

	TYPE :	<i>Standard working instructions (SWI)</i>		
	TITLE	<i>Decontamination procedure for 3-color naica® system (N10001.3)</i>		
	DOC NO. :	SWI- 00103	DATE :	20220818
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DOCUMENT HISTORY TABLE

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Decontamination procedure for 3-color naica® system (N10001.3)

Overview and context of the document

- This document provides the instructions to perform the decontamination of all the components of the naica® system in case of return at Stilla Technologies.
- The actions described in this protocol can be performed by a Stilla Technologies’ service specialist, by a distributors’ service specialist or by a client under the supervision of a Stilla Technologies’ or distributors’ service specialist.
- In case of a return of one or more instruments of the naica® system to Stilla Technologies, the following actions are required:
 - Clean and disinfect the instrument(s) that are supposed to return at Stilla Technologies. Be sure that all the procedures are carried out correctly, following the instruction present in the second section of this document “Decontamination Procedure – Instructions”,
 - Fill out and sign the “Decontamination certificate for naica® system (Prism3)”.
 - Pack the instrument to be returned in an adequate and protective packaging. Use the original boxes the naica® system was delivered in. Stilla Technologies will not be responsible for any damages incurred during transport of the instrument.
 - Stick the “*Decontamination Certificate*”, firmly on the external surface of the box along with any other documentation required for shipment.
 - Depending on the location of the naica® system, return the instrument at the following address:

<input type="checkbox"/> From Europe, China and Africa: Stilla Technologies Villejuif Biopark 1, Mail du Professeur Georges Mathé 94800 Villejuif, FRANCE Phone : (+33) 09 82 27 47 47 Email : support@stilla.fr	<input type="checkbox"/> From America, Asia (without China), Oceania Stilla Technologies Inc. 66 Cherry Hill Drive, Suite 110 Beverly MA 01915 USA Tel : 1-833-888-0150 Email : support@stilla-inc.com
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Reference Documents & standards

Reference	Document title	Date
SWI-00108	How to re-package a pump used for the naica® system	20210831
SWI-00109	How to pack a Geode instrument	20210916
SWI-00141	How to re-package a Prism3 instrument	20210831
SWI-00111	How to pack a naica® PC of the naica® system	20210830
QFD-00123	Decontamination certificate for naica® system (Prism3)	20210521

Decontamination procedure – Instructions

Material necessary for the decontamination procedure:

- Gloves;
- Glasses;
- Mask;
- Laboratory coat;
- Hydroalcoholic disinfectant solution for device’s surfaces commonly used for biological and medical devices (Ex. Phagospray).

Note: in case of anticipation of using a similar disinfection product due to non-availability of the above provided example references, Stilla Technologies recommends to first test any other alcohol-based product on a small, less visible, surface of the instruments.

- Decontaminant solution for device’s surfaces used for biological and medical devices, specifically targeting nucleases and DNA contaminations (Ex. RNase away).
- Standard laboratory paper towels.

Select the instrument (or the instruments) that will undergo the decontamination procedure and follow the instructions.

Instrument : Pump

Prerequisites:



- Switch off and unplug the pump from the power socket.
(For more information check the procedure “How to re-package a pump used for the naica® system”).

Removal and cleaning/sterilization of the detachable parts:

- Moisten a paper towel with the disinfectant/decontaminant cleaner and pass it through the external surfaces of all the detachable parts (they could be different based on the model of the pump).

Cleaning/sterilization of the instrument’s surface:

- Moisten a paper towel with the disinfectant/decontaminant cleaner and pass it through all the surface of the pump, paying attention to avoid the power connector.

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Instrument : Geode

Prerequisites:

- Shut off and unplug the Geode from the power socket.
- Remove the tube coming from the pump, from the rear side of the Geode.
(For more information check the procedure “How to pack a Geode instrument”).

Removal and cleaning/sterilization of the detachable parts:

- Open the lid of the Geode and take away eventual residual chips.
- Remove the rubber gasket laying on the edges of the thermo-block and trash it to an appropriate bin.
- Remove the magnetic frame laying on the thermo-block surface.
- On a bench, put several layers of paper towels and place the magnetic frame on top.
- Spray the disinfectant/decontaminant cleaner on the whole surface of the magnetic frame, on both sides and leave it for 5 minutes.
- With a clean and dry paper towel absorb the liquid in excess from the magnetic frame and rinse it if necessary.
- Please take notice that a Geode instrument may include several magnetic frames for the different naica® system chip consumable types. Ensure to perform the above-described procedure for all magnetic frames and for all magnetic adaptor(s) fitting in the internal part of the lid.
- At the end of the procedure, put all the disinfected/decontaminated tools in a clean zipper bag (not provided).

Cleaning/sterilization of the instrument’s surface:

- Moisten a paper towel with the disinfectant/decontaminant cleaner and pass it through all the surface of the Geode, paying attention to avoid the power connector.
- Clean the surface of the thermo-block and the internal surface of the lid in the same way.



Instrument : Prism3

Prerequisites:

- Switch on the Prism3 and the naica® PC, launch Crystal Reader software to open the Prism3 flap.
Take away eventual residual chips and remove the metallic chip holder.
Close the flap and shut off the instrument.
- Shut off and unplug the Prism3 from the power socket.
- Remove the USB cable coming from the PC, plugged on the rear side of the Prism3.
(For more information check the procedure “How to re-package a Prism3 instrument”).

Removal and cleaning/sterilization of the detachable parts:

- On a bench, put several layers of paper towel and place the metallic chip holder on top.
- Spray the disinfectant/decontaminant cleaner on the whole surface of the chip holder, on both sides and leave it for 5 minutes.
- With a clean and dry towel paper absorb the liquid in excess from the chip holder, rinse it if necessary.

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- Please take notice that a Prism3 instrument may include several metallic chip holders for the different naica® system chip consumable types. Ensure to perform the above-described procedure for all metallic chip holders.
At the end of the procedure, put all the disinfected/decontaminated tools in a clean zipper bag (not provided).

Cleaning/sterilization of the instrument's surface:

- Carefully read the procedure *"How to pack the Prism3"*
- It is important to lock the Prism3 instrument with the two security screws before moving the instrument. Stilla Technologies will not be responsible for any damages incurred during packaging and / or transport of the instrument, if the transportation locks have not been put in place correctly.
- Moisten a paper towel with the disinfectant/decontaminant cleaner and pass it through all the surface of the Prism3, paying attention to avoid the power connector.

Instrument : naica® PC

Prerequisites:

- Shut off and unplug the naica® PC from the power socket.
- Unplug the naica® PC from the power socket.
- Unplug the mouse and the keyboard, remove the cables connecting the naica® PC with the display and the naica® PC with the Prism3.
If present, unplug the barcode scanner.
(For more information check the procedure *"How to pack the naica® PC of the naica® system"*).

Removal and cleaning/sterilization of the detachable parts:

- Moisten a paper towel with the disinfectant/decontaminant cleaner and pass it on the surface of the mouse, the keyboard, the display and the barcode scanner.

Cleaning/sterilization of the instrument's surface:

- Moisten a paper towel with the disinfectant/decontaminant cleaner and pass it through all the surface of the naica® PC, paying attention to avoid the connectors on the rear side of the instrument.

Following the decontamination procedure continue to package the instruments as instructed in the documents listed in the section *"Documents reference & standards"*.

Fill the *"Decontamination certificate for naica® system (Prism3)"* and add it on the instrument boxes as described on page 2 of this document.