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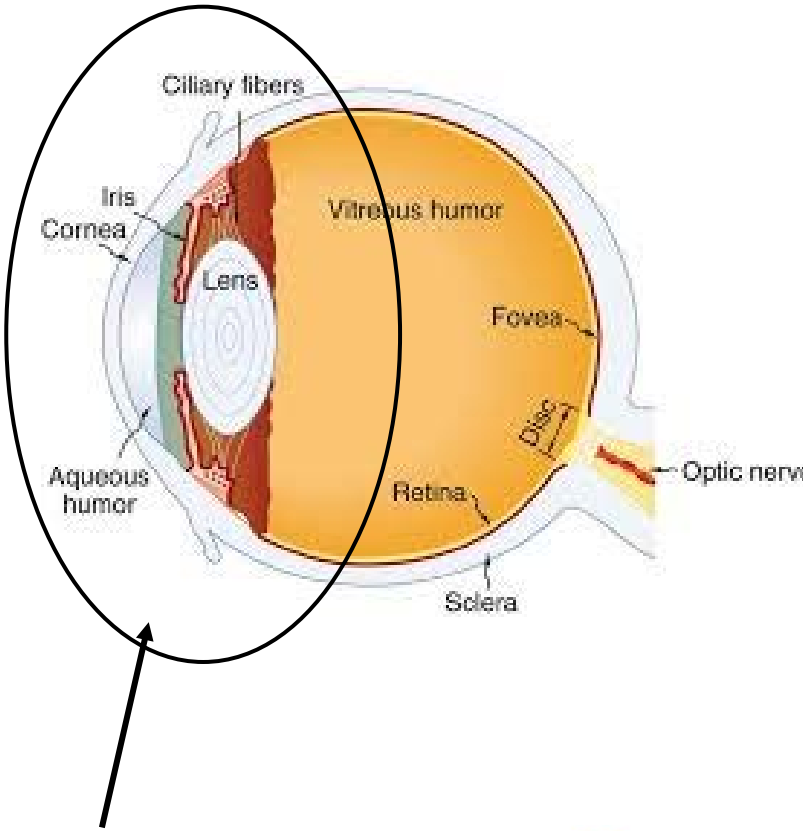
# *Clinical problems imaging the front of the eye*

- **1 of 6 LASIK patients turned away due to uncertainty over integrity of cornea**
- **Implanted contact lens may not be fitted well leads to movement and poor vision, due to optical biometry's narrow field – it cannot image where ICL anchors**
- **Cataract surgery may need followup LASIK – at surgeon's expense – due to poor fitting of intraocular lens – again due to optical biometry's narrow field, and handheld ultrasound's poor resolution**




**ArcScan images**



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# *The ArcScan Artemis 3*

- Very high frequency ultrasound
- Can see in the  eye where optical technologies (like OCT) cannot
- 6-10X better precision than current ultrasound devices

