Automatic Cleaning, Disinfection and Lubrication System

iCare+

OPERATION MANUAL

Please read this Operation Manual carefully before use, and file for future reference

CE 2797

MADE IN FRANCE

RD 160.iCare+.OPM.ENG.V22

"Congratulations for purchasing your new iCare+ device"

iCare+ is an innovative system whose function is to ensure the treatment of rotary dental devices (contra-angles, turbine) and dynamic dental devices. Its benefits are:

- iCare+ insures cleaning-disinfection and lubrication of dynamic dental instruments
- iCare+ allows the treatment of the inner and outer surfaces of different instruments (contra-angles, turbines etc)
- Complete treatment in less than 20 minutes
- Up to 4 instruments can be treated simultaneously and automatically
- The rotating transmission cleans, disinfects and lubricates contra-angles even more effectively
- Validation and traceability insured by embedded software
- 3 types of treatment are available: full, partial and short

CHAPTER 1 - INTENDED USE AND USERS

1.1 Intended use

iCare+ is an automated reprocessing device performing the necessary steps of decontamination and maintenance prior to sterilization. iCare+ is intended:

- To purge, clean, disinfect and lubricate dental handpieces defined as rotating instruments such as straight handpieces, contra angles and turbines.
- iCare+ should be used only with pre-cleaned dental handpieces.

 Danger	This symbol is intended to draw your attention to the obligation to sterilize instruments after reprocessing by the iCare+. Failure to do and/or not to comply with this step could expose you and your patients to potential biological risks of cross-contamination linked to insufficiently decontaminated instruments.

1.2 Intended users

iCare+ is a Medical Device intended to be used by all Qualified Professionals from the dental field in medical type environments such as private clinics, hospitals, dental offices and university laboratories.

CHAPTER 2 - SAFETY INSTRUCTIONS

2.1. Safety Symbols

Please read this operating manual as it includes important safety information using the symbols below:

Symbol	Description
 Warning	This symbol is designed to bring to your attention hazards that could result in serious injury or damage to the device if the safety instructions are not correctly followed. You are asked to read closely and understand properly each of the sections concerned immediately before using your iCare+ device.
 Caution	This symbol is designed to bring to your attention hazards that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed.
 Information	Text preceded by this symbol contains useful information for using your iCare+ device.

2.2 General safety instructions


Warning

The manufacturer, installer and importer are only responsible for the device's safety, reliability and performance if the aforementioned points have been respected

The user is advised to comply with the following instructions:

- Please report any serious incident that may occur in connection with the device and its consumables to the manufacturer as well as to your national authority
- The device must be used in accordance with the instructions given in this user's manual in terms of safety precaution and use of the system
- The power supply of the location where iCare+ will be used must comply with IEC requirements, or with local regulations in force


Warning

iCare+ device has been designed in accordance with current safety standards. Nevertheless, it is essential to comply with important safety measures in order to avoid any potential incident or even accident. Therefore, the safety recommendations below have to be taken into consideration.

- Use iCare+ only indoors
- Do not install or use iCare+ near a naked flame due to the risk of explosion
- Do not install or use iCare+ in direct contact with sunlight
- Ensure that the iCare+ device is placed in a well ventilated area
- Store iCare+ at temperature between 0°C and 50°C and humidity rate under 80%
- Use iCare+ at room temperature (18°C to 25°C)
- Do not place n.cid bottles near a heat source
- Do not turn the device upside down
- Place the device horizontally on a flat surface
- Only use NSK products when operating iCare+ (n.clean as cleaning product, n.cid as disinfection product, NSK Oil as lubrication product)
- During the installation of iCare+, leave a space of 5 cm free on each side
- Air supply pressure provided to iCare+ is set at 5,5 bar ± 0,5 bar
- Do not remove the bottles (n.clean or n.cid) while iCare+ is in use
- If the iCare+ is not used for a long period, switch it off.
- Only use original NSK components for the maintenance of iCare+. The use of different components may damage the device

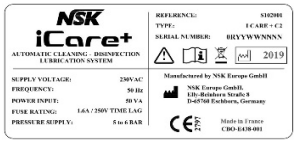
2.3 Safety labels

Adhesive safety labels have been placed on the iCare+ in important locations. These include storage instructions for the bottles, the device and information about the device's features.

Caution

The adhesive labels described below must be kept intact and should, if necessary, be replaced with the substitution labels provided with the accessories. In order to avoid damaging these labels, do not use abrasive products to clean your iCare+.

Table 1 - Safety labels

Picture of the label	Description	Position
	• LA-1 Oil label (for lubrication)	• Internal surface of the top cover
	• LA-2: n.clean label (for cleaning)	• Internal surface of the top cover
	• LA-3 n.cid label (for disinfection)	• Internal surface of the top cover
	• LA-4 Device identification label with serial number	• Rear cover of the device
	• LA-5 Warning label about risk of injury due to receptacle needles	• Between the bottle's receptacles

2.4 Others safety measures

Warning

All the safety measures referenced below must be followed closely in order to prevent the user being exposed to risks.

- Never handle the power cord with wet hands; risk of electrocution
- NSK does not warrant safety for any power cord other than the one provided in the package.
- Make sure the wall outlet has an earth connection with a differential (breaker)
- Be careful not to spill water into the device; fire risk as a result of short circuit
- Make sure to switch OFF the unit before any cleaning or maintenance action; risk of electrocution
- Do not attempt to dismantle any part of the device. In case of breakdown, directly contact your retailer
- Should the device begin to smoke or there is a smell of burning, switch off the iCare+ immediately and contact your retailer
- Do not use the iCare+ with flammable gases

CHAPTER 3 - DESCRIPTION OF THE DEVICE

3.1 Items requested for operation

Picture of the item	Description	Delivery
	• iCare control unit including: - Top cover - Front door - Drawer - Air filter - Pressure regulator	• Supplied without liquid and turbine adaptors Ref: S102001 iCare+ C2 Turbines: 2 / Contra-angles: 2 Ref: S103001 iCare+ C3 Turbines: 1 / Contra-angles: 3
	• USB key including: - Operating manual - Installation manual - I-Care software (Softcare)	• Supplied with control unit
	• Pneumatic installation set: T junction and 2000mm x Ø 6.0mm	• Supplied with control unit
	• Power cord Both EU and UK available	• Supplied with control unit
	• n.clean bottle Cleaning solution, 500ml	• To be ordered separately Ref: ACL600 (6 bottles)
	• n.cid bottle Disinfectant, 500ml	• To be ordered separately Ref: ACD600 (6 bottles)
	• Lubrication oil Bottle containing 1000ml	• To be ordered separately Ref: Z016117

3.2 Description of the control unit

A	Operating fluids lid
B	Front panel
C	Door
D	Drawer collecting operating fluids
E	Air filter / Pressure regulator

F	Power inlet with on/off switch and fuses
G	Oil tank
H	Receptacle for n.clean bottle
I	Receptacle for n.cid bottle
J	USB port for recording data

