On the cover: A drop of pure saline on a machined and hydrated Ultra O₂ Plus lens supported by a plastic mandrel. This picture shows the advancing contact angle of pure saline on Ultra O₂ Plus material of 22°C.
Introduction to Benz Research & Development
by Dr. Patrick H. Benz, president

Benz Research and Development continues to make technology breakthroughs in both high performance materials and manufacturing technology. Our company has been in existence for 28 years and has always focused on developing advanced technology and materials for the ophthalmic industry. Growing our business by developing superior technology to make superior products represents my personal philosophy. Today Benz Research & Development is active in developing high performance contact lens and intraocular lens materials as well as automated manufacturing technologies that drive market value and reduce costs. To better understand the position and expertise that our company holds as a technology company, please review some of our accomplishments shown on the following pages. We believe you will find Benz Research and Development represents Quality and Performance in both materials and manufacturing technology. Today, we produce 31 high quality, high performance polymer products. Our Company remains dedicated to developing advanced technologies that will bring powerful new products and new opportunities for our customers.

This photo shows a toric base curve with fully machined edge and diagnostic marks.
1987
Developed a unique and comprehensive purification process for 2-HHEMA monomer that has been the source of raw material for most of the soft lenses produced worldwide since 1987.

1989
Developed the first precision, isotropically expanding polymacon and haflicon contact lens polymers. These were the first commercially available materials that allowed soft contact lenses to be manufactured to order rather than manufactured for inventory. This development greatly reduced the cost of producing custom lenses.

1991
Developed a high volume process to produce precision ground contact lens blanks, where all surfaces are ground, eliminating the need to trim blanks before manufacturing a contact lens. Benz blanks remain the benchmark of the industry in their precision of diameter, squareness, parallel and thickness. This high volume manufacturing process is operated using Statistical Process Control.

1993
Developed and patented worldwide, an Optical Blocking and Inspection machine that delivers micron accurate radius measurement and concentric blocking. Patented 1994.

1994
Developed the first and still the only dimensionally stable soft contact lens material that remains 100% saturated on the eye. This family of performance materials is called Benz-G materials. Today, almost 10 years later, there is no other material available to the specialty lens manufacturer that matches the on-eye performance of Benz-G materials. Patented 1995. Achieved ISO 9001 certification for monomer, and polymer blank manufacturing and development.

1997
Developed Benz IOL25 UV, a unique and mechanically superior hydrophilic IOL material. This material allows IOL manufacturers to precisely hit target even at 35+ Diopters and create designs that can be inserted through 1.2 mm incisions. Patented 2002.

2001
Commercialized an automated lens manufacturing system utilizing micron accurate Optical Blocking. This system is called Integrated Lens Manufacturing (ILM) and can manufacture IOLs and contact lenses with several times the efficiency and precision of normal methods.

2002
Developed new process technology called ES which results in more durable G-materials.

2004
Validated the entire ILM-2 automated contact lens manufacturing system to be compliant with ISO 13485: 2003 standard requirements from blanks to finished lens. This is a state of the art manufacturing system available “turn-key” to our customers.

2005
Introduced Benz-G 72-IW, a 72% water G-material to replace lidofilcon (NAPALM) Polymers for high water applications. This is the first easily manufactured material in the 70-80% water content range that does not contain N-vinylpyrrolidone. Introduced ILM-3, the second generation ILM for hydrophilic IOL manufacture.

2006-07
Introduced Benz-G 4X 54% water G-material, a multi-modality capable high performance GMA hydrogel material designed for use as a molded lens as well as a custom lens. Introduced Benz Natural Yellow™, a unique compound utilizing nature’s own UV-A blocker and violet light filter. Available in all IOL materials. Introduced Ultra O2 Plus, a third generation high water hybrid GMA soft lens material with a Dk of 50.
The On-Eye performance of the lens materials you chose can provide strong advantages for marketing your lens products and give you valuable differentiation in the marketplace. The choice of lens material is an important decision for your business growth.

One of the biggest opportunities available to the custom lens manufacturer is in the area of high performance soft lens materials and the improvements they bring to on-eye lens performance that patients can see and feel. This opportunity is magnified today because consumer lens manufacturers are heavily promoting silicone hydrogel lenses for daily wear. Our second and third generation hydrogel materials offer the custom lens manufacturers a very positive and consistent patient response compared to silicone hydrogel lenses. Lens materials from Benz that exceed the criteria for high performance daily wear lenses are G-4X, G-5X and Ultra O2 Plus. Building a business strategy around these materials makes a lot of sense.

Another opportunity exists because most consumer lenses are still made of first generation hydrogels. This means that most molded lenses are not dimensionally stable. They also shrink, become tighter and lose their initial comfort as the wearing cycle progresses. This makes molded lenses look and feel generic and very similar to each other compared to high performance hydrogels. They all dry out, which means that they all show the following problems as the day progresses: dryness, shrinkage, tightness, reduced visual acuity, reduced oxygen transmissibility and reduced comfort. Marketing lenses made from Benz Second or Third generation materials G-4X, G-5X and Ultra O2 Plus solves these problems and makes for good business because they produce excellent results for the practitioner and noticeable improvements for the patient. High performance hydrogel lenses create a valuable separation between your products and low cost consumer lenses.
**p-HEMA**, Polymacon

Poly-Hydroxyethylmethacrylate (p-HEMA) is the oldest soft lens material. This material is familiar to manufacturers worldwide and relatively easy to fabricate into lenses of modest performance. Polymacon has a saturated water content of 38% (in the vial) and loses approximately 10% of its water content on the eye.

**2-HEMA lenses** are made mostly in very low cost markets, most other markets use higher performance lens materials.

**p-HEMA/MA, Methafilcon, Ocufilcon, Etafilcon**

Copolymers of HEMA and methacrylic acid are the most commonly used materials for disposable soft lenses and are typically found in a water content range of 55 - 60% (in the vial or blister). During wear these lenses lose approximately 10% of their water content and gain substantial protein accumulation because the positively charged tear protein, lysozyme, precipitates onto the negatively charged lens. Because of protein deposits, methafilcon-type materials are not commonly used for custom lenses outside the U.S.

