April 9, 2012

Re: STATIMs for Medical and Dental Instrument Loads

Dear SciCan Customer,

The Statim Cassette Autoclave is sold in over 90 countries around the world and meets and usually exceeds the requirements of many national and local standards.

One such standard is the EN13060:2004+A2 2010, adopted by the CEN National Members: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom. It is the responsibility of the CEN National Members to implement European Standards as national standards.

The Statim S autoclaves have been designed and tested to provide some of the quickest sterilization times on the market and meet or exceed the requirements set forth in EN13060:2004+A2 2010. The STATIM models 2000S and 5000S are in full compliance with this European standard as well as many other local guidelines.

EN13060

EN13060 is the European Standard for small steam sterilizers, i.e. steam sterilizers whose chamber volume does not exceed 60 litres. As a long-standing, active member of the working group responsible for this standard, SciCan is intimately familiar with the requirements of EN13060+A2 2010 and has designed the STATIMs 2000S and 5000S to meet these requirements.

This European Standard specifies the performance requirements and test methods for small steam sterilizers and sterilization cycles which are used for medical and dental purposes or for materials that are likely to come into contact with blood or body fluids. This Standard is intended for sterilizer manufacturers and is also used and referenced by many non-European health/regulatory authorities and sterilizer users.

At the heart of this Standard is the definition of the types of approved cycles: B, S, and N, as is defined in the beginning of EN13060:

B cycle – The sterilization of all wrapped or non-wrapped solid, hollow load products type A and porous products as represented by the test loads in the standard

S cycle – The sterilization of products as specified by the manufacturer of the sterilizer

N cycle – The sterilization of non-wrapped solid products.

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The STATIMs 2000S and 5000S perform S cycles as defined by EN13060: this means that they are capable of sterilizing products which have been tested and specified by SciCan as the manufacturer. In accordance with EN13060:2004+A2 2010 Section 7.1, STATIM sterilizers are tested on a microbiological basis and have proven to consistently achieve a sterility assurance level of 10^{-6} (or a 6-log reduction in microorganisms) for a variety of loads (solid, hollow, hinged, etc.). Furthermore, as required by Section 7.2 and 7.3, STATIMs 2000S and 5000S have passed Type testing, and each unit shipped has successfully undergone Works testing (the results of the Works test are provided with each unit). The continued high performance of the STATIMs 2000S and 5000S can be verified on a routine basis by using the SciCan PCD also provided with each unit.

STATIM units have been designed, optimized and tested to rapidly sterilize solid loads, and hollow loads, such as Phaco handpieces and dental handpieces, and there is ample microbiological test data to prove it (see below). Although they are not designed to sterilize porous loads, i.e. products which can absorb fluids, the STATIMs do pass the Bowie-Dick test

MICROBIOLOGICAL TESTING

Because STATIMs are S-cycle machines, they are very likely the sterilizers that have the most microbiological test data to prove their efficacy in destroying microorganisms, especially in medical and dental environments, while other autoclave manufactures rely on EN867-5:2001 approved PCDs (process challenge device) to claim load processing. STATIM users can therefore have the utmost assurance in the sterilization efficacy of the STATIMs. They have been microbiologically tested and proven to successfully and effectively sterilize a variety of instruments.

A PCD is a mechanical device which simulates the worst case of conditions for attainment of the specified sterilization conditions within the items to be sterilized as defined by EN867-5:2001, definition 3.2. The device is constructed so that a biological or non-biological indicator system can be placed within the device in the position which it is most difficult for the sterilizing agent to reach. The design of the process challenge device depends on the nature of the goods to be sterilized and the sterilization procedure.

