A Preliminary Evaluation of a Reusable Digital Sterilization Indicator Prototype

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ABSTRACT

Background: Sterilization of critical and semicritical instruments used in patient care must undergo a terminal process of sterilization. Use of chemical and physical indicators are important in providing information on the sterilizer's performance during each cycle. Regular and periodic monitoring of sterilizers using biological indictors is necessary in periodically validating performance of sterilizers. Data loggers or independent digital parametric indicators are innovative devices that provide more information than various classes chemical indicators. In this study we evaluated a prototype of an independent digital parametric indicator's use in autoclaves.

Aim: The purpose of this study was to evaluate the performance of an independent digital indictor/data logger prototype (DS1922F) that could be used for multiple cycles within an autoclave.MG

Materials and methods: Three batches of the DS1922F (150 samples) were used in this study that was conducted in a series. The first batch was challenged with 300 sterilization cycles within an autoclave and the data loggers evaluated to study failures and the reason for failure, make corrections and improve the prototype design. After changes made based on studying the first batch, the second batch of the prototype (150 samples) were challenged once again with 300 sterilization cycles within an autoclave and failure studied again in further improvement of the prototype. The final batch (3rd batch) of the prototype (150 samples) was challenged again but with 600 cycles to see how long they would last. Kaplan-Meier survival analysis analyses of all three batches was conducted (α = 0.05) and failed samples qualitatively studied in understanding the variables involved in the failure of the prototype, and in improving quality.

Results: Each tested batch provided crucial information on device failure and helped in improvement of the prototype. Mean lifetime survival of the final batch (Batch 3) of prototype was 498 (480, 516) sterilization cycles in an autoclave.

Conclusion: In this study, the final batch of the DS1922F prototype data logger was found to be robust in withstanding the challenge of 600 autoclave cycles, with a mean lifetime of more than 450 cycles, multiple times more than prescribed number of cycles.

Clinical significance: Instrument reprocessing is among the important aspects of infection control. While stringent procedures are followed in instrument reprocessing within the clinic in assuring patient safety, regular use of sterilization process indicators and periodic biological validation of the sterilizer's performance is necessary. Chemical indicators for use in Autoclaves provide information on whether the particular cycle's parameters were achieved but do not provide at what specific point in time or temperature the failure occurred. Data loggers and associated reader software as the tested prototype in this evaluation (DS1922F), are designed to provide continuous information on time and temperature of the prescribed cycle. Data loggers provide immediate information on the process as opposed to Biological Indicators that take from days to a week in obtaining a confirmatory result. Further, many countries do not have the sterilization monitoring service infrastructure to meet the demands of the end users. In the absence of sterilization monitoring services, use of digital data loggers for each sterilization cycle is more pragmatic.

Keywords: Sterilization indicators, Sterilization integrators, Digital data loggers, Kaplan-Meier Survival analysis.

INTRODUCTION

Sterilization is the act or process, physical or chemical that destroys or eliminates all forms of life, especially micro-organisms.[1] This definition may not reflect other mechanical forms of sterilization such as sterilization of liquids by mechanical filtration. An alternate definition states that sterilization is a process by which living organisms are killed or removed to the extent they are no longer recovered in standard culture media in which they previously have been found to proliferate.[2] This alternate definition incorporates

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both the 'process' as well as 'not detecting' microbes after culturing in suitable media resulting in a negative absolute (no growth or viable organisms). With respect to infection control, sterilization is the final process of a reprocessing cycle that attains the kill of all microbial life-forms including vegetative microorganisms, fungi, viruses and bacterial endospores. Thermal death time is the time required to kill all spores at a specified temperature during a sterilization cycle. D-value is the time required to inactivate 90% of the microbes/cells/spores (also referred to as decimal reduction time (DRT) or one-log reduction in the load). F-Value is the time in minutes to achieve complete kill of all spores at a temperature of 121ºC (250ºF). The way the D-value changes with temperature is referred to as the Z-value (slope of the logarithm measuring the interaction between D-value and time). The Q_{10} Value is a ratio measure of the inactivation rate with respect to temperature. These terms are important in understanding the science of heat sterilization, resistance of microorganisms to inactivation by heat, in validation of sterilizers and as comparisons during development of chemical indicators and integrators.

