General guidelines for use of the protocols of NewTom VGi evo
NOTES
This document is provided as a consultation manual intended for the device technicians.

CEFLA s.c. follows a policy based on the constant development and update of the product. For this reason, it reserves the right to change the content of this manual without prior notice.

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The original version of this manual is in English.

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INFORMATIVE NOTE OF THE MANUFACTURER ON THE MEDICAL DEVICES

The medical device referred to in this manual is an X-ray device compliant with Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Any tampering with, modification, updating or other change both of hardware¹ and software² of the device as supplied and installed by the company (and in the conditions specified in the attached documentation) may partially or totally compromise the device expected operation. This may also alter the safety features with consequent hazard increase for patients, operators and surrounding environment.

For this reason, should the user need to modify the device, he/she must request a written authorisation by CEFLA s.c.

Failure to comply with what is specified in this informative note will null and void the device warranty and the civil and/or penal responsibility for any consequent damage and/or accident and/or worsening of the patient, operator or other people health (including the surrounding environment) will be borne by the person who tampered with the device or his/her legal representative.
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1 Purpose of the document

This document was produced with the support of medical specialists as a means of reference to provide the user with general guidelines on the opportunities for use of the device NewTom™ VGi evo, giving an indicative overview of the protocols used for the most common examinations of ENT, dento-maxillofacial complex, temporomandibular joint and other areas of the human skull and neck.

This document is an attachment to the “User Manual” of NewTom VGi evo.
2 What is a CBCT

CBCT means a volumetric computerized tomography technique that uses "Cone-Beam". This technique allows you to scan through a single complete rotation of the tube-detector system around the patient anatomy to examine all the necessary data for the volumetric reconstruction of the anatomical region examined.

In CBCT, the scan system is composed of the X-ray source, which produces a beam of X-rays in conical geometry, and a solid state detector.

The X-ray beam is collimated on the detector and the pair source - detector rotates around the volume reconstruction of the machine by performing a sequence of digital radiographs.

The CBCT device using a cone-shaped beam to acquire the entire volume makes a single rotation. The result is an accurate image, obtained with a time of exposure to X-rays lower than for a conventional CT equal acquisition protocols.

![Basic Principles of a CBCT](image)

3 Scanning Modalities

Before taking an exam, it is recommended to choose the smallest field of view available considering the clinical area of interest and dimensions of the patient.

NewTom VGi evo offers the possibility to perform scans with 2 different options for each available field of view:

- **Regular Scan**: default option for image quality, scan time and exposure time
- **Eco Scan**: < exposure time for all modalities < scan time (only for HiRes modalities)

When performing a Regular Scan, the option Boosted Dose is also available. This modality offers better image quality at the expense of a greater dose.

For children, it is recommended using the lowest dose and fastest scanning mode available: Eco Scan.

**Positioning pre-sets**

Depending on the selected field of view, a number of default pre-sets might become available to the user. A pre-set can help the user by automatically positioning the patient support before accommodating the patient, reducing the overall time for the exam and the patient’s discomfort. After selecting a default pre-set, it is possible that the positioning has to be re-adjusted to accommodate the area of interest.
4 Working Protocols

The following paragraphs will discuss, as a guideline, the most widely used protocols of NewTom VGi evo.

Before performing an exam, it is recommended to prepare the patient for the examination. The collaboration of the patient can contribute to the correct execution of the scanning.

4.1 Petrosal Bones Imaging

Main indications:
Cholesteatoma, otosclerosis, ear infections, hearing loss, vestibular disorders, vertigo, cochlear implants study.

Patient positioning:
Before positioning the patient, make sure it has removed any glasses, dentures or acoustic furniture, and other metal objects from the area in question.
Then accommodate the patient inside the scanning area, either standing or sitting on a chair. Place their head on the chinrest, hard palate parallel to the ground, with dental arches closed.

It is essential to inform the patient and instruct the behavior that must be taken during the time of the examination, i.e. no swallowing, no movements of tongue and eyes, shallow breathing.

FOV used and centering patient:

- Separate petrosal bone (left/right): FOV 8x8 HiRes
- For children and small size patients it is recommended: FOV 5x5 HiRes

- Both rocks in a single exposure: FOV 15x5 HiRes
- For children and small size patients it is recommended: FOV 12x8 HiRes

- FOV 8x8 HiRes
  Before performing the scan, select a default pre-set covering the ENT area (upper arch and sinus). Alternatively, position the patient centering the lower axial laser between the nose and the upper lip. The sagittal laser should be positioned halfway of the hemiface under consideration.

