Owandy RADIOLOGY

EN • PRODUCT LAUNCH DOCUMENT

REV04, December 2018

I-MAX 3D

3D/2D WALL MOUNTED UNIT

INDEX

1. PRODUCT IDENTITY AND POSITIONNING

Key points	Unit design
3D Cone Beam Lightest on market Wall mounted concept NEW ! Multi-FOV: 12x10*, 9x9 to 5x5 cm 16 3D programs HD : 87 µm Face to face positioning 3D digital models The best Investment/Performance ratio NEW ! Face Scan Ready	

* *F.O.V 12x10cm in option (P/N EXTVOL3D12x10)*

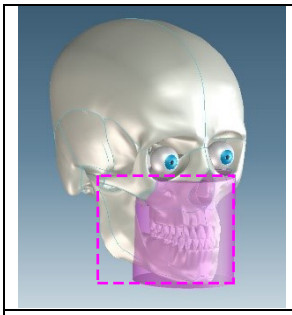
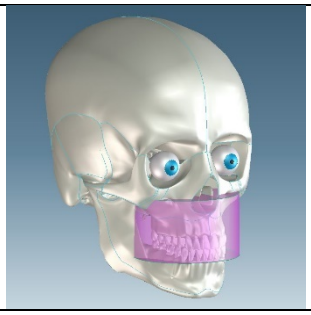
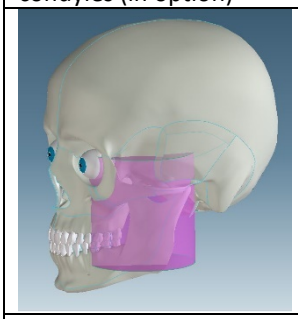
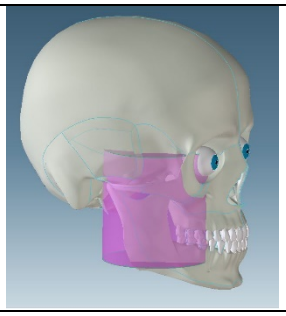
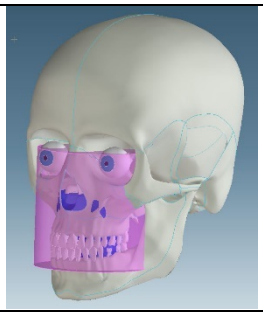
Main competitors advantages	

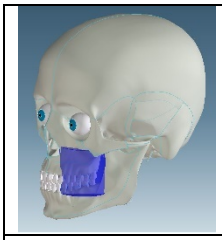
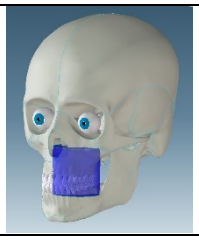
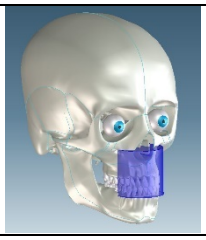
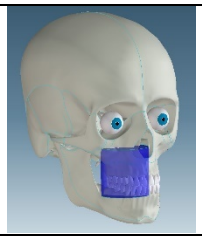
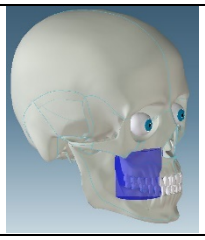
1. Multi FOV 3D Cone Beam	• Can be adapted for use with all kinds of dental practices
	• Implantology:
	  – 116x102 mm full mouth and condyles (in option)
	  – 86x93mm full mouth
	  – 86x50mm full arch
	• Endodontic: 50x50mm

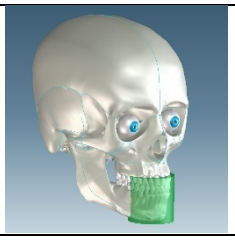
2. HD images	• 3D sensor resolution : voxel 87.5 µm (smallest cross-section)
3. 16 3D programs	• Full dental volume & condyles (in option) • Full dental volume • Left / right TMJ • Sinus • Maxillary volume / Mandibular volume • Frontal maxillary teeth • Left / right premolar maxillary teeth • Left / right molar maxillaryt eeth • Frontal mandibular teeth • Left / right premolar mandibular teeth • Left / right molar mandibular teeth
4. Lightweight and sophisticated design	• The lightest 3D panoramic unit on the market: 66,5kg • Install it on a wall as your intraoral generator • Takes up zero floor space • Stylish: makes surgery look good to patients
5. Easy to use	• “Face-to-face” patient positioning • Easy to handle equipment • Intuitive user interface • Imaging tools and enhancing filters automatically integrated into the control software.
6. Quick and easy to install in your surgery	• Lightweight and compact unit delivered as one single package • Exclusive “Easy-To-Install” system: the unit is delivered fully assembled with an “intelligent” system, requiring just one technician to fix it easily to the wall
7. Controlled budget	• Unit optimised for manufacturing • Lower installation costs, economical shipping costs • The best Investment / Performance ratio
8. Face Scan ready * ** OBJ or .PLY file must come from a third-party device*	• Communication with patients facilitated: he will project himself more easily, to accept the suggested treatment plan • Increases confidence in your expertise and know-how • Import .OBJ and .PLY files
9. CAD / CAM ready	• Scan of 3D models: impression trays, plaster models and radiological guides • Impot / export STL files

10.Surgical guides	• Superposition of STL and DICOM files • Thanks to the I-Max 3D / Quickvision 3D couple, you can create surgical guides in total autonomy

FOCUS : 16 multi FOV 3D programmes:

			
116x102 mm (Ø x H) Full dental volume & condyles (in option)	86 x 93 mm (Ø x H) Full dental exam	86 x 50 mm (Ø x H) Maxillary	86 x 50 mm (Ø x H) Mandibular
			
86 x 93 mm (Ø x H) Left TMJ	86 x 93 mm (Ø x H) Right TMJ	86 x 93 mm (Ø x H) Sinus	

				
Maxillary left molars	Maxillary left premolars	Maxillary frontal	Maxillary right premolars	Maxillary right molars
50 x 50 mm (Ø x H)				

				
Mandibulary left molars	Mandibulary left premolars	Mandibulary frontal	Mandibulary right premolars	Mandibulary right molars
50 x 50 mm (Ø x H)				

2. TECHNICAL CHARACTERISTICS

General features		
Manufacturer	**OWANDY RADIOLOGY** **77183 Croissy-Beaubourg, France**	
Class	Class II-b for European Directive for Medical Devices 93/42 Class I with type B applied parts according to IEC 60601-1 Class II for Canadian MDR Class II according to 21CFR-subchapter J (for 110-120V version)	
Protection degree	IPX0 standard device	
Line frequency	50/60Hz	
Maximum line current	14.5 A @ 115 V~	50/60 Hz
Power consumption	1.5 kVA @ 115 V~ 50/60 Hz 1.3 kVA @ 230 V~ 50/60 Hz	
Line apparent resistance	0.4 Ω max (99 – 132 V)	0.5 Ω max (198 – 264 V)
Line voltage regulation	--	< 3% à 99 V ~
Rated output voltage (kVp)	60 ÷ 86 kV, with 2 kV steps	
Anodic current	2 ÷ 12.5 mA, according to r20 scale	
Mechanical characteristics		
Focal spot to image receptor distance	52 cm (20.5")	
Telescopic motorized column run	66 cm (26")	
Maximum total height	219 cm (86")	
Weight (complete unit, wall mounted version)	67 kg	
Weight of optional unit support	6 kg	
Working conditions		
Minimum room size	120x115cm (47.2"x45.2")	
Recommended room size	160x150cm (63"x59")	
Unit footprint dimensions (mm)	***1107(wall side) x 953mm = 1m²***	
Maximum working temperature range	+ 10° ÷ + 35°	
Relative working humidity (RH) range	30% ÷ 75%	
Temperature range for transport and storing	- 20° ÷ + 70°	
Humidity range for transport and storing	< 95% without condensation	
Minimum atmospheric pressure for transport and storing	630 hPa	

