

EDITING

In this section are reported all the edits to the chapters of the object manual.

N° of Chnge	N° Manual Edition	OBJECT OF CHANGE	DATE
0	0	Release	23/05/2017
1			
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This manual contains the use and maintenance original instructions, it is considered as part and parcel of the machine, it must be read thoroughly before attempting any operations and it must be kept until final disposal.

If the machine is sold the manual must go with it.

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DOCUMENTS ATTACHED

- USER MANUAL FOR 3D SCANNER SOFTWARE
- EC MARKING

1. EC MARKING AND CONFORMITY DECLARATION

1.2. POSITION OF LABEL ON THE MACHINE



Picture 1 Position and EC marking plate

The label with EC marking is on the posterior part of the scanner.

2. CONFORMITY DECLARATION

The "conformity declaration" is found in the attachments of this manual.

3. INTRODUCTION

This manual refers to the 3D scanner and addresses the users, who, before performing any operation, use or maintenance, **must read and acquaint themselves** with the material in the following pages in order to use the machine correctly, avoiding the improper uses listed later on. Before turning the machine on make sure the user is suitable for the job.

The manufacturer refuses any responsibility for consequences deriving from:



- Use or installation not contemplated in this manual,
- Disassembly, modifications or replacement of original parts or components with parts or components of different origin without written agreements with the manufacturer,
- Unsuitable power supply,
- Serious inadequacy of the required maintenance

This manual reflects the technical standing at the time the machine was manufactured and it should not be considered inadequate just because based on new experiences it can be updated. The features and design of this machine may be modified without any notice, for a constant improvement of the product.

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4. NORM REFERENCES

In drafting this document, we have referred to what is reported in attachment I of Law n. 17 of 27/01/2010, implementation of the 2006/42/EC Directive.

In the planning, construction and realization of the machine a set of technical norms has been used as reference to meet the requirements of the laws in force on the subject of safety on the job (see attachment).

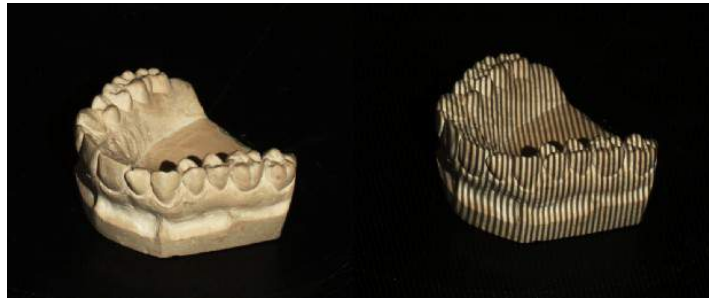
5. PRESENTATION OF THE MACHINE

NeWay is a sophisticated 3D optical scanner for the no contact acquisition of three-dimensional shapes.



Picture 2: NeWay Dental Scanner

The technology it uses is called active stereo vision: structured light patterns are projected on the surface of the object and acquired by two video cameras.



Picture 3

A)

B)

3D optical scan Principle:**A) Original object to acquire****B) projection of light patterns for 3D reconstruction.**

Advanced image processing algorithms retrieve depth data of the acquired surface. This approach guarantees high performances, flexibility and fast execution.

NeWay was specifically created to operate successfully in the dental field. The whole scanning phase is totally computerized and is performed with the aid of a mechanical rotating table that allows the acquisition of different views of the object. Thanks to this system, you can digitize very quickly models, dies, implants, impressions, articulators, waxups and much more.

6. GLOSSARY

The terms used in this manual have the following meanings:

- *3D scanner* – a machine created to acquire 3D images of opaque, solid objects;
- *Bedplate* – lower supporting structure, composed of screwed on steel plates;
- *Rotating clasp* – a support for the objects to be scanned located inside the equipment and having an intermittent, rotating movement.
- *Tilting* – rotating table movement that allows an excursion of 40° in both directions starting from point zero.
- *Optical head* – the component housing the optoelectronic components (2 black and white cameras and a DMD projector) which allow the acquisition of the object surface;
- *Electric motor* – actuator which rotates the rotating table;
- *Electric panel* – power device with a sectioning switch;;
- *Exposed person* – any person within the whole or part of the danger zone;
- *Operator* – people who have to install, operate, adjust, perform maintenance, clean, repair and transport correctly the machine having received all the relative instructions and read this manual.