**p-HEMA/NVP, Hefilcon A, B and C**

Copolymers of HEMA and N-vinylpyrrolidone (NVP) are some of the oldest materials in use for water contents below 55%. These polymers typically contain 25-50% NVP by weight. They are characterized by a soft “feel”, poor dimensional stability and a water loss on the eye of 10 - 12%.

**Silicone Hydrogels**

Silicone hydrogel materials remain an unproven high performance hope for the custom lens manufacturer. In order to get a true high Dk (>100) a silicone hydrogel material will typically have a Glass Transition Temperature (Tg) in the teens for normal machining and must be cryogenically machined or molded. Lower Dk silicone hydrogels may be machined, but more difficulty. Once the lens is successfully made, a material can be modified by adding hydrophilic components that “bleed out” during wear or by altering the surface through plasma treatments. Another approach is to just call a material a “silicon hydrogel” by adding a small amount of modified silicone monomer to a high water lens material. This approach results in a material with a Dk of 65 - 69 and a wettability problem. This is not a real improvement in Dk over an advanced high hydrogel (Dk 50). Both of these approaches have resulted in compromises in patient comfort without providing meaningful performance advantages for daily wear.

**p-HEMA/MA, Methafilcon, Ocutfilcon, Etafilcon**

Copolymers of HEMA and methacrylic acid are the most commonly used materials for disposable soft lenses and are typically found in a water content range of 55 - 60% (in the vial or blister). During wear these lenses lose approximately 10% of their water content and gain substantial protein accumulation because the positively charged tear protein, lysozyme, precipitates onto the negatively charged lens. Because of protein deposits, methafilcon-type materials are not commonly used for custom lenses outside the U.S.

**p-HEMA/NVP, Lidofilcon A, B, C and modified Lidofilcons such as Acofilcon A and B**

These copolymers and terpolymers based on methyl Methacrylate (MMA) and N-vinylpyrrolidone (NVP) are the oldest high water materials used for contact lenses. Lidofilcon materials are found in many versions, which are made by adding other monomers to the base MMA/NVP formulation. All lidofilcon and modified lidofilcon materials contain NVP as their primary hydrophilic component. Lidofilcon based materials range from 48% to 77% water content (in the vial) and contain 30% to over 70% NVP by weight. All lidofilcon based lenses are characterized by substantial dimensional instability and water loss on the eye, resulting in significant lens shrinkage. Water loss and lens shrinkage compromise lens fit, lens movement, oxygen permeability and comfort. Because these polymers bind water weakly, lenses lose 12 - 18% of their water content during the first hours of wear. All commercially available lathe-cut lenses above 60% are lidofilcon based materials except Benz Ultra O₂ Plus.

**p-GMA/HEMA, Hioxifilcon A, B, D and the hybrid GMA polymer Ultra O₂ Plus**

Copolymers of Glycerol Methacrylate (GMA) and 2-HEMA were the first truly new soft lens materials commercially available to specialty soft lens manufacturers in the past 25 years. This unique family of polymers is available in water contents of 49%, 54% and 59%. The GMA hybrid material Ultra O₂ Plus is a Third Generation high water soft lens material introduced in 2007. This completely new material has a water content of 75% on-the-eye all day long. Because these materials lose little or no water on-the-eye, they remain 100% dimensionally stable and retain their oxygen permeability during wear. Lenses made of these materials out-perform other hydrogel lens materials on-the-eye in dimensional stability, oxygen permeability, end of day comfort, wettability, scleral staining and visual acuity. All Benz GMA based materials lose less than 1% of their water content during wear.
There are basically only two families of hydrogel lens materials available to the custom lens manufacturers in the water content range of 48 to 75% water: G-materials and various versions of lidofilcon material, therefore a comprehensive comparison of the two families of materials is essential to understanding the strong selling advantage of G-Materials. (Methafilcon is used as a custom lens material only for the US).

**BENZ-G Materials versus Lidofilcon based Materials**

**Composition:** Lidofilcon is a USAN (United States Adopted Names) name for a co-polymer of methylmethacrylate (MMA) and N-vinylpyrrolidone (NVP). This lens material has typically been commercially available in a water content from 50 to 77%. Modified lidofilcon is defined here as a MMA/NVP copolymer with other monomer(s) added. N-vinylpyrrolidone is the primary hydrophilic monomer in all lidofilcon and modified lidofilcons and is responsible for the inherent ON-EYE characteristics of these lens materials. Modified lidofilcons are available in a water content range of 48 to 72% water.

High performance G-materials are based primarily on Glycerol Methacrylate. Hioxifilcon is the USAN name for the co-polymer composition of Glycerol Methacrylate (GMA) and 2-Hydroxyethylmethacrylate (2-HEMA). The products, G-4X and G-5X are Hioxifilcon D and A respectively. Ultra O2 Plus is a new hybrid polymer with a very high level of GMA and no 2-HEMA. Glycerol Methacrylate is the primary hydrophilic monomer in all high performance G-materials and is responsible for the unique ON-EYE characteristics of these materials. High performance G-materials are available in water contents of 54%, 59% and 75%.

These two families of lens materials, lidofilcon and high performance G-materials also behave completely different ON-THE-EYE. Lidofilcon lenses are characterized by large dimensional changes and substantial water loss ON-THE-EYE. High performance G-material lenses show essentially no dimensional change or water loss on-the-eye even at the end of the wearing cycle. Figure 1 shows a comparison of ON-EYE dimensional change of two types of lenses (lidofilcon A (ES 70) and hioxifilcon A (G-5XES)).

The large ON-EYE dimensional change of lidofilcon lenses is caused by two factors, substantial water loss and a significant dimensional change with changes in temperature. ON-EYE hydration levels of high performance G-material lenses and lidofilcon lenses (ES 70) is shown in Figure 2. High performance G-materials are the only custom lens materials that can maintain complete saturation during wear. High performance G-materials have the same water content ON-THE-EYE as in the vial. This critically important ability is missing in other custom lens materials.