According to Spaulding's classification of surfaces,[3] adaptations thereof by Favero and Bond,[4] and current patient care standards,[5-8] any critical instrument or semi-critical instrument used in patient/animal care must be reprocessed with a terminal level process of Sterilization. Critical Instruments in the field of dentistry, medicine, veterinary medicine, body/skin art (Tattoo) are those that are used to intentionally to penetrate the skin/mucosa and do come in contact with blood and body fluids. These devices must either be sterile single-use-disposable items, or reusable items that must be cleaned and sterilized between each use. These items are considered sharps and have the highest risk with respect to disease transmission. Semi-critical instruments are those that are not used to intentionally penetrate the skin/mucosa but are at risk of coming in contact with blood or saliva (body fluids). These devices must either be sterile single-use-disposable items, or reusable items that must be cleaned and sterilized between each use, or must be non-sterile but clean and hygienically preserved/stored single-use-disposables. These items are not normally considered sharps and have the similar risks as critical instruments with respect to disease transmission. Prior to sterilization, the reusable instruments must be cleaned/sanitized to remove as much bioburden (blood, tissue and other contaminants) by either using automated washers or sonication.[5-7] Sterilization may be achieved through physical, chemical and a combination of physical and chemical methods.[9] Some of the chemical methods would be to immerse in the US Food and Drug Administration approved immersion sterilants (glutaraldehyde, peracetic acid formulations, or hydrogen peroxide formulations among others) for an extended, period of time (usually 3-8 hours).[10] Other chemical methods, such as chemiclaving utilize a mixture of chemicals along with heat and pressure in a closed chamber for a given shorter period of time (usually about 90 minutes cycle time starting from cold through the heat process and cooling down to be handled for use).[11] Common physical methods are utilization of gamma-irradiation (normally used in industrial and commercial sterile device manufacturing),[12] heat alone in a slower dry-heat sterilization process (1-2 hours cycle time at 160º C or 320º F),[13] a rapid heat transfer sterilization process that is faster than dry heat (6-12 minutes cycle time for unwrapped and wrapped instruments at 190.6ºC or 375ºF)[13,14], and Steam Sterilization[9,13,14,15] (heat, pressure, steam) also known as autoclaving. Autoclaves have four cycles—the liquid cycle, slow cycle fast cycle and a flash cycle—the slow or standard cycle being 20 to 30 minutes at 121ºC or 250º F, the fast cycle at 132ºC for 4 minutes, and the flash cycle for 3 to 10 minutes at 132ºC or 270ºF at a higher pressure. A flash sterilization cycle is used in the event of devices needing to be sterilized for immediate use during a surgical appointment. With respect to different sterilizers used throughout the world, the most common one is the gravity displacement sterilizer that displaces the air in the chamber with steam by forcing the air downwards. This helps the steam come in contact with the instrument surface, helps to eliminate nonsterilized air pockets, and is better than just heat alone in the sterilization of instruments. More advanced systems (Class B sterilizers) that either create a vacuum in the chamber or those with multiple pulsating vacuum cycles initially followed by introduction of steam are more efficient in sterilizing hollow bore instruments (hand pieces used in dentistry).[16] Dryness of sterilized instrument pouches is very important in maintenance of sterility of stored instruments.[17] The process of sterilization should be regularly monitored using chemical indicators, chemical integrators and biological indicators (BIs).

Sterilization process indicators (chemical indicators): Chemical indicators and integrators are surrogate measures that provide an immediate result of whether the sterilization cycle was successful in meeting the sterilization parameters of temperature over time. Use of these indicators and integrators should be strongly encouraged. The ANSI/AAMI/ISO 11140-1:2005 Standard defines six classes of chemical indicators (CI).[18,19] Within each of these classes there are further subdivisions based on types of sterilization processes for which they are designed to be used. The classes are not hierarchical (ordinal) but only classified based upon the features (nominal or qualitative) and characteristics of the measurements achieved by the indicator. The indicators can be used for pack control (placed inside the pack), exposure

control and/or for evaluating sterilizer performance while placed in a sterilizer for a complete cycle (Table 1).[19-21]

Class 1 indicators are indicator tapes (Fig. 1A) and embossed/imprinted Labels (Fig. 1B) that are externally visible chemical indicators for use on instrument packs respectively. The function is only to show whether the pack has been processed through a sterilization cycle or not. Before going through a sterilization cycle, the tape is clear with faint white transverse stripes (A). After sterilization, the faint white transverse stripes turn black indicating that the instruments have gone through a sterilization cycle (B) as seen in Figure 1A. Labels that are embossed on sterilization pouches that change color are depicted in Figure 1B are also examples of class 1 indicators. A class 2 indicator (Bowie Dick) is used to measure air removal (vacuum) in autoclaves that have a vacuum cycle. Figure 2A shows the Bowie-Dick type test to measure the efficacy of air removal (vacuum) autoclaves with vacuum cycles. 'A1'is the pack cover before sterilization and 'B1' after sterilization (note the color change on the covers with the yellow dot turning

