trophon®

trophon® efficacy testing to European requirements

nanosonics
Infection Prevention. For Life.

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The trophon devices perform high-level disinfection of ultrasound probes in an automated cycle. The trophon device's closed and automated system uses ultrasonic vibrations and heat to convert high concentration (35%) hydrogen peroxide into mist particles. After disinfection, residual hydrogen peroxide is blown out of the chamber and passes through destructors, where it is broken down into environmentally friendly oxygen and water.

The trophon device has been tested according to the EN 14885:2018 standards for instrument disinfection in the medical area required for CE marking (referred to as 'Phase' tests throughout this document). Additional suspension and carrier tests have been performed beyond mandatory. EN testing for CE marking, and a selection of these are also shown in the tables that follow.

Efficacy testing overview

The tables summarise trophon device efficacy testing organised according to microorganism class (bactericidal, virucidal, fungicidal, mycobactericidal, sporicidal efficacy). Each class is broken down into two tables. The first table lists testing in NanoNebulant® disinfectant used by the trophon device, and the second table lists testing in the trophon device. The last column in the tables specify the type of test which are described in more detail below.

Suspension Tests

Phase 1 and Phase 2 Step 1

Suspension tests have been conducted on the trophon NanoNebulant disinfectant used by trophon according to Phase 1 and Phase 2, Step 1 EN standards. A selection of suspension tests with trophon NanoNebulant disinfectant are shown in the tables in this document.

Carrier Tests

Phase 2 Step 2

Carrier tests were performed by soaking carriers in trophon NanoNebulant disinfectant according to Phase 2, Step 2 EN standards. A carrier is a hard surface upon which microorganisms are seeded for disinfectant testing.

Modified carrier test in trophon device

In consultation with the notified body, TÜV Rheinland, Nanosonics has performed modified carrier tests to represent real-world use of the trophon device. Carriers were prepared according to the specified EN standard (or other standard) and suspended on a frame in the trophon device where they were tested under worst-case conditions. Time taken for the distribution of hydrogen peroxide mist onto the probe surface is 2 minutes.

Simulated-Use Tests

Simulated-use tests also go beyond the usual EN carrier testing methodology requirements and demonstrate the trophon device can high-level disinfect ultrasound probes that have been inoculated with the most resistant species of mycobacterium. All simulated-use tests were performed against *Mycobacterium terrae* according to ASTM E1837 – "Standard Test Method to Determine Efficacy of Disinfection Processes for Reusable Medical Devices (Simulated Use Test)". All tests were performed in the trophon device under worst-case conditions, and meet both FDA and ISO-15883-4 requirements.

trophon device bactericidal efficacy

Table 1.1 Testing according to EN standards in NanoNebulant. All organisms were tested with 60 minutes contact time as required by the specified standard. Shortest contact times tested shown below.

Bacteria	Shortest contact time tested (min)	Acceptance criteria (Log_{10} reduction)	Log_{10} reduction (Pass/Fail)	Meets	Phase
Staphylococcus aureus ATCC 6538	3	≥ 5	> 6 (Pass)	EN 13727 2012	Phase 2, Step 1 (Suspension test)
Enterococcus hirae ATCC 10541	3	≥ 5	> 6 (Pass)		
Pseudomonas aeruginosa ATCC 15442	3	≥ 5	> 6 (Pass)		
Staphylococcus aureus ATCC 6538	3	≥ 5	> 5 (Pass)	EN 14561 2006	Phase 2, Step 2 (Carrier test)
Enterococcus hirae ATCC 10541	3	≥ 5	> 5 (Pass)		
Pseudomonas aeruginosa ATCC 15442	3	≥ 5	> 5 (Pass)		

ATCC: American Type Culture Collection.

Table 1.2 Additional bactericidal testing in the trophon device. Carriers were tested in the trophon device under worst-case conditions. Time taken for the distribution of hydrogen peroxide mist onto the carrier surface is 2 minutes.

