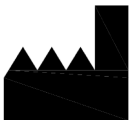




Instruction for Use

ARNE NLS Advisor



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REF


AR-100-NLS-EUR

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1. General Information

1.1 Device name or trade name (ARNE)

ARNE NLS Advisor.

Liability statement

ARNE B.V. makes no warranty, neither expressed nor implied, relating to sales of the device and disclaims warranty liability with regard to merchantability or suitability of use. ARNE B.V. will not be liable for injury or damage resulting from physicians and other clinicians qualified in newborn resuscitation's method or technique. ARNE B.V. will not be liable for injury or damage resulting from selection and use of any device for any particular patient or any patient's condition.

ARNE B.V. does not accept any liability for unsafe situations, accidents and/or damage or loss resulting from one of the following causes:

- Ignoring any warnings or instructions as shown on the device or contained in this Instruction for Use,
- Using the device for other applications or in other conditions than specified in this Instruction for Use,
- Implementing changes of any kind or nature to the device. This also includes the use of other spare parts and changing the internal operating program.

Caution for USA:

Rx only: "Federal law restricts this device to sale by or on order of a licensed physician."

1.2 Intended Purpose

The ARNE NLS Advisor is a clinical decision support system, designed to provide audio and visual guidance to delivery room teams providing life support, to newborn babies, directly after birth, in accordance with the international Newborn Life Support guidelines.

1.3 Indications for use

The ARNE NLS Advisor can be used for real-life newborn life support procedures as for training and simulation purposes of newborn life support procedures for delivery room teams.

1.4 Contra-indications

The ARNE NLS Advisor should not be used for life support procedures other than newborn babies, directly after birth, for which the international newborn life support resuscitation guidelines are designed for. Don't use ARNE NLS Advisor for newborn life support procedures, for babies born at less than 25 weeks of pregnancy.


1.5 Intended user

Caregivers trained and certified to provide (neonatal) life support to pre- and a-term babies, directly after birth, such as pediatricians, neonatologists, obstetricians, pediatric nurses, NICU nurses.

1.6 Patient target group(s)

Early, full, late or post term newborn babies in the need of life support, directly after birth.

1.7 Intended environment

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The ARNE NLS Advisor is designed to be used in perinatal, maternity, pediatric, obstetric, and neonatal acute healthcare settings as operating room and delivery rooms, where immediate management of newborn babies is taken care of after the transition from intra- to extra-uterine environment called birth.

1.8 Clinical benefits to be expected

The ARNE NLS Advisor is designed to reduce cognitive workload for the caregivers, by providing audio and visual guidance of the NLS resuscitation protocol, during real-life, training and or simulation of life support procedures for (preterm) newborn babies, resulting in better adherence to the international newborn resuscitation guidelines. Better adherence to these international resuscitation guidelines is known to result in better patient outcomes.

1.9 Known side effects, residual risks and complications

No known side effects, residual risks, or complications

1.10 Limitations of use

The ARNE NLS Advisor is designed to be used only by caregivers competent in performing (neonatal) life support procedures. Meaning having practical experience in the appropriate handling of the equipment used in newborn resuscitation, competent in skills as airway management and lung inflation, laryngoscopic inspection of the oropharynx, perform chest compressions and establish an umbilical venous access.

1.11 Regulatory information

1.11.1 Classification

CE-MDD classification Class I

1.11.2 Compliance

ARNE NLS Advisor is a CE marked medical device conform to the Medical Device Directive.

1.11.3 Essential performance

No essential performance.

1.11.4 Expected lifetime

10 years for hard- and software. Software requires regularly updates, for operating system and ARNE application.


1.11.5 Service life

10 years

1.11.6 Change of ownership

As soon as the device is purchased by the hospital, they are the owner of the device.


1.12 Warnings and precautions

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1.12.1 Warnings

Do not use ARNE NLS Advisor if it appears or is suspected to be damaged. Damage to the device can result in exposed electrical circuits that may cause harm.

- Do not adjust, repair, open, disassemble, or modify the ARNE NLS Advisor. Damage to the device may result in degraded performance.
- Electrical Shock Hazard: To protect against injury, follow the directions below:
 - o Avoid placing the device on surfaces with visible liquid spills.
 - o Do not soak or immerse the device in liquids.
 - o Do not attempt to sterilize the device.
 - o Use cleaning solutions only as instructed in this Operator's Manual (see Cleaning Instructions on page)
- Disconnect those devices that are charging on the USB port when replacing the battery in power-on mode.
- Keep the ARNE NLS Advisor away from humidity.
- The openings on the enclosure are for air convection. Protect the device from overheating. **DO NOT COVER THE OPENINGS.**
- Make sure the voltage of the power source is correct and stable before connecting the equipment to the power outlet. If the equipment is not used for a long time, disconnect it from the power source to avoid damage by transient over-voltage.
- Never pour any liquid into an opening. This could cause fire or electrical shock.
- If any of the following situations arises, get the equipment checked by service personnel:
 - o The power cord or plug is damaged.
 - o Liquid has permeated into the equipment.
 - o The equipment has been exposed to moisture.
 - o The equipment does not work well, or you cannot get it to work according to the user manual.
 - o The equipment has been dropped and damaged.
 - o The equipment has obvious signs of breakage.
- ARNE NLS Advisor should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.
- To ensure safety, avoid placing anything on the device during operation.
- To avoid risk of electrical shock, this equipment must only be connected to a supply main with a protective earth connection. Do not under any circumstances remove the grounding conductor from the power plug.
- To avoid electric shock, always turn off the ARNE NLS Advisor and physically disconnect the AC power before cleaning.
- Only use the AC power cable provided by ARNE B.V. using a different AC power cable could cause damage to the ARNE NLS Advisor. Check the power cord and plug to ensure that it is intact and undamaged.
 - o If there is any doubt about the integrity of the protective earth conductor arrangement, operate the ARNE NLS Advisor on battery power until the AC power supply protective conductor is fully functional.
- **DO NOT LEAVE THIS EQUIPMENT IN AN UNCONTROLLED ENVIRONMENT WHERE THE STORAGE TEMPERATURE IS BELOW -20°C (-4°F) OR ABOVE 60°C (140°F). IT MAY DAMAGE THE EQUIPMENT.**
- **External equipment intended for connection to signal input/output or other connectors, shall comply with relevant UL / IEC standard (e.g. UL 1950 for IT equipment and ANSI/AAMI ES 60601-1: 2005 AND CAN/CSA-C22.2 No. 60601-1:08 / IEC 60601 series for systems – shall comply with the standard IEC 60601-1-1, Safety requirements for medical electrical systems.**
- **Equipment not complying with UL 60601-1 shall be kept outside the patient environment, as defined in the standard. Unplug the power cord from the power adapter jack to disconnect the device.**
- **Replacement the battery by inadequately trained personnel could result in a HAZARD (such as excessive temperatures, fire or explosion).**
- **Installation of the equipment by service personnel.**

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- Any person who connects external equipment to signal input, signal output, or other connectors has formed a system and is therefore responsible for the system to comply with the standard IEC 60601-1, safety requirements for medical electrical systems.
- It may cause the danger of an explosion if the battery is incorrectly replaced. Replace only with the same or equivalent type recommended by the manufacturer.

1.12.2 Precautions

- Appropriate mounting and fixation of the ARNE NLS Advisor, using a suited VESA mounting bracket is essential and important, to prevent injuries and damage to the device caused by falling.
- Do not touch, press, or rub the display panels with abrasive cleaning compounds, instruments, brushes, rough-surface materials, or bring them into contact with anything that could scratch the display.
- Electrical Shock Hazard: Carry out periodic tests to verify that leakage currents of patient-applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1 and UL60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.

1.12.3 Reporting of serious incidents

In the case of an incident, please contact ARNE B.V. by email: **support@arne.health**

For Europe:

Serious incidents caused by this device shall be reported to the manufacturer and to the competent authority in your EU member state.

For Other Countries:

Follow local reporting requirements and in addition:

In all cases report to your service contact person for ARNE products or to ARNE B.V. directly.

1.13 Contact Information

ARNE B.V.


Zonneoordlaan 17

6718 TK Ede

The Netherlands

support@arne.health

Tel. +31-318657733

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2. Device description

2.1 Device functionalities

2.1.1 Clinical procedures

The ARNE NLS Advisor is designed to give audio and visual guidance for all steps of the newborn life support protocol during newborn life support procedures.

2.1.2 Principle of operation of ARNE NLS Advisor

The ARNE NLS Advisor consists of software and hardware. The ARNE NLS software application runs on a flatbed, touchscreen, medical-grade, dedicated, stand-alone computer with MSWindows-10 operating system.

If used in conjunction with a patient monitoring system, the ARNE NLS Advisor can receive vital signs data input, displayed on the ARNE NLS Advisor interface.

2.2 Installation

Installation will be required for the ARNE NLS Advisor by an ARNE B.V. representative, or a by ARNE B.V. certified distributor.

2.3 Compatibility of accessories

No accessories are used in combination with the ARNE NLS Advisor.


ARNE B.V. does not guarantee safety or performance if any accessories are used which are not mentioned here as compatible.

2.4 Configurations

No different configurations available.

2.5 Performance specifications

The displayed values are checked with the connected equipment at least every second.

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3. Unpacking & Installation

To unpack and inspect the ARNE NLS Advisor:

1. Remove the ARNE NLS Advisor from the shipping carton and examine it for signs of shipping damage.
2. Check all materials against the packing list. Save all packing materials, invoice and bill of lading.
3. If anything is missing or damaged, contact the ARNE Support at support@arne.health.

