



Global Laser Tech-Leader
Specialized in the laser devices
for the healthcare and beauty

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Laser Lancing Device:
HandyRay Series
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01

Company Profile

01



LAMEDITECH Co., Ltd has been developing and supplying specialized laser devices to promote healthy and beautiful lives based on laser miniaturization technology.

Our laser devices for the clinical and cosmetic treatment, which the miniaturization technology is applied to, are highly competitive in quality when compared to other competing products in the market.

Through the continuous research and development, LAMEDITECH commits to become a global top laser expertise company.

Vision & Mission

Vision

Become a global leader in advancing laser technology
for both health and beauty

Mission

Bring a healthier and happier life
through the most innovative laser technologies



Blood Collection Devices

Through laser minimization technology, LAMEDITECH has been manufacturing and supplying cutting edge laser blood collection devices to improve public health.



Medical and Beauty Devices

Through laser minimization technology we have been manufacturing and supplying medical purpose products for the skin, with the added ability to safely (with great effect on immunity) control skin disease, and inflammation.



Pet Devices

Through laser minimization technology, we have been manufacturing and supplying healthcare products for pets that focus on solving skin infection and overall health.

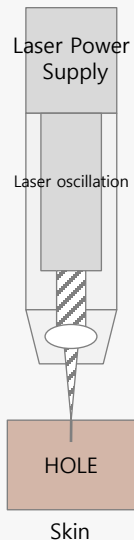
02

**Product Description:
Laser Lancing Device: HandyRay Series**

2. The technology & Features of Laser Lancing Device

Our lancing devices are a personal and hospital-use medical product. It is a needless, and relatively pain-free product designed for the collection of capillary blood.

Operation principle



- Through laser (Er: YAG) instead of a needle
- High energy is transferred once proper contact is made with the skin,
- Through high energy concentration, and in less than (1/10000 of a second), the skin is ablated where the blood can be then collected from the hole.

Product benefits

- No phobias associated with needles.
- No risk of secondary infection
- short ablation time and relatively low pain
- Skin sterilizing technology due to high temperature-laser
- No callus despite multiple procedures.

Applications

- Convenient for Type-1 diabetics and early-onset diabetics and those who are more sensitive to the pain and callus
- Can be used in both medical institutions as well as individual diabetics
- To sample capillary blood for various diagnostic devices

2-1. Larger Hospital-Use Laser Lancing Device: HandyRay-Pro

Our laser lancing device, the "HandyRay-Pro" is a product suitable for use in large hospitals and in specialized medical institutions where daily usage is high

Product Specifications

- Laser Type: Er:YAG
- Laser Wavelength: 2940nm($\pm 10\%$)
- Laser Intensity: 150~270mJ($\pm 20\%$)
- Laser Class: Class 3R
- Laser Level: 1~5 Level
- Product Voltage: 3.7V
- Perforation Size : 350 μ m
- Product Weight: 250g
- Product Size: 270x144x176mm



Product Advantages

- User-friendly design
- Ergonomic grip
- Battery level display
- Contact-type application
- Longer lifetime use
- Shorter charge time
- Charging cradle
- Full charge indicator
- Air-fan application

Applications

- To sample capillary blood for various diagnostic devices
- Long lifetime-usage means it is suitable for hospitals or labs with frequent blood testing done.
- Can be used in both medical institutions as well as individual diabetics

2-2. Individual Laser Lancing Device: HandyRay-Lite

Our laser lancing device, the "HandyRay-Lite" is a product suitable for use for individual users that need to manage blood sugar content daily. With its compact design, this is an ideal to fit in small places.