3. SENSORS AND XRAY GENERATOR CHARACTERISTICS

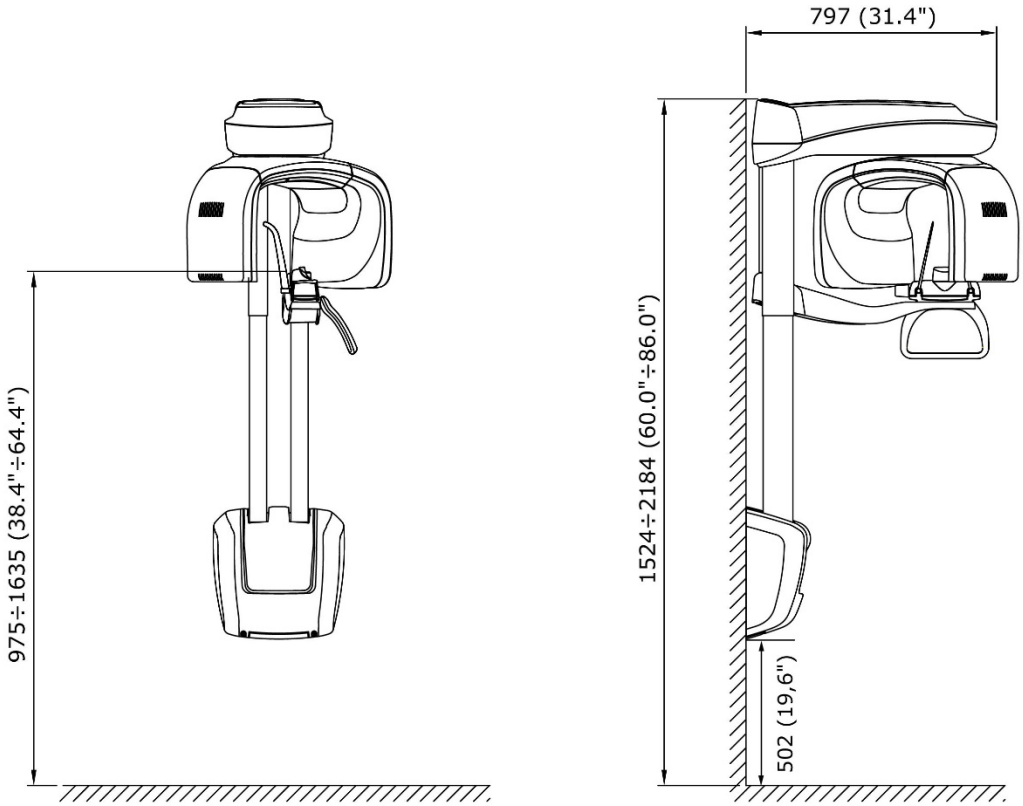
Tube-head features		
Model	MPV 05	
Manufacturer	Owandy Radiology	
Maximum tube voltage with accuracy	86 kV ± 8 %	
Maximum anodic current with accuracy	12.5 mA ± 10 %	
Duty cycle	1:16	
Nominal power	1.075 kW (86 kVp - 12.5 mA)	
Total filtration	≥ 2.5 mm Al eq. @ 86 kVp	
HVL (Half value layer)	> 3.2 mm Al eq. @ 86 kV_p	
Transformer insulation	Oil bath	
Cooling	By convection	
Leakage radiation at 1 m	< 0.5 mGy/h @ 86 kVp - 12.5 mA - 3s duty cycle 1/16	
Tube-head features		
Manufacturer	CEI	
Type	OPX 105-12	
Nominal focal spot size	0.5 mm EN 60336	
Inherent filtration	0.5 mm Al eq.	
Anode tilt	12°	
Anode material	Tungsten	
Nominal maximum voltage	110 kVp	
Filament max current	4 A	
Filament max voltage	6.7 V	
Anode thermal capacity	30 KJ	
Digital Sensor features		
Sensible area (H x L)	CMOS sensor 144 x 118.6 mm	
Voxel	87.5 µm (XD mode)	175µm (HD mode)
Pixel (H)	120 µm	240 µm (2x2 binning)
Laser centering devices		
2 laser beams are used for patient positioning. Beams align mid Sagittal and Frankfurt planes. Class 2 laser product according to IEC Standard 60825-1:2007.		
Wave length	650 nm	
Divergence	< 2.0 mRad	
Optical power on the working surface	< 1 mW	

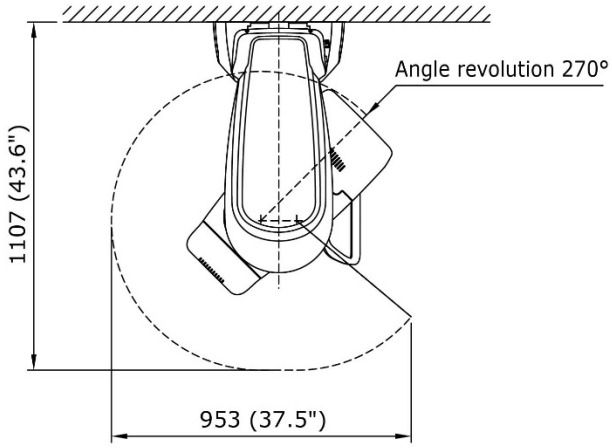
4. COMPUTER CHARACTERISTICS

Recommended configuration	
Operating system	Windows 10 - 64 bits
Processor	Core i7 (4 coeurs 8 threads) 3 GHz or higher
Memory	8 Go
Graphic board	nVidia 4 Go (ex : GTX 9 Go)
Main drive	SSD or SATA
Speed network connection practice	1 Gbit
Other	Slot for Ethernet 1 Gbit board (PCI-Express 4X minimum)