Table 1: Types of chemical indicators and prescribed uses based on performance claims

Class 1: Process indicator	Indicator tapes, Labels that are externally visible chemical indicators
Class 2: In specific tests	Bowie-Dick type to measure air removal (vacuum) and efficacy in autoclaves
Class 3: Single variable	Measures one variable in a sterilization process such as temperature and whether the parametric temperature was achieved (used mainly in dry heat sterilizers)
Class 4: Multivariable	React to two or more critical variables (show that at least two sterilization parameters were achieved, such as time and temperature)
Class 5: Integrating indicators	Chemical indicator that reacts to all critical variables and efficacious/comparable to bls/spore tests
Class 6: Emulating indicators	React to all critical variables but for specific sterilization cycle temperature and time

Fig. 1A: Examples of a sterilization tape that is used on the outside of an instrument pack (class 1 Indicator)

Fig. 1B: Color change in indicator seen on the outside of sterilization pouches showing that the pack has been processed through a sterilization cycle (class 1 indictor)

Fig. 2A: Bowie Dick type test pack that is used to test air removal in autoclaves that have a vacuum cycle

Fig. 2B: Bowie Dick test pack showing the indicators inside of the challenge pack that show uniform color change (from yellow transverse stripes changing to a black)

black. This outer indicator's function is similar to the class 1 indicator). Figure 2B shows the inside of the challenge pack where the indicator (placed within a penetration challenge of multiple layers of thick paper similar to card stock) to demonstrate removal of air and transfer of heat to bring about color change. Before the sterilization process it is yellow 'A2', and after sterilization it turns black uniformly 'B2'showing success in air removal followed by penetration of steam. The Bowie Dick type indicators should be used at the beginning of each day in sterilizers that use vacuum for air removal. A class 3 indicator is a single variable indicator that only measures one parametric variable, such as temperature and only demonstrates whether the given temperature of sterilization was achieved.[22] Class 4 indicators are designed to show whether two of the parametric variables of heat sterilization such as temperature and time were achieved. The sensitivity of class 4 indicators should lie within 25% of the expected values of the parametric temperature and

time of sterilization and should show a pass or fail of the process with a color change.[22] Class 5 indicators/integrators as seen in Figures 3A and B are considered equal in function to biological indicators and react to two or more parametric variables (showing that the parameters were met within 15% of the parametric values).[22] This device has a chemical that is located in a sealed chamber 'A1' as seen in Figure 3A that shows the back of the device. After the sterilizer reaches and maintains a given temperature for a prescribed time, this chemical moves to the right 'A2'. The results of whether sterilization parameters were achieved is seen on the front side of the device (Fig. 3B) that shows the pass/fail cut off point. If the sterilization was successful then the black line crosses over the pass/fail mark. This can only happen if the temperature and time parameters were achieved and the cycle was a success, showing color change from clear 'B1' to black crossing completely to the end 'B2'. Class 6 indicators are emulating indicators that have an accuracy of within 6% to at least 2 of the sterilization parameters.[22] These emulators are among the most accurate of the surrogate devices to BIs and are used in multiple countries around the world in lieu of BIs. An example of an ISO 11140-1 class 6 emulator is depicted in Figure 3C (2014 Sci Can Sterilization Emulators (STEAM), Toronto, Ontario, Canada). The SciCan Sterilization Emulator (STEAM) is intended for use in a steam sterilizer that uses a specific sterilization cycle of 134°C 3.5 minutes.