Product Specifications

- Laser Type: Er:YAG
- Laser Wavelength: 2940nm($\pm 10\%$)
- Laser Intensity: 100~180mJ($\pm 20\%$)
- Laser Class: Class 1
- Laser Level: 1~3 Levels
- Product Voltage: 3.7V
- Perforation Size : 300 μ m
- Product Weight: 113g
- Product Size: 23x37x159mm



Product Advantages

- Simple "bar-type" design
- Half the size of a smartphone
- $\frac{2}{3}$ weight of a smartphone
- Contact-type application
- Battery level display
- Diverse color range
- Laser Class 1 reduces risk

Applications

Used as a blood collection device for diagnostic devices using a small quantity of blood

2-3. HandyRay Series Comparison



Class 1 / 2940 nm

HandyRay-Lite (LMT-1000)

Individuals

23(W)x 37(D) x 159mm(H)/ 113g

1 full charge: 30 times, total: 10,000 times
(based on level 1)

5~6 secs (Based on Level 1)

3.7 Vdc check low battery with
LED indicator.

5 pin cable

10,000 times within a year

U.S FDA, CE, KFDA, GMP, ANVISA

1~3 level & 100-180mJ

1. Bar design type
2. More portable and affordable



Class 3R / 2940 nm

HandyRay-Pro (LMT-5000)

Large hospitals

37(W) x 144(D) x 176mm(H) / 250g

1 charge: 250 times, total: 30,000 times available
(based on Level 1)

1~2 secs (Level 1 standards)

7.4 Vdc battery level with
display function

Charging cradle

30,000 times within a year

U.S FDA, CE, KFDA, GMP, ANVISA

1~5 level & 150~270mJ

1. Air-vent,
2. smaller single-use cap size,
3. easier safety release function,
4. comfortable grip,
5. separate power and charging buttons

2-4. Target Benefits | Individual Users

The individual consumer **benefits** from using our laser lancing device



Individual User

Main Concerns

Pain and Phobia

Calluses / needle marks

Price

Benefits

- Needleless laser function
- Less pain due to short blood collection time
Appx. 80% of the users felt low or no pain

- No skin incision - No fingerprint damage (laser ablation applied)
- No needle marks or callus due to quick skin regeneration

- Patients prefer premium lancets such as the Softclix due to pain and other reasons
- Accounting for long term usage, our device is cheaper than premium lancets (Appx. 12% less based on 20,000 uses -> refer to following slide for full cost analysis)

Hospitals and other medical institutions will **benefit** from using our laser lancing device



Medical Institutions

Main Concerns

Secondary Infection

Price

Pain and Phobia

Benefits

- Needless procedure (no risk of sharing the same needle)
- No cross infection as there is no direct contact with a device due to use of single-use cap
- Major medical institutions use single-use safe lancets to prevent secondary infection
- Our single-use caps are cheaper on a long term basis (approx. 63% less based on 30,000 usages).
- Needless procedure
- Less pain than needle lancets that provide no depth adjustments
- Due to different levels, the HandyRay series allows variances to perforation depth, which allows for less pain

2-6. HandyRay-Pro Cost Effective Analysis

Analyzing the cost-effectiveness of "HandyRay-Pro" compared with other products

01

HandyRay-Pro vs other products

Unit USD

Classification	HandyRay-Pro(*)	Safe Lancet(**)
Lancing Device	\$900	\$0.147
Needle or other consumables	\$0.06	

(*) HandyRay-Pro = main device + 1 single-use cap (refer to Korean market price)

(**) Safe Lancet = \$0.147 (refers to Amazon.com prices)

