

External Q&A

Belimed Steam Sterilization Cycle for Contingency Reprocessing of 3M® N95 Respirators

3M has confirmed the material compatibility of specific N95 respirators one time using a special cycle in Belimed Steam Sterilizers. Below is a list of questions and answers designed to assist healthcare providers in implementing this process. Please reference the healthcare personnel/facilities protocol for specific instructions.

General Questions

Q: Where can I find more information about BELIMED Infection Prevention solutions?

A: Visit BELIMED.com and the “Coronavirus Update” landing page for additional information.

Q: Was functional testing completed to support the use of the cycle to decontaminate compatible 3M® respirators?

A: Yes. The respirator manufacturer - 3M completed testing on respirator performance and confirmed up to one (1) time reprocessing using BELIMED MASK 250 cycle does not have a detrimental impact on respirator fit or filtration performance.

Q: What is 3M’s stance on the use of the BELIMED MASK 250 cycle to decontaminate compatible 3M® N95 respirators?

A: BELIMED worked with 3M as we developed the protocol to provide respirator decontamination solutions to healthcare professionals. 3M has evaluated the performance of these respirators after processing and has approved the compatibility.

Q: Did the OEM approve use of the BELIMED MASK 250 cycle in BELIMED MSTV and MSTH Steam Sterilizers for reprocessing compatible 3M® respirators?

A: 3M has confirmed BELIMED MASK 250 cycle for use in decontamination of compatible 3M® N95 respirators. See 3M’s latest Technical Bulletin.

Q: Do I need to write separate policies and procedures for the BELIMED MASK 250 cycle?

A: Healthcare facilities should determine if separate policies and procedures are required. Recommended procedures are included in the document “Instructions for Healthcare facilities” available on the “Coronavirus Update” landing page of Belimed website.

Q: Are there Instructions available for the BELIMED MASK 250 cycle?

A: Yes. The document “Instructions for Healthcare personnel” is available on the Belimed website “Coronavirus Update” landing page and identifies how to load the chamber in order to successfully reprocess the compatible 3M® N95 respirators.

Q: Why are only certain respirators and steam sterilizer models included in the protocol?

A: Not all types of respirators are compatible with the conditions of a 250°F/121°C, 20 min steam cycle. Cup-shaped respirators are generally not compatible. The compatibility was tested and confirmed for the following 3M® flat-folded respirator models 1804, 1804S, 1805, 1805S, 1862+, 1863+, 1870+, 9205+, 9210+, 9320 + and 9330+ NIOSH-approved N95 respirators in the Belimed Steam Sterilizers – MSTV and MSTH.

Q: Which BELIMED steam sterilizers can be used to decontaminate compatible 3M® N95 respirators?

A: All Belimed Steam Sterilizers – MSTV and MSTH can be used to decontaminate compatible 3M® respirators. Only the BELIMED MASK 250 cycle is to be used. Other cycles on the steam sterilizers will damage the respirator.

BELIMED MASK 250 Cycle Questions

Q: Do I need to modify or change anything to an existing BELIMED Steam Sterilizer?

A: Yes. BELIMED service personnel are required to install the new cycle – MASK 250 cycle in the Belimed Steam Sterilizers.

Contact your local BELIMED- Service Support with the serial number of the Belimed Steam Sterilizer – MSTV or MSTH.

Q: Can I include instruments and other steam items when running the BELIMED MASK 250 cycle?

A: No.

Q: How are the compatible 3M® N95 respirators cleaned before I place them in the steam sterilizer?

A: The respirators do not need to be cleaned prior to putting them into the sterilizer. Any damaged or visibly soiled respirators should be discarded.

Q: How is the compatible 3M® N95 respirator prepared prior to putting into the steam sterilizer?

A: The individually marked respirator is packaged in a high temperature pouch and sealed prior to initiating the cycle. Any 7.5"x13" High Temperature pouch FDA cleared for steam sterilization would be suitable. Pouches may also be marked with a sharpie or ink marker for traceability.

Q: Are there other pouch sizes I can use to package the compatible 3M® N95 respirator?

A: Yes. The minimum size pouch is 7.5"x13", but larger pouches can be used. Respirators should only be packaged one per pouch regardless of pouch size. Using a larger pouch may reduce the number of respirators that can be processed in each cycle.

Q: Does the steam sterilizer require daily qualification testing?

A: Yes. Continue to do normal daily qualification testing on your steam sterilizers.

Q: Does a biological indicator need to be used within the BELIMED MASK 250 cycle for release of the compatible 3M® N95 respirators?

A: The use of a biological indicator is not required for the release of reprocessed respirators in the BELIMED MASK 250 cycle. The healthcare facility should maintain their documented processes for biological monitoring of the steam sterilizer.

Q: Do I need to use a Chemical Indicator (CI) when decontaminating the compatible 3M® N95 respirators in the BELIMED MASK 250 cycle?

A: No. The use of chemical indicator is not required for the release of reprocessed respirators in the BELIMED MASK 250 cycle. The healthcare facility should maintain their documented processes for monitoring of the steam sterilizer.

Q: What are the required parameters in the steam sterilizer using the BELIMED MASK 250 cycle process?

A: Once a BELIMED service technician installs the MASK 250 cycle, it will use the following parameters:

After a prevacuum phase the masks will be treated with 250°F/121°C (plateau temperature) at saturated steam conditions for 20 minutes (plateau time). These conditions are adequate for a sterilization of clean medical devices according to international standards. Since the respirators cannot be cleaned before the treatment, they are considered decontaminated and not sterile.

Q: Are there limitations on how many compatible 3M® N95 respirators can go in each cycle?

A: Yes. The chart below outlines the maximum number of masks per cycle given the model and size of the steam sterilizer. Respirators should not be stacked for decontamination.

Sterilizer Type/Model	Number of Trays	Number of Respirators
MSTV: 606	6 trays	72 respirators
MSTV: 609	9 trays	108 respirators
MSTV: 6012	12 trays	144 respirators
MSTH: 9612	16 trays	192 respirators
MSTH: 9615	20 trays	240 respirators
MSTH: 9618	24 trays	288 respirators

Q: Can the compatible 3M® N95 respirators be stacked in their pouches when placed in the steam sterilizer?

A: No. In order to achieve appropriate penetration of steam in the cycle, the respirators cannot be stacked on top of each other.

Q: Can the compatible 3M® N95 respirators be stored in the pouch after processing?

A: Yes. The respirators can be stored in the pouch after processing.

Q: Should the compatible 3M® N95 respirators be decontaminated in the BELIMED MASK 250 cycle after each use?

A: Each respirator can be processed only up to 1 time after use. The facility needs to follow the instructions provided on our “Coronavirus Update” landing page to identify whether the respirator has been processed and then discard the same.

Q: Do I need to reuse my same (per individual) respirator?

A: The BELIMED MASK 250 cycle in Belimed Steam Sterilizers has very high microbicidal efficacy on compatible 3M® N95 respirators. Nevertheless, because of the impossibility to clean respirators, it is strongly recommended to maintain a single-user approach and chain of custody on the respirator to minimize the risk of cross-contamination.

Q: Can I use the BELIMED protocol for decontaminating compatible 3M® N95 respirators in non-BELIMED Steam Sterilizers (e.g. Getinge® or Steris®)?

A: No. The protocol developed by BELIMED and validated by 3M is applicable only to Belimed Steam Sterilizers. Customers should refer to other manufacturers’ EUAs and/or protocols for processing N95 respirators in other equipment.