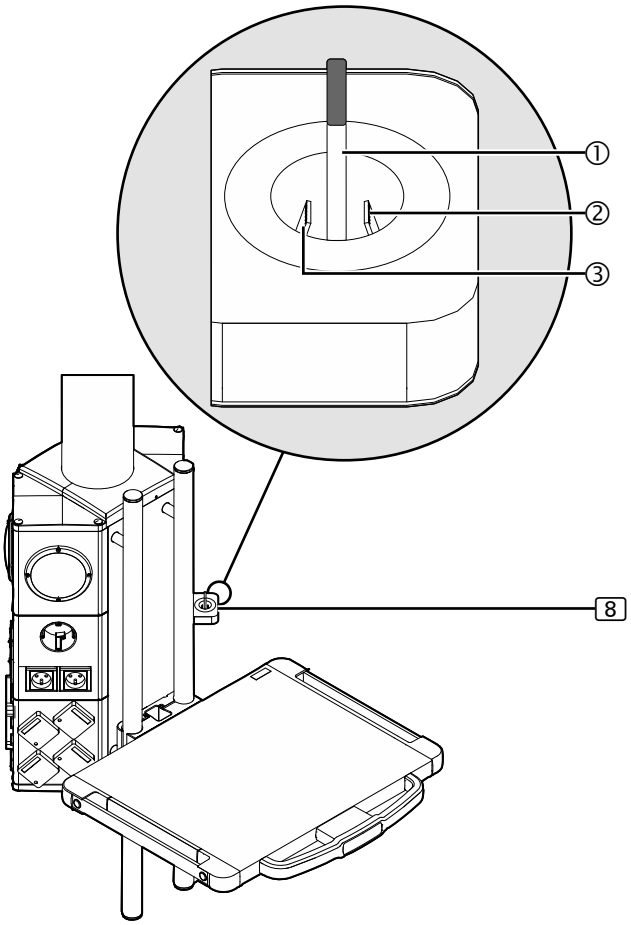
- Do not touch the pins of the plugs in the docking station with your fingers or handheld tools.
- To earth your body, touch the Multi-Function Rack (MFR) or a metal part of the Navigator M6 once.
- Minimise the electrostatic discharge hazard through preventive measures (e.g. air conditioning, air humidification, conductive floor covering or non-synthetic clothes).

Failure of medical devices

Portable and mobile high-frequency communication equipment (e.g. MP3 players, Apple iPods and iPhones) can interfere with medical electrical devices or indicators and put essential patient supply measures at risk:

- Switch your iPhone to flight mode to disable the RF transmitter.

Figure 15: MediSound-System Bluetooth



10.2 Operating the MediSound-System Bluetooth

(See „Figure 15“)

To activate the optional MediSound-System Bluetooth, connect an external media player to one of the 3 interfaces of the docking station [8] (e.g. MP3 players, smartphones, Apple iPhones or Apple iPods, not included in the scope of delivery).

The following 3 interfaces are available:
- Bluetooth receiver ①
- Lightning connector ②
- Micro USB plug ③

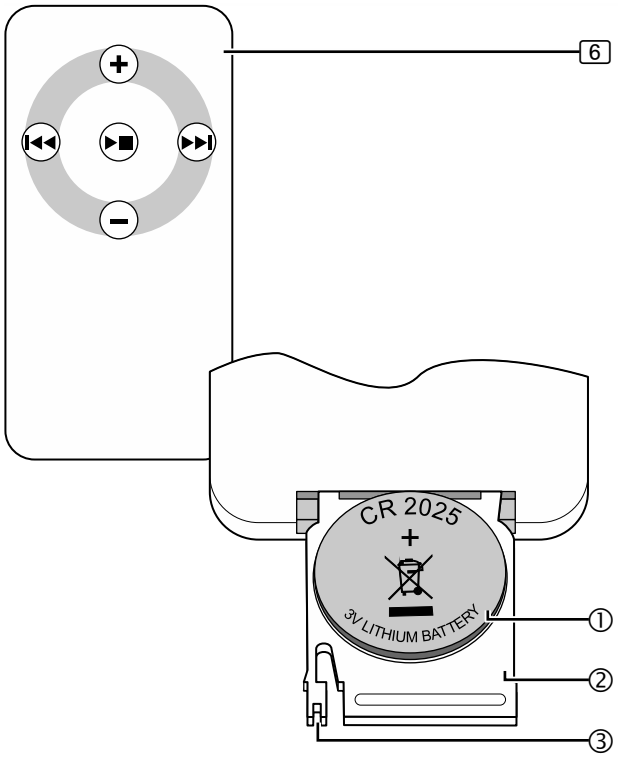
10.2.1 Using special adapters

1. Follow the safety instructions in Chapter 10.1 on Page 38.
2. To connect the external media players to the interfaces ①/②, use the adapters and cables provided by the manufacturer (not illustrated).

10.2.2 Operation

1. Switch your external media player to flight mode.
- For more detailed information on how to switch to flight mode, refer to the Operating Instructions of your external media player.
2. Operation is performed via the software of the external media player.

Figure 16: Removing the protective film of the battery of the remote control unit / Replacing the battery



10.3 Operating the MediSound-System Interface

10.3.1 Removing the protective film of the battery of the remote control unit

(See „Figure 16“)

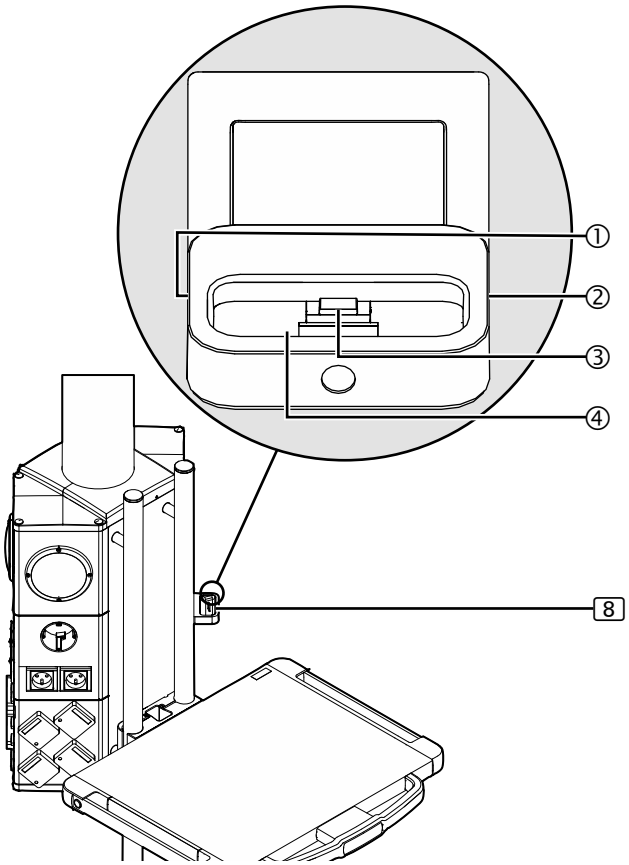
1. Push the unlocking mechanism ③ on the rear of the remote control unit [6] slightly towards the right and then remove the battery compartment ② from the remote control unit [6].
2. Remove the battery ① from the battery compartment ② and then remove the protective film underneath (not illustrated).
3. Place the new battery ① into the battery compartment ② as illustrated in the Figure and then push the battery compartment ② back into the remote control unit [6] until it audibly snaps into place.

