

RTmp

1 COMPUTER SYSTEM FOR QUALITY CONTROL CORRELATIONS

CROSS REFERENCE TO RELATED APPLICATION

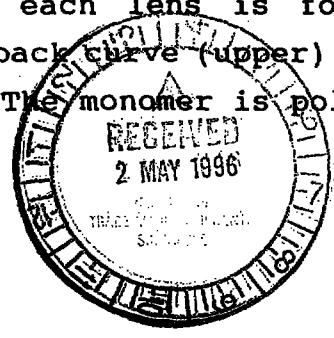
This application is a continuation-in-part of
5 U.S.S.N. 08/257,800 entitled COMPUTER SYTEM FOR QUALITY
CONTROL CORRELATIONS and filed June 10, 1994.

1. Field of the Invention.

10 This invention relates generally to a computer
system for a manufacturing facility for the production of
ophthalmic contact lenses, and, in particular to a
supervisory system for monitoring the production line
processes used in the manufacture of contact lenses in a
15 contact lens fabrication facility, specifically, with the
goal of investigating and optimizing the process of
contact lens sterilization.

2. Description of the Prior Art.

20 The direct molding of hydrogel contact lenses is
disclosed in U.S. Patent 4,495,313 to Larsen, U.S. Patent
4,680,336 to Larsen et al., U.S. Patent 4,565,348 to
Larsen, and U.S. Patent 4,640,489 to Larsen et al., the
25 entire disclosures of which are hereby incorporated by
reference in this patent application. Essentially, these
references disclose an automated contact lens production
process wherein each lens is formed by sandwiching a
monomer between back curve (upper) and front curve (lower)
30 mold sections. The monomer is polymerized, thus forming



a lens, which is then removed from the mold sections and
1 further treated and packaged for consumer use.

The manufacturing of contact lenses requires
tightly controlled conditions and processes, many of which
are monitored by computers and other control devices.
5 Much information, in the form of process conditions and
control data, for e.g., that occur during contact lens
manufacturing, may be gathered for quality control and
regulatory approval purposes. However, this entails the
acquisition of a tremendous amount of data for each
10 contact lens that is produced, and, additionally, requires
a means for processing the data acquired in a way that is
suitable for use by operators, engineers, and supervisors,
etc., so that they may properly perform their functions.

There is therefore the need to provide a quality
15 control system that can automatically acquire process
control data from a plurality of manufacturing process
controllers that control various aspects of contact lens
production at process stations in a contact lens
manufacturing facility, and, that can automatically
20 process the data for real-time display and archiving
purposes. More particularly, there is a need for a
quality control system that can automatically acquire data
generated from a sterilization controller that controls a
sterilization process performed to contact lenses that are
25 individually packaged but not cartoned, and that is
performed prior to their cartoning.

It would additionally be highly desirable to
provide a quality control system that can automatically
gather sterilization process control data for contact
30 lenses for subsequent generation of sterilizer cycle
condition records that includes: sterilization run

success/failure indication, lot number, and sterilization
1 run number from the sterilizer controller. These files
may be stored in an off-line database storage area and be
retrieved to analyze the trend of sterilizer performance
over a long period of time. Furthermore, in accordance
5 with the inventive processes described herein, these files
may be processed to automatically generate reports that
are suitable for compliance with Federal Food and Drug
Administration ("FDA") record-keeping requirements, and
are also useful for re-certifying the sterilizer.

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SUMMARY OF THE INVENTION

An object of the instant invention is to provide
a quality control system for a contact lens manufacturing
15 facility that automatically acquires process control data
from a plurality of manufacturing process controllers that
control contact lens production, and, that can
automatically process the data for real-time display and
off-line analysis purposes.

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Another object of the invention is to provide a
quality control system for a contact lens manufacturing
facility that implements a sterilization process for
sterilizing individual contact lens packages after their
primary packaging in blister packages and prior to their
25 cartooning.

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Still another object of the invention is to
provide a quality control system for a contact lens
manufacturing facility that includes a sterilization
apparatus controlled by a sterilization controller for
sterilizing individual contact lens packages prior to
their cartooning. Additionally, another object of the

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invention is to provide a quality control system that
1 gathers sterilization process control data from the
sterilization controller and subsequently generates
sterilizer cycle condition records that includes:
sterilization run success/failure indication, lot number,
5 and sterilization run number from the sterilizer
controller.

Yet still another object of the invention is to
provide a quality control system for a contact lens
manufacturing facility that includes an apparatus for
10 secondary packaging of sterilized blister packages
containing individual contact lenses in cartons.

A further object of the invention is to provide
a quality control system that incorporates means for
automatically printing and correlating labelling
15 information including lot number identification for all
contact lens packages produced.

The above objects are achieved in a quality
control system for an automated production line producing
contact lenses, the production line having a plurality of
20 contact lens process stations, including an automated
sterilization station for sterilizing a plurality of
contact lenses after their manufacture, and a packaging
station for packaging said lenses after sterilization,
wherein the system comprises:

25 (a) a first means for receiving contact lens
data including an associated lot number and lens power for
a lens lot prior to their manufacture; the lens lot
defining at least one batch of contact lenses;

(b) a plurality of process controllers for
30 controlling one or more process stations, each of the

controllers regulating a plurality of process control
1 devices at the process stations;

(c) means for tracking movement of the plurality
of lenses defined by the lens lot from the plurality of
processing stations to the automatic sterilization station
5 and the packaging station;

(d) second means for receiving data representing
the number of lenses that are input to the sterilization
station and recording sterilization data for each batch of
the lens lot together with reason codes for contact lenses
10 lost at the sterilization station;

(e) means for generating a summary report of the
total number of lenses input to the sterilization chamber
for a predetermined lens lot and the actual number of
lenses sterilized and packaged from the lot, the summary
15 report including lot number, expiration date, power and
sterilization data for each batch of contact lenses.

Further benefits and advantages of the invention
will become apparent from a consideration of the following
detailed description given with reference to the
20 accompanying drawings, which specify and show preferred
embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

25 The foregoing objects and advantages of a
quality control system for an automated production line
for producing contact lenses of the present invention, may
be more readily understood by one skilled in the art with
reference being had to the following detailed description
30 of several preferred embodiments thereof, taken in
conjunction with the accompanying drawings wherein like

elements are designated by identical reference numerals
1 throughout the several views, and in which:

Figure 1 is an organizational overview of the
sterilization monitoring system of the instant invention.

Figure 2 illustrates the hardware configuration
5 of the existing supervisory control system 100 shown
interfaced with the sterilizer monitoring node 20 and
sterilizer controller 25 of the instant invention.

Figure 3 illustrates a detailed hardware
overview of the supervisory controller's sterilizer
10 monitoring node 20 and data flow therein.

Figure 4 is a state data flow diagram showing
the internal states of the sterilizer monitoring node
while receiving data from the sterilizer controller 25.

Figures 5(a) and 5(b) illustrate, in detail, the
15 steri comm data acquisition process 50.

Figure 6 illustrates the major functional blocks
of the steri server process 50.

Figure 7 illustrates the `characterizeLine`
algorithm 300 for determining the nature of the data line
20 sent by the sterilization controller.

Figure 8 illustrates the `processDataLine`
algorithm 405 for processing the twelve (12) variables of
sterilizer phase data from the data line.

Figure 9 illustrates the `makePhaseFileEntry`
25 algorithm 440 to format the process variable information
for entry as a line in the corresponding phase file.

Figures 10(a) and 10(b) illustrate the
`evaluateTextline` process 450 for processing textual data
from the input data line.

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Figure 11 illustrates the StartOfRunEvent
1 procedure 466 invoked when a sterilizer run has started
from the beginning.

Figure 12 illustrates the doEndOfRunEvent
procedure 480 invoked when the end of a sterilizer run has
5 been detected.

Figure 13 illustrates the processAlarmLine
algorithm 500 for processing alarm data from the input
data line.

Figure 14 illustrates the updateAlarmStatus
10 algorithm 550 for updating alarm status after every line
evaluation.

Figure 15 illustrates the finishSteriRunReport
procedure 485 to generate the sterilizer run report.

Figure 16 illustrates the doEndOfRunCleanup
15 procedure 486 to finish the text line processing and print
the steri run report.

Figure 17 illustrates the addDurations procedure
630 for adding the phase time durations to the sterilizer
run report.

Figure 18 illustrates the addMinMax procedure
20 640 for adding the minimum and maximum phase variable
data to the sterilizer run report.

Figure 19 illustrates the openSteriRunReport
procedure for opening the steri run report file.

Figure 20 illustrates the closeAndPrintRunReport
25 procedure for closing the steri run report file.

Figure 21 illustrates in detail the
wakeUpCmdFunc process 280 invoked by the CELLworks system.

Figure 22 illustrates in detail the
30 endRunReportForTimeout process 290 that is called to
update the steri run report file.

Figure 23 illustrates in detail the
1 sterilization run report automatically generated for a
complete sterilization cycle.

Figure 24 illustrates the algorithm for contact
lens lot number information entry.

5 Figures 25(a) and 25(b) illustrate the
respective data structures stored in the statistics server
for the lot information before primary packaging (Figure
25(a)) and after primary packaging (Figure 25(b)).

Figure 26 illustrates a data flow diagram for
10 moving a lot by operator request.

Figure 27 illustrates the moveLot algorithm 680
for tracking lens lot movement throughout the production
line.

Figure 28 illustrates the start of the lot
15 reconciliation process which entails the reporting of the
quantity of lenses input to the sterilizer.

Figure 29 illustrates the procedure for entering
the number of lenses removed from the secondary packaging
process.

20 Figure 30 illustrates the lot close out flow
diagram.

Figure 31 illustrates a table depicting phase
file data entries in the four sterilizer phase files.

Figure 32 illustrates the
25 sterilization/secondary packaging lot reconciliation
sheet.

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DESCRIPTION OF THE PREFERRED EMBODIMENT

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Illustrated in Figure 1 is a general schematic diagram illustrating the sterilization monitoring system 10 for passively monitoring the sterilization and secondary packaging of contact lens packages. As will be explained in greater detail below, the sterilization monitoring system 10 of the invention is configured specifically to process sterilizer serial data and generate sterilization run reports.

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As shown in Figure 1, the sterilization monitoring system 10 comprises a sterilization chamber 15 having a sterilizer control device 25, which, in the preferred embodiment, is a PLC or dedicated process controller that controls the sterilization process and serially broadcasts the sterilization process data 16 and alarm data (when an alarm condition exists) as formatted ASCII characters to a dedicated printer 17, via data line 16a, as well as an intercepting sterilization monitoring node 20, via data line 16b, that is interfaced with an existing contact lens production line supervisor quality control system 100 ("existing supervisor system"). As will be explained in detail below, the sterilization node 20 will process the ASCII sterilizer data and automatically generates a sterilization run report, a portion of which is shown in Figure 22, and explained in detail below, at a second printer 18. The operational details of the existing contact lens production line supervisor quality control system 100 are disclosed in the above-identified co-pending patent application U.S.S.N. 08/257,800 entitled "Computer Program for Quality Control Correlations", assigned to the same assignee as the

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instant invention, the specification and disclosure of
1 which is incorporated herein by reference thereto. As
described in the above-identified co-pending patent
application U.S.S.N. 08/257,800, the existing supervisor
system automatically acquires process control data from a
5 plurality of programmable and non-programmable control
devices that control and monitor various manufacturing
processes, and, automatically processes the data for real-
time display and off-line engineering analysis and quality
assurance purposes.

10 Figure 2 illustrates the hardware configuration
of the existing Supervisor system 100 interfaced with the
sterilizer monitoring node 20 and sterilizer controller 25
via ARCNET HUB network devices 99a and 99b that support
communication between the sterilizer monitoring node, two
15 operator terminals 29a,29b (preferably manufactured by
Dynaterm), and, the existing supervisor system 100.
Preferably, the sterilizer monitoring node 20 includes a
33 MHz Intel '486 computer having the following modules
for performing the sterilization monitoring process:
20 sterilization communication module and process 50,
sterilization server module and process 60, a time server
70, and a file server 80. Each of these modules will be
described in greater detail hereinbelow.

Briefly, the supervisor system 100 interfaces
25 with and obtains control parameter data from the
sterilization monitoring node, and, at least seven
programmable logic controllers that control various
contact lens manufacturing processes such as disclosed in
co-pending patent application U.S.S.N. 08/257,654 entitled
30 "Consolidated Contact Lens Molding", assigned to the same
assignee as the instant invention, the specification and

disclosure of which is incorporated herein by reference.

1 These manufacturing processes include: transferring of
injection molded front curve lens molds to carrier pallets
as controlled by PLC 31; transferring of injection molded
back curve lens molds to carrier pallets as controlled by
5 PLC 32; monomer filling and contact lens mold assembly
operations as controlled by PLC 33; the precure, UV
curing, and lens de-mold operations as controlled by PLC
34; transfer of the front curve mold halves containing
molded contact lenses to a hydration chamber for contact
10 lens hydration as controlled by PLC 35; post hydration
operations including the generation of contact lens
inspection data consisting of pass/fail results as
determined by an automatic vision system incorporated in
an automatic lens inspection station as controlled by PLC
15 36; and, the primary contact lens packaging and lens
package consolidation aspect of the lens packaging
processes including such processes as solution exchange,
saline fill, package foil heat seal, etc., which occur
about a rotary index (packaging) dial (not shown) as
20 controlled by PLC 37. An eighth PLC, may be provided for
controlling various aspects of the secondary packaging
including transfer of packages from the sterilization
chamber to a secondary packaging area where the blister
packs are labelled and sealed in secondary packaging
25 cartons as described in co-pending patent application
U.S.S.N. 08/257,788 entitled "Apparatus and Method for
Sterilization and Secondary Packaging" assigned to the
same assignee as the instant invention and, the disclosure
of which is incorporated by reference herein. Secondary
30 packaging briefly includes the steps of printing/applying
bar-coded lot-number on the carton, printing the power and

expiration date on the carton, inserting the blister
1 packages into the carton and gluing carton flaps closed,
verification of the lot number, verification of the power
and expiration date, weighing the carton, loading and
closing the case and applying the case label, and, loading
5 and completing the pallet and applying the pallet label.

In the preferred embodiments, each PLC 31-38 is
a TI system 545 (Texas Instruments) and may include a TI
386/ATM coprocessor module for communicating with the
respective PLC across the backplane or by serial link (not
10 shown). It is understood that each PLC has its own memory
and addressing capabilities for storing and updating
blocks of data.

As shown in Figure 2, other programmable device
controllers, for example, those manufactured by Yushin
15 Corp., are provided in a contact lens production line for
controlling, respectively, the front curve mold machine
39a which produces the front curve lens molds at a rate of
eight every six seconds, back curve mold machine 39b which
produces the back curve lens molds, the primary packaging
20 machine 39c for producing the contact lens packages in
which the manufactured contact lens is inspected and
packaged. Another device controller 39d controls a vision
system (not shown) that automatically inspects the contact
lenses prior to their primary packaging.

25 Furthermore, in Figure 2, the existing
supervisory control system (control system) 100 includes
five (5) types of processing nodes: a Data Acquisition
Node 205 for communicating with each of the eight (8)
programmable logic controllers (PLCs), discussed above, by
30 means of communication lines 41 and TIWAY adapter card 42,
and also, for communicating with the device controllers of

the three mold machines, and the vision inspection machine
1 by means of an 8-channel serial card 44, shown connecting
the machines by dedicated asynchronous serial lines
43a,b,c, and d; a Relational Database Node 210 which runs
relational database software 212 and includes at least
5 three 200 megabyte hard disks provide for off-line data
storage consisting of production records and long-term
data histories; an Analysis and Routing Node 220 that
contains most of the software that is used to initiate
data gathering and processing of raw data from the eight
10 PLCs, and, that maintains "real-time databases". The
analysis and routing node 220 comprises modules such as:
the Statistics Server 225 that stores data within logical
user defined groups or datasets, is capable of generating
statistics and (optional) alarms on data sets, and, that
15 support statistical control charts and other displays; a
poller 226 which coordinates the acquisition of all data
from the PLCs, Mold Machines, and the Vision Inspection
Machine; a C-language Control Server 228 which is a
companion module to the Statistics server and directs the
20 Statistics Server to perform statistical functions needed
to support active displays; and, an alarm control server
229 which handles and maintains workcell alarms, warnings,
and exceptions that are activated according to defined
conditions.

25 The supervisor system 100 further includes four
or more identically-configured Operator Stations 230 that
handle the presentation of graphs and displays for the
operators of the production line including a module 90 to
support lot information entry and lot changes, and for
30 performing contact lens lot tracking and reconciliation as
will be described below; and, an Offline Analysis Node 240

that provides for analysis of data collected into the
1 Relational Database Node after the data is no longer on-
line, i.e., after a given run of the line. As shown in
Figure 2, ARCNET interface cards 201,211,221, 231, and,
241 are provided for each respective nodes
5 205,210,220,230,and 240 to support communication between
the various nodes via the ARCNET hub 99a. In the
preferred embodiment, all of the above-mentioned servers
are standard CELLworks software that are commercially
available software modules manufactured by FASTech
10 Integration located in Lincoln, Mass.

As mentioned above in view of Figure 2, there
are three types of input sources for the existing
Supervisor Controller 100: the eight PLCs, the controllers
39a-d for the Injection Molding, Vision Inspection and
15 primary packaging machines, and, data from the
sterilization monitoring node 20. The structures of event
blocks and data blocks that the supervisory control system
100 reads from each of the eight PLCs and the Vision
Inspection and primary packaging machines are described in
20 detail in the above-mentioned co-pending patent
application U.S.S.N. 08/257,800. Additionally, as
described in detail in the above-identified, co-pending
application, a relational database is created that is used
to store production records and long-term data histories.
25 The existing supervisory controller system 100 provides
for on-line and off-line access to this database and
includes the mechanism for generating informative graphs
including, but not limited to: scattergrams of process
parameters vs. contact lens inspection results, histograms
30 of defects by position on pallet, parieto chart of alarm
count and duration by machine, time plot of cumulative

inspection results, measured and calculated parameters
1 plotted vs. time as a single trend, wherein trend fixed
time scales are available to show data over minutes,
hours, days, and weeks.

5 Sterilization Monitoring Node

As shown in the detailed hardware configuration of
Figure 3, the sterilizer monitoring node 20 interfaces
with the existing supervisory system 100 by means of an
10 ARCNET interface card 21 to provide communication with the
existing supervisor system. An 8-channel serial card 22,
receives serial data from the sterilizer controller 25
from a dedicated asynchronous serial line 16b that is
split from the main sterilizer data line output 16 (Figure
15 2). A serial port 19 is provided in the node 20 for
communication of completed lines of sterilization process
data for complete or incomplete sterilizer runs, messages
indicating that data is complete or incomplete, or, that
a sterilizer run was or was not successful, and error log
20 information and phase file information to the report
printer 18 for sterilizer run, error log, and phase file
report generation.

The sterilization monitoring process 10 to be
described in greater detail hereinbelow comprises two
25 functional modules: the sterilization communications
module 50 ("steri comm server") and the sterilization
server module 60 ("steri server"). Briefly, the
sterilizer communication server 50 functions to receive
characters generated by the sterilizer controller via the
30 8-channel serial card 22. The sterilizer server module 60
processes all of the inputs and produces reports for a

variety of users. For instance, as shown in Figure 3, the
1 sterilizer server 60 processes the information to form
sterilizer run reports for printing via serial port 19,
and, additionally, generates the sterilization run report
file, sterilizer phase report file containing sterilizer
5 phase information of the four major sterilizer phases
(heat load, exposure, cool load, and cycle complete), and,
error log file for error information all for long term
disk storage 23. Preferably, the disk storage capacity is
at least 324MB but this is easily modifiable to any
10 capacity and may constitute any data storage media. Any
alarm or process data point that needs to be immediately
acted upon, processed, or stored for later off-line
analysis is routed to the existing supervisory controller
100 via ARCNET interface card 21 and ARCNET hub 99a
15 (Figure 1). Details of the sterilization monitoring
process 10 and the sterilizer process modules 50, 60
therein will be described in greater detail below.

