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Photoimmunotheraphy and other novel treatment modalities in personalized medicine

Seppo Orsila
8th Sep 2022

Optics and Photonics Days 2022

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WE DO LASERS AND OPTICS FOR PERSONALIZED MEDICINE AND BETTER LIFE

PERSONALIZED MEDICINE AND BETTER LIFE

- ❑ Exclusive supplier to 10+ pharmas, other Fortune 500 companies & well-known cancer centers
- ❑ 20+ years track record of semiconductor lasers & optics (400–2000 nm) for medical and high value-add applications
- ❑ Listed in NASDAQ First North

Life sciences

・ Oncology ・
・ Ophthalmology ・
・ Genetics & diagnostics ・

Other high value-add applications

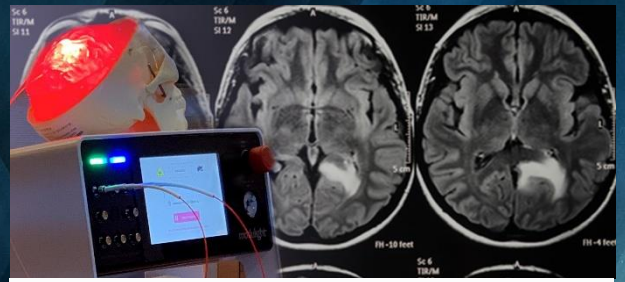
・ Quantum computing ・
・ Communications ・ Digital press ・
・ Weather monitoring ・ AR/VR ・
・ Environment & sensing ・

Services

・ Data analytics & Cloud for improving treatment efficacy ・
・ Pay-per-use (new indications) ・
・ On-site/online training and annual calibration ・
・ Lifecycle support with recurring service plans ・
・ Regulatory design & approvals ・
・ Regulatory and feature software updates ・

MEDICAL APPLICATIONS

Cancer



- Glioblastoma
- Head & Neck Cancer
- Bladder Cancer
- Lung Cancer
- Uveal Melanoma
- PDT – photodynamic therapy
- PIT – photoimmunotherapy
- Theranostics

Ophthalmology

- Wet AMD / CNV
- Dry AMD
- Diabetic Retinopathy
- Glaucoma
- Ocular Melanoma

Genetics, drug discovery, diagnostics

- Genetics
- NGS – Next-generation sequencing
- Fluorescence imaging
- Flow cytometry
- Drug discovery
- In vitro & in vivo research
- Optogenetics
- Fluorescence microscopy

OTHER HIGH VALUE-ADD APPLICATIONS

- Digital Press
- Graphic arts & display
- Quantum computing
- Metrology
- Entertainment & VR/AR
- Illumination
- Communications: 5G, Datacenters
- LiDAR
- Biology
- Diagnostics

Modulight covers the entire value chain

DISCOVERY & INNOVATION

- Clinical grade lasers used for discovery and product innovation
- Use of in-vitro and in-vivo illumination devices in pre-clinical phase
- Data storage into same cloud as clinical device data
- Cooperation with leading early-stage medical researchers

PROTOTYPING

- Iterative prototyping process together with the customer
- Tailoring of the technological solution
- Optimized prototyping process reducing time to market

TESTING / VALIDATION

- Clinical trials for safety and efficacy
- Validation of business idea and product
- Product improvement
- Follow-up of clinical trials via cloud
- Extensive training and support for surgeons and other clinicians

PRODUCTIZATION

- Design for manufacturing
- Data collection
- Sell-out monitoring
- Efficacy improvement & product analytics
- Consumables supply & selling

PRODUCTION

- 360° production FDA grade partner with comprehensive services
- Regulatory support and FDA visits
- 3rd party customer audit support and vigilance reporting
- Sell-out reporting and customer intimacy analytics

LIFE CYCLE MANAGEMENT

- Post market support
- Vigilance reporting
- Warranty & service
- Pre-emptive maintenance & annual calibrations
- Online / cloud materials and user support
- Responsible recycling

Modulight covers the entire value chain offering customized lasers as well as supply and lifecycle security to customers as well as ability to develop & optimize the laser with application first approach

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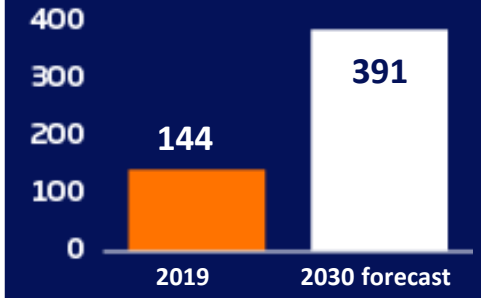
Long-term growth drivers in the market

