COVID-19 / SDX® System safety use

In this period of worldwide Pandemic, our habits and ways of life are disrupted and a lot of questions are arising for each of us.

Directly concerned by all which is linked to respiratory illnesses, and fully aware of all the possible questions asked by our users in this context regarding the proper use of our products for the best patient's treatment protecting them from all cross-contamination risk, we have created this specific guide referring to various instructions of good practices and hygiene already detailed in the User Manual of your device.

The two essential rules to respect for avoiding any cross-contamination are :

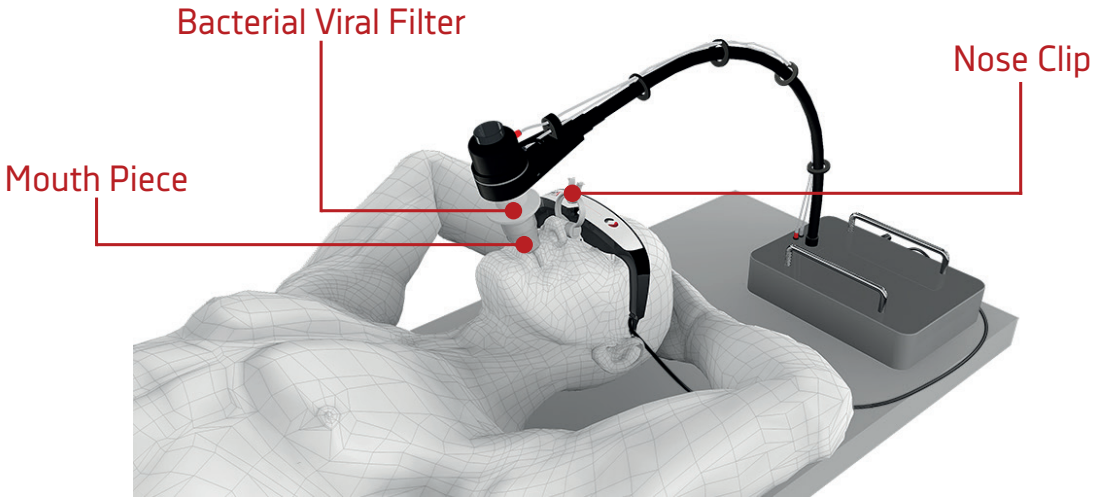
- Mandatory use of « single use » antibacterial and antiviral filters (BVF : Bacterial Viral Filter) for each patient
- Systematic decontamination of the product parts potentially soiled by a contaminated patient (or suspected to be)

I-THE SDX®SYSTEM, A SPIROMETER LIKE THE OTHERS : MANDATORY SINGLE USE CONSUMABLES TO AVOID ANY CROSS-CONTAMINATION

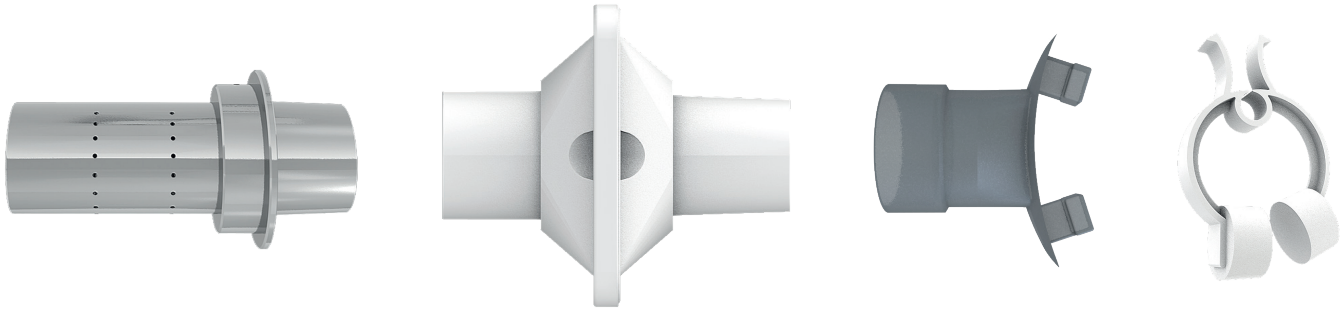
The SDX® System is a breathing control device used in Radiation Therapy for controlling the internal motions due to the patient's breathing.