10.3.2 Replacing the battery

(See „Figure 16“)

1. Push the unlocking mechanism ③ on the rear of the remote control unit [6] slightly towards the right and then remove the battery compartment ② from the remote control unit [6].
2. Remove the battery ① (type: CR 2025 / 3Volt) as illustrated in the Figure and place the new battery ① into the battery compartment ②.
3. Push the battery compartment ② into the remote control unit [6] until it audibly snaps into place.
- Dispose of the old battery ① in compliance with statutory requirements.

Figure 17: Interfaces for external digital media players on the docking station



10.3.3 Interfaces for external digital media players

(See „Figure 17“)

To activate the optional sound system, connect a digital media player to one of the 2 interfaces on the docking station [8] (e.g. MP3 players, Apple iPhones or Apple iPods, not included in the scope of delivery).

The following 2 interfaces are available:

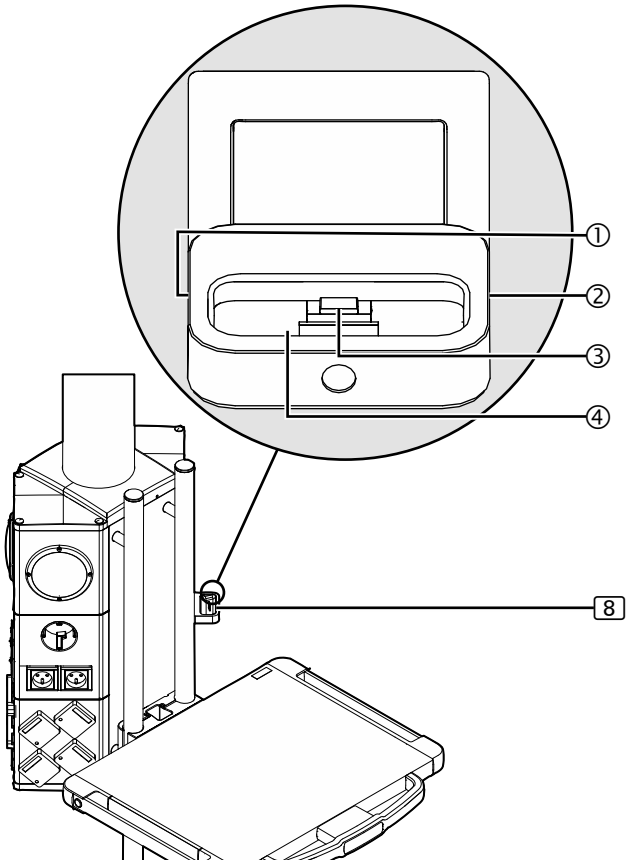
- For MP3 players:
  - An AUX 3.5mm stereo mini jack ② on the right-hand side for playing music data via the headphone output and
  - A mini USB socket (type B) ① on the left-hand side for the power supply of the external digital media player.

- For Apple iPods and iPhones:
  - An Apple interface (30-pole docking connector) ③ in the centre for transferring music data and supplying your Apple device with electric power.

Adapter for different dimensions

- Use the adapters provided by Apple (not illustrated) in order to insert Apple iPhones or Apple iPods of different dimensions into the pick-up device ④.

Figure 18: Connecting a digital media player



10.3.4 Connecting a digital media player

(See „Figure 18“)

Follow the safety instructions in Chapter 10.1 on Page 38.

For MP3 players

1. Connect your MP3 player to the AUX 3.5mm stereo mini jack ② on the right-hand side in order to play music data or
2. Connect your MP3 player to the mini USB socket (type B) ① on the left-hand side for power supply (for devices equipped with a corresponding connector).

- For more detailed information on the different connection options of your MP3 player refer to the Operating Instructions of the manufacturer.

For Apple iPods and iPhones

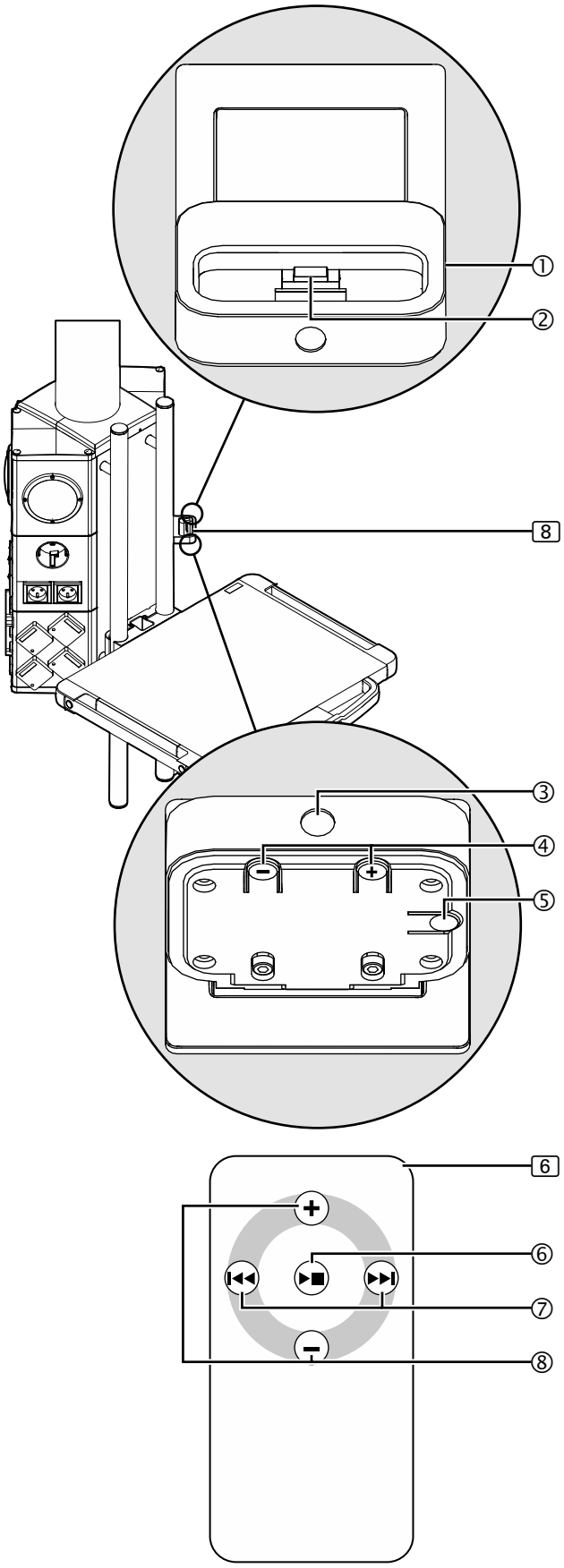
1. If available, engage the adapters provided by Apple (not illustrated) into the pick-up device ④ in order to ensure that the player is securely in place.