Fig.1 – Front view

Fig.2 – Rear view

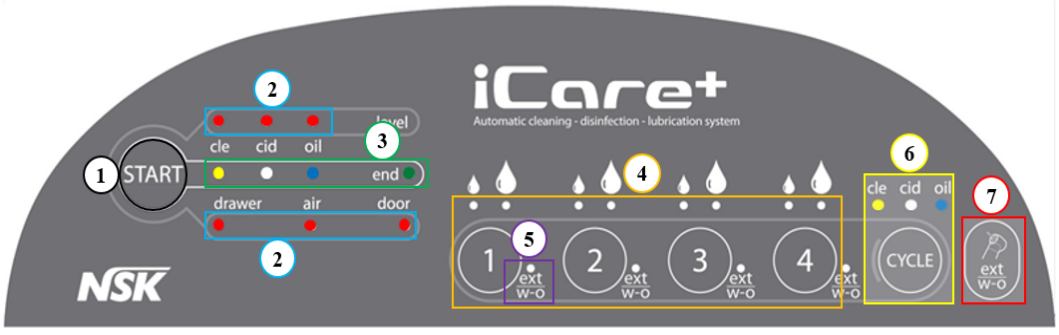
Fig.3 – Operating fluids

Fig.4 – USB port

3.3 Description of the front panel – Table 4

1	Start / Stop button
2	Warning indicators: Fluids and safety status
3	Cycle progress indicators
4	Instrument selection and oil volume setting

5	Instrument external spray indicator (when lit)
6	Cycle: Mode selection and indicators
7	Selection of external spray / without spray



CHAPTER 4 – INSTALLATION AND SET-UP

Warning

The use of controls, settings or the implementation of procedures other than those specified below may expose users and patients to danger.

4.1 Unpacking

Warning

Information

Upon receipt of the unit, look for any damage that may have occurred during transportation.

- When unpacking, check the items described section 3.1 are supplied
- If necessary, contact your supplier.
- Keep the original packaging for further use.
- Keep the packaging away from children.

4.2 Location

Warning

Information

Before installing iCare+, choose a suitable location as described below:

- The device should be positioned on a flat, solid and level surface
- The surface must be able to support the weight of the device in conditions of use: 16 kg
- The device should not be placed near a sink or any source that may cause moisture ingress
- The device should be placed in a properly ventilated room
- The device should be kept away from any source of heat

4.3 Installation

4.3.1 Connection to the air system

Insert the air supply tube in the air filter inlet, fixed on the Rear panel of the device: Fig.5. Be sure that the air tube is attached properly to the filter (see picture below). Connect the common port of the "T-junction" connector to the air compressor output and connect the output ports to your dental unit and iCare+: Fig.6.

Warning

Information

- Following the norm EN ISO 7494-2, the air quality provided to iCare+ has to be dry, clean and free from bacteria and contamination
- It is necessary to follow the above-mentioned parameters in order to avoid malfunction or damage to the unit
- The pressure of the air supply has to be between 5 and 6 bar
- The minimum air flow level required is 50 L/min

Fig.5 – Air Inlet

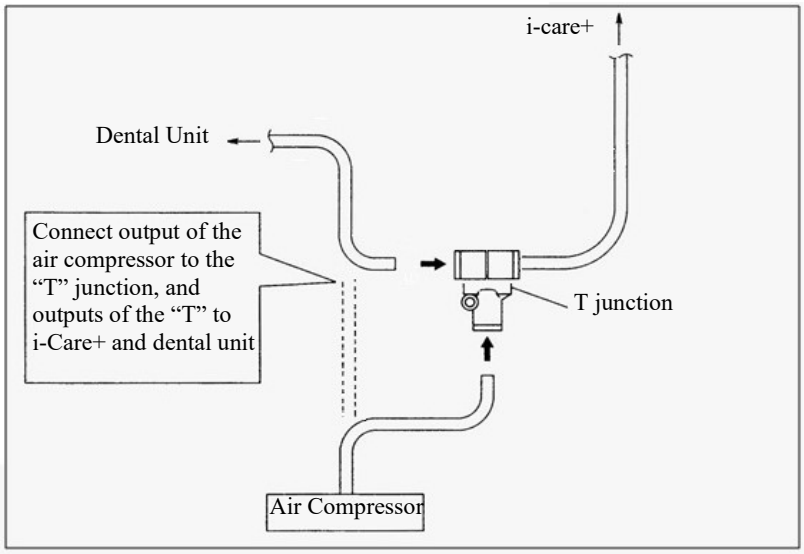


Fig.6 – Air connection

Warning

- The pressure of the air supply must not be under 5 bar or above 6 bar. A pressure sensor detects if the air pressure is too low or too high and stops the machine. The operator is alerted by an operating light indicator positioned on the Control Panel

Information

- Do not fold or deform the air supply tube
- If you experience difficulties during the installation, please contact your retailer
- The air filter has an effective filter size of 5µm

4.3.2 Connecting to the electric network

Insert the power supply cord supplied with the device in the socket located in the rear panel, refer to Fig -2, item F, and connect the power cord to the electric network. This power cord is a Class I cable.

Warning

- NSK do not warrant the use of other power cords other than the one provided with iCare+
- Connect the external power adapter only to an electrical network whose characteristics correspond to those indicated on the identification label, refer to Table 1: LA-4.

Information

- The electrical network used to power the unit must comply with the current standards. If necessary, your electrical system should be checked by a certified electrician.
- A fluctuation in the mains voltage or an electromagnetic field, which does not comply with the standard, may disrupt the operation of the device.

4.4 Consumables

4.4.1 Insertion of n.clean and n.cid bottles

To insert the consumables, proceed as follows:

- Open the rear lid Fig.7
- Remove the metallic cap from each bottle, in order to avoid damaging the receptacles needles: Fig.8.
- Insert the n.clean bottle upside down inside its receptacle: Fig.9.
- Push the n.clean bottle so that the needle goes through the rubber septum closing the bottle. Do not use excessive force as you may damage the needle.
- Use the same procedure to insert n.cid bottle: Fig.10.

