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ABSTRACT

A process for providing essentially fully degassed complementary concave and convex lens molds to filling and mold assembly stations, respectively, in a continuous or semicontinuous automated soft contact lens manufacturing system.

- 5 The process comprises the steps of injection molding the lens molds, immediately transferring the lens molds to an inert gas atmosphere, degassing the lens molds, and filling the lens molds with a polymerizable monomer under the inert gas prior to mold assembly.

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**COMPLETE SPECIFICATION
FOR A STANDARD PATENT**

ORIGINAL



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Invention Title:	LOW OXYGEN MOLDING OF SOFT CONTACT LENSES

The following statement is a full description of this invention, including the best method of performing it known to us

LOW OXYGEN MOLDING OF SOFT CONTACT LENSES

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BACKGROUND OF THE INVENTION

1. Field of the Invention.

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The present invention relates generally to a method for molding soft contact lenses, and particularly a low oxygen method for molding and handling lens molds to minimize defects in lens blanks produced therewith.

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2. Discussion of the Prior Art.

Contact lens blanks may be made in two-part molds of the type described and shown in U.S. Patent Nos. 4,565,348 and 4,640,489 by polymerizing a reactive monomer and a water displaceable diluent optionally in the presence of a catalyst, under conditions of elevated temperature or actinic radiation, generally ultraviolet light, as described in U.S. Patent No. 4,495,313.

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Typically, molds are formed, generally by injection molding, from a suitable thermoplastic, and the molds, usually in frames associating a number of such molds with support structure are shipped to and stored for use in a production facility for contact lens blanks. The lens blank production line then comprises stations for filling the concave lens molds with the polymerizable lens-forming composition, registering therewith in vertical displacement convex lens molds, urging the respective paired molds into molding engagement about the periphery of the polymerizable monomer pool, thereby displacing excess monomer and forming an incipient lens blank, curing the reactive monomer to form the lens blank, and demolding the lens blank all as described in the aforementioned U.S. patents or U.S. Patent Nos. 4,680,336 or 5,080,839 all of which are incorporated herein by reference.

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It is known that the use of lens molds maintained under normal atmospheric conditions leads to inhibition of, and thus incomplete curing of the reactive monomer composition at the surface of the lens, which in turn can adversely alter physical properties and optical parameters of the lens. This phenomenon has been traced to the presence of oxygen molecules in and on the lens mold surface, which is due to its inherent capability of the preferred polystyrene molding material to sorb quantities of oxygen. During molding of the lens, this oxygen can be released to the polymerization interface with the reactive monomer composition in amounts which exceed acceptable maximums as determined by empirical testing. More specifically, the oxygen copolymerizes rapidly with the reactive monomer but the polymerization chain thus formed is readily terminated, the result being a decrease in rate of monomer reaction, the kinetic chain length, and the polymer molecular weight. The criticality of oxygen level and the difficulty of implementing effective control protocols may be appreciated by recognizing that the level of oxygen at the reactive monomer/mold interface must be controlled to approximately 300 times less than the concentration of oxygen in air (3×10^{-3} moles/liter).

This recognized problem has been addressed in the art by careful but time consuming and laborious preconditioning of the molds utilizing chambers evacuated to a maximum of 1 torr and maintained in this condition for a period of not less than 10-12 hours. Any interruption of the work cycle such as might be caused by a power interruption requires reinitiation of the conditioning treatment. Extended thermal treatment is contraindicated with these preformed molds and mold frames to avoid warping, surface bubbling and the like which even in microscopic terms would destroy the

integrity of the surface for its purpose in defining a
1 lens of the requisite optical clarity. Thus, while
limited heating, e.g. 1 hour at 75°C, may be employed
there remained a need for a less cumbersome and more
reliable method to control oxygen levels at the mold
5 surface without distortion thereof.

However, even brief exposure of the molds to
air after degassing, as in normal manufacturing handling
is detrimental; it has been learned that even a 30
second exposure to air results in sufficient absorption
10 of oxygen to require 5 to 10 minutes degassing to
reacquire an acceptable condition. Accordingly, a
degassing operation immediately proximate the
manufacturing line, particularly for large volume
transfers of molds with different exposure times was
15 deemed impractical, and no real improvement over the
present system.

The problem is complicated by the fact that
the front and back curves of the juxtaposed mold
sections exhibit different thicknesses, leading to
20 potentially different exposure of the reactive monomer
composition to oxygen across the surfaces of varying
cross-sections which could result in distortion of the
lens and degradation of its optical properties,
including refractive index. Thus, the concentration
25 distribution of oxygen in the respective mold sections
or halves remains symmetrical for short degas times, but
becomes progressively less symmetrical for longer degas
times, and the anomaly can cause uneven cure and
different properties between the front and rear surface.
30 For example, the convex mold may be degassed within
about 2 hours, whereas the concave mold may not be
entirely degassed even after 10 hours.

The commercial demand for soft contact lenses
has dictated the development of continuous or at least

semicontinuous manufacturing lines. The criticality of manufacturing specifications in turn demands automated handling of the lens manufacturing operation.

It is thus desirable of the present invention to provide a method for the control of oxygen in a contact lens manufacturing system permitting the production of contact lens
5 blanks with substantially reduced defect levels.

It is also desirable to produce such contact lens blanks consistently with continuous or at least semicontinuous manufacturing lines to achieve high speed, high volume operations.

It is further desirable to integrate such manufacture with automated systems to
10 minimize handling and improve and shorten time delays in material transfer.

SUMMARY OF THE INVENTION

The invention involves the improved manufacture of lens blanks for soft contact
15 lenses and more particularly to subsystem operations, procedures and protocols implemented in a continuous or at least semi-continuous automated manufacturing line to provide at high speed, lenses of improved physical and especially optical characteristics, including reduced variability, for example as measured by standard deviation in base curve radii. The invention includes a method implemented by associated apparatus according to



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a protocol to control oxygen levels at the interface between the lens mold blank and the reactive monomer composition within levels for reliable production of lenses of acceptable optical quality under optimum manufacturing conditions.

Specifically, it has now been discovered that satisfactory control of oxygenation of the lens mold surfaces may be achieved upon the basis of considerations of diffusivity rates for oxygen molecules in or on the mold itself and interchange with the surrounding medium.

Accordingly the invention provides a process for providing degassed complementary concave and convex lens molds to filling and mold assembly stations, respectively, in a continuous or semicontinuous automated soft contact lens manufacturing system comprising injection molding said lens molds, and transferring said lens molds to an inert gas atmosphere within 30 seconds, degassing said lens molds in an inert gas, and filling one of said lens molds with a polymerizable monomer prior to mold assembly.

In accordance with the present invention, lens mold blank preparation is preferably integrated with lens blank manufacture to minimize time of exposure of lens blank molds to oxygen prior to implementation of the curing stage. Given that even a one minute delay between filling (introduction of the reactive monomer composition to the cavity of the concave lens mold section) and curing would require five hours of degas to achieve a target minimum of 1×10^{-8} moles/cm³ concentration of oxygen at the reactive monomer/mold interface, the facility of in line preparation of the lens mold blanks will be appreciated. Reduction in oxygen levels is thus achieved not by degas alone, as practiced in the prior method, but in the high temperature conditions obtained in the molding equipment, and the fresh molding of a fully degassed mold blank which is as soon as possible blanketed in an inert gas such as nitrogen for further handling through filling, precure and final cure.

In accordance with a second aspect of the invention, there is provided a process for preparing lens mold blanks for immediate use in a manufacturing system for the continuous or semicontinuous production of soft contact lens blanks comprising injection molding polystyrene mold lens blanks at a mold temperature of at least 450°F over a cycle of three to twelve seconds, transferring said lens mold to an enclosed zone under an atmosphere of nitrogen within about 12 to 15 seconds, degassing said lens mold under an inert atmosphere for at least about 3 minutes, and transferring said lens mold blanks to filling, precure and curing operations to form lens blanks.



- 5a -

It has been determined that a key parameter in controlling oxygen levels at the mold interface is the diffusivity of oxygen into and from the mold surface in response to ambient conditions, and thereafter to and into the mold/reactive monomer composition.