3.1 Preparation for use

Prior to setting up the ARNE NLS Advisor for use, perform the following steps:

1. Confirm that you have all system components:
 - ARNE NLS Advisor x1
 - Lithium battery (GALLOPWIRE 9789S12300) x2
 - AC Power Cord *) x1
 - AC power adapter x1
 - VESA mounting screws

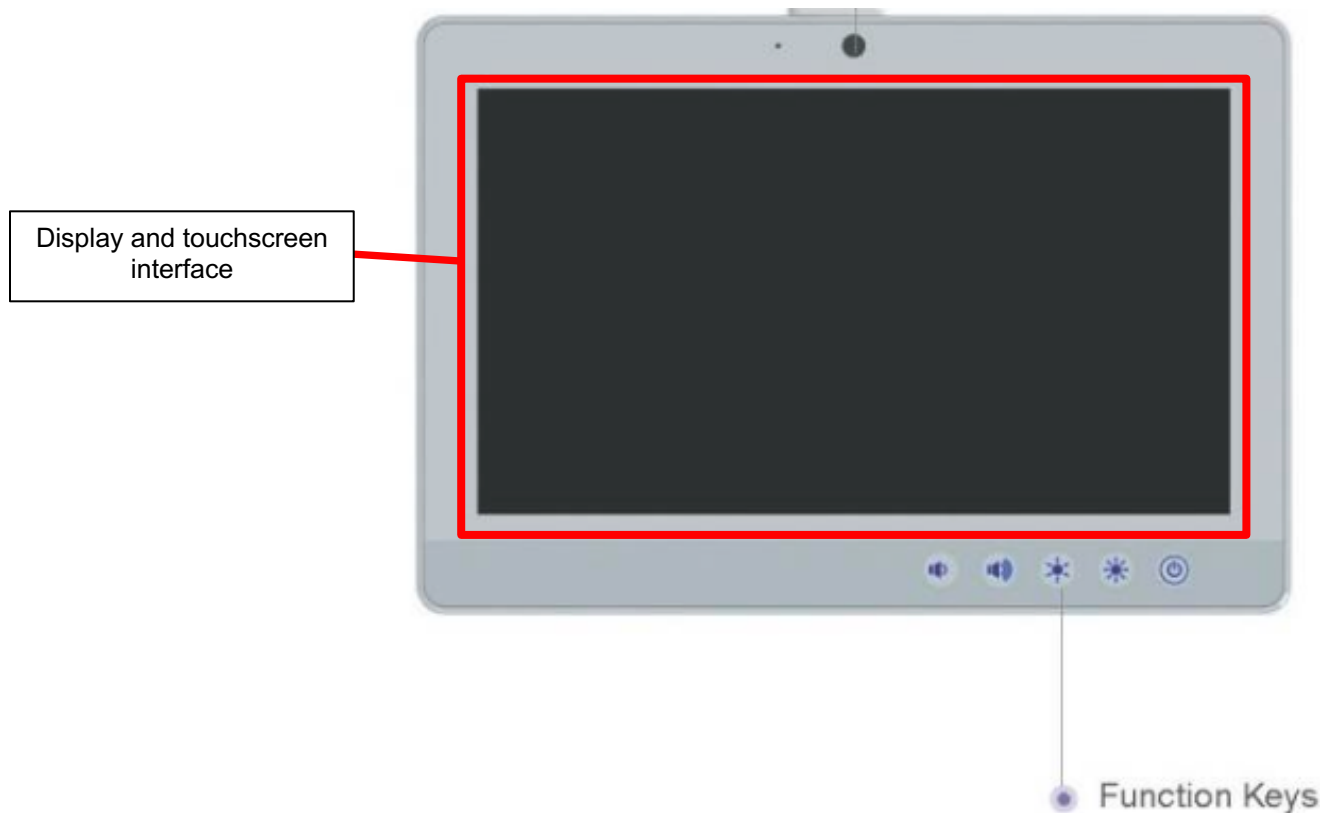
*) Use power cord: Listed, Detachable, Type SJT or above. 125/250 V minimum, 18 AWG/3C minimum, 3.0 m long maximum. One end terminates in 125 V, 10 A, with NEMA 5-15P or 250 V, 10 A with NEMA 6-15P, grounding type, the other end with an appliance coupler. Hospital grade.






2. Read the **Safety Information, Warnings and Cautions** on page .
3. Mount the ARNE NLS Advisor using a VESA MIS-D (100x100) of choice to a pole or rail on, or close to the resuscitation table. ARNE NLS Advisor should be mounted in such a way that the interface is visible to the whole delivery room team and easy to reach, within one arm length, in order to use the device interface during newborn life support procedures.
4. Charge the swappable batteries fully, before use of the ARNE NLS Advisor.
5. Connect the ARNE NLS Advisor to a patient monitor to receive data input for vital signs readings (see Configuring a patient monitor for usage with the ARNE NLS Advisor on page 18). For setting up connection with a patient monitoring device. If no patient monitor is available or patient monitor is not listed in 4.3.11, the ARNE NLS Advisor can be used without a patient monitor. ARNE NLS Advisor will function but will not interface vital parameters of the newborn baby.


4. Operating instructions

4.1 Device features

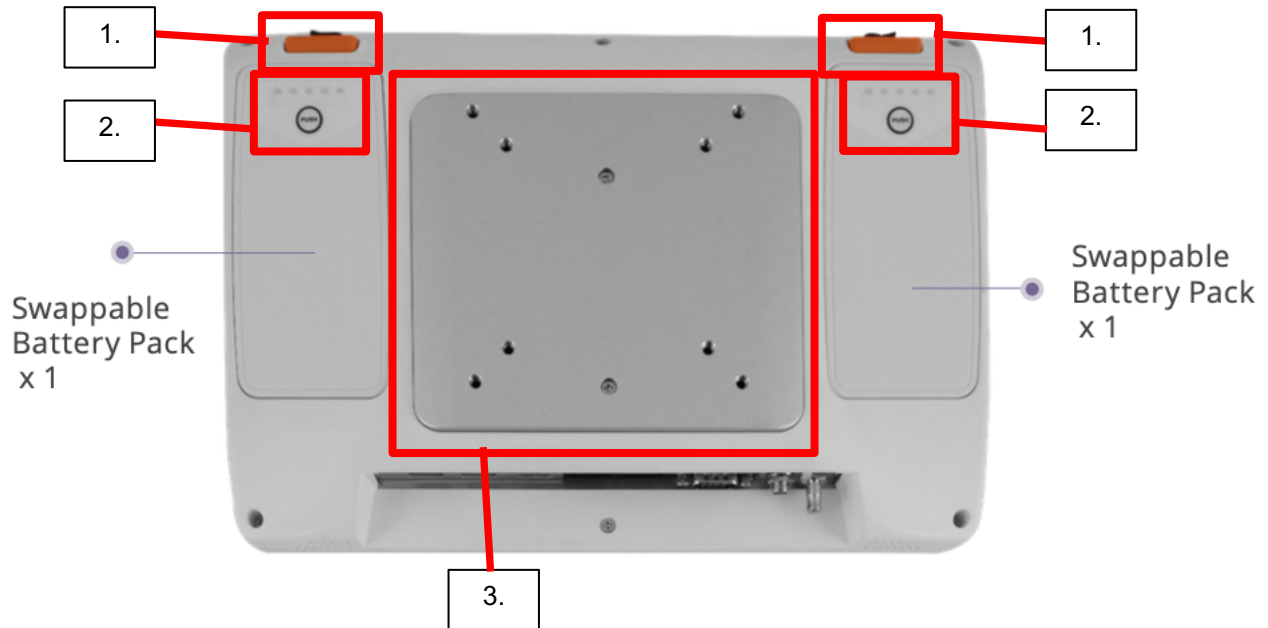
4.1.1 Device front side




Control Button	Function
	Press 2 seconds to turn on the power
	Increase LCD brightness
	Decrease LCD brightness
	Increase speaker volume
	Decrease speaker volume

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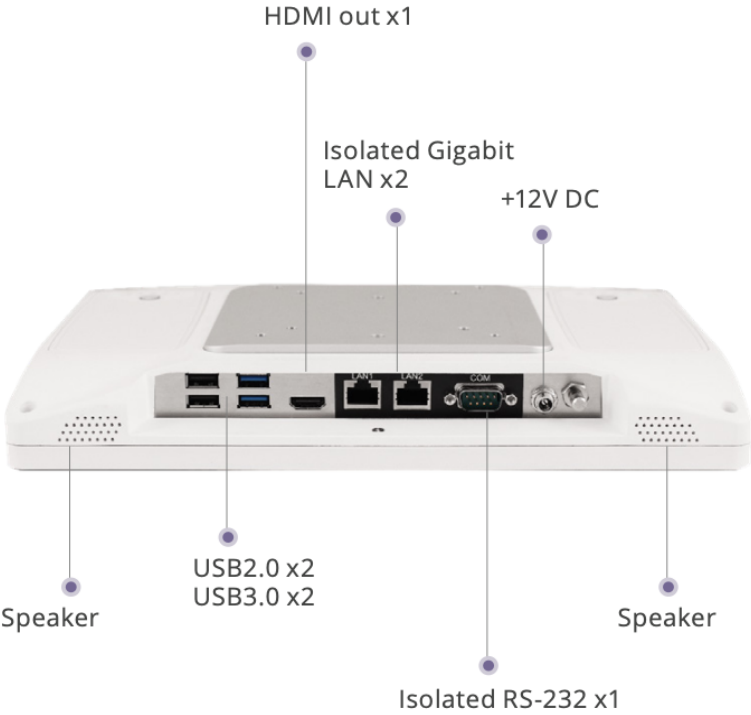
4.1.2 Device back side




1. Release buttons swappable batteries
2. Control button for battery charge indicator
3. VESA 75x75, 100x100 (75/100) mounting plate (use screw M4 type)