2. Switch your Apple iPhone to flight mode.

- For more detailed information on how to switch to flight mode, refer to the Operating Instructions of your iPhone.

3. Place your Apple iPod or iPhone in the centre of the Apple interface (30-pole docking connector) ③ to transfer music data and supply your Apple device with electric power.

Figure 19: Select the audio source (interface) at the bottom of the docking station and then select the music functions



10.3.5 Selecting the audio source (interface) at the bottom of the docking station

(See „Figure 19“)

Button ⑤ = switching between the 2 interfaces
- AUX 3.5mm stereo mini jack ① or
- Apple interface (30-pole docking connector) ②.

Luminous display ③ = indicates the interface selected
- The green indicator lamp on the luminous display ③ goes out if the Apple interface ② is selected.
- The green indicator lamp on the luminous display ③ lights up if the AUX interface ① is selected.

10.3.6 Operating the music functions

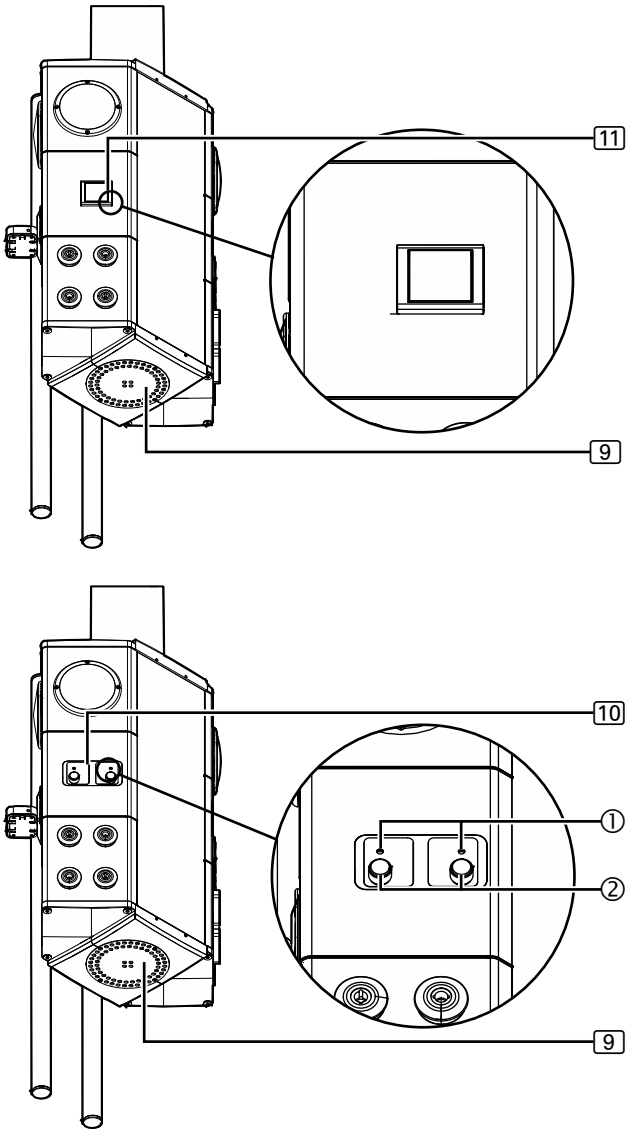
(See „Figure 19“)

For external digital media players on any interface:
- At the bottom of the docking station 8
  - Buttons ④ = Sound level + / –

- On the remote control unit 6
  - Buttons ⑧ = Sound level + / –

For external digital media players on the Apple interface ③:
- On the remote control unit 6
  - Button ⑥ = Start / Stop
  - Buttons ⑦ = Backwards / Forwards
  - Buttons ⑧ = Sound level + / –

Figure 20: Operating the lighting system



(See „Figure 20“)

The lighting system of the Navigator M6 is available in 3 variants:

1. Indirect lighting (SurroundLED basic C) on the top extension arm (not illustrated – see Operating Instructions of the pendant system)
2. Indirect Navigator M6 lighting [9] (SurroundLED basic F) in the bottom part of the Navigator M6
3. Combination of the 2 lighting systems (SurroundLED advanced)

The ON/OFF switch [11] switches the indirect extension arm lighting (not illustrated) or the indirect Navigator M6 lighting [9] ON or OFF.

If the 2 systems (SurroundLED advanced) are combined, the lighting is controlled via 1 rotary dimmer switch with luminous display [10] each per variant:

1. To switch on the lighting, press the corresponding rotary dimmer switch ②. The corresponding indicator lamp ① is illuminated whilst the lighting is switched on:
- Green indicator lamp ① = extension arm lighting (not illustrated),
- Yellow indicator lamp ① = Navigator M6 lighting [9].

2. To switch off the lighting, press the rotary dimmer switch ② once again:
- The corresponding indicator lamp ① goes out.