***Eyeseal (sterile consumable)***

***Price= $40*/eye***

***Price = $46k****

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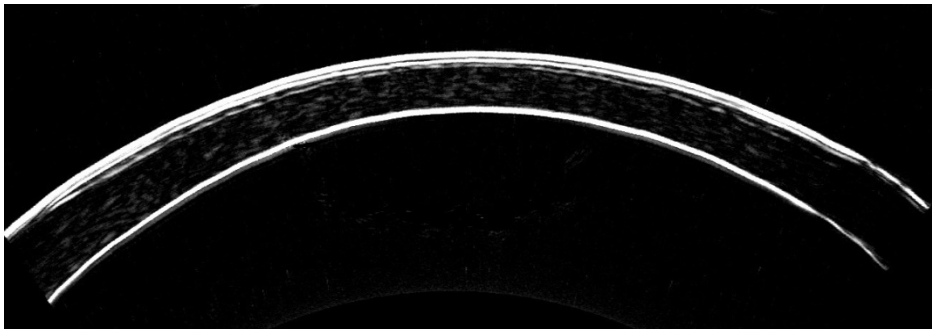
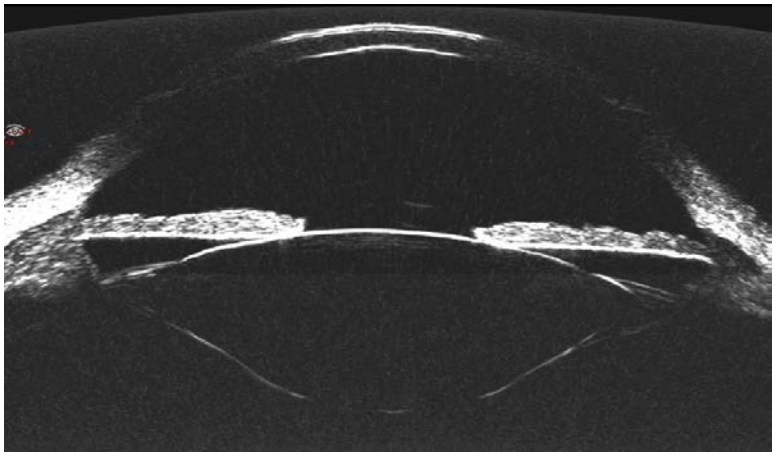
# *Better Images = Better Outcomes & Safety*

## ArcScan Cornea (with flap)

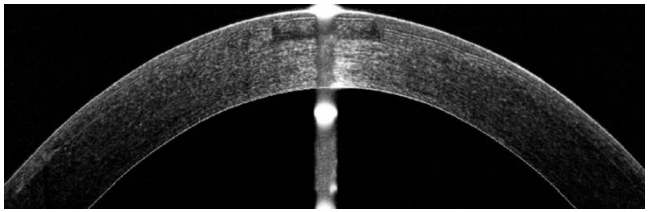


10mm

## ArcScan – anterior segment

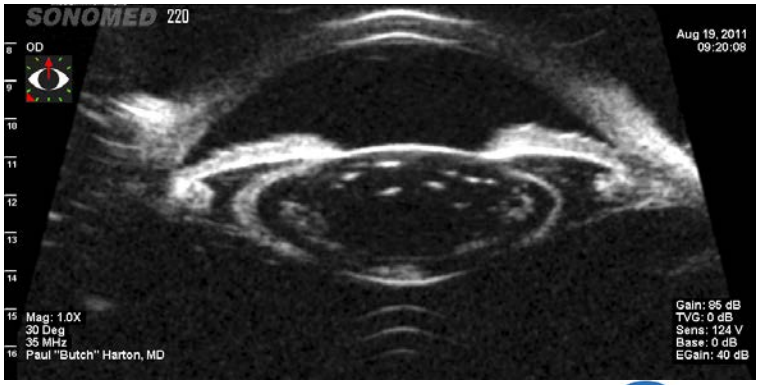


## OCT Cornea



6mm

## Handheld Ultrasound (UBM) – anterior segment

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# Financial forecast

| | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
|---|---|---|---|---|---|
| Instrument sales - units | 0 | 90 | 305 | 555 | 670 |
| Disposable sales - units | 0 | 18k | 85k | 195k | 312k |
| # of Employees* | 3 | 18 | 29 | 38 | 40 |
| Revenue | 0 | 5.6M | 22M | 44M | 60M |
| Operating Profit | (1.5M) | (1.3M) | 4.0M | 13.8M | 22.0M |

* Year end

14 ArcScan Cash Flow Model Q3 2014 Rev 3

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# *Exit strategy*
## *Building relationships now*

- **Major ophthalmic global strategics: focus on implants/pharma but increasing appetite for diagnostics to support growth of their IOL's**
  - Alcon (August 2014 announced acquisition of Wavetec)
  - B&L (Valeant)
  - AMO
- **Major ultrasound strategics interested in entry into ophthalmology**
  - GE ultrasound
  - Siemens
  - Toshiba
- **Ophthalmology diagnostics-only players**
  - Topcon
  - Ziemer
  - Zeiss
  - Lumenis