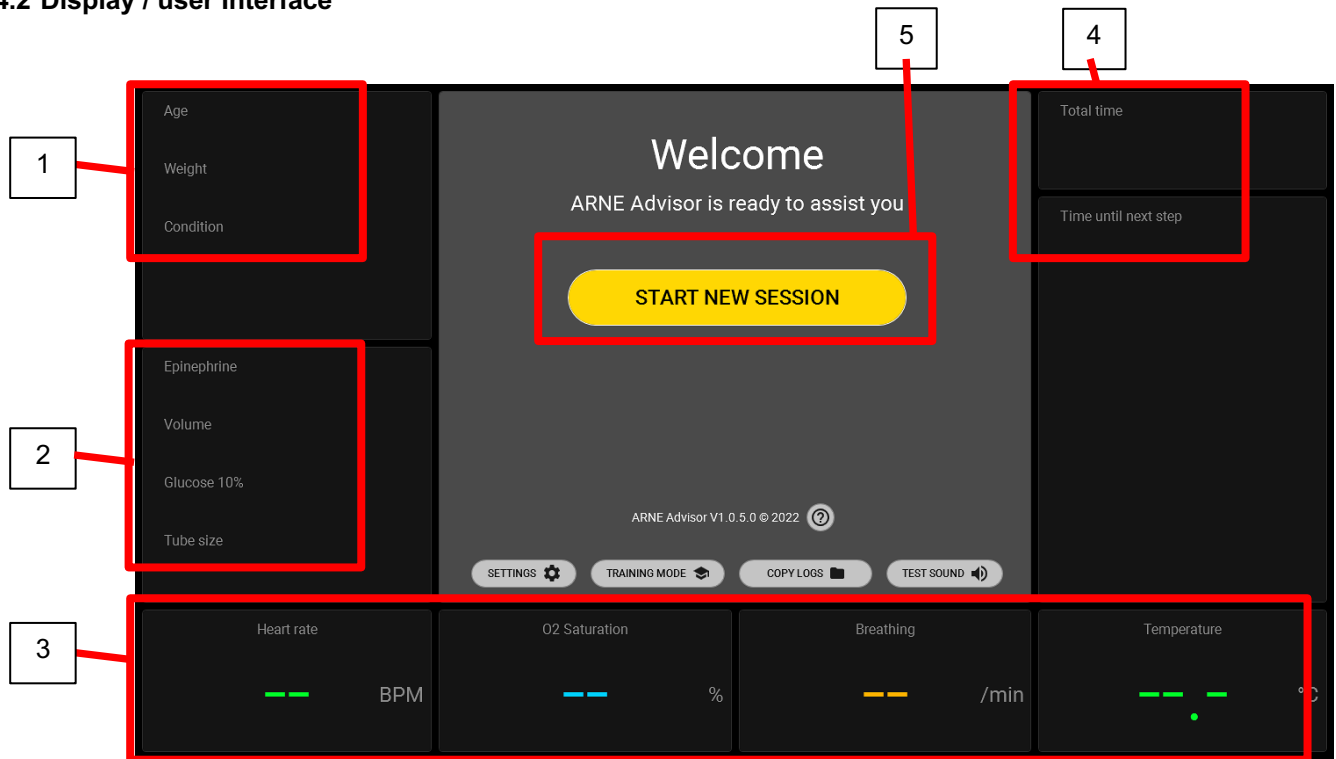
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4.1.3 Device bottom side




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4.2 Display / user Interface



- During the total time of a session, chosen gestational age, weight and optional newborn condition specifications will be visible:
 - Age, range from <24 weeks up to >42 weeks
 - Weight ranges from 500 gr up to 4500 gr.
 - (Possible) newborn conditioner birth specifications:
 - o Blood loss
 - o Congenital diaphragmatic hernia
 - o Cyanotic heart defect
- During the total time of a session the following information will be visible, calculated based on age and weight of the newborn baby:
 - Epinephrine in mcg.
 - Volume in ml.
 - Glucose 10% in ml.
 - Tube size in mm.
- In the case the ARNE NLS Advisor is connected to a patient monitoring device, monitoring the newborn baby, 4 vital parameters can be visible:
 - Heart rate in bpm
 - O2 saturation in %
 - Breathing rate in breaths/min
 - Temperature in Celsius
- The ARNE NLS Advisor will automatically keep track of the total elapsed time of a life support session. Simultaneously interval timing will be displayed, counting backwards the remaining time until the next step of the newborn life support algorithm. Both timing functionalities will start as soon as a new session is initiated.
- Start button for beginning a new Newborn Life Support Session

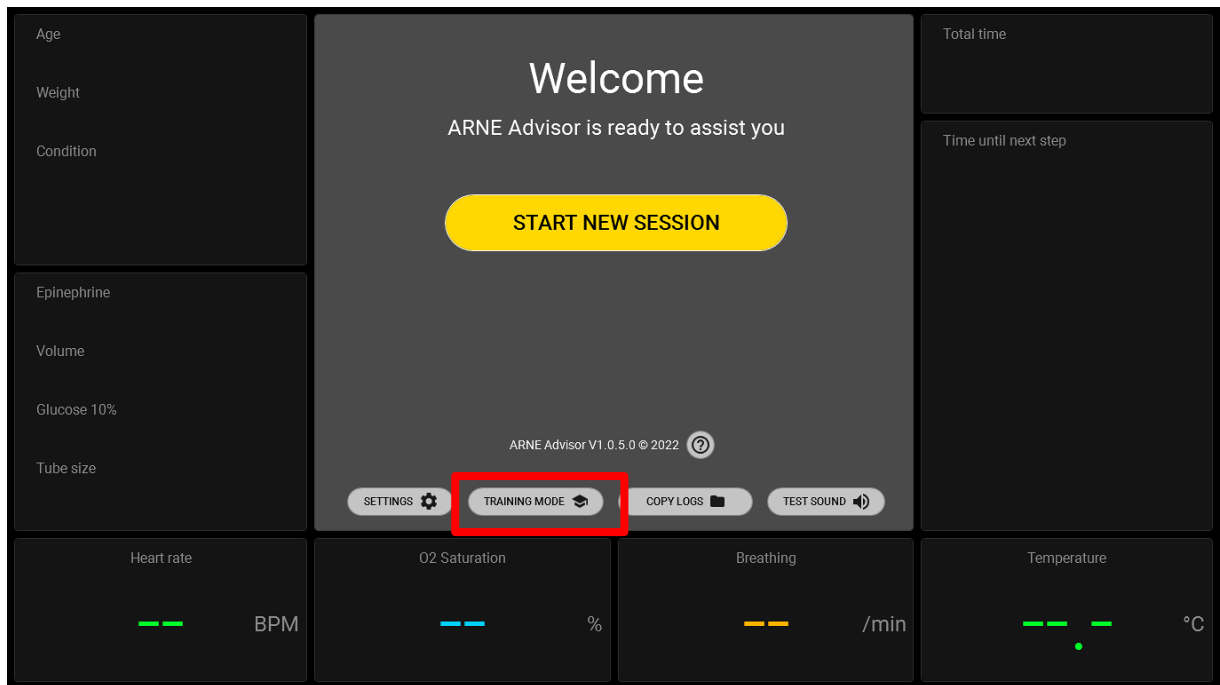
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4.3 Product Preparation

4.3.1 Training Mode

The ARNE NLS Advisor may be used in training mode, to allow working with simulated vital sign values. The simulated vital signs from the ARNE Vital Signs Simulator are only accepted by the ARNE NLS Advisor when it is in training mode.


To enter training mode, press the “TRAINING MODE” button on the welcome screen. You will be asked for a pin code. The default pin code is **13860**, but this may be changed in the Settings screen.

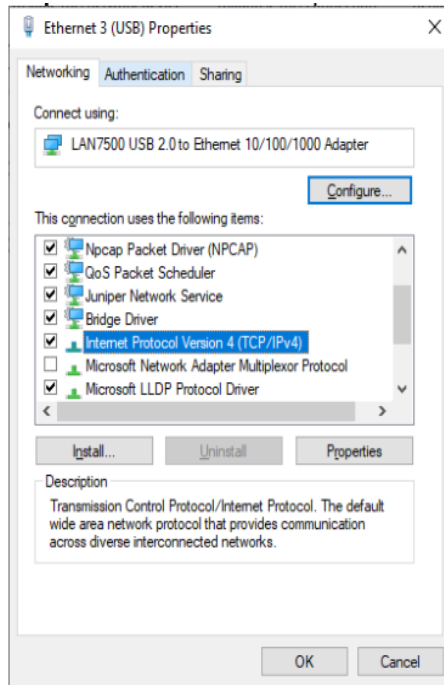


The ARNE Vital Signs Simulator application runs on a separate Windows computer (the trainer's computer) that is connected to the ARNE NLS Advisor via an Ethernet cable.

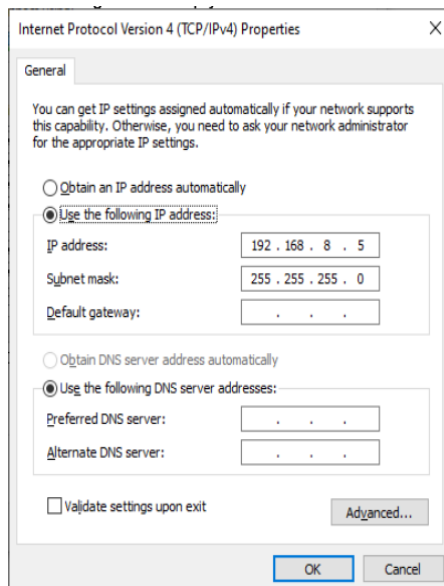
One-time setup of the vital signs simulator application on the separate trainer's Windows computer:

- On the trainer computer, select an Ethernet adapter to use for the crossover connection to the ARNE NLS Advisor. It is recommended (but not mandatory) to use an Ethernet adapter that is not used for other network connections, because the adapter needs to be configured for a static IPv4 address. This will typically not be compatible with a company network or private local network. For example, a separate USB Ethernet adapter could be used.
- Configure the Ethernet adapter IPv4 settings to a fixed/static IP address as follows:
 - Open the **Control Panel** and go to **Network and Internet** and from there to **Network and Sharing Center**
 - Click **Change Adapter Settings** on the left panel
 - Find the Ethernet adapter that is connected to the ARNE Device, right click, and select **Properties**. A window like this opens:


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- Open the **Internet Protocol Version 4 (TCP/IPv4)** properties.
- Fill in the IP address and subnet exactly as follows:
 - IP address: **192.168.8.5**
 - Subnet mask: **255.255.255.0**
 - Default gateway: leave empty
 - DNS settings: leave empty



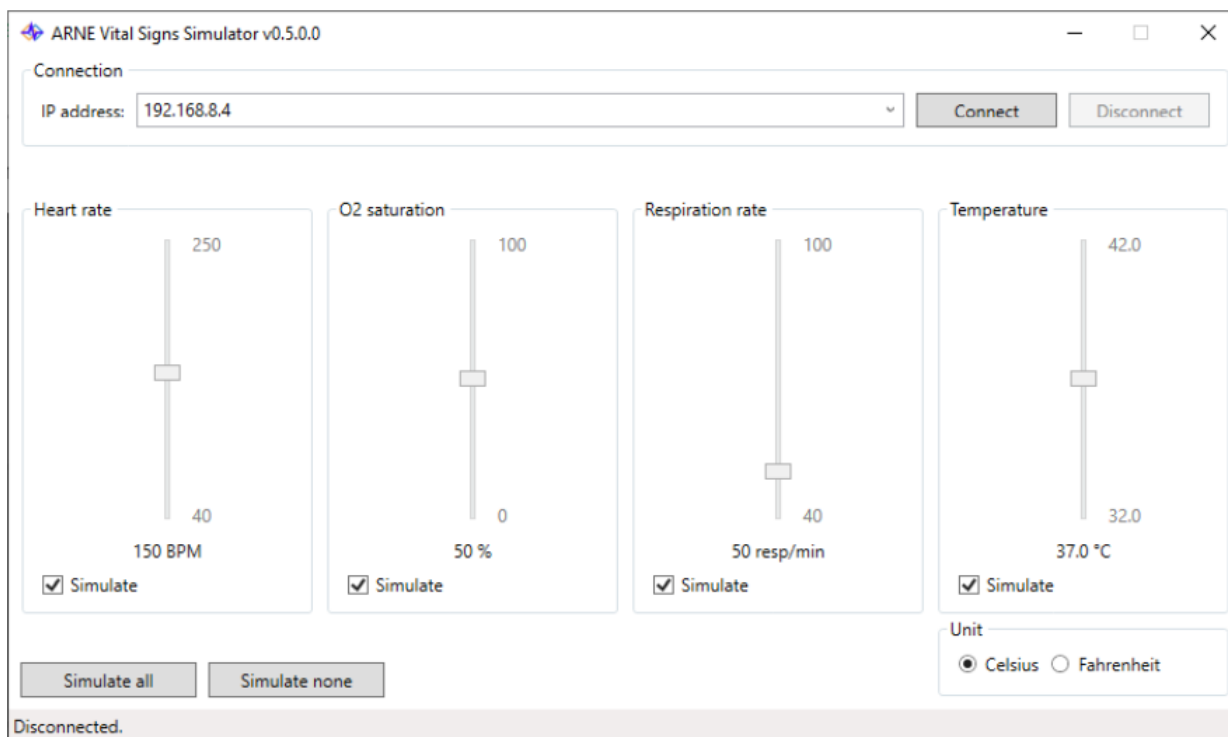
- Press **OK** and **OK** again to save the settings and close the window
- **Important:** do not configure the trainer computer to share its internet connection or local network connection with the ARNE NLS Advisor. The ARNE NLS Advisor must remain disconnected from hospital networks and from the internet.

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- Install the ARNE Vital Signs Simulator application, and, if needed, the .Net Core Desktop runtime.

Regular usage of the ARNE Vital Signs Simulator:

- Connect the trainer computer via the configured Ethernet adapter to the ARNE NLS Advisor on LAN1 (disconnect the IntelliVue cable if present), using an Ethernet **crossover** cable.
- Start the ARNE Vital Signs Simulator application. Make sure the IP address 192.168.8.4 is selected and press the **Connect** button to start sending simulated vital signs to the ARNE NLS Advisor.
- Individual vital signs may be toggled on or off via the Simulate-checkboxes.



To leave training mode, press **“EXIT TRAINING MODE”** on the welcome screen in the ARNE NLS Advisor.

Troubleshooting:


If the ARNE Vital Signs Simulator indicates that the data cannot be transmitted, check the following:

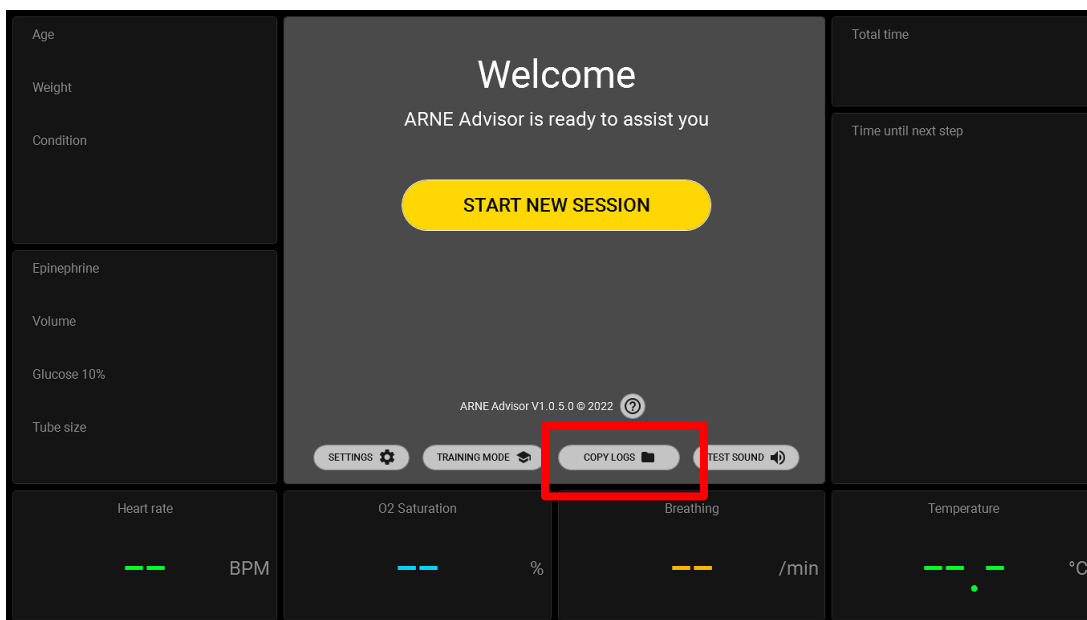
- Is the ARNE NLS Advisor connected via a crossover Ethernet cable on port LAN1?
- Is the ARNE NLS Advisor set to training mode?
- If the connection is lost at seemingly random intervals, and you are using a Gigabit (1000 Mbps) USB external Ethernet adapter, try setting the connection speed in the adapter’s Advanced Properties to ‘100 Mbps Full Duplex’ on the trainer computer. Sometimes USB Ethernet adapters cannot properly handle the 1000 Mbps speeds, and 100 Mbps Full Duplex is sufficient for this application.

4.3.2 Copying session logs

For each session, a session log is maintained containing details about which steps were followed, which choices were made by the user, the values of measures vital signs and the timing.

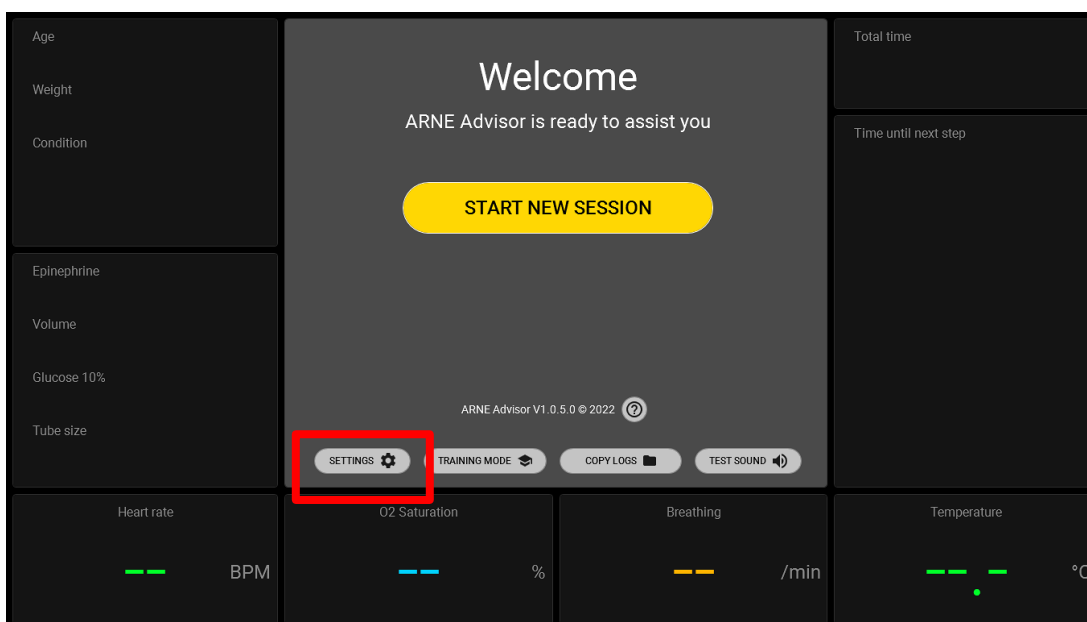
These logs can be copied from the welcome screen by pressing the **“COPY LOGS”** button. You will be asked for a pin code. The default pin code is **13860**, but this may be changed in the Settings screen.

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4.3.3 Settings

To change the settings of the ARNE NLS Advisor, press the “**SETTINGS**” button on the welcome screen. You will be asked for the settings password. The default password is [@rne\\$ettings](#). The password may be changed within the settings.



4.3.4 Default Advisor passwords

To change the settings for the ARNE NLS Advisor the **settings password** is needed, and to use the training mode or to copy the session logs the **training mode pin code** is needed. By default, the settings password is [@rne\\$ettings](#) and the training mode pin code is [13860](#).