Fig.7 – Top cover

Fig.8 – Bottle cap

Fig.9 – n.clean

Fig.10 – n.cid

Warning

- Use only n.clean and n.cid bottles supplied by NSK Europe GmbH. Efficiency of the device is optimized for cleaning and disinfection protocols validated using n.clean and n.cid products. NSK does not warrant the results from other manufacturers products, which could lead to a failure or damage of iCare+ and/or of the instruments connected on it.
- Never try to re-fill and re-use bottles. You may damage the iCare+
- To avoid injury caused by the needles, never put your hands inside the bottle receptacles.
- Do not forget to remove the metallic bottle cap prior to installation as you may damage the device

Information

To avoid confusion when inserting the consumable products, a colour coding is used:
- For n.clean solution, yellow sticker on the bottle and receptacle
- For the n.cid solution, grey sticker on the bottle and receptacle

4.4.2 Safety warning relating to n.cid and n.clean

Warning

- n.cid liquid and vapour are flammable. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. Do not smoke in the presence of n.cid. Keep container tightly closed in a cool, dry and well-ventilated place. Do not expose to or leave in direct sunshine.
- It is recommended to use protective glasses and gloves during handling of bottles or during emptying of waste drawer. Avoid any contact with skin and eyes.
- Following eye contact with n.clean, flush eyes with flowing water for several minutes holding eyelids apart. Remove contact lenses, if present and easy to do.
- Following n.clean ingestion: Rinse mouth and then allow the affected person to drink water.
- n.cid causes serious eye irritation. Following eye contact with n.cid rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. If eye irritation persists, seek medical advice/attention
- In case of contact of n.cid with skin, wash off immediately with soap and water. In case of skin reactions, seek medical advice.
- Following inhalation of n.cid, move affected person into fresh air. In case of irritation of the airways, seek medical advice.
- Following ingestion of n.cid, rinse mouth with water, and then drink plenty of water. Do not induce vomiting. Seek medical advice.

4.4.3 Filling the oil tank

The oil is poured directly into the tank. To fill the oil tank, proceed as follows:

- Shake the oil canister well
- Unscrew the oil tank cap Fig.11
- To avoid a spillage hazard, gently pour the oil in to the tank Fig.12
- Fill the tank up to 20 mm from the top edge of the tank. Fig.13
- After filling, replace the oil tank cap.
- Once the tank is filled and the cap properly secured, close the rear top cover.

Fig.11 – Oil tank

Fig.12 – Oil filling

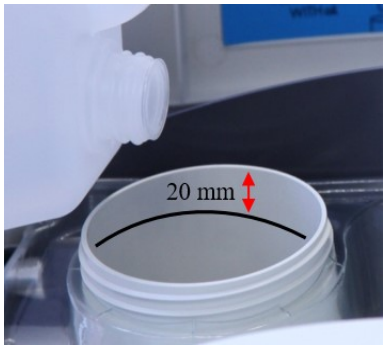


Fig.13 – Oil limit

Caution

- Always use NSK oil to ensure optimal lubrication
- Using other oil with iCare+ could lead to a failure or damage of the iCare+ and the instruments connected to it
- After filling the oil tank, ensure the cap is securely closed

4.5 Validation test

4.5.1 On-site validation

Prior to first use, your installer must perform an installation qualification (IQ), Operational qualification (OQ) and Performance qualification (PQ).

According to ISO 15883-1, the aim of this procedure is to obtain and document evidence that your device has been provided and installed in accordance with its specification.

Caution

- The warranty applies only to the extent that the on-site validation of the device has been observed
- Achievement of on-site validation is limited exclusively to professional dental installers who have been trained and qualified under the control of NSK
- After on-site validation keep a permanent record of the validation report

4.5.2 Periodical validation

Following ISO 15883-1, requalification of your device shall be performed at defined intervals. The defined interval can be determined by regulatory authorities or by risk analysis. We recommend to perform this periodical validation every year, in order to validate that the performance of iCare+ is still optimum or:

- If a review of records of routine tests of equipment performance indicates unacceptable deviation from data determined during the initial validation
- If changes are carried out on the equipment and installation that could affect the performance
- If equipment performance is unacceptable
- If process conditions are changed

Caution

- For periodical validation, only use your authorized supplier or NSK. Validation performed by an unauthorized person could result in your iCare+ being unsafe for you and your patients.
- Periodical validation is limited exclusively to professional dental installers who have been trained and qualified under the control of NSK.

CHAPTER 5 – DAILY USE

The function of the iCare+ is to ensure the cleaning and disinfection of internal and external surfaces of dental rotary and dynamic instruments, as well as their lubrication. Such items are potentially contaminated with pathogens and can be a source of infection for humans. Therefore, before being reprocessed using iCare+, these medical devices require a previous preparation as defined by Robert Koch Institute: RKI.

Caution

Before reprocessing, it is necessary:

- To check the product compatibility with the reprocessing method to be used
- To perform proper preparation as defined below

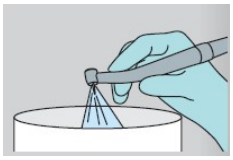
5.1 Preparation

Preparation must be performed in accordance with accepted engineering practice. It must also ensure that the concerned medical devices pose no risk to health when it is subsequently used, specifically focusing on infections. Therefore, the following precautions shall be considered:

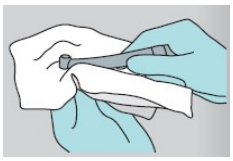
Warning

- For your safety during reprocessing, you shall minimize the risk of infection wearing protective gloves, spectacles, as well as mouth and nose protection
- Preparation must be performed within 10 minutes after the end of treatment. If this is not possible, the handpieces must be pre-treated with a non-protein-fixing cleaning solution, such as IC100 from Alpro Medical, according to the manufacturer's instructions
- Never immerse NSK handpieces such as contra-angles and turbines inside disinfecting solutions nor in ultrasonic baths

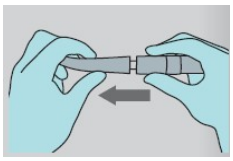
5.1.1 Preparation on site



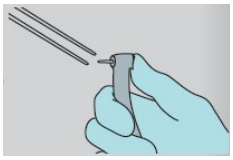
✓ First, debris and residues must be removed from the handpieces promptly after use flushing working channels. To do so, allow air and / or water to flow inside the handpiece immediately after treatment of a patient for at least 20 seconds.



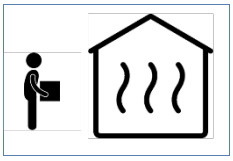
✓ As far as possible, blood and tissue must be prevented from drying, sticking and coagulating to the device. Therefore, wipe off the handpieces immediately afterwards with an approved disinfectant tissue, for example, Minuten Wipes from Alpro.



✓ To make all external and internal surfaces accessible, disconnect the handpieces, contra-angles and highspeed turbines from the coupling, or the fixed connection turbine from the hose.



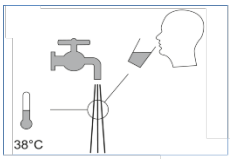
✓ Remove instruments such as drill, file or bur from the handpiece chuck system. If necessary, use tweezers and insert the instruments into disinfecting solution.



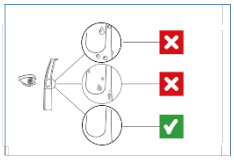
✓ Once the onsite preparation of the handpieces is complete, they will should be safely transported to the reprocessing site, avoiding injuries, contamination and damage.

5.1.2 Precleaning

✓ Preparation must be performed within 10 minutes after the end of treatment. If this is not possible, the handpieces must be pre-treated with a non-protein-fixing cleaning solution, such as IC100 from Alpro Medical, according to the manufacturer's instructions.



✓ A manual external pre-cleaning has to be performed, under running cold water using a soft brush for at least 20 seconds to remove visible contamination.



