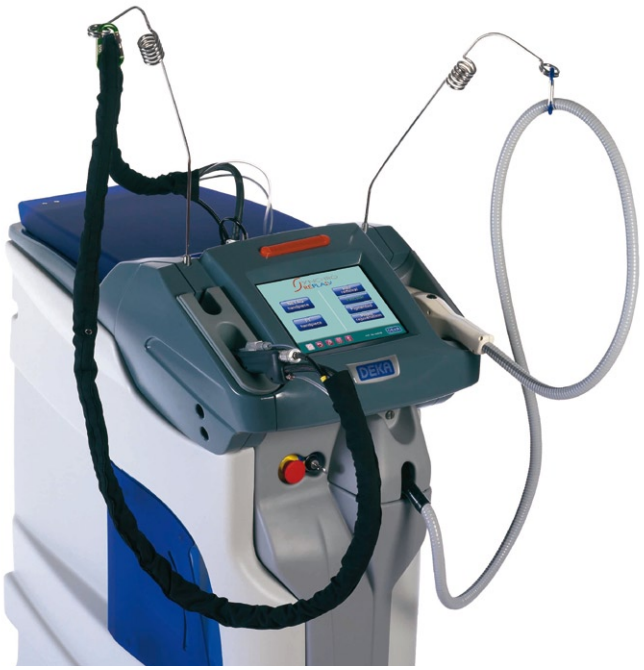

OPERATOR'S MANUAL

SYNCHRO REPLAY

Code: OM104A1-B1-C1-D1-E1_G.V02

S/N:

CE 0459

Date: 11/10/2011

DEKA

The Code of Excellence

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Dichiarazione di Conformità CE
CE Declaration of Conformity

DEKA M.E.L.A. Srl
Via Baldanzese 17
50041 Calenzano (FI)
Italy

certificata in accordo a / *certified according to*

EN ISO 9001 / EN ISO 13485

CERTIFICATI N° 7894 rev 3 e N° 7888 rev 3 emessi a Parigi da LNE/G-MED per le attività di progettazione, produzione, vendita, spedizione e manutenzione dei laser medicali ad uso terapeutico e chirurgico e dispositivi medici a sorgente luminosa, a radio frequenza e ad ultrasuoni.
CERTIFICATE N° 7894 rev 3 and N° 7888 rev 3 issued at Paris by LNE/G-MED for the activities of design, manufacturing, sales, delivery and maintenance of medical lasers with therapeutic and surgical uses and of medical light source devices, radio frequency devices and ultrasound devices.

CERTIFICATO CE N° 7891 rev 4, emesso a Parigi da LNE/G-MED per l'approvazione del Sistema di Assicurazione della Qualità, ALLEGATO II punto 3 della Direttiva 93/42/CEE concernente i dispositivi medici
EC CERTIFICATE N° 7891 rev 4, issued at Paris by LNE/G-MED for the Approval of Quality Assurance System, ANNEX II point 3 of MDD 93/42/EEC concerning Medical Devices

DICHIARA che il seguente dispositivo / *hereby DECLARES that the following device:*

Nome del prodotto / *Product name*

SYNCHRO REPLAY 0.7 SYNCHRO REPLAY 1.0 SYNCHRO REPLAY 1.4
SYNCHRO REPLAY 1.7 SYNCHRO REPLAY 2.4

È conforme ai requisiti dell'Allegato I della Direttiva 93/42/CEE, ed è marcato:
is in conformance with the requirements of the Medical Device Directive 93/42/EEC, Annex I, and it is marked with:

CE 0459

Classe IIb / *Class IIb*

Il Presidente
The President

Calenzano: 17 Giugno 2011, *June 17th,2011*

(Prof. Ing. Leonardo Masotti)

Le norme applicate sono / *Standards applied are*: EN 60601-1; EN 60601-1-2; EN 60601-1-4; EN 60601-1-6; EN 62366; EN 60601-2-22; EN 60825-1; EN 62304; EN ISO 14971; EN ISO 10993-1; EN 980; EN 1041. Qualsiasi modifica al prodotto non autorizzata dal fabbricante rende nulla questa dichiarazione. *Any modification of the product, not authorized by the manufacturer, will invalidate this declaration of conformity.*

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GLOSSARY

The following symbols and abbreviations may be used on the SYNCHRO REPLA:Y system and/or in this manual.