Sterilizer Controller

20 Figure 4 illustrates a schematic state diagram
showing the internal states of the sterilizer monitor node
20. Barring any alarm errors or communication timeout
errors, a normal sterilization run will begin after a
batch comprising a quantity ranging from about 1-14,000
25 individually primary (blister) packaged contact lenses are
loaded in the sterilization chamber, in the manner as
described in the above-mentioned co-pending patent
application U.S.S.N. 08/257,788 entitled "Apparatus and
Method for Sterilization and Secondary Packaging".
30 As shown in Figure 4, a normal sterilization run comprises
five consecutive states or phases: A START phase 161, a

HEAT LOAD phase 162, an EXPOSURE phase 163, a COOL LOAD
1 phase 164, and, a CYCLE COMPLETE phase 165.

After the node is in a start of run state 160,
which is initiated at the start of a run when the
sterilizer process hardware including the controller,
5 sterilization chamber, and process devices therein are
initialized, the START PHASE state 161, is entered for
very short duration while the sterilizer chamber
temperature is brought up to the process setpoints.
During the HEAT LOAD phase 162 the sterilization chamber
10 attains its maximum operating temperature of approximately
122.5° C., under optimal pressure conditions. In
preferred operating conditions, the HEAT LOAD phase is for
a duration of approximately five and one-half minutes (5.5
min.). During the EXPOSURE phase 163, as shown in Figure
15 4, the batch of lenses are maximally exposed to
sterilization conditions for a duration of approximately
thirty-one (31) minutes. During the COOL LOAD phase 164,
as shown in Figure 4, a drop of both temperature and
pressure conditions in the chamber is effected to enable
20 the batch of lenses to cool for a duration of
approximately ten (10) minutes. After the COOL LOAD
phase, the sterilizer enters the CYCLE COMPLETE phase 165,
where the sterilization process terminates for a time
duration of under one minute under normal conditions, and
25 a signal 167 is initiated to put the sterilizer node in a
standby or wait state 159. After this phase, the trays
containing the now sterilized lenses are positioned for
output from the sterilization chamber and the
sterilization chamber is either put in an idle or rest
30 state 159 before the next batch of contact lenses is to be
sterilized.

As shown in Figure 4, and, as explained in greater detail below, if an abnormal event (Communication timeout 168) occurs during any of the START CYCLE, HEAT LOAD, EXPOSURE, COOL LOAD, and CYCLE COMPLETE phases, the phase may be interrupted as shown by respective lines 160a, 162a, 163a, 164a, and, 165a as shown in Figure 4 to indicate that a communication timeout has occurred, i.e., the sterilizer node has not obtained any data for a specified time period, which, in the preferred embodiment, is approximately one line of data every 60 seconds. If the event that caused the timeout is rectified, signal 169 is generated to enable the sterilization monitor node 20 to again process data from the sterilizer controller 25. Since the sterilizer controller 25 was still communicating data during the timeout condition, logic built in to the algorithms explained below will direct the sterilizer node 20, via signals 161b, 162b, 163b, 164b, and 165b, to resume the sterilization monitoring process at the appropriate sterilizer phase.

20 Sterilization Monitor Processes

As shown in Figures 1 and 3, the sterilizer controller 25 provides one way communication with the sterilizer monitoring node 20 through an ASCII data stream on an RS-232 serial interface, and, the sterilizer monitoring node 20 is in two-way communication with the existing supervisory system 100 through the ARCNET hub 99a. In the preferred embodiment, during each of the above-described sterilization phases, the sterilizer controller 25 sends out one line of sterilization process readings at a frequency of preferably once per minute. If an alarm condition exists, as will be explained in further

detail below, the sterilization controller 25 will produce
1 and broadcast a line of data at a frequency of once every
two seconds.

With regard to Figures 1 and 3, there generally
illustrates the flow of data to and from the sterilizer
5 monitoring node 20 system for controlling the sterilizer
monitoring process. As mentioned above, algorithms are
implemented by each of the sterilization monitoring node
20 processing modules, i.e., the sterilization
communications server 50 and the sterilization server 60
10 to enable passive monitoring of all the data information
output from the sterilizer and, to communicate the data to
the data acquisition and analysis nodes of the existing
supervisor system 100. All information generated from the
sterilizer controller 25 is serially input to the
15 sterilization communication server 50 of the sterilizer
monitor node 20 for data acquisition. Specifically, the
sterilization controller 25 broadcasts complete lines of
serial data during each phase of the sterilization process
to the steri comm server 50. Each line of data will
20 comprise a number of characters, in the form of twelve
sterilizer process variable data, alarm information data
describing an alarm condition, or, textual information.
The steri server 60 incorporates data processing
capabilities for processing the input data acquired by the
25 steri comm server 50 to produce sterilizer run files and
reports 75, phase files and reports 85, error log files
95, etc., as will be described in greater detail below.

Additionally, as will be explained in greater
detail below, the following additional information is
30 input to the sterilizer server module 60: lot number
information which is input from the Statistics Server 225

of the existing supervisor system 100; and, time interval
1 wakeup data which is generated on a periodic basis by the
time server 70 of the sterilization node 20 for detecting
serial communication timeouts. The steri server processor
60 particularly processes this data as well as the real-
5 time raw sterilizer process measurement data, to generate
the following: a sterilization run number for storage and
subsequent reporting by the statistics server 225 (Figure
1); alarm messages, for input to the alarm control server
229 (Figure 1); sterilizer phase file data containing
10 information for each specific phase of the sterilization
process for storage in hard disk file 23 (Figure 3);
Sterilization Run Report file information, which is input
to the hard disk storage 23 for subsequent generation of
sterilizer run reports to be described in detail below;
15 and, sterilizer parameter value information which is input
to the control server 228 of the existing supervisor
control system 100 (Figure 1). Each of the above-
mentioned sterilizer data processing functions will be
described in greater detail below.

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Sterilizer Comm Process

CELLworks system is configured to execute the
steri comm server 50 when data is to be received. Figures
5(a) and 5(b) illustrate the steri comm data acquisition
25 process 50. The first step of calling the Cellworks steri
comm server 50 is to initialize the serial port hardware
as indicated as step 110. Next, at step 113 the serial
port is opened for communication and the input data buffer
(not shown) is flushed. Next, at step 115, the get_a_line
30 function is called by an infinite loop for acquiring a
line of serial data from the sterilization controller one

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character at a time. Specifically, as illustrated in
1 Figure 5(b), at the first step 124, the character count is
initialized to zero. Next, at step 126 the current
character count is compared with the size of the input
5 buffer (not shown). If the character count is greater
than the input buffer size, then an error message is
printed at step 127 and no characters are returned for
processing (step 128). As long as the character count is
less than the input buffer size, steps 131 and 133 are
10 performed for retrieving each successive character (step
131) and comparing the character to determine if it is an
end of file character (step 133). If the character is not
the end of file character, then the character is saved in
the input buffer at step 135, the character count is
incremented at step 138, and a determination is made as to
15 whether the character was an end of line character at step
140. If the character was not the end of line character,
then the process returns to step 126 to acquire the next
character. If the character was the end of line
character, then the process returns the number of
20 characters in the input line (step 141) and the line of
data is sent to the steri server's mailbox, i.e., buffer
location, at step 155 as shown in Figure 5(a). When the
current character is determined to be the end of file
character, this indicates that a serious error has
25 occurred. This may be occur when the serial line is
disconnected then reconnected. Therefor, if the current
character is determined to be the end of file character at
step 133, then, at step 144 of Figure 5(b), the serial
device is closed, reopened, and initialized. At step 145,
30 a determination is made as to whether an error occurred
when the serial port was opened. If no error has

occurred, then no characters are returned for processing
1 (step 146). If an error has occurred, then an error
message is printed at step 149 and the steri comm process
60 is aborted at step 152.

5 Sterilizer Server Process

Figure 6 illustrates the major functional blocks
of the steri server process 60 which comprises a steri
server QNX Mailbox System, indicated as element 250. The
QNX Mailbox System is the primary message routing engine
10 for the node, and, each server in the sterilizer node 20
is provided with a mailbox that accepts and sends command
or data messages. Depending upon the source of the
message, the steri server process 60 will implement either
of three functions: startCmdFunc 260; getSteriDataFromMbx
15 270; and, wakeUpCmdFunc 280, as illustrated in Figure 6
and explained in further detail below.

The CELLworks system is configured upon startup
to execute the startCmdFunc 260 when the command to start
steri server process 60 is received. This function
20 ensures that the steri server 60 and internal variables
therein are initialized and that all the QNX communication
mailboxes (not shown) are setup. Additionally, an entry
is placed in the error log file 95 (Figure 3) to indicate
that the system has started up, and, a request is made for
25 a future wake-up message from the Time Server 70 at a
prespecified time.

CELLworks is configured to implement the calling
of the getSteriDataFromMbx functional block 270 whenever
a message comprising the complete line of data from the
30 sterilizer comm process 50 appears in the Steri Server
mailbox. The getSteriDataFromMbx process 270 functions to

copy the message from the mailbox into local steri server
1 input buffer (not shown) and initiate the processing of
the message. Additionally, a check is made to determine
if the proper message line ending is present. The
getSteriDataFromMbx functional block 270 calls the
5 characterizeLine algorithm 300 for determining the nature
of the line of sterilizer data information sent from the
sterilization monitor only if the proper message line
ending is present. As will be explained below,
determining the nature of the line of sterilizer data
10 information and the processing of this data will involve
one or more of the following functions: evalTextline
indicated as block 440; processDataLine indicated as block
405; processAlarmLine indicated as block 500;
openSteriRunReport indicated as block 320; and,
15 updateAlarmStatus indicated as block 550.

As shown in Figure 7, the first step 302 of the
characterizeLine algorithm 300 is to record the current
time to aid in the detection of a possible communication
timeout. The next step 304 is to massage the line of data
20 to remove spurious printer control characters sent by the
sterilization monitor that could interfere with
characterization of the line as a line of data. Next, at
step 306, a determination is made as to if there are any
printable characters in the line and whether a sterilizer
run report file 85 has not been opened. If there are
25 printable characters in the line and a sterilizer run
report file has not been opened, then the
openSteriRunReport ("steri run report") file algorithm is
implemented at step 320.

30 The procedure for opening the steri run report
is illustrated in Figure 19, and as a redundant check the

first step 322 is to determine if the steri run report
1 file is already opened. If the steri run report file is
open the process will return to step 308 of the
characterizeLine process (Figure 7). If the file is not
open, then the following steps are performed prior to
5 opening up the steri run report file at step 330: First,
at step 324, the minimum and maximum values for each
variable of each phase of the sterilizer is initialized.
Then, at step 326, the saved start and stop times for each
phase are initialized for later calculation of phase
10 duration explained in detail below. Next, at step 328,
the initial run report file is set up with a default name
comprising the current date and time, "date_time_RPT", as
indicated. At step 330, the run report file is opened.
If it is determined at step 332 that an error has occurred
15 when opening up the report file, then, at step 334, a
retry file is set up to open every 15 minutes in the
preferred embodiment, and, at step 336, the error is
logged in the log report file. If it is determined at
step 332 that an error has not occurred when opening up
20 the report file, then, at step 338, a request is made for
the previously entered lot number to be sent to this
process from the statistics server, and the process
returns to the line characterization algorithm (Figure 7).

If a steri run report file has already been
25 opened in Figure 7, then communication timeout detection
is enabled at step 308. The algorithm then proceeds by
determining at step 310 if the line begins with a time
signature of the form:

30 hh:mm:ss (hours, minutes, seconds)

35

If the line does begin with such a time signature, then
1 the processDataLine algorithm is invoked at step 405
indicating that the data line contains process variable
data including twelve (12) variables of sterilizer phase
data. Else, at step 312, a determination is made as to
5 whether an alarm condition exists. If an alarm condition
exists, then the processAlarmLine algorithm is invoked at
step 500 for processing the alarm data and updating the
alarm control server of the existing supervisor system
10 100. If the line of data is determined to be textual in
nature, then the evalTextLine algorithm is invoked at step
450, for processing the text data. Whenever the
processing of an incoming line has been completed, the
updateAlarmStatus process is called at step 550 to the
check whether the alarm status has changed.

15 Figure 8 illustrates the processDataLine
algorithm 405 for processing the twelve (12) variables of
sterilizer phase data from the data line. After removing
any other remaining printer control characters from the
line at step 407, the line of data is added to the steri
20 run report at step 409. Next, the getDataLinetime
algorithm is invoked at step 410 to ensure that, for each
of the five sterilizer phases, the start time of the
current operating phase in addition to the phase stop time
of the previous sterilizer phase has been recorded in the
appropriate phase file. Next at step 412, the 12 process
25 variable values of the current data line are isolated and
saved as text. Then, the convertAndDoMinMax algorithm is
called at step 420 for converting each of the sterilizer
process readings from text format to floating point
30 format, and, updating the maximum and minimum values for
each of the twelve variables for the current sterilizer

phase. At step 425, it is determined if it is time to
1 update the variables in the phase files. If not, the
process returns to the characterizeLine algorithm as
indicated at step 427. If it is time to update the
variables, then at step 430, a message will be formulated
5 and sent to the control server 228 of the existing
supervisor control system 100 to make the twelve floating
process variables available for display, trending, and
inclusion in the engineering database (not shown) in the
manner as explained in detail in the above-mentioned co-
10 pending patent application U.S.S.N. 08/257,800. A
determination is then made at step 435 whether the current
sterilizer phase is in the heat load, exposure, cycle
complete or cool load phase. If the sterilizer is in one
of these phases, then the makePhaseFileEntry process is
15 called at step 440. If the sterilizer is not in one of
these phases, then a return is made to the calling
characterizeLine algorithm 280.

As shown in Figure 9, the makePhaseFileEntry
process 440 is called from the Process Data line algorithm
20 405 to format the process variable information for entry
as a line in the corresponding phase file. In the
preferred embodiment, there is a separate phase file on
disk for each of the four major sterilizer phases. When
a new entry is made, it is added to the end of the
25 appropriate phase file as follows: First, at step 445, it
is determined if process data has been obtained from the
start of the sterilizer run. If not, then the process
will return to the processDataLine algorithm at step 446.
If the current phase has started from the start cycle,
30 then the following information is gathered in line format:
the current lot number at step 448; the sterilizer run

number at step 451; the date at step 452; the time at step
1 454; an indicator to convey whether an alarm condition
currently exists or not at step 456; and, the current
twelve process values for the current sterilizer run at
step 458. Finally, at step 460, the entire line is
5 written to the current phase file.

Figure 31 illustrates the format of the above
described entries of a phase file 876 for storing
sterilizer phase information. Each row in the table of
Figure 31 illustrates represents one entry in the phase
10 file. The lot numbers are entered by the operators on the
operator stations 230 (Figure 1) of the supervisory
controller, and, the "mode" entry is a single character
designation of whether the sterilizer controller indicated
an alarm at that time or not.

15 Returning to the characterizeLine algorithm 300
as shown in Figure 7, if the data obtained from the
sterilizer controller is not alarm data or process
variable data, then the evalTextline is called at step 450
to process the line of text.

20 Figures 10(a) and 10(b) illustrate the
evaluateTextline process 450 for processing textual data
from the input data line. The first step 461 of the
evaluate text line process is to remove any remaining
printer control characters from the line, and, at step
25 462, adding the line to the steri run report. A
determination is made at step 463 if the text indicates
the start of a sterilizer run. If so, then a
StartOfRunEvent procedure is called at step 465 to perform
the following steps as shown in Figure 11: First, at step
30 467, an entry into the error log 95 (Figure 3) is made
indicating that the sterilizer run has started. Then, at

step 468, a flag is set to indicate that the current run
1 has started from the beginning (start of sterilizer run)
and, at step 469, that the current state is the start of
run state. Next, at step 470 of Figure 11, a message is
sent to the control server of the existing supervisor
5 system that the current state of the sterilizer is the
start of run state and the process returns to characterize
the next line of data (Figure 7).

In Figure 10(a), if the text did not indicate
the start of a sterilizer run at step 463, then, at step
10 464, a determination is made if the text indicates the
beginning of the start phase. If the text indicates the
beginning of the sterilizer start phase, then the
doStartPhaseEvent procedure is called at step 465 to set
a flag that the current state is the sterilizer start
15 phase, and, to send a message to the control server of the
existing supervisor system that the current state is the
sterilizer start phase state before returning to
characterize the next line of data (step 550, Figure 7).

If the text did not indicate the beginning of
20 the sterilizer start phase at step 464, then, at step 471,
a determination is made if the text indicates the
beginning of the sterilizer heat load phase. If the text
indicates the beginning of the sterilizer heat load phase,
then the doHeatLoadPhaseEvent procedure is called at step
25 472 to set a flag that the current state is the sterilizer
heat load phase, and, to send a message to the control
server of the existing supervisor system that the current
sterilizer state is the heat load phase. Additionally,
the HeatLoad phase file is opened for writing data thereto
30 and the procedure returns to characterize the next line of
data.

If the text did not indicate the beginning of
1 the heat load phase at step 471, then, at step 473, a
determination is made if the text indicates the beginning
of the sterilizer exposure phase. If the text indicates
the beginning of the sterilizer exposure phase, then the
5 doExposurePhaseEvent procedure is called at step 474 to
set a flag that the current state is the sterilizer
exposure phase, and, to send a message to the control
server of the existing supervisor system that the current
state is the sterilizer exposure phase. Additionally,
10 before returning to characterize the next line of data,
the Heat load phase file is closed and the Exposure phase
file is opened for writing the data thereto.

If the text did not indicate the beginning of
the sterilizer exposure phase at step 473, then, at step
15 475, a determination is made if the text indicates the
beginning of the sterilizer cool load phase. If the text
indicates the beginning of the sterilizer cool load phase,
then the doCoolLoadPhaseEvent procedure is called at step
476 to set a flag that the current state is the sterilizer
20 cool load phase, and, to send a message to the control
server of the existing supervisor system that the current
state is the sterilizer cool load phase. Additionally,
before returning to characterize the next line of data,
the Exposure phase file is closed and the Cool load phase
25 file is opened for writing the data thereto.

If the text did not indicate the beginning of
the sterilizer cool load phase at step 475, then, at step
477, a determination is made if the text indicates the
beginning of the sterilizer cycle complete phase. If the
30 text indicates the beginning of the sterilizer cycle
complete phase, then the doCycComp1PhaseEvent procedure is

called at step 478 to set a flag that the current state is
1 the sterilizer cycle complete phase, and, to send a
message to the control server of the existing supervisor
system that the current state is the sterilizer cycle
complete phase. Additionally, before returning to
5 characterize the next line of data, the Cool load phase
file is closed and the Cycle Complete phase file is opened
for writing the data thereto. Then, the process returns
to step 550, Figure 7 to characterize the next line of
data.