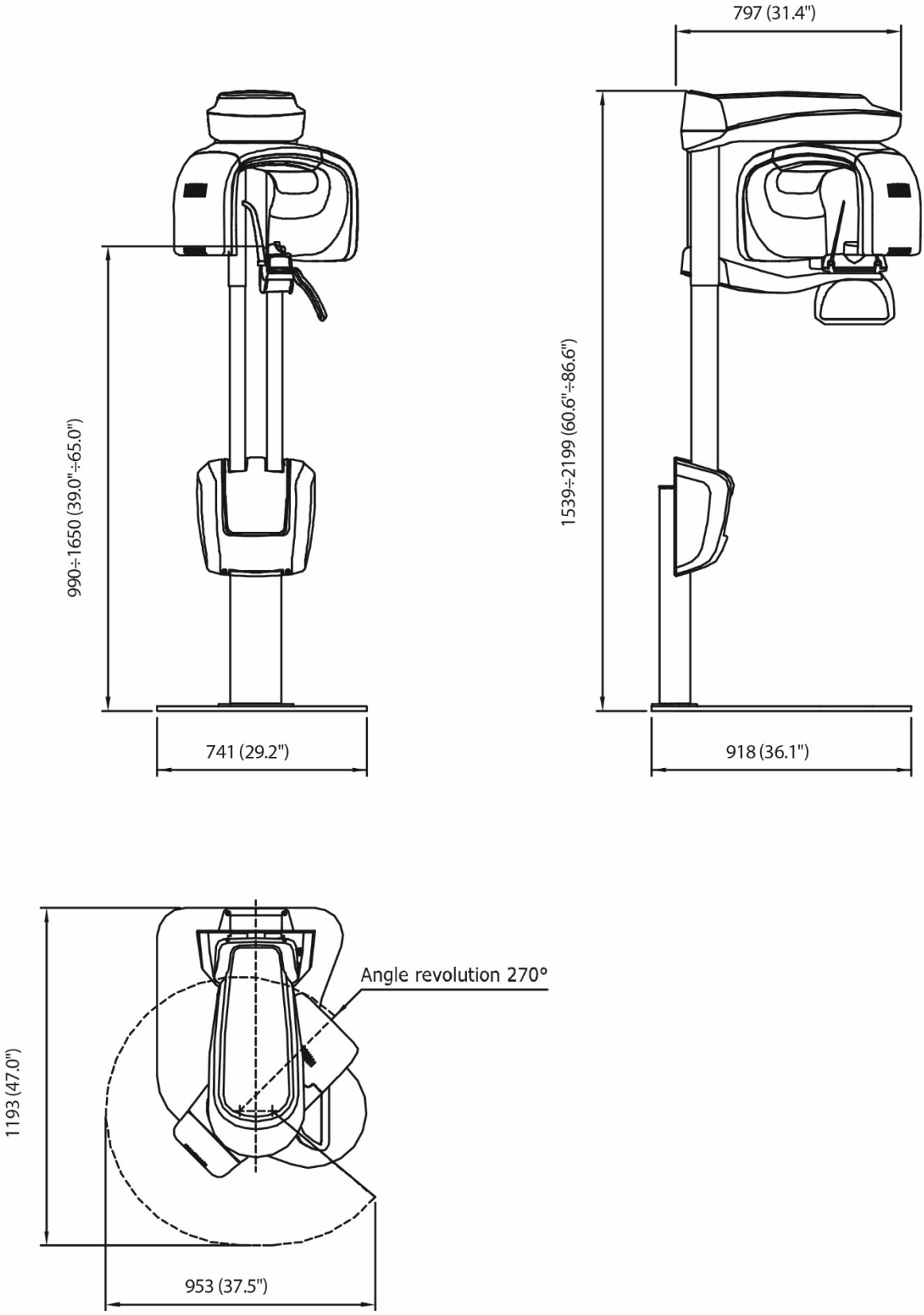
5. UNIT DIMENSIONS

Wall mounted version





Floor mounted version



6. 2D EXAMINATION MODES

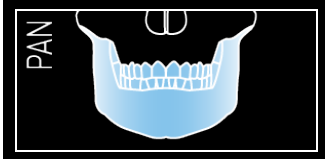
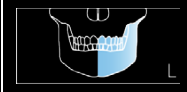
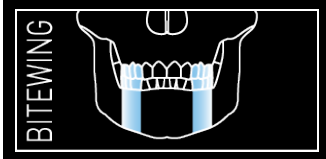
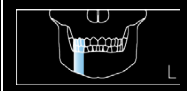
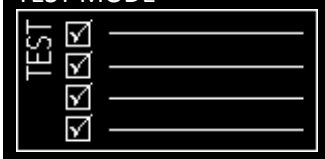
Exposure time	
Panoramic exam (PAN)	14 s Adult / 12.8 s Child
Emi-panoramic exam	7.7 s Adult / 7.1 s Child
Improved orthogonality panoramic exam	11.5 s Adult / Child
Reduced dose panoramic exam	11.6 s Adult / 10.4 s Child
Frontal dentition	4.1 s Adult / Child
Bitewing R, Bitewing L	3.1 s Adult / Child
Bitewing R&L	6.2 s Adult / Child
TMJ mouth closed/open	10.6 s per image for left and right joint in open and closed condition
TMJ single phase	5.3 s
Sinus P/A projection	9 s

Image magnification	**Geometric magnification**	**Magnification after software correction**
Adult / Child standard Panoramic	1 : 1.28 (constant over dentition part)	1 : 1 (*)
TMJ open/closed mouth	1 : 1.25 (nominal)	1 : 1 (*)
Sinus	1 : 1.27 (nominal)	1 : 1 (*)

Programs	
Examination selection type	• Automatic selection for Adult and Child, 3 Sizes • Manual selection also possible for each programs • Collimator with automatic positioning

(*) The declared image magnification value is valid after proper software calibration.

2D programs

PANORAMIC Programs range 	 Standard Panoramic  Low dose Panoramic  Half Panoramic Left  Half Panoramic Right  Frontal dentition Panoramic  Improve dentition Panoramic
BITEWING Programs range 	 Bilateral Bitewing  Bitewing Left  Bitewing Right
SINUS program 	Sinus Standard
TMJ (Temporal Mandibular Joint) Programs range 	 Standard TMJ  Single TMJ
TEST MODE 	 Test mode for 2D

7. 3D EXAMINATION MODES

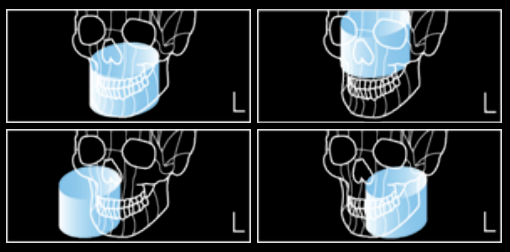
Exposure time	
3D exams (except TMJ 3D)	7 s
TMJ 3D	6.2 s
Exposure time accuracy	± 5% or ± 20ms whichever is greater