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# Management & Advisors

- **Andrew Levien – President & CEO**
  - 4 years with ArcScan
  - President of Norgren Fluid Controls manufacturer with medical devices division, $200MM in revenue
  - VP Global Operations Norgren, $1.3B revenue
  - Emerson Electric 12 yrs – Division SVP & GM, $250MM revenue
- **VP Sales & Business Develop**
  - Currently VP Sales of major Intra Ocular Lens Developer
  - President of new technology ophthalmic imaging device company
  - 10 years senior sales role ophthalmic surgical instruments
- **VP Engineering**
  - Lead the redesign effort for Artemis 3. Expert at bridging technology and clinical
  - Deep domain experience in signal and image processing, system engineering
  - Ready access to other engineering talent

- **Daniel Z. Reinstein, MD, FRCS** - Technical Director London Vision Clinic, renowned international expert on clinical applications of epithelium mapping. Co- inventor of Artemis technology-Cornell
- **Jack Holladay, MD, MSEE, FACS** - One of the most recognized names in ophthalmology today most notably authoring two of the most commonly used IOL sizing formulas: Holladay 1 & Holladay 2
- **D. Jackson Coleman, MD., FACS** – Currently Professor of Ophthalmology at Columbia University Medical Center. Formerly Chairman of the Oph Department at The New York Hospital and John Milton McLean Professor of Oph at Cornell University Medical College. Co-inventor of Artemis -Cornell
- **Ron Silverman , PhD** – Currently Professor of Ophthalmic Science, Department of Ophthalmology, Columbia University. Formerly Professor of Ophthalmology and Computer Science on faculty at Weill Medical College of Cornell University, New York. Co- inventor of Artemis technology-Cornell.



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# Status

- **Current round first close of $3MM, total round $4.5MM**
  - $1.5MM already committed
  - Doctor investors in past & current rounds
- **In operation since 2008**
  - 2nd generation prototypes, drastic improvement on predicate
  - 6 issued/allowed patents, 4 licensed patents, 13 pending
  - 40+ peer reviewed papers for refractive market
- **Letter of intent with major medical device manufacturer**
  - Completion of engineering and regulatory development (2.5M$ value) in exchange for global manufacturing/service
- **Cornell McGovern Center Incubator**
  - Access to extensive set of mentors, develop management team, access to extended Cornell investor network
  - Market study (Square 1) completed: Pricing & value propositions validated
  - Debt (secured & unsecured) restructuring complete
- **15 months from funding for FDA 510(k) approval**

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# Milestones & use of funds

$5.6MM revenue

$22MM revenue

| Year 1 | | | | Year 2 | | | | Year 3 | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 |
| Tech Transfer -ERI/Parker | | | Submit FDA & CE | FDA & CE Mark Clearances | Cornea Refractive Sales Launch (Americas) | | | Cornea Refractive Sales Launch (EUR) | | | |
| | Complete 2nd Gen Prototypes (3units) | | Preproduction (3 units), internal trials, KC screen trial | | Mfg Ramp-up | Cost Reduction | | ELP Studies | | ELP Launch | |

**$2.1MM**

- Complete Product Dev
- FDA and CE Mark clearances
- Complete internal, KC screen trials
- Mfg ramp, working capital

**$0.77MM cum revenue**

**$3MM**

- Build foundation of US sales force
- US refractive Launch
- 1st ELP study
- Complete product cost reductions
- Working capital

**$3.5MM cum revenue**

**$4.5MM**

- ***Achieve positive cash flow***
- European refractive launch
- Complete 2nd ELP study and launch US ELP app
- Working Capital

**$14.4MM cum revenue**

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# *Regulatory strategy*

- **Predicate device  Artemis 2 with 510(k) clearance**
  - Predicate is now out of market
  - Will enter market with similar claim of general imaging capabilities:
- **Prepare application for CE Mark at same time**
- **Will file letters of notification when  studies results become available and new SW modules added**
- **Manufacturing partner has long term relationships with notified bodies, site registration, and deep med device development and mfg experience (GMP 620)**
- **ArcScan quality plan links to most key elements of manufacturing partner's QSR system**