10 If the text did not indicate the beginning of
the sterilizer cycle complete phase at step 477, then, at
step 479, a determination is made if the text indicates
the end of the sterilizer run. If it is the end of a
sterilizer run, then a doEndOfRunEvent procedure is called
15 at step 480 to perform the following steps as shown in
Figure 12. First, at step 481 of Figure 12, an entry is
made in the error log that the sterilizer run has ended.
Then, at step 482, a flag is set to indicate that the
current state is the end of run state. Next, at step 483
20 of Figure 12, the Cycle Complete phase file is closed. At
step 484, the time of the most recent data line is saved
as the stop time for the Cycle Complete phase. Then, at
step 485, the finishSteriRunReport procedure is called to
generate the sterilizer run report as will be explained in
greater detail below. Another procedure indicated as the
25 doEndOfRunCleanup is performed at step 486 to finish the
text line processing and print the steri run report as
explained in greater detail below. Finally, at step 487,
since it is not known when the next sterilizer run will
30 begin, the communication timeout detection is disabled.

Referring back to Figure 10(a), if the text did

not indicate the end of the sterilizer run at step 479,
1 then, at step 488, Figure 10(b), a determination is made
if the current text line indicates the date. If the
current line does indicate the date, then the date is
saved at step 489 and the process returns to the evaluate
5 text line procedure. If the current line does not
indicate the date, then, at step 490, a determination is
made if the current text line contains the cycle count.
If the current line does contain the cycle count, then the
count is saved at step 491 and the makeSteriRunNumber
10 procedure is called at step 492 for building the
sterilization run number and sending the sterilization
number to the control server of the existing supervisor
system. In the preferred embodiment, the sterilization
run number is put together as a combination of the date,
15 sterilizer number, and the sterilizer cycle count and is
of the form:

YP1NNNN

where Y is the last digit of the year, P1 is the
sterilizer number of the production line, and, the NNNN is
20 the sterilizer cycle count. After the sterilization run
number is obtained, the process returns to the line
characterization algorithm.

If the current line does not contain the cycle
count, then nothing is done with the line as indicated as
25 step 494, and the process returns to the calling
characterizeLine algorithm (step 550, Figure 7).

Figure 13 illustrates the processAlarmLine
algorithm 500 for processing alarm data from the serial
data line. After removing any other remaining printer
30 control characters from the line at step 502, a list of

known alarm phrases is searched at step 505 to indicate if
1 a known alarm condition exists. Table 1 and Table 2 below
indicates various alarm phrases and alarm code data:

	Alarm Text from Sterilizer Controller	Alarm Code
5	CLEAN STEAM LOW	1
	COLD WATER LOW	2
	COMP. AIR LOW	3
10	CYCLE ABORT	4
	DOORS NOT CLSD	5
	DOORS NOT SEALED	6
	FAN FAILURE	7
15	HIGH TEMPERATURE	8
	HIGH WATER	9
	LOW TEMPERATURE	10
20	OVER PRESSURE	11
	PLANT STEAM LOW	12
	POWER FAIL	13
	PRES SENS. ERROR	14
25	PT ISOLATED	15
	SAM FAILURE	16
	STEAM FAILURE	17
30	TEMP SENS. ERROR	18

35

1	UNDER PRESSURE	19
	unknown alarm: this code used when there is alarm text that is not recognized	999

5	Condition Detected by Sterilizer Monitor Server	Alarm Code
	Communication timeout with sterilizer controller	01

10 If the alarm condition is unknown, i.e., a match
is not found between the alarm data phrase and the alarm
phrase table at step 507, then, at step 508, a
communication is made to the alarm control server of the
existing supervisor system that an unknown alarm has been
received and an active alarm condition is recorded. The
15 process then proceeds to step 515 to add the alarm line to
the steri run report. If a known alarm condition exists,
i.e., a match is found between the alarm data phrase and
the alarm phrase table at step 507, a determination is
made at step 509 if the alarm indicates a successful run.
20 If the indicator is a successful run alarm, it is recorded
at step 511 and the alarm line is added to the steri run
report at step 515. If the indicator is not a successful
run alarm, then, at step 513, a communication is made to
the alarm control server of the existing supervisor system
25 which alarm condition has occurred and it is recorded that
an active alarm condition exists. Finally, at step 515
the alarm line is added to the steri run report and the
process returns to the calling characterizeLine algorithm.

30 As mentioned above in view of Figure 7
illustrating the characterizeLine algorithm, after a line

is characterized and process variable data, alarm data, or
1 textual data information is processed, the alarm status is
updated by invoking the `updateAlarmStatus` process at step
550. Figure 14 illustrates the `updateAlarmStatus` function
in detail. The first step, indicated as step 552, is to
5 determine the status of a parameter (not shown) that is
supplied indicating if any alarm from the sterilizer
controller is currently active, and, sending data lines
every two seconds as described above. If so, then at step
554, a determination is made whether there is enough time
10 to clear the alarm or whether the currently active alarm
should be cleared by force. If not enough time has
elapsed to clear the alarm, i.e., if the time between the
last sterilizer data entry and the previous data entry is
two (2) seconds indicating that the alarm condition should
15 be cleared by force, then, at step 556, the current
sterilizer alarm state is set to indicate that no steri
alarms are active. If there is enough time to clear the
alarm, i.e., the time between the last sterilizer data
entry and the previous data entry is greater than two (2)
20 seconds indicating that the alarm condition data is not to
be cleared by force, then a determination is made at step
559 if a communication timeout alarm is active and if
recent data has been input. As mentioned above, a
communication timeout alarm occurs when data is received
25 at an interval greater than one minute, for e.g., when the
serial data line is temporarily disconnected. If a
communication timeout alarm is active and recent data has
been input, then at step 561, the current communication
alarm state forced to indicate that no communication
30 alarms are active and is set to provide such indication.
If a communication timeout alarm is not active or, recent

data has not been input, for e.g., end of a run, a
1 determination is made at step 563 if all alarms are
cleared. If all alarms are currently cleared, then at
step 565, a message is sent to the alarm control server of
the existing supervisor system to reset all sterilizer
5 related alarms. Else, if all alarms are not clear the
program returns to the calling characterize line process.

Referring back to Figure 12, at step 485, the
finishSteriRunReport procedure 485 is invoked when the end
of a sterilizer run is detected. As shown in Figure 15,
10 the first step 610 of the finishSteriRunReport procedure
is to determine if the flag to indicate that the current
run has started from the beginning (start of sterilizer
run) had been set as indicated above with respect to step
468, Figure 11. If the flag indicating that the cycle has
15 started from the beginning of the sterilization run is not
set, then, at step 612, a line is added to the
sterilization run report indicating that the data is
incomplete, and, at step 614, an entry is made to the
error log indicating that the data is incomplete. The
20 process then resumes to step 617. If the flag indicating
that the cycle has started from the beginning of the
sterilization run is set, then, at step 611, the
sterilization run number is added to the steri run report.
Next, at step 613, a determination is made as to whether
25 any of the four major sterilization phases has been
missed. If any of the four sterilization phases has been
missed in the current run, then a line is added to the
sterilization run report indicating that the data is
incomplete (step 612), and, an entry is made to the error
30 log indicating that the data is incomplete (step 614). If
none of the four sterilization phases has been missed in

the current run, then, at step 615, a line is added to the
1 sterilization run report indicating that the data is
complete. The next step, indicated as step 617 in Figure
15, is to determine if the sterilization controller issued
a successful run alarm indicating a valid cycle as
5 described above at step 511, Figure 13. If a successful
run alarm indicating a valid cycle has been generated by
the sterilization controller, then, at step 619, a line is
added to the sterilization run report indicating that the
run was successful. If a successful run alarm indicating
10 a valid cycle has not been generated by the sterilization
controller, then, at step 621, a line is added to the
sterilization run report file indicating that the run was
NOT successful. Finally, at step 630, a procedure is
called to add the time durations for each of the major
15 sterilization phases to the steri run report file, and, at
step 640, a procedure is called to add the minimum and
maximum values of the process variables for each of the
major sterilization phases to the steri run report file.

The addDurations procedure 630 of the
20 finishSteriRunReport procedure begins by adding the Phase
Duration header line of the sterilization run report as
indicated as step 631 of Figure 17. Next, a pointer is
set to the first of the four major phases, as indicated at
step 632. The following steps indicate the printing of
25 phase durations: At step 633, a label for the phase
duration is obtained; then, at step 634, the phase
duration is calculated using the saved phase start and
stop times obtained at step 326 of the openSteriRunReport
algorithm (Figure 19). Next, a determination is made at
30 step 635 as to whether the phase duration values for all
four major sterilizer phases have been processed. If the

phase duration values for all four major sterilizer phases
1 have been processed, then, at step 636, the resulting line
having the calculated phase durations for each of the four
major sterilizer phases is added to the steri run report
file and the program returns to step 640 of the
5 finishSteriRunReport procedure (Figure 15). If the phase
duration values for all four major sterilizer phases have
not been processed, then steps 633 and 634 will be
repeated for each successive phase pointed by the pointer
as indicated at step 638 of Figure 17.

10 The addMinMax procedure 640 called by the
finishSteriRunReport procedure begins by adding the
Min/Max header line to the sterilization run report file
as indicated as step 641 of Figure 18. Next, as indicated
at step 642, a line containing the twelve variable names
15 are added to the run report file. Then, a pointer is set
to the first of the four major phases, as indicated at
step 643a. For each phase, a line for the minimum
readings and a line for the maximum readings are to be
added to the file. The following steps indicate the
20 printing of minimum and maximum readings: at step 644, a
label for the phase's minimum values is added at the
beginning of a first line of the file; then, at step 645,
a line containing the twelve minimum values for the
variables for this phase are added; at step 646, the
25 resulting line of minimum values is added to the steri run
report file; at step 647, a label for the phase's maximum
values is added at the beginning of a second line of the
file; then, at step 648, a line containing the twelve
maximum values for the variables for this phase are added;
30 and, at step 649, the resulting line of maximum values is
added to the steri run report file. Next, a determination

is made at step 650 as to whether the Min/max values for
1 all four major sterilizer phases have been added to the
steri run report file. If the Min/max values for all four
major sterilizer phases have been printed, then the
process returns to step 486 of the doEndofRunEvent
5 procedure for printing of the sterilizer phase durations.
Until the Min/max values for all four major sterilizer
phases have been printed, step 644 through step 649 will
be repeated for each phase pointed to by the pointer as
indicated at step 643b of Figure 18.

10 Finally, after performing the addDurations and
addMinMax values, a return is made to the doEndofRunEvent
procedure 480 where the doEndOfRunCleanup procedure is
performed at step 486, as indicated in Figure 12.

Figure 16 illustrates the doEndOfRunCleanup
15 procedure 486. As shown at step 651, this procedure
implements the closeAndPrintRunReport procedure for
closing and printing the sterilization run report, as
described in further detail below with respect to Figure
20 steps 660 through 669. Furthermore, the
doEndOfRunCleanup procedure of Figure 16 will: initialize
20 all internal variables to no-run-in-progress conditions at
step 652; invoke the update alarm status procedure at step
653 and as described above with respect to Figure 14 steps
552 through 565; close the error log at step 654; and, at
25 step 655, communicate to the control server that the
sterilizer is currently in a standby or waiting state.
Finally, a return is made to step 487 of the
doEndofRunEvent procedure of Figure 12.

As illustrated in Figure 20, to close and print
30 the sterilization run report, the first step 660 is to
close the run report file. As mentioned above, if a

sterilizer cycle was determined to be incomplete, a
1 sterilizer run number may not have been obtained for the
incomplete run. Therefore, at step 662, a determination
is made if a sterilization run number has been obtained
for this run. If a sterilization run number has been
5 obtained for this run, then, at step 665, a new run report
name is configured that will preferably comprise the
sterilization run number followed by an underscore and the
lot number. At step 667, the run report file is renamed to
the new configuration. Finally, the run report file is
10 printed at step 669. If a sterilization run number had
not been obtained for this run, then, at step 663, an
entry is placed in the error log indicating that there is
no steri run number and the run report file is printed at
step 669 with the default file name which is initially
15 assigned as comprising the date and time as described
above with respect to step 328, Figure 19. After the run
report file is printed at step 669, the process returns to
step 652 of the doEndOfRunCleanup procedure 486 (Figure
16).

20 The printed sterilizer run report 800 for a
valid and complete run, as shown in Figure 23, and printed
by the printer 18 connected to the node 20, consists of:
the updated steri run report file name comprising the
sterilization run number followed by an underscore and the
25 lot number, as indicated as line 810; heading data,
indicated as lines 815, that includes: the date and time
a sterilizer run begins, lines 816a, 816b, respectively;
the name and number uniquely identifying the sterilizer,
lines 817a, 817b, respectively; a cycle counter number to
30 uniquely identify the sterilizer run, line 818; twelve
sterilizer process parameters, indicated as lines 819, of

which the Expose Timer therein indicates the target value
1 for the duration of the Exposure Phase; the program 822
which indicates the control program in the sterilizer
controller; and, the proptime, 824, indicating the column
headings for the output data lines, indicated as lines
5 825, that are sent to the existing supervisory controller
100 and sterilizer monitoring node 20 by the sterilizer
controller 25. Each of the data lines 825 additionally
include the time relative to the start of the run,
followed by a reading for each of the twelve signals
10 described in the header. Also provided are: the
sterilization run number indicated as line 812; the lines
of variable data for twelve process variable data labelled
V1-V12 and generated once every minute; the durations for
the four major sterilization phases, indicated as line 835
15 with label header line 830; the minimum and maximum
readings observed for each sterilizer variable during each
of the four major sterilization phases, as indicated as
lines 845, with a header line 840; the sterilization run
success failure assessment, indicated as line 850; and, if
20 all data has been received for the four sterilization
phases, i.e., for the current run, then the line 855
indicating that the data is complete. Additionally, a
line 805 for placing the signature of an operator or
engineer is provided in the steri run report. Alarm
25 information (for e.g., fan failure) may also be printed by
the sterilizer controller and any alarm text is printed on
a line by itself. The sterilizer controller will surround
the alarm text with printer control codes that cause the
text to be printed in red.

30 Although not shown, the dedicated printer 17
(Figure 1) will print out a sterilization run report

similar to the report shown in Figure 23 directly from the
1 sterilizer controller via serial data line 16a. However,
the report printed by dedicated printer 17 will not have
the phase duration and minimum/maximum value summaries,
and success/failure indications as provided in the
5 sterilizer run report generated by the sterilizer
monitoring node.

Figure 21 illustrates in detail the
wakeUpCmdFunc process 280, which is a software function
that is executable whenever the Time Server 70 (Figure 3)
10 sends a wakeup message to the Steri server process 60. As
illustrated in Figure 21, the first step 281 of the
wakeUpCmdFunc process is to request the time server to
send to the steri server 60 another wakeup message at a
specified time in the future. It is understood that this
15 is not a continuous process and that the time server 70
must be requested to send a wakeup message to the steri
server. The next two steps, indicated as steps 283 and
284 are to indicate if a communication timeout has
occurred. Specifically, at step 283, a determination is
20 made as to whether the steri server is initialized, the
timeout detection function is enabled, and that there is
currently no communication timeout alarm that is active.
If any of these conditions do not exist, then the process
will return to the CELLworks system as indicated at step
25 285. If all these conditions exist, then at step 284, a
determination is made as to if an undue amount of time,
for e.g., greater than one (1) minute, has elapsed since
the last receipt of data. A condition such as this would
occur if the serial data line has been temporarily
30 disconnected. If the amount of time since the last data
receipt is not excessive (not greater than 1 minute), the

process will return to the CELLworks system as indicated
1 at step 285. If the amount of time since the last data
receipt is excessive, then, at step 286, a communication
timeout alarm is indicated as active. Then, at step 287,
a communication timeout alarm message is sent to the alarm
5 control server of the existing supervisor system.
Additionally, at step 288, a communication timeout alarm
entry is made in the error log. Next, at step 290, an
endRunReportForTimeout process is called as illustrated in
Figure 22 and described in detail as follows: First, at
10 step 291, a determination is made as to whether a
sterilizer run report file is currently open. If a
sterilizer run report file is not currently open, then the
process returns to step 295 of the wakeUpCmdFunc process.
If a sterilizer run report file is currently open, then,
15 at step 292, a line is added to the run report file
indicating that a communication timeout has occurred, and,
at step 293, that there is incomplete run data for the
current sterilizer run. At step 294, an entry is made in
the error log that the run data is incomplete and the
20 process returns to step 295 of the wakeUpCmdFunc process
of Figure 21. At step 295, the doEndOfRunCleanup
procedure is called as described above with respect to
Figure 16. Finally, the communication timeout enable
function is disabled at step 296 and, at step 297, any
25 phase file that is currently open, is closed before
returning to the wakeUpCmdFunc process.

Lot Tracking and Reconciliation

As shown in Figure 2, lot number and power for
30 the lenses to be produced will be input by operators at
any of the four operator stations 230 located along the

production line. Then, the lot reconciliation and
1 tracking algorithms 90 that are resident at the stations
are implemented for calculating and recommending the
expiration date, lens center thickness, and other
variables for lot information storage. In the preferred
5 embodiment, the expiration date is sixteen months from the
entered system date, but the number of months may change
and the algorithm is easily modifiable by skilled
artisans.

As indicated in process flow diagram of Figure
10 24, an operator will first be queried to enter his/her
name and password as shown as step 671 which are then
verified at step 672 by the password files of authorized
individual names and passwords residing in the data
analysis node (not shown). Using the operator entry of
15 lens lot number, power value information and the current
date information at the operator stations, the lot
tracking and reconciliation algorithm 90 is implemented.
Specifically, at step 673, the entered lens lot number is
retrieved and the format of the lens lot number is
20 verified. From the verified lot number which contains a
digit that signifies whether the lot is for revenue or
trial ("R/T"), a determination is made at step 674 as to
whether the lot will be for revenue or trial. Next, at
step 675, the entered lens power value is retrieved and
25 the validity of the power factor is verified. A
determination as to whether the power factor is valid is
made at step 676. If not a valid power factor, the
operator is prompted to enter a new power factor for
validation (step 675). If the power factor is valid, the
30 algorithm will use look-up tables (not shown) to determine
the product code ("UPC") and lens center thickness

information for the lot at step 677. It should be
1 understood that the lot number, power value information,
lot expiration date, product code and other entries may be
displayed at the front of the production line, as shown at
step 678, and, at any of the operating stations until the
5 product reaches primary packaging. Additionally, the lot
number, power value information and other entries may be
changed until the lots product reaches primary packaging.

To aid in tracking lot movement, lot
reconciliation, and lot changeover procedures, a display
10 is available at either an operator station or a DynaTerm
display station 29a,b at the sterilizer node to enable an
operator to request for display in formatted fields, the
stored or previously entered lot number data including lot
number, product code, lens power, lens center thickness,
15 expiration date, whether the product is for revenue or
trial, as well as the current location of the lot on the
line. As will be explained in further detail below,
besides displaying the previous-entered information, the
sterilization run number, as provided by the Sterilization
20 server 60 of the sterilization node 20, may also be
displayed. It is understood that the each operator
station shown in Figure 2 has a specialized CELLworks
program for obtaining operator requests and displaying
information to the operator in formatted fields.

25

Lot Tracking

As mentioned above, an operator is capable of
sequencing the lot to the next part of the line. When the
lot enters production, six variables representing lot
30 number information are stored in the Statistics Server of
the existing Supervisory control system 100. These

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variables are lotnumber, UPC, R/T, Power, Thickness, and
1 Expiration and is shown having the data structure as shown
in Figure 25(a). Depending upon the manufacturing zone
where the lot is located, each data structure for the lot
is tagged with an "0" or "F" to respectively signify
5 whether the lot is prior to line, or, is at the front of
the line (injection molding, lens fab, cure, demold, etc.)
prior to packaging. When a lot starts into primary
packaging, the data structure of Figure 25(a) is tagged
with a "P" to signify that it is in packaging. When the
10 lot of lenses are in the tray loading area, sterilization,
or secondary packaging areas, the Statistics server 225
will store two additional variables onto the data
structure of Figure 25(a) to form new data structure as
shown in Figure 25(b). These variables are the input
15 quantity and loss quantity and are supplied to the system
during lot reconciliation. When a lot starts into the
sterilizer tray loader area, the variables are tagged with
an "L", and when the lot enters the sterilizer they are
tagged with an "S". When a lot enters secondary
20 packaging, the six lot information variables are tagged
with a "C" to signify cartooning. Thus, the feature of
the present invention is the ability for an operator to
track movement of a particular lot.