**High Performance G-Materials versus Popular Disposable Lenses**

The great majority of all consumer lenses sold worldwide are still made of a first generation hydrogel material, a co-polymer of 2-Hydroxyethylmethacrylate (2-HEMA) and Methacrylic acid (MA). This material has various USAN names: Methafilcon, Etafilcon (Acuvue 2) and Ocufilcon (Biomedics 55). The differences between these ionic hydrogels are minimal, consisting of slightly different levels of MA and different cross-linking compounds. The water contents (in the vial or blister) of these materials range from 55% to 60%.

As disposable lenses these materials are typically used for a maximum of two weeks and are then discarded. During this time the lenses become heavily coated with the tear protein Lysozyme, a positively charged protein that precipitates (denatures) onto the negatively charged lens material. Enzyme deposits are used regularly to maintain a clean lens surface. Since these lenses also lose 10%+ of their water during wear, they become smaller and tighter fitting (Figure 3). This shrinkage combined with the protein deposits results in a significant loss of comfort and reduced wearing time for many patients. These lenses also cause very significant irritation of the sclera (Figure 4). Therefore, it is not surprising that most patients noticed a significant difference in comfort in a 4 X 2 week contra-lateral study. Any patient that has problems with end-of-day comfort or difficulty obtaining excellent vision regardless of the correction are real opportunities for your custom lens business when you offer lenses made of high performance G-materials.

These second and third generation hydrogels are highly competitive with disposable lenses because of the advantageous properties provided by the high level of GMA in these lenses. G-4X, G-5XES and Ultra O2 Plus lenses out-perform popular consumer hydrogel lenses in: ON-EYE water content, oxygen permeability, dimensional stability, visual acuity, and end-of-day comfort.

Conjunctival staining as shown in Figure 4 using Lissamine Green was much higher for the Acuvue 2 (etafilcon) lenses than for G-5XES (Hioxifilcon) lenses because of the tightness of fit and shrinkage on-the-eye of Acuvue lenses. A contra lateral study of Acuvue 2 (etafilcon) lenses versus G-5XES (hioxifilcon) lenses for patient preference showed a strong preference for high performance G-material lenses (Figure 5).
Silicone Hydrogel lenses have been heavily promoted for their high Dk in recent years. The money being spent in both marketing and clinical research on behalf of these lens materials is truly impressive. The extensive marketing and the public awareness it is generating is having a strong “pull” effect in the market on both patients and practitioners towards silicone hydrogels which in turn results in custom lens companies wanting to offer custom lenses made from Silicone Hydrogel materials to their customers. Our position on Silicone Hydrogel materials for daily wear lenses is that the efficacy of silicone hydrogels for daily wear should be supported by sound clinical data, not marketing propaganda. The data definitely does not support the assertion that these lens materials are better for a daily wear modality than high performance hydrogel lenses.

Silicone Hydrogel lenses were originally developed for extended wear modality where their high Dk properties are definitely needed during the long closed eye periods of sleep. However, for daily wear it becomes much more difficult to make a strong case for Silicone Hydrogels when the actual measured oxygen transmissibility requirement for daily wear lenses is taken into account. Currently, most Silicone Hydrogel lenses are being worn as daily wear lenses. This is due in part to practitioners opting to avoid the increased risk of infection of extended wear and the obvious fact that many patients prefer to sleep without lenses in their eyes. Daily wear remains strongly preferred by patients worldwide. It is also preferred by most practitioners because it is a less risky modality than extended wear. Because of the overall preference for daily wear modality in most countries and the fact that custom lenses are essentially all daily wear lenses already, a review of some important clinical facts concerning Dk requirements for daily wear lenses is definitely needed.

The original work of Holden and Mertz in 1984 determined that the minimum requirement for daily wear soft lenses should be a Dk/T of 24. This value was obtained using both published and calculated Oxygen Transmissibility data of various first generation hydrogel lenses. Unfortunately, the Dk values used were for saturated lenses and were not corrected for water loss on-the-eye which is known to be 10 - 15% depending on the particular lens material. Correcting for water loss during wear would bring Holden’s minimum Dk/T value closer to 20. This is precisely the value that Brennan found to be the minimum Dk/T required to prevent corneal swelling using RGP lenses as controls (Figure 6). RGP lenses are not dependent on water content for their Dk, therefore drying out during wear was not a variable. The clinical results of this physiologic effect of a lens’s Dk/T on corneal swelling clearly shows that corneal swelling disappears above a Dk/T of 20 for daily wear.

Another significant clinical study by Brennan determined the physiologic affect of a lens’s Dk/T on corneal oxygen consumption at various lens Dk/T values (Brennan et al, Optometry and Vision Science, 2005; 82:467-472). RGP lenses were not dependent on water content for their Dk, therefore drying out during wear was not a variable. However, for daily wear it becomes much more difficult to make a strong case for Silicone Hydrogels when the actual measured oxygen transmissibility requirement for daily wear lenses is taken into account.

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What makes Benz-G Materials High Performance Soft Lens Materials?

BENZ-G materials are high performance soft lens materials because they are able to stay completely hydrated and dimensionally stable on the eye as well as extremely wettable. Staying hydrated during wear means that a 54% water high performance G-Material lens can provide an Oxygen Transmission of 20 Dk/T at 105 microns average lens thickness, and a 75% water content G-material lens can provide 20Dk/T all the way to 300 microns average lens thickness. This means that virtually any lens design can be a high performance daily wear lens. No other custom lens material can make that claim because they lose water as soon as they are placed on the eye. Also, for a custom lens manufacturer, knowing that the precision lens you produced has the same exact dimension on a patient’s eye has obvious benefits in lens design and fit as well as visual acuity. These high performance lens properties are a function of the polymer’s water compatibility. Water compatibility is a general term used here to describe a polymer’s affinity for water as opposed to its saturated water capacity or “water content”. In order to compare hydrogel materials, a reliable method was needed to predict the ON-EYE behavior of lenses made from hydrogel materials. During the early 1990’s we developed a method for predicting ON-EYE hydration of soft lens materials. This measurement is called Relative Water Balance and is defined as the time for a standardized test lens to dry by 10% of its water weight divided by the time for it to rehydrate, relative to a poly-HEMA control lens. The relative water balance of three high performance BENZ-G materials compared to other commercial materials is shown in Figure 10. The benefit of the higher Relative Water Balance of G-material is higher ON-EYE water content, higher dimensional stability, greater oxygen transmissibility and much better wettability.

