

PT. OPTIK TUNGGAL SEMPURNA

Jakarta, 29 September 2020

No : OTI/00285/DX/2020

Kepada Yth,
RS Mata Undaan
Jl. Undaan Kulon No.19, Peneleh, Genteng,
Surabaya - Jawa Timur 60274

Hal : Surat Permohonan Presentasi Alat Kesehatan Mata

Dengan hormat,

Bersama ini kami sampaikan bahwa perusahaan kami PT. Optik Tunggal Sempurna memohon ijin untuk Presentasi alat kesehatan mata, sebagai berikut:

Merk Product	: IRIDEX
Type	: Cyclo G6
Hari/ Tanggal	: Sabtu, 3 atau 10 Oktober 2020 (Tentative)

Demikian surat permohonan ini kami sampaikan, atas perhatiannya kami ucapkan terima kasih.

Hormat Kami,
Divisi Instrument


PT. OPTIK TUNGGAL SEMPURNA

Herdianto
085719184334


CYCLO G6™
Glaucoma Laser System

MicroPulse® P3

GLAUCOMA DEVICE



Innovative Cyclophotocoagulation
with MicroPulse Technology
Powered by the New CYCLO G6™
Glaucoma Laser System

 **IRIDEX**

SAFE

Efficacious

EFFICIENT

LASER

GLAUCOMA

SPECIFIC

NON-destructive

ESSENTIAL

REPEATABLE

NON-incisional

PREDICTABLE

ECONOMICAL

Excellent Safety Profile

The MicroPulse® P3 Glaucoma Device (MP3) powered by the CYCLO G6™ Glaucoma Laser System enables a versatile procedure with multiple safety benefits:

- Non-Incisional
- Minimal to no inflammation post-op
- Patient downtime is significantly low
- Repeatable
- Predictable

2014 Randomized study shows MicroPulse P3 has similar IOP reduction as G-Probe with higher success rate and no hypotony¹

	MicroPulse TSCPC	TSCPC
Pre-op IOP	36.5 mmHg	35.0 mmHg
N Total of 48	24 pts	24 pts
Average Follow-up	17.5 months	17.5 months
IOP Reduction	45%	45%
Success Rate (≤21 mmHg at 18 months)	75%	29%
Prolonged Hypotony	0	5
Mean # of Treatments	1.6	1.3



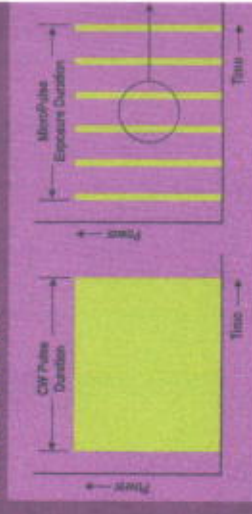
Pre Treatment.



Post Treatment with MP3. No detectable evidence of tissue damage.

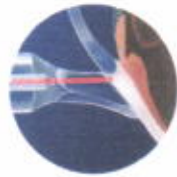
Images courtesy of A/Professor Paul Chew, NUHS

Proprietary MicroPulse® Tech
MicroPulse technology finely controls the “chopping” a continuous-wave (CW) laser of repetitive short pulses allowing tissue pulses and reduce thermal buildup preventing tissue damage.



Glaucoma Therapy Device Options

The patented MicroPulse® P3 and G-Probe™ devices are used to deliver laser energy for the treatment of glaucoma.



G-PROBE

Glaucoma Treatment Stage

Refractory

Reversible Drainage

Var



MP3 PROBE

Primary Open Angle

Var

PATENTED (No. 8,945,103)



Efficacy - Confidence in IOP Control

Long-term results from National University Hospital (NUHS), Singapore prospective clinical study²:

- 33% IOP reduction at 18 months, N = 38 patients
- 61% med reduction (2.1 to 1.3)
- 73% success rate with 1.3



IRIDEX

Specifications

Wavelength	810 nm infrared
Weight	3.9 kg (8.5 lb)
Dimensions	27 cm x 29.5 cm x 19.7 cm (10.6" W x 11.6" D x 7.8" H)
Connector Type	SmartProbe RFID with Laser Parameter Memory
Electrical	100-240 VAC, 50/60 Hz, <0.8 A
Cooling	Air cooled
Exposure Duration	CW-Pulse : 10-9000 ms in 549 increments and continuous pulse up to 60 seconds
Exposure Interval	CW-Pulse: 10-3000 ms in 542 increments and One Pulse
MicroPulse® Duration	MicroPulse: 0.05-1.0 ms in 19 increments
MicroPulse Interval	MicroPulse: 1.0-10.0 ms in 90 increments
MicroPulse Duty Cycle	Continuously adjustable from 0.5%-50%, and preset selections of 5%, 10%, and 15% duty cycles
Aiming Beam	Diode laser, 635 nm nominal
Treatment Power	50-3000 mW, depending on delivery device

Additional Features

- Countdown Timer with audible/voice confirmations
- Programmable user presets for up to 10 individual presets
- Optional power-adjust wireless footswitch (wired footswitch included)
- Color LCD Touchscreen interface
- Backlit control knobs and Treat/Standby button
- Optional Remote Control (high viewing angle, color LCD touchscreen)

Ordering

Product	Product Number	Units per Box
MicroPulse P3	15522	6
G-Probe™	15980	6
Laser Console	CYCLO-G6-SYSTEM	-

CYCLO G6 supports single-use devices only.

Specifications are subject to change without notice. IRIDEX, the IRIDEX logo and MicroPulse are registered trademarks and CYCLO G6, G-Probe and CW-P are trademarks of IRIDEX Corporation. All other trademarks are the property of their respective owners.

Products are covered by one or more of the following U.S. patents: 5,511,085; 5,982,789; 6,327,291; 6,540,391; 6,733,490; 7,766,904; 7,771,417; 7,909,816; 5,997,498; 6,073,759; 6,092,898; 6,217,594; 6,494,314; 6,585,679; 6,726,666; 6,800,076; 6,866,142; 7,537,593; 8,177,777; 8,945,103; 783783; 69530497.6; KR 348012; 0904615; 69706541.3; CA 2331837; AU 759193; JP 4149670; EP 1009684; CA 2286002; JP 449444; JP 4570696; JP 4819754; JP 5123973; JP 513306 U.S. and international Patents Pending may apply.



Emergo Europe

Molenstraat 15, 2513 BH, The Hague, The Netherlands, Tel.: (31) (0) 70 345-8570, Fax: (31) (0) 70 346-7299

IRIDEX | 1212 Terra Bella Avenue | Mountain View, CA 94043 | 800.388.4747 (U.S. inquiries)
info@iridex.com (U.S. & int'l inquiries) | www.iridex.com

©2015 IRIDEX. Printed in U.S.A. LT0596 2/2015