Oncology (cancer diseases)

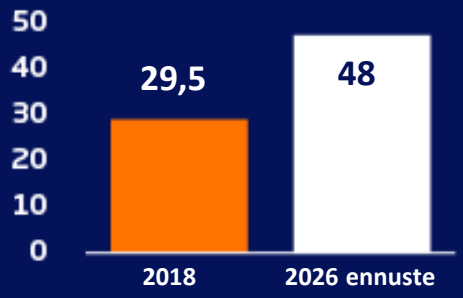
Market size billion. $ [1]



Main growth factor: Aging population worldwide

Ophthalmological diseases

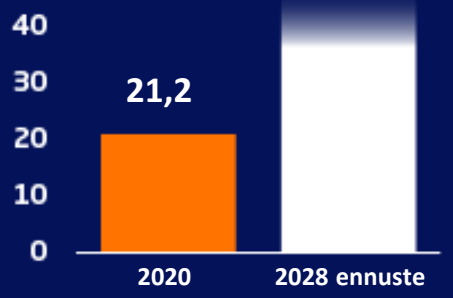
Market size billion $ [2]



Main growth factor: Continued increase in ophthalmic diseases with an aging population and increasing R&D investment

Genetics and Diagnostics

Market size billion $ [3]



Main growth factor: The need for personalized drug treatments for cancer[4]

[1)]Frost & Sullivan, Global Oncology Drug Market, 2021 [2)]Fortune Business Insights: Global Ophthalmic Disease Therapeutics Market, 2019 [3)]Grand View Research: Next Generation Sequencing Market Size, Share and Trends Analysis Report, 2021 (Sekvensointimarkkina 4 miljardia dollaria, kasvuennuste 14,4 % yhdistettyä vuotuista kasvuvauhtia vuodet 2020–2028); Endoscopes Market Size, Share and Trends Analysis Report, 2021 (Endoskooppien markkina 10,8 miljardia dollaria vuonna 2020, kasvuennuste 8% yhdistettyä vuotuista kasvuvauhtia vuodet 2021-2028); Flow 4ytometry Market Size, Share and Trends Analysis Report, 2021 (Virtaussytometrian markkina 6,3 miljardia dollaria vuonna 2020. Kasvuennuste keskimäärin 8,9 % vuosittain 2021–2027). [4)]Spear BB, Heath-Chiozzi M, Huff J. Clinical application of pharmacogenetics. Trends Mol Med. 2001 May;7(5):201-4. doi: 10.1016/s1471-4914(01)01986-4. PMID: 11325631; PMC, Personalized Medicine at FDA: The Scope and Significance of Progress in 2020.

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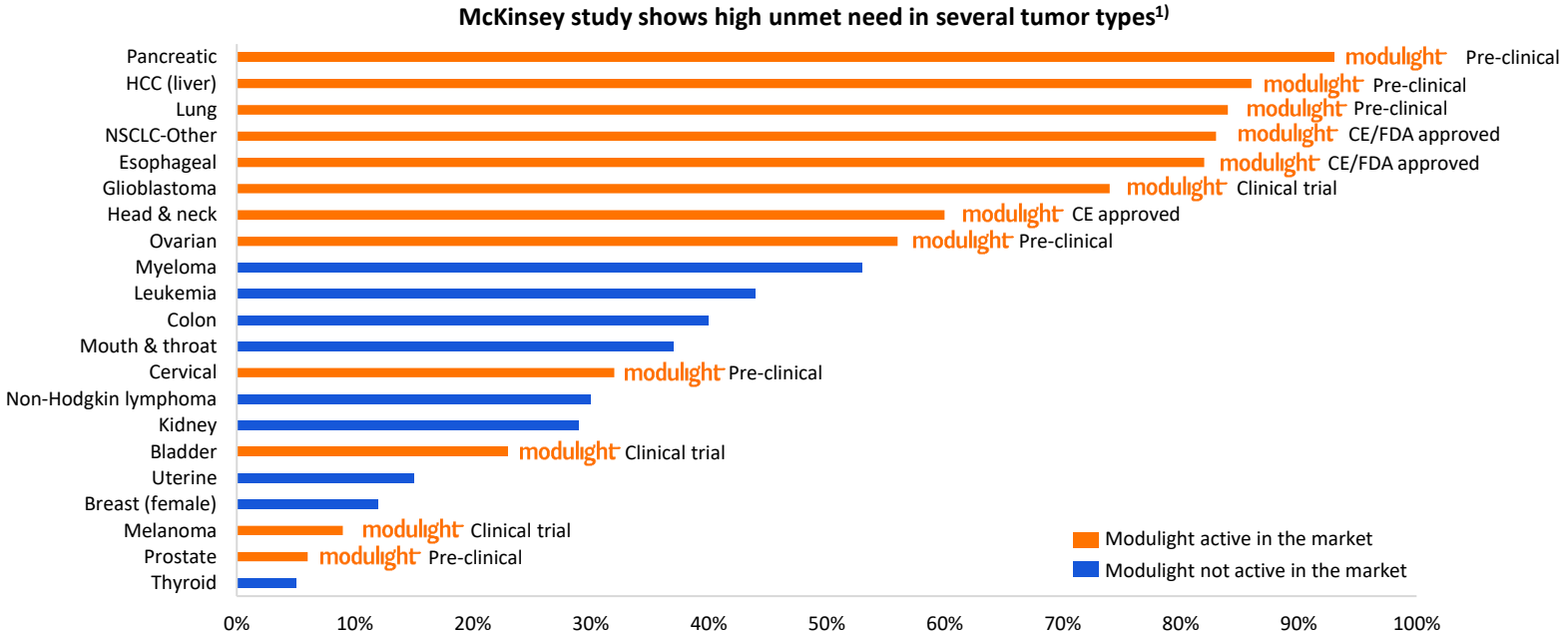
Significant potential in indications with high unmet need



