NAVI-30/NAVI-60

Vein Illuminator

Operation Manual

Before using the NAVI-30/NAVI-60 vein illuminator, please read this Manual carefully and follow the safety precautions and operating instructions contained herein.

MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD.

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Illustrations

- All the illustrations provided in this operation manual are for your reference only. The settings or data on the illustrations may differ from the actual settings or data of the product.

Version Information

Version: V2.0
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Add the UDI symbol and description
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After-Sales Service

Thanks for purchasing our vein illuminator.

- MEDCAPTAIN provides limited warranty for the product. That is, we provide free after-sales services for the product within the warranty period. The specific warranty period is stipulated on the sales contract. For details, please contact your local distributor. However, a product damage or fault is not covered by the warranty if it is caused by:
  - Operator error;
  - Improper use;
  - Out-of-range grid voltage;
  - Force majeure such as natural disasters;
  - Replacement with or use of any component, accessory or consumable other than authorized by MEDCAPTAIN; or
  - Other damages/faults not caused by the product.
- After the warranty period expires, MEDCAPTAIN shall continue to provide paid maintenance service within the service life of the product.
- Feel free to contact us or your local distributor if you have any problem in using the product.
- Contact our after-sales service department:

After-sales service provider: MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD.

After-sales service Address: 12th Floor, Baiwang Research Building, No.5158 Shahe West Road, Xili, Nanshan, 518055 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA

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Contents

1 Overview

1.1 Intended Purpose

The NAVI-30/NAVI-60 vein illuminator is used to observe and locate the superficial veins, and to assist medical personnel in venipuncture.

1.2 Contraindications

Direct eye exposure to the light emitted by this product is forbidden.

1.3 Undesirable Side-Effects

None

1.4 Intended User

The device is used by medical personnel who have received a training related to the use of this device.

1.5 Patient Target Groups

Adults, children and infants

1.6 Clinical benefits

The NAVI-30/NAVI-60 vein illuminator is a portable instrument that adopts an invasive method and supports real-time vein imaging to assist in finding superficial veins. The illuminator should not be regarded as the sole method to locate veins, and should be used only by qualified medical professionals, who should do so either prior to palpation to help identify the location of a vein, or afterwards to confirm the perceived location of a vein. When used properly, the vein illuminator enables users to locate easily certain superficial veins for patients, especially for someone with difficult vein access including

obese people, old people, infants, people with edema or nephritis and people having intravenous chemotherapy.

1.7 Product Features

As a portable professional medical device for vein imaging, the NAVI-30/NAVI-60 vein illuminator detects veins beneath skin by using infrared light and then indicates the vein positions on the skin surface above the veins by using light during operation. By observing the vascular system projected on the skin surface, qualified medical personnel can find a vein of appropriate size and position for venipuncture.

- Veins beneath skin are detected by using the near-infrared light and then projected on the body surface by using the high-definition vein illuminator, implementing real-time and accurate display of vein positions.
- This device can be placed at any place above the detection area to project the vein positions accurately. It does not need to be fastened at a specific position above the detection area for accurate projection.
- Easy to operate. Users can press to power on/off the device.
- Lightweight structural design, easy to take along.
- Handheld device for medical personnel. Ergonomic design, comfortable to hold it.
- Five projection colors are available for selection. The corresponding inverse color mode of each color can also be selected.
- The projection brightness can be adjusted to adapt to different operation environments.
- The size of the projection window can be adjusted to adapt to

different patients and different detection positions.

- This device can be used to detect and display the depth of the vein beneath skin.
- The NAVI-60 vein illuminator is equipped with a display screen to display various operation information like the remaining battery capacity, mode, color, and projection size.
- A lithium battery is built in to allow long-time portable use.
- This device can be used while it is connected to an external power supply for battery charging.
- This device can be used together with a support or trolley.

1.8 Model Differences

Product Model	Difference
NAVI-30	Without a display screen
NAVI-60	With a display screen

2 Safety

2.1 Warnings and Cautions

In this Manual, the precautions are classified by importance into warnings and cautions as defined below:

⚠WARNING:

The precautions related to safety and effectiveness. Failure to follow them may cause personal injuries.

⚠CAUTION:

The precautions related to guidance and suggestions. Failure to follow them may affect the normal use of the product.

Please read all warnings and cautions contained herein carefully.

⚠WARNING:

- Report any serious incident related to the vein illuminator to the local distributor or authority immediately.
- The vein illuminator must be operated by professional medical personnel or under the guidance of clinicians. In addition, the operator must receive a training related to the use of this device.
- High-frequency surgical equipment, mobile phones, wireless devices, and defibrillators may cause interference on the vein illuminator. Therefore, keep the vein illuminator away from these devices when using the vein illuminator.
- To avoid the risk of electric shock, connect the vein illuminator to only the power supply system with protective earth. In case that the power supply system does not have protective earth, disconnect the power cable of the vein illuminator from the power supply system and use the built-in battery to power the vein

illuminator.