Bacteria	Acceptance criteria (Log_{10} reduction)	Log_{10} reduction (Pass/Fail)	Meets	Modification
Staphylococcus aureus ATCC 6538	≥ 5	> 6 (Pass)	EN14561 2006 (Modified)	Carrier test in trophon device
Staphylococcus aureus CIP 4.83	≥ 5	> 6 (Pass)		
Pseudomonas aeruginosa ATCC 15442	≥ 5	> 6 (Pass)		
Enterococcus hirae ATCC 10541	≥ 5	> 6 (Pass)		
Methicillin resistant *Staphylococcus aureus* (MRSA) ATCC 43300	≥ 5	> 6 (Pass)		
Methicillin resistant *Staphylococcus aureus* (MRSA) ATCC 29247	≥ 5	> 6 (Pass)		
Methicillin resistant *Staphylococcus aureus* (MRSA – clinical isolate)	≥ 5	> 6 (Pass)		
Vancomycin-resistant enterococci ATCC 51299	≥5	> 6 (Pass)		
Chlamydia trachomatis (Serotype K) ATCC VR-887 strain UW-31/Cx	≥4	> 4 (Pass)	ASTM-E1053 2011 (Modified)	Carrier test in trophon device
Carbapenem resistant *Escherichia coli* CDC 81371	≤ 2 positives (growth) carriers out of 60 tested	No growth (Pass)	AOAC 991.47 1998 (Modified)	Carrier test in trophon device
Neisseria gonorrhoeae ATCC 43069	≤ 2 positives (growth) carriers out of 60 tested	No growth (Pass)		

ATCC: American Type Culture Collection.
CIP: Institut Pasteur Collection.
AOAC: Association of Official Analytical Chemists (an international standards organisation).
ASTM: American Society for Testing and Materials (an international standards organisation).

trophon device virucidal efficacy

Table 2.1 Testing according to EN standards in NanoNebulant. EN standards previously did not include a Phase 2, Step 2 test for virucidal efficacy at the time of CE marking. For testing to EN standards organisms were tested with 60 minutes contact time as required by the specified standard. Shortest contact times tested shown below. Table includes the German Society for Control of Viral Diseases (DVV) testing, required to make virucidal claims in Germany.

Viruses	Shortest contact time tested (min)	Acceptance criteria (Log_{10} reduction)	Log_{10} reduction (Pass/Fail)	Meets	Phase
Adenovirus type 5 strain adenoid 75 ATCC VR-5	1	≥ 4	> 4 (Pass)	EN 14476 2013	Phase 2, Step 1 (Suspension test)
Poliovirus type 1 LSc-2ab	1	≥ 4	> 4 (Pass)		
Murine norovirus Berlin 06/06/DE isolate S99	1	≥ 4	> 4 (Pass)		
Vaccinia virus Elstree strain	30 sec	≥ 4	> 4 (Pass)	DVV 2008	Required for virucidal claims in Germany (Suspension test)
Poliovirus type 1 LSc-2ab	30 sec	≥ 4	> 5 (Pass)		
Adenovirus type 5 strain adenoid 75 ATCC VR-5	30 sec	≥ 4	> 4 (Pass)		
Simian polyomavirus strain 40 (SV40)	30 sec	≥ 4	> 4 (Pass)		
Adenovirus type 5 strain adenoid 75 ATCC VR-5	3	≥ 4	> 3* (Pass)	DVV 2012	Required for virucidal claims in Germany (Carrier test)
Murine norovirus Berlin strain 06/06/DE Isolate S99	5	≥ 4	> 3* (Pass)		
Murine parvovirus (MVM) ATCC VR-1346	3	≥ 4	> 4 (Pass)		

ATCC: American Type Culture Collection.
DVV: German Society for Control of Viral Diseases.
*When cytotoxicity is evident > 3-log reduction in titer must be demonstrated beyond the cytotoxic level, as shown in the table (cytotoxicity > 2).

Table 2.2 Additional virucidal testing in the trophon device. Carriers were tested in a trophon device under worst-case conditions. Time taken for the distribution of hydrogen peroxide mist onto the carrier surface is 2 minutes.