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The training mode pin code can be entered using the touch screen. For the settings password, an external USB keyboard is required.

4.3.5 Change default ARNE NLS Advisor passwords

Upon first installation by a hospital IT administrator, it is recommended to change the built-in default ARNE NLS Advisor passwords, for security reasons. Both passwords can be changed in the Settings area, accessible using the settings password. Make sure that the ARNE Advisor is running as the regular 'Arne' user before changing settings, e.g. by power cycling the device (see section 4.3.6).

4.3.6 Windows administrator account

4.3.6.1. Constraints

The Windows administrator account 'Arneadmin' is available strictly for administrative tasks like installing an upgrade for the ARNE NLS Advisor application. The ARNE NLS Advisor application itself is designed to run under the regular 'Arne' user account. It is not supported to run the ARNE Advisor application while logged in as the 'Arneadmin' Windows account. For example, make sure to log out of the 'Arneadmin' account before changing settings (like the passwords or patient monitor setup) in ARNE NLS Advisor.

4.3.6.2. Log in as the Arneadmin account

- Connect a USB keyboard and optionally a USB mouse to the ARNE NLS Advisor device.
- Power up the ARNE NLS Advisor and wait for the application to appear.
- Press **ctrl + alt + delete**
- Select **'Sign out'**
- On the Windows lock screen, select the Arneadmin user
- Enter the Arneadmin password (this can be either the default password, or the password set by the hospital IT staff)

The default Arneadmin password is not listed in this end-user document for security reasons. Please contact ARNE B.V. for the default password.

Caution: The BIOS and Window Administrator passwords are set to a factory default. For security reasons it can be considered to have the hospital IT staff change one or both passwords. By consequence ARNE B.V. will no longer be able to access the system, in the case hospital IT staff loses the BIOS and/or Windows administrator passwords.

4.3.6.3. Log in as the regular account

Option 1:


- Restart or power cycle the ARNE NLS Advisor

Option 2:

- Press ctrl + alt + delete
- Select **'Sign out'**
- On the Windows lock screen, select the Arne user
- No password is required for this user

4.3.7 Preparation text to speech feature (audio messages)

The ARNE NLS Advisor uses audio messages, next to visual messages, to communicate all steps of the NLS protocol to the users of the device.

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In the default settings, the ARNE NLS Advisor's internal sound device (loudspeakers) is enabled. Make sure the internal loudspeaker volume is turned on, by using the volume buttons on the frontside of the device (see Device front side on page 9)

To connect an external headset or audio speaker via Bluetooth, the following steps must be taken to connect such a device.

Make sure you have the Bluetooth speaker/headset available, including the setup (pairing) instructions that came with it (pairing instructions may differ between various Bluetooth speaker/headset models).

1. In Windows, log in as the **Arneadmin** user (see 4.3.6.2.)
2. Press the **Windows key** and type **Bluetooth** and open the "Bluetooth and other devices settings"
3. Press the button "[+] Add Bluetooth or other device"
4. In the "**Add a device**" dialog, select the "**Bluetooth**" category (which has "audio devices" in its description)
5. Follow the instructions of the Bluetooth speaker/headset to set the speaker/headset in '**pairing**' mode
6. When the speaker/headset appears in the list of detected device, select the device and confirm to close the dialog.
7. Verify that only the newly connected headset is listed under the "Audio" heading in the Bluetooth settings window. If other audio devices are listed, remove them.
Note: the ARNE NLS Advisor will always use the default audio device of the PC for sound. In case of problems with the sound, or when replacing the speaker/headset with another Bluetooth speaker/headset, the administrator may change the sound device in Windows as follows:
 1. In Windows, log in as the **Arneadmin** account (see 2.3.3.2)
 2. Open the **Control Panel**
 3. Click on **Sound**
 4. Click on the tab **Playback** in the dialog that opens
 5. Click on the **speaker/headset** name in the list
 6. Press the button "**Set default**"
 7. Press the button "**OK**"
 8. Log back in as the normal Arne Windows user account.

4.3.8 Connecting an external screen via HDMI

It is possible to connect an external screen via HDMI.

Connect an external screen using HDMI cable (not included) to the HDMI port on the bottom side of the ARNE NLS Advisor (see Device bottom side on page 10).

The display of the ARNE NLS Advisor will be mirrored on the external screen.


Which screen(s) and audio device(s) are used by the ARNE NLS Advisor when an external screen is connected, is undefined.

4.3.9 Updating the ARNE NLS application

ARNE NLS application updates are supplied in the form of a Windows installer .msi package. This package includes both the application and the corresponding medical protocol. The process of acquiring this .msi package is outside of the scope of this document.

An IT administrator with access to the Windows administrator account (see 2.3.3.2) can install an update as follows:

- Optionally verify that the .msi file is signed by "ARNE B.V."
- Store the .msi file on a USB drive
- Insert the USB drive into the ARNE NLS Advisor
- In Windows, log in as the **Arneadmin** account (see 2.3.3.2)

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- Run the .msi package, and verify that the Windows security dialog shows the application publisher as “ARNE B.V.”
- Remove the USB drive from the ARNE NLS Advisor
- Power cycle the ARNE NLS Advisor
- After startup, verify in the About dialog that the intended new version has been successfully installed

4.3.10 Installing or updating the license

To use the ARNE NLS Advisor, a license is required. The license is valid for a limited time. When the license expires within 63 days, a warning popup will be shown when the ARNE NLS Advisor starts, advising you to update the license. After the license has expired, the ARNE NLS Advisor will still work for an additional 63 days, and a warning popup will be shown on start-up. After 63 days after the license expiration, the ARNE NLS Advisor can no longer be used, and an error message will be shown.

The license for the ARNE NLS Advisor can be installed or updated as follows:

1. Request a new license key file from ARNE B.V. for the specific ARNE NLS Advisor.
2. Copy the license key file to the root directory of a USB drive. Make sure no expired license keys for the same ARNE Device are on the USB drive. License keys for other ARNE NLS Advisors are allowed.
3. On the ARNE NLS Advisor:
 1. If it's turned on, shut down the device
 2. Insert the USB drive
 3. Turn on the ARNE NLS Advisor. The ARNE NLS Advisor will automatically detect the license and install it. You can verify in the About dialog that the license expiration date matches the newly installed license key.

4.3.11 Configuring a patient monitor for usage with the ARNE NLS Advisor

ARNE supports a connection to zero or one patient monitor at the same time.

4.3.11.1 Philips IntelliVue

ARNE supports a stand-alone (non-networked) Philips IntelliVue with product software version: F.01.43


Set up manual IP address:

- 1) Enter Service operating mode
- 2) Select **Main Setup**
- 3) Select **Bed information**
- 4) Select **Network**
- 5) Select **Manual IP address**, and configure these values:
 - a. IP address: **192.168.8.5**
 - b. Subnet mask: **255.255.255.0**
 - c. Gateway: **192.168.8.4**
- 6) Press **Store**
- 7) Power cycle the IntelliVue

Connect the LAN port of the IntelliVue with a **crossover** Ethernet cable to the LAN1 port on the ARNE NLS Device. Note that data received from an IntelliVue set to *Demo* mode is not accepted as valid data by the ARNE NLS Advisor.

4.3.11.2 Masimo Rad 5 / Radical 7 / Rad 8

ARNE NLS Advisor supports a Masimo Rad 5 / Radical 7 / Rad 8 connected via the RS-232 connection. The Masimo needs to have the Serial Output Port Mode set to **ASCII 1**. Refer to the Masimo user manual on how to configure this setting.

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4.3.11.3. Dräger Infinity Acute Care System

ARNE NLS Advisor supports a stand-alone (non-networked) Dräger IACS system with software version VG7.1.1, using the Infinity Export Protocol (revision 2.1). The IACS system consists of mainly three interconnected devices:

- M540 patient monitor
- C500/C700 cockpit display
- P2500/PS250 power/communications hub

All of these three devices are required to communicate with the ARNE device

Connect the IACS to the ARNE NLS Advisor via the Infinity Export RS-232 connection on the P2500/PS250 power/communications hub. This requires a Dräger RJ-22 to DB9 serial cable (for instance Dräger item MS22948). Refer to the Dräger IACS user manual for details.
There are no relevant software settings on the Dräger device.

Note that data received from an IACS in '*simulated patient data*' mode is accepted as valid data by the ARNE NLS device, because the Infinity Export Protocol does not indicate this simulation status. This is different from Philips IntelliVue monitor, where demo data is ignored by ARNE.

4.4 Error recovery

If the ARNE NLS device is on but the ARNE NLS application is not showing (a black screen), restart the device by switching it off and back on.

4.5 Resetting the application to its default settings

In case the password or pin code (see section 2.3.1) have been changed and lost, it is possible to reset the ARNE NLS device to its default settings.

