

IN-LINE STEAM STERILIZER

Related Applications

This application claims priority of a provisional application U.S. Ser. No. 60/360,904, filed on March 1, 2002 and entitled "In-Line Steam Sterilizer."

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Field of the Invention

The present invention relates generally to a contact lens manufacturing arts, and, in particular to a novel in-line sterilizer for an ophthalmic contact lens manufacturing system, sterilization tray and method for performing in-line sterilization of packaged contact lenses more efficiently and with
10 increased throughput.

Automated ophthalmic contact lens production processes are known wherein each lens is formed by sandwiching a monomer between back curve (upper) and front curve (lower) mold structure transported in a mold cavity. The monomer is polymerized (cured) to form a lens blank, and is subject to further
15 processing including, but not limited to: removing the lens blanks from their mold structures, i.e., de-molding; subjecting the lenses to a hydration process; transferring of the lenses to an individual blister package; automatic lens inspection of the lens, e.g., while contained in their blister pack; lens sterilization; and final packaging for consumer use. The reader may refer to U.S. Patent No.
20 5,555,504 entitled PRODUCTION LINE TRACKING AND QUALITY CONTROL SYSTEM for a description of an exemplary prior art ophthalmic lens production and packaging control system.

With respect to lens sterilization, a manufactured ophthalmic lens in an aqueous solution is sealed in a blister pack and sterilized in a steam sterilizer.
25 Example descriptions of packaged contact lenses and techniques for their sterilization are described in U.S. Pat Nos. 5,488,815 and 5,577,367. Particularly, in commonly-owned issued U.S. Patent No. 5,488,815, an apparatus is disclosed that contemplates the utilization of a conveyor system for the conveyance of a plurality of trays, each adapted to house therein a
30 specific quantity of interleaved pairs of arrays of blister packages, which are sequentially folded into paired interleaved positions, and then conveyed through the intermediary of a transfer conveyor into a respective metal tray so

as to fill spaces in the latter arranged in specified rows and columns. The metal tray, which is placed into an upended position in order to be able to receive the interleaved pairs of arrays of blister packages from a shuttle conveyor, upon being filled is then tilted back into a normally horizontal orientation and, if desired depending upon production requirements, up to three such array-filled metal trays may then be vertically stacked or superimposed, and also conveyed in a series of such stacked trays. A conveyor is adapted to convey the metal trays with the arrays of blister packages contained therein into a sterilizing chamber, such as an autoclave, in which the arrays of blister packages are collectively sterilized. Subsequent to the sterilization cycle having been completed, a secondary packaging procedure is implemented where the trays together with the sterilized arrays of blister packages are transported by a further conveyor towards an unloading arrangement in which the trays are unstacked and individual trays then sequentially upended. This enables the contents of the trays to be transferred to an unloading shuttle conveyor which, in turn, facilitates specified quantities of interleaved pairs of arrays of blister packages to be advanced in succession into a cartoner having open-ended cartons therein adapted to receive the arrays of blister packages.

Central to the prior art sterilization apparatuses and techniques is that the blister package array trays must be transferred from the manufacturing line to the sterilizer which is in a separate area off-line from the manufacturing stations. Thus, a major problem with that process is a potential for mixing sterile and non-sterile product at the off-line area. Other problems include extra material handling equipment, additional manufacturing floor space, and added in-process product inventory. Therefore, there has been a need, prior to the invention, to provide an in-line sterilization apparatus for a contact lens manufacturing and packaging facility that obviates the need for off-loading contact lens product for sterilization.

Additionally, these prior art lens sterilization processes provide for sterilization relatively late in the manufacturing process, prior to secondary packaging, i.e., placement of labeled lens blister packages in cartons, for

example. Given the nature of the equipment involved, i.e., the materials, the prior art equipment and ophthalmic lens sterilizing processes further do not adequately dry the packages which reduces the throughput as packages have to be rejected. This phenomenon currently prevents sterilized packages from immediately being packaged in a secondary packaging process, e.g., to cartons for shipping. In order to solve the "dryness" problem, longer sterilization process cycle times in excess of 1 hour are typically required in order to achieve the degree of dryness of the packages for secondary packaging. Therefore, there has been a need, prior to the invention, to provide an in-line sterilization apparatus for a contact lens manufacturing and packaging facility that ensures packages subject to a sterilization process meet requirements of dryness so that they may be immediately placed in cartons in a subsequent packaging step. It would be highly desirable to provide for an automated contact lens manufacturing facility, an in-line sterilization machine that sterilizes ophthalmic lens packages without having to offload product from the line.