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# *Market strategy overview*

- ***First* - *Refractive market* : LASIK KC screen & ICL sizing**
  - Get ArcScan into market quickly
  - Setup sales channel & establish profitability and cash flow

- ***Second* - *Cataract market* : predicting effective lens position and building doctor/patient confidence in premium lenses**
  - Leverage market presence from refractive launch: channel & brand
  - Execute necessary studies during refractive launch

- **Target premium surgeons/clinics – largely self pay**
  - Premium cataract surgeons – higher end lenses and diagnostics
  - 4X revenue/eye versus reimbursed – growing at 13% per year
  - Many premium surgeons doing both LASIK and cataract procedures in effort to build clinic volume



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# *ArcScan available market: refractive & cataract*
## *27MM procedures a year*
## *68,000 ophthalmologists (global)*

- **Refractive (LASIK) + ICL sizing**
  - Correcting curvature of the cornea (front of eye) and very bad vision (deeper)
  - **3.8MM** procedures - 600K US
  - 11,000 surgeons – 3,500 in the US

- **Cataract**
  - Removal of clouded lens (deeper inside the eye) and replacing with artificial lens (IOL – intraocular lens)
  - **23MM procedures** - 3.7MM US
  - 57,000 surgeons WW – 5,700 in US

- **Glaucoma, general, and retina markets not included in plan**
  - 120,000 surgeons worldwide – 9,600 US
  - Will consider  glaucoma, general ophthalmology for future upside



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# *Pricing strategy*
## *(based on market survey)*

- **Instrument - $46k**
  - Threshold of investment decision around $50k for most doctors, mean willingness to pay $48.5k
  - Set price strategically lower than most optical diagnostics ($50k-60k) and low enough to displace current ultrasound handheld ($10k-25k) as the next generation ophthalmic ultrasound tech
- **Disposable - $79 (for 2 eyes), allows large margin for doctor/clinic**
  - Survey range $35-$350, average of $127
  - Low price to drive procedure volume, high margin sale for clinic
- **Service - $4500/yr (TBD on evaluation of subscription model), this revenue currently not included in financial model, industry typical is 10%/yr of initial purchase price**

*"UBM is awkward to use. Even if Artemis was twice the price, it would be worth it."* **Robert K Maloney, MD**



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# *Sales channel*

- **Develop direct sales channel in US, reps & distributors non-US**
  - Headcount and budget model based on 2 Artemis instrument sales per person per month (for a good sales engineer)
    - Sales peak at ~800 units/year (year 8) = 34 equivalent sales people global
  - Build internal team to support outside sales
    - Highly technical sales support engineers – 1 per every 3 sales people
    - Inside sales support/customer service – 1 per every 4 sales people
- **Representative and distributors for non-US sales**
  - International pricing higher (15%) offsets higher cost for regulatory, distribution and reps
  - Regional distribution managers are direct heads

# *Entry market: Refractive*

## *Too many LASIK patients turned away*

**Current lack of anatomical details**

**result in doctors turning away 10-15%* of patients:**

**will pay for itself in 6-9 months**

- Cannot see cornea layers – epithelium thickness critical for safety/ fear of possible cornea failure (keratoconus)
- Cannot see LASIK flap from prior surgery – safety concerns for retouch in aging LASIK population for later cataract
- Cannot see behind the iris with precision for safe interocular contact lens (ICL) surgery, risk of very serious complications – lack of good diagnostic technology is holding back the market penetration of these devices

***Refractive Market* – 3.8M**** procedures annually global, **600K**** U

*** Square 1 independent survey for ArcScan, March 2014**

****Marketscope 2014 Report on the Refractive Surgery Market (draft version)**

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# *Refractive (LASIK)*

## *Cornea Layers*

***Epithelium for keratoconus screen***

**Competition (OCT)**

**ArcScan – Epithelium map, 10mm dia. (1µ precision)**

*"Visualizing the full epithelial profile would be a great benefit to the market"*