Molded lens

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molds readily accept via adsorption and absorption
1 mechanisms an unacceptably high level of retained but
migratable oxygen relative to the sensitivity of the
reactive monomer composition, particularly in the case
of the preferred polystyrene mold component. The
5 migration of oxygen responds to concentration such that
when a mold is subjected to a vacuum, it will migrate at
applicable diffusion rates to the lesser concentration,
in this instance the vacuum. Naturally, the surface of
the mold will be the last portion to fully degas,
10 leading to the unacceptably long degas times for
conditioning pretreatment. For similar reasons,
readsorption of oxygen will occur at the surface, and
reequilibration to the interior will again be controlled
by diffusion rates in the mold material, hence any
15 exposure to the atmosphere will rapidly result in
unacceptably high levels of oxygen at the mold
interface, which only relatively extensive conditioning
treatment will resolve, as a portion of the surface
situated oxygen will diffuse to the oxygen poor
20 interior, and then must be reacquired to the surface
prior to elimination to the vacuum, or inert gas medium.

The recognition that diffusion of sorbed
oxygen from the interior of the lens mold could lead to
disruption of lens quality even where surfaces had been
25 swept of residual oxygen, thus lead to a further
modification of processes for the handling of lens mold
for and through the molding process. Specifically,
every exposure of the lens mold to the atmosphere could
be expected to lead to further sorption of oxygen which
would diffuse in part to the interior of the part. In
30 consequence, surface flushing as with nitrogen would not
be sufficient to avoid molding problems derivative from
the presence of oxygen, as in an oxygen starved inert
atmosphere, the oxygen stored in the interior of the

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lens mold would readily and relatively rapidly desorb to the surface. Then, once the mold was filled with reactive monomer, no amount of flushing would resolve the problem.

5 It was then realized that for every atmospheric exposure, the lens mold would optimally be wholly degassed, hence only by minimizing the time of such exposures, and holding the lens mold under nitrogen for a time to permit essentially complete degassing could the problem be resolved satisfactorily. According to the invention, the injection molding operations previously performed off-site are physically integrated into the contact lens manufacturing line. With the preferred
10 high temperature and pressure of the mold equipment, the initially high oxygen levels on the pelletized feed are efficiently cleared and the fresh surfaces formed in the molding process are readily and preferentially purged of residual oxygen. The pelletized feed may also be degassed with nitrogen in the hopper of the injection mold.

15 According to a third aspect of the invention, there is provided a method for the continuous or semicontinuous production of soft contact lens blanks which utilises lens mold blanks capable of sorbing oxygen from the atmosphere and a polymerizable composition for the formulation of lens blanks comprising reactive monomer adversely affected in its curing by the presence of small amounts of oxygen, the improvements characterized by integrating the injection molding of lens
20 mold blanks with the soft contact lens manufacturing line so to utilize the heat of the molding process to provide essentially degassed lens mold blanks, and within 30 seconds transferring said lens mold blanks to an enclosed zone blanketed in inert gas, in which the blanks are maintained for a time commensurate to atmospheric exposure from 3 to 15 minutes.
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In accordance with a fourth aspect, there is provided a method of preparing soft contact lens blanks from reactive monomers therefor, the curing properties of which are adversely affected by the presence of oxygen in or upon paired concave and convex lens mold surfaces, the improvement which comprises:



(a) producing the lens molds proximate the lens molding operation under conditions of controlled temperature sufficient to essentially completely remove oxygen therein,

(b) transferring the lens molds with minimum exposure to the atmosphere
5 to and through an inert atmosphere for a period not less than 3 minutes, sufficient to remove oxygen therein,

(c) filling said concave lens mold with reactive monomer, and transporting said filled concave lens molds into incipient engagement with said convex lens mold in an enclosed zone maintained in reduced pressure,

10 (d) positionally interfacing said concave and convex lens molds in said reduced pressure zone to form a mold for said soft contact lens, and vertically displacing said respective lens molds to displace excess reactive monomer from and to sealingly engage the concave and convex molds about said lens blank to form same in the substantial absence of oxygen.

15 The invention may also provide a method for the continuous or semicontinuous automated production of soft contact lenses including the steps of filling concave lens molds with a reactive monomer composition, forming a mold assembly with a convex lens mold and molding and curing contact lens blanks,

the improvement characterised by integrating lens mold and lens blank
20 production lines, minimizing exposure of freshly prepared lens molds to the atmosphere, and degassing lens molds in an inert atmosphere correlatively to atmospheric exposure in relation to diffusion rates for oxygen in and through the lens mold composition, whereby levels of oxygen at the reactive monomer/lens mold interface in the molding step are no greater than 1×10^{-8} moles/cm³.

25 The invention may further provide a method for maintaining oxygen levels at or below 1×10^{-8} moles/cm³ at the interface between a polystyrene lens mold and a reactive monomer composition based upon an acrylate alkylacrylate monomer comprising injection molding complementary concave and convex lens molds, respectively, transferring said lens molds to a nitrogen atmosphere within 30
30 seconds, degassing said lens molds in an inert atmosphere and transferring said lens molds filling and mold assembly, respectively.



- 7b -

Improvements in injection mold design and modifications in operational parameters, US Patent No. 5,540,410 for Mold Halves and Molding Assembly for Making Contact Lenses, (incorporated herein by reference) have permitted advantageous reductions in cycle time. However, when the mold pieces are ejected
5 from the mold, even in conjunction with the preferred automated system they may be subjected during transfer operations to atmospheric conditions, in which circumstances oxygen can diffuse into the mold, hence such exposure in demolding and transfer operations is limited to no more than about 15 seconds in each mold transfer, preferably no more than 12 seconds, whereafter the mold elements

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are blanketed in an inert gas environment, preferably
1 nitrogen, provided in tunnel means incorporated about
the material transfer line and about the filling and
precure stations. The surface oxygen under these
conditions diffuses into the nitrogen and into the
5 depths of the mold element, away from the surface.

Based upon empirical studies involving
polystyrene lens molds in automated operations under
carefully controlled conditions it has been determined
that a lag time for degassing under nitrogen of at least
10 3 minutes is required for each exposure of the lens mold
of 15 seconds, for lens molds prepared under conditions
described in US Patent No. 5,540,410, although
correlatively longer and shorter degassing times may
apply for differing atmospheric exposures, or different
15 system protocols.

After an exposure of from about 1 to about 5
minutes to nitrogen, usually within three minutes, the
oxygen level at the surface is within tolerance limits,
and usually is essentially zero within instrument
20 capability.

The degassed concave lens mold sections are
forwarded to a filling or dosing station maintained
under nitrogen in which the reactive monomer is pooled
in the concave mold sections. The concave and
25 (degassed) convex lens mold sections are transferred to
a mold registry and engagement operation maintained
under vacuum, in which complementary concave and convex
mold sections are associated in operative molding
relation and aligned so that their axes of rotation are
30 collinear and their respective flanges are parallel, by
automated handling means. The concave and convex lens
mold halves or sections in operative molding relation
are then transferred to a precure station within the
nitrogen tunnel.

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Conveniently, degassing need not be effected
1 after precure firstly because the system is closed, that
is the reactive monomer is sealed between the paired
concave and convex lens molds, and the curing time is
sufficiently short such that diffusion of oxygen from
5 the exterior of the lens mold does not occur to any
degree to interfere with the molding process before it
has been completed.

The continuous process implementing the
features of this invention is effected utilize a lens
10 mold manufacturing zone, comprising first and second
injection molding stations for the formation of concave
and convex lens molds, respectively, and includes a
transport line upon which concave and convex lens parts
may be conveyed from zone to zone; an enclosed zone
15 ('nitrogen tunnel') maintained under nitrogen for
degassing mold halves or sections, filling concave mold
sections with reactive monomer composition, registering
concave and convex mold sections in aligned relation, as
aforesaid, and engaging same in mating molding relation
20 under vacuum conditions, and precuring said reactive
monomer composition with ultraviolet light to a gel-like
state, said zone including a continuation of the said
transport means for concave and convex mold sections,
and a cure zone in which the cure is completed and the
25 finished lens blank readied for demolding. It will be
appreciated that the entire process is integrated via
transport means, generally one or more conveyors upon or
in relation to which lens molds are assembled, arranged
or interleaved in the course of conveyance through the
30 said zones or stations in operational sequence. The
lens molds may for convenience be situated in or upon
mini-pallets (for example, fabricated of cast aluminum,
stainless steel or the like) containing a number of lens
molds (for example eight) arranged regularly thereon in

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spatial relation correlated with the treatment stations
1 and the automated material transfer equipment where
employed. All of the conveyance belts or tunnels are
under nitrogen or inert gaseous blankets.