Furthermore, as prior attempts to segregate sterile and non-sterile product implement manual procedures, it would be highly desirable to provide for an automated contact lens manufacturing facility, an in-line sterilization machine that inherently prevents the mixing of sterile and non-sterile product. It would be highly desirable to provide for an automated contact lens manufacturing facility, an in-line sterilization machine that sterilizes ophthalmic lens packages without having to offload product from the line, and, that is of improved design and capable of sterilizing a greater number of package containing trays that can be achieved in current systems, thus increasing throughput per unit volume. It would be highly desirable to provide for an automated contact lens manufacturing process a novel tray for supporting stacks of contact lens packages for conveyance in an in-line sterilization machine that employs a temperature and steam pressurization sterilization process in a manner such that packaged lens are sterilized, in a more expedient fashion, with virtually no package damage due to moisture, thereby enabling acceptable packages to immediately proceed to a subsequent packaging station. It would be highly desirable to provide for an automated contact lens

manufacturing process a novel tray and tray stacking structure that carries nested arrays of blister packages for simultaneous sterilization and durable to withstand the steam and temperature conditions in the sterilizer.

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Objectives of the Invention

Accordingly, it is an object of the present invention to provide an in-line sterilizing apparatus for sterilizing contact lens containing packages without off-loading the packages from the manufacturing line. It is another object of the present invention to provide a novel tray structure for carrying contact lens
10 containing packages in an in-line sterilizing apparatus that enables increased throughput per unit volume.

It is a further object of the present invention to provide a novel process for sterilizing contact lens containing packages in a novel in-line sterilizing apparatus that requires less sterilization time. It is still another object of the
15 present invention to provide a novel tray structure for carrying contact lens packages in a novel in-line sterilization apparatus that performs a sterilization under optimum timing, temperature and pressure conditions such that, the sterilization process provides adequately dry packages prior to their secondary packaging which immediately follows the sterilization.

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Another object of the present invention is to provide a control system and method for maintaining information relating to the tracking of contact lens packages conveyed on a novel transport structure for sterilization in a novel sterilization apparatus. It is yet still another object of the present invention to provide an in-line sterilizing apparatus for sterilizing contact lens containing
25 packages in an in-line sterilizing apparatus that is designed to inherently prevent mixing of sterile and non-sterile product. With respect to soft contact lens production, according to an aspect of the present invention, there is provided a sterilization system and method for automatically transporting a plurality of soft contact lens packages containing soft contact lenses to be
30 sterilized through an in-line apparatus, without off-loading packages from the line, but rather, placing them in novel sterilization trays for transport through a sterilizer under optimum conditions of temperature and time for enabling

increased throughput, wherein dryness of said packages is ensured so that the packages may immediately proceed for further secondary packaging.

Advantageously, the integration of the ophthalmic lens package sterilizer within the manufacturing line provides physical separation of sterile and non-sterile product. The result is that the product cannot move the sterile packaging area without going through the sterilizer. The integration also allows complete tracking of the product through the lens machine by the machine controller, ensuring that the product must go through a complete sterilization cycle before unloading to the secondary packaging area.

Brief Description of the Drawings

Figure 1 is a conceptual top plan view of a portion of the lens production facility including the various stations involved with loading of ophthalmic lens containing blister packages in novel tray units and their in-line sterilization according to the principles of the invention;

Figure 2 is a side elevation view of the in-line sterilizer station 50 including the tray stacking, novel sterilizer machine, and tray de-stacking stations;

Figure 3(a) is a top plan view of the novel tray unit according to the principles of the invention;

Figure 3(b) is a detailed close-up view of the circled portion 100a of the tray 100 illustrated in Figure 3(a);

Figure 4(a) is a side cross-sectional view of the novel tray 100 taken along line "E-E" illustrated in Figure 3(a);

Figure 4(b) is a front cross-sectional view of a portion of the novel tray 100 taken along line "F-F" of the tray 100 illustrated in Figure 3(a);

Figure 5 depicts the interleaved pairs of blister arrays 150 deposited in a respective cavity 120 of the novel tray 100;

Figure 6 illustrates the front elevation view of the in-line sterilizer machine shown receiving a stack of trays from a conveyor;

- 5 Figure 7 is a piping and instrumentation diagram illustrating the devices and operating parameters for performing steam sterilization according to the invention; and,

Figure 8 is a side elevation view of the latch mechanism 175 that retains the
10 stack of trays at the tray stacking station 25 of Figure 2.

Detailed Description of the Invention and Preferred Embodiments

The invention includes an apparatus for sterilizing ophthalmic lens packages comprising

- 15 a sterilizing chamber designed to accommodate a plurality of ophthalmic lens packages;
a means for transporting said ophthalmic lens packages to said sterilizing chamber;
a means for subjecting a plurality of ophthalmic lens packages to appropriate sterilization cycle when said ophthalmic lens packages are
20 contained within said sterilizing chamber;

wherein, said sterilizing chamber is disposed contiguously with prior processing stations and secondary packaging stations of a ophthalmic lens manufacturing line.

