VIMAP Technologies
Paseo de la Hispanidad,1 y 2
29130 Alhaurin de la Torre (SPAIN)
NIF: B17878075 - VAT: ESB17878075

VIMAP TECHNOLOGIES

Date: 29 of April 2020

VMX-1010A CO2 insufflator & Coronavirus COVID19. Cleaning aspect, cross-contamination risk and room contamination risk

Scope of VMX-1010A: Gas management device for virtual colonoscopy.
Specifies name: VMX-1010A
Brand/model: VIMAP Technologies
Manufacturer: Sopro a Company of ACTEON Group.
Country of origin: France
Manufacturing site: Avenue des Genévriers ZAC Athélia IV, 13705 La Ciotat Cedex, France.
Risk- based classification: Class IIa
Classification rule: Rule 11
GMDN code: 36747
HS code: 90189084
Medical device registration number of any approval code: LNE/G-MED NB n°0459 – Cert. 17802

Cleaning aspect of the device:

The instructions issued by the sterilization managers of each hospital or medical center must be followed in all cases.
These instructions will take precedence over the information contained in the present manual which is provided for guidance only.
Always unplug the device from the power outlet before cleaning.

After each use:
Discard the disposable tubing - do not attempt to sterilize it.
Clean up any splashes of liquid present on the device by wiping with a damp cloth.
The unit must be decontaminated before sending it to the after-sales service.

Cross contamination risk:

References of VIMAP Technologies single use administration sets available for VMX-1010A:
- AS-3W-Y-R35A (virtual colonoscopy or CTC)

Direction of the flow patient to machine: Before reaching any internal components of the machine or being vented in the room during the release of over pressures, the CO2 is going through a filter (see annex 2).

Direction of the flow machine to patient: Before reaching the patient, CO2 is going through the single filter of the administration sets.

VIMAP administration sets for VMX-1010A (see annex 2) are using a specific filter ref.: S30044 that is anti-bacteria, anti-viral and hydrophobic. For the protection against virus, minimum filtration is 99.9% (see laboratory report and drawing in annex 1).

The administration set is single use consumable and is changed at any patient, before every new exam.

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Room air contamination risk by release in the room of intra colonic contaminated CO2

VMX-1010A is releasing the pressure after the end of the exam electronically and automatically. An insufflated patient colon contains in average 1,5l of potentially contaminated CO2. With VMX-1010A, this quantity is filtered before being releasing in the room: There is low risk of contamination of the room by this quantity of contaminated CO2.

Technical explanation: When you stop the machine at the end of the exam, machine will open the release valve that is opened by default. We have 1 electronic valve for release of over pressures + 1 mechanical safety valves (only used in case of abnormal over pressure in case of electronic failure). The electronic release valve is open/closes and **naturally opened,** it means that when machine is off (power cut), or when you end the exam, it is fully opened.

This is the warranty that all quantity of CO2 present in the colon after insufflation will be going out of the patient colon after the stop/end of the exam will go through the administration set filter before being released in the CT room.

Conclusion:

VMX-1010A cross-contamination and room contamination risk **very low** due to the safe design of the device and due to anti-viral property of the filter used in administration sets.

Authorized Signatory:

Nicolas Costovici

Position: CEO

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ANNEX
1

Nelson Labs.
A Sotera Health company

Sponsor:
Tab Liu
Innovative Medical Manufacturing Co.
NO. 107 Lane 181, Sec. 1, Yongzhen Rd.
Zhunan Township, Miaoli C. 35057
TAIWAN

Viral Filtration Efficiency (VFE) at an Increased Challenge Level GLP Report

Test Article:	Sample PN: S30044 Sample LOT: A190114D #1, #2, #3, #4, #5, #6
Purchase Order:	POE19090I
Study Number:	1218906-S01
Study Received Date:	04 Sep 2019
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0010 Rev 13
Deviation(s):	None

Summary: This test procedure was performed to evaluate the VFE of test articles at an increased challenge level. A suspension of ΦX174 bacteriophage was delivered to the test article at a challenge level of greater than 10^6 plaque-forming units (PFU) to determine the filtration efficiency. The challenge was aerosolized using a nebulizer and delivered to the test article at a fixed air pressure and flow rate of 30 liters per minute (LPM). The aerosol droplets were generated in a glass aerosol chamber and drawn through the test article into all glass impingers (AGIs) for collection. The challenge was delivered for a one minute interval and sampling through the AGIs was conducted for two minutes to clear the aerosol chamber. The mean particle size (MPS) control was performed at a flow rate of 28.3 LPM using a six-stage, viable particle, Andersen sampler for collection. The VFE at an Increased Challenge Level test procedure was adapted from ASTM F2101.

This test procedure was modified from Nelson Laboratories, LLC (NL), standard VFE test procedure in order to employ a more severe challenge than would be experienced in normal use. All test method acceptance criteria were met.

Challenge Flow Rate:	30 LPM
Area Tested:	Entire Test Article
Side Tested:	Either Side
Challenge Level:	3.4×10^8 PFU
MPS:	~3.2 µm
Test Monitor Results:	Acceptable

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Curtis Gcrow
Study Director — Curtis Gcrow, B.S.