Biological monitoring of sterilizers that use heat: All sterilizers that are used in patient care must be tested for efficacy periodically using spores. Regulations on the use of biological monitoring vary in different countries. In the USA, monitoring must be done weekly using a biological indicator (BI) that is dispensed as a spore strip (mail-out to a microbiological monitoring service/laboratory) or as

Fig. 3A: Reverse side of a class 5 indicator/integrator showing before sterilization (A1) and after sterilization (A2)

Fig. 3B: Front side of a class 5 indicator/integrator showing before sterilization (B1) and after sterilization (B2)
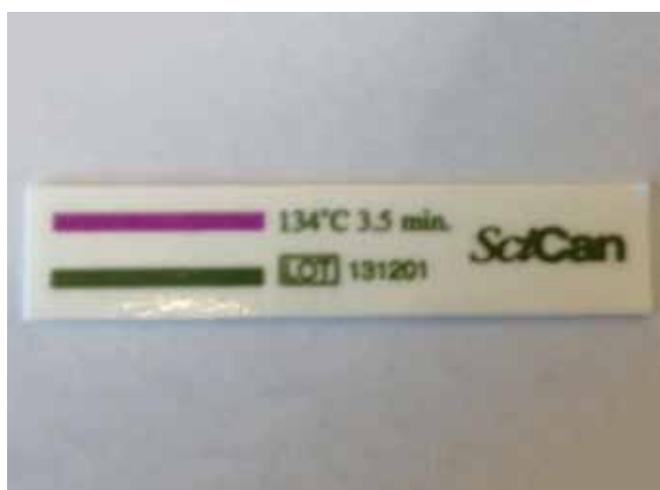
Fig. 3C: The SciCan sterilization emulator (STEAM) is intended for use in a steam sterilizer that uses a specific sterilization cycle of 134°C for 3.5 minutes (*Courtesy*: Provided by SciCan, Toronto, Ontario, Canada)

a spore ampoule (for in-office incubation); the records of the outcomes are maintained for possible audits.[5-7,15] Some countries mention periodic biological monitoring of sterilizers in their guideline without specifying how frequently,[23] and many countries that have standards[24] do not enforce the latter rigorously.[25-27] Biological monitoring of sterilizers for larger institutions that run extensive quantities of instruments has to be more rigorous with each run tested with multiple monitors, indicators and integrators. Smaller/individual clinics conduct weekly tests using spores (strips or ampule/vials). *Geobacillus subtilis* is used for testing dry heat sterilizers, and *Geobacillus stearothermophilus* (refer Figs 4A and B) is used for testing autoclaves and chemiclaves. The spore strips are run through the sterilization cycle (Fig. 4A) and mailed to sterilization monitoring service centers that process the spore strips. Results turnaround time is generally over 1 week. Alternatively, if using in-office measures (Fig. 4B) the screening results are available within the day and confirmatory result in about 3 days.[28]

While BIs, chemical indicators, integrating indicators and emulators are useful in validating a sterilization process, they are at best surrogate methods for studying the fundamental parametric values of temperature, pressure, time and in additional instances the negative pressure or vacuum in sterilization cycle. These surrogate measures only provide a Pass or Fail of a process. Data loggers, on the other hand, are useful in providing real time changes that can be visualized, but are expensive and cumbersome to use and are limited in use due to the number of leads that need to be placed within a sterilization chamber. What is required, is a multi-use self-contained data logger that measures real-time parametric values within any part of the chamber or within an instrument pack being sterilized. Further, the visual feedback of the cycle should be simple and immediate, for practical use in a clinical situation. These data loggers should have a feature of being programmed for multiple types of sterilization cycles (different sterilization parameters such as slow cycle, fast cycle or flash cycle). The software should also have visual read outs such as graphs and/or tables of the results and any parametric breach in the event of failure of the cycle or successful completion of the cycle (pass/fail). The storage of the measurements and outcomes should be protected and archived electronically either on a computer or remotely for retrieval in case of an adverse event. Once archived, the feedback must have a nonmanipulative cryptographic lock on the results including the cycle number, and a time/date stamp for each cycle. Currently, there are many table-top and wall mounted sterilizers that still use a printer for providing a sterilization cycle process feedback. If clinics utilize this feature for studying and retaining the printout, it is very cumbersome for those managing, documenting and preserving information let alone storage of these printouts. Newer table-top sterilizers[29,30] have features such as an included printer that provides parametric printout of the cycles and connectivity to data receiving devices (USB drives/computers). Even with these beneficial features these sterilizers have not been utilized effectively by the end-users. The data collection within the sterilizers with built-in data logging capacity is limited to the fixed placement of sensors that cannot be moved to other locations within the sterilizer. Furthermore, the temperature sensing functionality of these sterilizers must be calibrated periodically, and thus if used presents the operator with an additional reoccurring cost.