3. To control the luminous intensity, turn the rotary dimmer switch ② to the left (darker) or to the right (brighter).

12.1 General safety instructions

⚠WARNING

Electric shock hazard

The devices can carry an electric current and must be treated with the utmost care during cleaning and disinfection:

- If a mains plug exists, pull out the mains plug.
- Do not apply spray cleaning and/or spray disinfection.
- Do not spray liquid into power sockets, gas sockets or device openings and prevent the penetration of liquids.

12.2 Cleaning

Follow the safety instructions

1. Follow the general safety instructions prescribed in Chapter 12.1, "General safety instructions", on Page 43.

⚠WARNING

Risk of contamination and infection of the patient

Parts of the pendant system and the adaptions are made of plastic. Solvents can dissolve plastic materials. Strong acids, bases and agents with an alcoholic strength of more than 60 % can lead to the plastic materials becoming brittle. Detached particles can fall into open wounds. If liquid cleaning agents are allowed to penetrate the pendant system and the adaptions, excess cleaning liquid may drip into open wounds.

Cleaning agents

Recommended cleaning agents
Use a mild soap solution or a regular dishwashing product.

2. Wipe the surfaces of the devices with a moderately moist cloth; add a mild soap solution (dishwashing product) if required.
3. Afterwards, carefully wipe the surfaces dry with a clean cloth.

Continuation on the next page.

12.3 Disinfection

Follow the safety instructions

1. Follow the general safety instructions prescribed in Chapter 12.1, "General safety instructions", on Page 43.

⚠ WARNING

The device is not suitable for sterilisation

Avoid damage

- Make sure that no liquid penetrates the device whilst cleaning it.
- To prevent damage to plastic parts, refrain from using abrasives or alkaline, acidic or corrosive cleaning agents.
- Do not use bleaching agents on stainless steel parts.

Deploy trained technical specialists only and abide by national regulations.

- Cleaning/disinfection must be carried out by trained technical specialists only. The requirements of the national hygiene and disinfection committee must be complied with.

⚠ CAUTION

Health hazard

Disinfectants can contain substances hazardous to health which, when in contact with the skin and eyes, can cause injuries or affect the respiratory organs when inhaled. Observe the protective measures:

- Observe the hygiene regulations.
- Adhere to the disinfectant manufacturer's instructions.
- Perform surface disinfection every working day and in case of contamination.

Disinfection method

Wiping disinfection is the standardised disinfection method prescribed for the pendant system. Hygiene regulations and related safety instructions for the disinfection methods to be applied must be defined by the operator.

- In case of contamination with potentially infectious material (e.g. blood, body secretion or excrement) the surfaces must be immediately and specifically disinfected.
- Make sure you apply the disinfectant in the correct concentration.
- For surface disinfection do not spray, but wipe, the surfaces.
- Wiped surfaces may only be used after the disinfectant has dried.

13.1 General safety instructions

⚠WARNING

Electric shock hazard

Power cables are laid in the pendant system and the Navigator M6. Contact with energized components presents a danger to life from electric shock. Disconnect the device from the mains before any maintenance work:

- Disconnect all the poles of the pendant system and the Navigator M6 from the mains and prevent them from being reconnected.
- Check whether the end device (e.g. flat screen, etc.) is de-energised.
- Wait until the end device (e.g. flat screen, etc.) has cooled down.

⚠WARNING

Carrying out maintenance work

Maintenance work may only be carried out by qualified personnel who have been authorised and instructed by the operator.

13.2 Inspection

- Follow the general safety instructions prescribed in Chapter 13.1 on Page 45.
- The pendant system and the Navigator M6 must be inspected as specified in Chapter 21, "Inspection Plan".

In case of failure or damage, please contact your supplier.

13.3 Inspections

- Follow the general safety instructions prescribed in Chapter 13.1 on Page 45.
- All Nuvo devices must be inspected once a year by the operator as described below.

13.3.1 Gas inspection

Connections and marking, anaesthetic gas systems, flexible hoses.

In case of change or replacement of flexible gas supply lines for medical pressure gases and vacuum

- Leakage test, clogging test, solid contamination test, gas type test in accordance with DIN EN ISO 7396-1.

In case of change or replacement of flexible anaesthetic gas supply hoses

- Leakage test, flow test and pressure loss test in accordance with DIN EN ISO 7396-2.

The gas inspection can be carried out by the provider of the corresponding central gas supply system.

Continuation on the next page.

13.3.2 Mechanical test

- Damage to paintwork
- Cracks on plastic parts
- Deformation of the pendant system
- Loose parts

In case of failure or damage, please contact your supplier.

13.3.3 Inspection of pressure hoses and lines

Every 5 years

- Visual inspection of all pressure hoses and lines.

Every 10 years

- Major overhaul and replacement of pressure hoses and lines

Your supplier's service technicians have received the information and training required in order to carry out the inspection work.

13.4 Built-in components from third-party manufacturers

Built-in components from third-party manufacturers must be inspected and maintained as prescribed in the applicable Operating Instructions.

13.5 Repeated inspections

The repeated inspection must be performed in accordance with DIN EN 62353 standard.