Viruses	Acceptance criteria (Log_{10} reduction)	Log_{10} reduction (Pass/Fail)	Meets	Modification
Adenovirus type 5 strain adenoid	≥ 4	> 4 (Pass)	DVV 2012 (Modified)	Carrier test in trophon device
Murine norovirus, isolate S99	≥ 4	> 4 (Pass)		
Murine parvovirus (MVM) ATCC VR-1346	≥ 4	> 4 (Pass)		
Feline calicivirus (norovirus surrogate)	≥ 4	> 6 (Pass)	ASTM E1053-2011 (Modified)	Carrier test in trophon device
Polio Virus Type 1 ATCC LSc-2ab	≥ 4	> 4 (Pass)		
Herpes Simplex Virus Type 1 ATCC VR-733	≥ 4	> 5 (Pass)		
Hepatitis A Virus ATCC CRL-1688	≥ 4	> 4 (Pass)		
Human Immunodeficiency Virus Type 1 HTLV-IIIB	≥ 4	> 3* (Pass)		
Bovine Viral Diarrhea virus Oregon C24v-genotype 1	≥ 4	> 4 (Pass)		
Duck Hepatitis B virus (surrogate virus for Human Hepatitis B virus)	≥ 4	> 5 (Pass)		
Human papillomavirus HPV16	≥ 4	> 6 (Pass)		
Human papillomavirus HPV18	≥ 4	> 5 (Pass)		

*When cytotoxicity is evident > 3-log reduction in titer must be demonstrated beyond the cytotoxic level, as shown in the table (cytotoxicity > 2).
DVV: German Society for Control of Viral Diseases.
ASTM: American Society for Testing and Materials (an international standards organisation).
ATCC: American Type Culture Collection.

trophon device fungicidal efficacy

Table 3.1 Testing according to EN standards in NanoNebulant. All organisms were tested with 60 minutes contact time as required by the specified standard. Shortest contact times tested shown below.

Fungi	Shortest contact time tested (min)	Acceptance criteria (Log_{10} reduction)	Log_{10} reduction (Pass/Fail)	Meets	Phase
Candida albicans ATCC 10231	3	≥ 4	> 5 (Pass)	EN 13624 2013	Phase 2, Step 1 (Suspension test)
Aspergillus brasiliensis (niger) ATCC 16404	3	≥ 4	> 5 (Pass)		
Candida albicans ATCC 10231	3	≥ 4	> 6 (Pass)	EN 14562 2006	Phase 2, Step 2 (Carrier test)
Aspergillus brasiliensis (niger) ATCC 16404	3	≥ 4	> 5 (Pass)		

ATCC: American Type Culture Collection.

Table 3.2 Additional fungicidal testing in the trophon device. Carriers were tested in a trophon device under worst-case conditions. Time taken for the distribution of hydrogen peroxide mist onto the carrier surface is 2 minutes.

Fungi	Shortest contact time tested (min)	Log_{10} reduction (Pass/Fail)	Meets	Modification Phase
Candida albicans ATCC 10231	≥ 4	> 5 (Pass)	EN14562 2006 (Modified)	Carrier test in trophon device
Aspergillus brasiliensis (niger) ATCC 16404	≥ 4	> 5 (Pass)		

ATCC: American Type Culture Collection.

trophon mycobactericidal efficacy

Table 4.1 Testing according to EN standards in NanoNebulant. Organisms were tested with 60 minutes contact time or 5 minutes contact time as required by the specified standard. Shortest contact times tested shown below.

Mycobacteria	Shortest contact time tested (min)	Acceptance criteria (Log_{10} reduction)	Log_{10} reduction (Pass/Fail)	Meets	Phase
Mycobacterium terrae ATCC 15775	60	≥ 4	> 6 (Pass)	EN 14348 2005	Phase 2, Step 1 (Suspension test)
Mycobacterium avium ATCC 15769	60	≥ 4	> 6 (Pass)		
Mycobacterium terrae ATCC 15755	5	≥ 4	> 4 (Pass)	EN 14563 2008	Phase 2, Step 2 (Carrier test)
Mycobacterium avium ATCC 15769	5	≥ 4	> 4 (Pass)		

ATCC: American Type Culture Collection.

Table 4.2 Additional mycobactericidal testing in the trophon device. Carriers were tested in a trophon device under worst-case conditions. Time taken for the distribution of hydrogen peroxide mist onto the carrier surface is 2 minutes.