To reset the application to its default settings, the following steps must be taken:

1. In MS Windows, log out of the Arne account and log in to the administrator account (see 4.3.6.2)
2. Press the **Windows-key** and open a command prompt by typing the follow command and then pressing the **enter-key**:

cmd

3. Navigate to the ARNE B.V. applications settings directory **for the Arne user** (this is a different user than the currently logged in Arneadmin user) by performing the following commands:

cd C:\Users\Arne\AppData\Local\ARNE_B.V <press enter> **dir** <press enter>


This shows a list of subdirectories, one of which will start with 'Arne.Advisor.UI'. Perform the following command for that full directory name (you can type the first part of the name and use the TAB key to autocomplete):

cd Arne.Advisor.UI_xyz <use the actual name, then press enter>

4. Delete the application settings by typing the following command, and then pressing the enter-key:

del /S /Q user.config

5. Log back in to the normal Arne Windows user account. The settings should now be back to factory default.

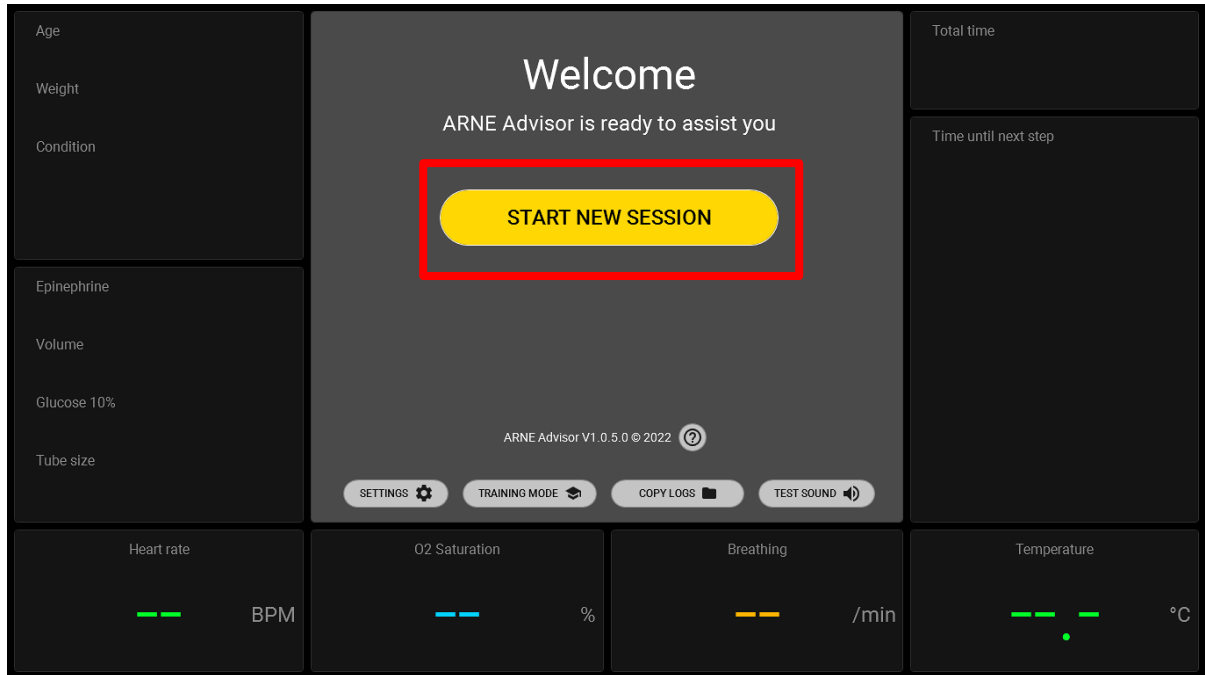
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4.6 Product Operation

4.6.1 Starting a Newborn Life Support session


4.6.1.1. Step 1

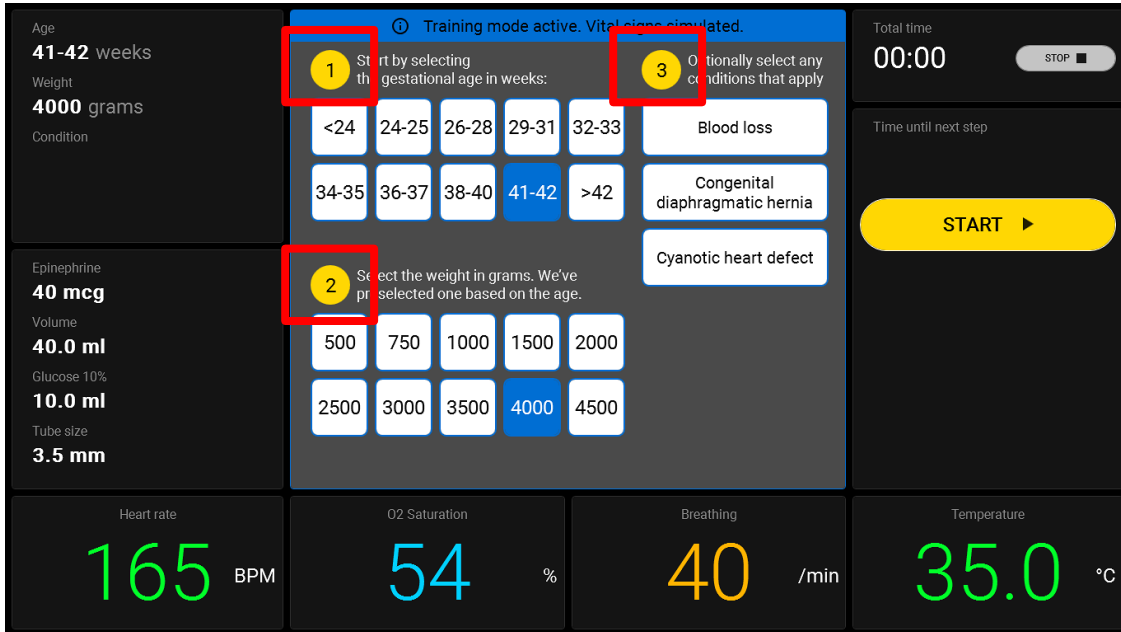
Push the **START NEW SESSION** button.



4.6.1.2. Step 2

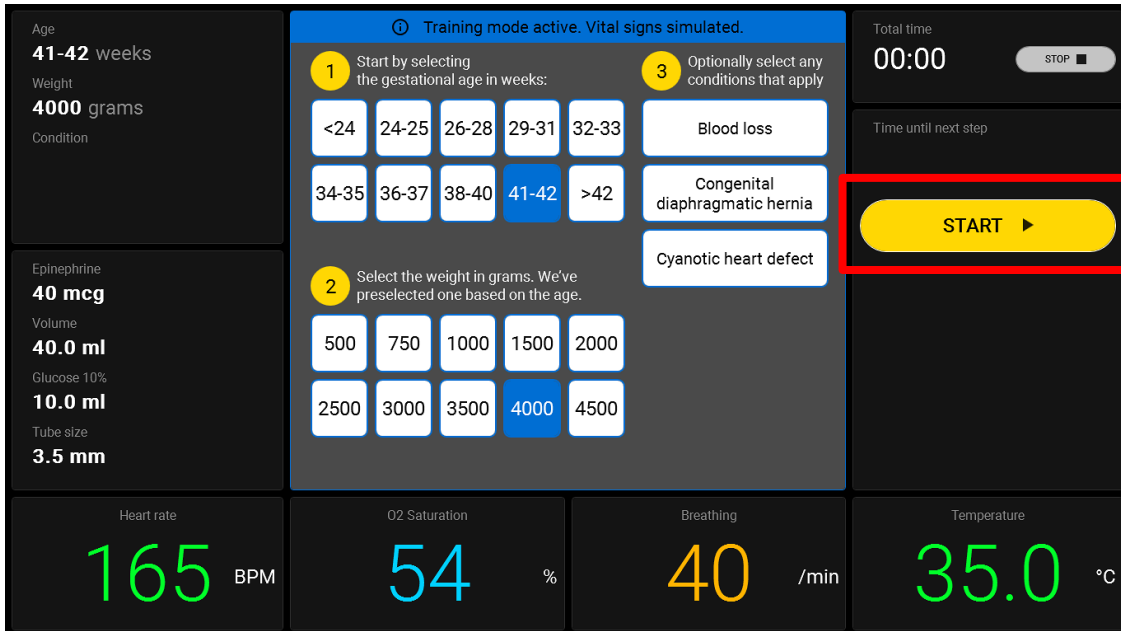
1. Select gestational **AGE** of the newborn baby
2. Select **WEIGHT** of the newborn baby
3. Optionally select any of the following specific newborn **CONDITIONS**:
 - a. Blood loss
 - b. Congenital diaphragmatic hernia
 - c. Cyanotic heart defect


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4.6.1.3. Step 3

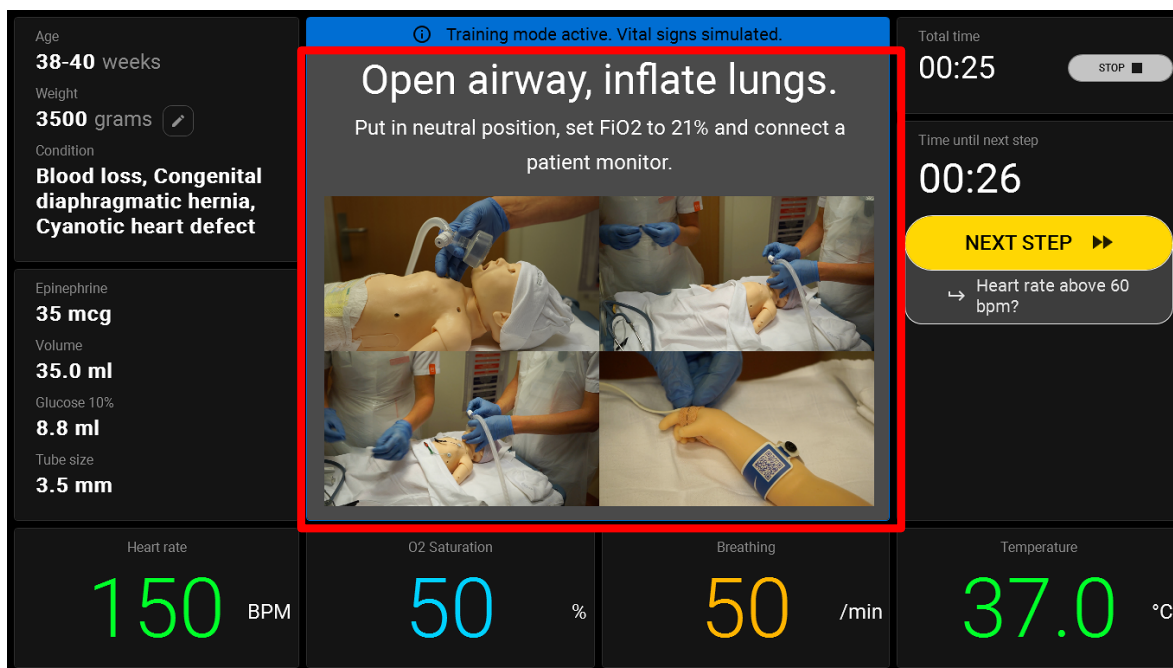
Push the **START >** button.