Wettability is also an important lens material property that affects patient comfort and preference. Unlike the bulk polymer property, Water Balance, wettability is a surface property and its measurement can be significantly affected by surface active contaminants. In fact, the current silicone hydrogels on the market all use either an added surface active component or chemically altered surface to make these polymers wettable. Therefore we have measured the advancing contact angle of pure saline on a very clean lens hydrated and autoclaved in pure saline. We call this the Pure Saline Contact Angle. The relative difference in Pure Saline Contact Angle of conventional poly-HEMA based polymers GMA /HEMA copolymers and a high GMA hybrid polymer is shown in Figure 11. As you can see, there is a substantial difference in wettability between these lens materials. The more wettable the material is, the flatter the drop or the lower the contact angle. For the purpose of material comparison it is useful to examine the percent change in the pure saline contact angle between each material rather than a particular angle. The contact angle is reduced by 24% in going from a poly-HEMA based lens to a 54% GMA/HEMA copolymer 54% lens. This amount of change in contact angle may be what is necessary for patients to consistently have a comfort preference between two materials. In a recent pilot study, 15 patients wearing GMA/HEMA copolymer lenses (54% and 59%) were introduced to the same lens made from the GMA Hybrid polymer (75%). The contact angle is further reduced by 27% in going from GMA/HEMA copolymer to the high GMA hybrid polymer, and the patients preference for the new material was almost total, 14 out of 15 preferred the new material and asked to change their lenses permanently. This suggests that a 24 – 27% improvement in wettability may be a very strong predictor patient preference if it is large enough. Go-Materials with their high Relative Water Balance are all much more wettable than conventional materials.
Benz Research and Development began an ambitious research project during the mid 1990s, to integrate optical blocking technology into a complete precision lens making technology. After over 12 years of development work, investing heavily in equipment, mechanical design and automation software, we have created many new manufacturing technologies that are highly beneficial to our customers. This significant investment in equipment alone, demonstrates the level of commitment that Benz Research and Development has made to the development of new technology for the manufacturing of contact lenses and IOLs. No other supplier of lens materials is making this kind of commitment to develop the automated technology for your future lens manufacturing needs and providing complete systems fully validated to the ISO 13485: 2003 standard requirements.

The following pages describe in detail many of the products available today from BENZ that have resulted from this research. We continue to work hard to expand the boundaries of lens making technology. Developing superior technology to make superior products for the contact lens and IOL industry – this is what Benz Research and Development is all about.
The first and easiest step a manufacturer can take to improve his manufacturing efficiency is to use blanks with precise and square dimensions. Benz Research and Development has perfected the technology required to produce millions of precisely dimensioned contact lenses and IOL blanks with state of the art efficiency. Using a precision blank containing a precision precut further improves manufacturing efficiency and reduces tool wear. Precision blanks with a precision precut is a manufacturing technology benefit available to all Benz Research and Development customers, Figure 13. All of our blanks are precision ground to micron tolerances using advanced high speed equipment and Statistical Process Control to guarantee quality.

The distribution plot of blank diameter for a 40,000 piece lot of G-3X low blue UV is shown in Figure 14. This entire lot is contained within a 0.01 mm diameter range.

Precision blank diameter provides an important quality benefit by allowing the manufacturer to use a consistent minimum collet force during base curve machining and blocking. A wide range of collet force, caused by inconsistent diameter, results in radial error and asphericity in the hydrated lens. Therefore, non-precision blanks affect your quality.

The precision squareness of Benz Research and Development blanks is achieved by a sophisticated grinding technique using Statistical Process Control. The distribution plot of squareness for a 40,000-piece lot of G-3X high blue is shown in Figure 15.

To fully utilize the manufacturing technology represented by Benz Research and Development precision ground blanks, the manufacturer needs to use similar precision dimensions in the collet of the lathe(s) used for base curve machining as well as the blocker collets. We recommend the Benz Optical Blocker for ultra precise blocking, the Benz Spindle and mandrels for low collet to collet runout.
The reality of soft lens manufacturing is that hitting the ordered power, cylinder, base curve and diameter specification is of critical importance because there is no such thing as “re-working” a soft lens once it has been machined, hydrated and inspected. The expansion value of a soft lens material directly affects the final hydrated specifications. There is no way to alter the hydrated lens expansion value of a soft lens material directly affects the final specifications. Therefore, a custom toric lens that does not hit power, cylinder, base curve and diameter is a total loss. Some manufacturers may save the lens, waiting for an eyeball that will match its specifications, but this is an inefficient way to run a manufacturing business. Other manufacturers make only certain base curves and diameters as a way of increasing manufacturing efficiency. This is not a true custom lens business and it puts them in competition with disposable lens manufacturers, which means competing on price primarily.

Variability of expansion in hydrophilic materials is caused by variability in the polymerization process. The greater the variability in the polymerization process, the greater the variability in the expansion values of the material. Benz Research and Development materials are made from ultra high purity monomer using state-of-art polymer synthesis technique technology at work. Eliminating a significant source of manufacturing variability by simply choosing the right material is real polymer technology at work.

Benz R & D uses the proven accuracy of Integrated Lens Manufacturing (ILM) to make identical precision test lenses from each lot of material. Each lot of blanks is statistically sampled and 33 identical test lenses are manufactured and carefully tested for radial and linear expansion. Typical standard deviations for radial and linear expansion of Benz materials are fractions of a percent.

To demonstrate how accurately an ordered prescription can be using Benz precision expansion material, lenses of high expansion G-5XES material were manufactured using the precision ILM process. Tables 2 and 3 show the ordered power and actual power as measured on a Zeiss-Humphrey lens analyzer.
MACHINING RECOMMENDATIONS

BENZ Ultra O2 Plus, G-5XES, and G-72HW

Environment Control: We recommend maintaining a Relative Humidity range of 35% at 21 ± 2°C.