14 Disposal of the Pendant System

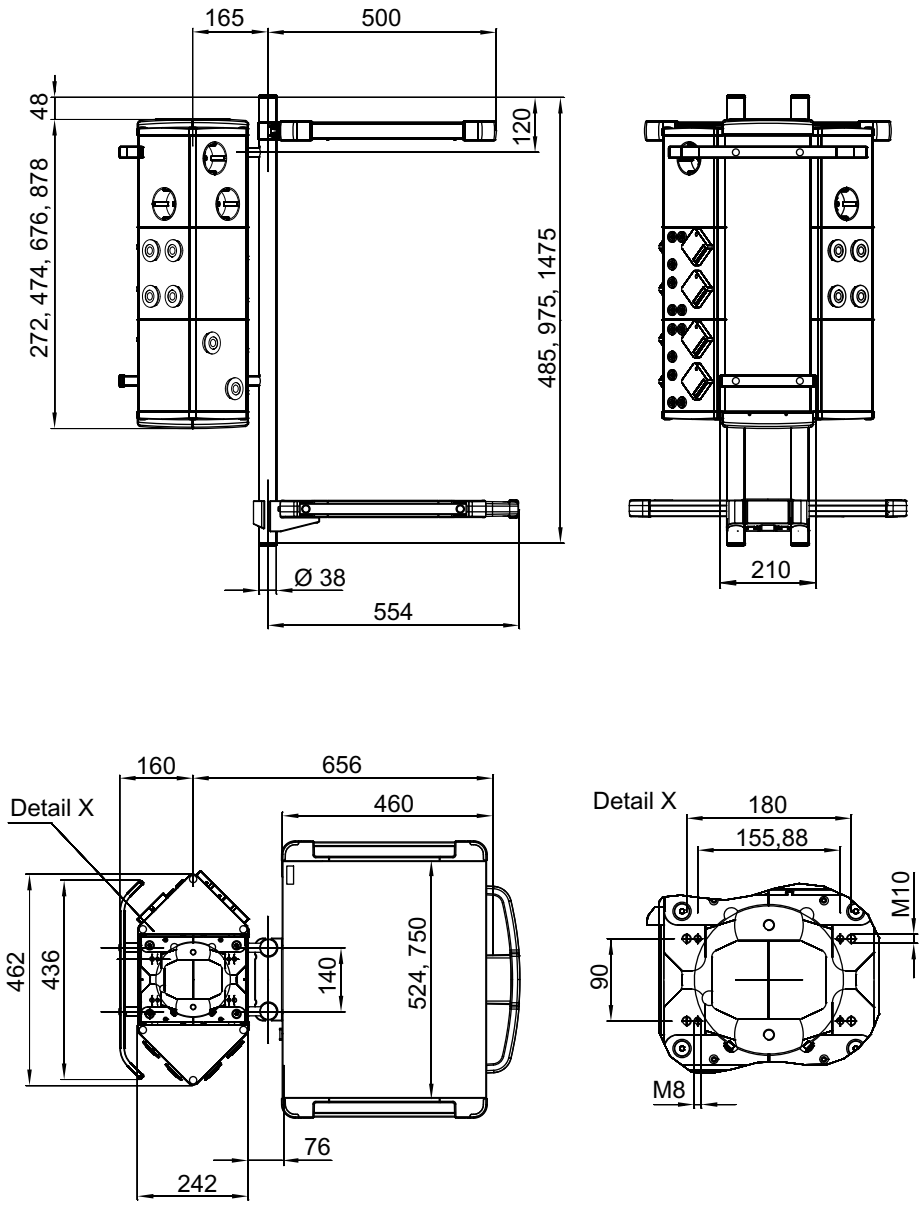
14.1 Disposal

- The Navigator M6 complies with the requirements of the 2011/65/EC RoHS Directive (on the restricted use of certain hazardous substances in electrical and electronic equipment).
- To prevent environmental damage and personal injury, we therefore request you to contact us or your authorised service partner if you intend to take the pendant system and the Navigator M6 definitively out of operation for the purpose of disposal.
- The pendant system and the Navigator M6 must be disposed of at a suitable collection point for recyclable waste in accordance with country-specific regulations.

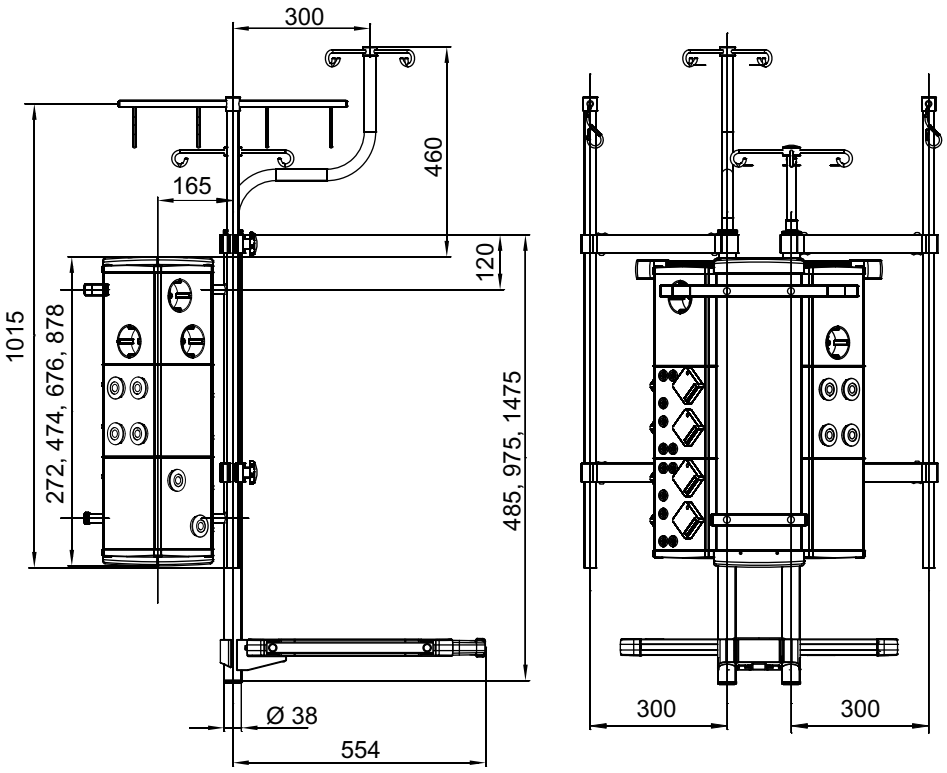
14.2 List of the materials used for the pendant system

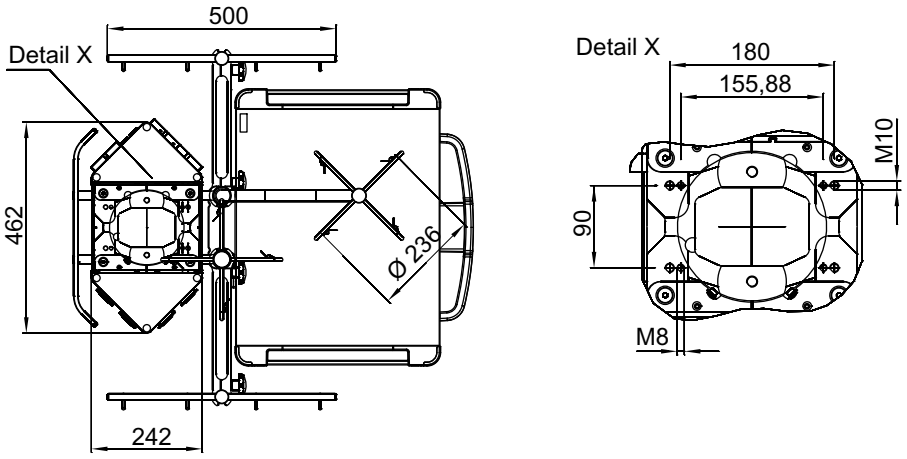
Component	Materials used
Mechanical load-carrying parts	Metal
Cover panels	Plastics
Cables	Metal, plastics

15.1 Navigator M6 with Multi-Function Rack (MFR)



15.2 Navigator M6 with infusion accessories





Modes of operation

The Navigator M6 is suitable for continuous operation.