In this preliminary evaluation we address testing a first generation of a series of non-tethered and self-contained data loggers in measuring two parameters of sterilization (temperature and time) for autoclaves. The prototype of this first generation device (continuously measures only temperature
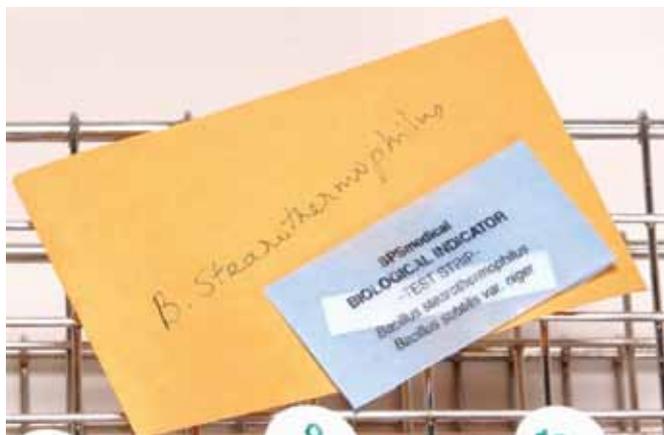
Fig. 4A: A mail-out biological indicator spore strip with *Geobacillus stearothermophilus* dispensed in a glassine envelope. After processing through a sterilization cycle, this spore strip must be mailed out to a sterilization monitoring service for processing and obtaining results

Fig. 4B: An In-Office sterilization monitoring system with ampoules containing spores that can be incubated within the clinic for confirmatory results

and time variables) has been manufactured by Maxim Integrated Inc., a semiconductor company based out of San Jose, California USA. The prototype of this device will hereafter be referred to as DS1922F (Fig. 5). The DS1922F is a small device that can be placed within a sterilization chamber for cycle logging as long as temperature parameters do not exceed 140ºC. It has the capacity to periodically measure and record two of the fundamental measurable parameters in autoclaves namely temperature and time. Once the device has gone through a sterilization cycle having been placed anywhere within the sterilizer chamber, it can be removed and placed into a reader station (Fig. 6) which in turn transfers the DS1922F data to a computer through a USB adapter (Fig. 7).

Once the data has been uploaded to the PC, the included software converts the measurements into a Graph of time and temperature, provides a result of pass or fail of the sterilization process given the specific sterilizer, and stores the data on the local PC for long-term record keeping (Fig. 8). This current interface has a user-friendly visual feedback of the results (Graph, pass-fail) and also has a cryptographi-

cally verified date and time stamp when saved. The software requires a one-time set up by the end user to accommodate the specific profiles of sterilizers and their sterilization cycles. After the one-time set up, the user may simply select from a drop-down list of profiles corresponding to the relevant autoclave when missioning the DS1922F digital device for another sterilization cycle. The DS1922F is specified to be used 150 times, after which it is programmed to be unusable. In summary, this solution can be used immediately after the cycle to determine to log/back-up cycle data locally in the event of a sterilization audit. Preservation of the data is dependent on regulations of the region. This device which is a first generation device is limited for use in autoclaves and cannot be used in dry heat sterilizers as the DS1922F's maximum temperature of exposure (upper limit) is 140ºC which is less than the operating temperature of dry heat sterilizers. The future generations or series of the data loggers are being designed to measure other additional parameters.

MATERIALS AND METHODS

The DS1922F prototype was developed, initially tested and calibrated for parametric functions (Temperature, Time). To be used in this study, the DS1922F specimens were initially tested for operational characteristics and also for battery voltage.

First Batch/Lot 1: The first batch of DS1922F prototypes consisted of 150 samples (n_1). Each sample was checked for parametric function and programmed to select for the sterilization cycle at 134ºC for 5 minutes of sterilization time. The total number of cycles run on this first batch were 300 cycles. After every cycle, the samples were removed from the sterilizer while a 25 minutes cool down period is observed. Then the samples were placed back into the autoclave additional cycling. After every 50 cycles, the DS1922F samples were read by a PC to verify that they were

Fig. 5: The DS1922F prototype data logger

Fig. 6: The DS1402 reader station with the DS1922F data logger attached for data transfer

