

## Advisory Notice on COVID-19 – Cleaning and Disinfection Instructions

### 3nethra neo – Wide-field Imaging System

This information is intended to be used for cleaning and disinfection of 3nethra neo – Wide-field Imaging System during and after the COVID-19 pandemic. These recommendations are intended to minimize the risk of transmission of COVID-19 when using the device for pediatric fundus imaging. The procedures were written taking into account the current and limited knowledge of the nature of COVID-19 transmission among human beings.



#### Precautions to be followed for cleaning and disinfecting the device

- Ensure that the probe is always cleaned with the lens pointing downwards in order to reduce the risk of damage to the probe caused by cleaning solution penetrating into the probe
- To reduce the risk of damage to the probe, do not exceed the recommended immersion time
- **Do not** immerse the entire probe in any liquid or solution
- **Do not** use any cleaning or disinfectant solution as a spray
- **Do not** spray water, bleach, or detergent liquid on the case or other parts of the device, as droplets can go inside the device and affect the functionality
- **Do not** subject the device to extreme sterilization (Autoclave, Ethylene Oxide, etc.)
- Turn off the main power and disconnect the power cable from the main switch and the device
- When using wet wipes, make sure to wring the solution out before cleaning
- Wipe and clean the parts gently
- While cleaning make sure no solution penetrates into the product

#### Cleaning agents recommended

##### Alcohol:

- **70% Isopropanol (IPA)**
- **70% Ethanol**

The materials described in the table are the key components of the fundus cameras manufactured by Forus Health and are compatible with the cleaning agents recommended in this procedure.

Device parts	Handheld probe	Outer cone + contact lens	Probe cap	Control box	Foot pedal	Braided sleeve (Cable cover connecting probe with control box)
<b>Materials</b>	ABS	PEEK/Ep oxy glue/ Glass	PP	PC Resin	ABS	Nylon
<b>Compatibility with alcohol</b>	✓	✓	✓	✓	✓	✓

## Instructions for cleaning the entire 3nethra neo system

**CAUTION:** Ensure that the front lens is free of stains and dust by keeping the outer cone area covered by a lens cap. Avoid touching the front lens to prevent fingerprints on the lens

- 1) Clean all the other outer parts of the device with 70% IPA/Ethanol swabs or lint-free wipes soaked in 70% IPA/Ethanol for at least 1 minute. Make sure the surface is visibly wet
- 2) Let the surface be air dried for at least 30 seconds or until there is no wetness on the surface before screening the patient
- 3) Clean the **probe, probe cable, control box docking station, foot pedal, cables, connectors, foot pedal case, accessories case, and suitcase** with 70% IPA/Ethanol. This is intended to minimize the risk of transmission of COVID-19 during operation, storage, and transport



Figure 1: 3nethra neo packed in suitcase

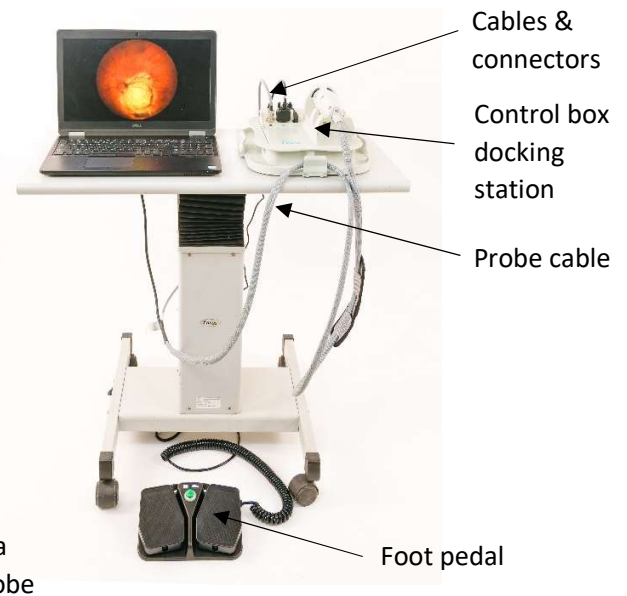


Figure 2: Assembled 3nethra neo

## Instructions for cleaning the lens and outer cone that comes in contact with the patient

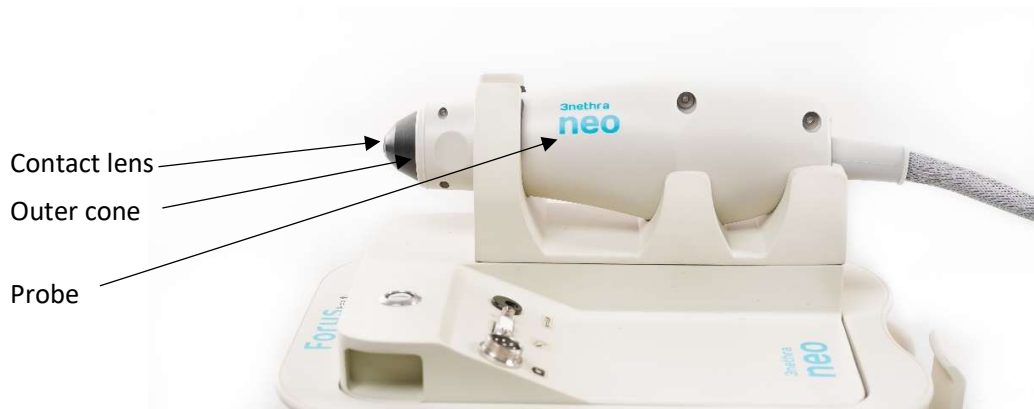
**CAUTION:** The contact lens and outer cone surfaces must be cleaned and disinfected before and after imaging patients.

**CAUTION:** Before using the probe on patients, inspect the contact lens for cracks/breaks, with and without the LED being on. If the lens has any type of damage, do not use the probe on patients. If the probe accidentally falls on any surface inspect for damage on contact lens and casing.

- 1) Wipe away excess coupling gel and debris if any from the contact lens and outer cone surfaces with sterile gauze moistened with sterile water. Repeat this step until there is no visible debris on the surfaces
- 2) Use an alcohol swab of 70% IPA/Ethanol and thoroughly wipe the contact lens and outer cone surfaces before using the probe on the patient for imaging. Make sure to clean the concave surface of the contact lens. Repeat the cleaning with multiple swabs
- 3) Wipe the contact lens and outer cone surfaces with sterile gauze moistened with sterile water to remove residual alcohol
- 4) Allow the lens to air dry for at least 30 seconds or until the surface is free of liquid
- 5) If the contact lens has any leftover coupling gel and debris remaining on the surface, repeat from step 1 onwards

**NOTE:** A combination of **Tristel® Duo** and **Tristel Dry Wipe** is also recommended for cleaning and disinfecting the contact lens and outer cone surfaces before and after imaging patients as described in the above protocol replacing 70% IPA/Ethanol. This recommendation is ONLY for markets (e.g. United Kingdom, European Union) where **Tristel® Duo** and **Tristel Dry Wipe** is recommended for clinical use. DO NOT use this cleaning agent for cleaning other surface areas of the device.

**CAUTION:** Refer to instructions from the manufacturers of the disinfectants and site guidelines. Do not exceed recommended soak times to reduce the risk of damage to the device.



**Figure 3: The probe of 3nethra neo**

## Reference for additional information

Forus Health recommends following the COVID-19 updates released by WHO and CDC for ophthalmologists. The information is available at:

<https://www.aao.org/headline/alert-important-coronavirus-context>

## Service and support

If you have any additional queries, contact the regional Forus Health distributor or Forus Health directly on the below-listed toll-free number or email ID.

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