Modulight is targeting indications where the need for new treatment options is high

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1) Unmet need defined as one- minus five-year survival rate in the United States
Source: McKinsey & Company (Delivering innovation: 2020 Oncology market outlook)

Case example: Cloud connected medical laser for glioblastoma

- Customer contacted Modulight because they needed a laser for brain cancer PDT
- Modulight developed a novel PDT laser ML7710i with internet connectivity and real-time treatment monitoring capabilities
- Laser has eight channels for illumination and for providing information on different interstitial processes
- Collected diagnostic data can be viewed from cloud.modulight.com during the treatment and later downloaded for more detailed analysis
- Laser already being used clinically to treat glioblastoma patients in Europe (de novo + recurrent)


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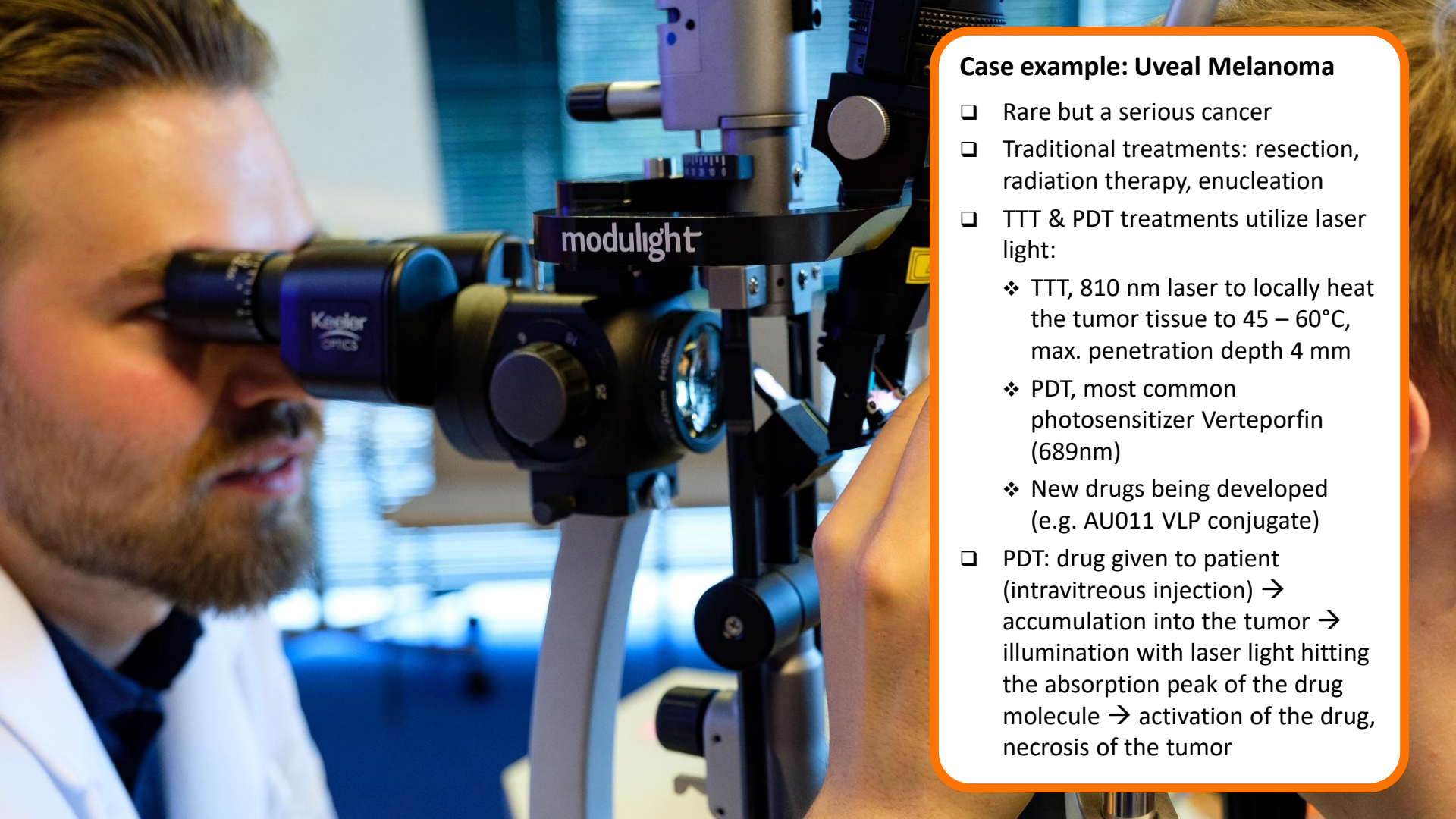