5 Aspects and preferred features of the contact
lens manufacturing system in part described and claimed
herein are detailed in US Patent No. 5,540,543 for
Apparatus for Removing and Transporting Articles from
Molds; US Patent No. 5,744,357 for Production Line Pallet
10 System; Australian Patent Application No. 20567/95 for Mold
Clamping and Precure of a Polymerizable Hydrogel; and US
Patent No. 5,540,410 for Mold Halves and Molding Assembly
for Making Contact Lenses, the disclosure of all of which
15 are incorporated herein by reference.

20 BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing objects and advantages of the
present invention for mold treatment and handling in a
contact lens molding system may be more readily
25 understood by one skilled in the art with reference to
the following detailed description of the invention and
its preferred embodiments, taken in conjunction with the
accompanying figures [wherein like elements are
designated by identical reference throughout the several
views.]

30 Figure 1 is a flow diagram of the continuous
process for lens mold production, treatment and handling
of molds and contact lenses in a low oxygen environment.

Figure 2(a) is a simplified plan view of the

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1 first section of an automated line for the molding of
hydrogel contact lenses, and includes diagrammatic plan
views of the injection apparatus and robotic material
handling devices used to prepare mold halves for the
lenses to be molded.

5 Figure 2(b) is a simplified plan view of a
second section of the automated line for molding
hydrogel contact lenses, which illustrates the filling
and assembly stations and a precure station utilized in
the practice of the present invention.

10 Figure 2(c) is a simplified plan view of a
third section of the automated line for molding hydrogel
contact lenses, which illustrates the curing ovens for
the lenses.

15 Figure 2(d) is a simplified plan view of a
fourth section of the automated line for molding
hydrogel contact lenses, which illustrates the demolding
station for the lenses.

20 Figure 3 is a diagrammatic view of an
apparatus that may be used as a degas ventilation system
in the practice of the present invention.

Figures 4(a) and 4(b) are top and side views,
respectively, of front curve mold half that may be used
in the practice of the present invention.

25 Figures 5(a) and 5(b) are top and side views,
respectively, of back curve mold half that may be used
in the practice of the present invention.

Figure 6 is a diagrammatic illustration of an
apparatus used to degas the monomer or monomer mixture
used in molding the lenses.

30 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is useful in a process
for forming soft contact lenses from a polymerizable

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hydrogel. The soft contact lenses are formed in a mold
1 assembly having a first concave or front curve mold half
31 and a second convex or back curve mold half 33. As
illustrated in Figures 4 or 5, the mold halves are
formed of polystyrene transparent to visible and
5 ultraviolet light, with a central curved section
defining a concave surface 31(a) and a central curved
section of the back curve of the front curve defining a
convex surface 33(a). A circular circumferential edge
31(c) is defined on the base or front curve mold 31 and
10 integral with the central curved sections are annular
essentially uniplanar flanges 31(b) 33(b). At least a
part of the concave surface 31(a) and the convex surface
33(a) have the dimensions of the front or back curves,
respectively of a contact lens to be produced in the
15 mold assembly, and sufficiently smooth that the surface
of the contact lens formed by polymerization of said
polymerizable composition in contact with the surface is
optically acceptable. The mold is thin enough and has
rigidity sufficient to transmit heat therethrough
20 rapidly and to withstand prying forces applied to
separate the mold halves during demolding.

The molds can be made from any thermoplastic
material which is suitable for mass production and can
be molded to an optical quality surface and with
25 mechanical properties which will allow the mold to
maintain its critical dimensions under the process
conditions employed in the process discussed in detail
below, and which will allow polymerization with the
initiator and radiant energy source contemplated. The
30 concave and convex mold members can thus be made from
thermoplastic resins. Examples of suitable materials
include polyolefins such as low, medium, and high
density polyethylene, polypropylene, including
copolymers thereof; poly-4-methylpentene; and

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polystyrene. Other suitable materials are polyacetal
1 resins, polyacrylethers, polyarylether sulfones, nylon
6, nylon 66 and nylon 11. Thermoplastic polyesters and
various fluorinated materials such as the fluorinated
ethylene propylene copolymers and ethylene
5 fluoroethylene copolymers may also be utilized.

It has been found that with the need for a
high quality, stable mold and especially for the use of
a plurality of molds in high volume operations the
choice of material for the molds is significant. In the
10 present invention the quality of production is not
assured by individual inspecting and sorting each lens
for power and curvature. Instead the quality is assured
by keeping the dimensions of each individual mold member
within very tight tolerances and processing molds in
15 particular sequential steps to give all lenses equal
treatment. Since polyethylene and polypropylene partly
crystallize during cooling from the melt there is a
relatively large shrinkage giving dimensional changes
difficult to control. Thus, it further has been found
20 that the most preferred material for the molds used in
the present process is polystyrene which does not
crystallize, has low shrinkage, and can be injection
molded at relatively low temperature/to surfaces of
optical quality. It will be understood that other
25 thermoplastics, including those mentioned above, may be
used provided they have these same properties. Certain
copolymers or blend of polyolefins that exhibit these
desirable characteristics are also suitable for the
present purposes as are polystyrene copolymers and
30 blends having such characteristics, as described more
fully in U.S. Patent No. 4,565,348.

For efficiency, ease of operation, and cycle
times, injection molding devices are preferred. The
preferred polystyrene is provided in the form of pellets

or particles of relatively high surface area which have
1 equilibrated fully with available oxygen available in
the atmosphere. As the cycle time for purposes of an
automated operation is minimized, average material
throughput is as little as 6 seconds under the inventive
5 conditions described in U.S. Application Serial No.
0_/_/_/, during which the material is heated to a
thermoplastic condition, extruded into the molds and
ejected or removed from the mold. However, the maximum
manifold temperature of 270-280°C is achieved only for a
10 fraction of the material throughput time, and the mold
temperature is only 215-220°C, hence it was surprising
that the injection mold operation was found capable of
delivering essentially fully degassed mold sections in
each cycle.

15 The injection mold equipment is typically
operated under conditions described in the aforesaid
Serial No. 0_/_/_/ including cycle times as short as
6 seconds or less. Unlike prior practice as described
in U.S. Patent No. 4,565,348, the mold is designed to
20 produce fully formed lens mold parts directly, that is
without associated support structure such as a frame;
there is in consequence no need to dissociate the part
from unneeded polymer material on demolding, and the
lens mold parts may be directly collected by automated
25 means for delivery to the transport means. In any given
cycle, any number of mold parts may be prepared but for
convenience of handling, typically 8 lens mold parts of
concave or convex configuration are prepared in a given
cycle and transferred by automated robotic means to a
30 pallet of cast aluminum in which they are received and
supported in a regular spatial array adapted for further
operations.

It should be understood that at most stages of
the continuous process, inspection means are operational

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to effect rejection of parts against reference criteria;
1 hence, following injection molding, inspection,
generally visual, employing photoelectric means, for
example, for such defects as haze, mold defect as in
configuration due to improper material feed and the like
5 may lead to rejection of a part and thus disposal. To
maintain the continuity and consistency in line
operations generally a whole mold cycle or pallet of
lens mold parts will be expelled from the line following
discovery of a defect in any one lens mold part. Each
10 of the pallets contain a unique bar code number for use
in pallet tracking and quality control procedures
utilizing bar code scanners.

The apparatus for removing and transporting
lens mold parts from the mold to the transport means
15 includes hand means for receiving the mold parts and a
support subassembly capable of sliding and pivotable
movement required for transfer of the mold parts to the
horizontally operating transport means. This and
related automated handling equipment is more fully
20 described in US Patent No. 5,540,543 for Apparatus for
Removing and Transporting Articles from Molds, the
disclosure of which is incorporated herein by reference.

Injection molds #1 and #2, as shown at 101 and
25 102 in flow diagram Figure 1, respectively mold front
curve and back curve lens mold parts or sections, in
matched sets and volumes; they may be located in tandem
as shown in Figure 2 or to shorten exposure to the
30 atmosphere still further, they may be located in a
common plane intersecting a bifurcated transport line,
even perpendicularly oriented thereto in the same plane.
In any of these cases, having regard for the possible
ejection of a pallet in the quality control procedure

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1 aforementioned, there is provided means adjacent the
2 mold registry and engagement station for receiving and
3 identifying pallets of concave and convex lens molds
4 respectively and registering convex mold parts in
5 vertically displaced relation with filled concave lens
6 mold parts for formulation of a mold forming assembly
7 for molding lens blanks.