7. ACCESSORIES

Model Holder

To be inserted in the machine (held with a magnetic lock); it has an adhesive part on which can be fixed a dental model.

Features the engages to adjust the reference rim.

It is included with NeWay Scanners.



Multidie Holder

To be inserted in the machine (held with a magnetic lock); it has nine positions to fit nine dies simultaneously.

Features the engages to adjust the reference rim.

It is included with NeWay Scanners.



Concept Quad Holder

To be inserted in the machine (held with a magnetic lock); it has two adhesive sides to insert the quadrant trays and 4 central positions to insert up to 4 dies at one time.



Generic Articulator Plate

To be inserted in the machine (held with a magnetic lock); it has two different holes to be lifted easily. It has a sponge-like surface to avoid the articulators to slip. Any articulator can be fixed on this plate up to a total height of 25 cm.

It is included with NeWay Scanners.



Articulator split cast

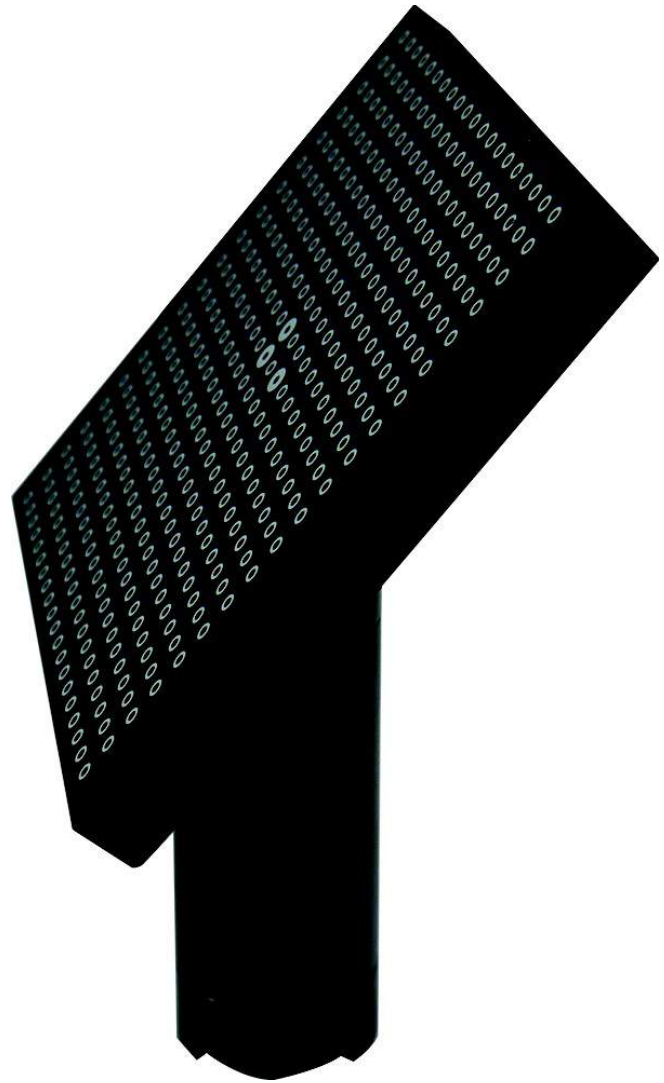
To be inserted in the machine (held with a magnetic lock); 6 different bases are available, one for each dental articulator available in the design software.



Master di Calibrazione

To be inserted in the machine (held with a magnetic lock); it has a plane surface with white dots for calibrating.

It is included with NeWay Scanners.



Reference Rim

Ring to be fit on the model holder and on the multi die support. It fixes to the bases with 3 metallic feet and held with magnets, it gets fixed and removed manually.

It is included with NeWay Scanners.



8. TECHNICAL DATA

General data	Standard of measurement	Value
Width	[mm]	500
Depth	[mm]	610
Height	[mm]	540
Total Weight (empty)	[kg]	18

Electrical Supply	Standard of measurement	Value
Single phase voltage	[V]	230 c.a.
Control voltage	[V]	12 c.c.
Power usage	[W]	70
Mains frequency	[Hz]	50
Max amps	[A]	4,72
Phases		2P+T

9. TRANSPORTATION – STORAGE

The buyer's personnel can install the 3D scanner in the operating area after reading this manual.