Fig. 7: The DS9490R USB adapter that attaches to the computer
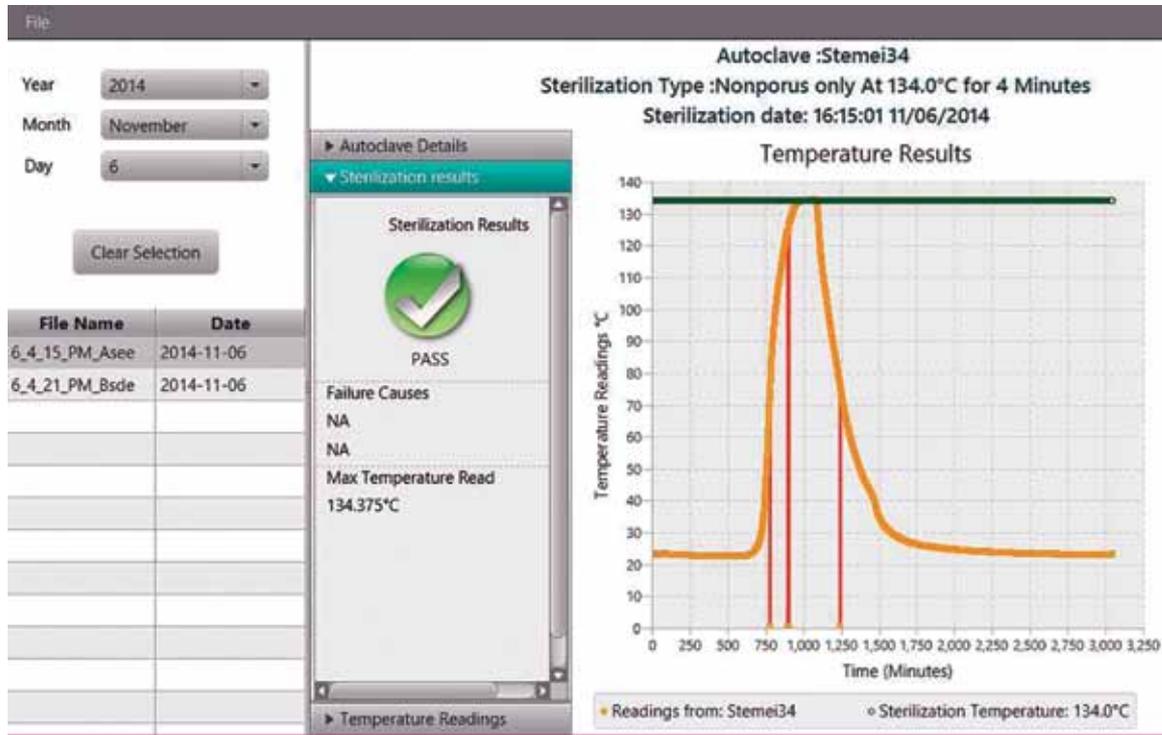
Fig. 8: Screenshot of the DS1922F software showing the results of a sterilization cycle. This software shows which sterilizer was tested, what cycle was used, and whether the cycle was successful (pass/fail). It also provides the cycle number, date and a visual graph of the cycle

still working properly. If any of the 150 DS1922F showed a failure (either could not be read by the PC or showed erratic data), it was taken out of the sample (discontinued) and further examination conducted to study the reason for failure. The remainder of the samples were processed until failure or until the 300th cycle. Failed specimens in all batches of the study were deconstructed and each component of the device examined qualitatively (visual inspection, testing for crimping of O-rings, ingress of water/moisture within the device, battery function) and simple descriptives of the data summarized with respect to the failure modes, such as failure of the battery, failure to prevent water ingress into the electronics thus rendering the DS1922F inoperable, and failure of the software to read/transfer data.

Second Batch/Lot 2: The second batch of the prototype also consisted of 150 samples of the DS1922F (n_2) and the same process of cycling and measurements were repeated as in the first batch.

Third Batch/Lot 3: The third batch of the prototype also consisted of 150 samples (n_3). This batch underwent 600 cycles of sterilization with the sameparameters as Batch 1 and 2. Apart from generating descriptive statistics, Kaplan-Meier Survival Analysis was conducted ($\alpha = 0.05$) using IBM® SPSS® Statistics Ver. 22.

