

ON-LINE STEAM SANITIZATION SYSTEM

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BACKGROUND OF THE INVENTION1. Field of the Invention

5 The present invention relates generally to an on-line steam sanitization system and method. More particularly, the subject invention pertains to an on-line steam sanitization system and method for sanitizing a production plant deionized water supply system, such as in a plant for manufacturing and packaging contact lenses.

10 The present invention relates to sanitization processes, which are related to sterilization processes. Sterilization is a process by which objects, materials or environments may be rendered sterile, which refers to the condition of an object, or an environment, which is free of all living cells, all viable spores (and other resistant and disseminative forms), and all viruses and subviral agents capable of replication. An effective sterilization process must therefore irreversibly inactivate all organisms. For most practical purposes the main criterion of sterility is satisfied by the failure to detect viable cells, spores, viruses, etc. on or in a given object, material or environment.

20 Methods of sterilization include physical methods such as heat, including dry heat and moist heat, radiation, pulsed energy such as light waves, filtration, ultrasonication, chemical methods, and also combined physical and chemical methods.

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1 The present invention employs and relates to
an on-line sanitization process and method, which in a
contact lens manufacturing and packaging plant makes the
equipment as clean as possible, eliminating microbes.
5 However, in this environment the validation effort
required to guarantee sterility is not economically
viable, and accordingly the process is referred to as a
sanitization process rather than a sterilization
process. A target bioburden is below 1000 organisms per
10 cubic liter.

10 2. Discussion of the Prior Art

Some plant production lines, such as those for
the production and packaging of contact lenses, have a
separate deionized water supply system with deionized
15 water pumps, supply lines, and related equipment which
supply deionized water to various areas of the plant
which require deionized water for the operations being
performed thereat.

Deionized water is generally distilled water
20 which has all minerals and chemical additives removed
therefrom, and is particularly suitable for immersing
contact lenses therein during manufacturing to allow
chemicals therein to leach out, and also for
transferring lenses from one processing step to the
next. The deionized water and an added surfactant allow
25 the lenses to equilibrate rapidly, reach an equilibrium
state in which the parameters of the lens do not change,
as is desirable for lens transfer and lens inspection.

Unfortunately, the deionized water supply does
30 not inhibit normal microbe buildup resultant from, among

1 other factors, the open air assembly of the parts of the
deionized water supply, and the added surfactant which
supports the life of the microbes. Accordingly, the
system has to be sanitized periodically, such as once
5 every several weeks. Sanitization entailed, inter alia,
disassembling the deionized water supply system positive
displacement pumps, which typically dispense microliter
dosages of deionized water, and replacing tubing,
filters, etc. which typically might take four persons,
10 each working 12-20 hours, for a total of 48-80 man
hours. During this operation, the disassembled
equipment which is returned to the deionized water
supply system is sanitized in a sterilizer, which could
be a steam and air mixture in an autoclave, or any
15 suitable sterilizer. Equipment such as pumps,
reservoirs and filters were sanitized in a sterilizer in
which steam was injected into the equipment without
disassembly of the equipment.

One disadvantage of the prior art approach to
sanitizing the deionized water supply system was the
20 possible contamination of the sanitized components by
contact with the operator's hands and other unclean
surfaces during assembly, and also necessary down time
for the production line, which was down during the
approximately 12-20 hour period, while the sanitizing
25 operation was being performed, and this on a production
line normally running 24 hours a day.

SUMMARY OF THE INVENTION

Accordingly, it is a primary object of the
present invention to provide an on-line steam
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1 sanitization system and method for a deionized water
supply system.

5 A further object of the subject invention is
the provision of a sanitizing operation which is
performed through all of the deionized water supply
system while the deionized water supply system is
closed, rather than disassembled and open to possible
recontamination as in the prior art sanitization
process, which provides a much more effective
10 sanitization operation than in the prior art, and also
substantially reduces the down time for the plant
production line.