Table 1 - Symbols and abbreviations

CE	Declaration of Conformity to Medical Device Directive 93/42/EEC
	Symbol for "Manufacturer"
	Electrical protection degree
I	Electrical protection type
	Symbol of footswitch connector
	Symbol of interlock connector
	Warning on system discarding (Directive 2002/96/EC)
NOHD	Nominal Ocular Hazard Distance
	Symbol of non ionizing radiation

Table 2 - Units of measurement

J	joule - unit of energy
mJ	millijoule - 1000mJ=1J
nm	nanometer - unit of laser wavelength, 1000000nm=1mm
s	second - unit of time
µs	microsecond - 1000000µs=1s
min	minute - unit of time, 1min=60s
Hz	hertz (cycles per second) - unit of frequency
A	ampere - unit of electrical current
VA	volt ampere - unit of absorbed electrical power
V~	unit of alternating voltage
Pa	pascal - unit of measure of atmospheric pressure

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1. INTRODUCTION

1.1. SYNCHRO REPLA:Y

The SYNCHRO REPLA:Y family is a medical laser family for a full range of the most effective hair removal, vascular and skin rejuvenation treatments.

Five different models are available:

Name	Code	Nd:YAG 1064nm	Alex 755nm	Alex Premium 755nm	IPL FT
SYNCHRO REPLA:Y 0.7	M104A1		X		Opt.
SYNCHRO REPLA:Y 1.0	M104B1	X			Opt.
SYNCHRO REPLA:Y 1.4	M104C1			X	Opt.
SYNCHRO REPLA:Y 1.7	M104D1	X	X		Opt.
SYNCHRO REPLA:Y 2.4	M104E1	X		X	Opt.

Each of these models can be equipped also with an optional pulsed light lamp of FT series, making these systems extremely flexible.

- Alexandrite 755 nm laser is a high power laser developed to effectively perform hair removal and pigmented lesions treatments. The high fluence along with the big spot sizes and repetition rate enables complete removal of hair follicles in any area of human body. The wavelength of 755 nm is the best adapted for hair removal especially for the skin types up to Fitzpatrick Type III due to its high melanin absorption.
- Nd:YAG 1064 nm laser is a high power laser with both Long Pulse and Short Pulse modes for effective treatments of vascular lesions, hair removal on all skin types and skin rejuvenation. The wavelength of 1064 nm is the best adapted to vascular lesions removal due to its high hemoglobin absorption. The 1064 nm wavelength has also good absorption in melanin making the 1064 nm as a solution for hair removal on all skin types. The Short Pulse is suitable for skin rejuvenation.

The optional contact cooling system which is integrated into the laser platform assures the highest rate of treatment safety with almost no presence of side effects.

1.2. About the Manual

The SYNCHRO REPLA:Y Operator's Manual provides operators with the following information about the system:

- Indications for use
- Safety
- System description
- Installation
- Use of the system
- Clinical Application
- Faults and troubleshooting
- Maintenance
- Accessories

Before using the system for the first time, please familiarize yourself with the information and instructions of this manual. This is essential to ensure an effective and optimal use of the system, to avoid damage to people or to the device and to obtain good results of treatment.

In compliance with the standards about usability IEC/EN 62366 and EN 60601-1-6, this manual is the necessary materials for training about the primary operating functions of this equipment.

In this manual we use different colours to highlight warnings:

- warnings on a grey background are remarks for a correct use of the system and of its accessories;
- warnings on a grey background and with a yellow triangle are remarks concerning safety.

Operators must read and follow all the remarks.

NOTE

When the symbol '*' is reported near an option's description, it means that the feature is available only for some SYNCHRO REPLA:Y's models.

CAUTION ***Possible risk for patient/operator***	**Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous light and laser radiation exposure.**

2. INDICATIONS FOR USE

The SYNCHRO REPLA:Y system is a medical device indicated for hair removal, skin rejuvenation and the treatment of vascular and pigmented lesions. In particular the following table contains the indications for the different laser sources:

Wavelength	Indications
755 nm (Alexandrite laser)	• Hair removal (suggested up to Phototype III) • Benign Pigmented Lesions removal
1064 nm (Nd:YAG laser)	• Vascular treatments • Hair removal (suggested on all skin types) • Skin rejuvenation

The following table shows the suggested use of different light filters of the FT pulsed light handpiece, for the indicated treatments and for the different skin types:

FT filter type	Vascular lesions	Pigmented lesions	Hair reduction
500 – 1200 nm	Phototype I, II	--	--
520 – 1200 nm	Phototype III	Phototype I, II,	--
550 – 1200 nm	--	Phototype III	Phototype I, II
600 – 1200 nm	--	Phototype IV	Phototype III
650 – 1200 nm	--	--	Phototype IV

The SYNCHRO REPLA:Y system must not be used for applications different from those specified above.