3D programs

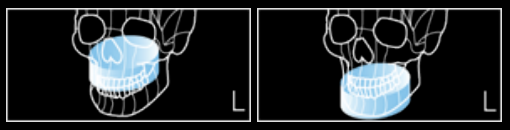
3D
Progracmes range

Full volume: 12x10 cm

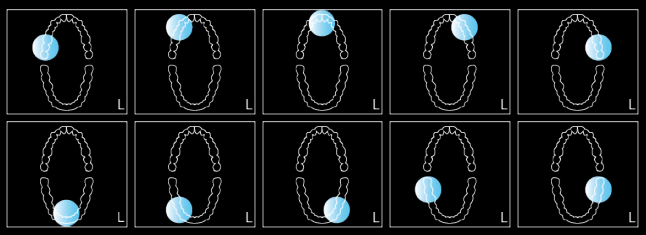
Full volume: 9x9 cm



Half volume : 9x5 cm

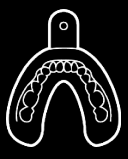


Small volume: 5x5 cm



Scan of 3D models

radiological guides



impression trays

plasters models

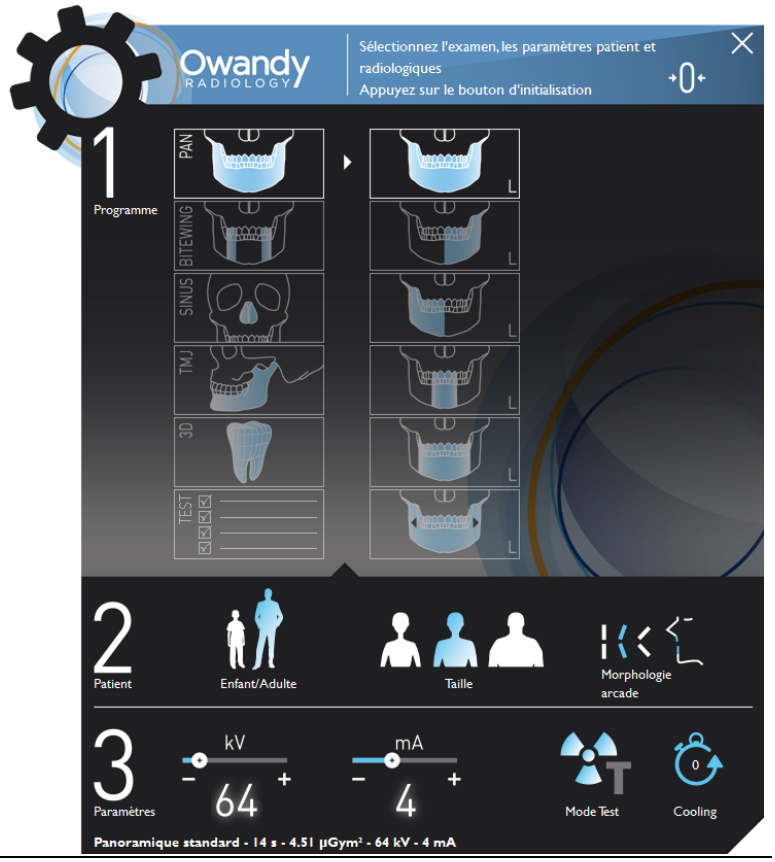
TEST MODE

Test mode for 3D

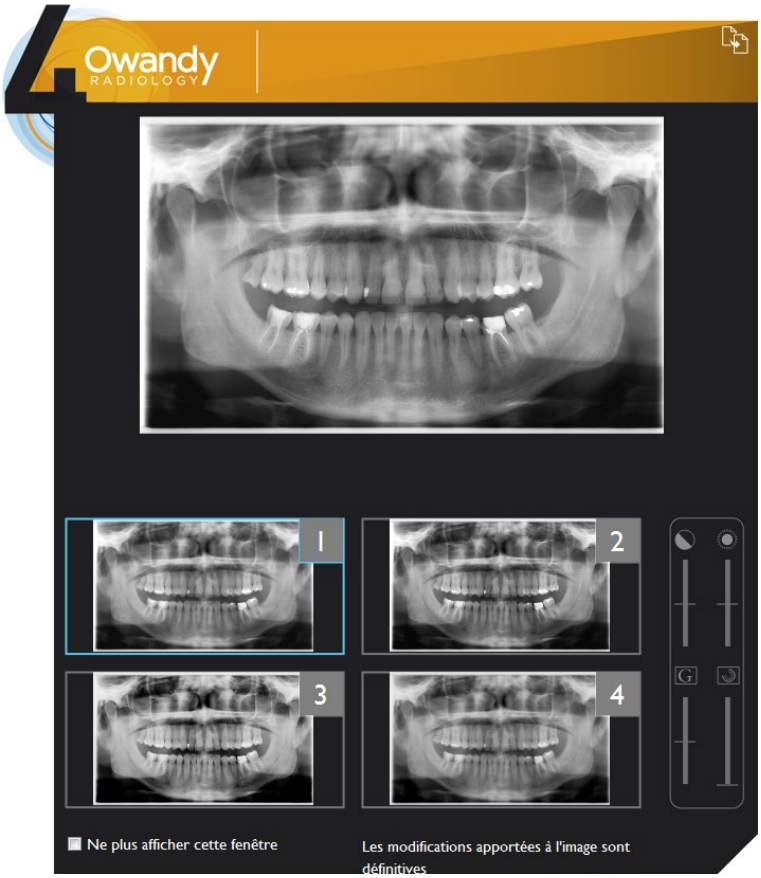
8. USER SOFTWARE INTERFACE

▶ Main settings window: default exam selected automatically..

▶ Main window with complete program selection menu, in extended view.

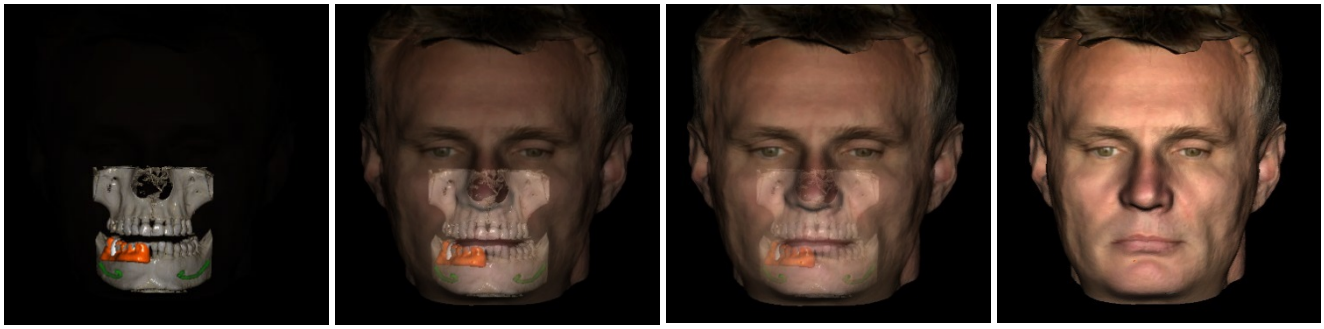


▶ Main window with the image live preview



9. QUICKVISION 3D / FACE SCAN

The purpose of Face Scan is to facilitate communication with patients.
To do this, simply import a .PLY or .OBJ file, acquired using a third-party device, into the QuickVision 3D software and associate a 3D volume.

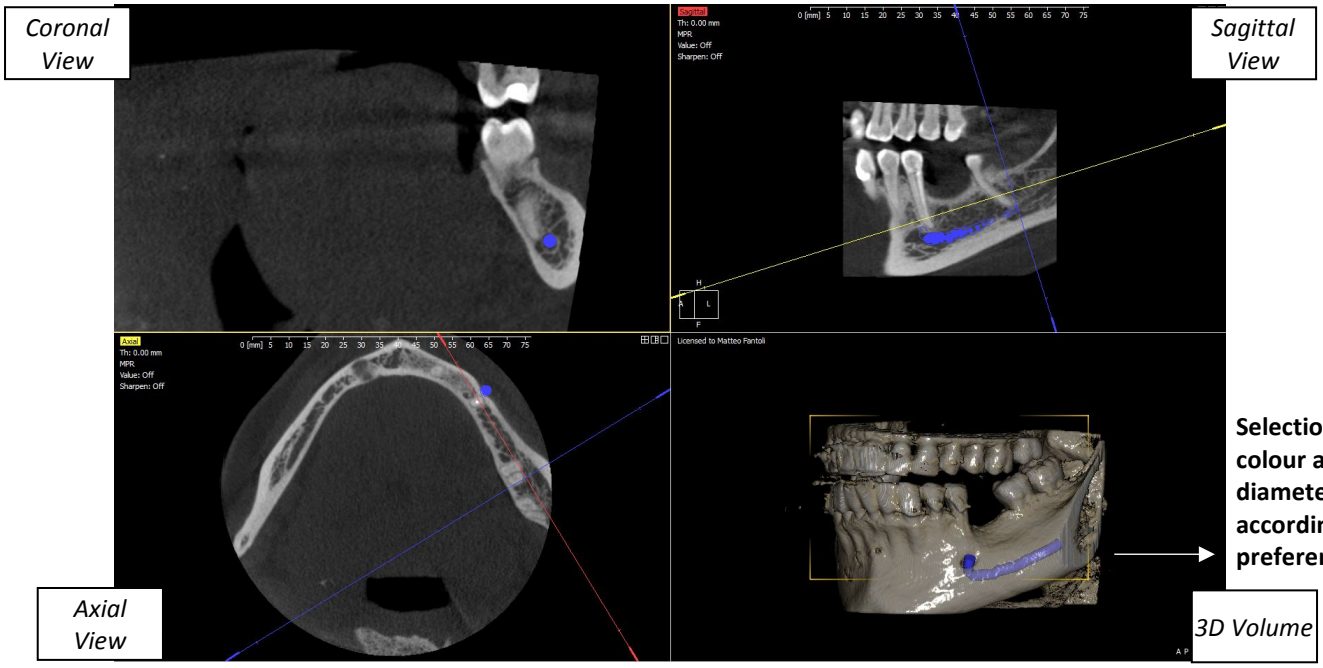


QuickVision 3D allows you to change densities to highlight bone structures and/or soft tissue.

