



**ATI**

*Advanced Medical Technologies Ltd.*



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**YOUR EYES, OUR VISION  
YOUR HEALTH, OUR MISSION**



OPEN your eyes...





to a new reality in  
ophthalmic diagnostics...





**DRUG-FREE...**  
**pupil dilation**





**NO MORE** waiting

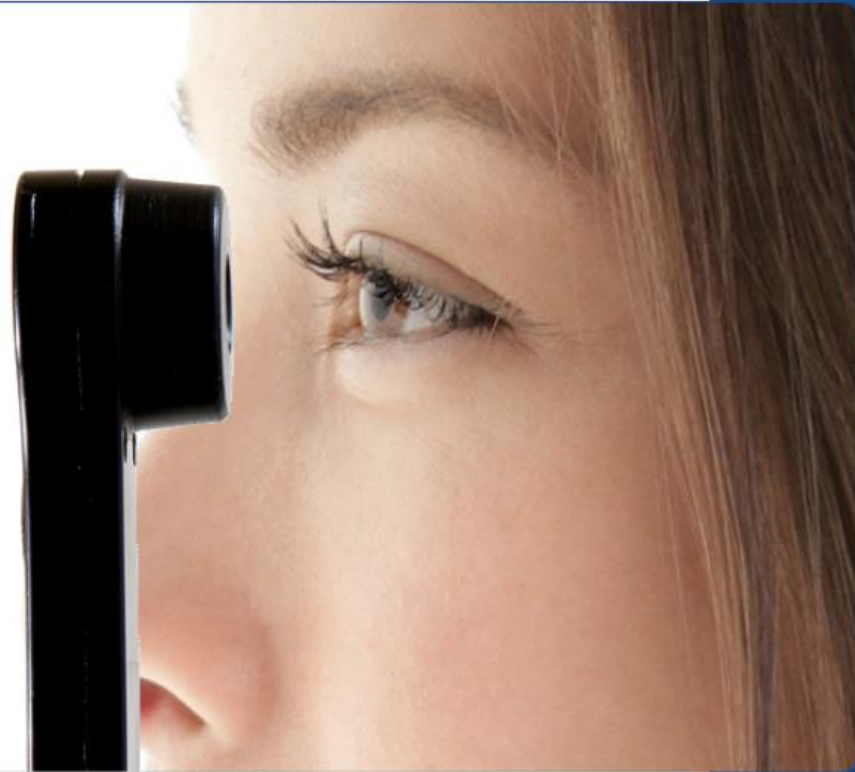




# FIM

## The world's first pupil dilation device

ATI introduces FIM, the world's first pupil dilation device. Unlike dilation drops, FIM achieves full dilation in less than two minutes and recovery within minutes, dramatically improving the examination experience.



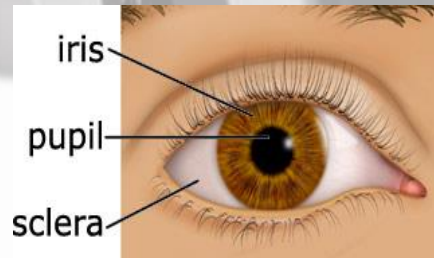


# The Pitch

**ATI introduces an innovative device**

**“FIM 2<sup>nd</sup> Generation”**

**Dilates Eye Pupils, faster and safer,  
without the need for dilating eye substances.**



# The Company

**Offices located in Ra'anana, Israel**

**IP: Patents IL167559, US 11/909,103,, JPN 2007-555773**

**CE Mark & ISO 13485: FIM CE Mark & ISO approval since 2012**

**Received Israel Ministry of Health  
"AMAR" approval.**



# The Team

**Professor Liora Katzenstein** - Chair Person

**Mr. Tomas Mendelsohn** - Co-Founder , BoD Director & CEO

**Mr. Ilan Ron** - Co-Founder & VP R&D

**Mr. Yaacov Cohen** - BoD Director

**Mr. Yoram Wilamovsky** - BoD Director

**Prof. David Varsano - MD.** - Chief Medical Officer

# Mydriatics Today -The Problem

## Time consuming:

- **Slow dilatation onset: up to 20-30 minutes – often a repeat application is necessary.**
- **Slow eye recovery: up to 8 hours – sometimes as long as 72 hours.**