Duty cycle of the height adjustment mechanism (only pendant systems MMP 90 / 200 and Navigator Lift ™ 150 / 250)

- The maximum duty cycle of the height adjustment mechanism on the motor arm (only pendant systems MMP 90 / 200 and Navigator Lift ™ 150 / 250) must not exceed 3 minutes:
  – If the height adjustment mechanism is actuated over a longer period of time, the electric motor of the motor arm may switch off automatically as a protection measure against overheating.
  – In order to prevent an overload of the electric motor, make sure you wait at least 30 minutes after actuating the height adjustment mechanism before putting the height adjustment mechanism into operation. Afterwards the height adjustment mechanism can be operated once again for 3 minutes.

Duty cycle of the electromagnetic brakes (only for pendant systems with electromagnetic brakes)

- The maximum duty cycle of the electromagnetic brakes (only for pendant systems with electromagnetic brakes) must not exceed 1 minute:
  – If the electromagnetic brakes are actuated over a longer period of time, the power pack may switch off automatically as a protection measure against overheating.
  – Once the power pack has switched off, it must cool down for 10 minutes and then be disconnected from the mains for 10 seconds before being switched back on again. Normal system operation may only be resumed afterwards. To prevent safety cut-offs, the maximum duty cycle should not be exceeded.

Duty cycle of pneumatic brakes

The pneumatic brakes are suitable for continuous operation.

Rating plate

The rating plate and further labels are attached to the Navigator M6 (see Chapter 4, "Rating Plate and Labels", on Page 24.

Maximum loading capacity (payload) on the Navigator M6

The Navigator M6 is suitable and approved for a maximum loading capacity (payload) specified in Chapter 6 on Page 28.

If you cannot clearly determine the maximum loading capacity (payload) as specified in Chapter 6 on Page 28, contact Nuvo in order to prevent damage to persons or property.

Dead weight of the pre-assembled components*

Sound system ..... pre-assembled*
Lighting system ..... pre-assembled*
Standard rail ..... pre-assembled*
Optional Multi-Function Rack (MFR) ..... pre-assembled*
* The maximum loading capacity (payload) of the Navigator M6 already includes the maximum loading capacity (payload) of the pre-assembled components.

Maximum loading capacity (payload) of the components

Optional standard rail ..... up to 10 kg
Optional Multi-Function Rack (MFR) ..... up to 168 kg*
* If required, the maximum loading capacity (payload) specified in the calculation in Chapter 6 on Page 28 must be reduced accordingly.

Electrical data

Rated voltage ..... 120 / 230 V
Rated frequency ..... 60 / 50 Hz
Rated current ..... up to 20 / 16 A per electric circuit
Maximum number of electric circuits ..... up to 4 electric circuits with 4 sockets each
Depending on the customer-specific equipment

Gas supply data (gas outlet points in accordance with DIN 13260-2)	Medical gases ..... in accordance with DIN EN ISO 9170-1 Compressed air ..... 5 bar Compressed air outlet, air motor ..... 10 bar Vacuum ..... 5 bar Anaesthetic gas suction ..... in accordance with DIN EN ISO 9170-2 Depending on the customer-specific equipment
Sound system data	Supply voltage ..... 12 V / DC Output power ..... 1.2 W Loudspeaker impedance ..... 8 Ohm Frequency response ..... 30 Hz ~ 20 KHz – 3 dB Output voltage lineout ..... 0.2 V / AC (depending on the mobile device) Signal-to-interference ratio, loudspeakers ..... 70 dB IR sensor frequency ..... 38 KHz
Protection class / type	Protection class in accordance with EN 60601-1 ..... I IP classification in accordance with IEC 60529 ..... IP 20
Noise level	Sound energy level ..... 65 db(A) (EN ISO 3746) not exceeded
Operation	Manual forces ..... < 100 N
Medical Device Directive 93/42/EEC	Classification ..... IIb
Applicable standards, laws and directives	• Medical Devices Act (MPG) • MDD 93/42/EEC – Medical Device Directive (MDD) • EN 60601-1: – Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance • DIN EN ISO 11197 – Medical Supply Units
Approvals of the standard equipment	• Recognised NRTL component

Models

- Navigator M6 on the Nuvo pendant system.

Approved adaptions

The following Nuvo products are approved as adaptions to the Navigator M6:

- Chapter 18, "Approved Nuvo Products", on Page 57,
- Chapter 19, "Approved Third-Party Products", on Page 57:
  - The components have been adapted to each other and are safe to operate. Any other type of installation, and in particular the use of components from third-party manufacturers, is strictly prohibited because these components can be potential sources of danger.
  - The combination of any other Nuvo product with the Navigator M6 must be approved by Nuvo Surgical. If applicable, the conformity assessment must be repeated.

Read the Operating Instructions for combined medical products

- The Navigator M6 is combined with products of other manufacturers as described in Chapter 19, "Approved Third-Party Products", on Page 57.
  To prevent dangerous overload, which can damage or lead to a collapse of the pendant system and the Navigator M6, the maximum loading capacities specified must be adhered to.
  - The party placing the device into operation is responsible for the validation of the overall system. A conformity assessment procedure shall be executed if required and a declaration in accordance with Article 12 of 93/42/EEC (Medical Device Directive, MDD) shall be provided.
  - Read the Operating Instructions provided by the third-party manufacturer to obtain the information required for the operation of the end device.
- Power packs intended for the supply of end devices must ensure electrical isolation and provide two protective measures in accordance with IEC 60601-1.

17.1 Guidelines and manufacturer's declarations

17.1.1 Electromagnetic emissions

The Navigator M6 is intended for use in the ELECTROMAGNETIC ENVIRONMENT specified below. The customer or the user of the Navigator M6 must ensure that it is used in such an environment.

Emission tests	Compliance	ELECTROMAGNETIC ENVIRONMENT – Guideline
RF emissions in accordance with CISPR 11	Group 1	The Navigator M6 uses RF energy only for its internal FUNCTIONING. Therefore, its RF emissions are very low and are not likely to cause any interference with electronic equipment nearby.
RF emissions in accordance with CISPR 11	Class A	The Navigator M6 is suitable for operation in professional healthcare facilities.
Harmonic emissions in accordance with IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions in accordance with IEC 61000-3-3	Complies	

17.1.2 Electromagnetic immunity

The Navigator M6 is intended for use in the ELECTROMAGNETIC environment specified below. The customer or the user of the Navigator M6 should ensure that it is used in such an environment.