As soon as the buyer receives the machine, he will have to check that the components have not suffered any damages during transport, if any are noticed he will have to notify the carrier and the manufacturer immediately.

The scanner is protected by auto-shaping foam cushions and placed in a cardboard box.



When using the machine for the first time special attention must be paid to anything that might seem to have an irregular operation and, if the case, contact Open Technologies S.r.l. immediately, explaining the anomaly noticed. .

1.3. STORAGE CONDITIONS

If the 3D scanner is not installed inside the buyer's premises but it is stored:

- outdoors, suitable covers and precautions must be arranged to protect the components of the machine from weather conditions (rain, snow, fog, humidity etc.). Check periodically for any damages that might take place in the course of time;
- indoors, no special precautions are required but just periodically check that the machine is stored correctly and the environmental conditions below are respected:

TEMPERATURE (-20 ÷ +45)°C

HUMIDITY (5 ÷ 85)%

1.4. MOVING INSTRUCTIONS

Moving can be carried out with the help of trans pallet, trolleys or by hand seen the reduced weight and dimensions.

1.4.1 Lifting

It is advised, for the operator to lift the machine holding it by its opposite sides.



The operator must pay attention when lowering the machine onto a surface to avoid crushing of the upper limbs.

10. INSTALLATION

Before the installation the 3D scanner must be taken out of the cardboard box and freed from the auto-shaping foam cushions. Please keep all this material for the whole guarantee term.



All packing material must be disposed of according to the law in force.

1.5. CLAMPING/ANCHORAGE AND VIBRATION DAMPING INSTRUCTIONS

The 3D scanner supports must rest on a perfectly horizontal flat surface (leveling the machine). The supporting surface must be at a certain height from the ground so that the scanning internal surface is between 800 and 1000 mm.

The supporting surface must guarantee the maximum planarity and be able to bear the weight of the machine and of the scanned objects (total mass 37 kg (daN)).

The scanned pieces are:

- Small plaster elements, representing palate or dental arches impressions;
- Steel “articulator”, dental instrument that simulates jaw movement (2 kg. max weight).

The supporting surface of the 3D scanner must not lodge equipment and machinery that may produce vibrations.

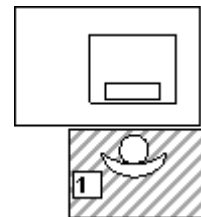


Rest the 3D scanner only on worktops that are stable, resistant and with a surface greater than the base.

1.6. REQUIRED SPACE FOR USE AND MAINTENANCE

The use of the scanner requires the presence of an operator in the following position:

- Front (Picture 4 [1]) to place and remove the objects to scan.
- The adjustments of the working parameters, the start command and processing of the scanned images take place in a video terminal station located nearby.



Picture 4 Work Station

The posts for the maintenance of the machine are:

- Front to clean the work top, bed and outer frame.

Keep at least 100 cm of space around, in all directions, around the machine, in order to be able to perform the cleaning, maintenance and all the necessary adjustments in total safety and with all the space required.



The 3D scanner has an opening on the back to release the internal heat, do not obstruct the openings with curtains, paper or by placing the 3D scanner next to panels, walls and shelves.

1.7. ALLOWED ENVIARONMENT CONDITIONS (TEMPERATURE, HUMIDITY, VIBRATINS, ELECTROMAGNETIC RADIATIONS)

Environment conditions for a correct functioning of the machine are:

- temperature between 0° and +40°C;
- humidity between 20% and 80%.

Where the 3D scanner is installed, the room must be free of dust and suspended aerosol.

Keep the scanner away from heat sources, direct sunlight or radiators.

If the 3D scanner has been in a colder place (outdoors or a warehouse) wait at least two hours before installing the machine in a warmer place – otherwise, condensation can form which compromises the scanner correct operation.

The 3D scanner must operate away from sources that generate a powerful electromagnetic interference (e.g.: electric welders, high frequency devices, high voltage cables). Even though in compliance with all the laws regulating electromagnetic immunity and that Open Technologies have done everything in their power to immunize the unit from electromagnetic interference, the scanner is after all a precision electronic device therefore powerful radio waves may interfere with the scans.