- The vein illuminator does not have a patient connection circuit. Prevent the patient from touching the vein illuminator.
- This vein illuminator can only identify veins, and it cannot effectively evaluate arteries.
- Do not use this product as diagnostic equipment or for any treatment purposes.
- This product is a class I continuous-operation device without waterproof protection design. Do not splash or drip any liquid onto or into the device, and do not immerse any part of the main unit in liquid. If any liquid splashes into the product during charging or operation of the product, immediately power off the product and stop using it.
- Only use the dedicated accessories provided by MEDCAPTAIN. Before use, check the power cable, power adapter, and other accessories. In case of any damage, stop using the product and contact the after-sales service department of MEDCAPTAIN.
- This product has a removable battery inside. Operate, store, and transport this product in strict accordance with the operation manual. Do not use the product in flammable and explosive environment.
- The lithium battery provided by MEDCAPTAIN is the original battery. If this product will not be used for a long time, fully charge it for storage. The service life or shelf life of the battery is one year.
- Do not discard the retired vein illuminator at will. The product contains a battery and therefore it must be disposed of according to the Technical Policy for Discarded Batteries Pollution Prevention in a professional manner.

Safety

- Do not disassemble or try to repair the vein illuminator. Otherwise, serious hazards may be incurred. The manufacturer and distributor shall not be responsible for any vein illuminator that has been disassembled, modified or used for any purpose other than its intended purpose.
- Do not apply this product on the skin with scar, tattoo, skin disease, or lots of hairs because they may interfere with the imaging of the product.
- This product must only be used for assisting medical personnel in vein locating or for training and teaching medical personnel how to use it. This product is not the sole method of vein locating and cannot completely substitute other vein locating methods that are based on reliable medical judgments or sight and touch judgments.
- If the vein illuminator falls to the ground or it is affected by an external force, stop using vein illuminator even if it appears normal. Contact your local distributor and have an inspection performed to judge whether the vein illuminator is operating properly.
- Do not service or maintain the vein illuminator or its accessory when it is being used on a patient.
- Do not try to upgrade the software of the vein illuminator. To upgrade the software, please contact your local distributor for help. The software upgrade must be executed by trained technicians. Otherwise, an error of the vein illuminator may occur. After software upgrade, the vein illuminator must be validated by trained technicians before use.
- Possibly hazardous optical radiation is emitted from this product.

⚠CAUTION:

- Do not touch the display screen by using sharp objects. Otherwise, the display screen may get damaged.
- Ensure that the vein illuminator is placed beyond the reach of the patient and other unauthorized persons.
- Ensure that the battery is always installed in the vein illuminator during use.
- If the vein illuminator fails to act as specified herein for unknown reason, power it off and report the conditions when the fault occurs to your local distributor or the after-sales service department of MEDCAPTAIN.
- Do not disassemble or reconstruct the vein illuminator without permission.
- This product requires maintenance by authorized personnel. The authorized personnel can ask for such materials as the service manual and list of spare parts from the manufacturer.
- The power adapter is a part of the vein illuminator.

2.2 Symbol Description

Symbol	Description
	Model number
	Caution
	Manufacturer
	Alternating current

	Refer to instruction manual/booklet
	General warning sign
RG2	Possibly hazardous optical radiation emitted from this product
	Date of manufacture
	Direct current
EC REP	Authorized representative in the European Community
SN	Serial number
MD	Medical device
UDI	Unique device identifier
CE	The device complies with the requirements of the Medical Device Regulation 2017/745.
	DISPOSAL: Do not dispose of this product as unsorted municipal waste. Separate collection of such waste for special treatment is necessary.
	Fragile, handle with care
	Keep away from sunlight
	Temperature limit

	Stacking limit by number
	This way up
	Keep dry
	Atmospheric pressure limitation
	Humidity limitation

3 Product Specifications

Name	Vein illuminator
Model	NAVI-30/NAVI-60
Dimensions	224 (W) × 68 (H) × 64 (D) mm
Weight	About 0.5kg
Power Adapter	Input: 100-240Vac 50/60Hz 1.5A Max Output: 12V ⎓ 3.5A Model of the power adapter:LXCP52-012
Battery	Built-in lithium battery: 7.3V, 2750mAh Battery model: 18650-2S1P Continuous operation duration of the lithium battery: not shorter than 2.5 hours at room temperature Time required for fully charging an exhausted lithium battery: not longer than 4 hours (the device is powered off during the charge) Charge mode of the lithium battery: The battery can be charged using a power adapter when AC input is available.
Display Mode	Projection mode
Light Source Type	Near-infrared light
Infrared Wavelength	850nm dual light sources
Optimal Focus Position	210mm±30mm