RESULTS

The total number of sterilization cycles that the prototypes in both Batch/Lot 1 and Batch/Lot 2 were 300 cycles, while

the number of cycles was 600 for Batch/Lot 3. All batches of the prototype showed very little failure over the number of sterilization cycles. Referring to Graph 1 in Batch/Lot 1 (Blue Line), the failure rate initially was 0% up to the 150th cycle and reached 5.3% at the 300th cycle. The reasons for failure in this group was mainly due to dead batteries (14), moisture entry into the DS1922F (1) electronics, and Lost Programming/Memory (1). Batch/Lot 2 (Orange Line) showed 4% failure at the 50th cycle, 3% at the 100th and rose up to 11% by the 300th cycle. Most of the failures were not due to the malfunction of the semiconductor circuit but were due to the Batteries (25) that either died or malfunctioned. Some of the failures were attributed to Graphic Error (4),
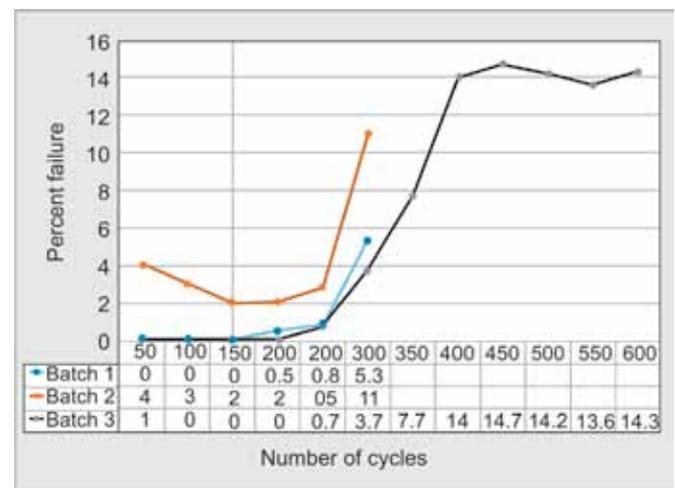
Graph 1: Percentage of failure rate *vs* sterilization cycles of the three test batches/lots left align this line

Moisture seepage into the device (3), and lost Programming/Memory. Batch/Lot 3 (Black Line) showed no failures up to the 200th cycle, with 0.7% failure at the 250th cycle, and reaching 14.7 only at the 450th cycle. Most of the failures were due to dead batteries (75), lost programming/memory (4), and 6 had moisture inside the device due to failure/debris of the moisture seals. Failure due to moisture ingress inside the device occurred in every case because of moisture seal crimping during assembly.

A more analytical approach toward studying failure in devices is the use of Kaplan-Meier (K-M) survival analysis. The K-M analysis provided the mean lifetime statistic for Table 2 as well as the plots for Charts 2 to 4. The figures show the cumulative probability of survival as a function of time/challenge (autoclave cycles). A K-M plot with nearly horizontal slope indicates a more durable product than one with a steeply decreasing slope. As the cycles/challenge was homogenous no log-rank test was performed.

Table 2 predicts lifetime statistics and the corresponding 95% confidence intervals (in parentheses) for Batches/Lots 1-3. Increasing shape factor represents less variation between specimens. Scale parameter (characteristic lifetime) indicates the number of cycles corresponding to a 63.2% probability of failure. Threshold parameter indicates the maximum number of cycles corresponding to 0% probability of failure. Kaplan-Meier survival analysis estimated a mean lifetime of 498 autoclave cycles for the average device. Some devices may fail prior to the mean lifetime (Graph 2).

DISCUSSION

The DS1922F is a self-contained electronic based parametric data collection device that is designed to monitor and record the temperature profile over time during a sterilization cycle. When placed inside an autoclave, it measures and logs temperature by recording data into the device memory. The use of this device is simple. Once the sterilization cycle is complete, the DS1922F is simply removed from the sterilization chamber and docked into a reader to download data to a computer. The software then displays the temperature measurements, indicates whether the sterilization cycle was successful, and keeps a record of the data for the desired amount of time in order to satisfy regulatory and liability requirements. The target markets for the DS1922F are those that use Autoclaves. It is likely possible to use the DS1922F with chemiclaves or pressure cooker sterilizers if temperature does not exceed 140°C, but Maxim has not performed the testing necessary to prove that the DS1922F is suitable for monitoring in these types of sterilizers. Target professions for DS1922F include, but are not limited, to patient care (Dentistry, Hospitals/Clinics), Veterinary Sciences, Body art or Tattoo Parlors, Laboratory/Life-Sciences. The customer entities could be large entities, such as hospitals or teaching institutions that run multiple large capacity cycles per day using a wall mounted sterilizer, or by individual businesses/offices that use small table-top sterilizers with smaller batches of instruments. One device per cycle should suffice for table-top sterilizers but multiple devices per cycle may be required for large-capacity sterilizers. The DS1922F can take temperature readings every second with ±1% error, providing a digital indicator on the computer screen of whether required sterilization temperature was reached for the required amount of time, and if not, when the failure occurred. Measured results are uploaded and logged onto the computer for long-term record keeping and historical proof of sterilization for each cycle. The DS1922F as an instant surrogate indictor to the biological indictor that takes 2 to 4 hours for initial results or up to 2 to 7 days for confirmatory results. The DS1922F does not require professional installation or calibration.