## Discomfort:

- **Irritated, red and stinging eyes, blurred vision.**
- **Unable to read, work or drive for 4-6 hours.**

## Risks: Provocation of Acute Glaucoma, Allergic Reactions, Eye Infection

The use of eye drops is time consuming for both patient and physician and has inherent side effects

## FIM (Field Induced Mydriasis)

The FIM dilates the pupil by the creation of a low emission electromagnetic (EM) field.

When the FIM device is switched on, dilation starts immediately.

When switched off, the pupil returns to 80% of its normal size in less than 2 minutes.

Emitted EM fields are well within medical device safety standards.

No side effects or any type of discomfort, common when using drops.  
Speeds up eye exams, enabling physicians to see many more patients.

## FIM (Field Induced Mydriasis)

**ATI already developed FIM 2<sup>nd</sup> Generation first prototype**

**The FIM 2<sup>nd</sup> Generation will be more robust than its predicate device**

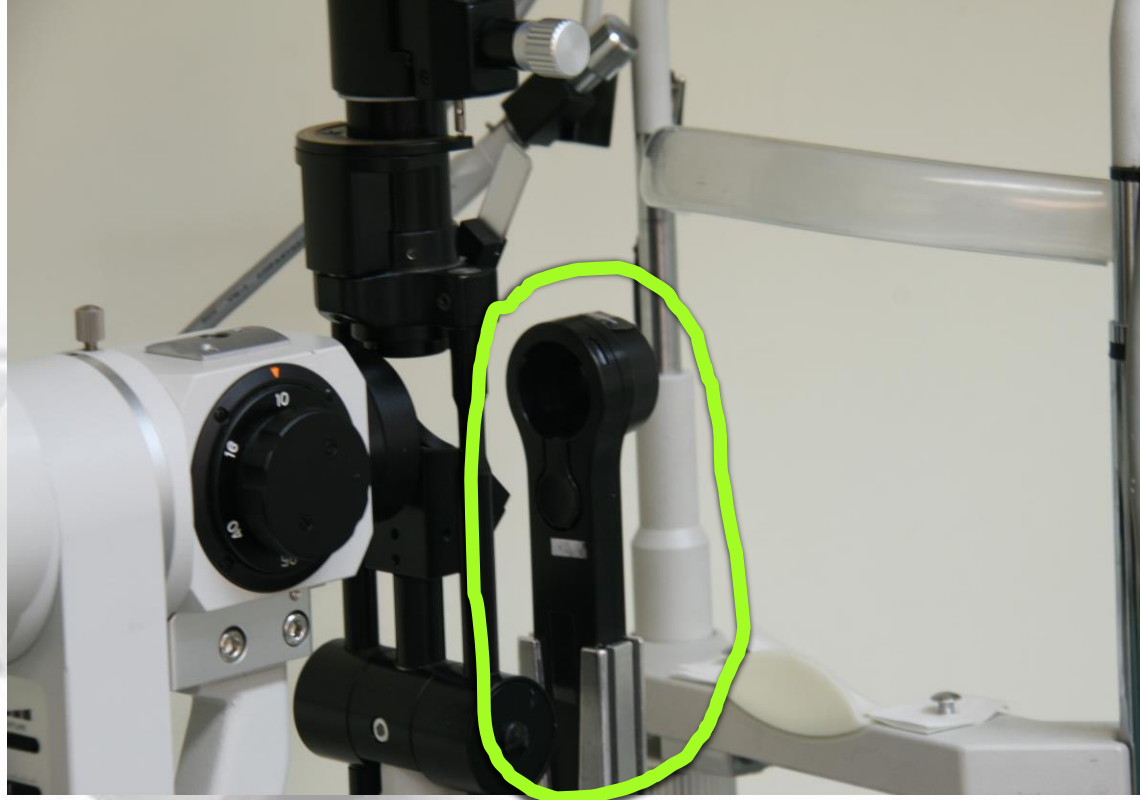
**A new era in ophthalmic eye treatment**

No side effects or any type of discomfort, common when using drops.  
Speeds up eye exams, enabling physicians to see many more patients.