15 It would be desirable to sanitize the
deionized water supply system on a production line in an
on-line manner by using steam directed therethrough,
rather than having to disassemble the equipment,
sanitize the disassembled equipment, and then reinstall
it as in the prior art. The use of steam in an on-line
sanitizing operation in the existing deionized water
supply system required that the production line
20 equipment be modified to withstand the pressure and heat
of the steam sanitizing operation. One such
modification entailed the removal of reservoirs, which
could not withstand the pressure of sanitization, and
their replacement with pressure regulators. The
25 pressure regulators reduce the pressure of the
sanitizing clean steam from approximately 40 psi to
approximately 15 psi, which the positive displacement
pumps can handle during the sanitization procedure.
30 During normal operations, the pressure regulators reduce

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1 the pressure of the deionized water from approximately
10 psi to approximately 1-3 psi which the positive
displacement pumps can handle.

5 The plant production line has a deionized
water supply system available therein, and also has
house steam available therein. House steam contains
chemical additives which make it unsuitable for an on-
line steam sanitization operation. Instead, pursuant to
10 the present invention, the house steam is used to heat
deionized water from the deionized water supply to
generate a clean steam therefrom which is suitable for
the sanitization operation on the deionized water supply
system.

15 One major advantage of the present invention
is that the sanitizing operation is performed through
all of the deionized water supply system while the
deionized water supply system is closed, rather than
disassembled and open to possible recontamination as in
the prior art sanitization process. The result is a
much more effective sanitization. With the prior art
20 open sanitization approach, the deionized water supply
system sometimes repopulated with microbes within 72
hours, as evidenced by the bioburden thereof. With the
closed sanitization approach of the present invention,
sometimes the deionized water supply system evidences no
25 repopulation with microbes between periodic maintenance
sanitization operations.

30 A preventative maintenance sanitization
operation pursuant to the present invention reduces the
down time for the plant production line to approximately

1 2 hours, compared to 12-20 hours as in the prior art,
and performs a much more effective sanitization
operation than in the prior art, often with no microbe
repopulation between periodic maintenance sanitization
5 operations, as evidenced by the bioburden thereof.

5 The present invention introduces pressure
regulation into the deionized water supply system, and
also utilizes a new manifold design. The old prior art
manifold used 16 tubes, one to each pump. The new
10 manifold has a symmetrical design with an equal number
of fixtures leading to each of the 16 pumps. The pumps
have also been changed from Kynar pump bodies to
stainless steel pump bodies to withstand the heat and
pressure associated with steam.

15 In accordance with the teachings herein, the
present invention provides an on-line steam sanitizing
system and method for a production plant deionized water
supply system, which includes deionized water pumps,
supply lines, and related equipment for supplying
20 deionized water to various areas of the production plant
which require deionized water for the operations being
performed thereat. The deionized water supply is
sanitized by an on-line steam sanitization procedure in
which steam is introduced into and through the deionized
25 water supply, without disassembly thereof for a minimum
sanitization period, after which the production plant
returns to normal operation.

30 In greater detail, the on-line steam
sanitizing system and method was developed for a plant
for the production and packaging of contact lenses. The

1 plant includes a predose facility wherein predoses of
deionized water are supplied to packages making them
ready to accept lenses to be deposited therein, and to a
lens transfer facility wherein measured doses of
5 deionized water are supplied to nozzles on robotic arms
for transferring lenses from one processing step to the
next.

The plant production line also has house steam
available therein, which contains chemical additives
which make it unsuitable for an on-line steam
10 sanitization operation. Accordingly, the house steam is
used to heat deionized water from the deionized water
supply to generate a clean steam therefrom which is
suitable for the sanitization operation.

15 The use of steam in a sanitization operation
in an existing plant deionized water supply system
required that the production line equipment be modified
to withstand the pressure and heat of the steam
sanitizing operation. The modifications included
20 removing reservoirs, which provided an open environment
and also could not withstand the pressure and heat of
sanitization, and replacing the reservoirs with pressure
regulators. The pressure regulators reduce the pressure
of the sanitizing clean steam from approximately 40 psi
to approximately 15 psi during the sanitization
25 procedure, which the positive displacement pumps can
handle. During normal operations, the pressure
regulators reduce the pressure of the deionized water
from approximately 10 psi to approximately 1-3 psi which
the positive displacement pumps can handle. The
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1 modifications further include utilizing a new manifold
design which has a symmetrical design with an equal
number of fixtures leading to each of the plurality of
pumps, and utilizing Kynar tubes and Kynar fixtures.

