COLTENE SciCan

Instructions for Healthcare Facilities: Decontamination of Compatible Flat-Fold Style N95 Respirators Using the SciCan BRAVO Chamber Autoclaves

Health Canada has authorized an **Interim Order (IO)** for the emergency use of the BRAVO 17V or 21V 121°C Porous Wrapped Cycle (hereafter referred to as the "BRAVO Autoclave") for use in decontaminating compatible flat-fold style respirators (3M 1870+, 9210+ models only) (hereafter referred to as "compatible N95 respirators") for single-user reuse by healthcare personnel in healthcare facilities. Healthcare personnel should follow these instructions, as well as procedures outlined by their healthcare facility, to decontaminate compatible N95 respirators using the BRAVO Autoclaves. The BRAVO Chamber Autoclaves are not compatible for respirators that are the moulded/cup style, have exhalation valves or authorized in the Non-NIOSH approved disposable filtering facepiece respirators manufactured in China EUA.

- **All compatible N95 respirators used in the BRAVO must be free of visible damage and soil/contamination (e.g., blood, dried sputum, makeup, soil, bodily fluids).**
- **Compatible N95 respirators that are visually soiled or damaged should not be collected for decontamination and should be appropriately discarded.**
- **Compatible respirators are 3M 1870+ and 9210+ models only.**
- **The BRAVO Chamber Autoclaves can be used for decontaminating compatible respirators up to a maximum of 10 decontamination cycles.**
- **Any compatible N95 respirator whose traceability is lost, or number of decontamination cycles is not able to be identified should be discarded.**
- **Decontaminated, compatible N95 respirators are not sterile.**
- **Do not use decontaminated, compatible N95 respirators in surgical procedures.**

Materials Needed:

- Pouches suitable for steam decontamination at 121°C
- Chemical Integrators and/or Biological Indicators (BI) for steam decontamination at 121°C

Compatible N95 Respirator Marking:

The healthcare facility should ensure that the chain of custody is maintained to minimize risk of cross-contamination. Prior to collection by the healthcare facility personnel, the healthcare personnel should label their own individual compatible N95 respirator with their name and/or identifier, and number of decontamination cycles (as shown below) with a permanent marker. The healthcare personnel should pouch the compatible N95 respirator in a plastic-paper pouch of an appropriate size that allows the respirator to lay flat (e.g., Chex-all II SKU 024010), and seal it. The compatible N95 respirator in the pouch should be placed at a designated collection station. See the *"Instructions for Healthcare Personnel"* for details.

Compatible N95 Respirator Collection and Transportation:

1. The healthcare facility should create a collection station at the point of generation (i.e., hospital/clinic floor/unit). Each station should have a tray or container provided by the healthcare facility to collect the pouches containing the compatible N95 respirators for decontamination with the following note: *NOTE: Only compatible N95 respirators in pouches should be placed at this collection station for decontamination. No other items will be decontaminated in the same decontamination cycle.*
2. The healthcare personnel who are assigned to decontamination (i.e., those with training for collection/transport of such materials) should collect the pouches containing the compatible

N95 respirators at the collection stations, and place them into the appropriate container for transportation, such as a closed case cart, to minimize risk of environmental contamination. The case cart should have a hospital/clinic-controlled tag or identifier that indicates the location in the hospital/clinic where the respirators were utilized.

3. The case cart should be transported to healthcare facility's decontamination area.

Use of the 121°C Porous Wrapped Cycle in the BRAVO Autoclave:

1. Unload the pouched, compatible N95 respirators and place them into the BRAVO Autoclave for decontamination. Healthcare facility staff should adhere to the healthcare facility's policies for documenting load contents for and use of the Bravo Autoclaves.
2. A maximum of 5 pouched, compatible N95 respirators (1 pouch per shelf) can be processed in the 121°C Porous Wrapped Cycle in the autoclave. An example of the correct organization of pouches is included on the right. (**Caution:** Do not combine any other load with the respirator load).
3. A specific orientation of the compatible N95 respirator in the pouch or pouches in the autoclave is not required.
4. A steam autoclave Chemical Integrator and or Biological Indicator may be used to monitor the cycle. The indicators may be placed on the pouch, inside the pouch, or within the chamber to provide an indicator that decontamination parameters are met. At least one indicator per cycle is recommended.
5. Use of the BRAVO Operator Manual instructions for initiating the 121°C Porous Wrapped Cycle and to verify a successful cycle completion is encouraged.
6. Upon completion of the cycle, the decontaminated, compatible N95 respirators are ready for use. Compatible flat fold style respirators may be processed a maximum of 10 times (3M 1870+, 9210+ models).