Product Specifications

Depth of Field of Imaging	>30mm
Infrared Radiation Energy	≤0.6mW/cm^2
Operating Conditions	Temperature: 5°C~40°C Humidity: 20%~90% RH, non-condensing Atmospheric pressure: 70~106.0kPa
Storage and Shipping Conditions	Temperature: -20°C~+55°C Humidity: 10%~95% RH, non-condensing Atmospheric pressure: 61.7~107.4kPa
Service Life	5 years
Classification	1. Class I/Internally powered equipment; 2. IPX0; 3. Not sterilized; 4. Not category AP/APG equipment; 5. Mode of operation: continuous
Date of Manufacture	See the product label.
Main Safety Standards	IEC 60601-1:2012 Medical Electrical Equipment, Part 1: General Requirements for basic safety and essential performance IEC60601-1-2:2014 Medical Electrical Equipment - Part1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility-Requirements and tests

4 Product Description

4.1 Structural Composition

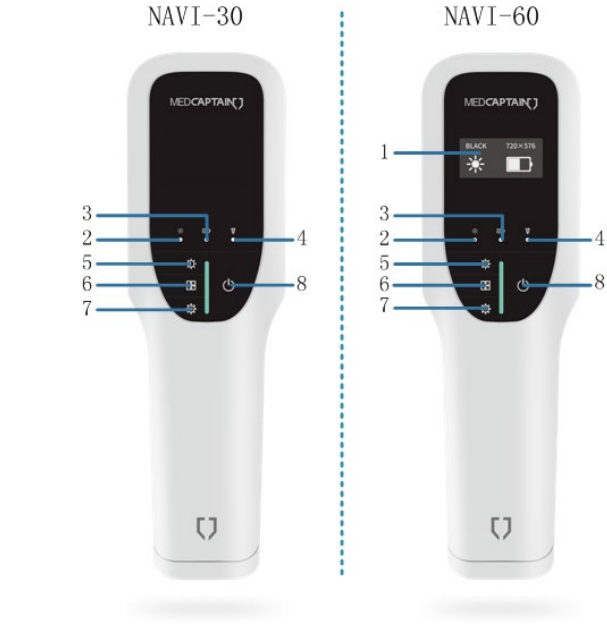
This product mainly consists of the infrared light source, image sensor (CCD), image processing chip, projection module, internal optical path module, power supply, and support. It does not come into contact with the patient during the use.

4.2 Operating Principles

Compared with the superficial skin, the hemoglobin in veins has a stronger absorption of near-infrared light. The vein illuminator is designed based on this principle. During use of the vein illuminator, the reflected infrared light is perceived by the CCD. After a series of digital image processing by the image processing chip, the vein illuminator shows the outline image of the veins and projects the image on the skin surface to reveal the vein distribution. Qualified medical personnel can observe and locate the vein for venipuncture or blood drawing according to the vein distribution image projected on the skin surface.

4.3 Main Unit

4.3.1 Front View



1 – Display screen
2 – Running indicator
3 – Battery indicator
4 – Power indicator
5 – Brightness button
6 – Size button
7 – Mode button
8 – Power button

- Display screen (**only NAVI-60 has a display screen**): Displays various operation information like the remaining battery capacity, mode, color, and projection size.
- Running indicator: This indicator is steady green when the device is in power-on state and extinguished when the device is in power-off state.

- Battery indicator:
  - When the device is connected to an external power supply and the battery is in charge state, the battery indicator is steady green. After the battery is fully charged, the battery indicator is extinguished.
  - When the battery is powering the device, the battery indicator is slowly blinking green. In case of low battery, the battery indicator is quickly blinking green. When the battery is exhausted, the battery indicator is extinguished.
- Power indicator: The power indicator is steady blue when the device is connected to an external power supply. When the device is in power-on state and not connected to any external power supply, the power indicator is slowly blinking blue.
- Power button: A user can press the power button to power on the device. When the device is in running state, a user can press the power button to power off the device. If the device is powered by the battery, it will be automatically powered off if no operation is performed within 4min.
- Brightness button: A user can press this button to adjust the projection brightness. Four brightness levels are available for selection.
- Size button: A user can press this button to switch the size of the projection image.
- Mode button: A user can press this button to switch between the basic mode, color mode, and depth mode. In addition, a user can press and hold this button and then release to switch the current display color.
- Basic mode: This mode is suitable for the users with different visual feelings.

- Green light mode, red light mode, blue light mode, and light purple mode: The noise is weakened to accurately show the vein distribution.
- Depth mode: The vein depth can be identified to assist medical personnel in inserting a needle.

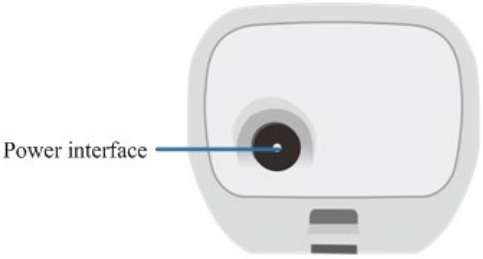
4.3.2 Rear View

1–Projection window: Used to receive infrared light and project an image.

2–Infrared lamp: Used to emit infrared light.

3–Battery compartment: rear cover of battery.

4.3.3 Bottom View



- Power interface: Used to connect to the power adapter.