# The FIM Device – 1<sup>st</sup> Generation



FIM Device



FIM 1<sup>st</sup> Generation Attached to Slit Lamp

# Advantages

**Non-contact and non-invasive, easy to operate & use**

**Fast dilation onset:** immediate (30-120 seconds)

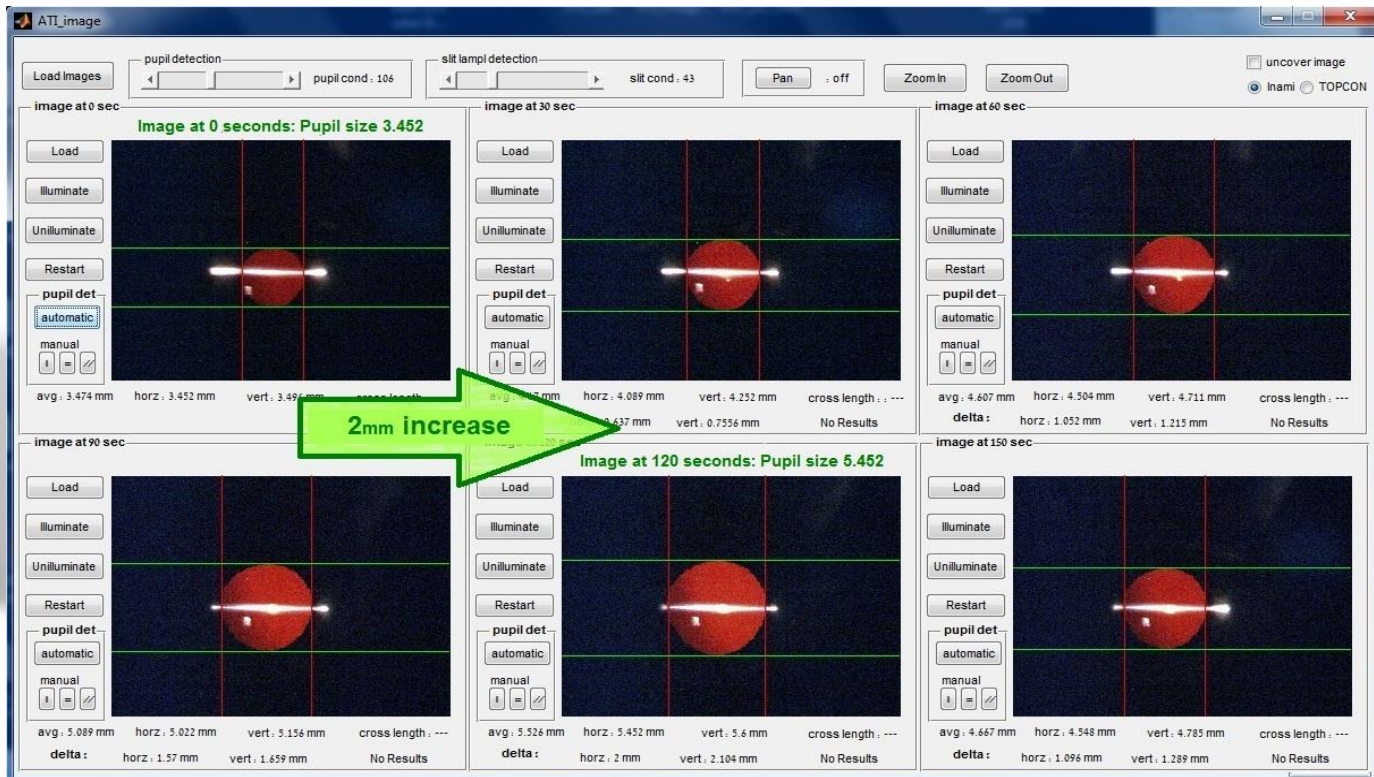
**Fast eye recovery** : immediate (30-120 seconds)

**No discomfort or side effects:**

Immediately after eye examination, patient is able to read, work and drive.