1.8. INSTRUCTIONS FOR CONNECTING THE MACHINE TO THE POWER SUPPLY

Power supply

The 3D scanner will be connected to a power supply with these specifications:

- 1 phase + neutral + ground supply;
- Tensione 100-240 V;
- Frequenza 50-60 Hz;

Moreover, the power line will have to be suitably protected from overloads and short-circuits coming from the mains mounted on the wall. A line will also have to be supplied, with the correct section, to ensure the ground link to the machine.



The sockets to be used for the machine must be able to bear the electrical intensity required during operation.

Command signals

The 3D scanner will have to be connected to an external personal computer in order to receive the start up command signals of the various devices needed for scanning.

The connectors are:

- a USB 3.0 connector.
- an HDMI connector.



Picture 5:

USB 3.0 connector



Picture 6:

HDMI Video connector



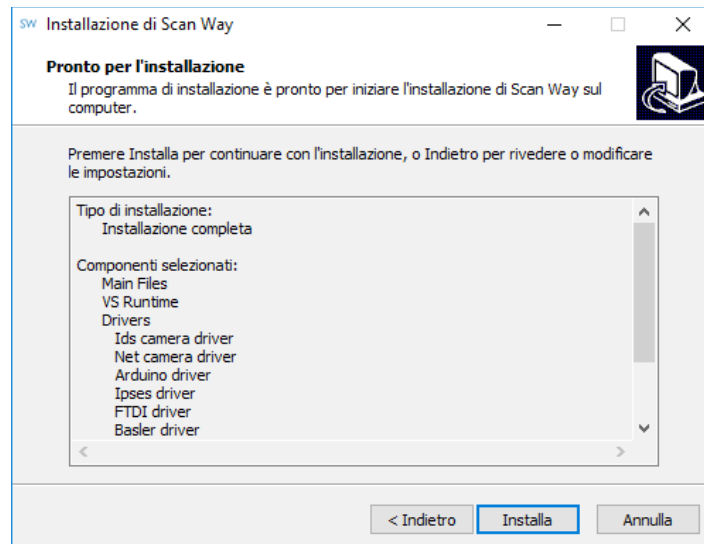
Before connection the scanner to the personal computer, perform the installation of the software and the drivers included.

1.9. SOFTWARE AND DRIVER INSTALLATION PROCEDURE

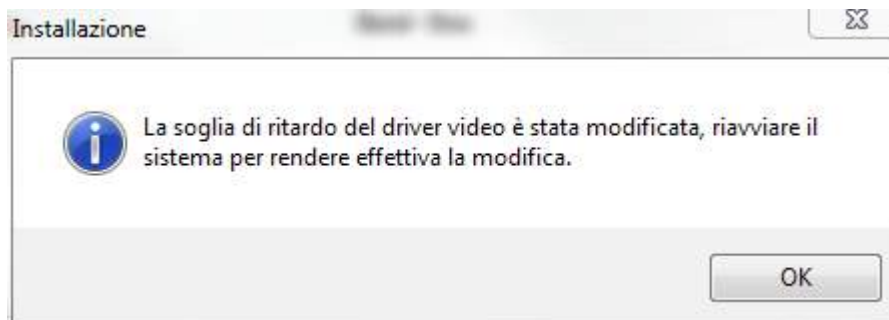
On the internal memory of the scanner is saved the installer for the ScanWay Software. This program installs the operational software for the scanner and the drivers needed for its operation.

To proceed with the installation start the ScanWay installer.

Follow the installation wizard accepting all the steps, mark all drivers for installation and click Install.



At this point the driver installation sequence is enabled (based of the previous selection), which will allow the scanner to run. No particular interaction is needed apart from confirming the different steps.



Upon finishing the installation, a message advises on restarting the system before starting its configuration.

1.9.1 Projector

The HDMI Connector (Picture 6) must be inserted into the personal computer secondary monitor port (Pict. 7b) this is the auxiliary monitor port in laptops or the video port furthest to the right in desktop computers.