8 In the course of or following complete
9 degassing of the lens mold sections as indicated at 104
10 in Figure 1, the pallets containing concave and convex
11 lens mold sections are ordered into interleaved relation
12 such that automated equipment may effect their operative
13 interengagement into molding relation.

14 The filling or deposition zone including the
15 precure station is enclosed and pressurized over its
16 entire length with an inert gas, conveniently nitrogen.
17 The amount of nitrogen is not critical, it being
18 suitable to use just enough nitrogen pressure to
19 effectively exclude the atmosphere under the operating
20 conditions experienced. In respective sections of the
21 filling or deposition zone included in the nitrogen
22 tunnel the freshly prepared lens mold blanks are
23 degassed, the concave lens molds are filled with the
24 reactive monomer composition, and the concave and convex
25 lens molds are placed into registry and urged into
26 complementary molding relation. The filling zone
27 surrounds a portion of the conveying or transport means,
28 which delivers to the zone pallets of concave and convex
29 lens mold sections, respectively, and at the terminus of
30 the zone carries pallets of paired and filled molds to
31 the precure zone. The filling zone illustrated in
32 Figure 2(b) at 40 is defined by a geometrically
33 appropriate, transparent enclosure, generally of
34 rectangular cross-section, formed of any suitable
35 thermoplastic or metal and thermoplastic construction,

As indicated at step 104 in Figure 1, the
1 monomer or monomer mixture is degassed prior to filling
the mold cavity. The degas apparatus is schematically
illustrated in Figure 6, wherein the monomer or monomer
mixture is provided in containers 100, typically 15
5 liters in volume. The container is connected to the
monomer degassing system by means of line 112. Suction
is developed by pump 114 to draw the monomer from the
drum 100, through line 112, to pump 114, and out the
pump discharge 116. While going through discharge line
10 116, the monomer passes through filter 118 in order to
remove any extraneous particulate contaminants that may
be present in the monomer.

The monomer is then provided to the inlet 120
of the degas unit 122. Within the degas unit, the
15 monomer is divided among a plurality of tubes 124, and
then recombined into a degas unit discharge 126. The
degas unit is operated under a low ambient pressure,
typically around 1-40 torr which is provided by vacuum
pump 128. This vacuum pump is attached to the degas
20 unit 122 by line 130 and discharges the excess air from
the degas unit by way of line 132. The tubing members
124 are formed preferably of a gas permeable tubing such
as STHT tubing produced by Sanitec, Inc. of Andover, New
Jersey from Q74780 Medical Grade Silicon Rubber
25 manufactured by Dow Corning of Midland, Michigan. While
two tubes are illustrated in Figure 6, it is understood
that a plurality of tubes, typically 10 tubes are
provided for the degas unit 122.

After the monomer exit the degas unit 122 by
30 discharge line 126, it passes through an oxygen monitor
134. This monitor measures the residual oxygen within
the monomer to insure that the degas unit is functioning
properly. If the oxygen content of the monomer is
indicated as being too high, operation of the production

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line can be halted until the problem is corrected in
1 order to avoid the production of defective lenses.

Once oxygen monitor 134 has determined that
the oxygen content of the monomer is sufficiently low,
the monomer passes through line 136 into manifold 138.
5 The manifold is used as a common source to supply a
plurality of precision dose pumps 140 regulated by pump
controllers 141 and used to fill the individual contact
lens mold at the monomer dosing station 50. The pumps
140 used to pump the processed monomer delivered to
10 manifold 138 are IVEK pumps made by the IVEK Corporation
of North Springfield, Vermont. These pumps provide
precision doses of degassed monomer to the mold cavities
31 via nozzles 142.

As was hereinafter previously described with
15 respect to Figure 1(a). The monomer is supplied from
pumps 140 to nozzles 142 via gas in previous supply
lines 141 which may include coupling blocks 143 to aide
in servicing the equipment. Each of the supply lines
141 is coupled to an associated discharge nozzle 142,
20 which are suspended directly over the path of the pallet
20 and the individual front curves 31 at the filling
zone 40. It should also be noted that the ambient
atmosphere surrounding pallet 20 at the time of filling
is a low oxygen N² environment. Pumps 140 are actuated
25 to deliver a controlled dose of 60 μ l to each of the
mold cavities 31.

Each of the nozzles 142 includes a teflon
dosing tip with an O.D. of approximately .070" and an
I.D. of approximately .040. Each tip is cut at
approximately a 45° angle, and is positioned to be
30 within .5 mm of the horizontal tangent of the front
curve 31 at the time of filling.

As the monomer or monomer mixture is pumped,
it pools upwardly around the tip, so that the angle of
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the tip is covered. The nozzle 142 is reciprocated
1 upwardly after filling the mold cavity and the pool of
monomer wicks the nozzle tip, and draws any excess
monomer from the face of the tip to avoid drop formation
on the tip. This wicking action increases the accuracy
5 of the dose, it pulls off potential drops of monomer and
it avoids any agitation of the monomer that might result
in bubble formation.

If drops of monomer form on the tip, there is
the possibility of contamination of a passing pallet or
10 the filling station from an inadvertent drop.
Individual drops of monomer, even when deposited into a
mold cavity, or on top of the monomer pool, have been
found to generate a "seed" site for a gas bubble. By
wicking the tip with the monomer pool, this possibility
15 is substantially eliminated.

As illustrated at 105 in Figure 1, the concave
lens mold sections are filled with the reactive monomer
composition, and then transported into and through a
vacuum chamber formed intermittently and integrally of
20 the nitrogen tunnel in which filled concave lens molds
are engaged with convex mold sections in vertical
alignment and in mating relation, such that the reactive
monomer composition is trapped between the optical
surfaces of the respective mold sections and at least
25 partially sealed by the engagement of the sealing ring
formed peripherally in each of the lens mold sections.
The vacuum is released and the mated mold is passed
through nitrogen to the precure station, an integral
part of the nitrogen tunnel.

30 Conveniently, the vacuum chamber is formed
upon and about a single pallet by the periodic
reciprocable motion of apparatus also comprising means
for alignment of the seating of the convex mold sections
upon the concave mold sections so their axes of rotation

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are collinear and their respective flanges are parallel.
1 Upon sealing engagement with the pallet the thus formed
chamber is evacuated in order to ensure that no gas
bubbles are entrapped between and upon the respective
optical molding surfaces. The degree of vacuum is
5 selected for the purpose of removing any gas bubbles at
the reactive monomer/mold interface entrapped in the
course of closure between the complementary mold
sections.

Precure is effected all as described in
10 Australian Patent Application No. 20567/95 for Mold
Clamping and Precure of a Polymerizable Hydrogel,
incorporated herein by reference.

The critical feature of the present invention
15 resides in the mold handling and treatment steps, in
which exposure of the freshly molded lens mold parts to
the atmosphere is limited, and a degassing step is
correlated with such atmospheric exposure as is
necessarily incurred despite automated continuous
20 operations. Thus, when coupled with vacuum registry and
engagement of mold halves or sections, and a precure
under nitrogen conditions the invention permits the
generation of high optical quality soft contact lenses
in volume and at high speed, with a low defect count
25 with superior optical qualities.

In accordance with the present invention and
as illustrated in Figures 2(a)-(d), first and second
injection molds 10, 11 are continuously cycled to
periodically produce (generally, from 3 to 12 seconds,
and preferably around 6 seconds) sets of concave and
30 convex lens mold parts or sections which are collected
from molds at the end of each cycle. In the geometric
configuration obtaining, (and preferred for better
manipulative exchange) the mold upon opening for

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demolding present the finished lens mold parts in or
1 close to the vertical plane, generally -5 to 10° from
the vertical. As illustrated in Figure 2(a) and noted
at 103 in Figure 1, the respective fingers of the
articulated hand means 12, 13 gently engage and receive
5 the set of molds and while maintaining same in
essentially the same spatial relation, rotates from a
plane generally perpendicular to the transport line
through 90° to a parallel plane above the transport
means while simultaneously or sequentially rotating
10 toward and engaging the horizontal plane of the
transport line, and releases the mold parts into
registry with carrier pallets 14, 15 therefor with
related spatial geometry located adjacent the production
line transport or conveyor means indicated generally at
16 in Figure 2(a). Obviously separate means feed
15 carrier pallets 14, 15 are in timed sequence with the
action of the collecting arms 12, 13.