As shown in the data flow diagram of Figure 26,
25 an operator may request movement of a lot by inputting
data such as the requested lot 875 being processed on the
line, and, to which location 880 on the production line to
which the lot is to be moved. A moveLot algorithm 680 is
implemented which will process the operator entered data,
30 as well as lot information data such as: lot number 881,
product code 882, power 883, lens center thickness 884,

expiration date 885, whether the product is for revenue or
1 trial 886, and, total lens input to the particular
location of the line 887 and the total lenses lost 888 (as
will be explained below).

Figure 27 illustrates the moveLot algorithm 680
5 for tracking lens lot movement throughout the production
line. As shown as step 680 in Figure 27, the source
location of the lens lot on the production line is
retrieved. Next, at step 683, a determination is made as
to whether the lot number is to be changed, for instance,
10 when a lot is to be split prior to entry in the sterilizer
15 as a preventative measure to eliminate defective
batches rather than a whole lens lot when there exists a
problem in the line. If the lot number is not to be
changed, then, at step 685, the lens lot and lot
15 information data such as: lot number, product code, power,
lens center thickness, expiration date, and whether the
product is for revenue or trial, is moved to the next line
location and tagged with a "P", "L", "S" or "C" indicator
depending at which point on the line the lens lot has
20 moved to. If the lot number is to be changed, then, at
step 687, the lens lot number is retrieved from the
operator and the format of the lens lot number is verified
at steps 689 and 690. If the entered lot number is not
valid, the operator is prompted to enter a new power
25 factor for validation (step 687). If the lot number
entered is valid, the algorithm will proceed to update the
above-identified lot information at step 692.

Lot Reconciliation

30 Due to the fact that product may be lost during
manufacture, or, may be removed for quality assurance

purposes, it is necessary to account for this product and
1 the reasons for their loss or removal prior to secondary
packaging. Lot reconciliation is the process whereby each
lens of a particular lot that leaves primary packaging,
hereinafter indicated as Zone 1, and enters sterilization
5 (sterilization tray loading), hereinafter indicated as
Zone 2, is accounted for at the time that the lot is
available for secondary packaging, (i.e., sterilization
tray unloading, cartooning, check weighing, and
labelling), hereinafter indicated as Zone 3.
10 Particularly, a lot reconciliation sheet 890, illustrated
in Figure 32, is generated that will indicate the number
of lenses input to the sterilizer (line 891) and number of
lenses available for secondary packaging (lines 899) as
well as verify the difference that is equal to the number
15 of lenses that have been lost or removed at each
particular zone (lines 892,893,894 and 895). The lot
tracking and reconciliation algorithm 90 in the existing
supervisor control system 100 supports data entry and
calculations for Lot Reconciliation.

20 Figure 28 illustrates the start of the lot
reconciliation process which entails the reporting of the
quantity of lenses input to the sterilizer 15 after
primary packaging. Before this quantity could be entered
at the operator terminals 230 or the DynaTerm Operating
25 consoles 29a,b (Figure 2), a determination is made at step
702 to determine whether the lot has cleared from primary
packaging, i.e., have been packaged in blister packs and
readied for sterilization. If not, then an error message
will be displayed at step 704 that an input quantity can
30 not be entered until the lot has cleared primary packaging
(Zone 1). If the lot has cleared primary packaging, then

the operator is prompted to enter his/her initials and the
1 actual quantity of lenses ready for sterilization at step
705. Next, at step 706, the lot information is updated to
reflect the new variable, quantity input, with the lot
number.

5 Just as a number representing the quantity of
lenses entering sterilization is entered, the number of
lenses removed from the sterilization (Zone 2) and
secondary packaging (Zone 3) areas must be recorded and
entered. As shown in Figure 29, at steps 710 and 720, an
10 operator may enter the number of product lost, the
particular zone where the product was lost, the reasons
why the product was lost or removed, and, the
sterilization run number, all at the operator terminals or
the DynaTerm Operating consoles. This information is all
15 referenced with a particular lot number that is input from
the sterilization server. This process may be repeated
several times while a lot is in one zone, for e.g., when
there are multiple incidents of lost lenses while in the
zone.

20 Specifically, at step 710, the zone number for
the current lot location is retrieved and a verification
is made at step 713 as to whether the zone number is
valid. If not, then the operator will be prompted to
enter the a correct zone number. If the lot number is
25 valid, then a determination is made at step 716 as to
which zone number was entered. If the current lot is in
Zone 2 or 3, then the operator is prompted to enter the
Sterilization run number at step 718 before entering the
number of lenses removed at step 720. If the current lot
30 is in Zone 1, then the operator is prompted to enter the
number of lenses removed at step 720. In response to

entering the number of quantity removed, at step 723, the
1 operator station or Dynaterm displays a reason selection
list for the operator to enter the particular reason(s)
why the lens packages were removed from production at step
725. As there may be multiple sterilization runs per lot,
5 product may be lost for a number of reasons per
sterilization run. Look-up tables (not shown) having
reason codes and their definitions are available on each
of the operator stations or DynaTerm consoles. Table 2
below details some of the reasons for lens removal:

10	REASON CODE	DEFINITION
	01	Removed_by_QA
	02	Lenses_to_Distribution
15	03	Foil_Tear_Mechanical
	04	Foil_Tear_Foil_Size
	05	Incorrect_Power_on_Foil
	06	Incorrect_Expiration_Date_on_Foil
20	07	Illegible-Print_on_Foil
	08	Misaligned_Print
	09	Misaligned_Foil
25	10	Misaligned_Perforation
	11	No_Solution
	12	Low_Solution
30	13	Incorrect_Lot_Number_on_Foil

1	14	Incomplete_Seal
	15	Perforation_Tear
	16	Blown_Seal/Package
5	17	Barcode_Not-Printed_In_Proper-Place
	18	Lot_Number_Not_In_Brackets
	19	Incorrect_#_Digits_in_Lot#_Barcode
	20	Incorrect_#_Digits_in_UPC_Barcode
10	21	Invalid_Barcode#_(Lot Number)
	22	Invalid_Barcode#_(UPC)
	23	Incorrect_Check_Digit
15	24	Spots_On-Barcode
	25	Void(s)_On_Barcode
	26	Low_Grade_Barcode_Scan_Verification
	27	Excess_Glue
20	28	Tabs_Unsealed
	29	Tabs_Unparallel
	30	Ink_Smears_Carton
25	31	Damage_To_Carton
	32	Foreign_Matter
	33	Cartoner_Rejected_at_Checkweigher
	34	Misaligned_Label
30	35	Print_Out_of_Shaded_Area_Carton

1	36	Incorrect_Case_Label_Info
	37	Jam_Array_Destroyed
	38	Cartoner_Jam_Carton_Destroyed
5	39	Conveyor_Transfer_Jam_Carton_Destroyed
	40	Jam_into_Belt_Array_destroyed
	41	Jam_out_of_Belt_Array_Destroyed
	42	No_Print_Foil
10	43	No_Perf_Foil
	44	Extra_Lens
	60	Supply_Your_Own_Reason

15 At step 727 in Figure 29, a determination is made as to whether the selection is made from the list displayed on the operator station, or, whether the operator entered a new reason for lens package removal. If the selection is made from the displayed list, then the
20 operator is prompted to enter his/her initials at step 731. If the operator entered a new reason for lens package removal, the description entered by the operator, which may be up to 34 characters, is retrieved at step 729
25 prior to operator initials entry at step 731. The next step 735 updates the lot reconciliation data which has the data structure depicted as shown in Figure 25(b) explained above.

30 After secondary packaging is complete, the last action to be performed during lot reconciliation is to close out the lot as shown in the process flow diagram of

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Figure 30. As shown in Figure 30, an operator will first
1 be queried to enter his/her name and password as shown as
step 740 which are then verified at step 742 by the
password files. The updated lot information data is
retrieved at step 745 and a determination as to if the lot
5 has cleared the prior zone is made at step 747. If the
lot has not cleared the prior zone, then an error is
reported at step 749 and the lot will not be closed out.
If the lot has cleared the prior zone, then the master lot
(or split lot) information is obtained by operator entry
10 at step 751. Then, at step 754, lot reconciliation
calculations are performed to total number of lenses lost
or removed. Next, at step 756, a determination is made
if the total number of lens packages lost or removed is
greater than the total number of lens packages input. If
15 the total number of lens packages lost or removed is
greater than the total number of lens packages input then
an error message is reported at step 758. If the total
number of lens packages lost or removed is greater than
the total number of lens packages input then a
20 determination is made at step 759 whether the total lost
or removed is more than one percent (1%) of the total
number input. If the total number of lens packages lost or
removed is greater than one percent, then an error message
is reported at step 761. If the total number of lens
25 packages lost or removed is less than one percent, then a
determination is made at step 764 whether the total lost
or removed is equal to or less than one percent of the
number of lenses input. If the lens package quantity
input equals the quantity output, then the lot is closed
30 out at step 768. If the total number of lens packages
lost or removed is less than one percent of the quantity

input, then the total loss of less than one percent is
1 reported to the operator at step 769, and the operator is
prompted for closure action at step 771. If the operator
elects to close the master lot (or split lot) at step 771,
then the master lot (or split lot) is closed at step 768.
5 Then, a lot reconciliation report is created for storage
and printing as indicated at step 775.

While the invention has been particularly shown
and described with respect to the preferred embodiments
thereof, it will be understood by those skilled in the art
10 that the foregoing and other changes in form and details
may be made therein without departing from the spirit and
scope of the invention, which should be limited only by
the scope of the appended claims.

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WE CLAIM:

1 1. A quality control system for an automated
production line producing contact lenses, said production
line having a plurality of contact lens process stations,
including an automated sterilization station for
5 sterilizing a plurality of contact lenses after their
manufacture, and a packaging station for packaging said
lenses after sterilization, wherein the system comprises:

(a) a first means for receiving contact lens
data including an associated lot number and lens power for
10 a lens lot prior to their manufacture; said lens lot
defining at least one batch of contact lenses;

(b) a plurality of process controllers for
controlling one or more process stations, each of said
controllers regulating a plurality of process control
15 devices at said process stations for manufacturing said
contact lenses;

(c) means for tracking movement of said
plurality of lenses defined by said lens lot from a said
plurality of processing stations to said automatic
20 sterilization station and said packaging station;

(d) means for receiving data representing the
number of lenses that are input to said packaging station
together with reason codes for contact lenses lost at said
sterilization station;

25 (e) means for generating a summary report of the
total number of lenses input to said sterilization chamber
for a predetermined lens lot and the actual number of
lenses sterilized and packaged from said lot, said summary
report including lot number and lens power data for each
30 batch of contact lenses.



2. The quality control system as claimed in
1 Claim 1, wherein a lens lot comprises a plurality of
batches of lenses, said sterilization station sterilizing
said one batch of contact lenses at a time and generating
a sterilization cycle run number for each batch
5 sterilized.

3. The quality control system as claimed in
Claim 2, wherein said summary report reconciles the number
of lenses input to said sterilization chamber with the
10 number of lenses packaged from said batch for each
sterilization cycle run number.

4. The quality control system as claimed in
Claim 2, wherein each lens lost or removed has associated
15 therewith a reason code, said summary generating means
including the lens package removal code with a
sterilization cycle run number.

5. The quality control system as claimed in
20 Claim 2, further including means for automatically
calculating a thickness specification and product code for
a given lens power.

6. The quality control system as claimed in
25 Claim 2, wherein the means for calculating a thickness
specification and product code includes a look-up table.

7. The quality control system as claimed in
Claim 2, further including means for automatically
30 calculating an expiration date for a given lens lot.



8. The quality control system as claimed in
1 Claim 2, wherein said tracking means includes means for
displaying the location of a particular lot on said
production line.

5 9. A sterilizer data processing system for an
automated contact lens manufacturing line for
manufacturing a plurality of contact lenses defined by a
lens lot, said contact lens manufacturing line including
an automated sterilization station for sterilizing said
10 lens lot after their manufacture, said automated
sterilization station including a sterilizer process
controller for controlling one or more phases of a
sterilization process, said process controller
periodically generating sterilization process data during
15 each said sterilization phase, said system including:

(a) means for receiving said sterilization data
from said sterilizer process controller; and,

(b) means for automatically parsing said
sterilization data into text information and sterilizer
20 parameter information, said means further processing said
text information and sterilizer parameter information to
automatically generate a sterilization run report
associated with a lot number for said sterilized lens lot.

25 10. The sterilizer data processing system for an
automated contact lens manufacturing line as claimed in
Claim 9, wherein said processing means further conveys
said sterilizer parameter information to data acquisition
devices in said automated contact lens manufacturing line
30 for display and storage thereof.



11. The sterilizer data processing system for an
1 automated contact lens manufacturing line as claimed in
Claim 9, wherein said process controller generates alarm
condition information, said processing means further
conveying said alarm condition information to data
5 acquisition devices in said automated contact lens
manufacturing line for display thereof.

12. The sterilizer data processing system for an
automated contact lens manufacturing line as claimed in
10 Claim 9, wherein said processing means further includes
means for evaluating the success or failure of a
sterilization run based on said text information and
sterilizer control parameter information for indication on
said sterilization run report.

15
13. The sterilizer data processing system for an
automated contact lens manufacturing line as claimed in
Claim 9, wherein said processing means further includes
means for evaluating whether a complete set of data has
20 been obtained for the current sterilizer run.

14. The sterilizer data processing system for an
automated contact lens manufacturing line as claimed in
Claim 9, wherein said text information includes the
25 current operating phase of said sterilization process.

15. The sterilizer data processing system for
an automated contact lens manufacturing line as claimed in
Claim 9, wherein said sterilizer parameter information
30 includes a plurality of isolated process values generated



by said sterilization process controller during each
1 operating phase of said sterilization process.

16. The sterilizer data processing system for
an automated contact lens manufacturing line as claimed in
5 Claim 9, wherein said processing means further includes
means for determining a phase duration time for each said
operating phase of said sterilization run, wherein said
phase duration time is included in said sterilization run
report.

10

17. The sterilizer data processing system for
an automated contact lens manufacturing line as claimed in
Claim 9, wherein said processing means further includes
means for determining a minimum value and maximum value of
15 said isolated process values for each said sterilization
phase, wherein said minimum and maximum of said isolated
process values are included in said sterilization run
report.

20

18. The sterilizer data processing system for
an automated contact lens manufacturing line as claimed in
Claim 15, wherein said processing means further includes
means for generating phase files for storing phase file
information for each of said sterilizer operating phases.

25

19. The sterilizer data processing system for
an automated contact lens manufacturing line as claimed in
Claim 9 wherein said sterilizer process controller
generates sterilizer data at a first prespecified time
30 interval, said sterilizer data processing system further
including means for determining whether said receiving

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* C L M S *

means receives said sterilization data from said
1 sterilizer process controller within said time interval.

20. The sterilizer data processing system for
an automated contact lens manufacturing line as claimed in
5 Claim 19 wherein said means for determining whether said
receiving means receives said sterilization data from said
sterilizer process controller within said time interval
includes a time server for generating a wakeup message
during each said first time interval.

10

21. The sterilizer data processing system for
an automated contact lens manufacturing line as claimed in
Claim 20, wherein said processing means generates a
communication timeout alarm message in the event that said
15 sterilization data is not received during each said first
time interval.

22. The sterilizer data processing system for
an automated contact lens manufacturing line as claimed in
20 Claim 9 wherein said receiving means is a communication
server.

23. The sterilizer data processing system for
an automated contact lens manufacturing line as claimed in
25 Claim 9 wherein said processing means is a sterilization
server.

24. The sterilizer data processing system for
an automated contact lens manufacturing line as claimed in
30 Claim 11 wherein said sterilizer process controller

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generates alarm condition information at a second
1 prespecified time interval.

25. A method for processing data generated in
an automated contact lens manufacturing line for
5 manufacturing a plurality of contact lenses defined by a
lens lot, said contact lens manufacturing line including
an automated sterilization station for sterilizing said
lens lot after their manufacture, said automated
sterilization station including a sterilizer process
10 controller for controlling one or more phases of a
sterilization process, said process controller
periodically generating sterilization process data during
each said sterilization phase, said method including the
steps of:

15 (a) receiving said sterilization data from said
sterilizer process controller; and,

(b) automatically parsing said sterilization
data into text information and sterilizer parameter
information; and,

20 (c) further processing said text information and
sterilizer parameter information to automatically generate
a sterilization run report associated with a lot number
for said sterilized lens lot.