Case example: Uveal Melanoma

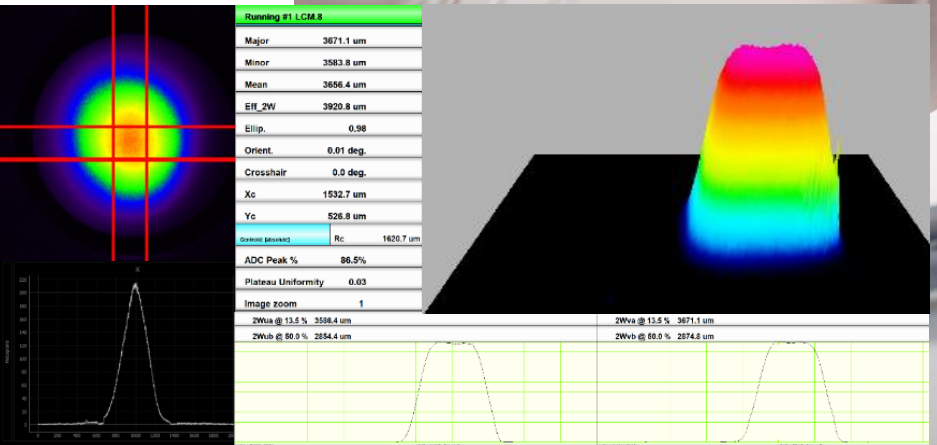
- Rare but a serious cancer
- Traditional treatments: resection, radiation therapy, enucleation
- TTT & PDT treatments utilize laser light:
  - TTT, 810 nm laser to locally heat the tumor tissue to 45 – 60°C, max. penetration depth 4 mm
  - PDT, most common photosensitizer Verteporfin (689nm)
  - New drugs being developed (e.g. AU011 VLP conjugate)
- PDT: drug given to patient (intravitreous injection) → accumulation into the tumor → illumination with laser light hitting the absorption peak of the drug molecule → activation of the drug, necrosis of the tumor

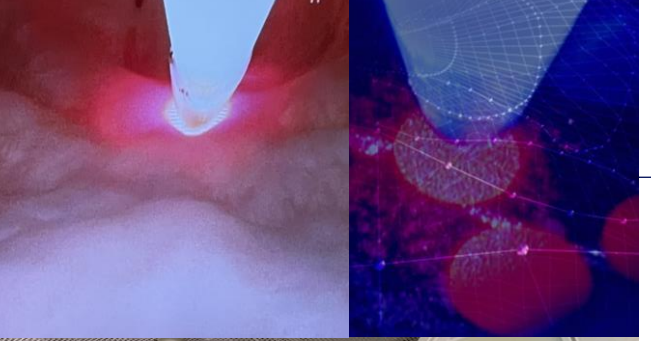
ML6710i – laser for AMD and other retinal treatments