Its technology of volumetric sensor (type Fleisch #2) comes from the pulmonology field in which guidelines and good practices are established by the ATS (American Thoracic Society - https://www.thoracic.org/)

The SDX System's good conditions of use are indeed the same as the ones performed in the pulmonology field, notably concerning the patient's hygiene and protection.
(https://www.thoracic.org/statements/resources/pft/PFT1.pdf).



As mentioned in your product's user manual, the single use of antibacterial filters is mandatory for avoiding any cross-contamination between your patients breathing in the SDX®System. For each patient, you will also have to use a nose-clip and a mouthpiece for avoiding any oral and nasal leakage.



The role of the antibacterial filter is to create a protective barrier between the patient and the breathing tube (or honey comb tube), for avoiding that any virus or bacterium contaminates the other part.

In these conditions of SDX® System's good use, there is none cross-contamination risk between your patients, as long as the antibacterial filters that you are using meet the applicable international standards.

The great majority of antibacterial filters supplied in pulmonology for practicing PFT (Pulmonary Function Testing) meet the ATS requirements, but in case of any doubt concerning the filters that you are using, please urgently consult the manufacturer for asking the tests reports (realized by independent laboratories such as Nelson Laboratories) certifying that the filter's membranes are answering well to the following criteria :

Specifications ATS/ERS : < 1,5 cm H2O/lps for a débit of 12 l/sec – Efficiency of the electrostatic membrane : > **99,9999** % concerning bacterium (BFE) : > **99,999** % concerning virus (VFE)

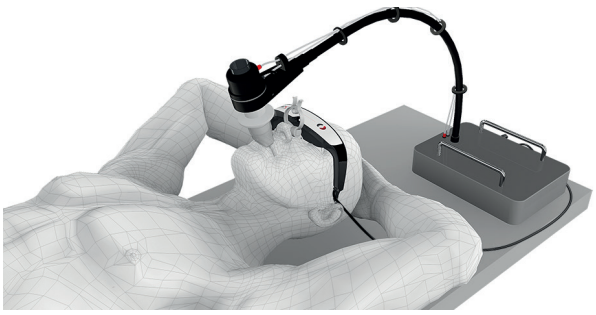
Strictly respecting these conditions and with regard to the size of the COVID-19 virus (Cf. Letter addresed by our partner GVS to its clients using their filters branded GVS in PFT), the filters that you are using will perfectly prevent from any contamination via this type of virus.

II-CLINICAL USE OF THE SDX® SYSTEM: CLEANING & DISINFECTION RECOMMENDATION

With the current pandemic and knowing that any patient could be infected, even without any clinical symptoms, DYNR® recommends a systematic disinfection of every parts of the SDX® System that could have been contaminated by the patient.