- FOV 15x5 HiRes
  Before performing the scan, select a default pre-set covering TMJ and ears. Alternatively, position the patient centering the lower axial laser between the nose and the upper lip. The sagittal laser shall stand in the middle of the patient’s face.
Example of adult patient positioning with laser activated (FOV 8x8 HiRes)

Example of adult patient positioning with laser activated (FOV 15x5 HiRes)

Example of pediatric patient positioning with laser activated (FOV 5x5 HiRes)

Example of pediatric patient positioning with laser activated (FOV 12x8 HiRes)

With FOV 8x8 HiRes, in the scout side, the acoustic meatus must be at the center of the field of study, including before the clivus and posterior whole mastoid.

Scout LL petrosal bone (Es. FOV 8x8 HiRes)
In the anterior-posterior scout, the anatomical region to be studied must involve the entire course of the petrosal bone, from the mastoid to the nasal cavity.

Scout AP Bone (e.g. FOV 8x8 HiRes)

With FOV 15x5 HiRes both petrosal bones can be acquired simultaneously. The centering must be carried out over the entire head of the patient.

In the scout side, put the center area between the condyle and the acoustic meatus.

Scout LL Bones (e.g. FOV 15x5 HiRes)

In the anterior-posterior scout, make sure that the packages are included within the field of acquisition.

Scout AP Bones (e.g. 15x5 HiRes)

Voxel recommended for reconstruction: isometric 0.15 mm.

NOTES

The use of High Resolution fields is especially recommended to acquire all the details of the structures in these clinical areas. In case of use of FOV 8x8 HiRes, the recommended practice is to acquire first the petrosal bone site of the lesion or suspected lesion, this to minimize the possibility of patient movement, particularly in elderly subjects, with difficulty in maintaining the position of immobility.
4.2 Massive Facial Imaging and paranasal sinuses

Main indications:
Chronic sinusitis, polyposis, anatomical variants (septal deviation, etc.). Predisposing to rhino-sinus symptoms, runny nose (suspected CSF fistula), facial fractures (cooperative patient), follow-up post-operative facial trauma, jaw asymmetry, dysplasia.

Patient positioning:
Remove dentures or mobile acoustic and any metal objects from the area in question. Then accommodate the patient inside the scanning area, either standing or sitting on a chair. Place their head on the chinrest, hard palate parallel to the ground, with dental arches closed. More stability is assured by the use of the bite.

It is essential to inform the patient and instruct the behavior that must be taken during the time of the exam.

![Patient position with use of the bite](image)

FOV used and centering patient:
- FOV 15x12 (or FOV 16x16) based on the size of the patient’s skull and cranial-caudal extension of the sinuses.
- For children and small size patients it is recommended FOV: 12x8
- Center the lower axial laser on the upper lip. The sagittal laser should be positioned in the middle of the patient’s face.
In the scout side, include the area from the frontal sinuses to the hard palate and from the nose (soft parts including, if possible) to the sphenoid sinuses.
Voxel recommended for reconstruction: isometric 0.30 mm.

**NOTES**
For this application, the use of Standard Resolution fields is especially recommended over High Resolution fields.
4.3 Orthodontic Imaging Massive Facial

Main indications:
Examination required by dentistry for intervention in cases of malocclusion and malformations (e.g. cleft palate).

Patient positioning:
The exam is usually performed on younger patients / young, so remember to wear your gown sealed and make sure it does not interfere with the scan at the level of the shoulders. Remove contaminated clothing and furniture and metal objects such as earrings or necklaces. Accommodate the patient inside the scanning area, either standing or sitting on a chair. Place their head on the chinrest, hard palate parallel to the ground, upper and lower molars in contact. Generally, as orthodontic studies focus on the closure of the mouth, the use of the bite is not recommended.

FOV used and centering patient:

- FOV 24x19, 16x16
- For children and small size patients it is recommended FOV: 16x16, 15x12
- Before scanning, select a pre-set covering the massive facial. Alternatively, center the lower axial laser at the level of the hyoid bone of the patient. The sagittal laser should be positioned in the middle of the patient’s head.

*Example of adult patient positioning with laser activated (e.g. FOV 24x19)*
In the scout side, it is important to include the following areas: from top to bottom, from the glabella to the hyoid bone and from front to back, from the nose (including the soft parts) to the cervical vertebrae (usually up to the fourth).

These are fundamental points of reference for the measurements carried out by dentists when planning intervention.