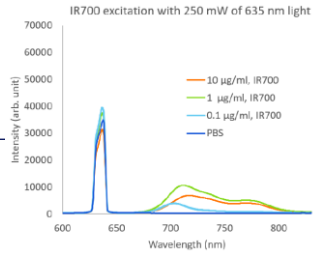
- PDT treatment – combination of a drug and laser light
- Drug given to patient → accumulation into the harmful blood vessels in the retina → illumination with laser light hitting the absorption peak of the drug molecule → activation of the drug, treatment of the retinal lesion
- Modulight ophthalmic laser, ML6710i: world's first medical laser with iPad app & cloud support
- Light coupled to Modulight beam shaper with superior performance
- Full treatment station: laser, iPad, beam shaper, table and slit lamp

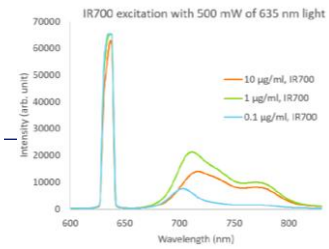
Case example: light sources for fluorescence imaging

- Example configuration for WLE had an adjustable white light source with large dynamic range:
  - Red 635 nm 0-1000 mW
  - Green 520 nm, 0-1000 mW
  - Blue 450 nm, 0-1000 mW
  - Precise power control also at the lower power range enables usage different illumination modes such as white light, fluorescence, and overlay
- Excitation light with central wavelength at 488 nm for fluorescein excitation. Other options include e.g., 785 nm ICG or IR800, 635 nm 5-ALA, or 689 nm IR700X
- Light output can be tailored to support e.g., industry standard endoscopic light guides without the need of additional external optical elements
- Active de-speckling method was implemented to decrease speckle contrast ratio at the sample
- Form factors in ML7710 (clinical system) and ML6600 (subsystem) available









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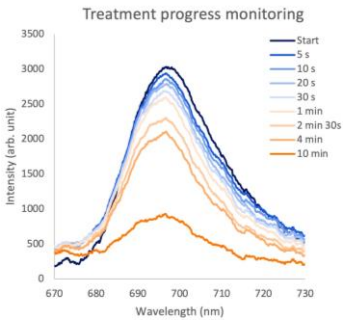
Case example: ML7710 for bladder cancer

- An existing customer contacted ML looking for a partner to support them in expanding to a new indication.
- Modulight started the work based on ML7710 platform as a comprehensive SW & HW partner. Modulight has tailored the overall solution for bladder cancer indication, including software & treatment flow, analytics from the treatment data, as well as the device side.
- The customer also needed support with application development and Modulight executed in vitro studies with customer drug at Modulight facilities → fluorescence feasibility study, cell viability study, etc.
- Modulight also carried out preliminary clinical testing in real cystoscopy operations with a volunteer patients to examine visual conditions in bladder.
- Modulight engineers are present in first treatments to ensure that everything goes smoothly.

Modulight Cloud Advantages

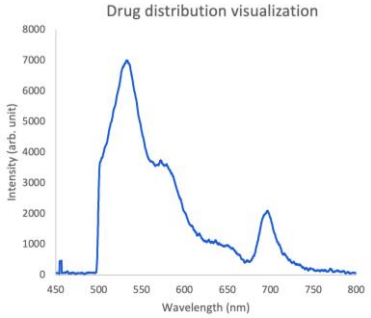
1. Improvement of efficacy
2. Go-To-Market
3. Real-time treatment data for therapeutic efficacy improvement
4. Usage data generation, analysis, and utilization
5. User support and monitoring, remote service management

Treatment protocol planning in Modulight Cloud



Protocols are obtained from Modulight cloud

Treatment data uploaded to cloud and feedback received from cloud



Running the treatment on the selected protocol

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Towards Personalized Devices

Efficacy

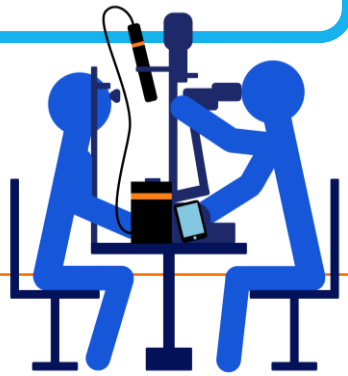
- ❑ New therapies and modalities provide better treatment response
- ❑ Faster and better deployment & training increases the population of patients receiving benefits of new therapies

Safety

- ❑ User authentication
- ❑ Immediate and personal contact channel directly to Modulight

Efficiency

- ❑ Adapt the device to your needs
- ❑ Increase convenience and usability



Modulight ML6710i Laser has received praising usability feedback from ophthalmologists. Especially the iPad user interface is seen very intuitive and fluent to use. Not to mention “high style points” of the design.

Thank you!
Questions?

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