13 Sep 2019
Study Completion Date

1218906-S01

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These results apply to the samples as received and relate only to the test details listed in this report. Results may not be reproduced except in full without written approval. Subject to NL terms and conditions at www.nelsonlabs.com

Results:

Test Article Number	Total PFU Recovered	Filtration Efficiency (%)
1	3.4×10^3	99.90
2	3.6×10^3	99.90
3	9.5×10^2	99.972

The filtration efficiency percentages were calculated using the following equation:

$$\%\,VFE = \frac{C - T}{C} \times 100$$

C = Challenge Level
T = Total PFU recovered downstream of the test article

Test Method Acceptance Criteria: The average VFE positive control challenge level shall be ≥ 1×10^6 PFU when the flow rate is ≥ 30 LPM. The average MPS of the challenge aerosol at 1 cubic foot per minute (CFM) (28.3 LPM) must be maintained at 3.0 ± 0.3 µm. Other challenge levels and MPS averages may be used as approved by the sponsor.

Procedure:

Challenge Procedure: The viral culture suspension was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The aerosol droplets were generated in a glass aerosol chamber and drawn through the test article into AGIs. The challenge was delivered for a one minute interval and the vacuum and air pressure were allowed to run for an additional minute in order to clear the aerosol chamber. Positive control runs were performed (no filter medium in the air stream) prior to the first test article run, after every 5-7 test articles, and after the last test article to determine the average number of viable particles being delivered to each test article. The MPS of the challenge aerosol was determined using a six-stage Andersen sampler.

Plaque Assay Procedure: The titer of the AGI assay fluid was determined using standard plaque assay techniques. Approximately 2.5 mL of molten top agar was dispensed into sterile test tubes and held at 45 ± 2°C in a waterbath. An aliquot of the assay fluid from the test article was added to the sterile test tubes along with approximately 0.1 mL of an *Escherichia coli* culture. The contents were mixed and poured over the surface of bottom agar plates. The agar was allowed to solidify on a level surface and the plates were incubated at 37 ± 2°C for 12-24 hours.

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Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	09 Sep 2019
Phase Inspected by Quality Assurance: Counting Procedure	12 Sep 2019
Audit Results Reported to Study Director	12 Sep 2019
Audit Results Reported to Management	12 Sep 2019

Scientists	Title
Sarah Smit	Supervisor
Curtis Gcrow	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved offsite location.

Laura Fahlsing
Quality Assurance

16 Sep 2019
Date

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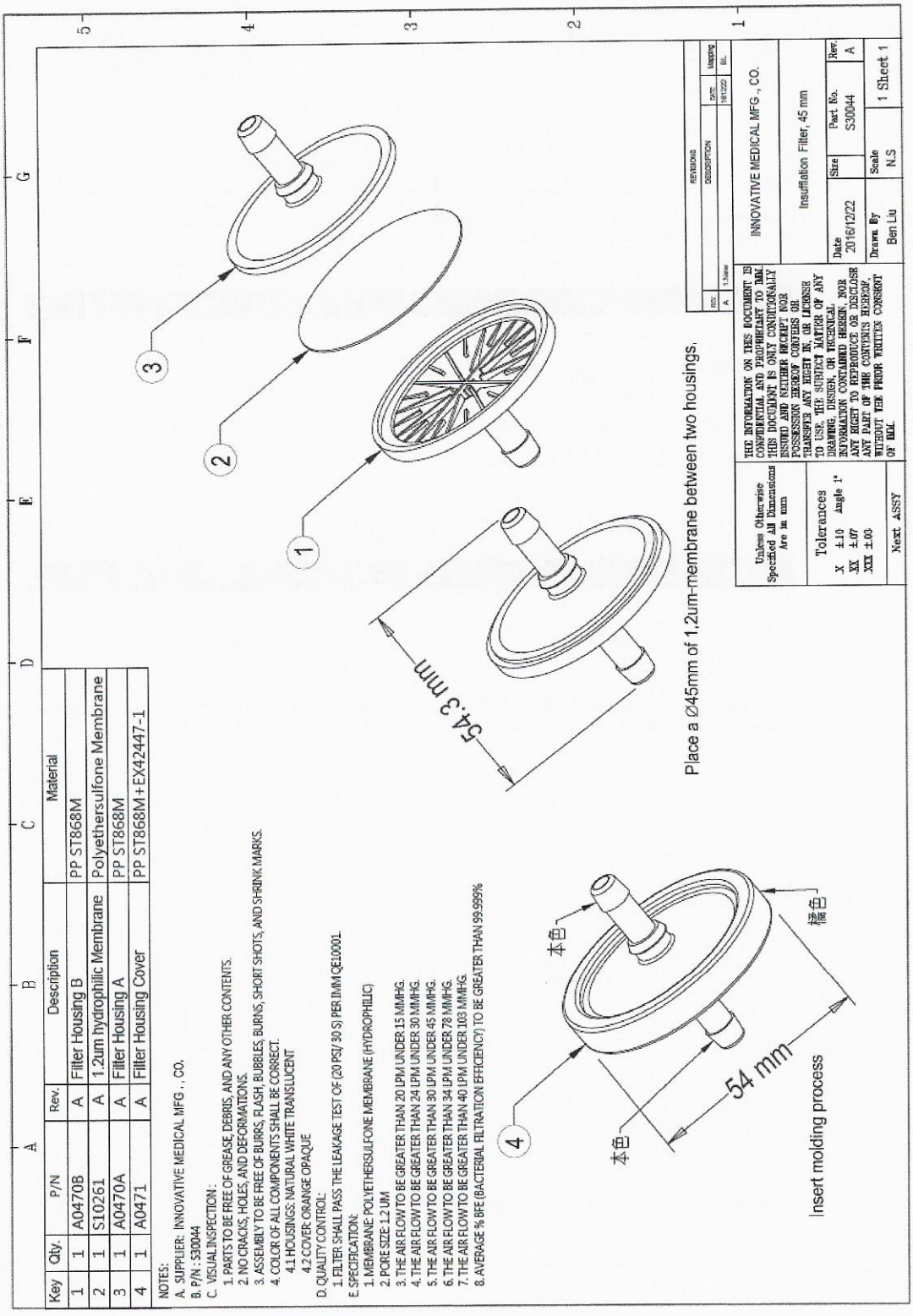