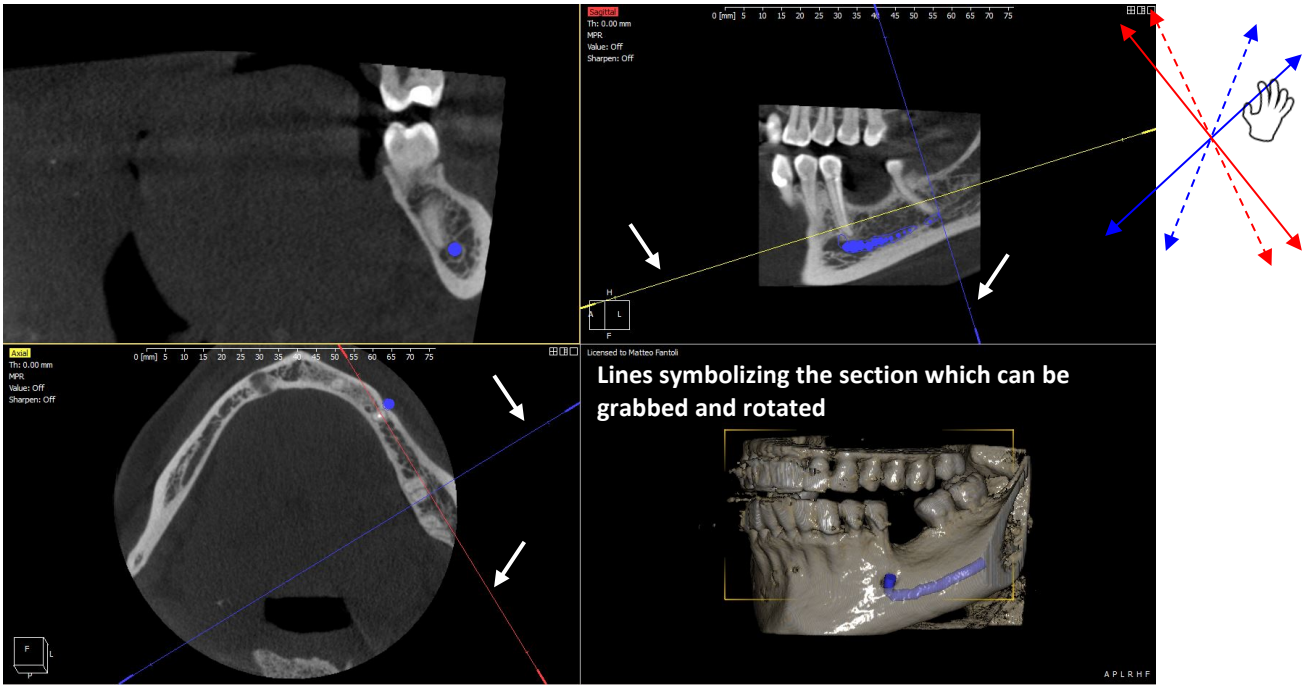
10. QUICKVISION 3D

DICOM VIEWER

Independent rotation of the various axes in each of the 4 screens, to display the area required.
Identifies the nerve and selects the right size and shape of implant.

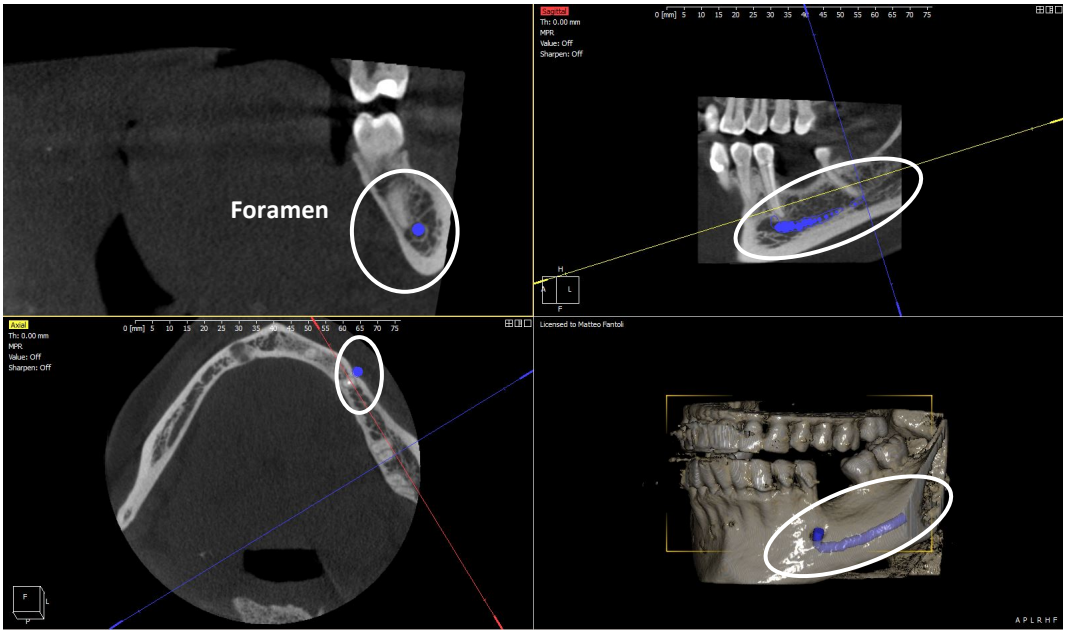


Sectioning plans automatically default to coplanar views with the global system (axial, sagittal and coronal)
Sectioning plan angles can be adjusted by entering the line relating to the section. Because these plans can be rotated, it's easy to analyse cross-sections from any position.
The original view can be restored by using the re-set command.

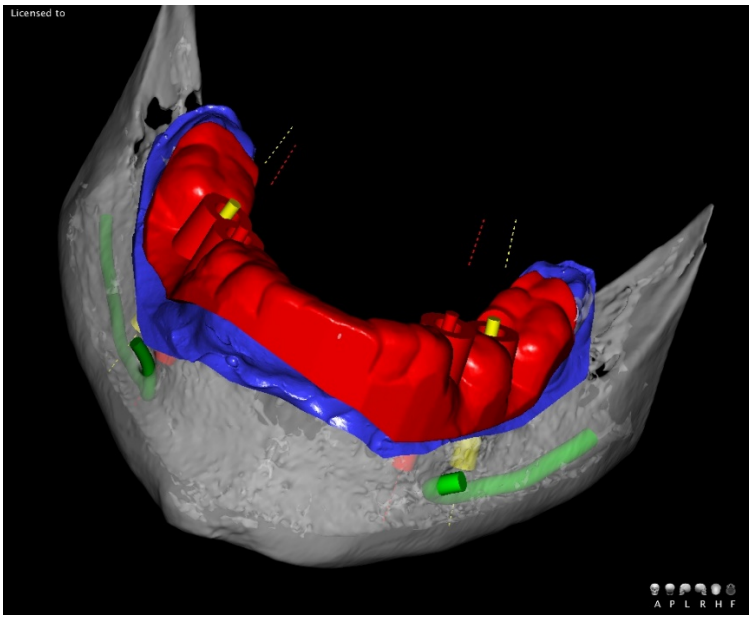


The mandibular nerve can be drawn in, to avoid touching it during the operation. 3 stages to obtain the mandibular nerve:

- Sectioning plan positioning so as to highlight foramina
- Selecting the point to highlight the section of the canal for various cross-sections
- Confirming operation

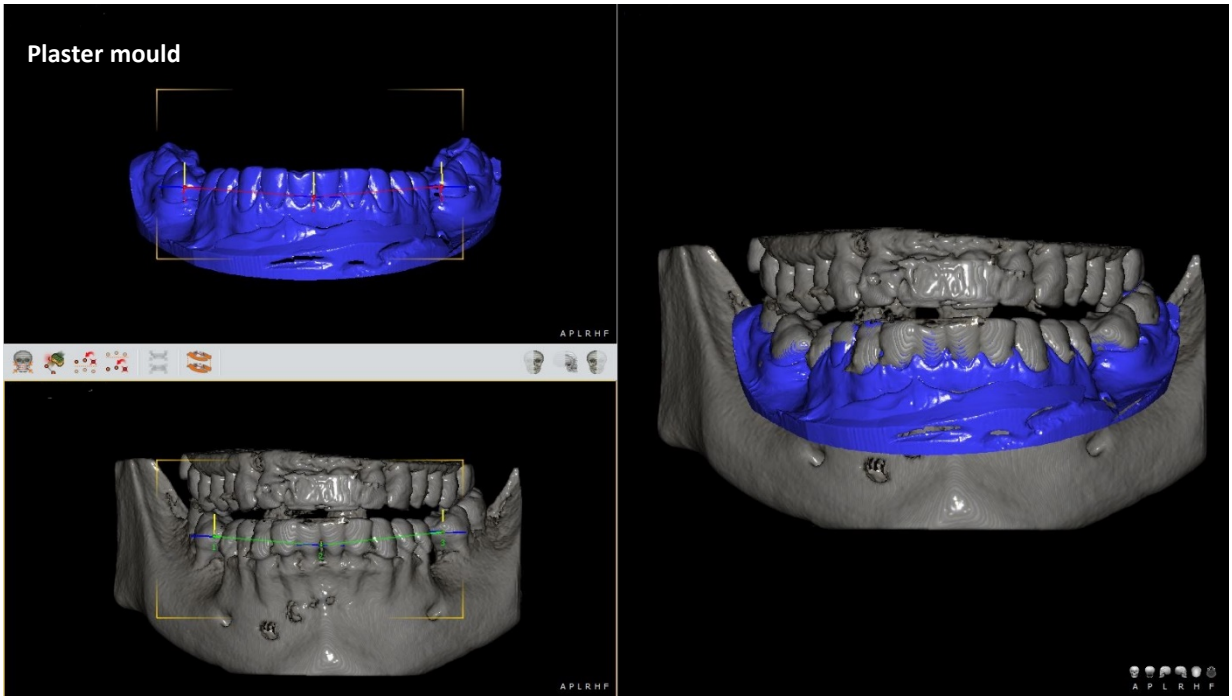


Option to create implants or import them from a library (Nobel®, etc.).
Option to rotate radiological images around the implant.