Mycobacteria	Acceptance criteria (Log_{10} reduction)	Log_{10} reduction (Pass/Fail)	Meets	Modification
Mycobacterium avium ATCC 15769	≥ 4	> 6 (Pass)	EN14563 2008 (Modified)	Carrier test in trophon device
Mycobacterium terrae ATCC 15775	≥ 4	> 6 (Pass)		
Mycobacterium terrae CIP 104321	≥ 4	> 5 (Pass)		

ATCC: American Type Culture Collection.
CIP: Institut Pasteur Collection.

trophon device sporicidal efficacy

Table 5.1 Testing according to EN standards in NanoNebulant. All organisms were tested with 60 minutes contact time as required by the specified standard. EN standards did not previously include a Phase 2, Step 1 or Phase 2, Step 2 test for sporicidal efficacy at the time of CE marking. However, sporicidal testing was performed in the trophon device which better represents real-world use (see Table 5.2, EN 14561 standard).

Bacterial endospores	Shortest contact time tested (min)	Acceptance criteria (Log_{10} reduction)	Log_{10} reduction (Pass/Fail)	Meets	Phase
Bacillus cereus ATCC 12826	60	≥ 4	>6 (Pass)	EN 14347 2005	Phase 1 (Suspension test)
Bacillus subtilis subsp. spizizenii ATCC 6633	60	≥ 4	> 6 (Pass)		

ATCC: American Type Culture Collection.

Table 5.2 Additional sporicidal testing in the trophon device. Carriers were tested in a trophon device under worst-case conditions. Time taken for the distribution of hydrogen peroxide mist onto the carrier surface is 2 minutes.

Bacterial endospores	Acceptance criteria (Log_{10} reduction)	Log_{10} reduction (Pass/Fail)	Meets	Modification
Bacillus cereus ATCC 12826	≥ 4	> 6 (Pass)	EN 14561 2006 (Modified)	Carrier test in trophon device
Bacillus subtilis subsp. spizizenii ATCC 6633	≥ 4	> 6 (Pass)		
Geobacillus stearothermophilus ATCC 7953	≥ 4	> 6 (Pass)		
Clostridium difficile ATCC 43593	≥ 4	> 4 (Pass)	EN 17126 (Modified)	Carrier test in trophon device
Clostridium sporogenes ATCC 3584	Kill all test spores on all carriers	No growth in any tubes	AOAC 966.04 (carrier: suture loops & porcelain penicylinders)	Carrier test in trophon device

ATCC: American Type Culture Collection.
CIP: Institut Pasteur Collection.

trophon device simulated-use testing

Table 6: Simulated-use tests in the trophon device. Simulated-use testing was also performed on ultrasound probes against *M. terrae* according to ASTM E1837, in the trophon device under worst-case conditions. Below is a selection of transducer types tested. Time taken for the distribution of hydrogen peroxide mist onto the probe surface is 2 minutes.

Transducer Manufacturer	Transducer Model Type	Acceptance criteria (Log_{10} reduction)	Log_{10} reduction	Meets
Manufacturer A	Endocavitary	≥6	> 6 (Pass)	ASTM E1837-96 (2007)
Manufacturer B	Convex	≥6	> 6 (Pass)	
Manufacturer C	Endocavitary	≥6	> 6 (Pass)	
Manufacturer D	Endocavitary	≥6	> 6 (Pass)	
Manufacturer E	Endocavitary	≥6	> 6 (Pass)	
Manufacturer F	Linear array	≥6	> 7 (Pass)	
Manufacturer F	Curved array	≥6	> 6 (Pass)	
Manufacturer G	Convex	≥6	> 7 (Pass)	

Nanosonics are the global leaders in ultrasound probe reprocessing, with over 34,000 trophon devices operating across thousands of hospitals in 30+ countries - protecting 27 million patients each year[1].

Contact a Nanosonics representative to discuss how trophon devices may be applicable to the different scenarios and workflows at your facility.

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Reference: 1. As of December 2024. Figures from Nanosonics Annual Report. *Nanosonics' industry-leading compatibility program delivers rigorous compatibility testing, with over 1300 probes from 28 original equipment manufacturers (OEMs) approved and endorsed for trophon devices.