5 The deionized water is introduced into the
deionized water supply system through a shut-off valve,
which is closed during the steam sanitization operation,
and opened thereafter. The clean steam is also
introduced into the deionized water supply through a
10 shut-off valve, which is opened during the steam
sanitization operation, and is closed thereafter.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing objects and advantages of the
present invention for an on-line steam sanitization
system and method may be more readily understood by one
15 skilled in the art with reference being had to the
following detailed description of several preferred
embodiments thereof, taken in conjunction with the
accompanying drawings wherein like elements are
designated by identical reference numerals throughout
20 the several views, and in which:

Figure 1 illustrates a piping schematic
diagram for the deionized water supply of a plant
production line for the production and packaging of
contact lenses.

25 Figure 2 is a more detailed piping schematic
of the deionized water supply for a plant production
line for the production and packaging of contact lenses;

Figure 3 is a detailed piping diagram for the
deionized water supply of a predose facility; and
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1 Figure 4 is a detailed piping diagram for the
deionized water supply of a lens transfer facility.

DETAILED DESCRIPTION OF THE DRAWINGS

5 Referring to the drawings in detail, Figure 1
illustrates a piping schematic diagram for the deionized
water supply for a plant production line for the
production and packaging of contact lenses. The plant
production line is normally supplied with deionized (DI)
water at 10. Deionized water is generally distilled
10 water which has all minerals and chemical additives
removed therefrom, and is particularly suitable with an
added surfactant for immersing contact lenses therein
during manufacturing to allow chemicals therein to leach
out and equilibrate quickly, and for transferring lenses
15 from one processing step to the next. The deionized
water allows the lenses to equilibrate, reach an
equilibrium state in which the parameters of the lens do
not change, as is desirable for lens transfer and lens
inspection.

20 The plant production line is also normally
supplied with house steam at 16 through a ball valve 18
and check valve 20. Unfortunately, house steam contains
chemical additives which make it unsuitable for an on-
line steam sanitization operation. Instead, pursuant to
25 the present invention, the house steam is used in a DI
steam generating vessel 22 to heat deionized water from
the deionized water supply to generate a clean steam
therefrom at 24 which is suitable for a sanitization
operation on the deionized water supply system. The DI

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1 clean steam 24 is supplied at approximately 121°C at 15
psi gage.

5 The plant production line illustrated in
Figure 1 is for the production and packaging of contact
lenses, and includes three facilities 26, 28 and 30
which require deionized water in their operations. A
predose facility 26 supplies predoses of deionized water
to packages making them ready to accept lenses to be
deposited therein. The lens transfer facilities 28 and
10 30 supply deionized water to nozzles on robotic arms for
transferring lenses from one processing step to the next
in operations performed between hydration and packaging
in post hydration.

15 During normal operation of the plant
production line, the predose facility 26 and the lens
transfer facilities 28 and 30 are supplied with
deionized water from the house deionized water supply 10
through a valve 32, which must be sanitized
periodically, such as once every several weeks.

20 Accordingly, periodically such as every three
weeks, the plant production line is shut down, and the
production plant deionized water supply is sanitized by
an on-line steam sanitization system as illustrated in
Figure 1. Then, the house deionized water supply is
25 shut off by valve 32, and clean steam is introduced, by
opening valve 34, into and through the deionized water
supply systems of the predose and lens transfer
facilities 26, 28 and 30. The clean steam should flow
through and sanitize the equipment for a minimum
predetermined sanitization period, such as 30 minutes,
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1 and the entire operation of converting from production
to sanitization and back to production takes one man
approximately 2 hours, compared to 12-20 hours as in the
prior art. Thus, the present invention results in a
5 substantial decrease in lost production time of the
plant.