✓ Inspect for cleanliness and repeat external pre-cleaning under running cold water if necessary.

5.2 Installation of the instruments

With iCare+ device, it is possible to connect 2 kinds of instruments by means of 2 different connectors:

- Air turbine connector for dental turbines.
- E-type connector for dental contra-angles.

• To connect an instrument, start by opening the door
• Do not use the door as a support, do not put anything on the door when open

5.2.1 Installation of the turbines

To connect a turbine with Midwest 4 holes coupling according to ISO 9168 standard:

- Connect the turbine directly to the turbine connector of the iCare+: Fig.14
- Screw the retaining nut down until it fits securely: Fig.15
- Take care of the turbine connector position, the head should be oriented toward the front of the door
- Close the door.

To connect a turbine with another connection type:

- It is necessary to install the corresponding coupling adaptor Fig.16
- Insert the adaptor and screw the retaining nut down firmly, check the positioning of the coupling's connections
- Please refer chapter 10 for the list of available coupling adaptors.

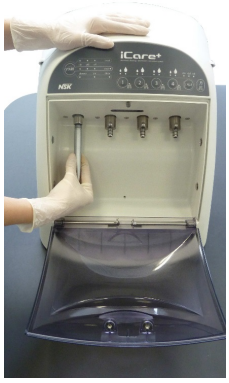


Fig.14 – Connection of a turbine

Fig.15 – Screwing the retaining nut

Fig.16 – Coupling adaptor

- It is necessary to use specific iCare+ air turbine adaptors. These are especially designed to deliver the right volume of product required for each instrument.
- NSK does not guarantee correct operation of the device with any other coupling.

5.2.2 Installation of contra-angles

To connect a contra-angle or a hand piece, in accordance with the ISO 3964 standard, simply open the door and connect the contra-angle on the E-type connector (see Figure 17).

Fig.17 – Connection of a contra angle

Fig.18 – iCare+ C3: coupling for 3 contra-angles

- Insert the contra-angle in the connector until you hear a "click" to ensure that the contra-angle will be well maintained during the different phases of treatment.

Caution

Before using iCare+:

- Please make sure to remove any bur from the chuck
- Make sure also to remove any support/holder for snap-on caps
- Failure to do so could result in the dirt and liquid inside the instrument not being expelled

5.3 Removal of the instruments

Once the cycle has finished, you will hear a "Beep" sound and the green operating light indicator "end" will be illuminated.

- Open the door
- Remove the instruments from their couplings as below.

5.3.1 Removal of the turbines

• To remove a standard turbine with Midwest coupling:
  - Unscrew the retaining nut
  - Remove the turbine by pulling down the instrument

• Removing a turbine with NSK® connection from its adaptor:
  - Move up the retaining ring of the adaptor.
  - Remove the turbine by pulling it down while keeping the retaining ring in the upright position.

• Removing a turbine with Kavo and Sirona® connection from its adaptor:
  - Remove simply the turbine by pulling down on the instrument.

• Removing a with W&H® connection from its adaptor:
  - Move the retaining ring of the adaptor up.
  - Remove the turbine by pulling it down while keeping the retaining ring in the upright position.

• Removing a turbine with Bien-Air® connection with from its adaptor:
  - Press the button on the adapter.
  - Remove the turbine by pulling it down while keeping the button pressed.

Fig.19 – NSK

Fig.20 – Kavo / Sirona

Fig.21 – W&H

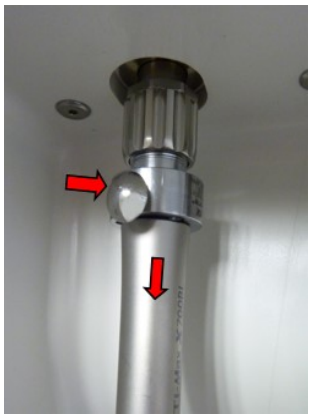


Fig.22 – Bien Air

5.3.2 Removal of the contra-angles

For removing a contra-angle, in accordance with the ISO 3964 standard, follow the description below:

- Start by opening the door
- Push the release button
- Remove the contra-angle by pulling it down while the release button is pressed.

5.4 Programming the iCare+ device

5.4.1 Function of the control panel

The Control panel is composed of a series of control buttons and light operating indicators. As shown Fig.23, and 24, the control panel includes 7 operating keys and 25 light indicators as follows:

- (K1) Start-up key
  This key is used to start the operating cycle. Pressing and holding this key will abort the cycle
- (K2) to (K5) Instrument keys
  These four keys switches enable to select/deselect the instruments to be reprocessed as well as to select the volume of lubricant to be dispensed
- (K6) Operating cycle key
  This key is used to select the reprocessing cycle to be performed as follows:
  - Full cycle: Cleaning + Disinfection + Lubrication
  - Partial cycle: Cleaning + Lubrication
  - Short cycle: Lubrication only
- (K7) Spray key
  In conjunction with (K2) to (K5) this key is used to define if the handpiece has an external spray channel or no spray channel

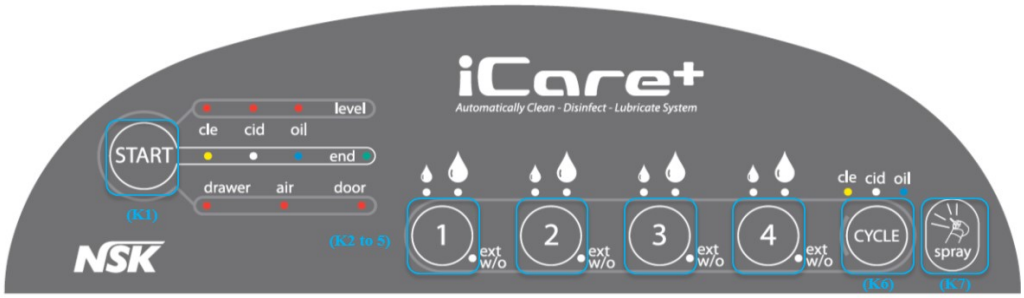


Fig.23 – Operating Keys

- (1) Cycle status indicators
  These indicators show which step of the reprocessing cycle is in progress
- (2) Warning indicators
  When lit these six indicators display “Warning information” for:
  - Low consumable level: n-id, n-clean, oil
  - Safety sensor: drawer, air pressure, door status
- (3) Instrument selection indicators
  When lit these indicators show which instruments are selected and the quantity of the lubricant to be delivered
- (4) Spray indicators
  In conjunction with (3) these indicators display if the selected handpieces have been defined with an external spray channel or no spray channel
- (5) Mode indicators
  These indicators are used to show the selected reprocessing cycle

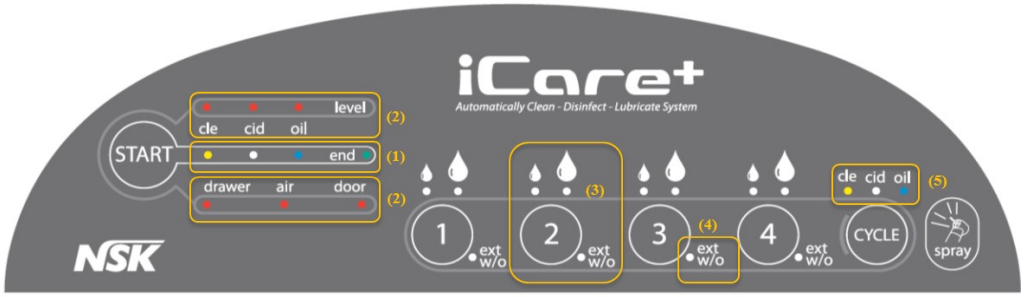


Fig.24– Light Indicators

5.4.2 Setting of the reprocessing mode

After switching on the device using the power switch (refer to Fig.2 / F), and installation of the instruments as described section 5.2, you can now select the reprocessing mode.