4.4 Accessories

No.	Accessory Name
1	AC power cable
2	Power adapter
3	Accuracy test card

⚠CAUTION:

- All accessories of this device must be provided by the manufacturer. Otherwise, this device may be damaged, an electric shock may be caused, or the device may fail to reach specifications asserted in the operation manual.

5 Installation Description

5.1 Environment Requirements

To ensure normal operation of the vein illuminator, please ensure that the installation environment meets the following requirements:

- If a support is used, the installation workbench must be smooth and steady.
- No power supply interference exists.
- No corrosive or flammable gas should be present.
- No flammable and explosive materials should be present.

5.2 Open Package Inspection

Before opening the package, please inspect the packaging box carefully. In case of any damage, please contact your local distributor or the after-sales service department of the manufacturer immediately.

1. Take the vein illuminator and accompanied accessories out of the packaging box.
2. Check whether the accessories in the packaging box are consistent with those on the packing list, and check whether there is any mechanical damage on the device or its accessories. In case of any doubts, please contact the local distributor or the after-sales service department of the manufacturer immediately.

5.3 Connecting the Power Supply

Place the vein illuminator in an environment meeting the requirements stipulated in section 5.1, and connect the device to an external power supply.

1. Use the AC power cable and power adapter provided by the manufacturer.
2. Connect the AC power cable and power adapter.

3. Connect one end to the power interface at the bottom of the vein illuminator.

4. Connect the other end to a matching AC power socket.

⚠WARNING:

- Do not touch the power plug with a wet hand. If any liquid or liquid residue exists on or around the power plug or power socket, remove this liquid or liquid residue before plugging in the device. Otherwise, an accident may occur.
- Use the power cable provided by the manufacturer to ensure that the device is properly grounded. If the device is not properly grounded, the safety performance cannot be guaranteed and an electric shock may occur.

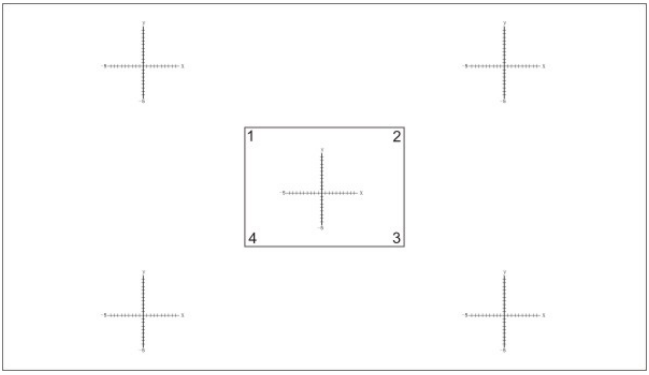
⚠CAUTION:

- The plug of the AC power cable must be firmly and fully inserted into the power socket.
- Do not install the vein illuminator at a place where the power plug is difficult to be disconnected from the power socket.

5.4 Checking the Device Accuracy

Since the vein illuminator is a precise device, before powering on it for the first time or after transporting it, the operator must check the accuracy of the device using an accuracy test card.

Place the accuracy test card in the projection area of the device, and check the positional deviation of the projection image and test card image at the optimal focus position (the projection hole is 210±30mm away from the test card). If the deviation is smaller than 1mm, the device can be used properly. If the deviation is larger than 1mm, stop using the device and contact the local distributor or the after-sales service department of MEDCAPTAIN immediately.



6 Operating Instructions

6.1 Powering On the Vein Illuminator

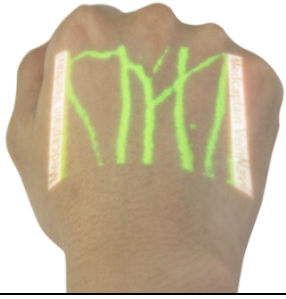
After installing the vein illuminator, power on the vein illuminator according to the following steps:

1. Press the power button to power on the device. The running indicator is illuminated, and the device starts to project 6s later.
2. Check the accuracy of the device according to section 5.4. After that, the device can be used to observe the superficial veins. During actual use, the user can adjust the projection distance until the English letters at both sides of the projection image achieve the optimal effect (or become the clearest).

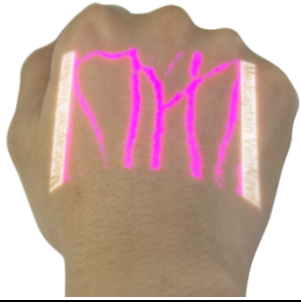
6.2 Setting the Mode

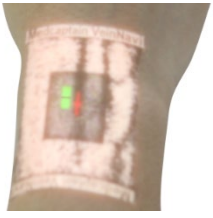
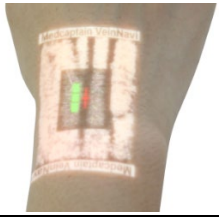
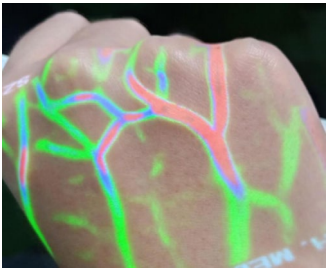
The vein illuminator is suitable for the users with different visual feelings. A user can press the mode button to set the mode. Seven modes are available for selection: basic mode, green light mode, red light mode, blue light mode, light purple mode, depth mode, and inverse color mode. In any mode except depth mode, a user can press and hold the mode button and then release to switch to the inverse color mode of the current mode. In inverse color mode, the vein color and skin color in the projection image are inversed.