- As used herein the terms "ophthalmic lens" includes but is not limited to hard
25 contact lenses, soft contact lenses, rigid gas permeable contact lenses, intra-ocular lenses and lenses for eyeglasses. The ophthalmic lenses inspected in this invention may or may not contain vision correction. The preferred lenses are soft contact lenses with or without vision correction. Soft lenses may be made of conventional hydrogels and are generally prepared from monomers
30 including but not limited to hydroxyethyl methacrylate (HEMA), vinyl pyrrolidone, glycerol methacrylate, methacrylic acid and acid esters; or silicone hydrogels. Examples of soft contact lenses include but are not limited

to etafilcon A, genfilcon A, lenefilcon A, polymacon, aquafilcon A, balafilcon A, lotrafilcon A and silicone hydrogels as prepared in U.S. Pat. No. 5,998,498, US Pat. App. No. 09/532,943, a continuation-in-part of US Pat App. No.

09/532,943, filed on August 30, 2000, U.S. Pat. Ser. No. 09/957, 299 filed on

5 September 20, 2001, U.S. Patent No. 6,087,415, U.S. Pat. No. 5,760,100, U.S. Pat. No. 5,776, 999, U.S. Pat. No. 5,789,461, U.S. Pat. No. 5,849,811, U.S. Pat. No. 5,965,631, U.S. Pat. App. No. 60/318,536, entitled "Biomedical Devices Containing Internal wetting Agents," filed on September 10, 2001 and its non-provisional counterpart of the same title, filed on September 6, 2002.

10 These patents as well as all other patent disclosed in this application are hereby incorporated by reference in their entirety.

Numerous processes are known for making ophthalmic lenses, including various processes to make soft contact lenses. While the present invention is applicable across the board to all ophthalmic lens processes, a preferred practice, along with its correlative manufacturing line stations, will now be described in the context of a soft contact lens, it being understood that the present invention is not limited to such lenses.

As used herein the phrase "ophthalmic lens packages" refers to the primary packaging for individual ophthalmic lenses, or more commonly known a blister packages. Examples of said packages include but are not limited to the packages disclosed in U.S. Patent Nos. 4,691,820; 5,054,610; 5,337,888; 5,375,698; 5,409,104; 5,467,868; 5,515,964; 5,609,246; 5,695,049; 5,697,495; 5,704,468; 5,711,416; 5,722,536; 5,573,108; 5,823,327; 5,704,468; 5,983,608; 6,029,808; 6,044,966; and 6,401,915, U.S. Pat. App. Ser. No. 60/436,109 filed on December 23, 2002 entitled "Contact Lens Packages Containing Additives" and, U.S. Pat App. Ser. No. 10/183,133 filed on June 26, 2002, entitled "Contact Lens Packages". All of the aforementioned patents and patent applications are hereby incorporated by reference.

30 As used herein the term "sterilizing chamber" refers to an enclosure that is used to sterilize ophthalmic lens packages. Said chamber may be opened, automatically or manually, to permit entry and exit of said packages.

Further said chamber must be constructed to allow, either or both, heating or cooling by of any of a number of methods which include but are not limited to dry heat, steam heat, jacketed cooling, and the like. Temperature modification of said chamber sterilizes ophthalmic lens packages contained therein. As used herein "means for transporting" includes but is not limited to conveyor belts, pulleys, and other mechanized system used to move items along a manufacturing line. In the preferred embodiment means for transporting includes "sterilizing trays." Said sterilizing trays have external walls and internal walls dividing said tray in order to enable to hold a plurality of ophthalmic lens packages in the most efficient orientation for sterilizing said packages. The preferred orientation for sterilizing said packages is with the package held vertically, as depicted in Figure 5. As used herein "means for subjecting" includes but is not limited to pressure, heat and steam sources and regulators.

As used herein "prior processing stations" include but are not limited to any stations an ophthalmic lens manufacturing line such as lens formation, hydration, inspection and the like. Specific examples of such processing stations are disclosed in U.S. Pat No. 4,958,280, entitled "Apparatus and Method for Satisfying Disposable Contact Lens Prescriptions," which is hereby incorporated by reference in its entirety. In the preferred embodiment of this invention, the prior processing stations include any or any combination of the following means for loading said sterilizing trays with ophthalmic lens packages, means for transferring the loaded sterilizing trays to the sterilizing chamber, means for unloading said sterilizing trays, and means for transferring the sterilized ophthalmic lens packages to said second packaging station.

As used herein the term "sterilization cycle" refers subjecting said packages to different temperatures and pressures in order to sterilize said packages and ophthalmic lenses contained therein. As used herein, "secondary packaging" includes but is not limited to cartons, shrinking wrapping or other methods of enclosing the individually packaged ophthalmic lenses in multiple containers. Examples of such secondary packaging are

disclosed in U.S. Pat. No. 5,577,367 which is hereby incorporated by reference in its entirety. An example of an embodiment of the invention is illustrated in greater detail in reference to the following figures.