The front curve mold parts or halves are
removed from the injection mold 10 in an inverted
orientation to avoid any possible contact with the
20 optical surface 31(a) of the mold half. The front curve
halves are then inverted by robotic transfer hand 19 and
deposited on a stationary pallet therebelow.

The articulated robotic transfer arm 18
25 deposits the back curve mold parts directly on a
production line pallet 20 that has been momentarily
paused by a clamping means 21.

After receiving the sets of mold parts, the
pallets are advanced by the belt conveyors 22, 23, in
the direction indicated by the arrows in Figure 2(a)
30 into a low oxygen environment, generally indicated by
housing means 24. Housing means 24 is pressurized with
 N_2 as indicated, and may optionally be equipped with the
nitrogen ventilation lock illustrated in Figure 3 at

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each entry and egress point of the low oxygen
1 environment, including entry points 24(a) and 24(b).

Figure 3 is a diagrammatic representation of a
nitrogen ventilation system that could be utilized
advantageously at 24(a), 24(b) and 24(c), respectively.
5 As illustrated in Figure 3, the N₂ tunnel enclosure 24
surrounds a conveyor such as conveyor belt 23 in Figure
2(a). The conveyor belt 23 transports a pallet 20
filled with mold parts into the N₂ tunnel through opening
43. Opening 43 may be open to atmosphere with the
10 tunnel pressurized, or it may be closed with a movable
door (not shown) that is opened each time a pallet is
loaded with mold parts. An exhaust vent 44 may also be
provided to provide a controlled exhaust for the
pressurized N₂ and to exhaust any O₂ which enters with
15 ambient atmosphere. If the N₂ exhaust is used, it may
also be equipped with a check valve to maintain 0.1
inches of N₂ pressure within tunnel 24.

While the nitrogen ventilation lock has been
described and illustrated with respect to entry lock
20 24(b), it is understood that it could also be installed
at entry port 24(a) and egress port 24(c). The purpose
of the nitrogen lock is to avoid excess N₂ dissipation
from the N₂ tunnel enclosure 24.

Usually, the carrier pallets containing
25 concave and convex mold parts respectively, are then
interspersed or interleaved alternately upon the
transport means at station 50, prior to entry on the
required production line conveyor 25, but are
independently identifiable to the control means for
handling same at the molding forming station so to
30 compensate for any missing pallet.

A two step robotic handling is used in the
preferred embodiment in order to keep up with the 6 sec
mold cycle time. The first robotic transfer by arms 12,

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13 to intermediate carriers 14, 15 is accomplished in
1 approximately 3 seconds, and during the remaining
interval, the intermediate covers 14, 15 move to a
pickup point for the articulated robotic transfers arms
17, 18. The articulated robotic arms 17, 18 then
5 transfer the sets of mold parts to mold carriers
particularly adapted for use with the production line of
the present invention, as will be hereinafter explained
in detail.

As aforementioned, the lens mold parts or
10 segments are transferred to the nitrogen tunnel 24
within 12-15 seconds, and degassed for a period of time
sufficiently to remove substantially all of the sorbed
oxygen in and on the part. Generally, tolerances are
such that a 3 minute exposure is sufficient, provided by
15 a zone of suitable length within enclosure 24 at
constant speed or coverings 22, 23 and 25, or by a
tortuous passageway in a shorter zone.

Following satisfactory degassing of the lens
mold blanks, and within the nitrogen tunnel 24, the lens
20 molds are conveyed to filling station 30 within the
filling zone 40 illustrated in Figure 2(b). Within the
filling station 30, each of the front curves 31 is
filled with the reactive monomer composition, that is
the monomer composition is pooled via metering flow of
25 about 60 μ l of reactive monomer composition into each
lens mold part to essentially over fill the mold cavity
which results from combining mold parts 31 and 33. The
reactive monomer composition is itself carefully
degassed as previously described to minimize the
30 presence of oxygen.

Each such concave mold is then assembled with
its complementary convex mold partner in a vacuum
station 31 by automated means which inverts sets of back
curve mold halves in vertically displaced registry with

the filled concave lens mold parts, releasing the convex
1 back curve mold parts into and upon the surface of the
filled concave front curve lens mold. As noted at 106
in Figure 1, the paired molds now in molding relation
are intermittently transported integrally from the
5 treatment and filling and assembly zone 40 through
nitrogen, to a precure station 32 in which the mold
halves are clamped together under predetermined pressure
for a predetermined period of time. The clamping step
aligns the mold halves, removes excess monomer from the
10 mold cavity, and seats a compliant second mold half
against a more rigid first mold half for the precure
step. The clamping pressure aligns flanges formed on
the first and second mold halves to ensure that the
flanges are parallel and that the respective curves of
15 the molds are aligned. The clamping pressure also seats
the sealed mold half against an annular edge formed on
the first mold half to essentially sever any excess
monomer from the molded lens.

The clamping pressure may be applied by an
20 annular air cylinder or spring driven annular cylinder
which allows actinic radiation to pass through the
annulus of the cylinder and through one or more of the
mold halves and into the hydrogel. The means may
include a means for controlling the duration and
25 intensity of the clamping pressure, and the duration and
intensity of the actinic radiation.

After a predetermined clamping period, the
hydrogel is exposed to actinic radiation, such as a UV
light source, to partially cure the monomer or monomer
30 mixture to a gel state.

The precure station 32 is also enclosed within
a low oxygen zone, maintained by a separate hood 41, and
connected to the filling zone 40 by a short transition
tunnel 24(d).

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In the preferred embodiment the radiation
1 source may be actinic, electron beam or radioactive
source, but preferably is an ultraviolet lamp which
irradiate the monomer at 2-4 mW/cm² for 5-60 seconds, but
preferably 30 seconds. Radiation may also be from a
5 high intensity UV source that is pulsed or cycled.

After a second predetermined period of
exposure under clamping pressure, the clamping action
and the UV radiation are removed, and the partially
precured hydrogel lens is then transported in the mold
10 to the extended curing tunnel illustrated in Figure 2(c)
for complete polymerization and cure.

The pallets containing the precured lens
blanks sandwiched between the lens mold blanks are
passed through a nitrogen lock 24(c) at the end of the
15 nitrogen tunnel 24 to a cure zone. The monomer/diluent
mixture is then cured in a UV oven whereby
polymerization is completed in the monomer(s). This
irradiation with actinic visible or ultraviolet
radiation produces a polymer/solvent mixture in the
20 shape of the final desired hydrogel lens. As noted at
107 in Figure 1, the final cure may be under N₂ or under
ambient atmosphere, since a complete cure is effected
before O₂ in the atmosphere can migrate through either of
the mold halves.

Figures 2(b) and 2(c) illustrate the cure zone
25 of the production line in which the present invention is
practiced. To maintain sufficient residence time, of up
to 24 minutes in the cure zone, while maintaining a high
cycle time at the front end of the line, the single
conveyor line 24(a) is doubled to a pair of lines 34, 35
30 by means of the precure transfer arm 36 and a shuttle
ram 37 which transfers half of the output from precure
station 32 from conveyor 34 to conveyor 35. The two

separate lines are then recombined at station 38,
1 immediately after the demolding step at station 33.

The cure is completed by a plurality of IR
ovens 39 and 39(a) which provide UV radiation at an
average intensity of 3 to 3.5 mW/cm² and a controlled
5 temperature of 45°C to 65°C, which may be varied from
oven to oven.

After the polymerization process is completed,
the two halves of the mold are separated in a demolding
step by the demolding apparatus 33 in Figure 1(d)
10 leaving the contact lens in the first or front curve
mold half, from which it is subsequently removed.
Preferably, the flanges of the front and base mold
halves are gripped and pulled away from each other,
either in directly opposite directions or through an
15 angle in a prying sort of motion. Advantageously, the
assembly is first heated moderately to facilitate
separation of the polymerized article from the mold half
surface. The front and base curve mold halves are used
for a single molding and then discarded or disposed of.
20 After the demolding step, the solvent is displaced with
water to produce a hydrated lens, which when fully
hydrated and buffered, will be of the final shape and
size and then packaged, as noted at 108 in Figure 1.
The final size, in most cases, is nominally 10% larger
25 than the original molded polymer/solvent article.