In depth mode, align the long side of the red cross in the middle of the projection with the vein to be detected. Then, you can observe that the green indicator is illuminated to indicate the vein depth information. (Only applicable to NAVI-30)

Mode	Image	Remarks
Basic mode		The image is monochrome.
Green light mode		The image is green.
Red light mode		The image is red.

Operating Instructions

Blue light mode		The image is blue.
Light purple mode		The image is light purple.

Depth mode		NAVI-30: 1 bar of green light: The vein depth is 0~2mm (shallow).
		2 bars of green light: The vein depth is 2~4mm (relatively shallow).
		3 bars of green light or none: The vein depth is 4mm or above (deep).
		NAVI-60: Red light: The vein depth is 0~2mm. Blue light: The vein depth is 2~4mm. Green light: The vein depth is at least 4mm.

Inverse color mode		In any mode except depth mode, a user can press and hold the mode button and then release to switch to the inverse color mode of the current mode.

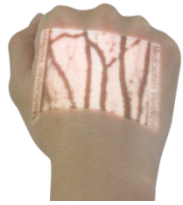
6.3 Adjusting the Brightness

Four levels of projection brightness are available for selection to match different use environments. A user can press the brightness button to adjust the brightness. See the following figures.

Level 1 brightness (darkest)	Level 2 brightness
	
Level 3 brightness	Level 4 brightness (brightest)
	

6.4 Adjusting the Size

Three different sizes of projection image are designed to make the device be suitable for different groups of people, especially for children and infants. A user can press the size button to switch the size. See the following figures.

Minimum Size	Middle Size	Normal Size
		
360*192 pixel	360*288 pixel	720*576 pixel

6.5 Powering Off the Vein Illuminator

After use, press the power button to power off the device.

7 Common Faults

- **The device cannot be powered on after being connected to the power adapter.**

  Possible cause:

  a. The device is not properly connected to the external power supply or the external power supply has no voltage.

  b. The power board in the device is damaged because an incorrect power adapter is used.

  Check method:

  a. Check whether the device is properly connected to the power adapter by checking whether the power indicator is steady on.

  b. Check that the device can be powered on when it is powered by battery and cannot be powered on when it is connected to the power adapter.

- **The projection image is blurring or obvious spots can be found in the image.**

  Possible cause: The lens is dirty.

  Solution: Clean the lens according to the method described in section 8.2.

- **The device cannot be powered on when battery is used to supply power.**

  Possible cause: The battery is exhausted, or the battery is damaged because it was stored in a humid environment.

Solution: Connect the **device** to the power adapter for charging the battery (the battery indicator is extinguished when the battery is fully charged), or directly use the external power supply to power the device. If the device still cannot be powered on, it may be abnormal. In this case, contact the after-sales service department of MEDCAPTAIN.

- **The continuous operation duration of the battery is insufficient.**

  Possible cause: The battery is not fully charged, or the continuous operation duration of the battery decreases due to natural deterioration.

  Check method: Connect the device to the power adapter. If the battery indicator is blinking, the battery is not fully charged. If the battery indicator is not illuminated, the battery is already fully charged. The decrease in the continuous operation duration of the battery is caused by increase in number of charge/discharge times, which is natural and inevitable.

  Solution: If the continuous operation duration of the battery is too short, the battery needs to be replaced. Please consult the after-sales service department of MEDCAPTAIN about battery replacement.

- **The device does not respond or breaks down occasionally.**

  Possible cause: The device has been used for a long time and the internal temperature is too high.

  Solution: Power off the device for a moment to cool down the device.

8 Cleaning and Disinfection

It is highly recommended that the materials and methods listed in this chapter be used for cleaning and disinfection of the device. If other materials or methods are used, the device may be damaged or its service life may be shortened.

⚠CAUTION:

- In case of any doubts about the use of the detergent or disinfectant, please consult the local distributor.
- Please dispose of the wastes generated after the cleaning and disinfection according to the relevant regulations of the local hospital.

8.1 Preparations

1. Before cleaning and disinfection, power off the device and disconnect the power cable from the device.
2. Wear a pair of rubber gloves and a gauze mask to prevent contaminants from splashing onto your skin during the cleaning and disinfection.
3. You are not allowed to disassemble this device for cleaning and disinfection. To disassemble this device for further cleaning and disinfection, please contact the local distributor.
4. Prepare several pieces of soft medical gauze, a detergent container, and a disinfectant container.

8.2 Cleaning

⚠WARNING:

- Do not immerse the device in the detergent solution.
- Prevent the solution from seeping into the device.
- Do not use halogenated solvent, petroleum-based solvent, glass detergent, acetone, or other irritant detergents.
- Only manual cleaning is allowed to be adopted for this device. Do not adopt the automatic cleaning mode for this device.