Table 4

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Machining Recommendations for Benz G-4X, G-3X

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Environment Control: We recommend maintaining a Relative Humidity range of 35% at 21 ± 2°C.
Precision and productivity have always been key ingredients for the success of lens manufacturing, both contact lenses and IOLs. Today a modern CNC lathe can produce highly complex geometries with ultra smooth surfaces. These lathes provide excellent precision for one step, but once the part is removed from the collet, the precision is lost. Therefore, lathe precision has not necessarily resulted in ultra precision contact lenses because the precision of front side machining is lost during each of three discrete mechanical steps: blocking (2) and second side machining (1). Significant precision is lost during these steps as the part moves from collet-to-collet. Before the total lens manufacturing process can become very precise, collet-to-collet precision repeatability must be improved. We have solved the problem of collet-to-collet repeatability by using technology specifically developed to address the two components of collet-to-collet precision: run-out and position.

Collet run-out occurs because the collet’s center of rotation does not match the lathe spindle’s center of rotation. This mismatch of rotational symmetry typically produces a collet run-out of 20 to 40 microns. During the first lathe step the base curve is machined on the spindle’s spin center and with the spindle’s run-out, which is typically in the range of a micron. If the part is removed from the lathe collet and placed back into the same collet, the part’s run-out will be the run-out of the collet relative to the spindle, 20 to 40 microns. This loss in precision is compounded through blocking and front curve machining, (3 more collets). In the Benz spindle the mismatch of the collet to its spindle is eliminated by precision lapping the collet cone into the spindle shaft until reaching the desired collet/spindle run-out.

The second component of collet-to-collet precision is repeatability of position. We have solved this by designing a precision dead-length collet and a precision steel mandrel, see Figure 19.

Using this precision dead-length system and precision dimension blanks, it is no longer necessary to measure the position of the surface before beginning first side machining. This saves time on every lathe machining cycle. Figure 17 shows a picture of the Benz mandrel with a precision blank attached and the same mandrel and the centering ring used for wax mounting the blank into the mandrel.

Front surface mandrels are shown in Figure 18. There are 8 color-coded plastic mandrels available in order to provide optimum blocking of most contact lenses, including high expansion soft lens materials. The Benz spindle with precision lapped dead-length collet and precision mandrels for soft lens and IOL manufacturing plus blank mounting centering rings are all available as technology products from Benz R & D.

### Table 6

<table>
<thead>
<tr>
<th>Reading  #</th>
<th>Total Indicated Run-out</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.0036</td>
</tr>
<tr>
<td>2</td>
<td>0.0038</td>
</tr>
<tr>
<td>3</td>
<td>0.0039</td>
</tr>
<tr>
<td>4</td>
<td>0.0036</td>
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<td>6</td>
<td>0.0041</td>
</tr>
<tr>
<td>7</td>
<td>0.0034</td>
</tr>
<tr>
<td>8</td>
<td>0.0025</td>
</tr>
<tr>
<td>9</td>
<td>0.0036</td>
</tr>
<tr>
<td>10</td>
<td>0.0029</td>
</tr>
<tr>
<td>Average</td>
<td>0.0035</td>
</tr>
<tr>
<td>STDEV</td>
<td>0.0005</td>
</tr>
</tbody>
</table>

Figure 17

Figure 18

Figure 19
Recommendations for Soft Contact Lenses:

Hydration of lenses made from hydrophilic materials serves two functions. First, hydration transforms the “dry” plastic into a soft hydrogel. Second, it cleanses the lens by removing residuals from the lens. During this process you must follow sterile controls and keep bioburden levels low to ensure no biological growth on lenses while hydrating.

**Benz G-3X, G-4X, G-5XES, Ultra O2 Plus:**

Lenses made with G-materials will hydrate much faster than lenses made from other materials of comparable water content. Place lenses into the Borate Buffer pH 7.2 isotonic saline and allow the lens to sit in solution while stirring for a minimum of:

- Benz G-3X: 3 hours
- Benz G-4X: 2 hours
- Benz G-5X: 1.5 hours
- Benz Ultra O2 Plus: 1 hour

Hydrate for the minimum time specified at constant temperature \(T = 20 \pm 2^\circ C\). A minimum 10 ml per lens should be used for hydration.

**Benz G-72HW and Methafilcon:**

A two-step process best achieves lens hydration for this type of ionic material.

**Step 1:** hydrate lenses for a minimum of 14 hours at a constant temperature of \(T = 20 + 2^\circ C\). A minimum 10 ml per lens should be used for hydration.

**Step 2:** transfer the lenses into a pH 7.2 isotonic saline and allow lenses to remain in solution while stirring for a minimum of 3 hours.

After hydration, lenses should be rinsed, autoclaved, and stored in the pH 7.2-buffered saline solution for packaging and sterilization.

**Direct Hydration**

This technique allows for hydration of a lens directly from a mandrel eliminating the use of solvents for deblocking and additional handling of finished lenses in the dry state. Preparation for lens hydration starts at the blocking step. During the blocking process, the finished base curve is blocked onto a precision plastic mandrel, using a water-insoluble wax. After front curve latexing and polishing, the plastic mandrel is inserted into the saline solution and as the lens hydrates, it will expand and detach itself from the wax, eventually falling into the saline solution as shown in the sequence above. The lenses are clean and contain neither wax nor solvent residues. Precision plastic mandrels are available from Benz R & D, Figure 20.

The hydration tray is composed of a tray-top with holes cut to allow placement of the plastic mandrel with the finished lens placed face down (to allow immersion in the saline). The tray top is designed to allow the lens mandrels to be inserted while on a table without the bottom tray. The tray-bottom contains polished wells capable of holding about 20 ml of the appropriate buffered saline. The top/bottom fit is designed to have the dry lens fully immersed in the saline and to cleanly release from the mandrel as it expands. Once the lenses are hydrated, the top is removed and inspection, cleaning and packaging can take place. Hydration trays of various sizes are available from Benz R & D, Figure 21.