After the 121°C Porous Wrapped Cycle in the BRAVO Autoclave is complete:

1. Following completion of the 121°C Porous Wrapped Cycle in the Autoclave, the Chemical Integrator and/or Biological Indicator should illustrate a "PASS" reference color. If the cycle is successful, the respirators have been exposed to the appropriate steam autoclave parameters. If the indicator does not match the "PASS" criteria, the compatible N95 respirators should not be considered decontaminated and either repackaged and decontaminated through another 121°C Porous Wrapped Cycle in the BRAVO Autoclave or discarded. Please note that successful completion of the cycle does not indicate sterility of the decontaminated, compatible N95 respirators.
2. Healthcare facilities should utilize existing processes to decontaminate the case carts and the transport trays or container for reuse and delivery of decontaminated, compatible N95 respirators back to patient areas.
3. Decontaminated, compatible N95 respirators that match the "PASS" criteria should be loaded back in clean trays or containers and placed in a closed case cart following the healthcare facility's policy for identifying/labeling processed loads. The documentation needs to include a clean copy of the location identifier to ensure return of the respirators to the original location in the facility for distribution to healthcare workers.
4. The healthcare facility should ensure that the chain of custody is maintained to minimize risk of cross-contamination. Upon return of the decontaminated, compatible N95 respirators to the appropriate individuals, the respirator should be checked for the following:
    a. Ensure that the name or other identifier and number of decontamination cycles is still legible. Any compatible N95 respirator whose traceability was lost, or number of decontamination cycles is not able to be identified should be discarded.
    b. Any compatible N95 respirator that is visually damaged or soiled should be discarded.
    c. Any compatible N95 respirator that has exceeded a maximum of 10 decontamination cycles should be discarded.
    d. Ensure that the compatible N95 respirator is returned to its previous user.

5. The healthcare facility should make available the "*Instructions for Healthcare Personnel: Preparation of Compatible Flat-Fold Style N95 Respirators for Decontamination Using the SciCan BRAVO Chamber Autoclaves*" upon return of the decontaminated, compatible N95 respirators.

Additional Information:

1. Prior to use, healthcare personnel should inspect decontaminated, compatible N95 respirators for visible damage and soil/contamination (i.e., blood, dried sputum, makeup, soil). Respirators that are damaged or contain visible soil should be discarded. Healthcare personnel should also verify that the correct, individually marked respirator is returned to them and perform a seal check to verify the integrity of the respirator prior to use.
2. N95 respirators may be safely stored in pouches.
3. It is strongly recommended to maintain chain of custody on the compatible N95 respirator to minimize the risk of cross-contamination between individuals.

Reporting to SciCan Ltd.:

Healthcare facilities should report any discoloration or other signs of degradation with a decontaminated, compatible N95 respirator to SciCan Ltd., and the healthcare facility should discard the respirator.

Healthcare facilities using the decontaminated, compatible N95 respirators should monitor healthcare personnel who use such respirators for signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection and promptly report such information to SciCan Ltd., so that SciCan Ltd. can provide a weekly report to Health Canada. Reports of adverse health indications should be reported up to and including 14 days after the last contact with suspected SARS-CoV-2 virus.

Advisories on Chemical Integrators/Biological Indicators:

In the event of a Chemical Integrator and/or Biological Indicator shortage, the following instructions should be followed to determine proper decontamination of the compatible N95 respirators in the 121°C Porous Wrapped Cycle of the BRAVO Autoclaves.

The autoclave can be connected to an external data recorder to allow the recording of the cycle data on to a USB memory stick (or printer, if installed), which can then be downloaded to a PC for cycle archiving and management.

1. Switch off the autoclave and open the service compartment door.
2. Insert both ends of the 9-pin connector into the serial ports of the data recorder and the Bravo unit and secure them with the screws. The serial port of the autoclave can be found next to the biological filter.
3. Insert the power connector pin into the data recorder and then plug in the power supply.
4. Fully insert the USB stick into data recorder.
5. Switch on the autoclave.