Picture 7: b)

If the monitor port is DVI see (Picture 8)



Picture 8:

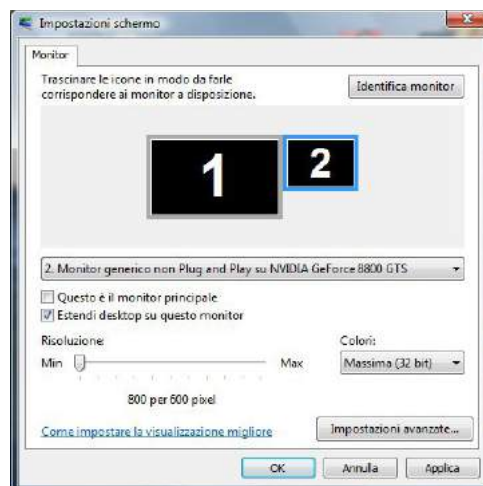
It will be necessary to use a DVI-HDMI connector as shown in Picture 9 :



Picture 9

After inserting the HDMI connector you need to proceed with the secondary monitor setup:

- Open "Screen" in Windows control panel;
- select setup: the "Screen Properties" panel will have to show two monitors as in Picture 10:



Picture 10

If the monitors are not two, it may be necessary to restart the computer so that the the operation system can identify the secondary monitor. If the problem persists, check that the HDMI cable is properly connected to the scanner;

- Monitor "2" must show to the right of monitor "1";

1.10. REMOVAL AND ELIMINATION OF WASTE MATERIAL

The 3D scanner does not produce any waste material.

1.11. USER'S PRECAUTIONARY MEASURES

The user must:

- ➔ Keep all the fixed and moving protections, in their place,
- ➔ Avoid placing any liquids on the external structure or nearby,
- ➔ Avoid moving, removing or modifying manually the rotating clasp;
- ➔ Check the electric switch periodically,
- ➔ Use properly mounted sockets and do not use damaged or worn out cables;
- ➔ Make sure the machine is unplugged before moving it;

- Avoid inserting any metal objects, like clips, metal cables or flammable objects like matches or pieces of paper inside the 3D scanner through the vents;
- Avoid inserting fingers or other body parts or any other object in the rent that allow the movement of the rotating clasp.
- Avoid touching the plug with wet hands;
- Avoid connecting more than one device in just one electric socket;
- Avoid placing heavy objects on the electric cable, bending it, pulling it or twisting it;
- Insert the plug all the way in;
- Connect to the scanner only grounded devices;
- Put back in their place all the danger, warning and requirement signs that might come off.



The manufacturer declines any responsibility arising from accidents caused by the partial or total removal of these protection devices.



DANGER VOLTAGE



**READ THE MANUAL
THOROUGHLY**



11. MACHINE SPECIFICATIONS

1.12. DETAILED DESCRIPTION OF THE MACHINE

The 3D scanner has a solid external structure. All the panels are integral part of the tool and must not be removed or tampered with in any way so not to compromise the correct functioning of the apparatus.

On the back of the scanner there is the port for the electrical connection and the power switch of the machine; another switch is available on the front of the scanner and allows completely switching on the apparatus. In the frontal part of the scanner can be found the scanning area framed by the optical head and the central clasp that allows inserting the accessories described in chapter 7.

The optical head lodges the opto-electronic components for the acquisition of the object surface.

NeWay's Optical Head comprises two video cameras and a DMD projector. The set up of these three components allows one single scanning field.



Any other application not present here has not been contemplated by the manufacturer and, therefore, cannot be performed.

1.13. REPAIRS AND/OR SAFETY DEVICES DESCRIPTION




The 3D scanner is fitted with external metal panels, which keep electrical parts (feeders) out of reach.

The electrical motor for the rotating table and the projector work on low voltage (12V).



The manufacturer declines any responsibility arising from accidents deriving from partial or total removal of the protective panels.

1.14. UNAUTHORIZED USES OF THE MACHINE

	Using the 3D scanner with damaged wires or plugs
	Using the 3D scanner with open or removed panels
	Do not expose the 3D scanner to the rain nor place it in places where water is present (bathtub, basin, sink or washtub, wet floor, near a swimming pool or any similar situations).

1.15. INDICATIONS ON NOISE EMISSIONS

The noise the machine produces, intended as the level of sound pressure in the workplace, is <80 dB (A).

1.16. INDICATIONS ON VIBRATIONS, RADIATIONS AND FINE PARTICLES EMITTED BY THE MACHINE

The unit does not emit any vibrations, fine particles or radiation when operating.