Referring to Figure 1, there is shown a simplified diagrammatic top view of a portion 10 of a contact lens production facility including a processing station designed to enable expedient and consolidated packaging of manufactured ophthalmic lenses in an aqueous solution contained in an individual blister package, and a processing station designed to enable their expedited sterilization with increased throughput. Preferably, as known in the art, an individual formed ophthalmic contact lens is placed into an individual plastic "blister" package containing an aqueous solution. In the preferred embodiment, each individual blister package is removably attachable to one or more other packages to form a blister pack array comprising three blister packages, for example (not shown). Thus, a formed ophthalmic lens is loaded in each blister pack of the array and is sealed in accordance with techniques known in the art. Next, the formed and sealed blister pack arrays 22 are transferred to a tray loading station 20, where they are loaded into a novel sterilizer tray (not shown), as will be described in greater detail herein. In the preferred embodiment, two formed and sealed blister pack arrays 22 are interleaved (nested) in a manner prior to transference to a tray loading station 20 by rotating one array and placing a second array on top of the other. The blister pack array has been designed to provide the interleaving feature. Coordinated with the activity of packaging and nesting the blister package array in an interleaved manner, a novel sterilizing tray unit (not shown) designed to receive and support the blister packs for conveyance through the in-line sterilizer unit is indexed from an empty tray stack (not shown) proximate the tray loading station 20 to receive the packages at the tray loading station 20. Preferably, at the tray loading station 20, the novel in-line sterilizer tray is suitably indexed and oriented for enabling a gripper mechanism 28 to automatically pick and transfer each interleaved pair of blister arrays into a correspondingly indexed cavity formed in the tray. Preferably, the tray is situated horizontally while the gripper mechanism picks five (5) pairs of blister pack arrays and places them vertically into one (1) row

comprising five tray cavities designed to receive the nested pair. Next, the tray filled with the plurality of interleaved pairs of blister arrays is automatically conveyed by a servo-controlled belt driven conveyor, for example, in the direction labeled "A", into a tray stacking station 25 where a stack of trays are formed. In the preferred embodiment, nine trays, each filled with the plurality of interleaved pairs of blister package arrays, is stacked one on top of each other and automatically conveyed, in the direction labeled "B", to an immediately adjacent in-line sterilizer 50 where they are subject to an efficient steam/heat sterilization process as will be explained in greater detail herein. The design of the in-line sterilization station 50 coupled with the novel sterilization tray design that permits stacking enables increased lens sterilization throughput levels heretofore unachievable. Moreover, the novel in-line sterilizer design permits implementation of new sterilization process parameters that ensures the dryness of every blister pack array, which is essential for subsequent automated secondary packaging. Further, as shown in Figure 1, after the sterilization cycle is complete, the tray stack comprising the sterilized blister pack arrays is automatically conveyed, in the direction labeled "C", to an immediately adjacent tray de-stacking station 60 where, in an essentially a reversed process, the trays are one-by-one destacked. The individual de-stacked tray is then automatically conveyed, in the direction labeled "D", to an unload station 70 where the blister packs of each tray are picked-up for transference to a secondary packaging station where they are suitably placed in cartons as part of a secondary packaging procedure.

Figure 2 is a side elevation view of the in-line sterilizer station including the tray stacking station 25, novel sterilizer machine, and tray de-stacking stations. As shown in Figure 2, the tray stacking station 25 operates as follows: a first sterilizer tray 100 filled with the plurality of interleaved pairs of blister package arrays is automatically conveyed from the tray loading station on a tray carrier 160. This tray carrier serves to index the tray one (1) row at a time through the tray loading process and then indexes to the stacking position. Under precise program control, the stacker cylinder 170 is actuated to elevate the tray carrier carrying the tray 100, in the direction labeled "G",

above the level of conveyor 180, e.g. a belt driven roller, or like conveyor system, where the sterilizer tray is latched and held into place by a latch mechanism 175. The latch is actuated by an air cylinder which opens with air and closes with spring force. The spring force allows the trays to push past
5 the latch and closes on the tray to hold it in place. The cylinder is then actuated to retract the tray carrier 160 to retrieve the next tray unit including the plurality of interleaved pairs of blister package arrays. In the second iteration, the process repeats and the tray carrier is elevated for placement underneath the tray stack in a stackable manner. The latch mechanism is
10 actuated to hold the second tray having the first tray in a stacked configuration thereon, as will described herein with respect to Figure 8. After a predetermined amount of iterations, e.g., nine (9) in the preferred embodiment, the latch mechanism is holding a nested stack of nine sterilizer trays 200. The latch is finally released and the stack 200 of sterilizer trays becomes supported by
15 conveyor 180 which is driven to convey the stack into the in-line sterilizer machine 50 in the load direction as indicated in Figure 2. Preferably, the sterilizer includes a motorized roller conveyor 195 which is synchronized with the conveyor 180. This allows the stack of trays to load into the sterilizer. After sterilization, the stack unloads to the conveyor 181 at the de-stacker station 60
20 where the top tray 100 of the stack 200 is transferred to another tray carrier 161. The interleaved arrays of blister packs are unloaded using a similar gripper mechanism used to load the tray as described with respect to Figure 1.