The reprocessing cycle is composed of 3 different phases:

- Cleaning phase: 6 min (for 4 instruments)
- Disinfection phase: 9 min (for 4 instruments)
- Lubrication phase: 1.5 min (for 4 instruments)

The cycle button (K6) selects one of the 3 reprocessing cycles which are available, the cycle indicators (5) are lit accordingly:

- Full maintenance cycle: Cleaning/Disinfection/Lubrication (by default)
- Partial maintenance cycle: Cleaning/Lubrication (press the button once)
- Short maintenance cycle: Lubrication only, similar function as Care3 plus and iCare, (press the button twice)
- A third press on the Cycle button enables the user to reset the choice of cycle

Fig.25 – Full mode

Fig.26– Partial mode

Fig.27– Short mode

5.4.3 Selection of the instruments

By default, all instruments are selected. If you have less than 4 instruments, you need to manually select the instrument to be reprocessed as well as the lubricant oil volume to be dispensed:

- Small drop corresponds to a normal volume (Short cycle)
- Large drop corresponds to a specific volume for certain contra-angles (long cycle for surgical or 1:5 contra-angle for example)
- Unlit light indicators (3) indicate that the instrument is deselected and then the related instrument position will not be activated
- By default, low oil volume is selected. Press the button corresponding to the position the instrument is connected to, press once to select the large volume (large drop indicator) and twice to deselect the instrument

The volumes of the consumables to be dispensed and the sequence of injection of the products are directly programmed and monitored by the device itself, according to an accurately defined and validated protocol by a microbiological institute.

Except oil volume, the operating parameters cannot be modified.

5.4.4 Selection of the type of instrument

Your iCare+ enables to reprocess two kinds of instruments:

- Instrument with only one drive channel and without spray
- Instrument with 2 channels: both W/A and drive channels, with internal spray

All the different instruments that can be treated with iCare+ are mentioned in the following table for C3:

	Instrument 1	Instrument 2	Instrument 3	Instrument 4
Only drive channel		Contra-angle or handpiece with external spray / without spray		
W/A and drive channel	Turbine /Air scaler	Contra-angle or handpiece with internal spray		

By default, instrument standard setting is “internal spray”. As illustrated in Fig. 28, to set external or without spray instrument:

- Press “Spray” key and the key corresponding to the position of the instrument simultaneously
- To indicate that internal spray is disabled, the corresponding indicator is now illuminated

Fig.28– Without spray setting

If the internal spray is disabled by mistake or the internal spray is blocked, the unit detects it and will alert you. For instance, this may occur in the following scenarios:

- An instrument has been selected as an “external spray instrument” (but in reality, the instrument has an internal spray)
- An instrument that has been installed with external spray without using the button “ext W/O”
- An instrument which has been installed which has a blocked internal spray channel

In such a case the iCare+ will alert you to the issue:

- Unit will abort the cycle
- “Air warning Indicator” LED will blink
- Unit will emit an audible alert
- The position of the instrument is shown using blinking indicators (oil indicator and/or ext-WO).

Fig.29– Warning

To restart the unit:

- First open the door
- Remove the instrument (to reduce the remaining pressure)
- Reconnect the instrument
- Then close the door.

If the problem happens again:

- Remove the handpieces
- Push the key “Start” to interrupt the cycle.
- Check the instruments for possible blocked channels.

5.5 Launching the reprocessing cycle

Once the reprocessing cycle is selected and instruments setting achieved, press the “Start Key” (K1) to launch the cycle (see Figure 23).

- “Start Key” launches the selected cycle for the selected instruments. If a problem occurs or if you wish to stop the cycle the “Start Key” stops the unit when pushed and held
- The cycle is then interrupted, the settings and selections are recorded and the device is in standby mode. Pressing “Start Key” again, allows the reprocessing cycle relaunch from the beginning with the same settings
- In case the door is open while the unit is in standby mode, the settings and selections are then reset to default

When reprocessing cycle is launched, the status indicators on the control panel indicate the progress of the cycle and the treatment chamber is illuminated using the same colour code.

- Yellow indicator = Cleaning phase
- White indicator = Disinfection phase
- Blue indicator = Lubrication phase
- Once the cycle is completed the green indicator is illuminated to inform the user that the instruments are ready for further steps.

Fig.30– Indicators during cycle in progress

Caution

- When the “oil drop” indicators are switched off, the related instruments are not selected
- Before first use, or after a long period of no use, run the device without instruments

Purge and Initialisation	Cleaning phase	Disinfection phase	Lubrication phase
High pressure air is used for removal of elements which soil the instrument and clog the internal channels. For example : oil residue, body fluids, and metal particles.	Cleaning is the removal of initial contamination. The purpose of cleaning is to leave as little residue as possible, since this can adversely affect disinfection	Disinfection is the reduction of the number of viable organisms of the instruments. The devices operates using chemical disinfecting agents which are used to neutralize the remaining agents.	Lubrication is a maintenance step. Lubricants reduce noise, friction and prevent wear and accumulation of wear debris. This step uses a high pressure air blowing oil inside the instrument.

Operating cycle

Caution

- In order to facilitate external cleaning, you need to perform pre-cleaning as defined in section 5.1
- Use disinfectant wipes to handle the instruments while connecting them to the unit
- At the end of the cycle, open the door and remove the instrument using a disinfectant wipe

CHAPTER 6: USER MAINTENANCE

iCare+ requires two different types of maintenance:

- Routine maintenance, periodically performed by the user such as cleaning of the device
- Specific maintenance performed by a dental technician: e.g. annual validation and repair

Caution

Periodical validation and repair are limited exclusively to professional dental installers who have been trained and qualified under the control of NSK

6.1. General cleaning guidelines

Caution

- Cleaning operations should be performed only after having disconnected the iCare+ from the main power supply
- Do not smoke in the room where the device is kept

You should clean the iCare+ as recommended below:

- Always use a soft cloth to clean the metallic and plastic parts of the device
- Only use detergents that contain a very low level of alcohol (with no protein fixation agent)
- Never attempt to clean areas that are difficult to access with sharp objects
- Be careful when cleaning the Control panel and never use aggressive detergents