The soft contact lens blanks are formed from a
reactive monomer composition which typically
incorporates in addition to the reactive monomer a water
displaceable diluent in the case of the preparation of a
hydropic lens, a polymerization catalyst to assist in
30 curing the reactive monomer a cross-linking agent and
often a surfactant to aid in mold release.

The curable compositions preferably include
copolymers based on 2-hydroxyethyl methacrylate ("HEMA")

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and one or more comonomers such as 2-hydroxyethyl
1 acrylate, methyl acrylate, methyl methacrylate, vinyl
pyrrolidone, N-vinyl acrylamide, hydroxypropyl
methacrylate, isobutyl methacrylate, styrene,
ethoxyethyl methacrylate, methoxy triethyleneglycol
5 methacrylate, glycidyl methacrylate, diacetone
acrylamide, vinyl acetate, acrylamide,
hydroxytrimethylene acrylate, methoxyethyl methacrylate,
acrylic acid, methacryl acid, glyceryl methacrylate, and
dimethylamino ethyl acrylate.

10 Preferred polymerizable compositions are
disclosed in U.S. Patent No. 4,495,313 to Larsen, U.S.
Patent No. 5,039,459 to Larsen et al. and U.S. Patent
No. 4,680,336 to Larsen et al., the disclosures of which
are hereby incorporated herein by reference. Such
15 compositions comprise anhydrous mixtures of a
polymerizable hydrophilic hydroxy ester of acrylic acid
or displaceable ester of boric acid and a polyhydroxyl
compound having preferably at least 3 hydroxyl groups.
Polymerization of such compositions, followed by
20 displacement of the boric acid ester with water, yields
a hydrophilic contact lens. The mold assembly utilized
in the present invention may be employed to make
hydrophobic or rigid contact lenses, but the manufacture
of hydrophilic lenses is preferred.

25 The polymerizable compositions preferably
contain a small amount of a cross-linking agent, usually
from 0.05 to 2% and most frequently from 0.05 to 1.0%,
of a diester or triester. Examples of representative
cross linking agents include: ethylene glycol
diacrylate, ethylene glycol dimethacrylate, 1,2-butylene
30 dimethacrylate, 1,3-butylene dimethacrylate, 1,4-
butylene dimethacrylate, propylene glycol diacrylate,
propylene glycol dimethacrylate, diethylglycol
dimethacrylate, glycol dimethacrylate, diethylglycol

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dimethacrylate, dipropylene glycol dimethacrylate,
1 diethylene glycol diacrylate, dipropylene glycol
diacrylate, glycerine trimethacrylate, trimethylol
propane triacrylate, trimethylol propane
trimethacrylate, and the like. Typical cross-linking
5 agents usually, but not necessarily have at least two
ethylenically unsaturated double bonds.

The polymerizable compositions generally also
include a catalyst, usually from about 0.05 to 1% of a
free radical catalyst. Typical examples of such
10 catalysts include lauroyl peroxide, benzoyl peroxide,
isopropyl percarbonate, azobisisobutyronitrile and known
redox system such as the ammonium persulfate-sodium
metabisulfite combination and the like. Irradiation by
ultraviolet light, electron beam or a radioactive source
15 may also be employed to catalyze the polymerization
reaction, optionally with the addition of a
polymerization initiator. Representative initiators
include camphorquinone, ethyl-4-(N,N-dimethyl-
amino)benzoate, and 4-(2-hydroxyethoxy)phenyl-2-
20 hydroxyl-2-propyl ketone.

Polymerization of the polymerizable
composition in the mold assembly is preferably carried
out by exposing the composition to polymerization
initiating conditions. The preferred technique is to
25 include in the composition initiators which work upon
expose to ultraviolet radiation; and exposing the
composition to ultraviolet radiation of an intensity and
duration effective to initiate polymerization and to
allow it to proceed. For this reason, the mold halves
30 are preferably transparent to ultraviolet radiation.
After the precure step, the monomer is again exposed to
ultraviolet radiation to a cure step in which the
polymerization is permitted to proceed to completion.
The required duration of the remainder of the reaction-

can readily be ascertained experimentally for any
1 polymerizable composition.

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THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A process for providing degassed complementary concave and convex lens molds to filling and mold assembly stations, respectively, in a continuous or semicontinuous automated soft contact lens manufacturing system comprising injection molding said lens molds, and transferring said lens molds to an inert gas atmosphere within 30 seconds, degassing said lens molds in an inert gas, and filling one of said lens molds with a polymerizable monomer prior to mold assembly.
2. The process of Claim 1, wherein the lens molds are molded under atmospheric conditions, and transferred from the injection molder to said inert gas within about 15 seconds.
3. The process of Claim 2, wherein the lens molds are maintained under said inert gas for a period up to fifteen minutes.
4. A process for preparing lens mold blanks for immediate use in a manufacturing system for the continuous or semicontinuous production of soft contact lens blanks comprising injection molding polystyrene mold lens blanks at a mold temperature of at least 450°F over a cycle of three to twelve seconds, transferring said lens mold to an enclosed zone under an atmosphere of nitrogen within about 12 to 15 seconds, degassing said lens mold under an inert atmosphere for at least about 3 minutes, and transferring said lens mold blanks to filling, precure and curing operations to form lens blanks.
5. The process of Claim 4 wherein concave lens molds are filled with an acrylate reactive monomer composition at an oxygen concentration at the lens mold/reactive monomer interface of not greater than 1×10^{-8} moles/cm³.
6. A method for the continuous or semicontinuous production of soft contact lens blanks which utilises lens mold blanks capable of sorbing oxygen from the atmosphere and a polymerizable composition for the formulation of lens blanks comprising reactive monomer adversely affected in its curing by the presence of small amounts of oxygen, the improvements characterized by integrating the injection molding of lens mold blanks with the soft contact lens manufacturing line so to utilize the heat of the molding process to provide essentially degassed lens mold blanks, and within 30 seconds transferring said lens mold blanks to an enclosed zone blanketed in inert gas, in which the blanks are maintained for a time correlative to atmospheric exposure form 3 to 15 minutes.



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7. A method of preparing lens mold blanks substantially as hereinbefore described with reference to the preferred embodiment.

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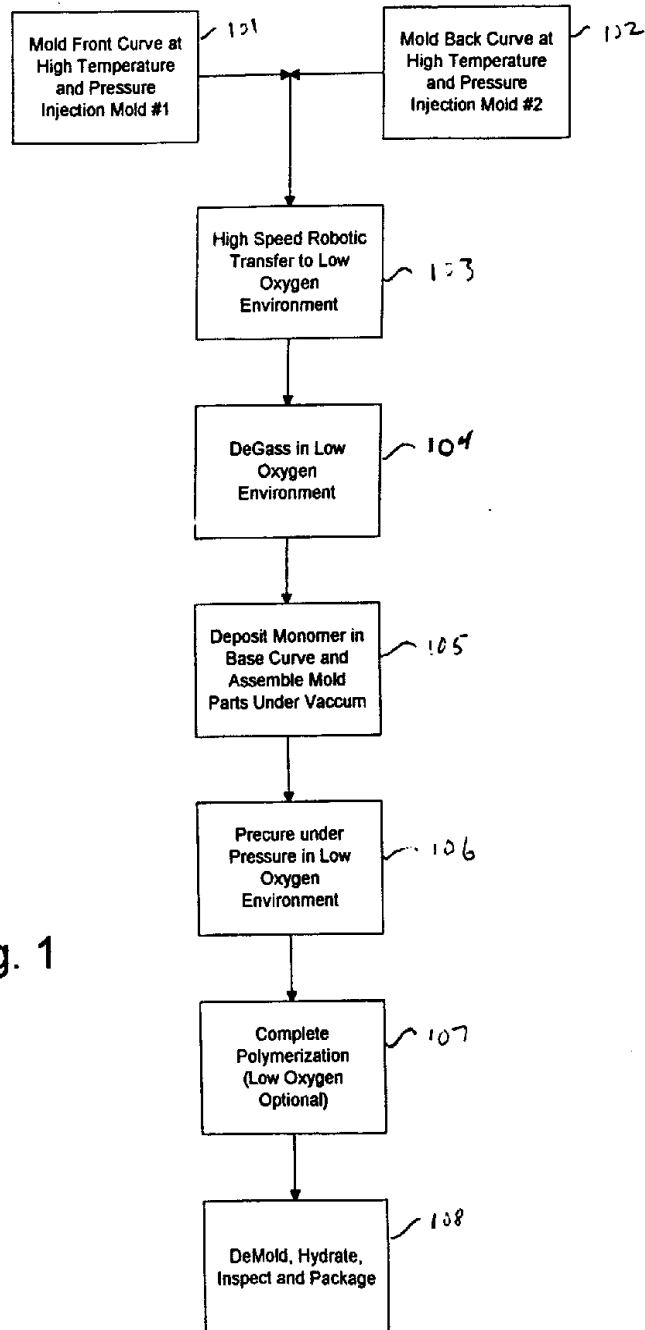