---

**Table 7**

<table>
<thead>
<tr>
<th>Isotonic Saline</th>
<th>Borate Buffer pH 7.2, 295 mOs</th>
</tr>
</thead>
<tbody>
<tr>
<td>NaCl</td>
<td>8.01 grams</td>
</tr>
<tr>
<td>H3BO3</td>
<td>2.47 grams</td>
</tr>
<tr>
<td>Na₂B₄O₇ • 10H₂O</td>
<td>0.14 grams</td>
</tr>
</tbody>
</table>

**Table 8**

<table>
<thead>
<tr>
<th>Solution for G-72 HW and Methafilcon</th>
<th>Borate Buffer pH 7.2, 295 mOs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Na₂CO₃</td>
<td>7.0 grams</td>
</tr>
<tr>
<td>NaHCO₃</td>
<td>1.25 grams</td>
</tr>
<tr>
<td>H3BO3</td>
<td>2.47 grams</td>
</tr>
<tr>
<td>Na₂B₄O₇ • 10H₂O</td>
<td>0.14 grams</td>
</tr>
</tbody>
</table>

The weights for the buffered saline formulas are based on a 1 Liter volume solution. The borate solution shows excellent performance through the sterilization process (autoclaving) and leaves the lenses free of residue.
Optical Blocking was invented and patented worldwide by Benz Research and Development in 1994. Since building our first machine twelve years ago, we have greatly expanded the functions and overall ability of the Optical Blocker for manufacturing contact lenses and IOLs. The Benz Optical Blocker today represents the only commercially available blocking interface between base curve machining and front curve machining that achieves accuracy and precision comparable to the lathes currently used in the contact lens and IOL industries. The Benz Optical Blocker is designed and built to deliver unequaled accuracy and precision through years of trouble free use. Our original blocker is still in every day use at Benz R & D.

The Benz Optical Blocker provides many manufacturing advantages and can be used as a stand-alone machine operated manually, by robot, or fully integrated into an automated system, Integrated Lens Manufacturing.

Optical Blocking eliminates the common manufacturing problems associated with blocking:

• Prism error
• Edge thickness
• Center thickness variations

Increased yield with improved quality are the obvious benefits of Optical Blocking. Additional benefits to your manufacturing competitiveness that may not be obvious are:

1. Automatically sets toric axis and offset blocks to the ordered cylinder axis to ± 0.5°
2. Automatically provides micron accurate radius measurements of spherical radius as well as major, minor axis of toric lenses and a permanent record of all measurements
3. Automatically rejects base curves that do not meet tolerances you set
4. Calibrates your lathes for radius and sphere to tolerances that you set and provides a real time process control record of lathe calibration.

The money you currently spend everyday manually performing these steps is saved using Optical Blocking in your manufacturing process. An Optical Blocker that is used in a toric lens manufacturing process is closely associated to the oscillating tool lathe used to produce the base curve toric surface, so that the finished base curve can include a finished edge, front bevel and diagnostic marks (on the front bevel), all of which can be performed during the base curve cycle on the lathe, Figure 16. The base curve can now be blocked on the offset to the ordered cylinder axis. The front curve can then be machined with a common 2,3, or 4-axis machine. No additional oscillating tool step is needed for a custom toric lens. The money saved in time and equipment alone using this manufacturing approach more than pays for the cost of an Optical Blocker. Market figures show that 70 to 80% of custom toric lenses are prismatically stabilized lenses.

Specific Features Of The Optical Blocker

1. Measures radius of curvature with ± 2 microns accuracy
2. Measures both major and minor cylinder radii with ± 2 microns accuracy
3. Positions apex of concave and convex lenses with ± 1 microns accuracy
4. Concentric blocking - average max - min variations in edge thickness of 5 microns, see Table 9
5. Cylinder alignment on FCM to better than 0.5° accuracy
6. Constant center thickness of contact lenses ± 5 microns
7. Measures 10° offset radius of curvature for lathe sphericity adjustments
8. Calibrates lathes for radius and sphere
9. Provides “dead-length” apex blocking - constant distance between front curve mandrel base and apex of mounted base curve lens
10. High accuracy decentration for prismatic stabilization for off-set blocking of torics
11. Full suite of DIP and motion control routines for manual lens analysis
12. Includes full automatic, semi-automatic and manual modes of operation
Integrated Lens Manufacturing (ILM-3) is a lens manufacturing process developed and refined over the past 12 years. Benz Research and Development has spent millions of dollars developing the component systems and automation technology used in ILM. In ILM each lens manufactured has a discrete identity. This identity is defined by order number and the bar code numbers associated with each portion of the manufacturing process:

- base curve manufacturing and blocking
- front curve manufacturing and hydration
- inspection, packaging, labeling and shipping

These three separate bar codes are associated with each lens from the first machining step through labeled vial. All data associated with each lens, including the order, the practitioner, the patient and all manufacturing data from each step is saved in the Oracle 10 database of ILM-3.

The Benz Automation Program is a large C program that coordinates the communication and storage of all data associated with each order including machining parameters created by the front end design program for spherical and toric lens designs that is accessible for further customization by each manufacturer.

ILM utilizes the following manufacturing technology in a fully integrated system:

- The Benz precision collet/spindle assembly with Benz mandrels
- The Benz Optical Blocker
- The Benz ILM automation program utilizing an Oracle-10 database
- Custom ILM part handling robot effectors
- Real-time re-calibration of all lathes for radius and sphere
- ILM in-feed and out-feed tracks and transfer tracks with bar code readers and sensors
- Design front end program for spherical and toric lens designs that is accessible for further customization by each manufacturer
- Windows-based operator interface for all manufacturing operations including Order/Entry, Maintenance, Quality Control, Inspection, Packaging and Labeling. Shipping interface to accounting software for automatic billing options.

ILM Systems Operation:

The ILM system has been designed for both function and flexibility. The system can be used in two modes: semi-auto and fully auto, or any combination at the same time. The system allows the process manager to select each machine mode, thereby optimizing operation time and allowing for other functions like maintenance and diamond change, that take a single machine off line while the remaining equipment remains in automation.