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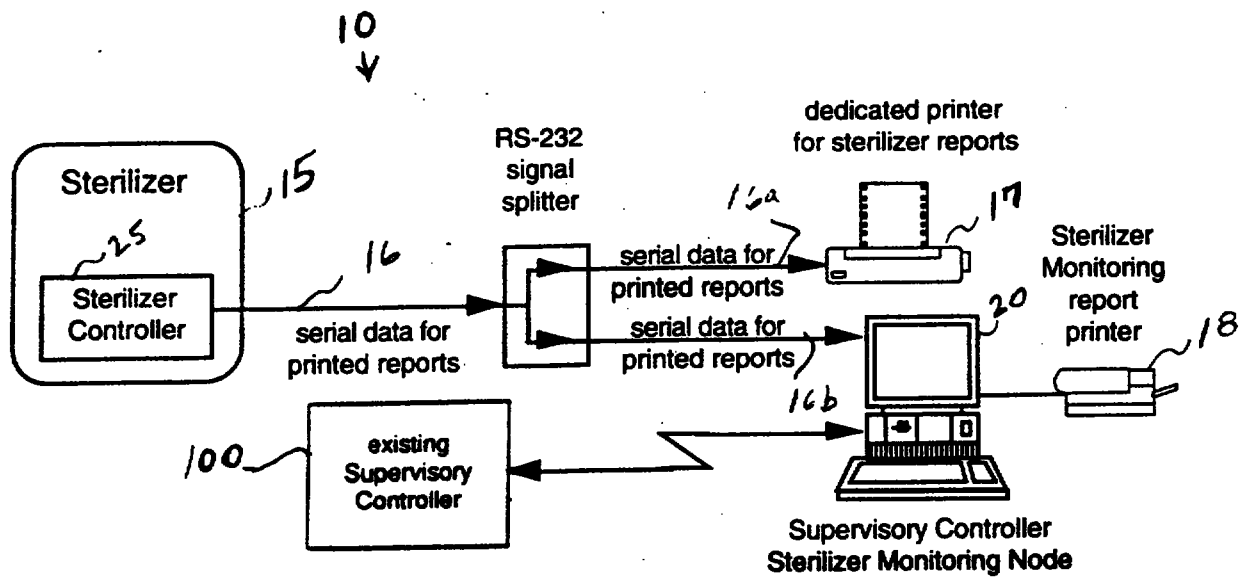


Fig 1

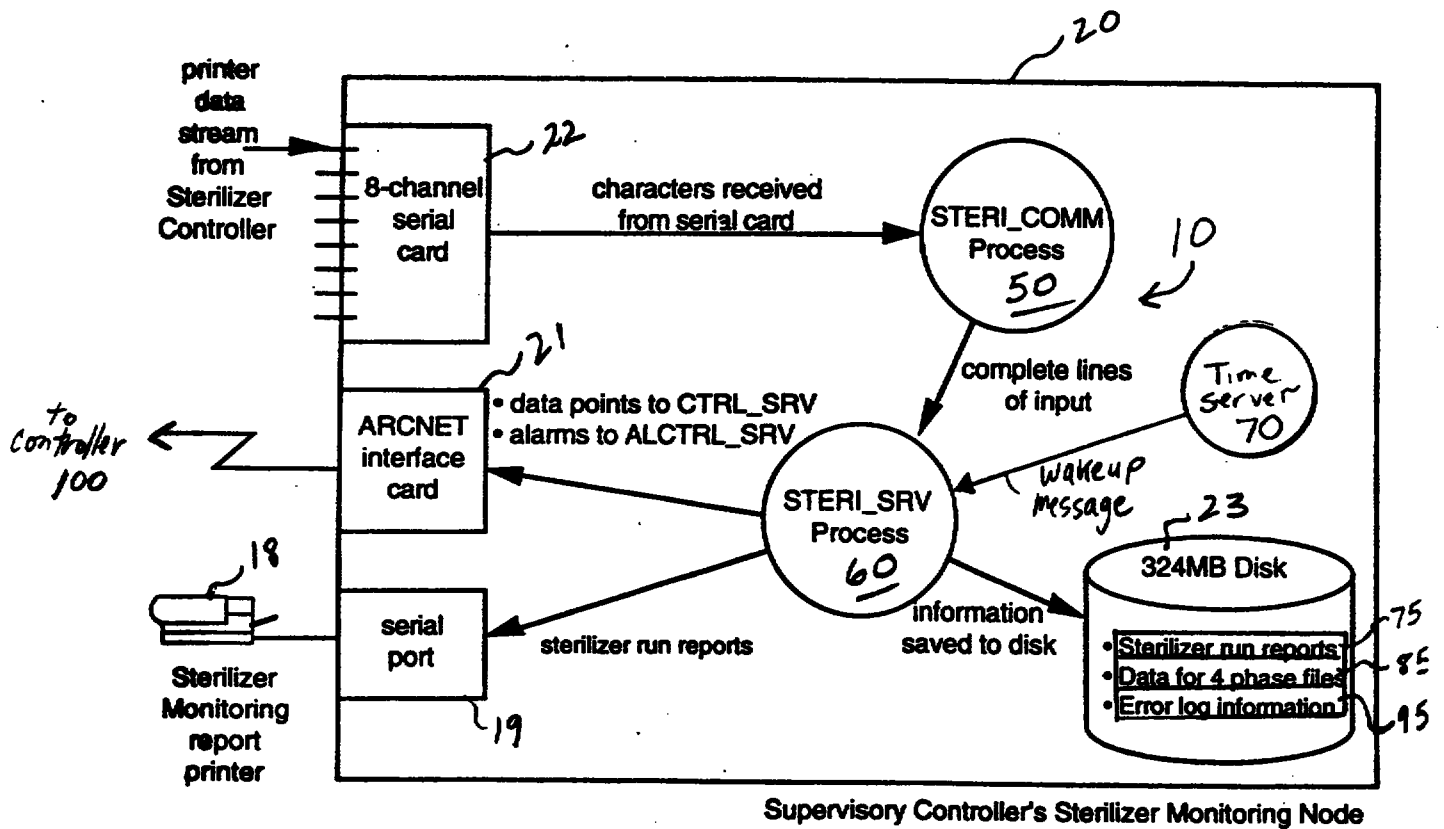


Fig 3

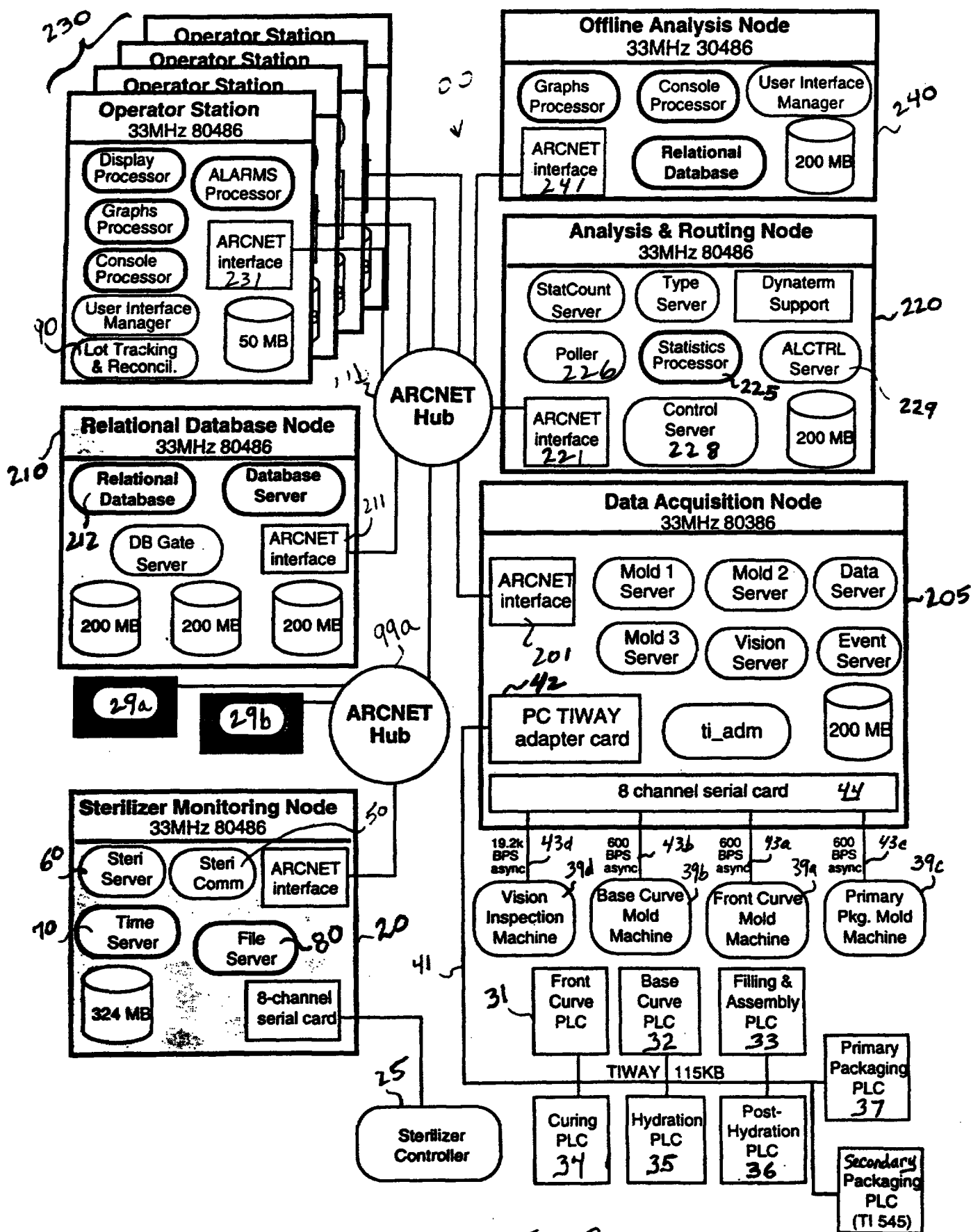
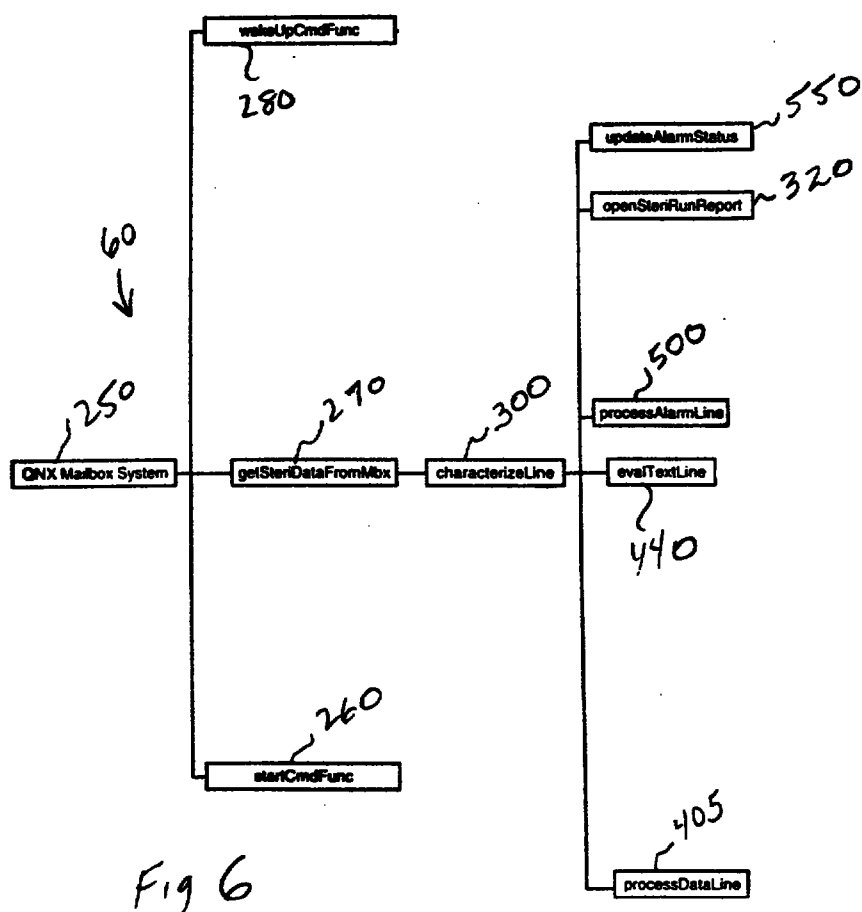
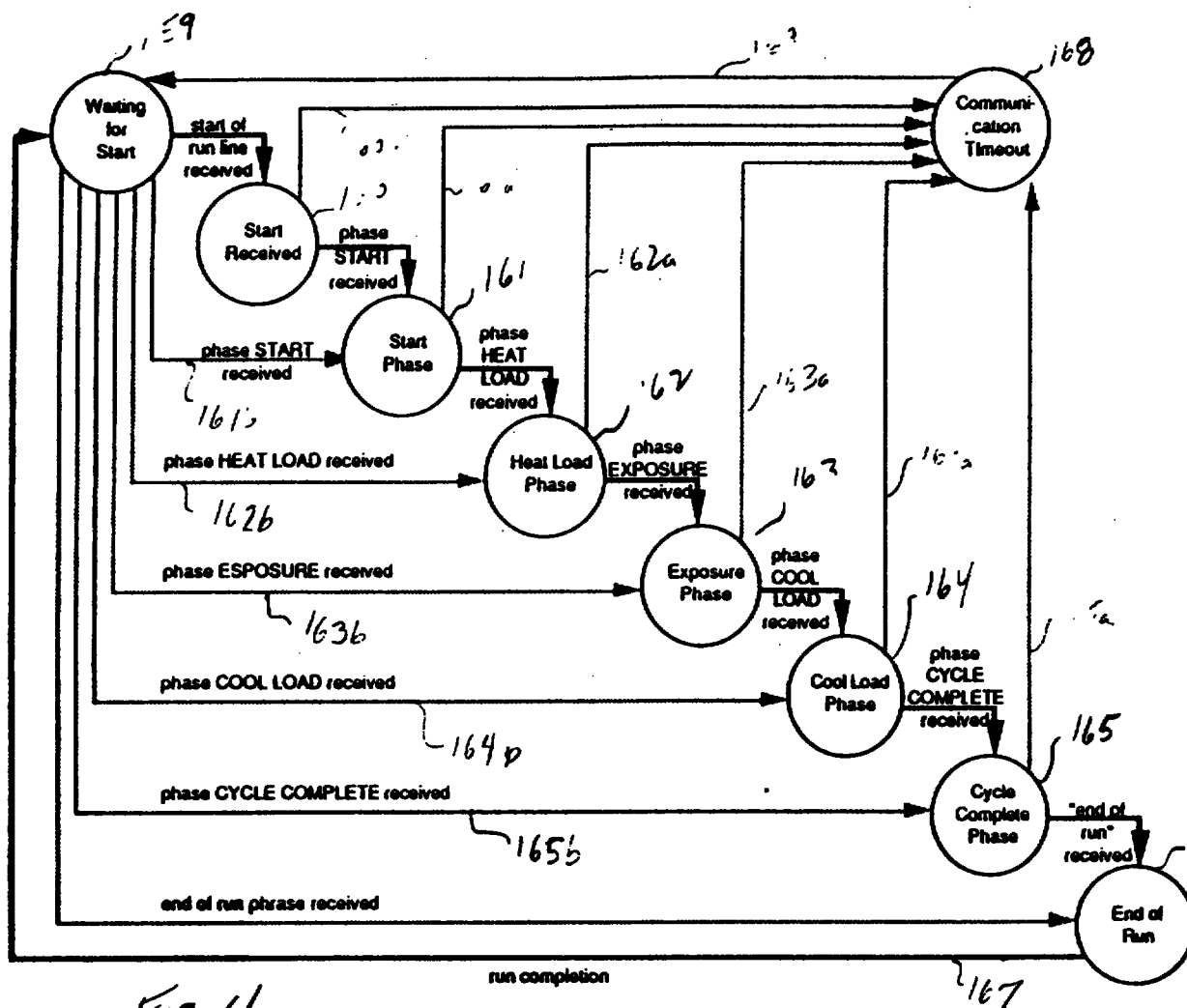


Fig 2



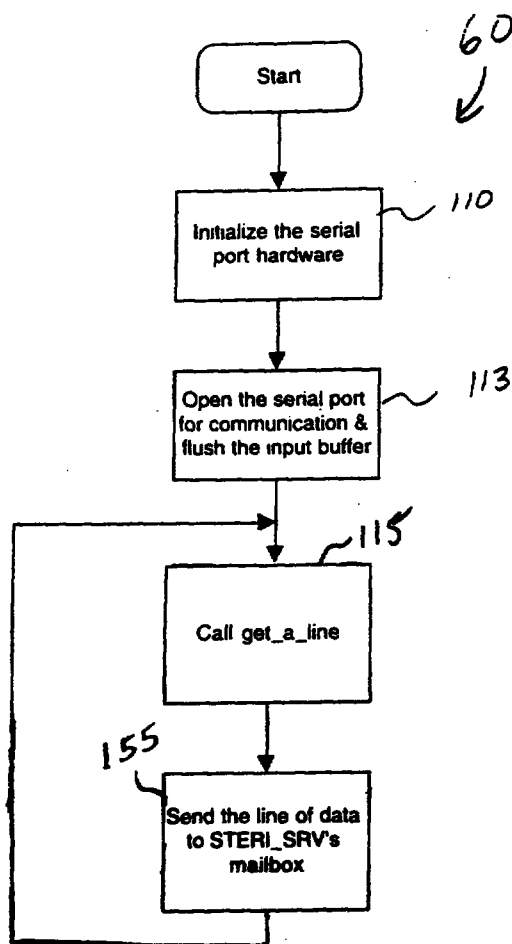


Fig 5(a)

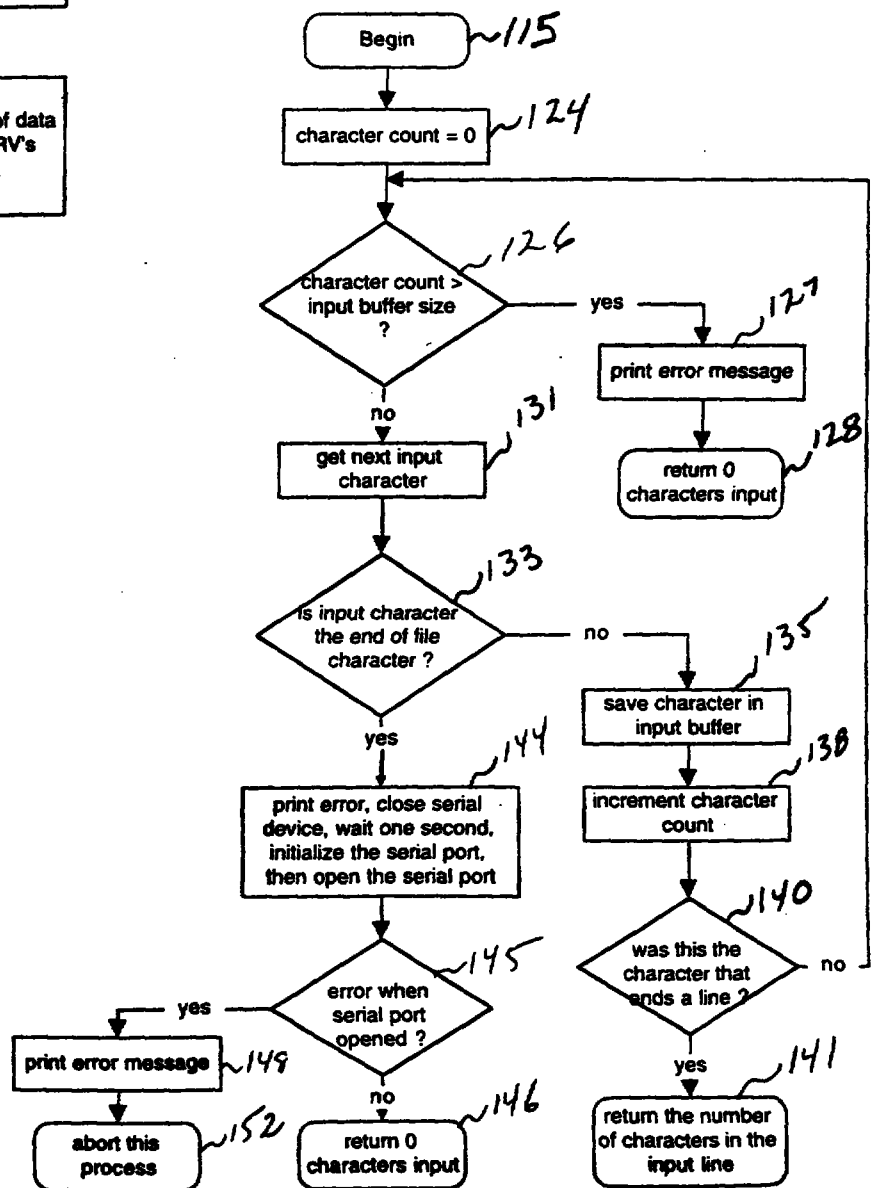


Fig 5(b)