6.2 General maintenance guidelines

Frequency / Number of cycles		Operation	Reference	Section
Every week	50	Cleaning the treatment chamber	--	6.2.1
Every week	50	Cleaning the external parts	--	6.2.2
2-3 times per week	15	Emptying the used products drawer	--	6.2.3
Every week	50	Cleaning the drawer	--	6.2.4
When needed		Replacing the O'ring	On demand	6.2.6
When blown		Replacing the fuse(s) of the supply inlet	On demand	6.2.7
When needed		Replacing the junction support blister	S103106	6.2.5
Each year		Annual validation		4.5.2

6.2.1 Cleaning the treatment chamber

As the door is removable, the treatment chamber can be easily cleaned. To do so, proceed as follows:

- Open the door
- If in place, disconnect and remove the instruments
- Pinch the 2 spring-loaded tabs on the door (in red)
- Remove the door to easily access the chamber
- Use a soft cloth or a sponge to clean the chamber
- If necessary, rinse it
- Follow the same procedure to clean the door
- We advise the use alcohol wipes for this part of the device to ensure you remove with efficacy possible stains
- Once complete replace the door
- Switch on the device and check the proper activation of the door sensor: Fig. 24 (2)

6.2.2 Cleaning the external parts

Clean the external parts with a soft cloth, as mentioned in the part 6.1. Do not use scouring agents or highly abrasive products.

6.2.3 Emptying the used products drawer

The drawer should regularly be emptied. Emptying the drawer should be done either:

- After each use
- At the end of the day
- When the warning indicator “drawer full” is illuminated: Fig. 24 (2)

To empty the drawer, proceed as follows:

- Remove the drawer from the device by sliding it forward: Fig: 31
- Remove the clips attaching the lid to the tray Fig: 32 / Fig.33
- Dispose of the used product

Fig.31 – Drawer

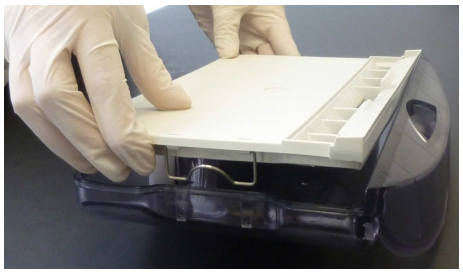


Fig.32 – Removal of the clips

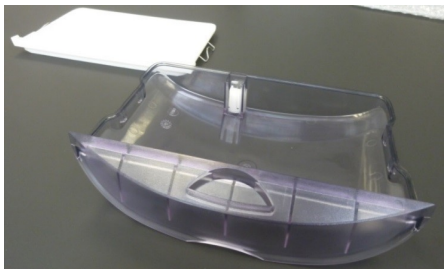


Fig.33 – Tray and lid

Consumable products used in conjunction with iCare for reprocessing such as Oil, n.clean and n.cid solutions are formulated to be disposed of in the sewage disposal.

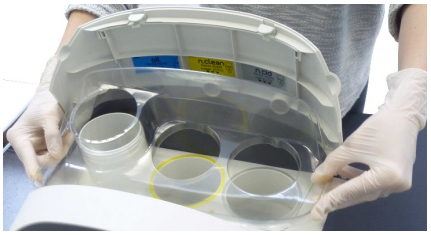
Prior to doing so, the soiled fluids should be diluted using water in a 4:1 ratio: 4 volume of water for 1 volume of soiled fluids

6.2.4. Cleaning the drawer

To avoid depositing residues or to remove them, it is advised to clean the drawer weekly. To proceed, as explained section 6.2.3, extract the drawer, remove the clips on both sides of the tray and then remove the cover of the drawer. Then clean it with alcohol wipes.

6.2.5 Replacing the junction support blister

The blister allows the collection of possible drops of consumables during refill/bottle change. It should be replaced at least once each year.



- Open the back top cover
- Remove the soiled blister
- Then place the new one directly on to the support junction
- Ensure that the new blister has properly sealed

Caution

- When removing the soiled blister, do not empty out the used products in to the iCare+, on the surface of it or on the floor

6.2.6. Replacing the O-ring joints on the E-type connector

- Push the O-ring joint
- Remove them from the E-type connector
- Gently insert the new O-rings into the corresponding grooves
- Check the new O-rings are not damaged

6.2.7. Replacing the fuse on the power supply inlet

The fuses need to be changed when blown:

- Press down simultaneously on and pull the two tabs at the end of the fuse holder in order to unlock it
- Remove the fuses from the holder and replace with new ones using the correct rating
- Replace the fuses in the fuse holder and insert them in to the housing.
- Push to lock

Caution

For Europe never use other fuses than those described below:

- Voltage: 250VAC
- Rating: T 1,6AH 250V

CHAPTER 7: INFORMATION FROM WARNING INDICATORS

As shown in Fig.34, warning indicators inform in real time about abnormal operating conditions.

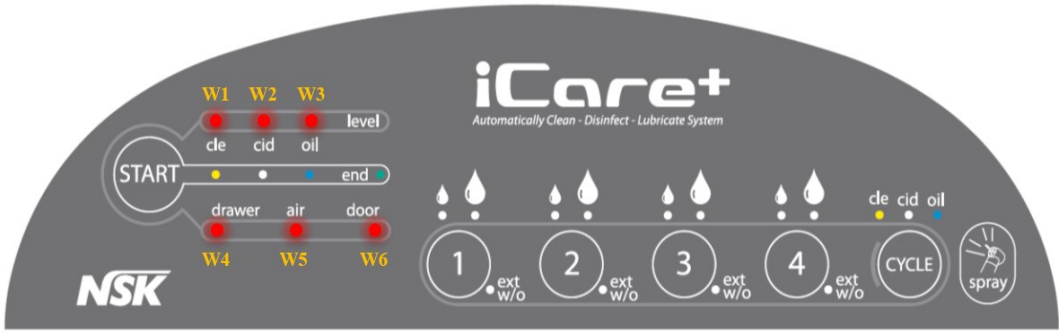


Fig.34– Warning Indicators

- "W1" n.clean indicator informs the operator that n.clean level is too low. In such a case the device stops.
  - It is necessary to replace the bottle with a new one in order to restart the device
  - Remove the empty bottle and replace with a new one
  - To install a new bottle, refer to section 4.4.1.

- "W2" n.cid indicator informs the operator that n.cid level is too low. Repeat the procedure for n.clean as above.

- "W3" oil indicator informs the operator that oil level is too low. In such a case the device stops.
  - It is necessary to refill the oil tank to restart the device
  - To refill the oil tank, refer to section 4.4.3.

- "W4" drawer indicator informs the operator about either two kind anomalies:
  - The drawer is not properly positioned or absent. In this case, check if the drawer is present and correctly inserted. If necessary, extract the drawer and insert it again.
  - The drawer is full and might overflow. In this case, remove the drawer and empty it as described section 6.2.3.