After the cycle is finished, it is important to check the decontamination results. The report (option) of the decontamination parameters is an additional verification tool. See below for an example of a Bravo Autoclave printed report.

The decontamination parameters for the (121°C Porous Wrapped Cycle) of the BRAVO Autoclave should be within the following thresholds:

Decontamination Time (121°C Porous Wrapped Cycle): -0/+1% = 2 seconds
Decontamination Cycle Temperature (121°C Porous Wrapped Cycle): "Specified temp" -0/+4 -121°C -125°C
Saturated Steam Pressure (121°C Porous Wrapped Cycle): (gauge pressure) - 105kPa - 132kPa

Cycle Report (extended)
at the operator's request

Model	Bravo17
S/N	03 BM 0001
Ver. SW	Exxxx/BMyyyyyy
Counter	0007/0015
Selection	134c POROUS/WRAPPED
Temperature	134 °C
Pressure	2.10 Bar
Process time	4 min
Stand-by	HIGH
Pre-vacuum	FRACTIONATED
Drying	STANDARD

CYCLE START 19/11/02 09:52

Time		T1	P	T2	T3	T4
00:01	CS	075.1	-0.00	130.9	115.2	093.4
00:11		074.9	-0.28	133.3	114.2	094.0
00:21		074.4	-0.46	146.3	113.2	094.5
00:31		074.3	-0.57	152.6	112.2	095.0
00:35	..	074.3	-0.59	154.2	111.9	095.2
00:51	..	078.9	-0.62	152.2	110.4	095.6
01:01	..	074.9	-0.73	146.6	109.6	095.7
01:27	..	047.8	-0.78	149.3	107.7	095.7
01:57	..	047.8	-0.80	155.3	105.8	095.4
02:07	..	076.5	-0.57	149.9	105.2	095.1
02:17	..	081.1	-0.49	142.1	104.6	094.6
		---		---		
		---		---		
08:15	...	068.4	-0.76	151.8	104.7	102.3
08:22	...	061.1	-0.80	153.6	104.5	101.7
08:32	..	097.4	+0.01	154.7	104.0	100.8
08:42	...	104.6	+0.24	148.9	103.7	101.0
		---		---		
		---		---		
15:04	...	135.5	+2.15	143.3	111.7	131.7
15:19	...	135.9	+2.17	148.5	113.5	132.6
15:28	...	135.3	+2.16	153.6	115.9	133.0
		---		---		
		---		---		
19:19	...	135.5	+2.15	157.4	126.5	132.5
19:34	...	134.4	+1.07	157.0	126.8	131.2
19:49	...	108.3	+0.25	156.4	126.8	119.9
19:53	..	104.4	+0.00	156.1	126.6	116.2
20:04	...	094.2	- 0.50	155.1	125.9	112.4
20:19	...	069.2	-0.73	153.7	124.5	112.9
20:34	...	059.2	-0.81	152.3	123.4	113.5
20:49	...	053.8	-0.87	151.2	122.9	113.6
20:57	...	048.4	-0.90	150.9	122.7	113.5
21:04	...	047.1	-0.80	151.0	122.5	113.5
23:31	...	042.3	-0.89	153.3	122.0	112.2
		---		---		
		---		---		
26:55	...	094.9	-0.90	153.3	121.7	112.3
27:10	...	101.4	-0.67	154.0	121.7	112.3
27:25	...	105.4	-0.57	153.7	121.5	112.3
		---		---		
		---		---		
29:15	...	112.6	-0.47	149.6	119.1	111.2
29:28	...	115.2	-0.10	143.0	118.4	110.7
29:43	CE	115.8	-0.04	147.4	110.1	110.7
16:20	MAX	135.9				
18:11	MIN	135.4				

Drying pulses 05
CYCLE END 19/11/02 10:17

STERILIZATION: POSITIVE

OPERATOR

EXTENDED REPORT
REQUESTED BY THE OPERATOR

Note: The electronic control system monitors the various phases, while checking that the various parameters are respected. If any type of anomaly is encountered during the cycle, the program is immediately interrupted, an alarm sounds and a code is displayed along with a message explaining the nature of the problem.

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