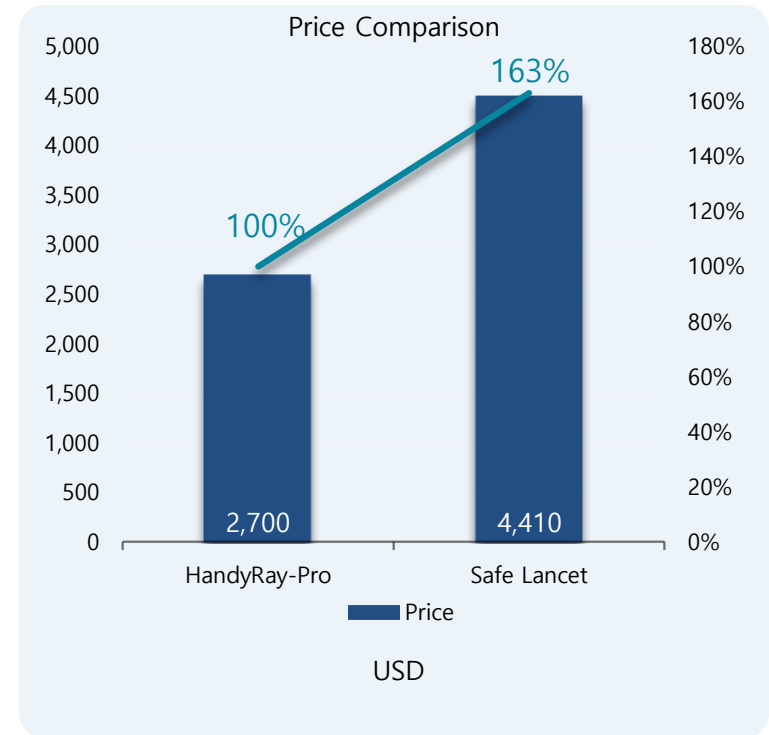
02

Cost after 30,000 uses

Product	Price (USD)	Cost ratio (%) compared with HandyRay-Pro
HandyRay-Pro	\$2,700	-
Safe Lancet	\$4,410	+63%

(*) HandyRay-Pro is lower cost than other products when compared each other based on Min. 30,000 times as shown above.

- HandyRay-Pro is available more than min. 30,000~50,000 times.



2-7. HandyRay-Lite Cost Effective Analysis

Analyzing the cost-effectiveness of "HandyRay-Lite" compared with other products

01

HandyRay-Lite vs other products Unit USD

Classification	HandyRay-Lite(*)	SoftClix(***)
Lancing device	\$220	\$15
Needle or other consumables	\$0.06	\$0.1

(*) HandyRay-Lite = main device + 1 single-use cap
(refers to Korean market price)

(**) SoftClix = main device + 1 exclusive lancet piece ~5000 clicks
(refer to Amazon.com prices)

02

Cost after 10,000 uses

Product	Price (USD)	Cost ratio (%) compared with HandyRay-Lite
HandyRay-Lite	\$820	-
SoftClix	\$1,015	+24%

(*) HandyRay-Lite is cheaper after adjusting for 10,000 uses when compared with to the SoftClix. brand



2-8. HandyRay-Pro vs Other Products

Based on the final consumer price and the number of product warranties, the cost and comparison of "HandyRay-Pro" are as follows.

HandyRay-Pro Consumer Cost	Warranty	HandyRay-Pro Cost Per Use	Single-use cap Consumer Cost (100 per box)	Single-use cap Cost Per Use	Total Cost Per Use
900 USD	30,000 times	0.03 USD	6 USD	0.06 USD	0.09 USD
Division Cost	3 Times per Day (Annual Cost)	5 Times per Day (Annual Cost)	10 Times per Day (Annual Cost)	50 Times per Day (Annual Cost)	100 Times per Day (Annual Cost)
HandyRay-Pro	98.5 USD	164.3 USD	328.5 USD	1,642.5 USD	3,285 USD
Safe lancet	160.9 USD	268.2 USD	536.6 USD	2682.8 USD	5365.5 USD

2-9. HandyRay-Lite vs Other Products

Based on the final consumer price and the number of product warranties, the cost and comparison of "HandyRay-Lite" are as follows.