**Dr. Steve Schallhorn**

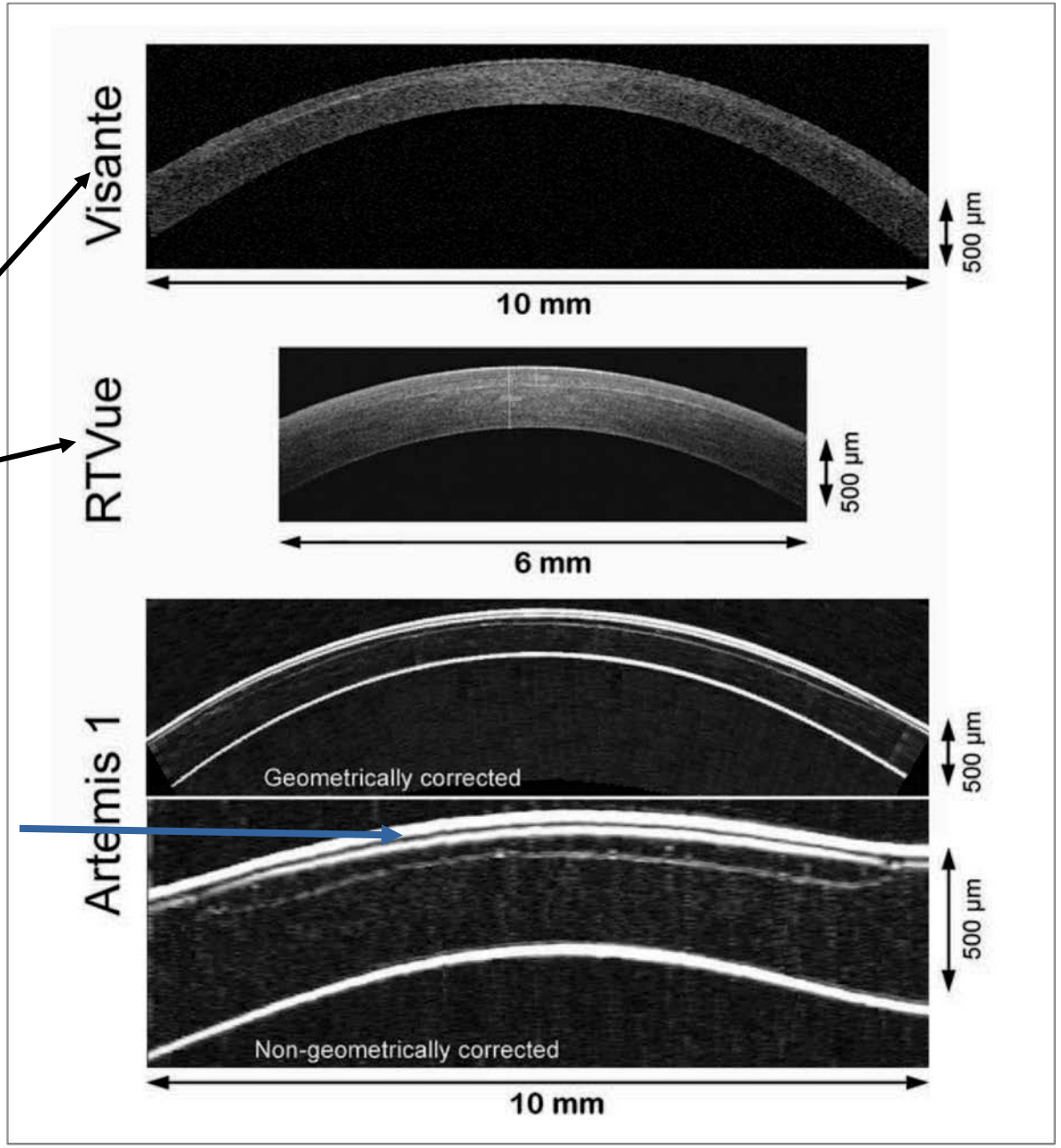
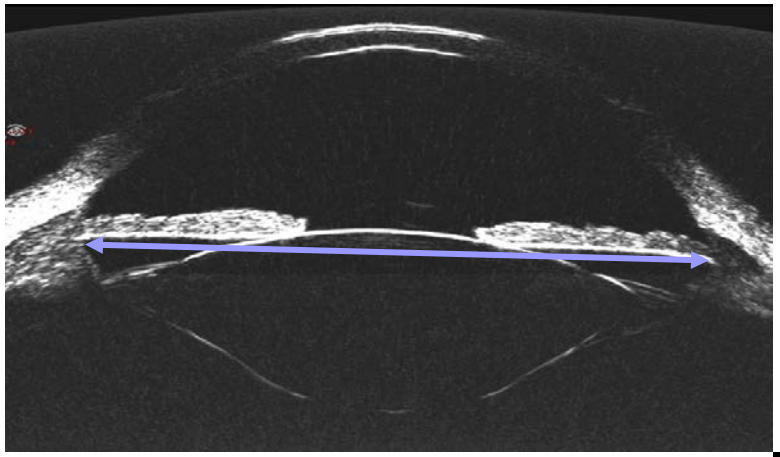