The performance of the StatimS autoclaves have been validated via microbiological testing, conducted by well respected researcher and leader in the field of infection control, Dr. Chris Miller PhD, former Director of Infection Control Research & Services at Indiana University USA and his successor Dr. Charles Palenik, MS, PhD, MBA. Their research focuses on infection control, primarily in the development of testing procedures to provide validation of devices and chemicals designed to control the spread of infectious agents. Their efforts concentrated on the development of special methodologies that can measure microbial killing that occurs when performing a particular infection control procedure. Their testing (see attached) concluded the STATIMs can successfully sterilize a wide range of instruments such as:

- B&L Ophthalmology instruments
- Rudolf Medizintechnik GmbH Endoscope accessories

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- Alcon Ophthalmic Phaco handpiece
- Miltex Medical Instruments
- Becton Dickinson 30 gauge needles
- Medical Workshop forceps
- Variety of Dental handpieces

To regularly validate the STATIMs and ensure they continue to attain the specified sterilization conditions, the STATIM Process Challenge Device (PCD) has been designed in order to demonstrate that the sterilization parameters required and validated during microbiological testing have indeed been obtained. This device tests the unit and ensures that the mechanical components and software controls are functioning correctly and match those of the units tested during microbiological testing.

HYGCEN EN13060 CERTIFIED

To further confirm and certify that STATIMs meet the EN13060 standard, testing was performed by an independent 3rd party laboratory where they performed rigorous testing on the autoclave, as the attached certified report will indicate.

- Dynamic pressure testing of the chamber
- Empty chamber
- Massive load single wrapped
- Drying massive load single wrapped
- Hollow load
- BD test
- Additional testing / bio-indicator

FACTS

The STATIMs 2000S and 5000S are the sterilizers of choice for the medical/dental office because:

- EN 13060 does not require, or even recommend for that matter, the use of a B cycle for lumened instruments or handpieces. The use of an S cycle is perfectly appropriate.
- EN 13060 stated that a B cycle is appropriate for products as represented by the test loads in the standard. The equivalency of the Helix PCD (the test load used for hollow loads of type A) to a real device with intricate inner features, such as a handpiece, has

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never been established. By comparison, STATIM has been repeatedly proven with actual devices such as real handpieces.

- SciCan is member of the EN 13060 working group, and there is no plan in the near or distant future to remove S cycles from the EN 13060 standard - especially now that other European manufactures have (re)-launched their own S cycle autoclaves.
  Almost all B cycle sterilizer manufacturers also offer S and N cycles : there are other autoclaves on the market today that are sold as unwrapped/wrapped dental hand piece autoclaves yet they do not offer a B cycle, only an S cycle. The STATIM is and will remain a strong, viable and compliant option for many years.
- The terminology of “Flash sterilization” has recently be changed to “immediate use steam sterilization”, which generally refers to the reprocessing of unwrapped loads. STATIM has been validated for both unwrapped and wrapped loads.
- SciCan has numerous microbiological tests with dental instruments and handpieces, wrapped and unwrapped, more than any other sterilizer manufacturer. Our proof of efficacy is based on real devices, not a proxy test device like the Helix PCD which is used by B cycle sterilizer manufacturers.
- STATIM is fully compliant with EN 13060. Confirmed by third party testing.
- All STATIM models have been validated to effectively dry wrapped loads if 3 simple rules are followed:
  - install the STATIM as per their instructions
  - arrange wrapped loads as indicated in the user manual and without overloading
  - regularly apply STAT-DRI as indicated in the user manual

PERFORMANCE

The STATIMs 2000S and 5000S are the sterilizers of choice for the medical/dental office because:

- They are the fastest autoclaves from start to sterile
- They are versatile: they can efficiently reprocess both unwrapped and wrapped loads
- They have the most extensive microbiological testing of medical and dental instruments and handpieces, the ultimate validation of effective sterilization
- They are built on a proven, reliable technology
- They are intuitive and very easy to operate and maintain
- They offer a small footprint and an increased working surface compared to chamber autoclaves

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In summary, the STATIMs 2000S and 5000S are ideally positioned for use in sterilization in the dental office because they are the fastest on the market, comply with the applicable standards and guidelines, and have been validated using the ultimate proof, i.e. microbiological testing on the widest range of actual, typical instruments used in the dental environment.

SciCan is committed to ensure their autoclaves meet the highest standards of manufacturing and approved for use in every country around the world. We take pride in our products and in knowing the ever changing global requirements in every region of the world

Thank you again for your interest in SciCan products and we look forward to servicing your sterilization needs now and in the future.

We hope that this letter provides you with the information that you require to have full assurance that the StatimS Cassette Autoclaves meet and/or exceed the EN13060 requirements.

Should you require further information, please contact us at any time.

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