HandyRay-Lite Consumer Cost	Warranty	HandyRay-Lite Cost Per Use	Single-use cap Consumer Cost (100 per box)	Single-use cap Cost Per Use	Total Cost Per Use
220 USD	10,000 times	0.022 USD	6 USD	0.06 USD	0.082 USD
Division Cost	3 Times per Day (Annual Cost)	5 Times per Day (Annual Cost)	10 Times per Day (Annual Cost)	50 Times per Day (Annual Cost)	100 Times per Day (Annual Cost)
HandyRay-Lite	89.79 USD	149.65 USD	299.3 USD	1496.5 USD	2993 USD
Softclix	111.1 USD	185.2 USD	370.5 USD	1852.4 USD	3704.8 USD

The “HandyRay-Pro” has a guaranteed 30,000 use warranty.
The lifetime of the HandyRay-Pro, depends on the number of daily uses.

Warranty	No. of Daily Uses	Length of Use (Years)
30,000 times	3 times	27 years 2 months
	5 times	16 years 2 months
	10 times	8 years 1 months
	50 times	1 years 8 months
	100 times	10 months

Rounded up to the nearest week/month.



The “HandyRay-Lite” has a guaranteed 10,000 use warranty.
The lifetime of the HandyRay-Lite, depends on the number of daily uses.

Warranty	No. of Daily Uses	Length of Use (Years)
10,000 Times	3 times	9 years 2 months
	5 times	5 years 6 months
	10 times	2 years 10 months
	50 times	6 months

Rounded up to the nearest week/month.



05

Certifications

03

3-1. Certifications

Our “HandyRay” series products are certified by the following domestic and international bodies, including but not limited to the US FDA, CE, and NET certifications

LaMeditech Certifications



2017. 06
KGMP



2012. 02
Europe ISO 13485
certificate



2016. 04
Venture company
certificate



2012. 04
Company R&D center
registration

HandyRay-Pro Certifications



2019. 06
CE marking



2019. 02
KFDA approval
Medical Class
Level 3



2019. 07
NET approval



2020. 5
FDA(510k)
approval



2020. 5
ANVISA
approval

HandyRay-Lite Certifications



2019. 07
NET approval



2020. 06
KFDA approval
Medical Class
Level 3



2020. 06
FDA(510k)
approval



2020. 12
CE marking



2020. 5
ANVISA
approval

04

Clinical Test Results

04

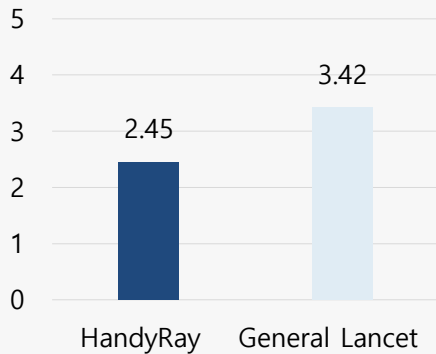
Purpose

Comparing the pain assessment of Laser lancing device HandyRay (LMT-3000) and other blood collection needles

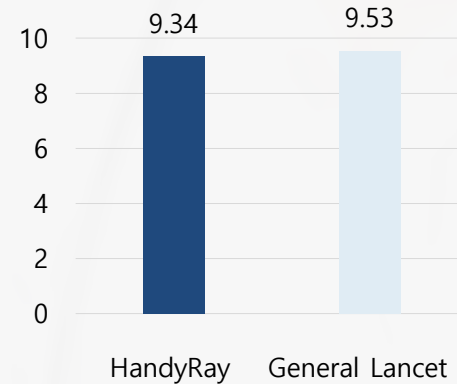
Testing Institution	D University Hospital, Department of Endocrinology, Obstetrics and Gynecology
Subjects	40 Healthy males, females both pregnant and not pregnant. (80 cases: both left and right hand)
Purpose	The LMT-3000 will act as the test device, while the control device will be the syringe devices that use disposable needles. From this experiment, we will determine which method is the most effective and least painful
Results	<p>When collecting blood using LMT-3000, there was no statistically significant difference in superiority and safety in reducing pain.</p> <p>Therefore, LMT-3000 has demonstrated sufficient effectiveness and safety as a blood collection device compared to disposable lancets.</p>