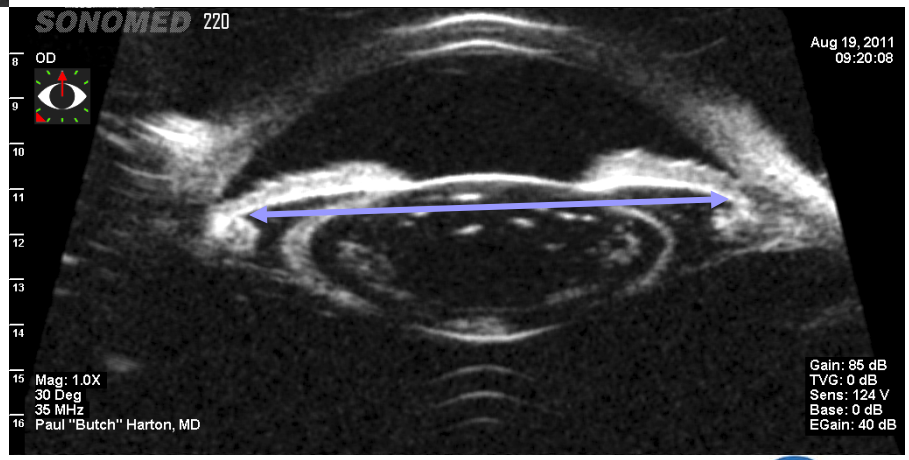

**Figure. B)** B-scans of postoperative LASIK corneas for devices capable of imaging a LASIK flap 3 months postoperatively.

# Refractive - ICL sizing
## Avoiding post-op complications
### Comparison to Ultrasound Bio-Microscope (UBM)



**Anterior Segment – ArcScan**
**(dimension shown - 25µ precision[1])**

**Anterior Segment – UBM Sonomed Vumax 2**
**(same dimension >400µ precision[2])**




1. Anterior segment biometry with 2 imaging technologies: Very-high-frequency ultrasound scanning versus optical coherence tomography; J Cataract Refract Surgery 2008; 34:95–102, Pinero, Alio, Plaza; based on ATA measurement
2. Repeatability of the ciliary sulcus-to-sulcus diameter measurement using wide-scanning-field ultrasound biomicroscopy: J Cataract Refract Surg 2011; 37:1251–1256; Yokoyama et al



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# *Square 1 survey*
# *Refractive market validation*

- **LASIK – Keratoconus screen**

The surgeons performing LASIK (8 of 10) indicated on average that they would use the Artemis 3 on 53% *of their LASIK patients*

- **Refractive - ICL sizing**

The surgeons implanting ICLs (8 of 10) indicated that they would use the Artemis 3 on *100% of their ICL patients*