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4.6.1.4. Step 4

Follow the Newborn Life Support instructions in the center part of the display.



Age: 38-40 weeks
Weight: 3500 grams
Condition: Blood loss, Congenital diaphragmatic hernia, Cyanotic heart defect
Epinephrine: 35 mcg
Volume: 35.0 ml
Glucose 10%: 8.8 ml
Tube size: 3.5 mm

Training mode active. Vital signs simulated.

Open airway, inflate lungs.
Put in neutral position, set FiO₂ to 21% and connect a patient monitor.

Total time: 00:25
Time until next step: 00:26
NEXT STEP → Heart rate above 60 bpm?

Heart rate: 150 BPM
O₂ Saturation: 50 %
Breathing: 50 /min
Temperature: 37.0 °C

4.6.1.5. Step 5

After every step choose **NEXT STEP >>** or choose between the **YES** or **NO** button to proceed to the next step in the Newborn Life Support protocol.



Age: 38-40 weeks
Weight: 3500 grams
Condition: Blood loss, Congenital diaphragmatic hernia, Cyanotic heart defect
Epinephrine: 35 mcg
Volume: 35.0 ml
Glucose 10%: 8.8 ml
Tube size: 3.5 mm


Training mode active. Vital signs simulated.

Dry the baby and place a cap.
If possible, delay clamping of the cord for 60 seconds.
Stimulate spontaneous breathing.


Total time: 00:04
Time until next step: 00:26
NEXT STEP → Is the baby breathing?

Heart rate: — BPM
O₂ Saturation: — %
Breathing: — /min
Temperature: — °C

Or choose between the **YES** or **NO** button to proceed to the next step in the Newborn Life Support protocol.

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Age
24-25 weeks

Weight
750 grams 

Condition

Epinephrine
10 mcg

Volume
7.5 ml


Glucose 10%
1.9 ml

Tube size
2.5 mm

Training mode active. Vital signs simulated.

Heart rate above 100 bpm?

Check heart rate by auscultation or attach monitor.



Total time
00:46 STOP

Time until next step
00:02

YES

↳ Good colour and tone?

NO

↳ Ventilate the baby.

Heart rate
-- BPM

O2 Saturation
54 %


Breathing
40 /min

Temperature
35.0 °C

4.6.2 Editing the weight during a session

Directly after starting a session, you will be asked to enter the weight of the baby. The weight impacts treatment recommendations. It is possible to change the weight of the baby during the session by clicking the pencil icon next to it (see button on the image below in the red square). Treatment recommendations and protocol steps dependent on weight will be automatically updated.

Age
24-25 weeks

Weight
750 grams 

Condition

Epinephrine
10 mcg

Volume
7.5 ml


Glucose 10%
1.9 ml

Tube size
2.5 mm

Training mode active. Vital signs simulated.

Heart rate above 100 bpm?

Check heart rate by auscultation or attach monitor.



Total time
00:46 STOP

Time until next step
00:02

YES

↳ Good colour and tone?

NO


↳ Ventilate the baby.

Heart rate
-- BPM

O2 Saturation
54 %

Breathing
40 /min

Temperature
35.0 °C

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5. Cleaning Instructions

The ARNE NLS Advisor is a reusable device. The device is supplied and is intended to be used non-sterile.

WARNING: To avoid electric shock, always turn off the ARNE NLS Advisor and physically disconnect the AC power and all patient connections before cleaning.

CAUTION: To avoid permanent damage to the ARNE NLS Advisor, do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any other cleaning solution not recommended.

To surface clean the ARNE NLS Advisor:

- Wipe the outer surfaces using a dampened soft cloth with one of the recommended cleaning solutions; water or 70% rubbing alcohol) twice or until the surfaces are free of any visible residue.
- Use a vacuum cleaner to absorb the dust, dirt, hair, and other particles out of the device. Over time these items can restrict the airflow in a computer and cause circuitry to corrode.
- Use cotton swabs moistened with water or rubbing 70% alcohol for wiping hard to reach areas on the device.


Note: Pay particular attention to cracks, crevices, and hard to reach areas of the device.

- Repeat the above cleaning step using a fresh wipe.
- Allow the ARNE NLS Advisor to dry thoroughly before using again.

CAUTION: To avoid permanent damage to the ARNE NLS, do not use excessive amounts of liquids to clean the device.

The surfaces of the ARNE NLS Advisor may be cleaned with the following solution(s):

- 70% Isopropyl Alcohol

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6. Maintenance Instructions

6.1 Battery Operation and Maintenance

The ARNE NLS Advisor includes two swappable lithium-ion rechargeable batteries. When starting up, always ensure that the device is AC powered.

Before using the ARNE NLS Advisor without the AC power connection, check the battery charge status indicator, by pushing the battery charge status indicator button and ensure that the battery is fully charged (See **Battery Charge Status Indicator** on page 10)

Note: When battery run time is significantly reduced, it is advisable to completely discharge and fully recharge the battery.

6.2 Repair Policy

ARNE B.V. or an authorized service department must perform warranty repair and service. Do not use malfunctioning equipment. Have the device repaired.

Clean contaminated and/or dirty equipment before returning, following the cleaning procedure described in Cleaning Instructions on page . Make sure the equipment is fully dry before packing.

To return the device for service, refer to the **Return Procedure** below.

6.3 Return Procedure


Clean contaminated/dirty equipment before returning, following instructions in Make sure the equipment is fully dry before packing. Contact ARNE B.V. via support@arne.health and ask for an RMA number. Package the equipment securely, in the original shipping container if possible, and enclose or include the following information and items:

- A letter describing in detail any difficulties experienced with the ARNE NLS Advisor. Include the RMA number in the letter.
- Warranty information, a copy of the invoice or other applicable documentation must be included.
- Purchase order number to cover repair if the ARNE NLS Advisor is not under warranty, or for tracking purposes if it is.
- 'Ship-to' and 'bill-to' information.
- Person (name, telephone/fax-number, and country) to contact for any questions about the repairs.
- A certificate stating the ARNE NLS Advisor has been decontaminated for bloodborne pathogens.
- Return the ARNE NLS Advisor to the shipping address listed below.

Contact ARNE.B.V.

ARNE B.V.

Zonneoordlaan 17
6718 TK Ede
The Netherlands
support@arne.health

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6.4 Limited warranty

ARNE B.V. warrants to the original end-user purchaser the ARNE-branded hardware product (ARNE LNS device) and any software media contained in the original packaging against defects in material and workmanship when used in accordance with ARNE B.V.'s user manuals, technical specifications, and other ARNE B.V. published guidelines for a period of 12 months and any batteries for six (6) months from the original date the Product was obtained by the end-user purchaser. ARNE B.V.'s sole obligation under this warranty is the repair or replacement, at its option, of any defective Product or software media that is covered under the warranty. To request a replacement under warranty, Purchaser must contact ARNE B.V. and obtain a returned goods authorization number so that ARNE B.V. can track the Product. If ARNE B.V. determines that a Product must be replaced under warranty, it will be replaced, and the cost of shipment covered. All other shipping costs must be paid by the purchaser.

6.5 Exclusions

The warranty does not apply to any non-ARNE B.V. branded product or any software, even if packaged with the Product, or any Product that was: (a) not new or in its original packaging when supplied to purchaser; (b) modified without ARNE B.V.'s written permission; (c) supplies, devices, or systems external to the Product; (d) disassembled, reassembled, or repaired by anyone other than a person authorized by ARNE B.V.; (e) used with other products, or other accessories, not intended by ARNE B.V. to be used with the Product; (f) not used or maintained as provided in the operator's manual or as otherwise provided in its labeling; (g) reprocessed, reconditioned, or recycled; and (h) damaged by accident, abuse, misuse, liquid contact, fire, earthquake or other external cause.

No warranty applies to any Product provided to Purchaser for which ARNE B.V., or its authorized distributor, is not paid; and these Products are provided AS-IS without warranty.

6.6 Limitation of warranty


Except as otherwise required by law or altered by the purchase agreement, the above warranty is the exclusive warranty that applies to the Product and software media, and ARNE B.V. does not make any other promises, conditions, or warranties regarding the Product. No other warranty applies, express or implied, including without limitation, any implied warranty of merchantability, fitness for a particular purpose, satisfactory quality, or as to the use of reasonable skill and care. See the licensing terms for the terms and conditions that apply to and Software accompanying the Product. Additionally, ARNE B.V. will not be liable for any incidental, indirect, special, or consequential loss, damage, or expense arising from the use or loss of use of any Products or Software. In no event shall ARNE B.V.'s liability arising from any Product or Software (under contract, warranty, tort, strict liability, or otherwise) exceed the amount paid by the purchaser for the Product or Software. The above limitations do not preclude any liability that cannot legally be disclaimed by contract.

6.7 Sales end-user agreement (with restrictions)

This document is a legal agreement between you ("purchaser") and ARNE B.V. ("ARNE") for the purchase of this Product ("Product") and a license in the included or embedded Software ("Software") except as otherwise expressly agreed in a separate contract for the acquisition of this Product, the following terms are the entire agreement between the parties regarding your purchase of this Product. If you do not agree to the terms of this agreement, promptly return the entire Product, including all accessories, in their original packages, with your sales receipt to ARNE B.V. for a full refund.


Restrictions

- Copyright Restrictions: The Software and the accompanying written materials are copyrighted. Unauthorized copying of the Software, including Software that has been modified, merged, or included with other software, or the written materials is expressly forbidden. Purchaser may be held legally responsible for any copyright infringement that is caused or incurred by Purchaser's failure to abide by the terms of this Agreement.
- Use Restrictions: Purchaser may physically transfer the Product from one location to another provided that the Software is not copied. Purchaser may not electronically transfer the Software from the Product to any other device. Purchaser may not disclose, publish, translate, release, distribute copies of,

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modify, adapt, translate, reverse engineer, decompile, disassemble, or create derivative works based on the Software or the written materials.