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ANNEX

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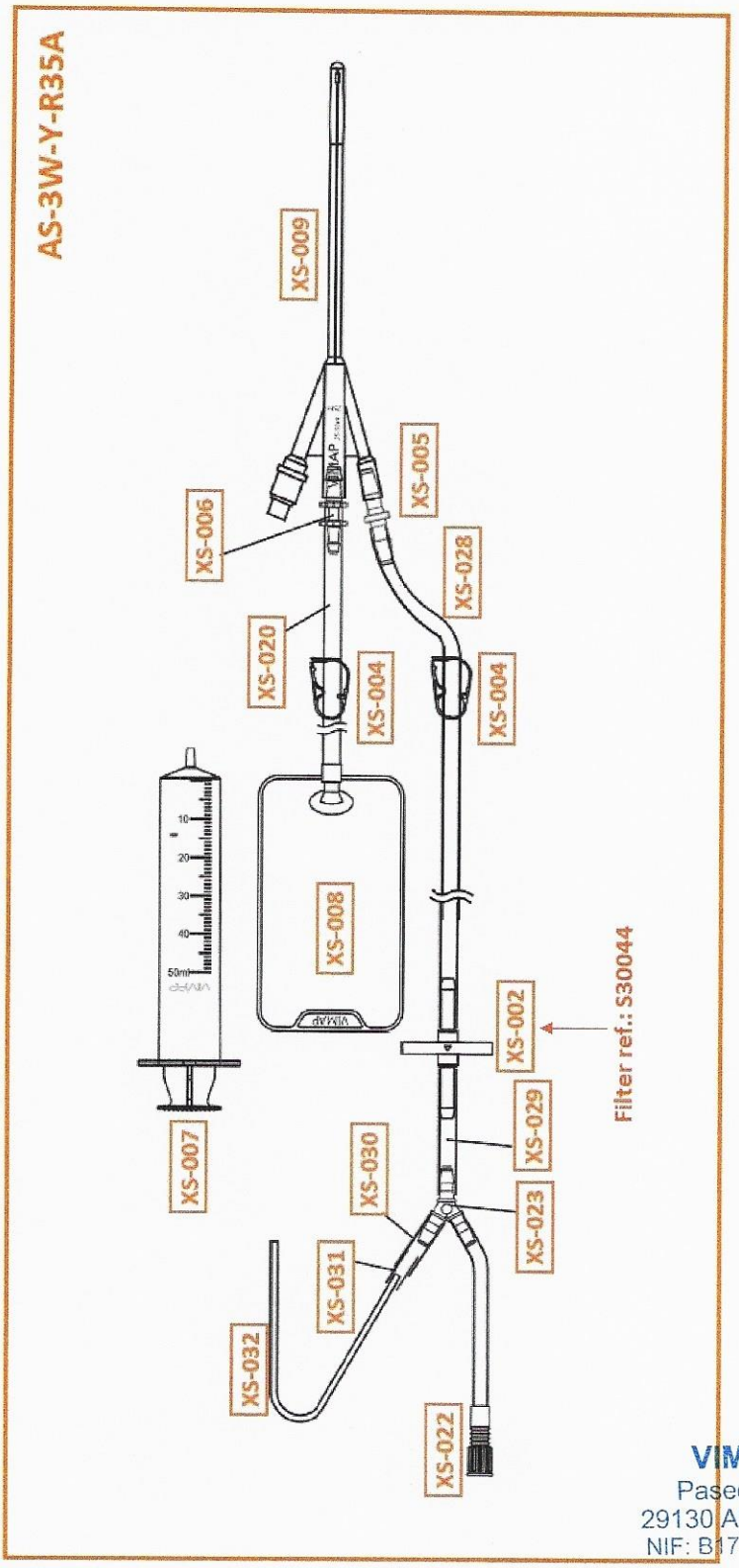

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