Operational Modes:

- AUTO: In auto, the A/PC determines when a lathe or blocker can be loaded based on whether the robot assigned to that lathe or blocker is ready, whether the part tracks for that lathe or blocker have parts, and whether the out-feed tracks for the lathe or blocker are full. Parts are pre-fetched according to assigned sequences of manufacturing steps within a cell. When either a lathe or a blocker is on its last step of a process, it sends a signal to the A/PC, which in turn signals a robot to initiate the appropriate pre-fetch sequence. A track’s full or empty status is determined by the state of the track’s sensor, which is read by the A/PC software. Barcode readers are attached to each in-feed track for reading the mandrel barcode for the next part in the track. When the track’s sensor indicates a part is in the track and the robot that services the track is activated, the robot will pick up the part from the in-feed track, remove the finished part from the machine, place the next part into the machine and then take the finished part to the blocker or finished lens track. ILM uses both 2 and 3 hand effectors.

- SEMI-AUTO: In semi-auto, the ILM software controls all machines, the lens design parameters and the manufacturing sequences are coordinated through the Automation Control PC (A/PC), which runs the automation program and contains the database that holds the information that is the basis for all actions within the system. Lathes, mills and blockers operate without robot interaction. The operators use the barcode readers attached to each machine to scan the steel mandrels before placing them in the machine. The A/PC sends the appropriate information to each machine.
MIXED MODE: In mixed mode, the system manager selects which machines will run under which mode, allowing the operator to run in combined/selected modes for purposes of testing, calibrations, maintenance, etc. The operator can take machines in and out of auto mode and run in either semi-auto or manual within the same cell.

The Order Entry (O/E) program allows communication with the system database. O/E is used to enter all production orders and to provide high-level production control, like deleting production orders and sorting the production queues and prioritizing orders for daily production. High priority orders can be introduced into the system at any time, and the A/PC will re-arrange the queue using the priority in-feed and out-feed tracks.

Auto-Lathe Calibration

One of the unique features of the ILM-2 is auto-lathe calibration. This feature allows for automatic adjustments to be made to all the lathes in the system for radius and sphere. During start-up, two calibration parts are machined on each lathe, one to calibrate and a second to verify both the radius and the sphere adjustments. During the production day, calibration parts can be automatically run on the lathes in the system at an interval chosen by the operator. Lathes can be maintained to tighter operational tolerances using the precision of the Optical Blocker inspection and the auto-calibration feature. All basecurve lathes are 100% monitored because all basecurves are optically inspected before being blocked.

An example of a DAC ALM calibration record and all of its basecurve radius measurements is shown in Figure 25.

Productivity of ILM-3

The productivity of ILM-3 has been extensively studied at BRD. We have tested a 2-lathe, 1-blocker, 1-robot cell for more than three years, see Figure 26. In the ILM-3 approach, prismatically, stabilized custom toric lenses are manufactured by first machining the basecurve, toric cylinder, complete edge, front bevel and diagnostic marks (placed on the front bevel) all on a DAC ALM OTT lathe during the basecurve operation. After the basecurve step, the part is taken directly to the optical blocker, where the part is optically inspected for major and minor radius and blocked off set from the center to create the prism stabilization. The toric cylinder angle is also set via the blocker rotary table at this time. After blocking the robot takes the part to the automated deblocking and cleaning station.

The robot then picks up the blocked part with cleaned mandrel and places it into the front surface lathe. Finished lenses are placed in the finished lens output track or the priority finished lens output track. The base curve manufacturing cycle time for toric lenses made from Benz-G materials averages 3.5 minutes. This determines the production rate of a single cell ILM-2 system at approximately 17 toric lenses per hour (Figure 27).

By adding 1 ALM OTT lathe, transfer track and robot to the above single cell ILM-3 system, creating a second 1 lathe cell for front surface, twice as many basecurve operations can be performed in the same time or approximately 34 toric lenses per hour. The number of operators remains the same, only the productivity doubles, see Figure 27.
ILM-3 Performance, toric parameter accuracy:

To determine the true accuracy of ILM-3 toric lens manufacturing we have made many tests utilizing 30 identical lens prescriptions and measured each lens both dry and wet on the Zeiss-Humphrey Lens Analyzer. We also calculated what the wet power should be from the measured dry power and compared this to the actual measured wet power. The results of two of these tests are shown in Table 10.

As the data clearly show, the accuracy and precision of ILM-3 in toric lens manufacturing is extremely high, especially when you consider that half of the measured standard deviation of sphere and cylinder measurements is due to lens analyzer measurement error. The error of axis measurement is too great to measure the Optical Blocker axis error but is definitely less than ±0.6°.

Validation of ILM-3 to ISO 13485:2003

For validation tests, we have used actual prescriptions from a group of participating practitioners and the orders were processed as received with no batching or arrangement of parameters for manufacturing ease.

By manufacturing a wide range of parameters, as received, we validated the average yield and reliability of ILM-3 to such a statistical assurance level that parameter inspection is eliminated, only statistical verification of parameters is required. The validated range of parameters are:

- Spherical Lenses ±25D
- Prismatically Stabilized Toric Lenses
  - Sphere ±25D
  - Cylinder ±1D in .1D increments
  - Axis 0-180° in 1° increments

The distribution of parameters of the lenses made from actual prescriptions is shown in Figures 28, 29 and 30.

Actual Yield of Prescription Lenses for Validation Test

<table>
<thead>
<tr>
<th>QUANTITY MADE</th>
<th>QUANTITY YIELD</th>
<th>PERCENT YIELD</th>
</tr>
</thead>
<tbody>
<tr>
<td>637</td>
<td>602</td>
<td>94.5</td>
</tr>
</tbody>
</table>

There were no losses due to parameter errors

To operate ILM-3 as a no inspection process, a series of verification lenses (2-4) are run at three different times during the day: 1) immediately after system calibration at start-up 2) at mid-point of the production day and 3) at the end of the production day. These lenses are parameter verified, which in turn verify the entire day’s production. The ILM-3 has passed FDA inspection for statistical parameter verification.
Profitability of ILM-3

Installing an ILM process is not inexpensive. However, the return on investment is very substantial, particularly if your company has a significant business in custom soft toric lenses. Using the worksheet shown in Table 11, you can determine the appropriate gross profit potential from a 12 hour day, operation for the ILM two cell configuration shown in Figure 31. This configuration has a productivity of 338 lenses per day at 94+% guaranteed yield in the vial using G-4X or G-5XES material.