In the anterior-posterior scout, make sure that the patient is positioned correctly, keeping the nasal septum in the middle of the field.
Voxel recommended for reconstruction: isometric 0.25 mm.
4.4 Dental Arches Imaging

Main indications:
Implantology, dysodontiasis, included items, surplus items, cysts etc.

Patient positioning:
Remove contaminated clothing and furniture and metal objects, such as earrings or necklaces. Accommodate the patient inside the scanning area, either standing or sitting on a chair. Place their head on the chinrest, hard palate parallel to the ground, positioning the bite between the upper and lower front teeth, so you do not have overlapping teeth.

FOV used and centering patient:
- For the upper jaw, FOV 12x8, 10x10
- For children and small size patients it is recommended FOV 10x5, 8x8
- Select a pre-set covering the upper arch; bigger fields of view allows also the examination of the sinus. Alternatively, center the lower axial laser on the lower lip. The sagittal laser should be in the middle of the patient’s head.

Example of adult patient positioning with laser activated (e.g. upper arch, FOV 12x8)

Example of pediatric patient positioning with laser activated (e.g. upper arch, FOV 8x8)
The anterior-posterior and lateral scouts should not include too much of the inferior dental arch.

![Scout LL with FOV 12x8](image1)

![Scout AP with FOV 12x8](image2)

- For the lower arch, use FOV 12x8, 10x10
- For children and small size patients it is recommended FOV 10x5, 8x8
- After choosing a FOV, select a pre-set covering the inferior arch. Alternatively, center the lower axial laser below the chin, and the sagittal laser in the middle of the patient’s face. Opt for the FOV 15x12 in case of disease of the mandibular branch, in that case centering the axial laser at the level of the hyoid bone.
• For both arches use the FOV 15x12 or 12x8 with centering the lower axial laser below the chin.
• For children and small size patients it is recommended FOV 10x10, 8x8.
Example of adult patient positioning with laser activated (e.g. both arches, FOV 15x12)

Example of pediatric patient positioning with laser activated (e.g. both arches, FOV 10x10)

Voxel recommended for reconstruction: isometric 0.15 mm to 0.20 mm.
4.5 Temporomandibular Joint

Main indications:
Temporal mandibular joint syndrome, articular dysfunctions, TMJ dislocation, TMJ trauma, osseous ankylosis, neoplasms, heterotopic bone growth, abnormalities in and around the joints.

Patient positioning:
When performing exams on patients with closed mouth, it is very important to acquire in maximum teeth contact (CO Centric Occlusion or maximum intercuspation). This position will allow to gather information between teeth and joint and therefore establish if there is a traumatic overloading of the joint.

FOV used and centering patient:

- FOV 15x12
- For children and small size patients it is recommended FOV: 15x5, 12x8
- After choosing a FOV, select a pre-set covering the TMJ. Alternatively, center the lower axial laser at the level of the hyoid bone. The sagittal laser should be set in the middle of the patient’s head.

*Example of adult patient positioning with laser activated (e.g. FOV 15x12, mouth open)*

*Example of pediatric patient positioning with laser activated (e.g. FOV 12x8, mouth open)*
NOTES
In order to evaluate this clinical area, the usual practice is to perform the scan twice, one with mouth open and one with mouth closed. Alternatively, a study of moving structures can be performed through the CineX function (FOV 19x17), which acquires dynamically a sequence of X-ray images stored as a video.
4.6 Sections of the Neck and Upper Cervical Spine

Main indications:
Arthrosis, traumas, post surgery check, hernias and discal protrusion (in patient where is not possible to perform an MRI), pathologies of the single metamers and bone abnormalities.

Patient positioning:
Remove dentures or mobile acoustic and any metal objects from the area in question. Then accommodate the patient inside the scanning area, either standing or sitting on a chair. Place their head on the chinrest, hard palate parallel to the ground, with dental arches closed. While the use of the bite is not fundamental, it can assure more stability.
It is essential to inform the patient and instruct the behavior that must be taken during the time of the exam.

FOV used and centering patient:
• FOV 16x16
• For children and small size patients it is recommended FOV: 15x12
This examination could require to set the chinrest in a high position. Center the lower axial laser at the level of the hyoid bone.

Example of adult patient positioning with laser activated (e.g. FOV 16x16)

Example of pediatric patient positioning with laser activated (e.g. FOV 15x12)
Scout AP of the neck with FOV 16x16

Scout LL of the neck with FOV 16x16
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