***"Inappropriately cancelling LASIK patients because of suspicious corneal topography in eyes with normal stroma is a pressing clinical issue. There would be great utility to enhance patient care for a high resolution UBM "*** **Steve Schallhorn, MD ***

***"US market is overdiagnosing keratoconus – Artemis could be a powerful selling tool."*** **Robert K Maloney, MD ***

*** Quotations are doctors from Square 1 survey, these same doctors also available as references**



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# *Refractive go to market strategy*

- **Leverage 40+ peer reviewed papers, minimal new trials required to enter market**
  - Primary applications: KC screening, **ICL sizing**, complex cornea repair
- **First target *premium and high volume* combined refractive/cataract combined surgeons**
  - US High volume/premium market first, 568 surgeons 2/3* of total US market
  - Market link to premium cataract surgeons for 2nd launch
- **Europe launch 6 months after US, less concentration of procedures but larger number of unit sales**
- **ROW after Europe launch – opportunistically where can establish channel quickly**

***Marketscope 2014 Refractive Surgery Market (draft version)**



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# Refractive market assumptions

***Assumed global market adoption of only 18% or only 716k procedures/yr of total 4M in year 10,***

| Target Market | Total # of Surgeons* | Average Procedures per Surgeon* | Market Adoption** | Surgeons who will adopt | Years to full penetration |
|---|---|---|---|---|---|
| US Premium & High Volume | 568 | 739 | **30%** | 170 | 3 |
| US Non-premium | 2840 | 72 | **15%** | 426 | 4 |
| Western Europe | 2512 | 252 | **20%** | 496 | 6 |
| Other wealthy & Japan | 999 | 576 | **16%** | 160 | 5 |
| ROW, India, China, LAM | 3662 | 434 | **16%** | 586 | 7 |

*** Marketscope 2014 Refractive Surgery Market (draft report)**
**** Supported Square 1 independent market study for ArcScan, March 2014**

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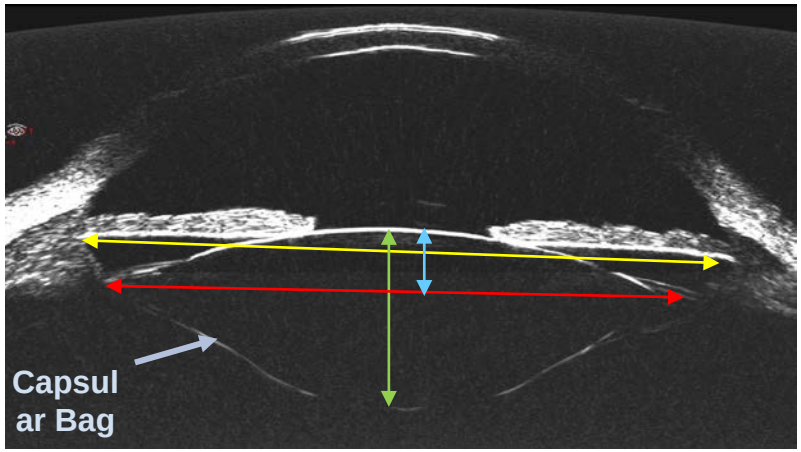
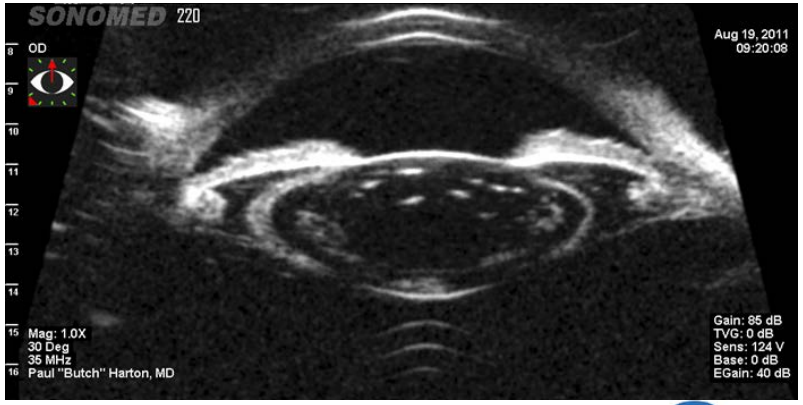
# 2nd Market: Cataract - the bigger opportunity
# Effective lens position