Figure 8 is a side elevation view of the latch mechanism 175 that retains the stack of trays at the tray stacking station 25 of Figure 2. As shown in Figure
25 8, latching fingers 175a,b under spring control are actuated by the stacking cylinder 170 when extended (Figure 2) to nest the next successive tray 101 at the bottom of the tray stack. The elevation of the stack by the tray carrier and stacking cylinder causes the latch fingers to disengage from the first tray, and catch the next upward moving tray in the stack where the latch fingers again
30 engage the peripheral ridge portion 107 at each side of the tray 100. Although not shown in Figure 8, while in upward movement, in the direction labeled "G", the spring is actuated so that the latch fingers will eventually engage the

respective ridge portion 107 at each side of the bottommost tray 101 for supporting the stack thereon.

Figure 6 illustrates the front elevation view of the in-line sterilizer machine Figure 6 shown receiving the stack of trays 200 on a conveyor.

5 More particularly, as shown in Figures 5 and 6, a conveyor 195, such as a roller type conveyor provided within the sterilizer, is communicatively situated at an equal height "h" in the sterilizer as the conveyor 180 of the tray stacking station so that the tray stack 200 may be directly transported to within the confines of the sterilizer chamber 53. Prior to transference, under program
10 control, the doors of the sterilizer are opened, e.g., vertical doors may be retracted. The stack is conveyed from conveyor 180 to 195 within the sterilizer in synchrony. After the sterilizer is loaded, the doors are closed and the sterilization cycle begins.

As shown in Figures 6 and 7, in the preferred embodiment, the
15 sterilizer 50 is a jacketed pressure chamber 53 having two doors 56 with the jacket 307 surrounding the chamber 53 so as to provide extra heat during the sterilization cycle as shown in Figure 7. In an example embodiment, the dimensions of the in-line sterilizer chamber is approximately 650 mm in height, 450 mm wide and 650 mm deep, thus providing less than a cubic
20 meter (1 m^3), which using the novel sterilization trays of the invention, is sufficient to provide a capacity per unit of chamber volume of approximately three (3) times greater than prior art versions. Preferably, the sterilizer machine is a complete system with mechanical/electrical process components, an internal sterilizer tray conveyor 195, and control system. The
25 sterilizer 50 is integrated into the manufacturing machine to provide much higher throughput per unit volume. As will be explained in greater detail, this throughput/volume is achieved by implementing the novel sterilization trays used. Meeting the requisite "dryness" criteria is achieved by the design of the sterilizer, use of the novel trays, and the sterilization process parameters
30 implemented during the sterilization cycle, as will be explained.

Further the invention includes a method of sterilizing ophthalmic lens packages comprising

transporting a plurality of said ophthalmic lens packages to a sterilizing chamber;

subjecting said plurality of ophthalmic lens packages at least one sterilization cycle within said sterilizing chamber;

- 5 wherein, said sterilizing chamber is disposed contiguously with prior processing stations and secondary packaging stations of a ophthalmic lens manufacturing line.

The terms ophthalmic lens, packages, sterilizing chamber, prior processing station, sterilization cycle, and secondary packaging stations all have their
10 aforementioned meanings and preferred ranges. An embodiment, that illustrates, but does not limit, this invention is disclosed below.

Figure 7 is a piping and instrumentation diagram illustrating the major devices and controls utilized for performing steam sterilization according to the invention. As shown in Figure 7, and explained in greater detail herein, the
15 expedited and efficient lens package sterilization process is enabled under the programmed control and supervision of an enhanced programmable logic control system (PLC) or like equivalent control device 99. In a first sterilization cycle referred to as the PREHEAT Phase, the function is to pre-heat product and internal chamber with dry heat only, to prevent steam condensation on
20 product. The steps involved with this process includes: starting the fan motor which is indicated at 302 in Figure 7; initiating the start of the Preheat Sequence Timer with a pre-set value of 2.0 minutes in an example embodiment described. In a next step, a jacket steam valve that is indicated at 304 in Figure 7 is opened and a Jacket Pressure Switch 308 setpoint is
25 controlled, which, in the example embodiment described, is at a switch setpoint value of about 2.0 bar, for example. Air valves 310 and drain valves 320 are then actuated to control the air pressure of the chamber at air overpressure setpoint with a small percentage of the alarm limits. In an example embodiment, the air overpressure setpoint value is a saturated steam
30 pressure at + 1.05 bar and is set within the overpressure alarm limits of +/- 0.2 bar, for example. When the Preheat Sequence Timer reaches the pre-set value, the process advances to the next phase.