Fig. 1

9 06 35 20557

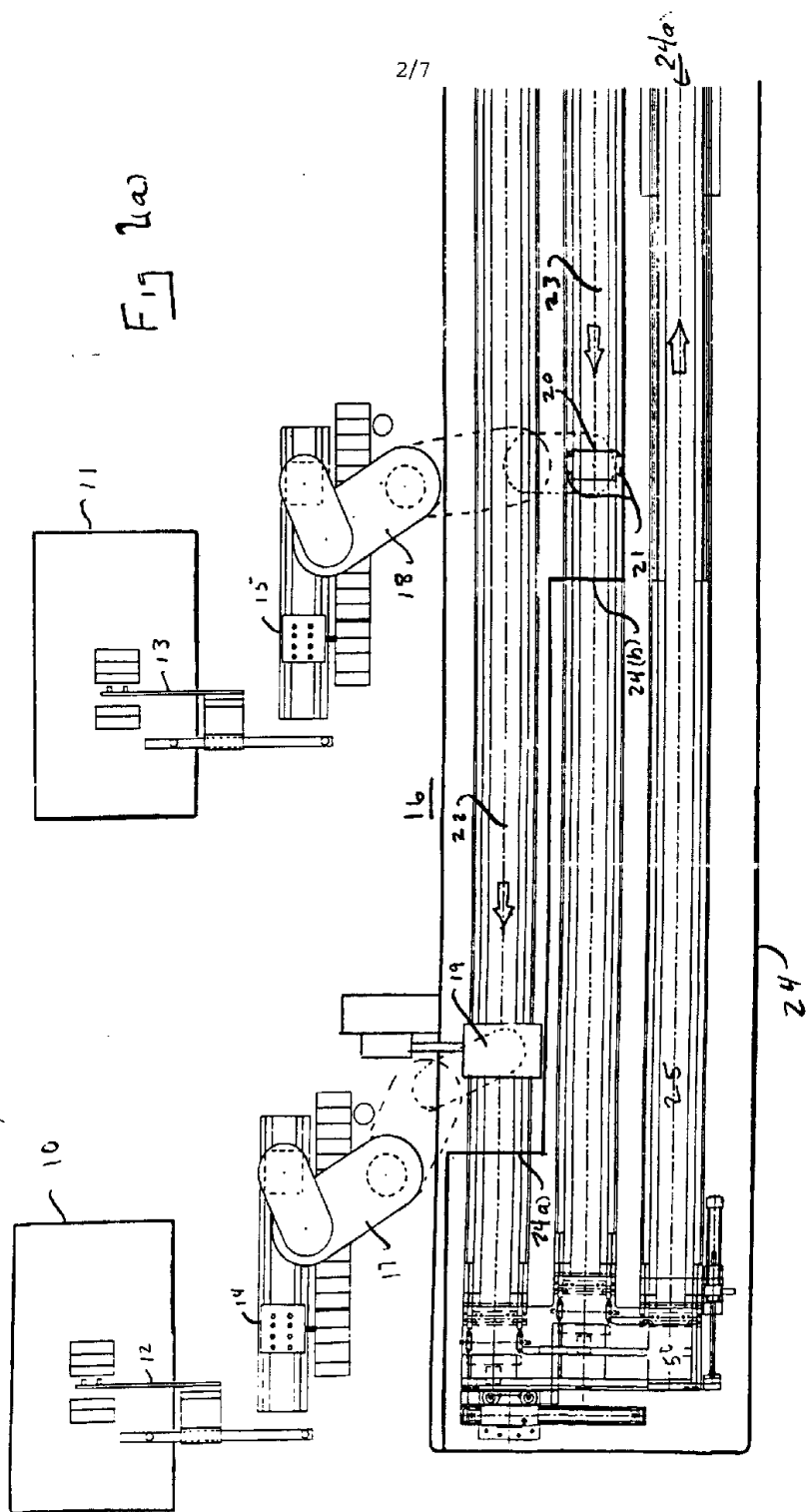
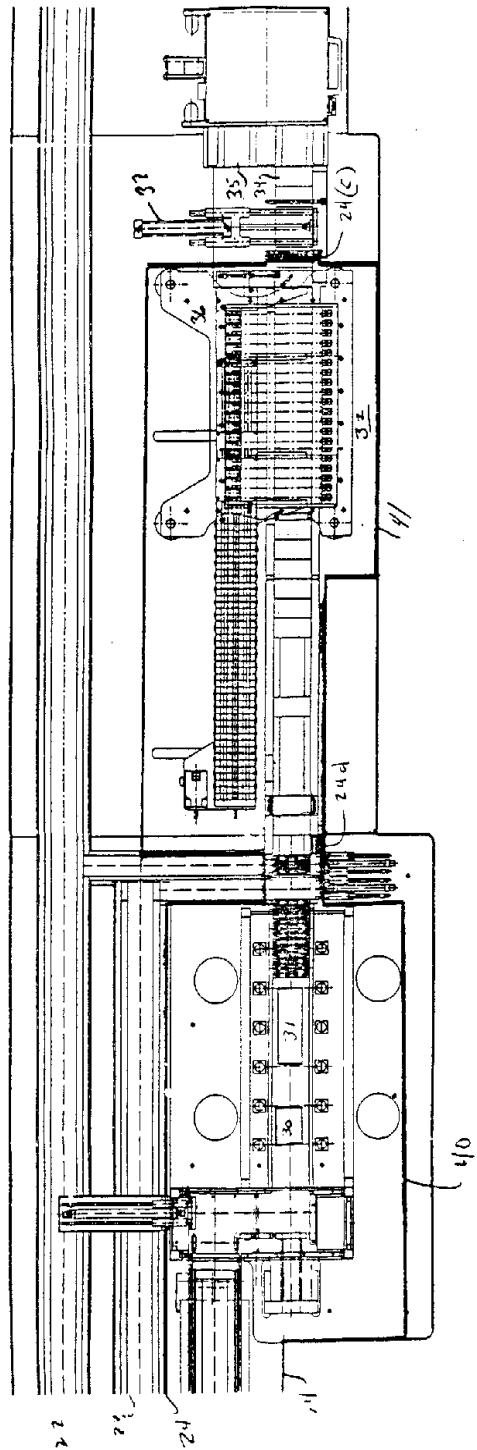


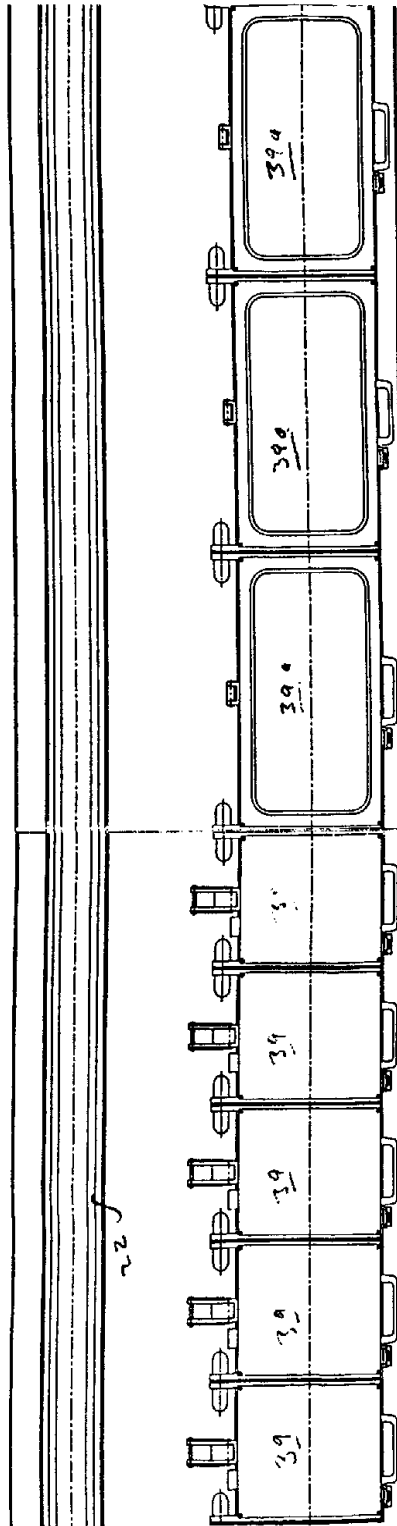
Fig 2(b)