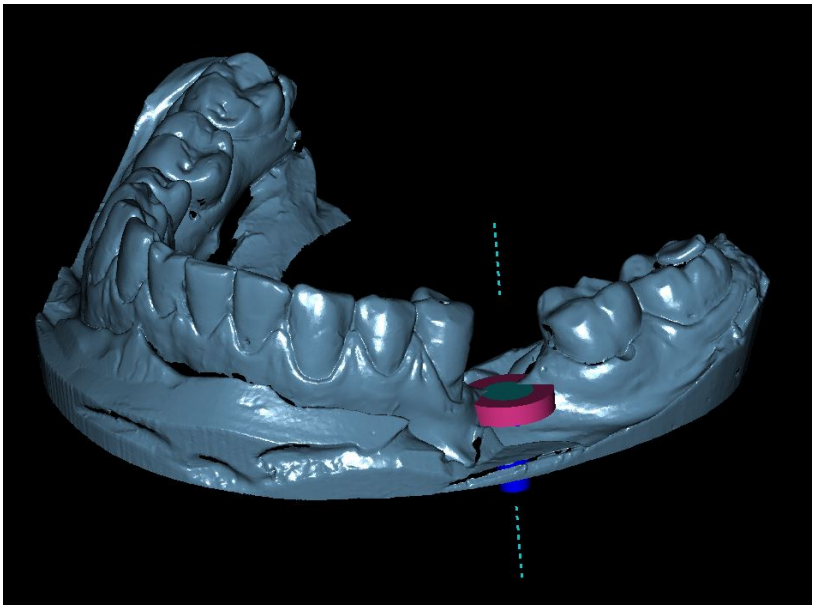


Overlaying

In this view, various objects can be overlaid when reconstructing the 3D patient volume.
This can be very useful, in order to correctly position the plaster mould used to model the surgical guide on, or to adjust the implant fixations or other positioning elements.

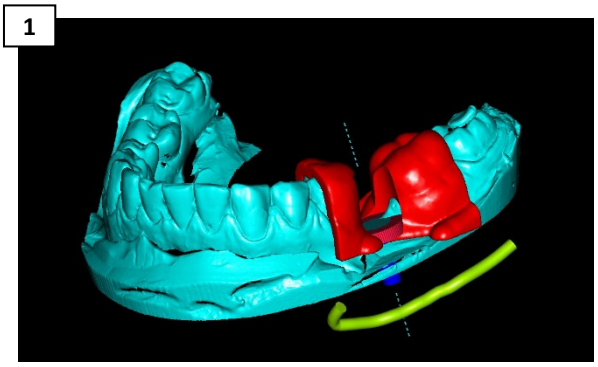


This can hide the reconstruction of the patient's 3D volume in order to be able to see one or more elements.



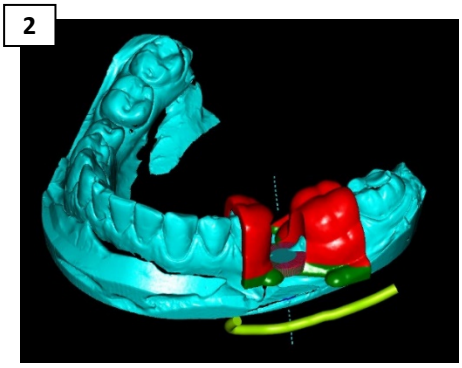
Surgical Guide Design

1



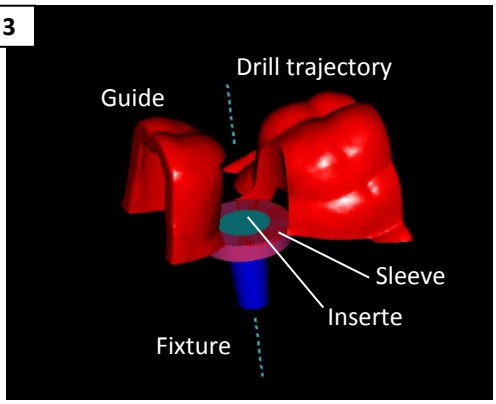
- Draw the mandibular nerve.
- Select the fixations, position them and adjust their size.
- Overlay the plaster model scan.
- Add the ring, the insert and the surgical guide.

2



- Finalize the surgical guide by adapting it to the plaster model.

3



- Select a view that will display the final model of the surgical guide.

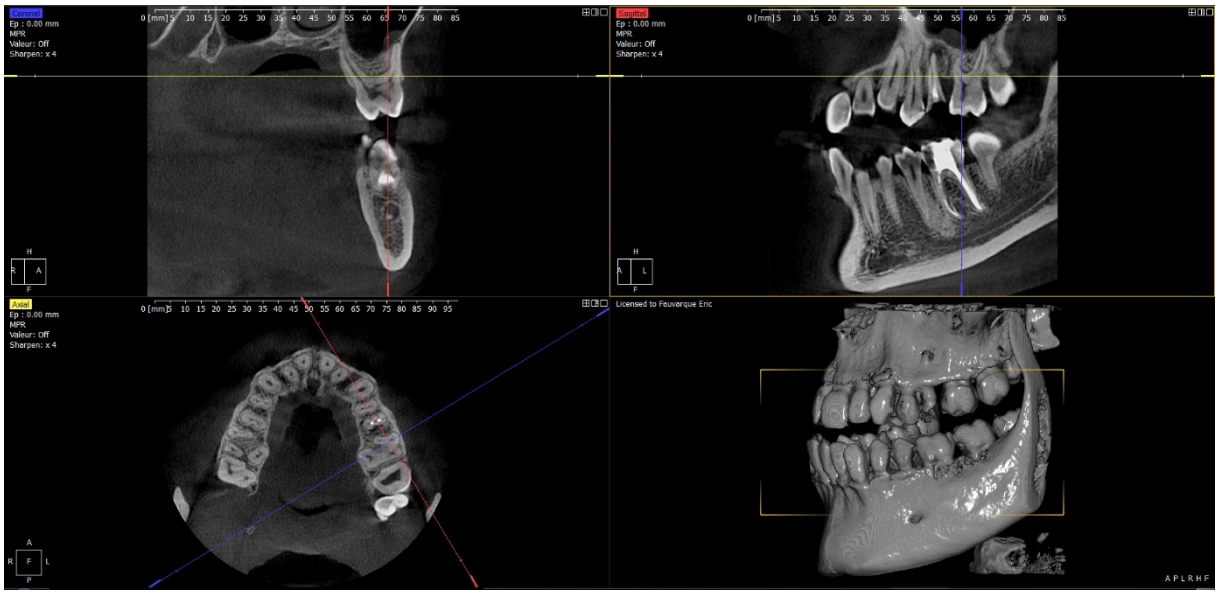
4

- Download the project in order to generate an STL file and to print your drill template in 3D. Alternatively, you can send the patient's plaster mould and 3D volume to the specialist centre, which will be able to both plan the implant and create the drill template for you.

11. 5 STAGES OF GUIDED SURGERY

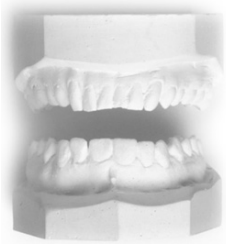
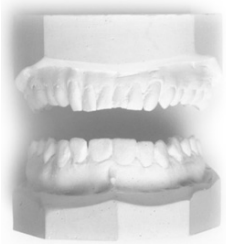
STAGE 1
3D imaging to produce a DICOM image

- Full-mouth imaging in just one exposure (3D I-Max).
- Integrated and optimised system for implant planning.