- "W5" pressure indicator informs the operator about air pressure problems such low air pressure, air leakage, no air and excessive air pressure. In such a case, iCare+ cannot restart the cycle until the problem is solved
  - Check the O-ring of the e-type, if necessary, insert new O-rings: Refer to section 6.2.6.
  - Check the air compressor and air connection: Refer to section 4.3.1

- "W6" door indicator means the door is open or not properly closed. Make sure that nothing obstructs door closing, and close the door to start any cycle.

The iCare+ is controlled by a micro-processor which checks, in real time, operating conditions. If a problem occurs, it is detected, and then the iCare+ will stop immediately.

CHAPTER 8: TRACEABILITY

The reprocessing of the instruments has to be performed in accordance with the regulation in force as well as following the latest recommendations. To ensure the efficiency of the reprocessing performed by iCare+ and enabling the traceability of the handpieces, reprocessing data is recorded internally and uploaded to the USB key, refer to section 3.3, Fig.4.

To ensure traceability, the software "SoftCare+" supplied with the device enables you to check the data relating to the reprocessing cycles. Please refer to software user manual to retrieve cycle information.

CHAPTER 9: TROUBLE SHOOTING

Problem	Possible cause(s)	Solution(s)
The device does not switch on	Is the power supply cord connected to mains?	Connect the power supply cord to mains
	Is the power supply cord properly connected to the iCare+?	Insert the power cord plug into the device's main connector
	Is the main switch positioned in the "ON" position?	Turn the main switch to the "ON" position
	Are the fuses working?	Change the fuses with the same model
The device does not start the reprocessing cycle	Is the door open? (door LED illuminated)	Close the door properly
	Are the n.clean or n.cid indicators illuminated?	Change bottles and prime
	Is the Oil indicator illuminated?	Fill the Oil tank
The device does not operate correctly	Is the air supply tube properly connected to the device?	Connect the air supply tube to the device's connector
	Air pressure supplied between 5 and 6 bar?	Set the air supply pressure between 5 and 6 bar
	Is short mode selected?	Select Long mode
	Are the instruments properly installed?	Reconnect the instruments securely

CHAPTER 10: BREAK-DOWN GUIDE

Other problems, not previously listed in the chapter 5 (Error messages from operating light indicators) and in chapter 7 (Possible failures), are explained in the following chapter.

10.1. Usual errors

10.1.1. Consumables level sensors

Corresponding indicators are illuminated and an audible signal can be heard. Please change the bottle or refill the oil tank, and push "START" key to prime the product. Refer to section 7.

If the bottles and/or oil tank are not empty, the sensor could have detected a bubble inside the product line. Please push "START" button to fill the product line.

10.1.2. Drawer and door sensors

Corresponding indicators W4 and W6 are illuminated and an audible signal can be heard. Refer to section 7.

- Remove the drawer and empty it. Make sure that the drawer is in appropriate position
- Please ensure that the door is properly closed
- Please push "START" key to ensure the problem is solved

10.1.3. Air sensor

Two different warning messages relate to air sensor problems:

- Indicator W5 is illuminated continuously and an audible signal can be heard
- Indicator W5 is blinking and an audible signal can be heard

In case "Air" indicator W5 is continuously illuminated and a "Beep" signal can be heard, the air pressure is lower than 5 bar or higher than 6 bar.

- To restart the unit, first, check the air pressure at the inlet of the machine. It is necessary to have between 5-6 bar at the inlet
- Once this is done, press "START" button to reset the error.

In case "Air" indicator W5 is blinking conjointly with instruments indicators as shown Fig.29, the device has detected a problem with the related instrument. Root cause could be either:

- Wrong setting in case of use of external spray instrument (a)
- Channel blocked inside the instrument (b)
- Blocked tube inside the unit (c)

(a) Wrong setting:
Verify the "spray setting" setting of the instrument. Refer to section 5.4.3 to check function of external spray instrument.

(b) Channel blocked inside the instrument:
Once the "spray setting" of the instrument has been verified, remove the instrument and replace it with a similar one in order to check if the problem persists. If not, the instrument is probably blocked.

(c) Tube blocked inside the unit:
The unit can detect if one of the tubes inside the machine is blocked. To confirm the problem, disable the instruments and try to restart the device. If it works this confirms the problem. Failing that check the O-ring, and contact your NSK dealer.

10.2 Fatal error

If all warning indicators W1 to W6 are blinking and 3 "audible signals" are heard, a main error occurred. In such a case, please contact your NSK dealer directly.

CHAPTER 11: SPECIFICATIONS

11.1 Technical Specifications

I-Care+ Device	
Electrical data:	
Input voltage:	85 to 264 VAC
Frequency:	47 to 63 Hz
Power:	50 VA
Fuse:	T 1,6AH 250V
Environmental data:	
Use temperature:	At room temperature 18°C to 25°C
Humidity rate for use:	Max 80% @ 31°C, linear decrease to 50% @ 40°C
Maximum altitude for use:	2000m
Atmospheric pressure range for use:	700-1060 hPa
Transportation and storage temperature:	0 to 50°C
Humidity for transportation and storage:	10-80%
Atmospheric pressure range for transportation:	500-1060 hPa
Mechanical data:	
Overall dimension:	H: 405 mm / W: 355 mm / D: 400 mm
Required space for installation:	H: 455 mm / W: 455 mm /D: 450 mm
Transportation weight:	14kg
Maximum weight, fully loaded, in conditions of use:	16kg
Maximum noise level:	< 60 dBA
Working pressure:	>5 bar and <6 bar
Air filtration:	5µm
Maximum heat output:	Not significant
Compliance:	
Electrical safety:	IEC 61010-1: 2016
Electromagnetic Compatibility:	EN 61326-1: 2012
Performance:	ISO 15883-1
Cleaning:	ISO 15883-5
Cytotoxicity:	ISO 10993-5
Classification:	
Following MDD:	Class II b class in accordance with rule 15 of annex IX
Following MDR:	Class II b class in accordance with rule 16 of annex VIII
Other:	
Manufacturer:	NSK Europe GmbH, Elly-Beinhorn Strasse 8 D - 65760, Eschborn, Germany
Additional features:	Fully micro-processor driven and controlled

Consumables	
n.clean and n.cid:	
Packaging:	500 ml, PEHD bottle to be pierced
Transportation and storage temperature:	Transportation: -20°C/+40°C – Storage: -10 to 30°C
Biological performance for n.clean (1)	Cleaning effect: Practice test with test soil according to EN 15883-5
Biological performance for n.cid (1) (2) (3) (4) (5) (6)	(3) Bactericidal (EN 13727) / MRSA (suspension test) / Yeasticidal (EN13624) / Tuberculocidal (EN 14348).
Notes (*) (1) The products must be used only at room temperature (18°C / 25°C) (2) Spectrum of activity in 5 minutes after pre-cleaning with n.clean (3) Test criteria: Dirty conditions, room temperature (4) Test criteria: Clean conditions, room temperature (5) Test criteria: Without soiling, room temperature	(4) Virucidal: (EN 14476, EN 16777) against non-enveloped adeno- and noroviruses as well as all enveloped viruses (5) Virucidal (suspension test) against enveloped viruses, e.g. HBV, HCV, HIV, influenza and coronaviruses. (6) Expected disinfection level: Intermediate level when used as directed in this user manual