Cleaning procedure:

1. Completely immerse a piece of soft medical gauze in neutral or slightly alkaline detergent solution, wring out the gauze, and then use the gauze to wipe the device surface.
2. Wipe all the surfaces of the device in sequence until all the contaminants are removed from the device surface.
3. Drip several drops of absolute ethyl alcohol on a piece of lens paper and use this lens paper to gently wipe and clean the lens surface along the same direction.
4. Ensure that all the edges and corners of the device are completely cleaned.
5. After the cleaning, use a piece of dry medical gauze to remove the residual detergent solution.

The following table lists the detergents recommended for the device.

Table 8-1 Recommended detergents

Detergent Name	Cleaning Method
Clean water	Wipe
Soapy water (pH value: 7.0~10.5)	Wipe

8.3 Disinfection

⚠WARNING:

- Do not immerse the device in the disinfectant solution.
- Prevent the solution from seeping into the device.
- Use the disinfectant according to its operation manual.
- Do not autoclave the device.
- Only manual disinfection is allowed to be adopted for this device. Do not adopt the automatic disinfection mode for this device.

Disinfection procedure:

1. Before the disinfection, clean the device according to the method provided in section 8.2.
2. Completely immerse a piece of soft medical gauze in the intermediate-efficiency or high-efficiency disinfectant solution, wring out the gauze, and then use the gauze to wipe the device surface.
3. Wipe all the surfaces of the device in sequence. For the contact time of the disinfectant, see the operation manual of the disinfectant.
4. Drip several drops of disinfectant solution on a piece of lens paper and use this lens paper to gently wipe and clean the lens surface along the same direction.
5. Ensure that all the edges and corners of the device are completely disinfected.
6. After the disinfection, immerse another piece of soft medical gauze in clean water, wring out the gauze, and then use the gauze to wipe the device surface for removing the residual disinfectant solution.

The following table lists the disinfectants recommended for the device and the required contact time for the disinfection.

Table 8-2 Recommended disinfectant solutions

Disinfectant Solution Name	Contact Time	Disinfection Method
75% alcohol	3min	Wipe
70% isopropanol	3min	Wipe
3% hydrogen peroxide	30min	Wipe

8.4 Air Drying and Transportation

⚠WARNING:

- Do not dry the device by using a drying machine or similar products.
- Connect the device to the power supply again after the device is completely dry.

1. After cleaning and disinfection, place the device in a shady, cool, and ventilated environment for air drying.
2. If you are not going to use the device soon after air drying, place the device in its original package for storage and transportation.

9 Maintenance

⚠CAUTION:

All preventative and corrective maintenance and all such activities should be performed by Qualified Service Personnel only, with reference to the Service Manual.

9.1 Regular Maintenance

To ensure safe use and lengthen the service life of the vein illuminator, please conduct regular maintenance and check. Table 9-1 lists the maintenance plan.

Table 9-1 Maintenance plan

Maintenance Item	Frequency	Maintenance Method
Appearance check	Before each use	See section 9.1.1.
Power adapter and power cable check	Before each use	See section 9.1.2.
Accuracy check	Every two years	See section 9.1.3.
Electrical safety test	Every two years	See section 9.1.4.

9.1.1 Appearance Check

- Appearance check: Check that no crack or damage exists.
- Button operation: Check that the buttons can be smoothly pressed and function properly.
- Check that all the sealing parts and the installation of the vein illuminator are normal and no crack exists on any materials.

9.1.2 Power Adapter and Power Cable Check

- Check the appearance of the power adapter and power cable. If a surface damage or poor contact between plug and socket is found, contact the distributor for replacement in time.
- If the AC/DC power indicator is not illuminated after the vein illuminator is connected to an AC/DC power supply or the vein illuminator cannot be started, contact the distributor for maintenance in time.

9.1.3 Accuracy Check

Check the device accuracy according to section 5.4. If the accuracy exceeds the reference range, contact the local distributor or the after-sales service department of MEDCAPTAIN for calibration of the device accuracy.

9.1.4 Electrical Safety Test

To ensure safety, please conduct a dielectric strength test, leakage current test, and ground impedance test according to the method stipulated in IEC60601-1.

9.2 Battery Maintenance

9.2.1 Battery Overview

The NAVI-30/NAVI-60 vein illuminator is equipped with a built-in battery to ensure normal operation of the vein illuminator in case of an external power failure. The battery starts to be charged when the vein illuminator is connected to an external power supply. In case of a sudden power failure, the system automatically switches to the battery supply mode without interrupting the operation of the vein illuminator. If the external power supply recovers from the failure before the built-in battery is exhausted, the system

automatically switches from battery supply mode to external power supply mode to ensure uninterrupted operation of the vein illuminator.

⚠WARNING:

- If you have any doubts about the integrity or wire of the protective earth, unplug the device for the battery to power the device.