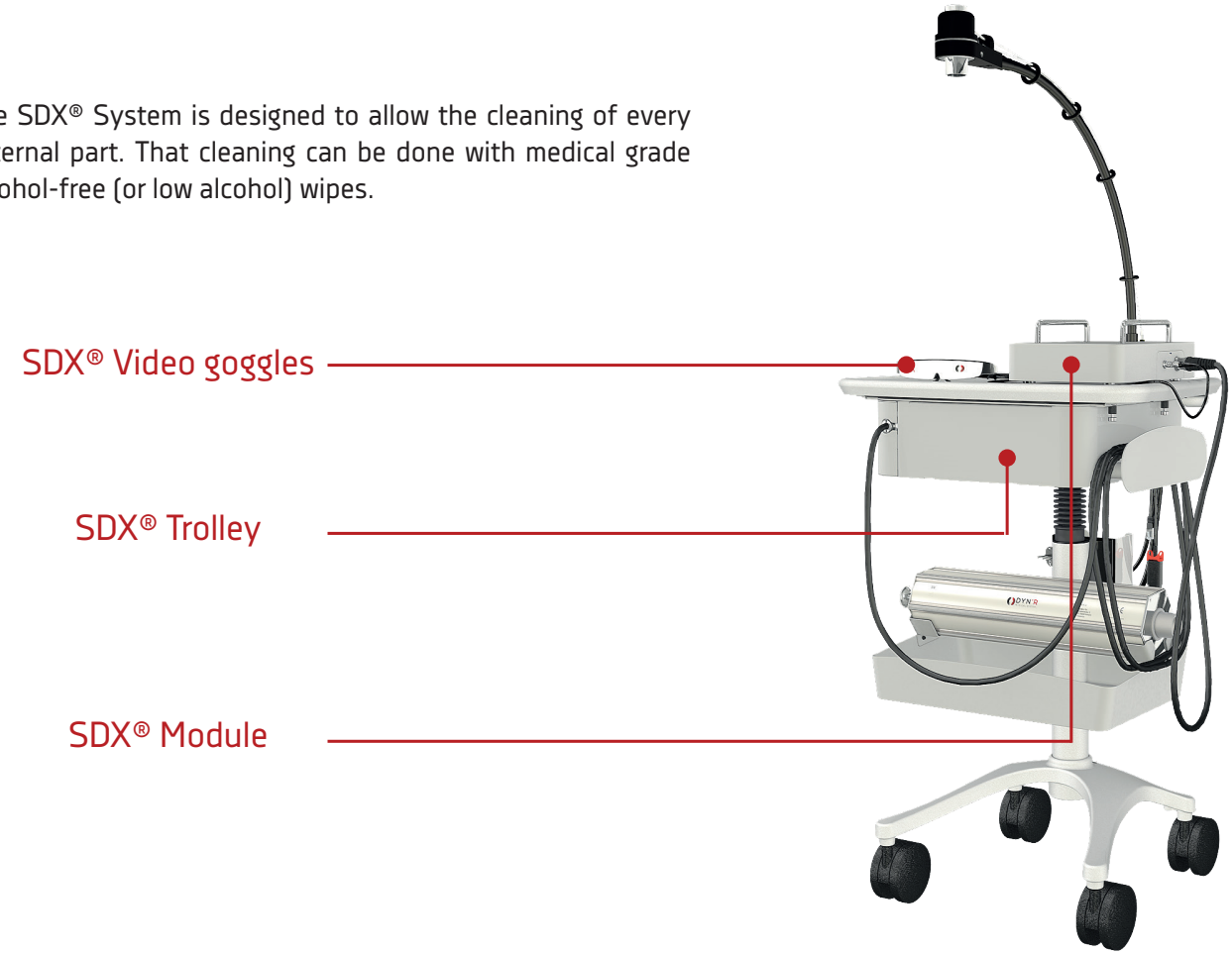
There are two parts of the SDX® System that can be possibly contaminated:

- The parts of the product in direct contact (or that could be in direct contact) with the patient (e.g: video goggle)
- The parts into which the patient is breathing (breathing tube)



II.1 - Parts in direct contact with the patient

The SDX® System is designed to allow the cleaning of every external part. That cleaning can be done with medical grade alcohol-free (or low alcohol) wipes.



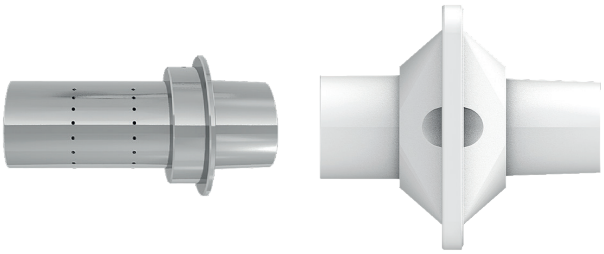
After every patient's treatment, it is strongly recommended to clean & disinfect the video goggles that were in direct contact with the patient's skin.

Use of an eye-shield:
The direct contact with the patient's skin can be reduced by using an eye-shield. When using an eye-shield, the number of parts in contact with the patient's skin is reduced: the eye shield, the nasal back curve and the goggles temples (placed on the ears)
It is recommended to remove the eye-shield before cleaning & disinfection of the video goggles.

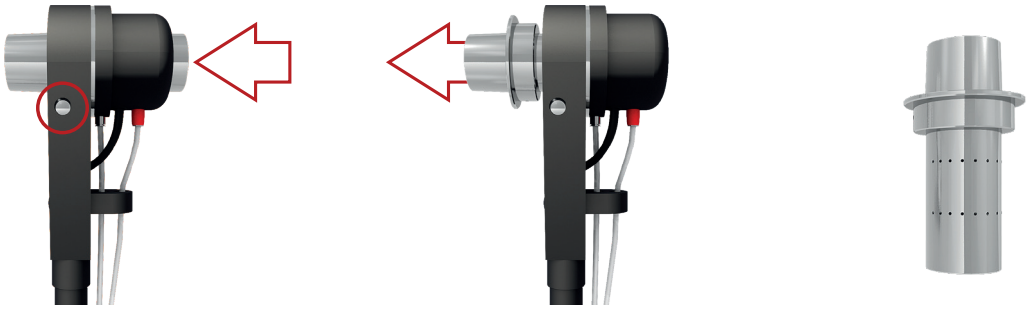
WARNING: The lenses of the video goggles are recovered by a plastic that can be easily scratched if cleaned with abrasive products. It is recommended to use a microfiber cleaning pad soaked with a little quantity of saline solution. Directly spray the solution on the lenses, carefully wipe away by doing a slow circular movement until the lenses are cleaned & dry.
The remaining surface of the video goggles and eye-shield can be cleaned and disinfected by using a disinfectant wipe with low alcohol content (or alcohol-free). The same wipe must be used only one time on the video goggles / eye-shield.