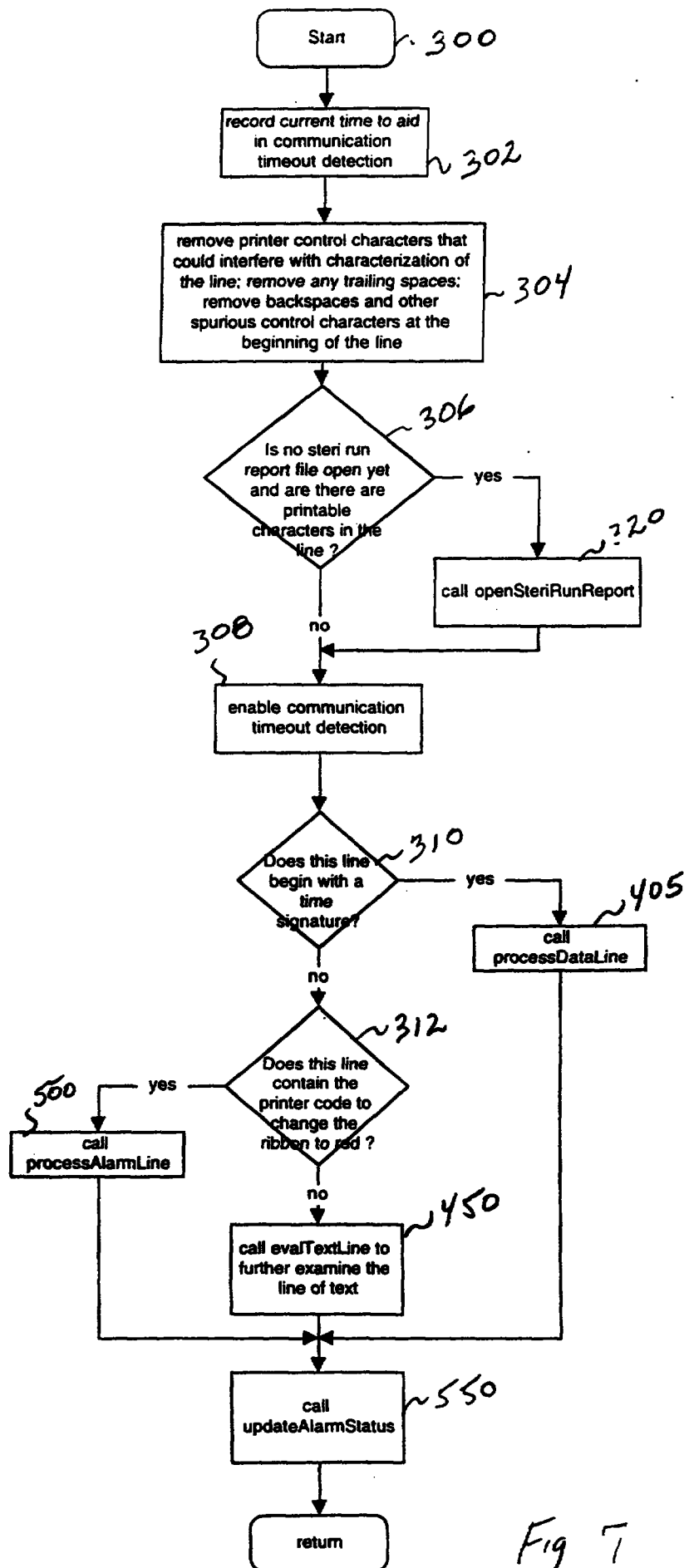
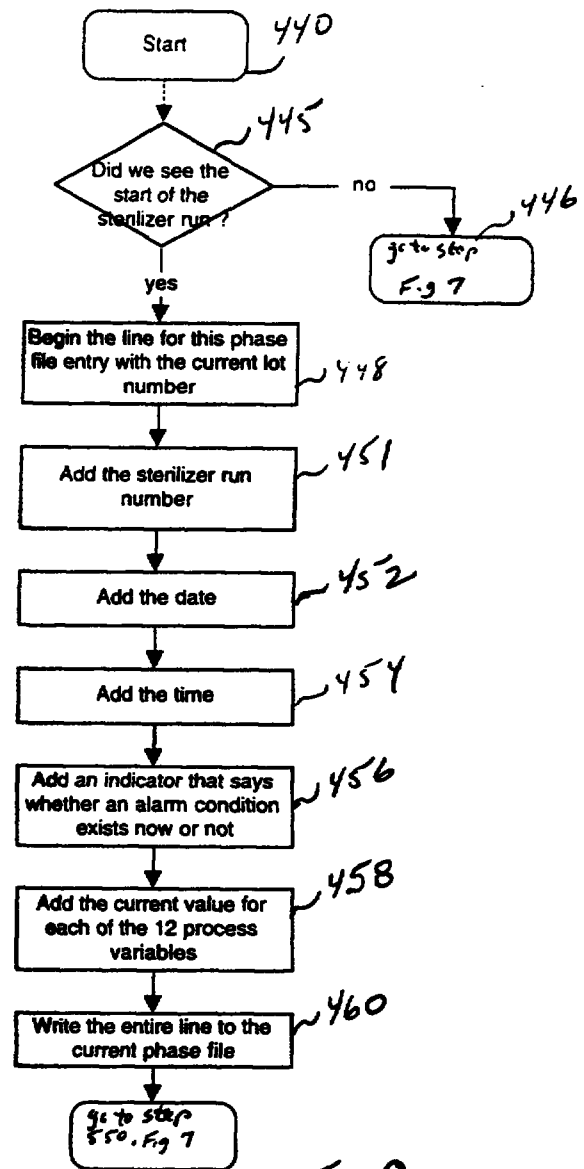
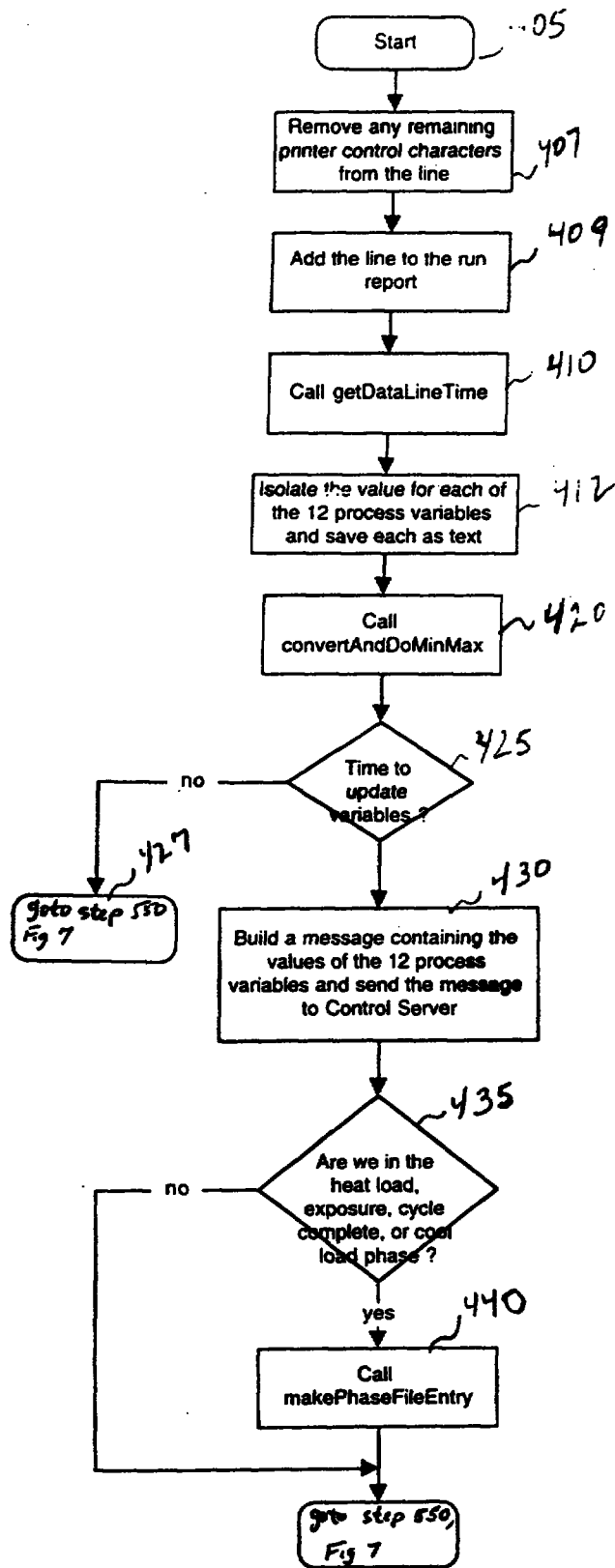


Fig 7



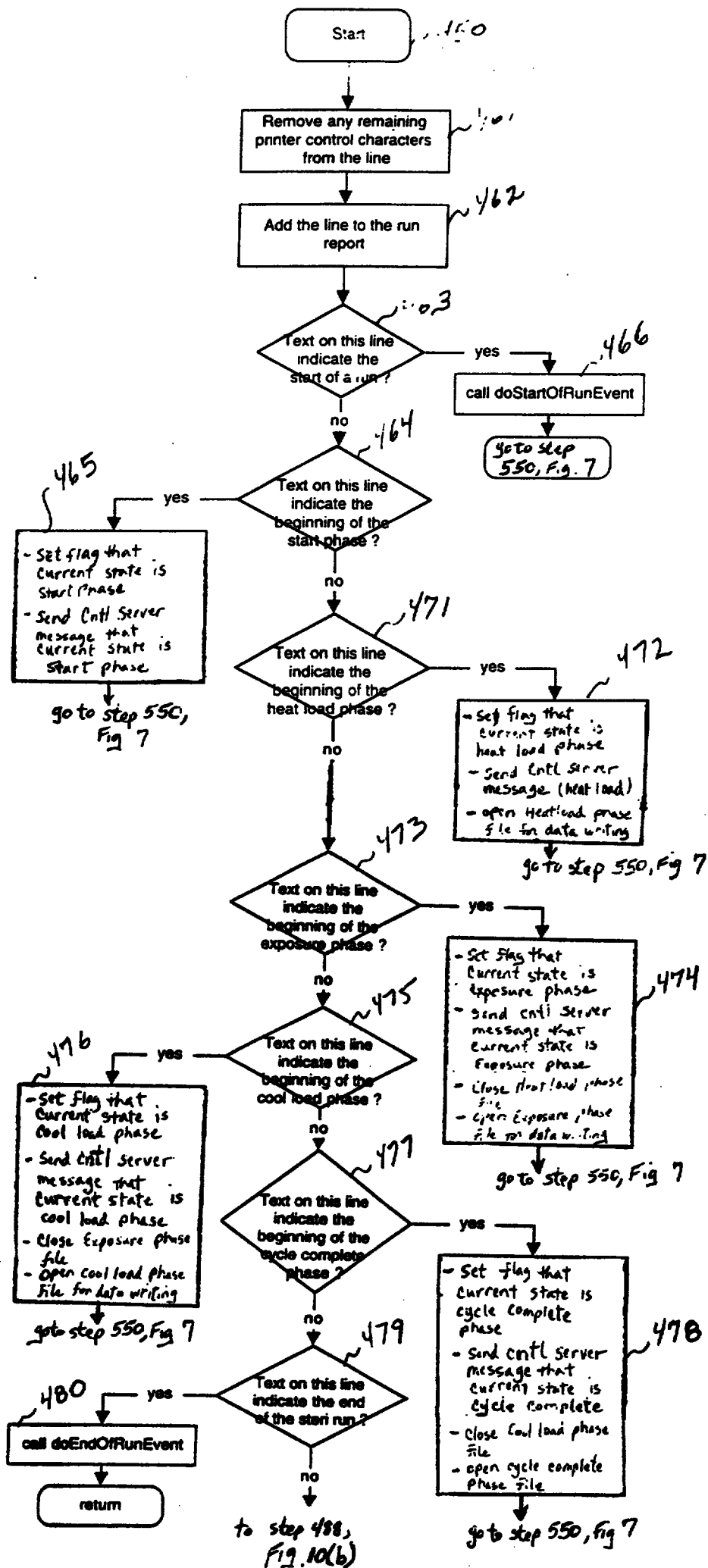
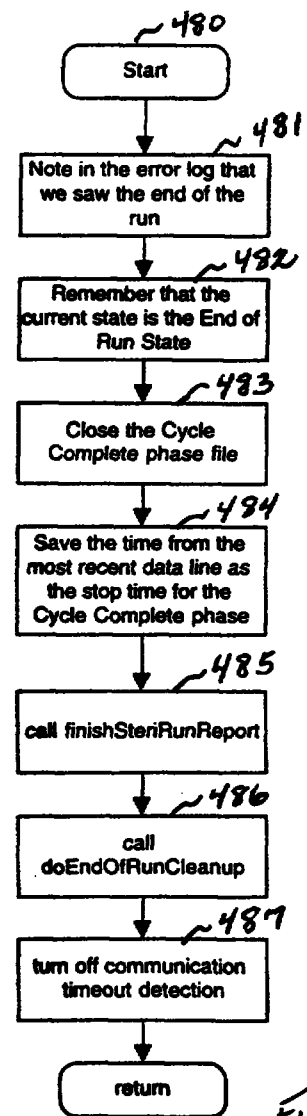
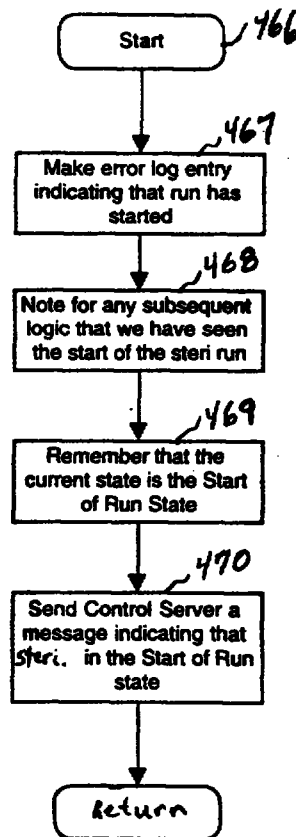
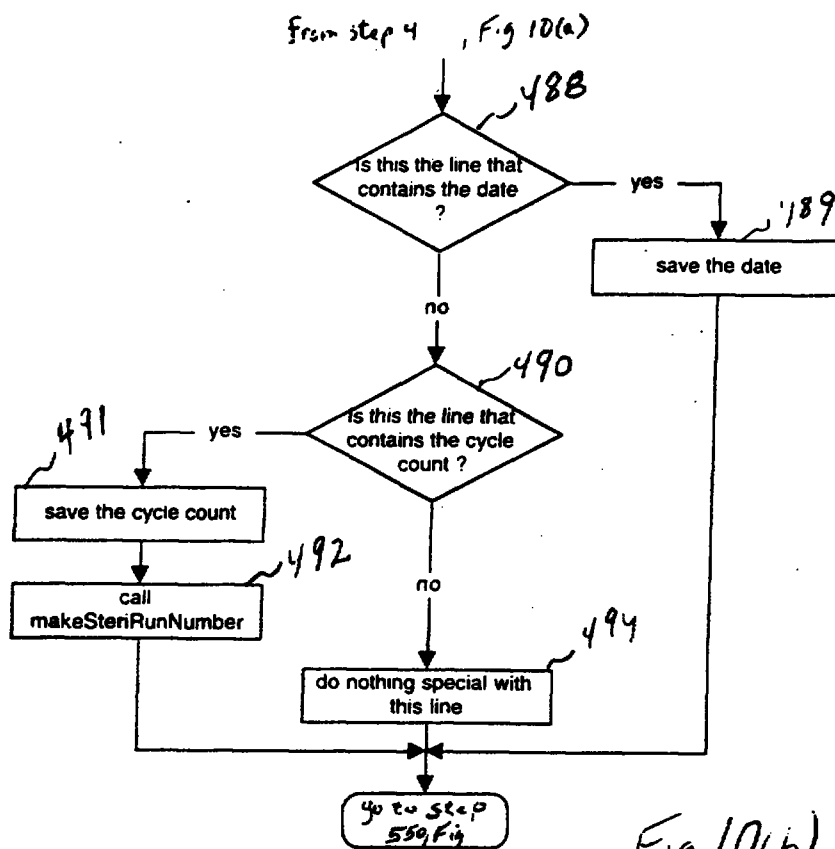


Fig 10(a)