9.2.2 Using the Battery

- Before using the device for the first time or using the device after the device is not used for a long time

Before using the vein illuminator for the first time, charge the built-in battery. Power off the vein illuminator and connect it to an external power supply for at least 10 hours until the battery is fully charged. After that, you are allowed to use the vein illuminator.

- Battery optimization

1. Power off the vein illuminator.
2. Connect the vein illuminator to an AC power supply to charge the battery for over 10 hours uninterruptedly.
3. Disconnect the vein illuminator from the AC power supply for the battery to power the vein illuminator until the battery is exhausted.
4. Connect the vein illuminator to the AC power supply again to charge the battery for over 10 hours uninterruptedly.

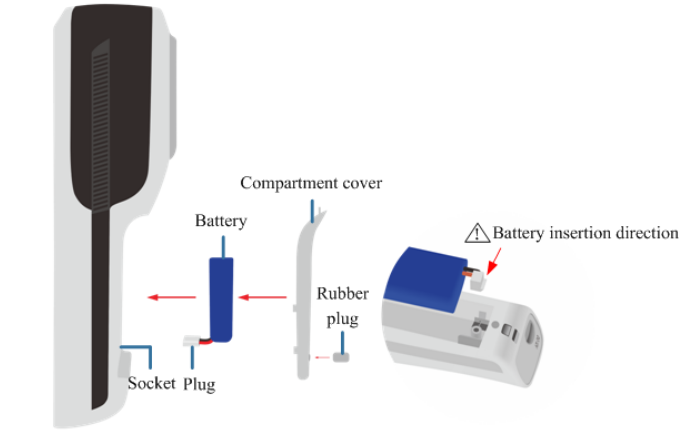
⚠CAUTION:

- Before using the built-in battery, check the battery to ensure that sufficient power is available. Recharge the battery if required.
- Improper use of the battery may shorten the service life of the battery.
- Frequent use of the battery will shorten the service life and continuous operation duration of the battery.

- If this product will not be used for a long time, fully charge it for storage.

9.2.3 Replacing the Battery

1. Remove the rubber plugs from the retaining screws on the battery compartment.
2. Remove the retaining screws, and take down the battery compartment.
3. Take out the old battery, and install a new battery in the battery compartment.
4. Insert the battery plug into the socket in the direction shown in the following figure. Hold the socket when inserting or removing the battery. Do not hold the battery and pull the socket.



⚠CAUTION:

- The service life or shelf life of the battery is one year. It is recommended that the battery be replaced in time.
- Aging may shorten the continuous operation duration of the

battery. Please check and replace the battery at regular intervals.

- Replace the battery when the vein illuminator is not in use.
- Remove the battery if the vein illuminator is not likely to be used for some time.
- Battery replacement must be finished by trained technicians. Otherwise, a danger may be incurred.

9.3 Storage

- Avoid water spill.
- Do not store the vein illuminator in a hot and humid place.
- Store the vein illuminator far away from excessive vibration, dust, and corrosive gas.
- Store the vein illuminator out of direct sunlight and ultraviolet ray to avoid color fading.

9.4 Transportation

The vein illuminator is allowed to be transported using a common vehicle, but it must be protected from the drastic impact, vibration, and rain and snow splash during the transportation. In addition, the vein illuminator must be transported in accordance with the requirements specified in the order contract.

9.5 Environmental Protection and Recycling

Disposing of this product correctly will help to save valuable resources and prevent any potential negative effects on human health and the environment which could otherwise arise from inappropriate waste handling.

After this product or its parts have exceeded its service life, please contact the dealer where you purchased the product for more information on the disposal.

WARNING:

- Dispose of the disposables according to the instructions of the local infection control policy.
- Remove the internal battery from the control board, dispose of them in accordance with the local country regulations.
- Dispose of electronic components other than batteries safely in accordance with local regulations.

Appendix A Electromagnetic Compatibility (EMC)

⚠CAUTION:

- The NAVI-30/NAVI-60 vein illuminator complies with EMC standard IEC 60601-1-2:2014.
- Users must install and use the NAVI-30/NAVI-60 vein illuminator based on the EMC information provided in the accompanying document.
- Portable and mobile RF (Radio-Frequency) communication devices may affect the performance of the NAVI-30/NAVI-60 vein illuminator. Avoid strong electromagnetic interference during the use, for example, stay away from mobile phone and microwave oven.
- For the declaration of emissions CLASS and group and Immunity level, please see the Appendix.
- The NAVI-30/NAVI-60 vein illuminator is suitable for Professional healthcare facilities environment, e.g. hospitals except for near active HF surgical equipment and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high. Due to conducted interference and radiated interference, it may be difficult to ensure electromagnetic compatibility in other environments.
- To assure that the NAVI-30/NAVI-60 vein illuminator remains safe with regard to electromagnetic disturbances throughout the expected service life:
  - Conduct periodic maintenance based on the recommended maintenance/service interval and method provided in the operation manual.

- After each maintenance, ensure that the internal structure, shielding system, and grounding system of the device remain complete and effective.