Another advantage of the present invention is
that the sanitizing operation is much cleaner and more
effective as it is performed through all of the
10 deionized water supply system while it is closed, rather
than disassembled and open to possible recontamination
as in the prior art sanitization process. The result is
a much more effective sanitization process. With the
prior art open sanitization approach, the deionized
15 water supply system is sometimes repopulated with
microbes within 72 hours, as evidenced by the bioburden
thereof. With the closed sanitization approach of the
present invention, sometimes the deionized water supply
system evidences no repopulation with microbes between
20 periodic maintenance sanitization operations.

Figure 2 is a more detailed piping schematic
of the deionized water supply for a plant production
line for the production and packaging of contact lenses.
During a sanitization operation, clean steam from a
sterilizer as shown in Figure 1 is introduced at the
25 upper left at 40, with condensate collecting in a steam
trap 42. The clean steam flows through a ball valve 44,
through steam pressure regulator 46, by pressure gage
48, through ball valve 50, through a T fitting 52, in
one leg 54 downwardly to a further T fitting 56, in one
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1 leg 58 to the left, through an adaptor 60, 3/8" comp. to
1/2" sanitary, pressure regulator 62, by a pressure gage
64, through an adaptor 66, 3/8" comp to 1/2" sanitary,
to a predose facility 68 which feeds 16 predose nozzles
or needles 70. Returning to T 56, the right leg 72
5 leads to an adaptor 74, 3/8" comp to 1/2" sanitary,
pressure regulator 76, gage 78, an adaptor 80, 3/8" comp
to 1/2" sanitary, to a Kynar T 82, and then to both lens
transfer facilities 84, each of which feeds 16 transfer
nozzles 85. Returning to T 52, the right leg 86 flows
10 to a pressure relief valve 88, a check valve 90, and a
degasser 92, which is a vacuum vessel to degas the
deionized water during normal production, up to a ball
valve 96. The vacuum degasser is supplied with a vacuum
by a vacuum pump 98, operating through a vacuum relief
15 valve 100, and a pressure gage 102.

Figure 3 is a piping detail diagram for the
deionized water supply of a predose facility. In Figure
3, all fittings and tubing are Kynar, and all fittings
have steel grippers. Fluid (either deionized water
20 during normal operation or clean steam during a
sanitizing operation) flows through a central tube 110,
Kynar tubing 3/8" OD x 1/4" ID, to a 3/8" Kynar T 112,
and then divides to the left to one additional 3/8"
Kynar T 114, and one additional 3/8" Kynar L 115, and
25 also divides to the right to one additional 3/8" Kynar T
114, and one additional 3/8" Kynar L 115.

The arrangement includes four symmetrical legs
116, 118, 120 and 122, one leg depending from each T 114
or L 115. Only the left-most leg 116 of the four
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1 symmetrical legs 116 is illustrated in detail in Figure
3, and it will be explained in detail with the
understanding that the other three legs 118, 120 and 122
are substantially identical. Fluid flows through the
5 3/8" L 115 to a 3/8"-1/4" reducer 124 and then to three
successive 1/4" Ts 126 and a last 1/4" L 128. Fluid
then flows to the right (in Figure 3) in four
substantially identical legs 130, 132, 134 and 136.
Each leg includes a 1/4" tube 138, a union 140, a
10 positive displacement pump 142, the output of which
flows through a 1/4" L 144, through a 1/4" OD x 1/8" ID
Kynar tube 145, through locks 146 (manufactured by
Luer), which are essentially medical fittings, to Teflon
or stainless steel nozzles or needles 148, through which
15 a dosage of deionized water is injected into a package
or container for handling a contact lens therein.