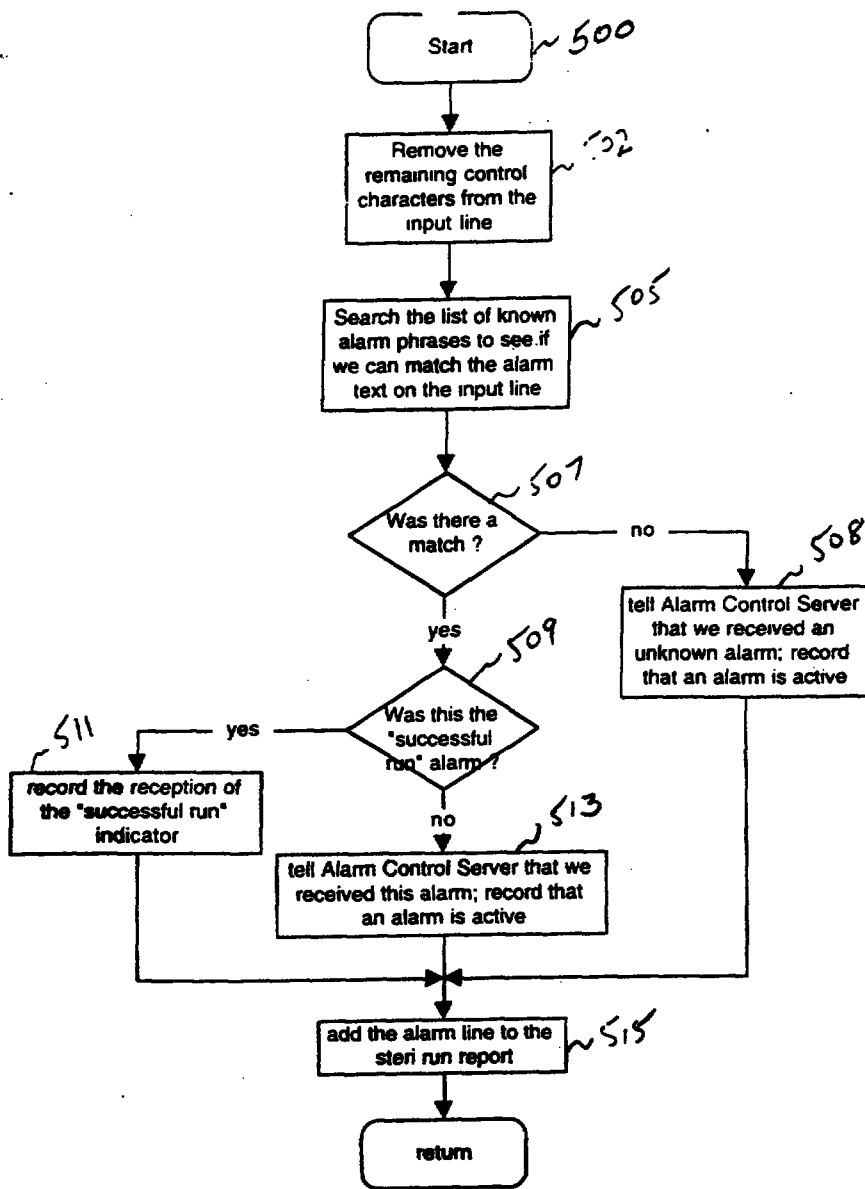


Fig 13

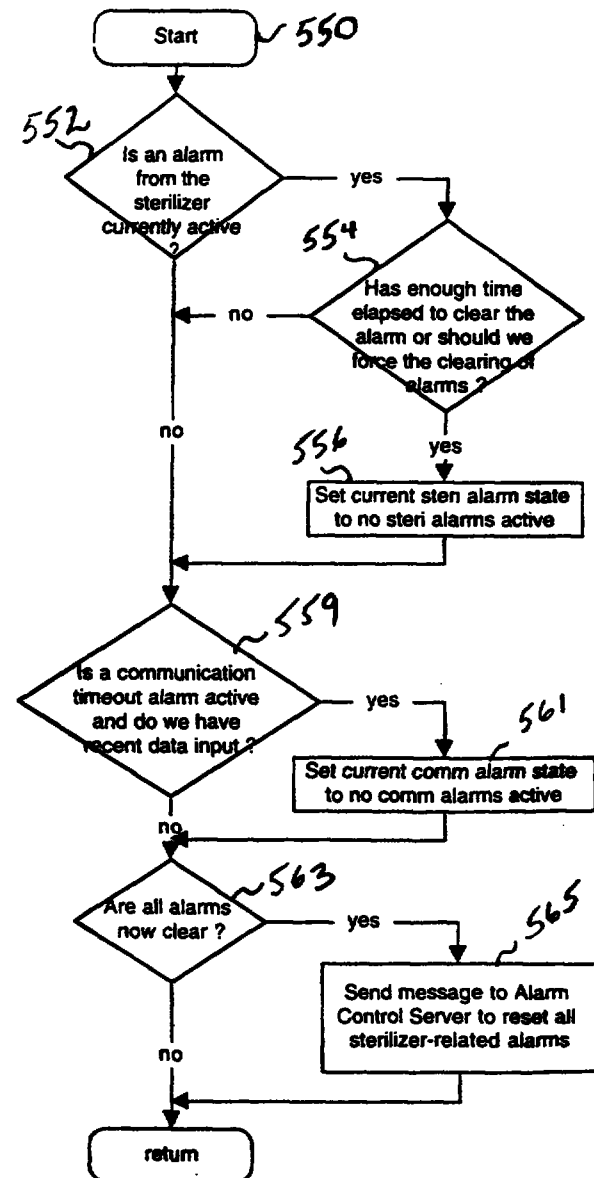


Fig 14

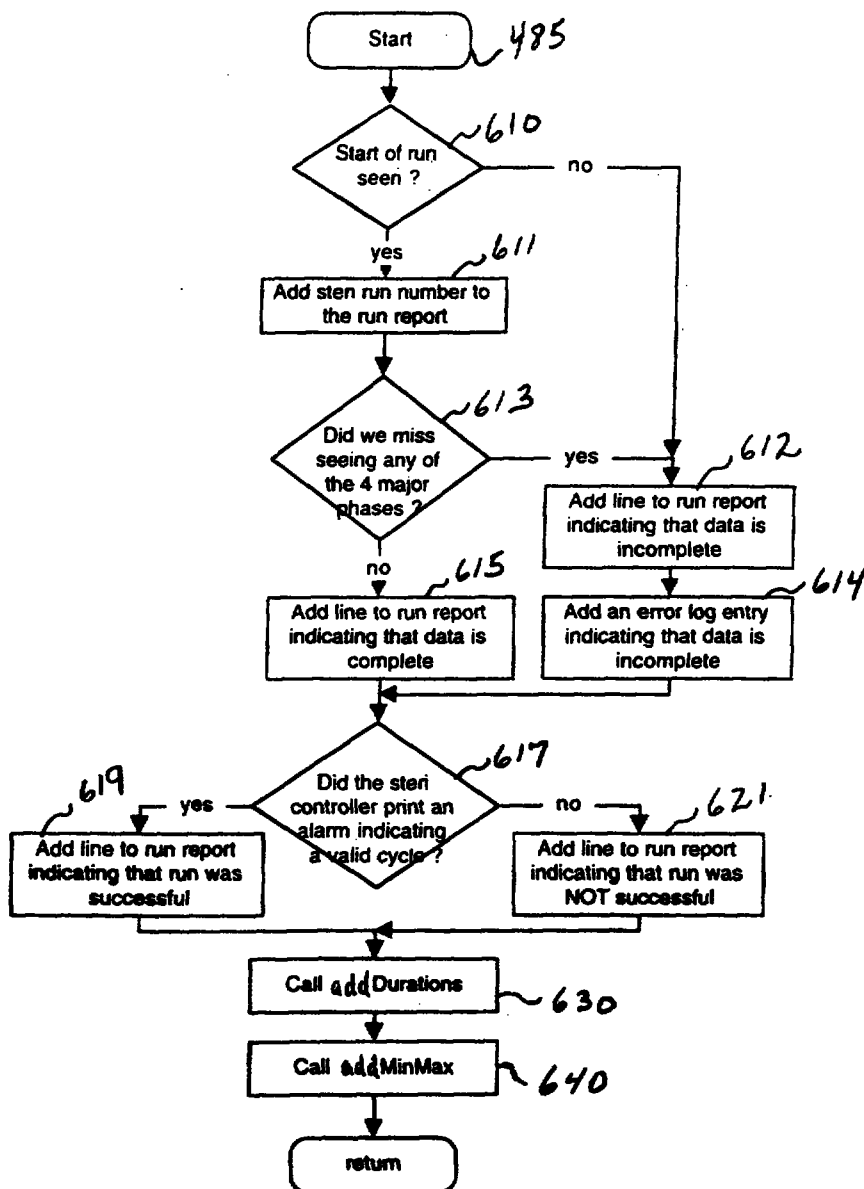


Fig 15

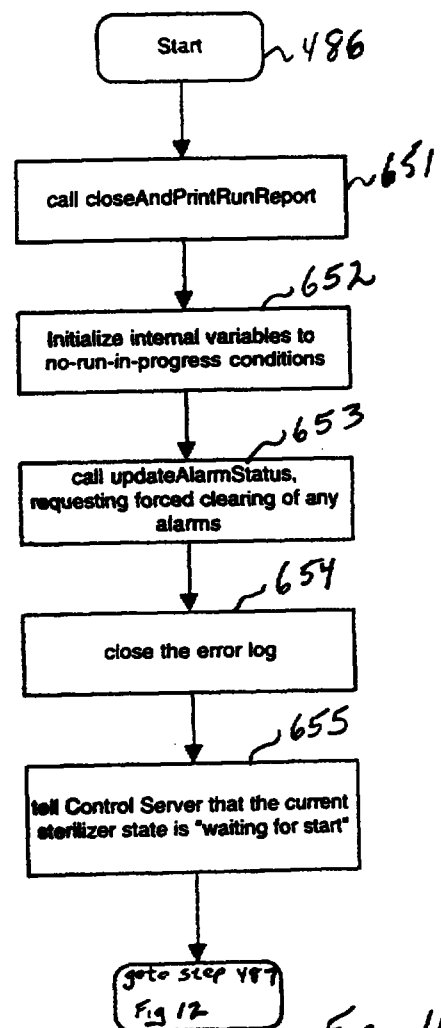


Fig 16

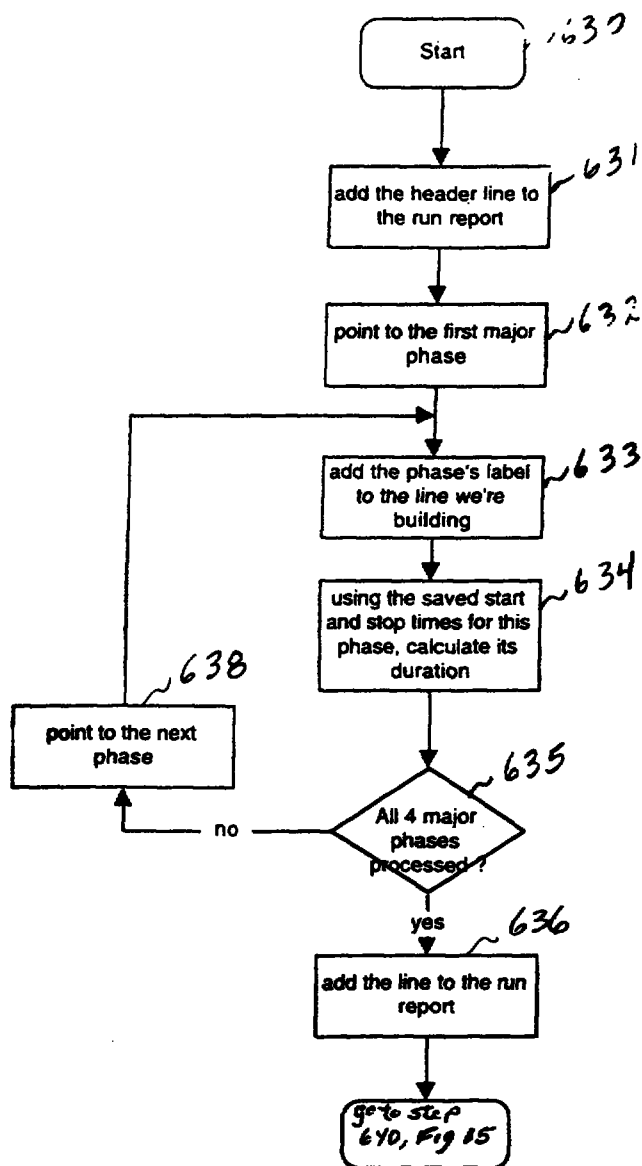


Fig 17

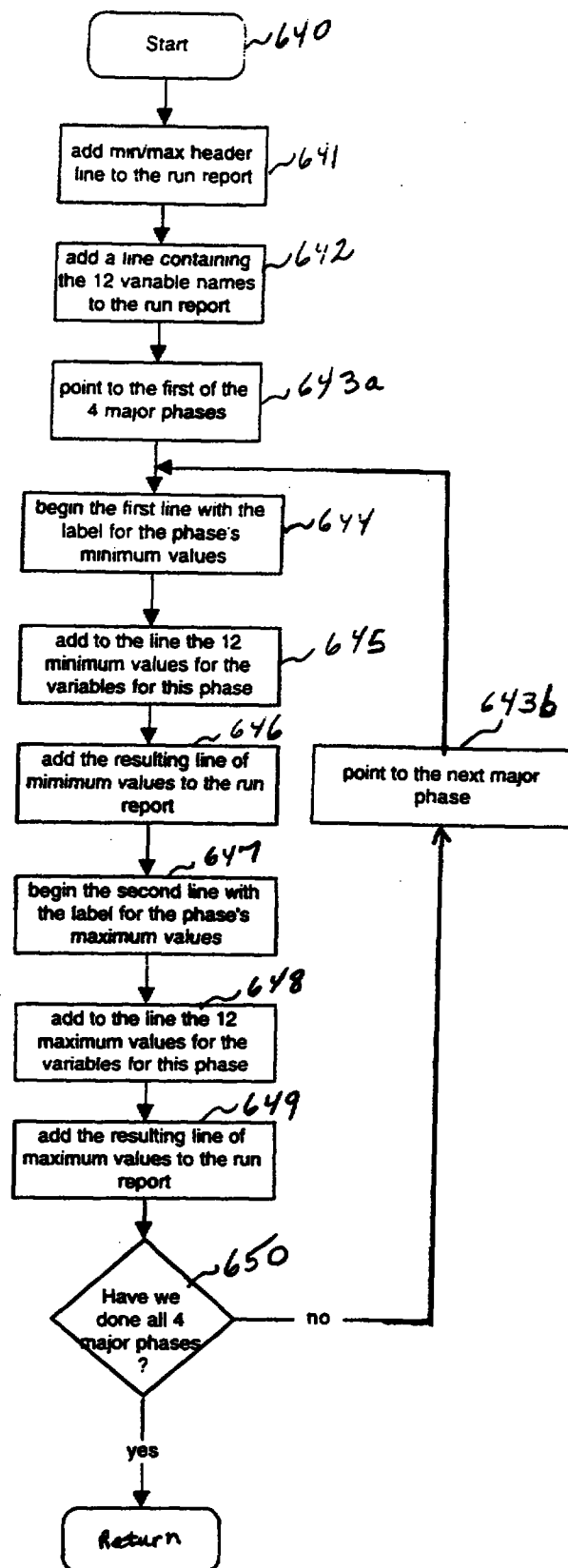


Fig 18

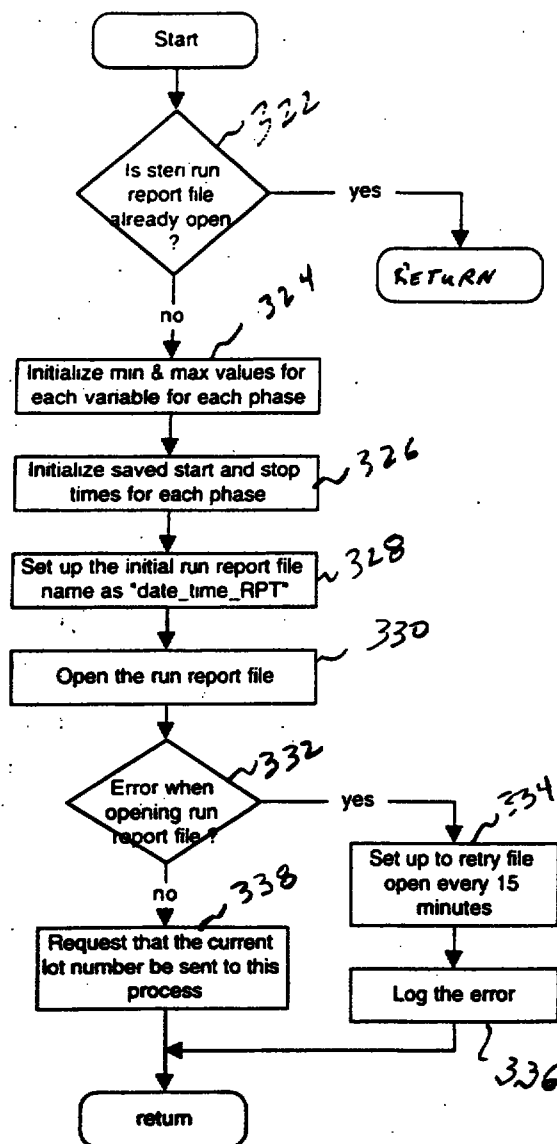


Fig 19

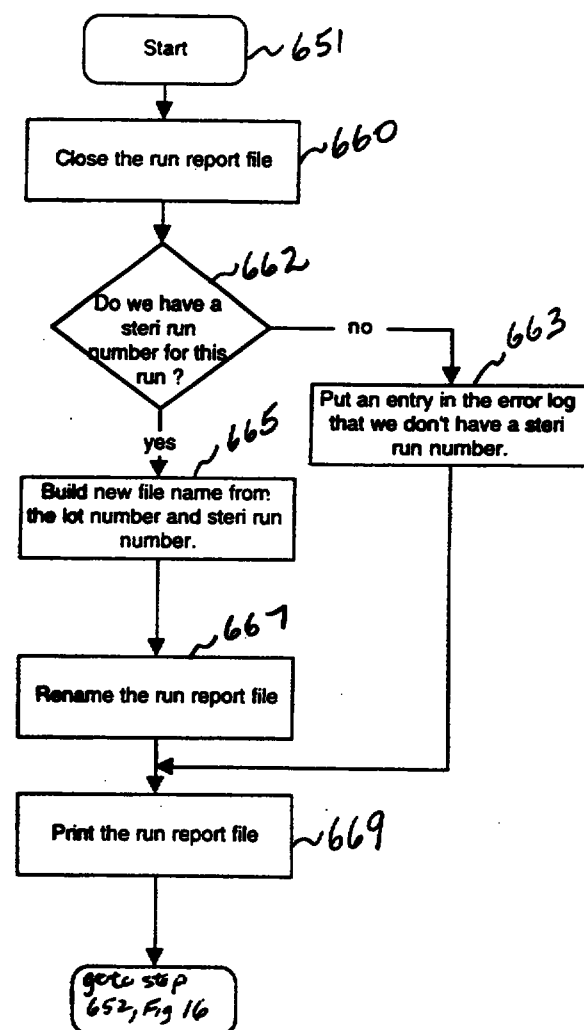
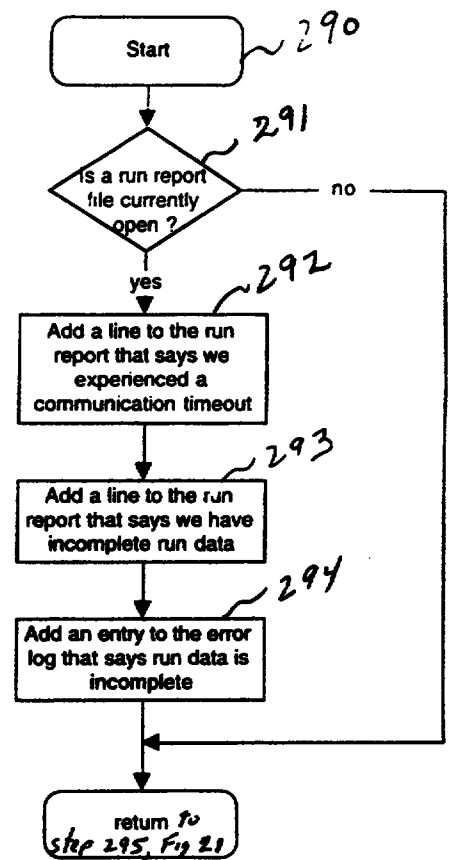
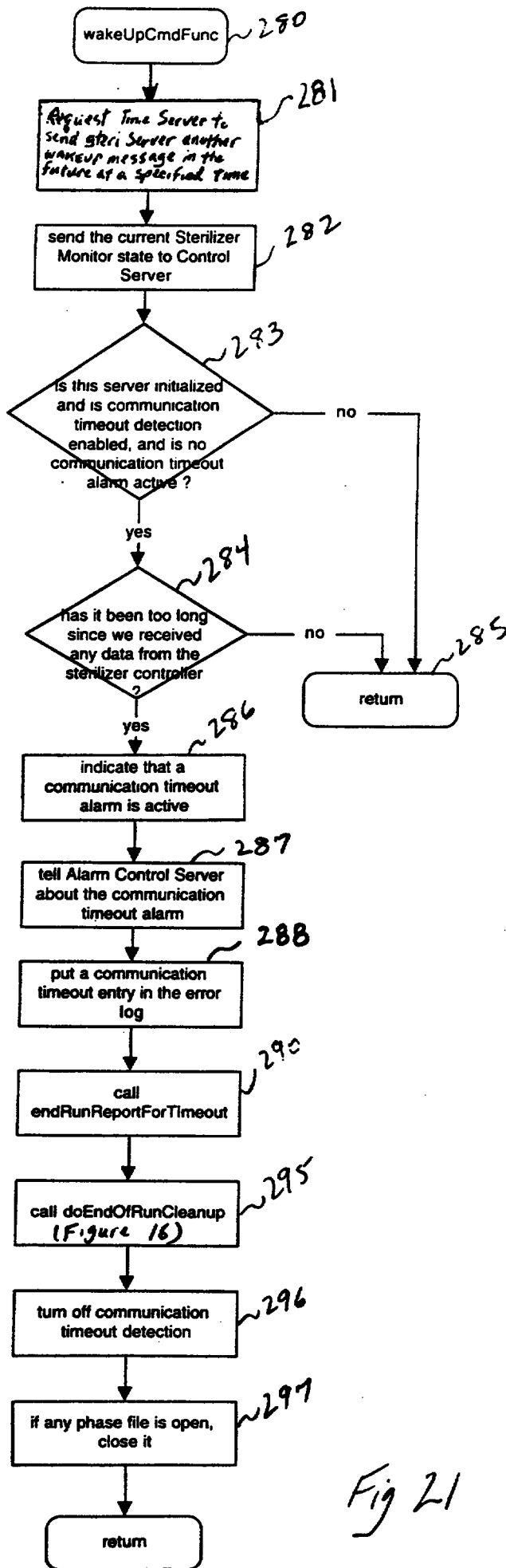


Fig 20



710
STERILIZER RUN NUMBER

816a - DATE _____

816b - PROCESS START _____

817a - AUTOCLAVE NAME _____

817b - AUTOCLAVE NUMBER _____

817c - CYCLE COUNTER _____

818 - PARAMETERS

FAN SPEED HIGH _____

OVERPRESSURE _____

ALARM VAR HIGH _____

ALARM VAR LOW _____

TEMP VAR DELAY _____

FAN SPEED ALM _____

GRAV DIS TEMP _____

EVACUATE SLOW _____

STEAM RING-DRAIN _____

EXPOSE TIMER _____

RADIATOR COOLING _____

ORDER PRESS ALM _____

OVER PRESS ALM _____

SIGNALS

1 _____

2 _____

3 _____

4 _____

5 _____

6 _____

7 _____

8 _____

9 _____

10 _____

11 _____

12 _____

800

822 - PROGRAM:

PROGTIME	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12
START												
00:00:00	x	x	x	x	x	x	x	x	x	x	x	x
HEAT LOAD												
00:00:00	x	x	x	x	x	x	x	x	x	x	x	x
00:00:17	x	x	x	x	x	x	x	x	x	x	x	x
00:01:28	x	x	x	x	x	x	x	x	x	x	x	x
EXPOSURE												
00:05:00	x	x	x	x	x	x	x	x	x	x	x	x
00:05:49	x	x	x	x	x	x	x	x	x	x	x	x
00:06:49	x	x	x	x	x	x	x	x	x	x	x	x
COOL LOAD												
00:36:27	x	x	x	x	x	x	x	x	x	x	x	x
00:36:49	x	x	x	x	x	x	x	x	x	x	x	x
00:37:49	x	x	x	x	x	x	x	x	x	x	x	x
CYCLE COMPLETE												
00:46:04	x	x	x	x	x	x	x	x	x	x	x	x
VALID CYCLE												

825

805 - SIGNATURE: _____

812 - Sterilizer run number: _____

855 - A complete set of data was obtained from the sterilizer controller.