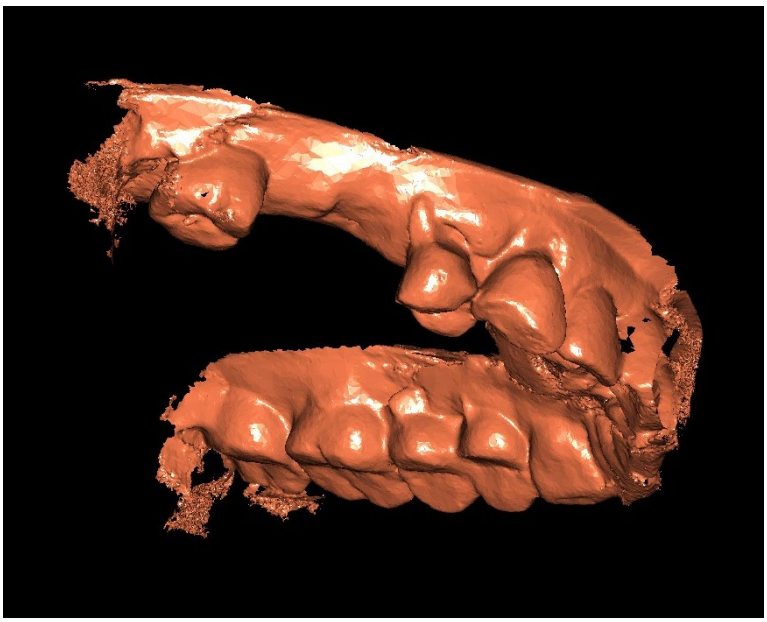


STAGE 2
Create an STL file of the dental impression

- 4 méthods to obtain an STL file

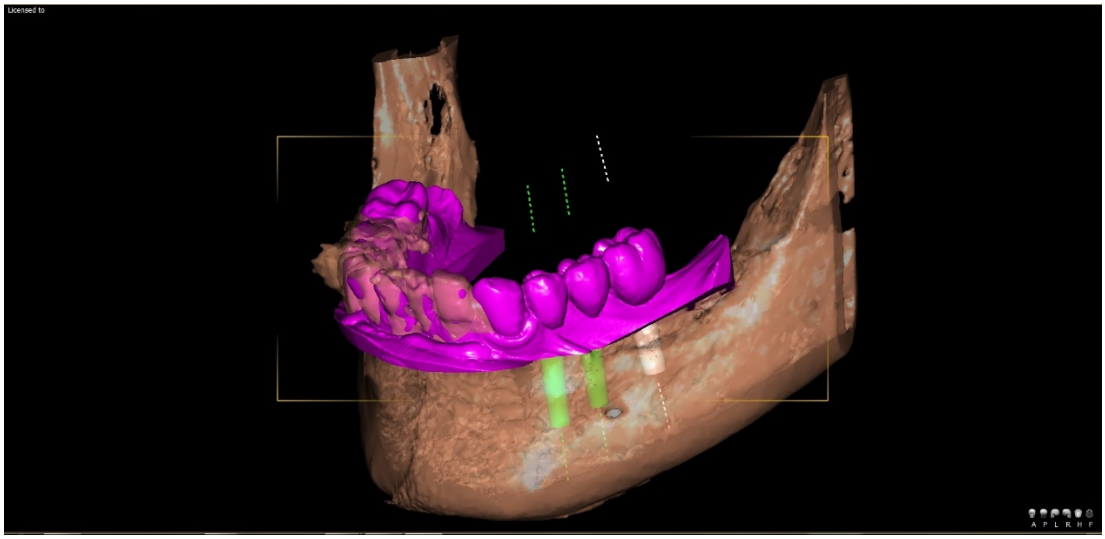
Method 1	**Method 2**	**Method 3**	**Method 4**
Traditional dental impression ↓ Create the plaster model ↓ Scan plaster model in a lab to obtain an STL file ↓ Import the STL file into QuickVision	Traditional dental impression ↓ Create the plaster model ↓ Scan plaster model with I-Max 3D (DICOM) ↓ Convert the DICOM file into an STL file	Traditional dental impression ↓ Scan dental impression with 3D I-Max (DICOM) ↓ Convert the DICOM file into an STL file	Dental impression taken directly using an intraoral camera (STL file) ↓ Import the STL file into QuickVision
			

Result of the 4 methods: STL file

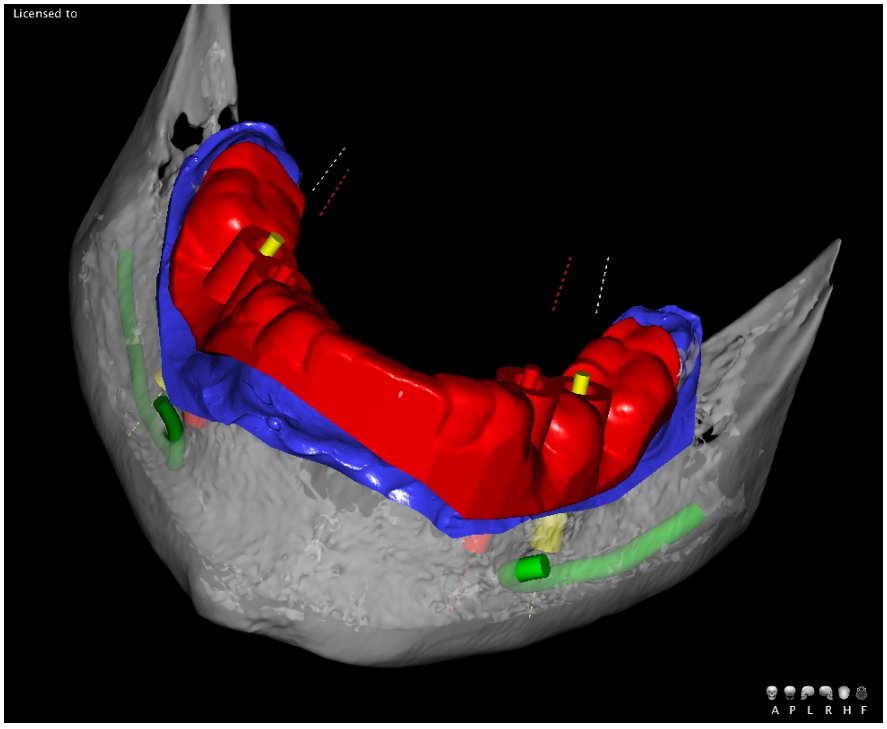


STAGE 3
QuickVision 3D : superposition, planification et création du guide

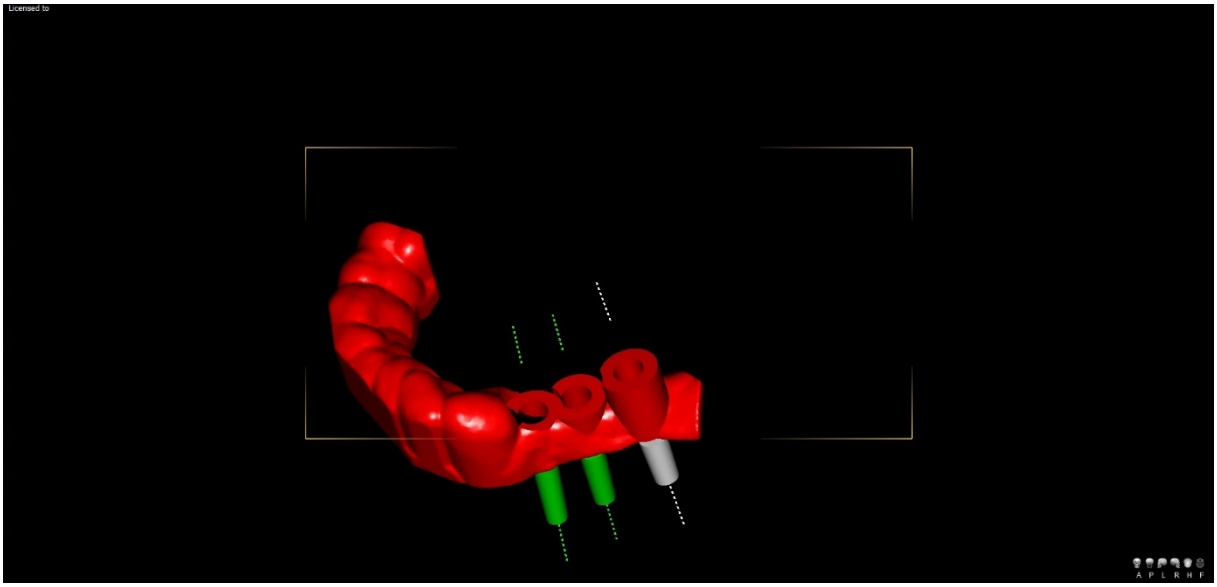
- Overlay DICOM and STL files to obtain a complete image with soft and hard tissue. Demo video available on our YouTube channel Owandy Radiology (Superimpositioning_OWANDY RADIOLOGY_QuickVision 3D)