In the second sterilization cycle referred to as the Sterilization Cycle HEAT LOAD Phase, the function is to heat the product with steam and dry heat to a sterilization temperature. The steps involve opening a jacket steam valve 304 and setting the jacket pressure switch to a setpoint value of approximately 2.0 bar. Then, one or more air valves and drain valves 310, 320 are actuated in order to control the chamber pressure at air over-pressure setpoint within a +/- percentage of the alarm limits. In an example embodiment, the air overpressure setpoint value is a saturated steam pressure at + 1.05 bar and is set within the overpressure alarm limits of +/- 0.2 bar, for example. The Steam Control Valve that is indicated at 305 in Figure 7 is opened to achieve a temperature setpoint value plus overshoot. In an example embodiment described, the temperature setpoint value is 124.0° C with an overshoot value of about 0.6° C. When the minimum chamber temperature reaches the temperature setpoint value minus the overshoot value (123.4° C), an Exposure Start delay timer, preset to a value of 1.0 minute begins counting and when the Exposure Start timer reaches 1.0 minute, the process advances to the next phase.

In a third sterilization cycle referred to as the Sterilization Cycle EXPOSURE Phase, the function is to hold the product at sterilization temperature for minimum sterilization time. After the 1.0 minute time period of the preceding paragraph is reached, an Exposure Sequence Timer commences which is pre-set to an Exposure Timer Value of 18.0 minutes. Then, one or more air valves 310 are actuated in order to control the chamber pressure at air over-pressure setpoint within a +/- percentage of the alarm limits. In an example embodiment, the air overpressure setpoint value is a saturated steam pressure at + 1.05 bar and is set within the overpressure alarm limits of +/- 0.2 bar, for example. Then, the Steam Control Valve 305 opens to the setpoint value, which, in the example embodiment, is 124.0° C. In the preferred embodiment, all temperatures are maintained within no more than 1° C of the Exposure Temperature setpoint. Then, the jacket steam valve 304 is then closed. When the Exposure Timer reaches a pre-set value, the cycle advances to the next phase.

In a fourth sterilization cycle referred to as the Sterilization Cycle AIR COOL Phase, the function is to cool the package product with air flowing into the chamber to remove steam vapor. In this phase, an Air Cool Phase Sequence Timer is commenced which is at a pre-set value of about 4.0

5 minutes. Then, one or more air valves and drain valves 310, 320 are actuated in order to control the chamber pressure at air over-pressure setpoint within a +/- percentage of the alarm limits. In an example embodiment, the air overpressure type is a ramp control; ramp setpoint value is set to -0.04 bar/minute; and, an overpressure alarm limit values: +/- 0.2 bar. 10 Then, the steam valve 305 is closed; and, when Air Cool Timer reaches a pre-set value, the cycle advances to the next phase.

In a fifth sterilization cycle referred to as the Sterilization Cycle WATER COOL LOAD Phase, the function is to cool the product with water flowing into the internal heat exchanger chamber indicated at 315 in Figure 7, in order to 15 condense remaining steam vapor and cool product to final temperature for unloading to secondary packaging area. First, one or more air valves and drain valves 310, 320 are actuated in order to control the chamber pressure at air over-pressure setpoint within a +/- percentage of the alarm limits. In an example embodiment, the air overpressure type is a ramp control; a ramp 20 setpoint value being set to -0.04 bar/minute; and, an overpressure alarm limit values of +/- 0.2 bar. Then, a Water Valve 325 opens to fill the internal heat exchanger 315. When maximum chamber temperature reaches a second cool phase setpoint, the cycle advances to an Exhaust phase. In an example embodiment, the water cool load phase setpoint value is equal to 65.0° C.

25 In a sixth sterilization cycle referred to as the Sterilization Cycle EXHAUST Phase, the Chamber drain valves 320 are opened and the Air valves 310 are closed. The Water valve 325 is opened. When the chamber pressure reaches a setpoint value, the cycle advances to an End of Cycle phase. In an example embodiment, the Exhaust phase setpoint value is 0.1 30 bar. The sterilization cycle is now complete.

In the preferred embodiment, given the design of the sterilizer chamber and the process parameters utilized, the total sterilization cycle time is

approximately forty (40) minutes which is a fairly dramatic improvement over the sterilization cycle times in prior art sterilizer equipment.

Referring now to Figure 3(a), there is illustrated the novel plastic tray unit 100 for carrying nested stacks of blister pack arrays carrying ophthalmic lenses for input to the sterilizer machine. A detailed close-up view of a portion 100a of the tray 100 is illustrated in Figure 3(b). In the top view of the plastic tray 100 shown in Figure 3(a), the tray includes an external wall 102 bounding the perimeter of the tray, and four internal divider walls 104a – 104d, which form five tray columns 110a-110e. As shown in Figure 4(a) which illustrates a side cross-sectional view of the novel tray 100 taken along line “E-E” illustrated in Figure 3(a), the cavities 120a, 120b,...,120v are shown separated by the divider walls 115 formed there between. When the tray 100 is indexed for loading at the blister pack loading station 20 (Figure 1), the tray is oriented horizontally with the divider walls 115 extending upward. Thus, as shown in Figure 5, the interleaved pairs of blister arrays 150 may easily be deposited in a respective cavity 120 separated from each other by the divider walls 115 in the manner illustrated, and supported by the plastic tray bottom 101. It should be understood that the configured interleaving of a nested array of packages for sterilization according to the invention, is substantially similar to the configuration of the interleaved nested array of packages that will be ultimately packaged in a carton at the subsequent secondary packaging station (not shown).