1.17. INDICATIONS ON GASSES AND FUMES EMITTED BY THE MACHINE

The unit does not emit any gasses and fumes when operating.

1.18. ELECTRIC SYSTEM INFORMATION

See electrical diagram attached.

12. OPERATION

1.19. LOADING

The loading operation of the objects to scan includes:

- Placing the objects inside the 3D scanner laying them carefully on the chosen model holder and attaching said support to the magnetic clasp at the base of the scanning area.
- Make sure the object is correctly placed in the 120X100mm scanning area. The scanning area is at a height of 90mm from the scanner's opening base. The model holders and provided supports are designed to grant a correct positioning of the objects in said area. Take particular care in using the correct accessory for any type of object.
- Scanning operations start using the management software- ScanWay.



Picture 11: Clasp and Model Holder



Do not place objects heavier than 2Kg on the model holders attached to the clasp.



The scanner does not work with transparent, light reflecting objects and with black objects.

1.20. CONTROLS DESCRIPTION

Concerning the commands and actions available in the 3DScanning manager software, please read the Software manual attached to this User Manual.

1.21. UNLOADING THE OBJECT

The unloading operation of the object includes:

- Removing the Reference rim, if present;
- Extraction of the used accessory;
- Removing the scanned object from the used accessory.

If the Articulator plate is used:

- Removing the scanned articulator;
- Removing the scanning plate.

1.22. STOPPING MEASURES

Stop the machine by:

- pushing the front button;
- switching off with the back main switch.

During maintenance operations, it is advisable, for safety purposes, to unplug the machine as well as switching it off.

1.23. UNAUTHORIZED USES






<u>IT IS FORBIDDEN:</u>	
	To operate the 3D scanner if the safety devices supplied with the installation are not present or working.
	To use the machine outdoors in the rain.
	To modify or tamper with the machine.
	To clean during scanning.
	To carry out ordinary maintenance without unplugging the machine.

Table 1 Unauthorized uses


1.24. INSTRUCTIONS FOR THE IDENTIFICATION AND LOCALIZATION OF MALFUNCTIONS DAMAGE AND RE-INSTALLATION AFTER REPAIR

Tabella 2 Trouble Shooting

MALFUNCTION	CAUSE	SOLUTION
The scanner does not start	No power.	Check cable connections.
	The machine is off.	Make sure the switch on the back is lit and that the scanner is on.
No image reception on the personal computer.	Video cable not connected correctly.	Make sure the video connection cable (HDMI) is properly connected to the right port on the 3D scanner and on the personal computer.
	USB cables incorrectly connected.	Make sure the USB connection cables are both properly connected to the ports on the 3D scanner and on the personal computer.
	Damaged video cable.	Replace the video connection cable (HDMI). ⁽¹⁾
Noise	Worn electromotor	Repair or replace ⁽¹⁾
	Projector out of order	Check the projector ⁽¹⁾
Electrocution when touching the metal structure of the machine.	Damaged, worn cables in contact with the metal parts.	Check the wiring of the electric supply ⁽¹⁾
The motor does not turn	Cable incorrectly connected.	Check the white USB cable connections.
	Feeder out of order.	Check feeder ⁽¹⁾
	Feeder cable breaking.	Replace cable ⁽¹⁾

1.25. INSTRUCTIONS ON THE USE OF PERSONAL PROTECTION DEVICES

The personal protection means to use are:

<ul style="list-style-type: none"> – Split leather gloves for lifting and moving. 	
--	---

Please remember that the individual protection device (IPD) the operators use must have EC marking and reference to the UNI law.

1.26. INSTRUCTIONS ON REQUIRED TRAINING

Scanning must be performed by personnel that have received specific training for the correct operation of this machine.

The training of the operators should, at least, cover the following topics:

- Operation and general knowledge of the mechanical, electric, electronic parts;
- Information on manual handling;
- information on commands (scanning software);
- Information on safety provisions, specific risks, the use of command devices, forbidden behavior, advisable behavior, etc;

¹⁾ Contact Open Technologies S.r.l.