- Transfer Restrictions: In no event may Purchaser transfer, assign, rent, lease, sell, or otherwise dispose of the Product or the Software on a temporary basis. Purchaser shall not assign or transfer this License, in whole or in part, by operation of law or otherwise without ARNE B.V.'s prior written consent; except that the Software and all of Purchaser's rights hereunder shall transfer automatically to any party that legally acquires title to the Product with which this Software is included. Any attempt to assign any rights, duties or obligations arising hereunder other than as set forth in this paragraph shall be void.

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7. Disposal of the Device

Waste Electrical and Electronic Equipment (WEEE) Disposal Instructions




According to the WEEE Directive 2008/98/EC, all categories of electrical and electronic equipment (EEE) covered by this directive in the ANNEX I should be disposed of and collected separately and use the best available treatment, recovery, and recycling techniques.

EEE contains hazardous substances to the human health and environment, but EEE is also a valuable resource of raw materials. Therefore, it is important to collect WEEE separately from other wastes.

ARNE B.V. products are subject to the Directive, and we therefore urge you to dispose of the equipment separately from “normal” household waste and make sure that it is properly treated, recovered, or recycled to protect human health and the environment.

For a Return Material Authorization, contact ARNE B.V. at support@arne.health

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8. Troubleshooting

In this section you find information about troubleshooting the system. For a list of messages, refer to the Error message section 8.1.

For reporting errors in the software to the ARNE B.V. service organization, see the Contact information section.

8.1 Error messages


The following tables list the error messages that the Advisor can display in various scenarios or screens in the application. The tables list only the English (US) translation of the messages. The Advisor shows most error messages in the configured user interface language; all exceptions are noted in the Details column.

8.1.1 Device start-up errors

Description	Result	Required action	Details
Your license for the ARNE Advisor expires in X days. Please contact the system administrator to renew the license.	Advisor shows a dialog with this message at start-up. Advisor can be used normally after the user acknowledges the dialog.	Contact the system administrator to renew the license within X days.	The value of X varies depending on the situation.
Your license for the ARNE Advisor has expired. After Y days, the application will no longer work. Please contact the system administrator to renew the license.	Advisor shows a dialog with this message at start-up. Advisor can be used normally after the user acknowledges the dialog.	Contact the system administrator to renew the license within Y days.	The value of Y varies depending on the situation.
Your license for the ARNE Advisor has expired.	Advisor does not start.	Contact the system administrator to renew the license.	-
The license file is invalid or was not found.	Advisor does not start.	Contact the system administrator to repair or renew the license.	-
An error occurred while loading the medical protocol.	Advisor does not start.	Contact the system administrator to investigate the problem.	-
Failed to start the ARNE Advisor application.	Advisor does not start.	Contact the system administrator to investigate the problem.	This message is always displayed in English.

8.1.2 Power errors

Description	Result	Required action	Details
It is not possible to start a new session on battery power. Please connect the device to a power outlet.	Advisor returns to the home screen after the user acknowledges this dialog. It is not possible to start a session.	Connect the device to a power outlet.	-
Mains power was lost; the device is now running on battery power. You can finish the current session, but you won't be able	If a session is active, the user can continue the session after acknowledging the dialog.	Connect the device to a power outlet.	This message can be displayed both during a session

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to start a new one until the device is reconnected to a power outlet.	If no session is active, it is not possible to start a new session until the device is reconnected to a power outlet.		and outside of a session.
---	---	--	---------------------------

8.1.3 Audio errors

Message Description	Result	Required action	Details
Headset is not detected or not connected. Please make sure the headset is connected, charged, and turned on.	Sessions can be started, but text-to-Speech audio is not available during the session.	Make sure the headset is properly connected via Bluetooth to the correct ARNE device. Make sure the headset is charged and turned on.	This message can be displayed when using the audio test button.

8.1.4 ARNE NLS Advisor pin code errors


Message Description	Result	Required action	Details
The entered pin is incorrect. Please try again.	The user cannot access the training mode and session log transfer features.	Enter the correct pin code. Or, contact the system administrator to reset the pin code.	This message can be displayed when attempting to enable training mode and when attempting to access the session log transfer feature.

8.1.5 Session log transfer errors


Message Description	Result	Required action	Details
Error: No USB drive found.	Session logs cannot be transferred to the USB drive.	Insert a valid and writable USB drive with sufficient available space.	-
Error: Unable to copy logs to USB drive.	Session logs cannot be transferred to the USB drive.	Insert a valid and writable USB drive with sufficient available space.	-
Error: Unable to create log directory on USB drive.	Session logs cannot be transferred to the USB drive.	Insert a valid and writable USB drive with sufficient available space.	-
Error: Unable to get USB drive information.	Session logs cannot be transferred to the USB drive.	Insert a valid and writable USB drive with sufficient available space.	-

8.1.6 Administrator settings errors

Message Description	Result	Required action	Details
The entered password is incorrect. Please try again.	The user cannot access the administrator settings screen.	Enter the correct administrator password. Or, contact the system administrator to reset the password to the default value.	This message can be displayed when attempting to access the administrator settings screen.


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The current password is incorrect.	The administrator password has not been changed.	Enter the correct current administrator password in the corresponding field and try again.	This message can be displayed when attempting to change the administrator password in the settings screen.
The new password and the confirmed password are different.	The administrator password has not been changed.	Enter the same new administrator password in the two corresponding fields and try again.	This message can be displayed when attempting to change the administrator password in the settings screen.
The new password must be at least 8 characters long and contain at least one letter.	The administrator password has not been changed.	Enter a new administrator password that complies with the given requirements in the two corresponding fields and try again.	This message can be displayed when attempting to change the administrator password in the settings screen.
The current pin code is incorrect.	The pin code has not been changed.	Enter the correct current pin code in the corresponding field and try again.	This message can be displayed when attempting to change the pin code in the settings screen.
The new pin code and the confirmed pin code are different.	The pin code has not been changed.	Enter the same new pin code in the two corresponding fields and try again.	This message can be displayed when attempting to change the pin code in the settings screen.
The pin code may only contain digits.	The pin code has not been changed.	Enter a new pin code that complies with the given requirements in the two corresponding fields and try again.	This message can be displayed when attempting to change the pin code in the settings screen.
The pin code must be exactly 5 digits long.	The pin code has not been changed.	Enter a new pin code that complies with the given requirements in the two corresponding fields and try again.	This message can be displayed when attempting to change the pin code in the settings screen.











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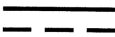
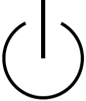
8.1.7 Other errors





An unexpected error has occurred. You will be taken back to the home screen.	Advisor returns to the home screen automatically after the user acknowledges this dialog. Any active session is stopped.	Advice: restart the device. Advice: contact the system administrator to investigate the problem.	-


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9. Explanation of Symbols

General			
Symbol	Explanation	Symbol	Explanation
	Manufacturer and manufacturing date		Compliant with European regulations on medical devices. Conformity is assessed by notified body with identification number.
	Medical Device		Unique Device Identifier
	Catalog number		Serial Number
	Consult instructions for use, Indicates the need for the user to consult the instructions for use.		Caution, Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Please read Instructions for use prior to first use		Dispose of equipment according national and/or local regulations

Electrical safety			
Symbol	Explanation	Symbol	Explanation
	Alternating current		Direct current
	Stand-by		


Transport & Storage Conditions			
Symbol	Explanation	Symbol	Explanation
	Keep dry		Temperature limit
	Keep away from heat		Humidity limitation

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10. Appendix A- Technical Data & Specifications

Main Specifications	
Processor	Intel Skylake Dual-Core i5/Celeron 3955U
System Memory	DDR4 up to 16GB
OS Support	Microsoft Windows 7 Microsoft Windows 8.1 Microsoft Windows 10 Ubuntu 18.04 LTS IGEL (thin client solution)
Graphics	Intel HD Graphics 520
Storage	M.2 SSD up to 512Gb (optional)
Wireless Communication	802.11 ac/a/b/g/n + BT 4.0 (optional)
Touch	Project Capacitive Touch / resistive Touch
Speaker	3W x2
Security	TPM 2.0
Display	
Display Size	11.6"
Resolution	1366 x 768
Max. Colors	262K
Contrast Ratio	500:1
Luminance(cd/m2)(TYP)	250
I/O	
USB	USB 3.0 x2, USB 2.0 x2
Video Out	HDMI out x1
COM	COM port x1
Ethernet	Gigabit LAN x2
DC-in	12V DC-in x1
Mechanical and Environmental	
VESA	75/100 mm VESA mount
Operating Temperature	0 C~35C(32F~95F)
Storage Temperature	-20C~60C(-4F~140F)
Storage Humidity	10%~95%@40C, non-condensing
Degree of Protection	Front Panel: IP65, Rear IPX1
Dimension	300(L) x 185(W) x 345(H) mm
Net Weight	1.9kg
Gross Weight	2.6kg
Package Dimension (W x D x H)	420(L) x 185(W) x 345(H) mm
Certifications	CE: EN 60601-1-2:2015(V4.0) EN 60601-1:2006/A1:2013(V3.1) FCC: Part 18 Class B UL: ANSI/AAMI ES60601-1:2012 (V3.1) cUL: CAN/CSA-C22.2 No. 60601-1:2014 (3.1)
Power Supply	
Model	Adapter ATM065-P120
Input	100-240V AC, 50-60Hz
Output	12v, 5A

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Model	Adapter ATM090T-P120
Input	100-240Vac, 50-60Hz
Output	12V, 7A
Battery	
Manufacturer	Onyx
Model	OPM-P05T(2INP8/36/41-3)
Type	Lithium-ion battery
Capacity	32.72Wh
Output ratings	7.2Vdc, 4545mAh

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10.1 Product dimensions in mm