Referring back to Figure 4(a), along the perimeter of each plastic tray 100, is the external wall 102 which is shown as extending above height of the divider walls 115. As shown in Figure 4(b) which depicts a front cross-sectional view of a portion of the novel tray 100 taken along line “F-F” of the tray 100 illustrated in Figure 3(a), a top portion 103 of the external wall 102 includes a recessed or “lip” portion 106 that preferably forms an internal shelf about the substantially the whole periphery of the tray and that is designed to stackably engage a bottom portion of the next tray that is to be stacked thereon. Thus, the bottom portion 101 of the tray is designed for easy stacking placement within the peripheral recess portion 106 of each tray for

enabling nested stacking of the trays at the tray stacking station. Figure 3(b) further shows openings 109 formed in the bottom of the tray 100 to provide circulation of steam and air to the sealed blister pack arrays. Furthermore, in view of Figure 4(b), the external wall is provided with a peripheral ridge or flanged portion 107 that accommodates the placement of the latch fingers for supporting the trays during at the tray stacking station, as described with respect to Figure 8. In the preferred embodiment, a single plastic tray 100 is designed to support the weight of at least a stack of nine trays for input to the sterilizer machine. Moreover, the material of the plastic tray is not only designed for strength to support the weight of the trays but to additionally endure the temperature and pressure of the steam sterilization cycle. In the preferred embodiment, the tray is injection molded plastic such as Polyether Imide Ultem® brand manufacture by General Electric.

Referring back to Figures 3(a), 3(b), and 5, as mentioned, each column 110a-110e of the tray 100 formed between internal divider walls 104a – 104d includes a plurality of internal divider walls 115, which in the example embodiment shown in Figures 5, 3(a), and 3(b), amounts to twenty-one (21) dividers. Between each pair of dividers 115a,b are formed the cavity 120 for retaining an individual array of blister packs (not shown). In this embodiment, the twenty internal dividers form twenty-two (22) cavities, each cavity 120 for carrying a nested pair of interleaved packages carrying 3-pack arrays in a proper orientation for sterilization. Thus, in a preferred embodiment, there are 110 cavities formed in the tray, with each cavity accommodating a total of six lens packages (interleaved pair of three blister packs each). Thus, the amount of packages carried per tray amounts to 660. With the single tray capable of supporting nine tray stacks in the preferred embodiment, the total number of blister packages that may be conveyed for simultaneous sterilization in the novel sterilizing chamber, amounts to about 5,940. A further advantage is that the molded plastic tray provides the additional benefit of being lightweight relative to a metal tray (for example), which makes it easier to convey in and out of the sterilizer. A stack of metal trays weigh

approximately two (2) times the weight, which would require a larger motor, rollers and more durable system for conveying the stack.

The integration of the sterilizer in-line with the rest of the ophthalmic lens manufacturing facility that enables sterilization and packaging without
5 disrupting the product flow, inherently provides a physical barrier between sterile and non-sterile packaging areas. That is, the product cannot move the sterile packaging area without going through the sterilizer. Further, the design enables continuous uninterrupted processing whereby as a new stack of trays containing ophthalmic lenses are input from the stacking station to the
10 sterilizing chamber, the previous tray stack that had just been sterilized are output from the chamber. Further, the integration also allows complete tracking of the product through the lens machine by the machine controller, insuring the product must go through a complete sterilization cycle before unloading to the secondary packaging area. Integration of the sterilizer
15 control system 99 (Figure 7) with the lens machine control system further provides complete tracking of the product through the packaging and sterilization process.

Another advantage of the in-line sterilizer design is a higher output per unit volume of sterilizer chamber. This capacity reduces floor space required
20 for sterilization and in-process product inventory. The sterilization process time and use of the stacking sterilization trays provide this capacity. The process also provides a dry package following sterilization, required by immediate packing of the product following sterilization.