Table 2: Lifetime statistics for the three batches/lots of the DS1922F showing the mean lifetime of 498 cycles as seen in batch/lot 3

	Batch/lot 1	Batch/lot 2	Batch/lot 3
Number of specimens	150	150	150
Censored specimens	134	117	64
Mean lifetime	N/A	N/A	498 (480, 516) cycles
Shape parameter, β	N/A	N/A	1.45 (1.20, 1.76)
Scale parameter, η	N/A	N/A	391 (336, 456) cycles
Threshold parameter, γ	N/A	N/A	243 cycles
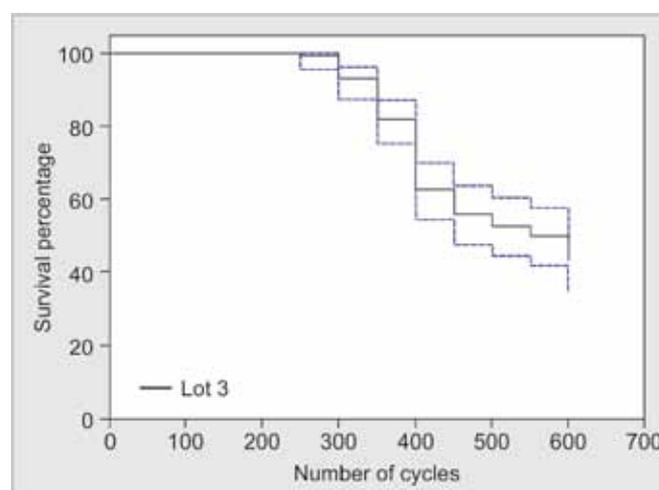
Graph 2: Kaplan-Meier survival analysis results for Batch/Lot 3 (600 cycles) 'Solid line represents the cumulative probability of survival. The dotted lines represent the 95% confidence interval of the solid line. The black dot represents right-hand censored data points'

The total number of cycles the DS1922F can be used is preprogrammed to 150 cycles after which it is cryptographically locked and cannot be used. In this study, the mean lifetime cycles for the DS1922F was more than 450 cycles which is 3 times more than its officially specified life. Furthermore, should a DS1922F fail while it is monitoring a cycle, the study has shown that the included PC software is able to alert the user and recommend that the instruments in the cycle be re-sterilized with a new DS1922F.

Today, a new and emerging field in medicine and dentistry is endosseous implants that provide sterile implants. While the implants are sterile and are not to be re-sterilized if the pack is already open, the instruments used in inserting and restoring implants that are used (such as Burs (drill bits), Hand pieces (high speed drills), torque wrenches, abutments and other accessories) need to be sterilized by the end user and the sterilization process validated immediately. The DS1922F could play a significant role in providing information on the cycle's parameters immediately and provides a safety-net without a prolonged waiting time. In many instances the implants in dentistry are placed immediately after the extraction of a tooth and in such instances, the DS1922F is invaluable. While it cannot be used in dry heat sterilizers, this device can be used for all cycles of an autoclave (liquid cycle, the slow cycle, fast cycle and the flash cycle), either by being placed within an instrument pack/cassette along with instruments, by itself in a sterilization pouch, or by itself without being placed in a sterilization pouch. Implants that are marketed as nonsterile in the medical field (endosseous implants that need to be sterilized) and the instrument pack that is used to place these implants must be sterilized. With the increase in utilization of endosseous implants it has become necessary to monitor each sterilization cycle that reprocesses instruments used in implant placement.

CONCLUSION

Instrument reprocessing including sterilization of instruments, use of chemical and physical indicators, monitoring of sterilizers and servicing of sterilizers on a regular basis is important in sterility assurance. In this preliminary study, we evaluated a prototype data logger designed to withstand the environment in an autoclave chamber and provide continuous information on two of the sterilization cycle parameters, namely temperature and time. Although, the final device may be allowed to track only 150 cycles, data from this evaluation indicated that the final series of the prototype was robust enough in withstanding the extreme challenge of heat within the sterilization chamber and lasted a mean of more than 450 lifetime cycles. The reader software and the display of the data logger's information was easy to use and provided clear graphic information on the sterilization cycle.

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