- The Emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

WARNING:

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Only the following cables provided by the manufacturer allowed to be used to meet the electromagnetic emission and anti-interference requirements.

No.	Cable Name	Length	Shielded
1	AC power cable	2.5	No
2	Power adapter	1.6	No

- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of theNAVI-30/NAVI-

60 vein illuminator, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

<table>
<tr><td colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</td></tr>
<tr><td colspan="3">The NAVI-30/NAVI-60 vein illuminator is intended for use in the electromagnetic environment specified below.
The customer or the user of the NAVI-30/NAVI-60 vein illuminator should assure that it is used in such an environment.</td></tr>
<tr><td>Emission test</td><td>Compliance</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>RF emission
CISPR 11</td><td>Group 1</td><td>The NAVI-30/NAVI-60 vein illuminator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>Radio-frequency emission
CISPR 11</td><td>Class A</td><td rowspan="3">The NAVI-30/NAVI-60 vein illuminator is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emission
IEC61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuation and flashing
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Appendix A

Guidance and manufacturer's declaration – electromagnetic immunity			
The NAVI-30/NAVI-60 vein illuminator is intended for use in the electromagnetic environment specified below. The customer or the user of the NAVI-30/NAVI-60 vein illuminator should assure that it is used in such an environment.			
IMMUNITY test	IEC60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV,±4 kV,±8 kV, ±15 kV air	±8 kV contact ±2 kV,±4 kV,±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient (EFT) IEC61000-4-4	±2 kV 100KHz AC power cable ±2 kV 100KHz DC power cable(>3m) ±1 kV 100KHz SIP/SOP cable(>3m)	±2 kV 100KHz AC power cable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV Line-to-line	±0.5 kV, ±1 kV Line-to-line	

	±0.5 kV, ±1 kV,±2 kV Line-to-ground AC power cable DC power cable(>3m) ±2 kV Line-to-ground SIP/SOP outdoor cable	±0.5 kV, ±1 kV,±2 kV Line-to-ground AC power cable	
The voltage dips, and interruptions IEC 61000-4-11	0% 0.5 cycle At 0º, 45 º, 90 º, 135 º, 180 º, 225 º, 270 º and 315 º ; 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 º 0% 300 cycle	0% 0.5 cycle At 0º, 45 º, 90 º, 135 º, 180 º, 225 º, 270 º and 315 º ; 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 º 0% 300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the NAVI-30/NAVI-60 vein illuminator requires continued operation during power mains interruptions, it is recommended that the NAVI-30/NAVI-60 vein illuminator be powered from an uninterruptible power supply or a battery.

Power frequency magnetic fields (50/60Hz) (PFMF) IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The NAVI-30/NAVI-60 vein illuminator is intended for use in the electromagnetic environment specified below. The customer or the user of theNAVI-30/NAVI-60 vein illuminator should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment –guidance
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80MHz; 6 Vrms in ISM bands[a] Between 0.15MHz and 80	3 Vrms 150 kHz to 80MHz; 6 Vrms in ISM bands Between 0.15MHz and 80 MHz; 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the NAVI-30/NAVI-60 vein illuminator, including cables, than the recommended separation distance calculated from the equation applicable to the

	MHz; 80% AM at 1 kHz		frequency of the transmitter. Recommended separation distance
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2.7 GHz; 80% AM at 1 kHz 27V/m:380-390MHz; 28V/m:430-470MHz; 9V/m:704-787MHz; 28V/m:800-960MHz; 28V/m:1700-1990MHz; 28V/m:2400-2570MHz; 9V/m:5100-5800MHz;	3 V/m 80 MHz – 2.7 GHz; 80% AM at 1 kHz 27V/m:380-390MHz; 28V/m:430-470MHz; 9V/m:704-787MHz; 28V/m:800-960MHz; 28V/m:1700-1990MHz; 28V/m:2400-2570MHz; 9V/m:5100-5800MHz;	$d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80M~800MHz $d = 2.3\sqrt{P}$ 800M~2.7GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m)[b]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], a should be less than the compliance level in each frequency range[d]. Interference may occur in the vicinity of equipment marked with the following symbol:

Appendix A

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which theNAVI-30/NAVI-60 vein illuminator is used exceeds the applicable RF compliance level above, theNAVI-30/NAVI-60 vein illuminator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating theNAVI-30/NAVI-60 vein illuminator.

Appendix A

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m

Recommended separation distances between portable and mobile RF communications equipment and the NAVI-30/NAVI-60 vein illuminator				
The NAVI-30/NAVI-60 vein illuminator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NAVI-30/NAVI-60 vein illuminator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NAVI-30/NAVI-60 vein illuminator as recommended below, according to the maximum output power of the communications equipment.				
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = 1.2\sqrt{P}$	80M~800MHz $d = 1.2\sqrt{P}$	800M~2.7GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73

Appendix A

1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

NOTE 3: An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix B Network Security

Operating environment：

- Hardware configuration： NAVI-30/NAVI-60 vein illuminator dedicated hardware platform
- Software environment： none
- Network conditions： none

Security software： none

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