Interference immunity test	Test level in accordance with IEC 60601	Test result
Electrostatic discharge in accordance with IEC 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	passed
Electrical fast transients / bursts in accordance with IEC 61000-4-4	±2kV 100kHz repetition rate	passed
Surges Line-to-line in accordance with IEC 61000-4-5	±0.5kV, ±1kV	passed
Surges Line-to-earth in accordance with IEC 61000-4-5	±0.5kV, ±1kV, ±2kV	passed
Voltage dips in accordance with IEC 61000-4-11	0% U_T; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degrees	passed
	0% U_T; 1 period and 70% U_T; 25/30 periods Single phase: at 0 degrees	passed
Voltage interruptions in accordance with IEC 61000-4-11	0% U_T; 250/300 periods	passed
Power frequency magnetic field immunity in accordance with IEC 61000-4-8	30A/m 50Hz or 60Hz	passed

Please note:
U_T is the a.c. mains voltage prior to application of the test level.

Cont.

The Navigator M6 is intended for use in the ELECTROMAGNETIC environment specified below. The customer or the user of the Navigator M6 should ensure that it is used in such an environment.

Interference immunity test	Test level in accordance with IEC 60601	Compliance level
Immunity to conducted disturbances, induced by radiofrequency fields IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM frequency bands from 0.15 MHz to 80 MHz 80 % AM at 1 kHz	passed
High-frequency electromagnetic fields in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	passed
NOTE 1 At 80 MHz and 800 MHz, the higher value applies. NOTE 2 These guidelines may not apply in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		
[a] The field strength of stationary transmitters, including the base stations of mobile phones and mobile land mobile radios, amateur radio stations, AM and FM radio and TV broadcasting transmitters, cannot be precisely predetermined theoretically. To assess the electromagnetic environment due to stationary RF transmitters, an electromagnetic site survey should be considered. If the field strength measured in the location in which the Navigator M6 is used exceeds the applicable RF compliance level above, the Navigator M6 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Navigator M6. [b] Field strengths over the 150 kHz to 80 MHz frequency range should be less than 3 V/m.		

17.1.3 Test specifications

Test specifications for the INTERFERENCE IMMUNITY of ENCLOSURES against high-frequency wireless communication facilities

Test frequency MHz	Frequency band [a] MHz	Radio service [a]	Modulation [b]	Maximum power W	Distance m	IMMUNITY TEST LEVEL V/m
385	380 to 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM [c] ± 5 kHz stroke 1 kHz sine	2	0.3	28
710	704 to 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700 to 1998	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

NOTE
To reach the IMMUNITY TEST LEVELS, the distance between the transmitting antenna and the ME DEVICE or ME SYSTEM can be reduced to 1 m if required. The 1 m test distance is permitted in accordance with IEC 61000-4-3.

[a] For certain radio services only the frequencies for the radio connection from the mobile communication device to the base station ("up-link") are indicated in the table.
[b] The carrier must be modulated with a square wave signal with a 50 % duty cycle.
[c] As an alternative to frequency modulation (FM), pulse modulation with a 50 % duty cycle at 18 Hz can be used because pulse modulation would also represent the worst case (but not the actual modulation).

⚠WARNING

Do not operate this device immediately next to or together with other devices stacked on top of each other because this could result in improper operation. If operation in the described manner is unavoidable, this device and all other devices should be monitored in order to ensure proper operation."

⚠WARNING

The use of other ACCESSORIES, other converters and other cables than those prescribed or provided by the MANUFACTURER of this device can lead to increased ELECTROMAGNETIC INTERFERENCE EMISSIONS or reduced electromagnetic immunity of the device, and thus improper operation.

⚠WARNING

PORTABLE RF communication devices (radio equipment, including ACCESSORIES such as antenna cables and external antennas) should not be used at a distance of less than 30 cm (12 inches) from the Navigator M6 components and cables specified by the MANUFACTURER. Be aware that the performance of the device can be reduced if this safety rule is not observed.

Products approved for use on the Navigator M6	Maximum load bearing capacity
Nuvo accessories as described in Chapter 20 on Page 58	See Chapter 20 on Page 58

19 Approved Third-Party Products

Third-party end devices with CE mark approved for use on the Multi-Function Rack (MFR).
Flat screens
Infusion accessories

Third-party end devices with CE mark approved for use on the shelf.
HF surgical devices
Endoscopy devices
Respiratory apparatuses
Patient monitors
Flat screens

For more detailed information on how to install additional end devices to the Navigator M6, please contact Nuvo customer service so as to prevent damage to persons or property: Phone: +1 (800) 663-1152 (USA and CANADA) Phone: +1 (814) 899-4220 (INTERNATIONAL)
The party placing the device into operation is responsible for the validation of the overall system. A conformity assessment procedure shall be executed if required and a declaration in accordance with Article 12 of 93/42/EEC (Medical Device Directive, MDD) shall be provided.