The SYNCHRO REPLA:Y system must not be used for surgical applications or any applications of an invasive nature.

CAUTION

Possible risk for patient/operator

THE USE OF THE SYNCHRO REPLA:Y SYSTEM IS RESERVED FOR QUALIFIED AND TRAINED MEDICAL PERSONNEL.

DEKA M.E.L.A. s.r.l. is not responsible for the direct or indirect effects arising out of or in connection with, or resulting from the application or use of the system that are not a direct consequence of design or manufacturing defects of the device or parts thereof. The manufacturer shall not be responsible of the success of the treatment.

CAUTION

Possible risk for patient/operator

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3. WARNINGS

This manual is not intended to be a complete guide to the use of the system.
DEKA M.E.L.A. s.r.l. recommends that all users first seek training that includes, but is not limited to, the following aspects of operation:

- Basic Laser/Light Energy Physics
- Laser/Intense Flashlamp Light Safety
- Tissue Interaction
- Operating Procedures
- System Set-Up Procedures
- Potential Hazards

DEKA M.E.L.A. Srl shall not be liable nor responsible of the safety and performance in the following cases:

- if the system is not used in compliance with health and safety rules and regulations in force;
- if the precautions and instructions contained in the present manual are not observed;
- if the system is not used by qualified and trained personnel;
- if the installation, any modification, recalibration or maintenance are not performed by qualified personnel authorised by DEKA M.E.L.A. s.r.l.;
- if the environment in which the system is located and used does not conform with all electrical, laser, etc. safety prescriptions specified by the applicable international and local regulations and international guidelines in force.

DEKA M.E.L.A. s.r.l. reserves the irrevocable right to provide, upon written request, maintenance personnel authorised by the same, with electrical diagrams, components lists, adjustment instructions and any information relating to the parts of the system which are considered to be repairable.

WARNING
Do not modify this equipment without authorization of DEKA M.E.L.A. Srl.

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4. PREMISES

The following instructions must be scrupulously observed.

4.1. Delivery – Inspection of goods received

Unless otherwise agreed between the manufacturer and the customer, the delivery of the goods shall be ex works (INCOTERMS 2000) even if it has been expressly agreed that the transport or part thereof shall be the responsibility of the manufacturer on the customer's behalf.
Upon delivery, all risks inherent to the system shall be transferred to the customer. Therefore, any damage to the system during transport shall be to the customer's account.
It shall be the customer's responsibility to inspect upon delivery and in the presence of the carrier, the integrity and condition of the goods received; to verify correspondence between the goods delivered and those described in the transport documentation; to immediately bring to the carrier's attention any divergence and/or damage noticed.

4.2. Working environment

The environment in which the device is located and operated must be suitable and comply with the relative legal requirements and regulations in force, applicable also to the associated systems, concerning the use and storage thereof in complete safety to persons and objects. The operation, workplace health and safety measures and any other activities shall be the exclusive responsibility of the relevant person(s) in charge and must be performed in compliance with local laws and Regulations and, where applicable, in compliance with European Directives (Council Directive 89/391/EEC and subsequent).

4.3. Responsibilities

The manufacturer shall guarantee the conformity of the product with EC safety and hygiene requirements according to the applicable Directives.
The use of the system shall be the exclusive responsibility of the operator who shall be obliged to apply the necessary and adequate diligence and skills.
The manufacturer shall be responsible in terms of and within the exclusive scope of current regulations applicable to the production and marketing of medical devices.

The manufacturer shall not be responsible for unfavourable consequences resulting from installation, use or maintenance which does not comply with the instructions in the present manual or resulting from failure by the user to apply the care, precautionary measures and safety regulations necessary to avoid such consequences.

4.4. Laser Safety Officer

We recommend prior consultation of the IEC TR 60825-8 Safety of laser products, Part 8: Guidelines for the safe use of laser beams on humans (2006-12, Second edition), which is a guideline on how to apply laser safety in medical practices.
In accordance with Point 3.1 of the abovementioned guidelines, we recommend that a Laser Safety Officer be appointed and a precise definition of the relative responsibilities established.