- Maintenance and inspection;

Besides this training, which conveys all the basic elements necessary to work safely, the so-called hands on training or collaboration is just as important. It is not sufficient to know the machine from a theoretical point of view, but it is necessary to operate it next to experienced personnel able to supply all the practical notions coming from experience and contingent situations they come across. Only after a complete course you can have a worker able to operate in total safety.



At delivery, Open Technologies S.r.l. qualified personnel will train the customer, this is formalized, with signing the training report.

13. MAINTENANCE

Any maintenance intervention performed on the 3D scanner can take place only after the machine has been unplugged, and a warning sign “WORK IN PROGRESS NO MANEUVERING” should be affixed.



1. NATURE AND FREQUENCY OF INSPECTIONS

The 3D scanner routine maintenance should include an idling trial operation in order to identify abnormal noises operation irregularities etc.,

It is necessary to keep a register (see Maintenance Register included at the end of this manual) to note down all the maintenance operations and the relative comments.

The name of the service man and the date the operation was carried out must also be clearly identifiable.

If some components need to be replaced, only original parts or parts approved by the manufacturer must be used.

The use of non-original parts will not only void the guarantee, but can also compromise the correct operation of the machine.



Maintenance interventions must be carried out by Open Technologies S.r.l. personnel or by authorized qualified technicians, under the manufacturer’s written authorization, otherwise the warranty will decay immediately.



At delivery the Open Technologies S.r.l. qualified personnel or authorized resellers will train the customer, this is all formalized with the signing of the training report.

Tabella 3 maintenance checks of the components

Tasks	Size and check Materials used	d ²	w	m	3 m	6 m	12 m	18 m	24 m
Clean the exterior of the 3D scanner	Use a soft, dry cloth	1							Do not clean with inflammable substances such as benzene, thinners or wet cloths.
External connection cable	Check that the external connection cable is intact: no cracks or cuts in the insulating tape.			X					If there are cracks or cuts replace the cable immediately with a new one or one made by a qualified electrician.
Test power switch	Operating the switch you check that there is no power	1							
Check external connectors (USB, HDMI).	Make sure the connectors are intact.		1						If the connectors are damaged they must be replaced immediately with new ones by a qualified technician.
Overall inspection of the conditions of the electrical system.						X			Refer to Open Technologies S.r.l. customer service or to a qualified technician.

1.27. INSTRUCTION RELATIVE TO THE INTERVENTIONS PERFORMED EXCLUSIVELY BY QUALIFIED PEOPLE (MAINTENANCE PERSONNEL, SPECIALISTS)

All electric interventions will have to be performed by a technician authorized by Open Technologies S.r.l.

1.27.1 Electric system

Check the switch is in working order, check for contact wear and tear and, if necessary, replace any. Periodically check that the voltage is correct, in order to avoid malfunctions or break downs.

1.27.2 Terminals

Just a periodical check to make sure the terminals are fastened properly, also, make sure the number on the wire can be read and matches the terminal it is fixed to. Make sure the terminals are not damaged, if so, replace it.

1.27.3 Electric Motor

Clean the electric motor by removing the dust on the frame, which could impair cooling, also make sure the vents are not clogged.

Check, while the motor is running, the loudness and the presence of any slack in the supports.

Contact Open Technologies S.r.l. in case of any minimum slack and/or marked noise.

Check current absorption and voltage, matching them with those indicated on the tag.

² d=days, w=weeks, m=months.

1.27.4 Projector

Contact Open Technologies S.r.l. customer assistance for any anomaly the projector might show.

1.27.5 Adjustment of the machine

In the case of anomalies during image acquisition, you might have to have the machine adjusted, contact Open Technologies S.r.l. customer service.

14. EMERGENCY SITUATIONS

1.28. FIRE-FIGHTING EQUIPMENT

The parts of the machine, which can catch fire, are the electric components (electromotor, projector, cables, feeders). In all these cases, the best extinguisher is carbon dioxide (CO₂) or the ABC powder, keeping in mind that by using the ABC powder you can permanently damage the electric and electronic components. Using water is forbidden and it is only allowed when the electricity has been turned off in the whole building.



Using water to extinguish fires is forbidden and it is possible only with the electricity turned off.

1.29. HARMFUL EMISSIONS/ DISPERSION WARNINGS

The only harmful emissions are produced:

- from the production of toxic fumes in case of a fire.