Figure 4 is a piping detail diagram of the
deionized water supply of a lens transfer facility. In
Figure 3, all fittings and tubing are Kynar, and all
fittings have steel grippers. Fluid (either deionized
20 water during normal operation or clean steam during a
sanitizing operation) flows into a central tube 210,
Kynar tubing 3/8" OD x 1/4" ID, to a 3/8" Kynar T 212,
and then divides to the left to one additional 3/8"
Kynar T 214, and one additional 3/8" Kynar L 215, and
25 also divides to the right to one additional 3/8" Kynar T
214, and one additional 3/8" Kynar L 215. The
arrangement includes four symmetrical legs 216, 218, 220
and 222, one leg depending from each L 215 or T 214.
Only the left-most 216 of the four symmetrical legs is
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1 illustrated in detail in Figure 3, and it will be
explained in detail with the understanding that the
other three legs 218, 220 and 222 are substantially
identical. Fluid flows through the 3/8" L 215 to a
5 3/8"-1/4" reducer 224 and then to three successive 1/4"
Ts 226 and a last 1/4" L 228. Fluid then flows to the
right (in Figure 4) in four substantially identical legs
230, 232, 234 and 236. Each leg includes a 1/4" tube
238, a union 240, a positive displacement pump 242, the
10 output of which flows through a 1/4" x 1/8" reducer 244,
through a 1/8" OD x 1/16" ID tube 246, to lens transfer
nozzles 248, through which a dosage of deionized water
is injected into a package or container for transferring
lenses from one processing step to the next.

15 While several embodiments and variations of
the present invention for an on-line steam sanitization
system and method are described in detail herein, it
should be apparent that the disclosure and teachings of
the present invention will suggest many alternative
20 designs to those skilled in the art.

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WHAT IS CLAIMED IS:

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1. An on-line steam sanitizing method which comprises, supplying deionized water through a production plant deionized water supply system, which includes deionized water pumps, supply lines, and
5 related equipment, to supply deionized water to various areas of the production plant which require deionized water for the operations being performed thereat, and sanitizing the production plant deionized water supply
10 by an on-line steam sanitization procedure in which steam is introduced into and through the deionized water supply, without disassembling the deionized water supply system, for a predetermined sanitization period, after which the production plant is returned to normal
15 operation.

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2. An on-line steam sanitizing method for a production plant as claimed in claim 1, wherein the deionized water is supplied to a production plant which produces and packages contact lenses.

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3. An on-line steam sanitizing method for a production plant as claimed in claim 2, wherein the deionized water is supplied to a predose facility for supplying predoses of deionized water to packages making them ready to accept lenses to be deposited therein, and to a lens transfer facility for supplying measured doses
25 of deionized water to nozzles on robotic arms for transferring lenses from one processing step to the next.

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4. An on-line steam sanitizing method for a production plant as claimed in claim 2, wherein a source
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1 of house steam heats deionized water from the deionized
water supply to generate a clean deionized steam
therefrom, and the clean deionized steam is used in the
sanitizing step.

5 5. An on-line steam sanitizing method for a
production plant as claimed in claim 1, wherein the use
of steam in a sanitizing operation in an existing
deionized water supply system required modifying the
production plant equipment to withstand the pressure and
10 heat of the steam sanitizing step.

15 6. An on-line steam sanitizing method for a
production plant as claimed in claim 5, wherein said
modifying step includes removing reservoirs, which could
not withstand the pressure and heat of sanitization, and
replacing the reservoirs with pressure regulators.

20 7. An on-line steam sanitizing method for a
production plant as claimed in claim 6, including
reducing the pressure of the sanitizing clean steam from
approximately 10 psi to approximately 1-3 psi with the
pressure regulators.

25 8. An on-line steam sanitizing method for a
production plant as claimed in claim 5, wherein said
modifying step includes utilizing a new manifold design
which has a symmetrical design leading to each of the
pumps.

30 9. An on-line steam sanitizing method for a
production plant as claimed in claim 8, including
utilizing in the symmetrical design an equal number of
fixtures leading in each line to each of a plurality of
pumps in a symmetrical arrangement.



1 10. An on-line steam sanitizing method for a
production plant as claimed in claim 5, wherein the
modifying step includes utilizing Kynar tubes and Kynar
fixtures.

5 11. An on-line steam sanitizing method for a
production plant as claimed in claim 3, including
introducing deionized water into the deionized water
supply system through a shut-off valve, and closing the
10 deionized water shut-off valve during the steam
sanitizing step, after which it is opened, and
introducing the clean steam into the deionized water
supply through a shut-off valve, and opening the clean
steam shut-off valve during the steam sanitization
operation, after which it is closed.