Still further the invention includes a sterilizing tray for conveying arrays
25 of ophthalmic lens packages, each of which includes at least one ophthalmic lens immersed in a sterile aqueous solution, through a sterilizing chamber in a manufacturing line for sterilizing said packages prior to packaging in secondary packaging, said sterilizing tray comprises an external wall surrounding a perimeter of said tray and having and a number of internal
30 divider walls forming columns therebetween, each divider wall comprising a plurality of cavities for holding a plurality of packages in a nested configuration, said cavities for holding the plurality of packages, in an

orientation optimized for sterilization in a sterilizing chamber, wherein said tray is designed for strength to support the weight of a plurality of trays and endure the temperature, and pressure of the steam sterilization. In the preferred embodiment of this invention, said sterilizing tray is made of a lightweight plastic material. In another embodiment of this invention said sterilizing tray comprises openings either or both, above and below said the perimeter wall said tray to provide optimum heating or cooling, of said packages contained therein. Yet still further the invention includes An ophthalmic lens manufacturing line comprising:

10 a first station for successively loading arrays of packaged ophthalmic lenses into respective cavities formed in a plastic tray receptacle;
a second station for successively stacking a plurality of plastic tray receptacles each loaded with an array of packaged ophthalmic lenses;
a third station comprising a sterilizing chamber designed to
15 accommodate simultaneous sterilization of a plurality of ophthalmic lens packages;
a conveyor means for synchronously conveying said stack of loaded plastic tray receptacles from said second station to said third station for sterilizing said ophthalmic lens included in said plastic tray;
20 wherein, said sterilizing chamber of said third station is disposed contiguously with said second station to enable continuous sterilization of said ophthalmic lens packages without disrupting said manufacturing line.

While the invention has been described in connection with a preferred embodiment, it is not intended to limit the scope of the invention to the particular form set forth, but on the contrary, it is intended to cover such
25 alternatives, modifications, and equivalents as may be included within the spirit and scope of the invention as defined by the appended claims

What is claimed is

1. An apparatus for sterilizing ophthalmic lens packages comprising
a sterilizing chamber designed to accommodate a plurality of ophthalmic
lens packages;
5 a means for transporting said ophthalmic lens packages to said sterilizing
chamber;
a means for subjecting a plurality of ophthalmic lens packages to an
appropriate sterilization cycle when said ophthalmic lens packages are
contained within said sterilizing chamber;
10 wherein said sterilizing chamber is disposed contiguously with prior processing
stations and secondary packaging stations of a ophthalmic lens manufacturing
line.
2. The apparatus of claim 1 wherein said means for transporting said
15 ophthalmic lens packages to said sterilizing chamber is a conveyor system.
3. The apparatus of claim 1 further comprising a means for transporting
said ophthalmic lens packages from said sterilizing chamber.
- 20 4. The apparatus of claim 3 wherein said means for transporting said
ophthalmic lens packages to the said sterilizing chamber is the same as the
means for transporting said ophthalmic lens packages from said sterilizing
chamber.
- 25 5. The apparatus of claim 4 wherein said transporting means comprises a
conveyor system.
6. The apparatus of claim 1 wherein said transporting means comprises a
sterilizing tray.
- 30 7. The apparatus of claim 1 wherein said sterilization cycle comprises
heating with dry heat or heating with steam.

8. The apparatus of claim 7 wherein said sterilization cycle further comprises cooling.

5 9. The apparatus of claim 1 wherein the appropriate sterilization cycle comprises heating for approximately 18 minutes.

10. The apparatus of claim 1 wherein the appropriate sterilization cycle comprises heating at approximately 124 °C.

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11. The apparatus of claim 1 wherein said ophthalmic lens packages are transported to said sterilizing chamber in sterilizing trays and from sterilizing chamber directly to said secondary packaging station using a means for unloading said sterilizing trays.

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12. A method of sterilizing ophthalmic lens packages comprising transporting a plurality of said ophthalmic lens packages to a sterilizing chamber;

subjecting said plurality of ophthalmic lens packages at least one

20

sterilization cycle within said sterilizing chamber;

wherein, said sterilizing chamber is disposed contiguously with prior processing stations and secondary packaging stations of a ophthalmic lens manufacturing line.

25 13. The method of claim 12 wherein said sterilization cycle comprises a first, a second, a third, a fourth, a fifth and a sixth sterilization cycle wherein said first cycle pre-heats said packages with dry heat, said second cycle heats said packages with steam and dry heat, said third cycle maintains said second cycle for a period of time,
30 said fourth cycle removes residual steam vapor
said fifth cycle cools said packages, and

said sixth cycle opens one or more drain valves, closes one or more air valves and subsequently heats said packages to dryness.

14. A sterilizing tray for conveying arrays of ophthalmic lens packages,
5 through a sterilizing chamber in a manufacturing line for sterilizing said packages prior to packaging in secondary packaging,

said sterilizing tray comprises an external wall surrounding a perimeter of said tray and having and a number of internal divider walls forming columns therebetween, each divider wall comprising a plurality of cavities for holding a
10 plurality of packages in a nested configuration, said cavities for holding the plurality of packages, in an orientation optimized for sterilization in said sterilizing chamber, wherein said tray is designed to support the weight of a plurality of trays and to endure the sterilization cycles of said sterilizing chamber.

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