15. DECOMMISSIONING

1.30. ORDINARY

At the end of the work activity, the operator will:

- remove the objects attached to the clasp
- press the electric switch to turn off the machine.

1.31. SCRAPPING DISPOSAL

During scrapping, separate the machine parts according to their material: steel, plastic, electric (cables, connectors) electronic.

Scrapping operations must start with the disassembly of the components (electromotor, feeders, video cameras, electronic card drivers) and then remove the metal panels.

16. RESIDUAL RISKS RELATED TO THE MACHINE

Risks	Dangerous area	Dangerous situation	Dealing with residual risks	Risks
Usage			Description	
Mechanical hazards caused by:				
Crushing	Low rim of the machine	Transport and moving. Normal use expected.	Placing the equipment on the work surface.	Warnings are in the instruction manual.
Electrical hazards				
People coming in contact with live elements (direct electric contact).	Electric cables, external structure of the machine.	Installation, adjustment, calibration. Normal use expected. Testing, maintenance, cleaning..	Cable breakage.	Warnings are inside the instruction manual.
People coming in contact with elements that become live in case of fault (Indirect electric contact).	Metal structure of the apparatus.	Normal expected. Adjustment and calibration.	Wattage cable breakage.	Test periodically that the grounding system is efficient and in compliance with the regulatory guidelines. Test periodically the efficiency of the safety switches on the external power panel.
Thermal hazards				
Burns caused by flames or explosions and by heat radiation.	Internal video -.projector	Normal use expected. Cleaning	Internal back light lamp.	Follow the indications in the instruction manual.
Radiation hazards				
Infrared rays, visible light and ultraviolet.	Internal scanning area.	Normal use expected.	The video projector generates a beam of high intensity.	Follow the indications in the instruction manual.
Hazards deriving from power faults or breakage of parts.				
Restoring power after an interruption.	Electric Circuit.	Normal use expected, unusual foreseeable.	Accidental starting.	Unauthorized use instructions in the instruction manual.
External influences on the electric devices,	Electric Circuit	Normal use expected,	Environment conditions.	Use limitation instructions in the instruction manual.
Loss of stability/ toppling over of the machine	Area around the apparatus.	Normal use expected, set up.	The collapse of the apparatus supporting structure during its positioning.	Instructions in the instruction manual.

17. ALLEGATO A



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DICHIARAZIONE DI CONFORMITA' CE

(DIRETTIVA 2006/42/CE D. Lgs 17/2010 ALLEGATO II, part A)

Produttore: **Open Technologies S.r.l.**

VAT ID: IT03598170177

Indirizzo: Via G. Matteotti n. 161-163a 25086 Rezzato (BS)

SI DICHIARA CHE

il prodotto denominato: **NeWay dental scanner**
 modello: **NeWay**
 Numero di serie: **da OPTREV-N-0100 a OPTREV-N-1500**
 anno: **2017**

Soddisfa le seguenti condizioni:

- Direttiva macchine (Direttiva 2006/42/CE), and Legislazione nazionale (D.Lgs. 17/2010);
- Direttiva bassa tensione (Direttiva 2006/95/CE),
- Compatibilità elettromagnetica (Direttiva 2004/108/CE)
- Direttiva ROHS 2011/65/EU

si dichiara inoltre che sono state applicate le seguenti (parti/clausole di) norme armonizzate:

- UNI EN ISO 12100-1 "Sicurezza del macchinario — Concetti fondamentali, principi generali di progettazione — Parte 1: Terminologia di base, metodologia (ISO 12100-1:2003)"
- UNI EN ISO 12100-2 "Sicurezza del macchinario — Concetti fondamentali, principi generali di progettazione — Parte 2: Principi tecnici (ISO 12100-2:2003)".
- UNI EN ISO 14121-1:2007, "Sicurezza del macchinario - Valutazione del rischio - Parte 1: Principi".
- CEI EN 60204-1 "Equipaggiamento elettrico delle macchine"

La persona autorizzata a costituire il fascicolo tecnico è il dott. ing. Gabriele Zanetti.

Rezzato, li 07/06/17

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Mr. Matteo Carocci.....(Sign)⁽¹⁾

¹ Nome completo e identificazione (in stampatello) della persona con facoltà di firma (delega notarile) in nome del produttore