The innovative & advanced FIM technology saves both physician and patient time and eliminates the side effects when using eye drops

# Case Study



A fundus examination requires a pupil size of  $\geq 4 - 4.5$  mm. In this particular case this was achieved with the FIM in 120 seconds.



# Competitive Comparison

	<b><u>Eye Drops</u></b>	<b><u>FIM Device</u></b>
<b>Dilation onset</b>	<b>20-30 minutes</b>	<b>Seconds after start</b>
<b>Recovery rate</b>	<b>Up to 8 hours</b>	<b>Less 2 minutes</b>
<b>Post-exam effects</b>	<b>Blurred vision, stinging, red eyes, unable to work or drive up to 8 hours</b>	<b>None</b>
<b>Elderly</b>	<b>Difficult to use</b>	<b>Easy to use</b>
<b>Patient safety</b>	<b>Provocation of acute glaucoma, allergic reactions, eye , infections</b>	<b>No side effects</b>

**Without side effects: patient comfort and safety improve.  
 With shorter exam times: more patients can be seen.**

# Going to Market

## Launch strategies:

International Business  
Development & Marketing  
focused on:

Establishing  
a distribution  
network

Strategic  
partnerships  
(OEMs)

2<sup>nd</sup> Gen.  
**FIM Launch**  
2<sup>nd</sup>. Q. 2023

# Annex A: - Regulation & Validation

The FIM 1<sup>st</sup> G. device passed safety and EMC tests of the Israel Standard Institute.

The FIM 1<sup>st</sup> G. received European CE approval and complies with received certification of ISO Standard 13485.

ATI received Israel's Ministry of Health "AMAR" certification.

Expects to submit to the FDA in 2023 in the USA

Proof of concept & proof of market have been established.

# Annex B: AMAR - CE Mark + ISO 13485

**CERTIFICATE**

Number: 300544CE01

**CE MARKING OF CONFORMITY MEDICAL DEVICES**

Issued to:  
**ATI - Advanced Medical Technologies Ltd**  
11b Hayetzira St.  
Raanana 43663  
Israel

For the product category:  
**Field Induced Mydriasis devices to provide pupil dilation**

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC Directive which apply to them.

**0344**

Documents that form the basis of this certificate:  
**Certification Module 3006811CN, initially issued October 15, 2012**  
Addendum, initially issued October 12, 2012

DEKRA hereby declares that the above mentioned manufacturer fulfills the relevant provisions of Medical Devices Regulation, that CE Marking of the Directive 90/269/EEC of June 14, 1990 concerning Medical devices, including all subsequent amendments, and that for the above mentioned product category the Conformity Assessment Procedure Number 17 is in combination with Annex 13 to be used for products, as specified by the Manufacturer in accordance with the provisions of the Council Directive 90/269/EEC of June 14, 1990. The responsible personnel and the certificate to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integral part of the certificate.

This certificate is valid until: October 1, 2015  
Issued for the first time: October 12, 2012

DEKRA Certification B.V.

Mr. G.J. Zeebroek  
Managing Director

Mrs. A.A.M. Lan  
Certification Manager

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All testing, inspection, auditing and certification activities of the former NEN4000 Quality are an integral part of the DEKRA Certification Group.

DEKRA Certification B.V. | Uithoornweg 110, 8121 AP Arnhem | P.O. Box 5145, 6802 ED Arnhem, The Netherlands  
T +31 (0) 26 200 2000 | F +31 (0) 26 200 2000 | www.dekra-certification.com | Company registration: 09050068

**ADDENDUM**

Belonging to certificate: 300544CE01

**CE MARKING OF CONFORMITY MEDICAL DEVICES**

Field Induced Mydriasis devices to provide pupil dilation.

Issued to:  
**ATI - Advanced Medical Technologies Ltd**  
11b Hayetzira St.  
Raanana 43663  
Israel

This certificate covers the following products:  
**FIM (Field Induced Mydriasis), model M01 (Class III)**

Initial date: October 12, 2012

DEKRA Certification B.V.