4-2. Clinical Test Results

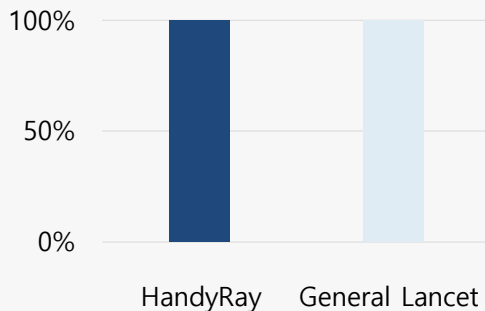
Relative Pain



Blood Flow Comparison



ABO Confirmation and Success Rate



Clinical results: There were no differences in blood type measurement from existing blood lancet needle

Blood degeneration (Blood-gas analysis)

Blood-gas analysis

Item	Clinical Results
PH analysis	No significant result
CO ² analysis	No significant result
O ² analysis	No significant result
Glucose analysis	No significant result
Lactate analysis	No significant result
Hematocrit analysis	No significant result

4-3. Clinical Test Results 2

NIPS score before and after blood collection

	Median	Min Value	Max Value	IQR
LMT-5000 NIPS Difference	0	0	3	0-0
Lancet NIPS Difference	1	0	7	0-3

Clinical Results: It was confirmed that LMT-5000 had less pain than lancets.

Blood collection success rate

		Lancet	
		Success	Failure
LMT-5000	Success	40	0
	Failure	0	0

Clinical results: 100% success rate was shown for both devices, confirming that there was no difference.

Number of blood collection attempts

	Median Value	Min Value	Max Value	IQR
LMT-5000 Number of blood collection	1	1	3	1-2
Lancet Number of blood collection	1	1	2	1-1

Clinical Results: The median number of blood collections in both device modes is 1, confirming the same.

Neonatal blood collection



Point of blood collection

	Immediately after blood collection	1 day after blood collection
LMT-5000		
Lancet		



Biochemical and Pain Comparisons Between the Laser Lancing Device and Needle Lancets for Capillary Blood Sampling: A Randomized Control Trial

First published: 07 July 2020 <https://doi.org/10.1002/lsm.23298>

Yoo, W.S., Min, J., Chung, P.-S. and Woo, S.H. (2020). Biochemical and Pain Comparisons Between the Laser Lancing Device and Needle Lancets for Capillary Blood Sampling: A Randomized Control Trial. *Lasers Surg Med.* doi:10.1002/lsm.23298

Abstract

Background and Objectives

Patients around the world use a lancing device to perform self-monitoring of blood sugar (SMBG). However, there are always fears of needles and pain. Therefore, less painful devices are being developed. The purpose of this study was to compare the usefulness and safety of a laser lancing device (without a needle) to a conventional needle lancet (with a needle) for capillary blood sampling.

There was no difference in biochemical results between the laser lancing device group and the conventional needle lancet group. The laser lancing device demonstrated comparatively lower pain than the conventional needle lancet.

and 102.25 ± 1.12 mmol/L in the conventional needle lancet group, and there were no significant differences between the two groups. The pH, CO₂, O₂, lactate and hematocrit levels of the blood were also compared between the two groups. In the first trial, the median pain score (interquartile range) of patients using laser lancing device was 2.0 (1.0–3.0), whereas it was 2.5 (2.0–4.0) in the conventional needle lancet group ($P = 0.029$). In the second trial, one week later, the median pain score in the laser lancing device group was 2.5 (1.0–4.0), whereas it was 3.5 (2.25–4.0) in the conventional needle lancet group ($P = 0.001$). The difference in pain scores between the first and second trials was significant in the conventional needle lancet group ($P = 0.007$), but not in the laser lancing device group ($P = 0.150$).

Conclusion

There was no difference in biochemical results between the laser lancing device group and the conventional needle lancet group. The laser lancing device demonstrated comparatively lower pain than the conventional needle lancet. *Lasers Surg. Med.* © 2020 Wiley Periodicals LLC.