The maximum per day gross profit can be calculated by multiplying the Yield, Average Sale Price of lenses made and Total Blanks (360) and subtracting the Direct Costs (Table 11).

Per day profitability Formula for Single Cell ILM-3

\[(\text{total yield} \times \text{ASP}) - \text{Direct Cost} = \text{Profit} \]

\[(338 \times \$25) - 1,349.00 = 7,101.00 \]

At 80% capacity the profit per day is

\[(271 \times \$25) - 1,188.00 = 5,587.00 \]

ILM-3 software allows for unlimited expansion of the number of production cells. The 2-cell system shown in Figure 31 has the capacity of 338 custom toric lenses per 12 hours of operation (including 1 hour for starting and calibration). The ILM-3 system for 700 lenses per day is a 3-cell system (not shown), consisting of 2-cells as in Figure 25 and 1-cell with 2-DAC ALM lathes. The labor to run these larger systems remains the same as the single cell.

### The ILM-2 Quality System

The Benz Integrated Lens Manufacturing Process (ILM-3) was developed with quality products in mind and is part of the overall Quality Management System of Benz Research & Development. ILM-3 is compliant with the stringent quality system requirements of ISO 13485, which embraces the principals of good manufacturing practices and quality system regulations. These quality standards and regulations satisfy the specific quality management requirements for the development and manufacture of medical devices.

As a result, ILM-3 is a fully documented, controlled and validated process that delivers a product of consistently high quality. ILM-3 is a turn-key process for the manufacture of prismatically stabilized toric lenses and sphrical lenses. ILM-3 is fully validated for automated manufacture of toric lenses to +12.0D of sphere and up to 8.0D of cylinder with the toric axis in 1o increments 0 to 180o. Spherical lenses are validated +2.5D. ILM-3 is validated for statistical sampling parameter verification.

### Direct Cost of ILM-3 Custom Toric Lenses Using The 2-Cell Configuration Operating At Capacity On A 12 Hour Day Basis

<table>
<thead>
<tr>
<th>Item Description</th>
<th>Per Day Cost ($)</th>
<th>% Cost at 80% of Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost of blanks as (G-4X)</td>
<td>360 @ $1.18</td>
<td>425</td>
</tr>
<tr>
<td>Operators</td>
<td>20 @ 15 Hr. +20%</td>
<td>288</td>
</tr>
<tr>
<td>Average Total Cost</td>
<td>6 ringing + 1 tool wk</td>
<td>92</td>
</tr>
<tr>
<td>Diamond Tool Cost</td>
<td></td>
<td>74</td>
</tr>
<tr>
<td>Average Other Materials</td>
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</tr>
<tr>
<td>Wax, Saline, Vials, Shoppers, Labels</td>
<td></td>
<td>104</td>
</tr>
<tr>
<td>Visual Wet Inspection</td>
<td>1 @ $15 Hr. +20%</td>
<td>144</td>
</tr>
<tr>
<td>and Vial Preparation</td>
<td>100% visual inspection</td>
<td>144</td>
</tr>
<tr>
<td>Inverting Additive</td>
<td>statistical parameter</td>
<td></td>
</tr>
<tr>
<td>and Label verification</td>
<td>verification</td>
<td></td>
</tr>
<tr>
<td>Sub Total</td>
<td>1,079</td>
<td>950</td>
</tr>
<tr>
<td>Daily Overhead</td>
<td>Direct Cost x .25</td>
<td>270</td>
</tr>
<tr>
<td>Total Direct Cost</td>
<td>338 lenses x (271 lenses)</td>
<td>1,349</td>
</tr>
<tr>
<td>Total Direct Cost Per Lens</td>
<td>3.99</td>
<td>4.38</td>
</tr>
</tbody>
</table>

Table 11: This table includes total cost, blanks to inspect, packaged toric ready to ship

### Profitability of ILM-3

Installing an ILM process is not inexpensive. However, the return on investment is very substantial, particularly if your company has a significant business in custom soft toric lenses. Using the worksheet shown in Table 11, you can determine the appropriate gross profit potential from a 12 hour day, operation for the ILM two cell configuration shown in Figure 31. This configuration has a productivity of 338 lenses per day at 94+% guaranteed yield in the vial using G-4X or G-5XES material.

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In today’s highly competitive environment of consumer contact lenses, it is more important than ever to clearly differentiate the benefits of your company’s products and services from those of the disposable lens companies. This is essential for growth as well as holding onto your lens price in today’s market. Benz Research and Development offers materials and technologies that can dramatically impact your ability to favorably differentiate products and services for both small and larger market businesses.

For a custom lens business selling 100 to 200 lenses per day, your business must focus on high value added lenses such as custom toric, multifocal and any special lens for medical practices. You can increase your position in this value oriented market by making these lenses from G-4X, a material that is easy to machine, inherently more comfortable to the patient, dimensionally stable to give superior visual acuity and meet the 20Dk/T criteria (at 105 microns). Offer the higher performance G-Materials G-5XES and Ultra O2 Plus only if you can meet the environmental constraints of these materials and sell them into high value (high selling price) markets along with an excellent warranty. You can increase your quality and toric lens manufacturing efficiency by adding a Benz Optical Blocker which is about the cost of a DAC ALM OTT. You can also add auto loaders to your basecurve (toric) lathes and run part of your toric manufacturing at night, unattended to reduce labor cost per lens.

For the custom lens manufacturer that is selling 200+ lenses per day there are additional advantages provided by Benz materials and technology. All high performance G-materials can be offered as quarterly replacement totally custom lenses by investing in ILM-3. The G-4X material can be offered in conventional (1 year) or quarterly modality and the G-5XES and Ultra O2 Plus can be offered in either quarterly or 6-pack per year modalities because your total direct lens cost is approximately $5/toric lens. Make all your G-material spheres and torics on ILM-3 and the same operator monitoring production on ILM-3 can manufacture multifocals and others such as bi-torics using an DAC ALM OTT with an auto loader. This is very efficient manufacturing of very consumer friendly lens materials and modalities. All Spheres and torics can be shipped within two days using this manufacturing approach – we guarantee it! A strong reputation for fast dependable service will further enhance your product’s value.