Mr. G.J. Zeebroek  
Managing Director

Mrs. A.A.M. Lan  
Certification Manager

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**CERTIFICATE**

Number: 3000811

The management system of:  
**ATI - Advanced Medical Technologies Ltd**  
11b Hayetzira St.  
Raanana 43663  
Israel

including the implementation meets the requirements of the standard:  
**ISO 13485:2003**

Scope:  
Design, development, manufacture and distribution of Field Induced Mydriasis (pupil dilation) device for retinal and other eye examinations

Certificate expiry date: October 1, 2015  
Certified for the first time: October 12, 2012  
Certificate effective date: October 12, 2012

DEKRA Certification B.V.

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משרד הבריאות  
המנהל לטכנולוגיות רפואיות ומשאבות  
Health Technology and Infrastructure Administration  
Medical Devices Department  
מדינת ישראל  
STATE OF ISRAEL

**אישור רישום בפנקס האביורים והמכשירים הרפואיים**

**ניתן בואת אישור, כי בהתאם לבקשת רישום מס : 26240001 האביורים / מכשירים רפואיים (אמ"ר) הבאים :**

שם האב"ר	FIM - Field Induced Mydriasis
קוד האב"ר	FIM is a drug-free, non-invasive device, inducing a temporarily and quick pupil dilation (mydriasis) without a need for eye drops, and with rapid recovery
התיור	FIM is a drug free, non-invasive device, inducing a temporarily and quick pupil dilation (mydriasis) without a need for eye drops, and with rapid recovery
שם בעל רישום וכתובת	ATI ADVANCED MEDICAL TECHNOLOGIES LTD. : 11B HAYETZIRA ST. RAANANA, 43663 ISRAEL
שם יצרן וכתובת	ATI ADVANCED MEDICAL TECHNOLOGIES LTD. : 11B HAYETZIRA ST. RAANANA, 43663 ISRAEL
שם אג"ר וכתובת	א.מ.ת.ג. : ק"ר, תיבה 15, תל אביב, ישראל
שם ספק וכתובת	איקום : תחנה 17, רמת השרון 43605 ISRAEL

**התנאים**

התנאים:  
- ילי הרואות הרצון שאשתו ג"ן ניק המאשר DEKRA  
- המשנה שלוש חות דעת לרצון הארכת תוקף הרישום - אחת מכל זכרון שכן נעשה שלוש בעברית  
- אישור בתאם אישור CE שנעשה בידי מנהל  
- מאשר שלוש בתאם להראות הרצון כי שאשתו על ידי הקן המאשר בלי, בכת חלים המאשר בלבד  
- השימוש מוגבל לרפואים שהורצו המוסמך על הרצון  
- הבערת לרישום זמני  
- הגבלת הפעלת לרצון הרואות תוקף של רישום זה יש להקן חות דעת בעברית לעיל


**נרשמו בפנקס האביורים והמכשירים הרפואיים במשרד הבריאות תוקף האישור לשיווק אמ"ר הינו ליעדים ולהתוויות המתוארים לעיל בלבד האישור בתוקף עד: 31/01/2015**

29/11/2013  
מנהל היחידה לאמ"ר  
המ"ר ד"ר נדב שניר

המ"ר  
המ"ר  
המ"ר

High Standards & Quality

# Summary



**The “FIM” - An eye pupil dilating Medical Device & Technology, minimizes the waiting time and overcomes the drops side effects.**

**It replaces the use of eye drops with a non-contact, non-invasive device without changing the medical practice.**

**There is currently no such device/technology except from ATI.**

**To achieve our objectives for 2023 we seek a total investment of 2.5m\$ for the FIM 2<sup>nd</sup> Generation.**

**(Based 1 US\$ = 4.00 Nis)**



**ATI**

Advanced Medical Technologies Ltd.

# Thank You

**For More Information  
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**Office: +972-9-7467771  
mailto: [tomas@ati-amt.com](mailto:tomas@ati-amt.com)**