850 - The sterilizer controller reported a valid cycle.

830
PHASE DURATIONS (H:MM:SS)

HEAT LOAD 44.17 EXPOSURE 55.17 COOL LOAD 44.17 CYCLE COMPLETE 44.17

835

840
MINIMUM AND MAXIMUM VALUES

	1	2	3	4	5	6	7	8	9	10	11	12
HEAT MIN	x	-	-	-	-	-	-	-	-	-	-	-
HEAT MAX	x	-	-	-	-	-	-	-	-	-	-	-
EXPS MIN	x	-	-	-	-	-	-	-	-	-	-	-
EXPS MAX	x	-	-	-	-	-	-	-	-	-	-	-
COOL MIN	x	-	-	-	-	-	-	-	-	-	-	-
COOL MAX	x	-	-	-	-	-	-	-	-	-	-	-
COMP MIN	x	-	-	-	-	-	-	-	-	-	-	-
COMP MAX	x	-	-	-	-	-	-	-	-	-	-	-

845

Fig 23

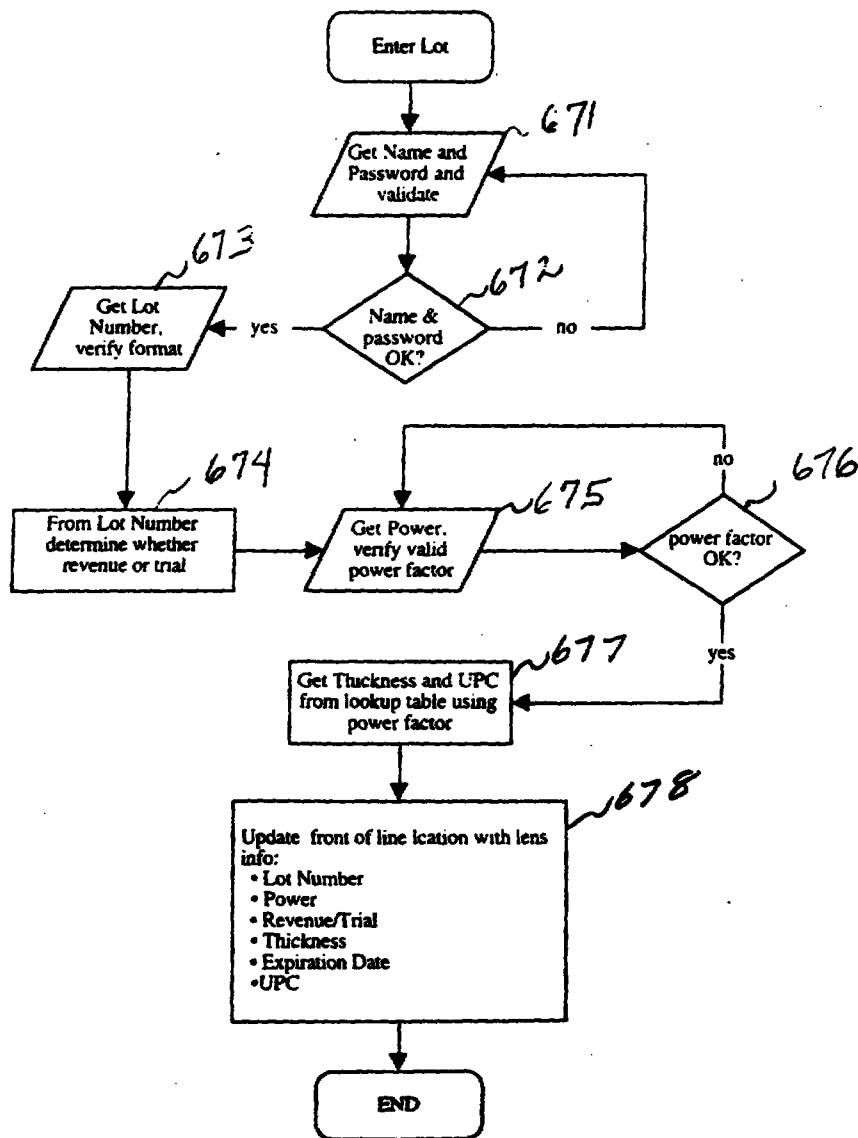


Fig 24

LotNumber	UPC	R/T	Power	Thickness	Expiration
-----------	-----	-----	-------	-----------	------------

Fig 25(a)

LotNumber	UPC	R/T	Power	Thickness	Expiration	input qty	loss quantity
-----------	-----	-----	-------	-----------	------------	-----------	---------------

Fig 25(b)

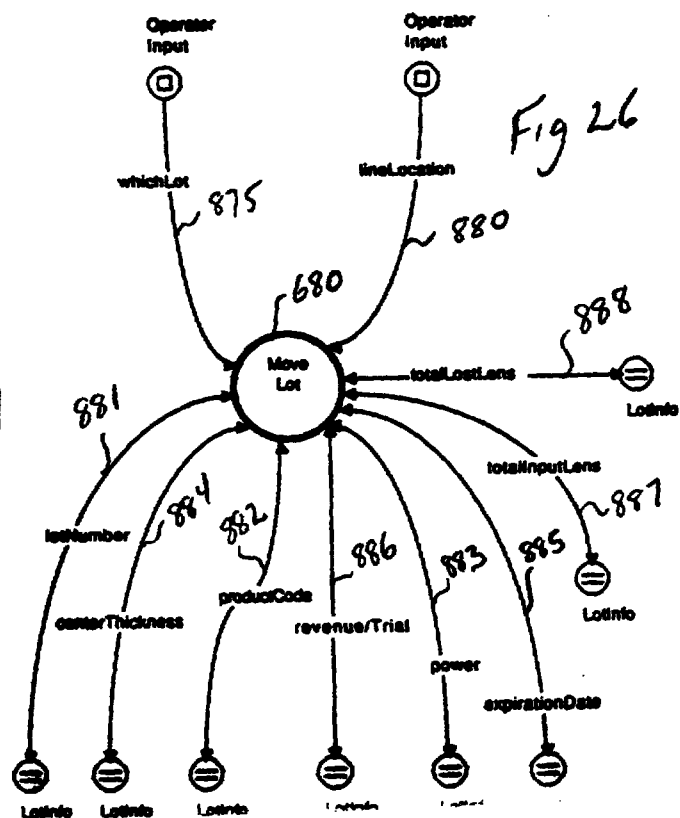


Fig 26

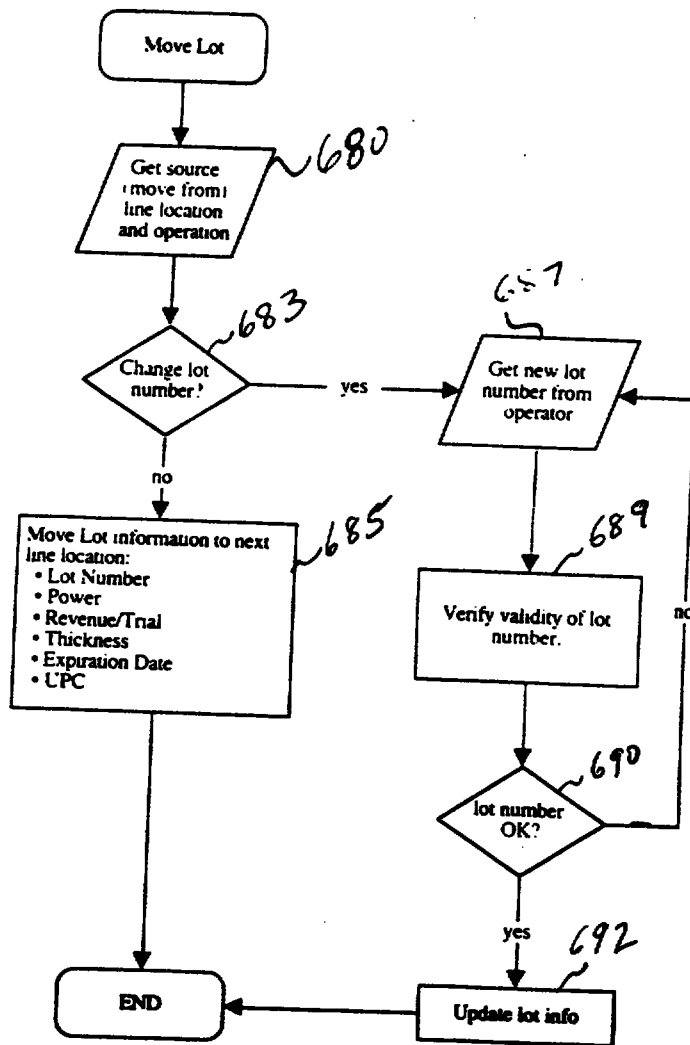


Fig 27

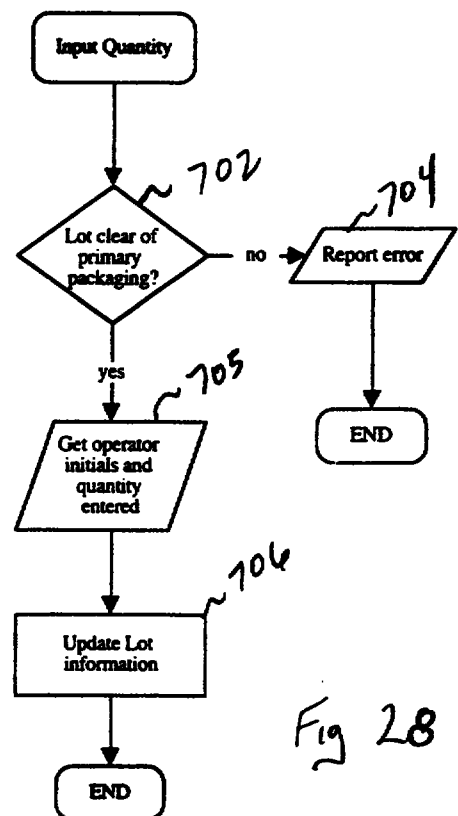


Fig 28

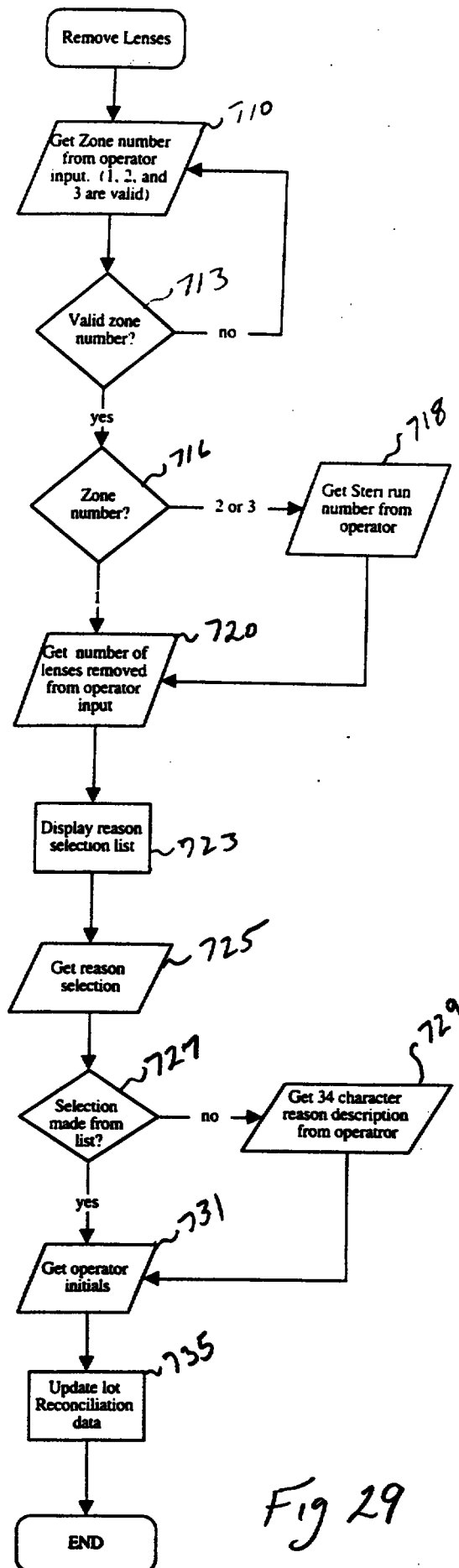


Fig 29

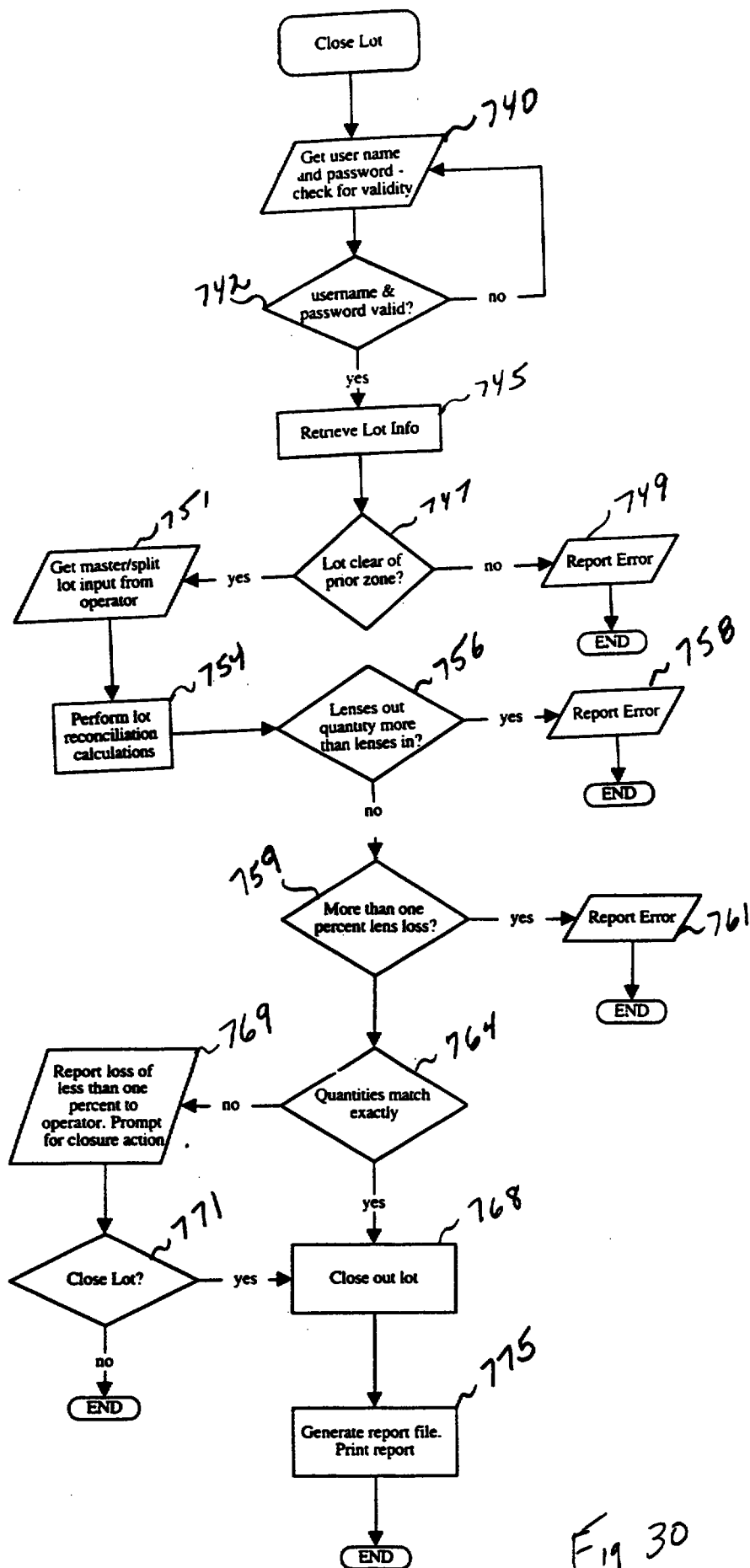


Fig 30

876

lot number	date	time	mode	variable #1 reading	variable #2 reading	. . .	variable #12 reading
lot number	date	time	mode	variable #1 reading	variable #2 reading	. . .	variable #12 reading
.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.
lot number	date	time	mode	variable #1 reading	variable #2 reading	. . .	variable #12 reading

Fig 31

STERILIZATION / SECONDARY PACKAGING LOT RECONCILIATION SHEET

STERILIZATION RUN # (S)

MASTER LOT # _____

LENS POWER + - _____

MASTER SPLIT (CIRCLE) _____

REVENUE TRIAL (CIRCLE) _____

891 # OF LENSES ENTERING ZONE #1 (STERI TRAY LOAD) - A = _____

892 SIGNATURE _____ DATE _____

893 # OF LENSES REMOVED AT ZONE #1 (STERI TRAY LOAD) - B = _____

894 SIGNATURE _____ DATE _____

895 # OF LENSES REMOVED AT ZONE # & # (STERI TRAY UNLOAD/CARTONING & CARTON CHECKWEIGH/LABELING) - C = _____

896 SIGNATURE _____ DATE _____

897 # OF LENSES REMOVED BY QUALITY ASSURANCE - D = _____

898 SIGNATURE _____ DATE _____

899 # OF LENSES EXITING ZONE #4 (CARTON CHECKWEIGH/LABELING) - E = _____

900 SIGNATURE _____ DATE _____

901 TOTAL OF ALL LENSES LEAVING THE CELL - F = _____

902 B + C + D + E

903 LOT RECONCILIATION - G = _____

904 A - F

905 VERIFIED BY _____ DATE _____

906 (A Technician)

907 LOT TRANSFER DATE _____

890
↓

Fig 32

COMPUTER SYSTEM FOR QUALITY CONTROL CORRELATIONS
ABSTRACT OF THE DISCLOSURE

1

A sterilizer data processing system for an automated contact lens manufacturing line that manufactures a plurality of contact lenses defining a lens lot, the manufacturing line including an automated sterilization station for sterilizing the lens lot after their manufacture, the automated sterilization station including a sterilizer process controller for controlling one or more phases of a sterilization process and periodically generating sterilization process data during each sterilization phase includes a device for receiving the sterilization process data from the sterilizer process controller and a device for automatically parsing the sterilization data into text information and sterilizer parameter information and further processing the text information and sterilizer parameter information to automatically generate a sterilization run report associated with a lot number for the sterilized lens lot.

20

25

30

35