15 12. An on-line steam sanitizing method for a
production plant as claimed in claim 1, wherein a source
of house steam heats deionized water from the deionized
water supply to generate a clean deionized steam
therefrom, and the clean deionized steam is used in the
sanitizing step.

20 13. An on-line steam sanitizing method for a
production plant as claimed in claim 1, including
introducing deionized water into the deionized water
supply system through a shut-off valve, and closing the
25 deionized water shut-off valve during the steam
sanitizing step, after which it is opened, and
introducing the clean steam into the deionized water
supply through a shut-off valve, and opening the clean
steam shut-off valve during the steam sanitization
30 operation, after which it is closed.



1 14. An on-line steam sanitizing system for a
production plant deionized water supply system which
includes deionized water pumps, supply lines, and
related equipment, to supply deionized water to various
5 areas of the production plant which require deionized
water for the operations being performed thereat, and a
sanitizing steam input to the production plant deionized
water supply, which is sanitized by an on-line steam
sanitization procedure in which sanitizing steam is
10 introduced from the sanitizing steam input into and
through the deionized water supply, without disassembly
thereof, for a predetermined sanitization period, after
which the production plant is returned to normal
operation.

15 15. An on-line steam sanitizing system for a
production plant as claimed in claim 14, wherein the
production plant includes facilities for the production
and packaging of contact lenses.

20 16. An on-line steam sanitizing system for a
production plant as claimed in claim 15, wherein the
plant production line facilities include a predose
facility wherein predoses of deionized water are
supplied to packages making them ready to accept lenses
to be deposited therein, and a lens transfer facility,
25 which includes nozzles on robotic arms, to which
measured doses of deionized water are supplied for
transferring lenses from one processing step to the
next.

30 17. An on-line steam sanitizing system for a
production plant as claimed in claim 15, wherein the



1 production plant facilities include a source of house
steam, and a sanitizing vessel in which house steam is
used to heat deionized water from the deionized water
supply to generate a clean deionized steam therefrom
which is suitable for the sanitization procedure.

5 18. An on-line steam sanitizing system for a
production plant as claimed in claim 14, wherein the use
of steam in a sanitizing operation in an existing
deionized water supply system required that the
10 production plant equipment be modified to withstand the
pressure and heat of the steam sanitizing operation, and
the modifications include the addition of pressure
regulators which reduce the pressure of the sanitizing
clean steam or distilled water.

15 19. An on-line steam sanitizing system for a
production plant as claimed in claim 18, wherein the
modifications include a manifold which has a symmetrical
design leading to each of a plurality of pumps.

20 20. An on-line steam sanitizing system for a
production plant as claimed in claim 19, wherein the
symmetrical design includes an equal number of fixtures
leading in a symmetrical arrangement to each of the
plurality of pumps.

25 21. An on-line steam sanitizing system for a
production plant as claimed in claim 18, wherein the
modifications include Kynar tubes and Kynar fixtures.

30 22. An on-line steam sanitizing system for a
production plant as claimed in claim 16, including a
shut-off valve, through which deionized water is
introduced into the deionized water supply system, which



1 is closed during the steam sanitization operation and is
opened thereafter, and a second shut-off valve, through
which clean steam is introduced into the deionized water
supply, which is opened during the steam sanitization
operation and is closed thereafter.

5 23. An on-line steam sanitizing system for a
production plant as claimed in claim 14, wherein the
production plant facilities include a source of house
steam, and a sanitizing vessel in which house steam is
10 used to heat deionized water from the deionized water
supply to generate a clean deionized steam therefrom
which is suitable for the sanitization procedure.

15 24. An on-line steam sanitizing system for a
production plant as claimed in claim 14, including a
shut-off valve, through which deionized water is
introduced into the deionized water supply system, which
is closed during the steam sanitization operation and is
opened thereafter, and a second shut-off valve, through
which clean steam is introduced into the deionized water
supply, which is opened during the steam sanitization
20 operation and is closed thereafter.

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