- Predicting effective position (ELP) of implanted lens (IOL) is one of largest sources of vision error
- Seeing behind the iris with precision – no one else can do – gives missing information needed to make accurate lens position prediction
- Surgeon confidence in implanting ***premium*** IOL's is significant market issue – better images of lens capsule pre and post operatively will bridge this confidence gap
- **22.6M procedures per year global - 3.7M procedures US***




*ArcScan*




*Sonomed Vumax 2*

* 2013 Marketscope Report on Global IOL Market



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# *Square 1 survey*
# *Cataract market validation*

## Effective Lens Position

The surgeons performing cataract surgery (9 of 10) indicated that they would use Artemis 3 on average *63% of the time on their premium cataract patients*, **with 6 of the 9 indicating that they would use it on *100% of their premium cataract patients* if it could help predict effective lens position (ELP)**

***"We must know all of the specifications of the bag to properly implant accommodative IOLs, both those available now and those coming in the future."*** **Dan Durrie, MD ***

***"If you had data to understand ELP, this would revolutionize how we calculate IOL power in the future."*** **Robert Weinstock, MD ***

***"Current technologies are getting us with 0.50 diopters in about 85% of our patients. If ArcScan could determine ELP that could drive outcomes to 90 – 92% within a 0.50 Diopter, then surgeons would adopt it."*** **Dick Lindstrom, MD ***

*** Quotations are doctors from Square 1 survey, these same doctors also available as references**



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# *Cataract go to market strategy*

- **Timing to follow closely (within 1+ year) the success of ArcScan in the refractive market**
- **Primary applications premium lenses**
  - Pre-op lens sizing: ELP and lens tilt/ rotation
  - Superior images will bridge lack of surgeon/patient confidence in premium lenses
- **Conduct trial/study plan in parallel with refractive launch for effective lens position (ELP) prediction**
- **Leverage market link to premium/high volume refractive surgeons/clinics**
- **Global rollout similar to refractive – focus on premium self-pay lenses and diagnostics, US first**



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# Cataract market assumptions

- ***Assumed adoption of 1.1M procedures/yr of total 24M or only 5%***
- ***Premium IOL to be 9% to total market growing at 13.2% 2013-2018 ****

| Target Market | Total # of Surgeons* | Average Procedures per Surgeon* | Market Adoption** | Surgeons who will adopt | Years to full penetration |
|---|---|---|---|---|---|
| US | 5,670 | 646 | **10%** | 567 | 5 |
| Western Europe | 8,060 | 451 | **7%** | 564 | 6 |
| Other wealthy & Japan | 8,124 | 367 | **7%** | 569 | 6 |
| ROW, India, China, LAM | 35,339 | 350 | **2%** | 707 | 7 |

*** Marketscope 2013 Report on Global IOL Market**
**** Square 1 independent market study for ArcScan, March 2014, discounted reflecting delay to market after refractive**



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# *Thank you!*

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# *Extra slides*

# Competing technologies & features

| Instrument Features by Instrument Type | Non contact | Precision Cornea Layers | Flap Detection | Behind Iris precision (ICL sizing, ELP) | ASP$ |
|---|---|---|---|---|---|
| **ArcScan** | ✓ | ✓ | ✓ | ✓ | **46k$*** |
| Optical Coherence Tomographers | ✓ | ✗ | ✗ | ✗ | **50-60k$** |
| Scheimpflug Cameras | ✓ | ✗ | ✗ | ✗ | **50-60k$** |
| Handheld Ultrasound | ✗ | ✗ | ✗ | ✗ | **10-27k$** |

*** Square 1 independent survey for ArcScan, March 2014**



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