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ORIGINAL RESEARCH

TRANSFUSION

Comparison between a laser lancing device and lancet for capillary blood sampling, capillary blood hemoglobin measurement, and blood typing

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Abstract

Background: Blood donor screening includes tests using capillary blood,

Use of a laser lancing device for capillary Hb measurement and blood typing **showed accurate results, with significantly reduced skin puncture pain.**

paired cHb results obtained with the laser lancing device and a strong correlation ($r = 0.927$, $p < .001$) without any significant difference (.113) and a substantial agreement ($\kappa = 0.654$) for the identification of participants with a low Hb level (<12.5 g/dl). cHb levels were significantly higher than vHb levels with both lancing devices (mean differences: 0.5 g/dl). The results of blood typing using the laser lancing device showed 100% accuracy. Use of the laser lancing device showed significantly lower skin puncture pain scores ($p < .001$).

Conclusion: Use of a laser lancing device for capillary Hb measurement and blood typing showed accurate results, with significantly reduced skin puncture pain. Laser lancing devices could be feasible for donor screening tests.

KEYWORDS

capillary blood sampling, donor screening, hemoglobin, lancet, laser, pain

1 | INTRODUCTION

Abbreviations: cHb, capillary blood Hb; Er:YAG, erbium:YAG; Hb, hemoglobin; NRS, numeric rating scale; POC, point-of-care; RBCs, red blood cells; vHb, venous Hb.

Blood donor screening tests include several laboratory tests performed at the donation site, including measurement of the donor's hemoglobin (Hb) concentration and



Short Communication

Technology/Devises

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Check for updates

Comparison of Laser and Conventional Lancing Devices for Blood Glucose Measurement Conformance and Patient Satisfaction in Diabetes mellitus

Jung A Kim^{1,2}, Min Jeong Park¹, Eyun Song¹, Eun Roh¹, So Young Park¹, Da Young Lee¹, Jaeyoung Kim³, Byung Cheol Park⁴, Ji Hee Yu¹, Ji A Seo¹, Kyung Mook Choi¹, Sei Hyun Baik¹, Hye Jin Yoo¹, Nan Hee Kim^{1,5}

LMT-1000 reduced puncture pain by 75.0% and increased satisfaction by 80.0% compared to a lancet.

Blood sampling was performed on each hand using the LMT-1000 or a conventional lancet. The primary outcome was correlation between glucose values from the LMT-1000 and that using a lancet. And we compared the pain and satisfaction of the procedures. The capillary blood sampling success rates with the LMT-1000 and lancet were 99.3% and 100%, respectively. There was a positive correlation ($r=0.974$, $P<0.001$) between mean blood glucose levels in the LMT-1000 (175.8 ± 63.0 mg/dL) and conventional lancet samples (172.5 ± 63.6 mg/dL). LMT-1000 reduced puncture pain by 75.0% and increased satisfaction by 80.0% compared to a lancet. We demonstrated considerable consistency in blood glucose measurements between samples from the LMT-1000 and a lancet, but improved satisfaction and clinically significant pain reduction were observed with the LMT-1000 compared to those with a lancet.

Keywords: Blood glucose self-monitoring; Diabetes mellitus; Lasers; Pain

INTRODUCTION

Self-monitoring of blood glucose (SMBG) has been proven to reduce glycosylated hemoglobin (HbA1c) level and is useful for optimizing glycemic control and preventing diabetic complications by helping one understand their pattern of blood glucose level and facilitating lifestyle modifications [1-4]. Despite the importance of SMBG in glucose control, only 33% of

patients with diabetes perform SMBG routinely [5] because of puncture pain, fear of needles, inconvenience, complexity, cost, and increased risk of infection [6]. Lancing pain is the main reason for noncompliance among patients with diabetes.

Recently, LAMEDITECH developed a lancing device, LMT-1000 (HandyRay-Lite, LAMEDITECH, Seoul, Korea), that uses a 2,940 nm single-pulse (erbium-doped yttrium aluminum garnet or erbium YAG) laser that generates high energy

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Thank You