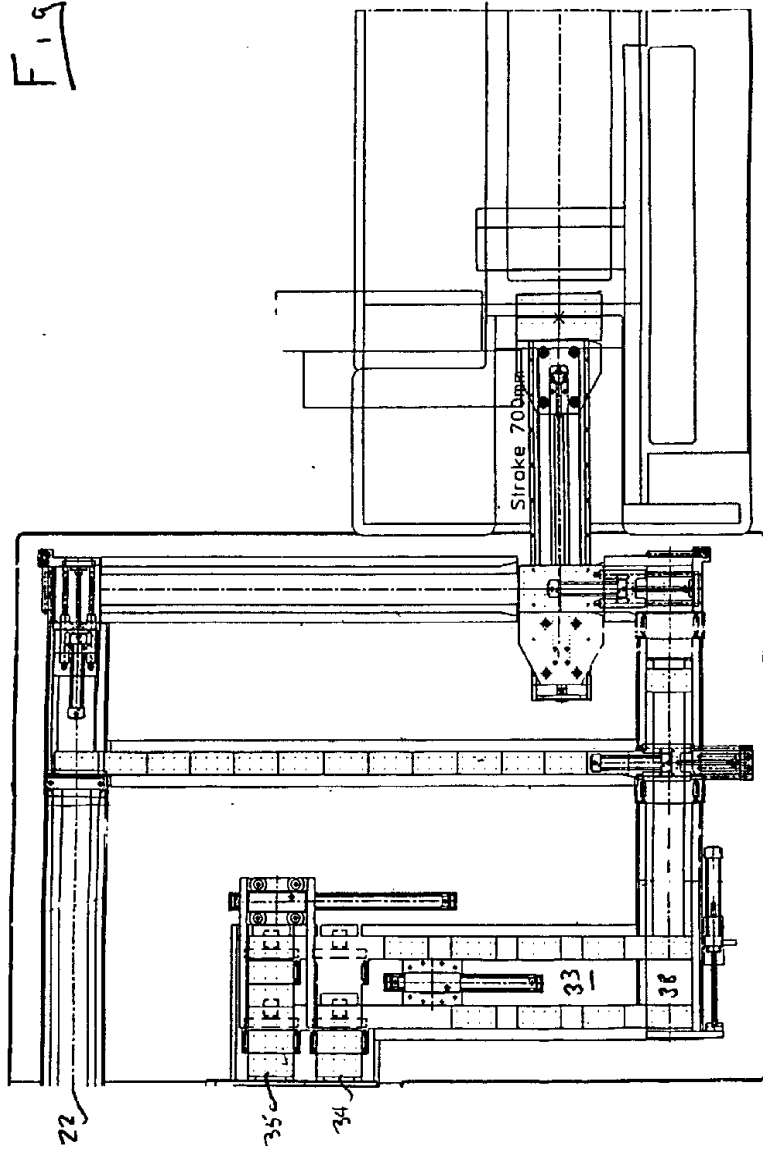
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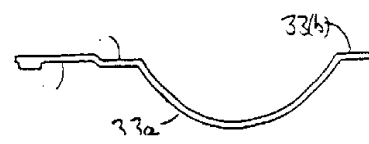
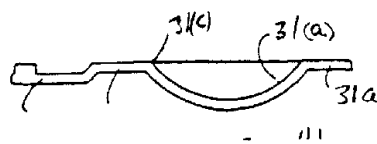
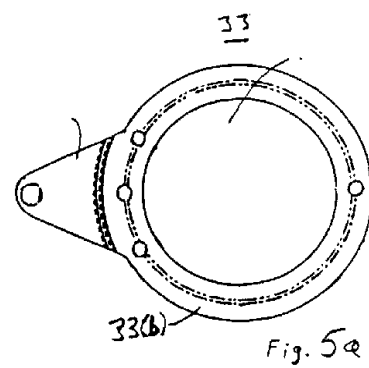
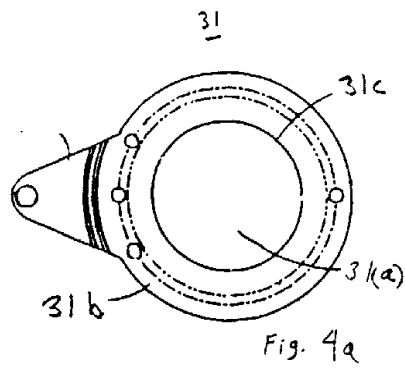
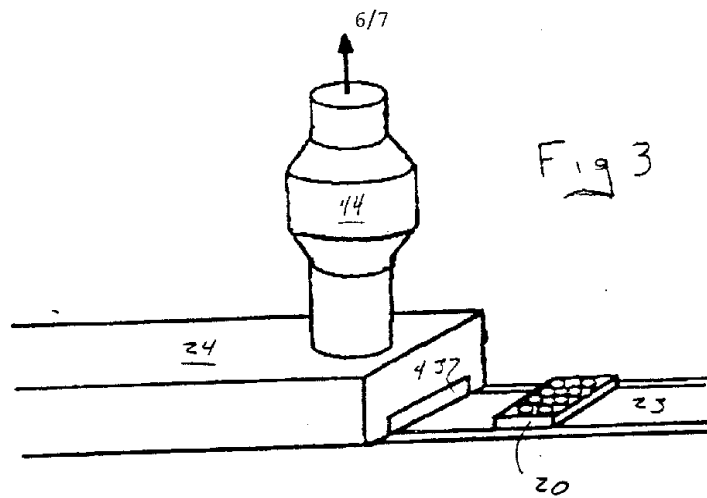
Fig 2(c)

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F. 192(d)





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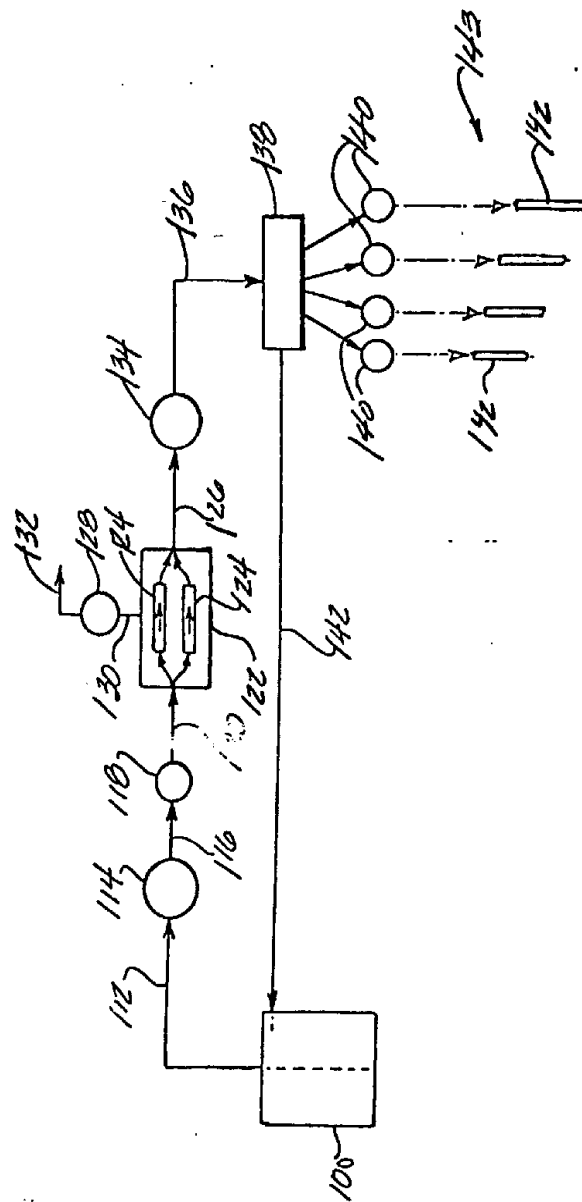


Fig. 6.