- Quick, easy and intuitive implant treatment planning Demo video available on our YouTube channel Owandy Radiology (Implant create and place_OWANDY RADIOLOGY_QuickVision 3D)



- Quick, easy and intuitive implant treatment planning Demo video available on our YouTube channel Owandy Radiology (Implant create and place_OWANDY RADIOLOGY_QuickVision 3D)

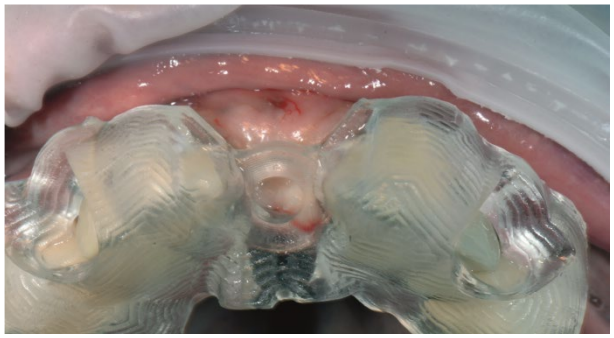


STAGE 4

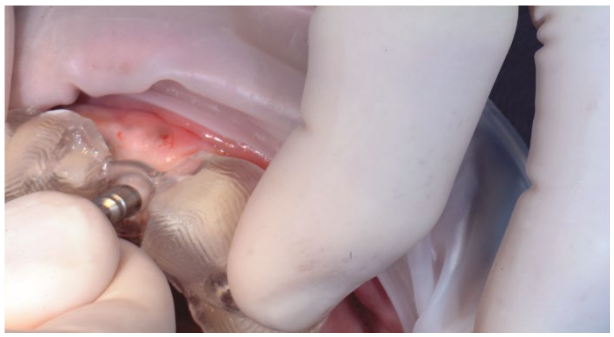
3D printing of the surgical guide on a Form 2 (Formlabs) type printer, or by the laboratory

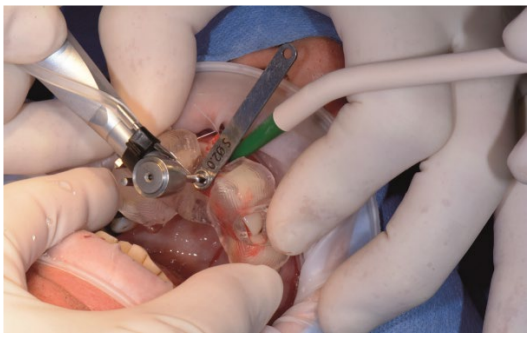
Top quality guided surgery.
Time-savings (no subcontracting).

STAGE 5
Implant placement: a safe and accurate surgical operation

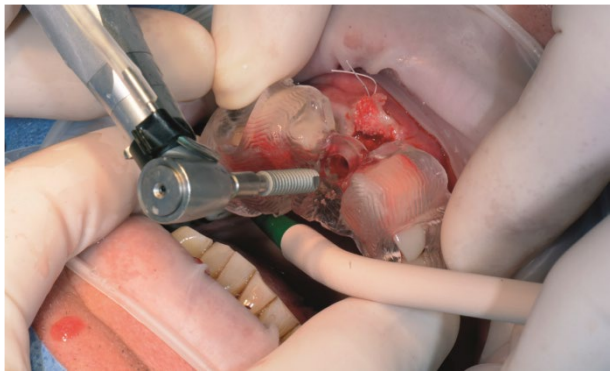


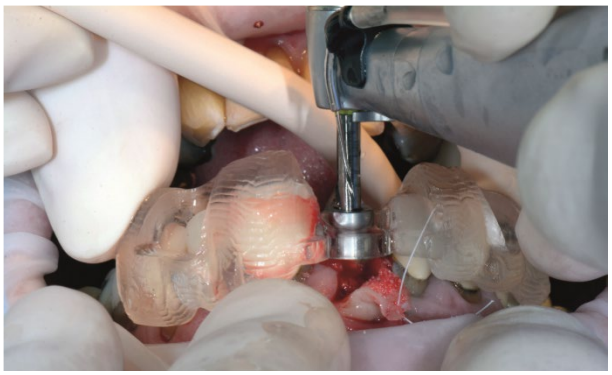
The guide is placed in the mouth and its position controlled using the windows.



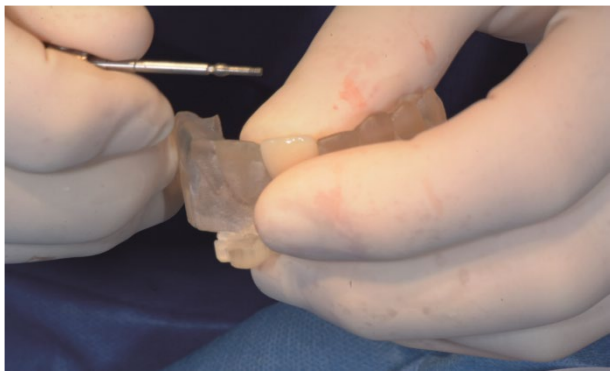


A circular scalpel is used to mark the gums, to carry out flapless surgery or, in this case, surgery with a small flap.

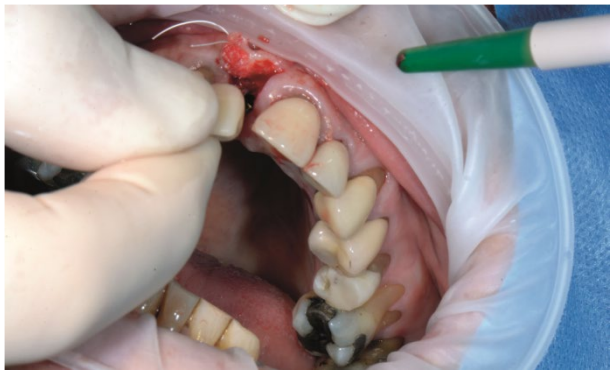




The implant is positioned using the guide, which ensures the perfect axial, vertical and rotational positioning with regard to the indexation.

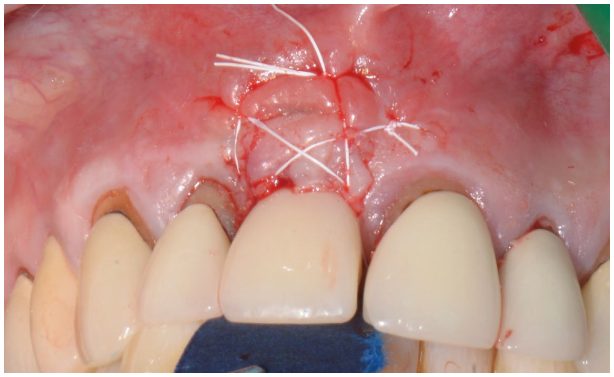


The laboratory screw is removed.



The prosthetic is placed and screwed onto the implant. It finds the right position in alignment with the other teeth.

Connective tissue roll is used to repair gum tissue.



Stitches are done using PTFE 4/0 Cytoplast thread.
The occlusal command is used to check the underbite.

End of the document