II.2 - The breathing tube (« Honey Comb Tube »)

The main part of the Spirometry sensor is the breathing tube (or "Honey Comb Tube") to which the antibacterial filters are connected. It is in this part that the patient's filtered air will pass both in inspiration and expiration.



The antibacterial filter is acting as a bacterial & viral barrier (as explained above) but it can happen that a patient touches the tube with his hands, or coughs in the Honey Comb Tube direction before or after that the antibacterial filter was correctly plugged... In such a situation, as indicated in your product User Manual, the breathing tube can be easily removed for cleaning with appropriate solutions.



The Honey Comb Tube is an assembly of different elements (tube, security locking, central axe, sheet metal strip) all made with austenitic stainless steel.

The two following products were tested and are recommended by DYN'R® for the decontamination of the SDX® System Honey Comb Tube :

BACTINYL® 6G PE is a high-grade glutaraldehyde disinfectant for endoscopes, surgical medical instruments and non-sterilizable equipment, medical devices.

CLASS IIB.

- Bactericidal : NF EN 13727, NF EN 14561
- Mycoactericidal : NF EN 14348, EN 14563
- Fungicidal : NF EN 13624, EN 14652
- Sporicidal : EN 14347
- Virucidal : NF EN 14476 sur Poliovirus, Adenovirus, Herpes simplex virus, Pseudorabies virus

CIDEX OPA
Instrument high performance Disinfectant.

- Offers a high level of disinfection
- Contains ortho-phtaladehyde (0.55 %)
- Glutaraldehyde free with minimal odor
- Reusable for up to 14 days
- Easy to rinse
- Soak Time – 10 hours at 20 °C and 25 °C : Bactericidal, tuberculocidal, virucidal (including HIV-1) and fungicidal properties
- Soak Time – 32 hours at 20 °C and 25 °C : Sporicidal properties
- May be disposed of down the sink according to local regulations

Recommended procedure for cleaning, disinfecting and rinsing of the breathing tube :

01 - Wear appropriate personal protective equipment and read the instructions of your disinfectant product, to possibly adapt the procedure recommended below;
02 - Fill a clean sink or an appropriate size receptacle (do not use a hand basin); alternatively, an ultrasonic cleaner with appropriate water and detergent may be used. The detergent dilution and water temperature should be in accordance with the manufacturer's instructions and local policies. Note : the use of the ultrasonic bath is to provide an additional cleaning mean of any physical particle or dirt on the Honey Comb tube;
03 - Fully submerge the parts in the detergent solution. Ensure that no air bubbles remain in lumens or serrations, by irrigating them with running water;
04 - Gently agitate the parts to remove all visible dirt, taking care to keep the device under the surface of the water to prevent splashing and spraying or leave the Ultra sound cleaner running for the recommended time;
05 - Remove the item from the sink or from the machine and drain any excess detergent prior to submerging the item in a second sink or receptacle containing clean rinsing water;
06 - Rinse the item thoroughly with clean and cold running water;
07 - Remove and drain the device and then dry it thoroughly using clean and oil free compressed air;
08 - After cleaning, dispose of any cleaning materials safely in the appropriate waste containers in accordance with your local policy;
09 - Carefully inspect all surfaces and gaps of the internal parts of the Honey Comb tube. These parts must be perfectly clean and free of particles and/or dirt. Inspect the matrix and capillaries for detecting possible mechanical damages and/or remaining dirt in the airflow path of the matrix;
10 - Remove your personal protective equipment and decontaminate your hands;
11 - Complete any necessary documentation to record that you have cleaned the device and to describe the method and solutions you used;
12 - After repositioning the Honeycomb Tube, be sure to check the calibration of your device before any new use (see Calibration procedure and Calibration check in your user manual).

Please feel free to contact us if you have any question or if you need any additional information.

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