Designation	Dead weight	Maximum payload
Filing basket with holder	0.9kg	2kg
Storage tray, stainless steel, 300 x 240 mm	1.0kg	9kg
Hooks for standard rail	0.2kg	3kg
Examination light with flex arm	3.0kg	---
Halogen lamp LUX 50 FX	1.7kg	---
Halogen lamp LUX 50 SX	1.6kg	---
Holding clamp, 25 x 10mm, with 25.3 mm hole	0.3kg	6kg
INFU crossbar	0.8kg	10kg
Infusion extension	2.6kg	10kg / 4 x 2kg
Infusion holder with 3 holes and star handle	0.7kg	4kg
Infusion cross, bent	1.8kg	4 x 2kg
Infusion cross, straight	1.8kg	4 x 2kg
Infusion rack	3.0kg	30kg / 4 x 2kg
Catheter basket 480 x 150 x 100 mm	1.0kg	3kg
Catheter basket 280 x 150 x 100 mm	1.0kg	3kg
Refuse bag holder with standard rail claw	0.8kg	5kg
Standard rail claw, 2 counterbores for M5 screw	0.2kg	4kg
Standard rail claw, 4 counterbores for M5 screw	0.3kg	4kg
Rail fastening device	0.3kg	1.8kg
Dual drawer	18.0kg	10kg
Single drawer	10.9 kg	10kg
S-INFU od	1,8kg	4 x 2kg
Operating shelf 500 mm width, without standard rail, with switch with two brake buttons and two up and down buttons	8.3kg	50kg
Operating shelf 500 mm width, with standard rail, with switch with two brake buttons and two up and down buttons	8.9kg	50kg
Operating shelf, 750 mm width, without standard rail, with switch with two brake buttons and two up and down buttons	9.0kg	50kg
Operating shelf, 750 mm width, with standard rail, with switch with two brake buttons and two up and down buttons	9.6 kg	50kg
Standard shelf, 500 mm width, without standard rail	6.9kg	50kg
Standard shelf, 500 mm width, with standard rail	8.1kg	50kg
Standard shelf, 750 mm width, without standard rail	7.6kg	50kg
Standard shelf, 750 mm width, with standard rail	8.8kg	50kg
Operating shelf 2nd gen. 520 mm with 2 brake buttons	8.2kg	80kg
Operating shelf 2nd gen. 750 mm with 2 brake buttons	10.5kg	80kg
Standard shelf 2nd gen. 520 mm without standard rail	7.2kg	80kg
Standard shelf 2nd gen. 520 mm with standard rails	9.5kg	80kg
Standard shelf 2nd gen. 750 mm without standard rail	8.0kg	80kg
Standard shelf 2nd gen. 750 mm with standard rails	10.3kg	80kg
For the specifications of the Haeberle equipment and endoscopy carts refer to our Nuvo Pendant Manager configuration software or contact your partner in our sales department.		
To order accessories please contact our sales team.		

21 Inspection Plan

Navigator M6 combined with ☐ Navigator ☐ MMP90/85 ☐ OSC400 ☐ SpacePort ☐ Navigator Lift ☐ MMP200 ☐ OSC600

System data

Supplier: _____

ART CODE: _____
Date of installation: _____
Nuvo serial number: _____
Operator's ID number: _____
Device location _____

Important information

This inspection plan is only valid in combination with the applicable Nuvo Installation and Operating Instructions which must be used as complementary documents.

The pendant system must be inspected by Nuvo or a company authorised by Nuvo for the following points at the intervals specified below:

Visual inspection (to be performed once a year)	n/a	NOK	OK
• The pendant system parts are free of deformation and damage (scratches, cracks, etc.).*			
• The pendant system is free of paint damage.*			
• The covers are available and correctly positioned.*			
• All the rating plates and labels are available and clearly legible.			
• All the canopy fixing screws are available and fixedly mounted.			

Visual inspection (every other year; annually after 12 years)	n.a.	NOK	OK
• The ceiling panel is flush with the raw ceiling and the ceiling anchoring device is correctly in place.			
• The connections between the interface plate and the ceiling panel are securely in place and free of damage.			
• The connections between the flange and the Drop tube on the interface plate are securely in place and free of damage.			
• The pendant system parts are free of deformation.*			
• The terminals on the interface plate are securely in place and free of damage.			
• The pendant system is securely positioned; adjust the rotational stops if required.			
• At least 1 rotational stop has been set on every pivotal point, has been correctly mounted and is effective.**			
• The extension arms can be easily positioned after releasing the pneumatic or electromagnetic brake.			
• The brake valves have been vented and close properly; the brake buttons operate smoothly.***			
• The mechanical brakes (friction brakes) have been correctly adjusted; readjust if required.***			
• All sockets (if existing) are fixedly mounted and function properly.**			
• All gas sockets (if existing) are fixedly mounted and function properly.**			
• The gas type and gas tightness of all gas hoses and gas sockets (if existing) have been inspected by an authorised body.**			
• All cables/lines and any hoses installed must be inspected and replaced after 10 years and in case of visible damage.**			
• The screw-type connectors have been positioned correctly and inspected for the torques specified in the Installation Instructions.			
• The system is free of paint damage.*			
• All the plastic parts are available, in position and free of cracks.*			
• Visual inspection of the cable kit for pressure marks and/or chafe marks.			
• Visual inspection of the cable kit for abrasion in the housing.			
• Collision damage – all welded joints are free of cracks.**			
• Collision damage – all end stop components are free of cracks.			
• At least 1 rating plate and 1 plate indicating the maximum system load are available and clearly legible.			

Applies additionally and exclusively to Navigator™	n/a	NOK	OK
• The (optional) BrakeGuides light up when pressing the corresponding brake button.*			
• The (optional) extension arm lighting lights up when actuating the switch (on the Navigator M6).**			

Navigator M6 combined with ☐ Navigator ☐ Navigator Lift ☐ MMP90/85 ☐ MMP200 ☐ OSC400 ☐ OSC600 ☐ SpacePort

Applies additionally and exclusively to Navigator Lift™ 180 / 250 / MMP 90 / 200	n/a	NOK	OK
• The height adjustment mechanism with electric motor operates smoothly all along the travel path defined.**			
• The upper vertical lift operates properly and is correctly adjusted; readjust if required.**			
• The lower vertical lift operates properly and is correctly adjusted; readjust if required.**			
• The trapezoidal spindle operates smoothly, functions properly and is sufficiently lubricated; relubricate if required.*			

Applies additionally and exclusively to Navigator Lift™ 180 / MMP 85 S and SpacePort	n/a	NOK	OK
• Load compensation / spring tension correct, readjust if required**			

Electrical safety	n.a.	NOK	OK
• Safety testing in accordance with DIN EN 62353 (only applicable if live conductors are incorporated).			

Notes

Confirmation of installation work carried out

The work mentioned above has been carried out, including any adjustments and visual inspection required:

Date *Name (in block letters)* *Signature / Stamp*

* Damaged, deformed or missing components should be replaced as a precautionary measure. For more detailed information refer to the pendant system supplier.

** If one of the designated points is found to be non-conformant during inspection, the pendant system must be taken out of operation immediately and with the utmost care in order to prevent further damage to persons or equipment. The system supplier must be notified immediately.

*** Does not apply to Navigator™.

The Medical Device Booklet (Medizinproduktebuch) which is part of every medical product in accordance with the German Medical Devices Operator Ordinance (MPBetreibV) must be kept available on site. Service and maintenance work as well as safety inspections must be documented in this Medical Device Booklet. Inspection reports like this must be filed in the corresponding Medical Device Booklet.

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