11.2 Symbols

CE	EC conformity of the products with European requirements
CE 2797 CE 0123	The CE numbers refer to the notified body which has validated the product's conformity
	Identification of the Manufacturer
	Manufacturing date
	Follow WEEE Directive (2002/96/EC) for product and accessory disposal
CH REP	Authorized representative for Switzerland
	Consult operating instructions
	Caution, refer to attached instructions
	For indoor use only
	Use by date
	Number of items inside the packaging
	Caution, Flammable, refer to attached instructions
	Keep Dry
LOT	Lot number
SN	Serial number
REF	Part number
MD	Medical device
	Indication of the range of humidity level
	Indication of pressure range
	Indication of temperature range
	Protective gloves recommended
	Protective glasses recommended
UDI	Unique Device Identification
	Electronic Instruction For Use: Consult nsk-library.com for the last release in force
#	Model: iCare+ C2 / iCare+ C3

CHAPTER 12: ACCESSORIES AND PART LIST

12.1 Main items

Item	Part Number
• n.clean, 500 mL PEHD bottle (6pcs) Not supplied with the device. Must be ordered separately	ACL600 CE
• n.cid, 500 mL PEHD bottle (6pcs) Not supplied with the device. Must be ordered separately	ACD600 CE 0123
• Maintenance Oil, 1 L PEHD bottle Not supplied with the device. Must be ordered separately	Z016117
• iCare+ PTL Adaptor Not supplied with the device. Must be ordered separately	Z1127010
• iCare+ KV Adaptor Not supplied with the device. Must be ordered separately	Z1127011
• iCare+ SR Adaptor Not supplied with the device. Must be ordered separately	Z1127012
• iCare+ WH Adaptor Not supplied with the device. Must be ordered separately	Z1127013
• iCare+ BA Adaptor Not supplied with the device. Must be ordered separately	Z1127014
• 4/6 mm diameter tube Supplied with the device	On demand
• Power Cord Supplied with the device	On demand
• USB Key of operation manual Supplied with the device including EIFU	On demand

12.2 Accessories

Item	Part Number
• E-type O-ring joint (6 pieces)	Y0312074080
• Blister	S103106

- PTL Adaptor refers to adaptor(s) to be used for air turbines with NSK® PTL connection.
- KV Adaptor refers to adaptor(s) to be used for air turbines with KAVO® Multiflex connection.
- SR Adaptor refers to adaptor(s) to be used for air turbines with SIRONA® connection.
- WH Adaptor refers to adaptor(s) to be used for air turbines with W&H® connection.
- BA Adaptor refers to adaptor(s) to be used for air turbines with BIEN-AIR® connection.

CHAPTER 13: EMC INFORMATION

The iCare+ device complies with IEC 61326-1 standard.

Guidance and manufacturer's declaration - electromagnetic emissions		
iCare+ is intended for use in the electromagnetic environment specified below. The user of iCare+ should assure that is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - Guidance**
RF Emissions EN 55011	Group 1	iCare+ should not cause any interference in nearby electronic equipment.
RF Emissions EN 55011	Class B	iCare+ is suitable for use in all establishments, including domestic establishments and those directly connected to public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics Emissions EN 61000-3-2	Class A	
Voltage fluctuations Flicker emissions EN 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetics immunity			
iCare+ is intended for use in the electromagnetic environment specified below. The user of iCare+ should assure that is used in such an environment.			
Immunity test	**EN 61326-1 Test level**	**Compliance level**	**Electromagnetic environment - Guidance**
Electrostatic discharges (ESD) EN 61000-4-2	+/- 4kV contact +/- 4kV air	+/- 4kV contact +/- 4kV 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 and burst. EN 61000-4-4	+/- 1kV for power supply lines	+/- 1kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	+/- 0.5kV line(s) to line(s) +/- 1kV line(s) to earth	+/- 0.5kV line(s) to line(s) +/- 1kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	0% Ut during 10ms 0% Ut during 20ms 70% Ut during 200ms 0% Ut during 5 sec.	0% Ut during 10ms 0% Ut during 20ms 70% Ut during 200ms 0% Ut during 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of iCare+ requires continued operation during mains power interruptions, it is recommended that iCare+ be powered from an uninterruptible power supply.
Magnetic field EN 61000-4-8	2 V/m	2 V/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity			
iCare+ user shall ensure that the device is used in the electromagnetic environment specified below.			
Immunity test	**EN 61326-1 Test level**	**Compliance level**	**Electromagnetic environment - Guidance**
Conducted RF EN 61000-4-6	3V eff 150kHz to 80MHz	3V rms	Portable and mobile RF communications equipment should be used no closer to any part of iCare+ including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ de 80MHz à 800MHz $d = 2.3\sqrt{P}$ de 800MHz à 2.7GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters are determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol (*)
Radiated RF EN 61000-4-3	3V /m 80MHz to 2.7GHz	3V/m	
(*) Symbol: 			

NOTE 1 At 80MHz and 800MHz, 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 Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobiles 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 iCare+ is used exceeds the applicable RF compliance level above, the iCare+ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the iCare+.
b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

Cables and accessories	Maximum length	Complies with	
AC cord	2m	RF emissions, Harmonic emissions	EN 61000-3-2
		Voltage fluctuations / flicker emission	EN 61000-3-3
		Electrostatics discharges (ESD)	EN 61000-4-2
		Electric fast transient / burst	EN 61000-4-4
		Surge EN 61000-4-5	
		Voltage dips, short interruptions and voltage variations on power supply input lines	EN 61000-4-11
		Magnetic fields	EN 61000-4-8
		Conducted RF	EN 61000-4-6
		Radiated RF	EN 61000-4-3

Recommended separation distance between portable and mobile RF communications equipment and the iCare+

iCare+ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of iCare+ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the iCare+ 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)		
	150kHz to 80MHz d=1.2√P	80MHz to 800MHz d=1.2√P	800MHz to 2.5GHz d=2.3√P
0.001	0.12	0.12	0.23
0.01	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitter rated at a maximum output power not listed above, the recommended separation distance « d » in meters (m) can be estimated 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 transmitters manufacturer.

NOTE 1 At 80 Mhz and 800Mhz, the separation distance for the higher frequency is applicable.

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

CHAPTER 14 - WARRANTY

The manufacturer will warrant the quality of the product for one year after purchase, against manufacturing errors and defects in equipment under conditions of normal installation and after-sales monitoring. NSK reserves the right to analyse and determine the cause of any problem. The parts considered as consumables are not covered by the manufacturer’s warranty.
Please note that if you do not observe what is written in this operation manual or for any consumables or recommended liquids, the warranty will not apply.

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Note:
Specifications are subject to change without notice
Printed paper form of this operating manual is available free of charge upon request