Dentail Second Opinion

Computer-Aided Detection for Intraoral Bitewing and Periapical Dental Radiographs

CLIENT USER MANUAL & LABELING

Software Version 1.0
Document Revision 1.0

CE

Table of contents

1. Labeling and Symbols

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CE	Dentail is a medical device, CE-marked according to the Medical Devices Regulation EU 2017/745.
	**Manufacturer**: Dentail AB Andra Parkvägen 1, 237 36 Bjärred Sweden Phone: +41 76 450 42 11 E-mail: dra.johansson@gmail.com The date of manufacture is shown in the software.
	**Read all instructions before use!**
	The catalog number is DTSO Rev1. Current product version is shown in the software (Version x.y.z).
	**W A R N I N G !** This symbol alerts the user to the risk of possible injury, death or other serious adverse reactions.
	**C A U T I O N !** This symbol alerts the user to the risk of possible injury, death or other serious adverse reactions.

2. Important Safety Precautions

To operate DTSO safely and according to its intended purpose, the following prerequisites must be met:

- The product must be installed properly before being put into clinical use.
- The product may only be used by authorized personnel.
- The product may only be used in accordance with its intended use.
- The user has read and understood the Intended user, Warnings, And Operating Instructions in the “Instructions For Use” before using the product and followed all safety precautions.
- Any incident or harm to a patient or operator that might be caused by the product must be reported to the manufacturer or distributor.
- The user has a general understanding of how to use a personal computer that is running one of the compatible operating systems listed in the “Installation” section below.

2.1 Warnings

The following warnings apply to the use of all DTSO software:

- **CAUTION: DTSO IS NOT INTENDED TO OFFER A DIAGNOSTIC ASSESSMENT.** Further clinical investigation of any detected potential pathologic and nonpathologic features that may appear in radiographs is always required.

- DTSO is to be used with visual and tactile oral examination and patient risk assessment.

- Users should regularly confirm that the computer on which the DTSO Client software is operating is free of viruses or malware.

- Users should regularly confirm that the DTSO Client software has been updated with the latest security patches.

- Do not use DTSO software without proper training. Operator training and review of the DTSO user manual is required prior to using the system.

- Users should use the Confidence/Accuracy function to view DTSO detections at all three confidence threshold settings prior to taking any Second Opinion® detections

into consideration.

- DTSO system may make a detection and highlight a region where no pathologic or nonpathologic feature exists. Users must always exercise their professional interpretative skills when reviewing the regions that have been detected by DTSO.

- DTSO may not detect or mark all regions that are indicative of a pathology. Users must always exercise their professional interpretative skills to determine whether any pathologic and nonpathologic features warranting clinical attention are present in radiographs processed by DTSO.

- Effectiveness and safety have been established only for detections in bitewing and periapical radiographic image types. Any features detected and highlighted on radiographs types other than bitewing and periapical cannot be used by the clinician to assist in radiographic evaluations. As an added safety provision, prior to detection processing, DTSO deploys a Model that classifies submitted radiographs into types: Bitewing, Periapical, and Other. If an image is categorized as Other, the DTSO Client will display a message to the user indicating that the image type is not supported.

- All images submitted for DTSO processing must be JPEG, RVG, DCM, TIFF, PNG, and DIC. DTSO may not function properly if an image in an unsupported format is submitted.

3. Product Description

3.1 Product Variants

DTSO is available in two variants. The user can choose to either use proprietary DTSO Frontend or use a third party Image Handling Software to upload radiographs to DTSO API. Third party software can integrate seamlessly with DTSO API without affecting the safety and performance of the MD.

4. Regulatory Information

Dentail is a Class I medical device, CE-marked according to the Medical Devices Regulation EU 2017/745. The product is in compliance with European standards according to table 2.

Table 2. Compliance with European standards

ISO 13485:2016	Quality management systems – Requirements for regulatory purposes
IEC 62304:2015-06	Medical device software – Software life cycle processes
ISO 14971:2019	Medical Devices – Application of Risk Management to

	Medical Devices
IEC 80001-1:2010-10	Application of risk management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities
MEDDEV 2.12/2 rev2	POST MARKET CLINICAL FOLLOW-UP STUDIES
MEDDEV 2.7/1 revision 4	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
EU 2017/745	Medical Devices Regulation

5. Intended Use

Dentail is a business intelligence software, indicated for use by dental health professionals as an aid in the assessment of bitewing and periapical radiographs of permanent teeth in patients. Dentail employs computer vision technology, developed using machine learning techniques, to detect and draw attention to regions on bitewing and periapical radiographs where caries may appear.

Dentail's computer-generated detections are not diagnostically valid and may not supersede a clinician’s independent radiographic assessment.

5.1 Intended User

The intended users of DTSO are dentists in various settings including primary care (e.g., family dental practice, hospital-based dentistry and dental service organizations), dental specialists, oral maxillofacial radiologists who review radiographs across these settings. DTSO is intended to be used in controlled forms at the caregiver's "workplace". Workplace is defined according to where the patient treatment takes place, thus where the clinical activity and the user are active. Use outside the workplace may occur but is not recommended.

5.2 Intended Patient Population

DTSO is applicable to all types of dentistry patients. The intended purpose of the product is e.g. applicable regardless of age, gender, weight and health condition. Dentail does not apply any limitations to the patient target group.

5.3 Indications

When used for diagnostic purposes, the device will be used to diagnose and document diseases and conditions such as dental caries, periodontal disease, tooth and jaw injuries, in orthodontic treatment and other conditions that are encountered by general practitioners and specialists in the dental care field.

5.4 Contraindications

There are no known contraindications.

5.5 Side Effects

There are no known direct risks related to the use of the device to the safety or health of the user or the patient. Patients have no direct contact with the device. Indirect inherent risks are: (a) the device may not detect pathologic or nonpathologic features that present in radiographs (false negative detections); and (b) that the device may detect pathologic or nonpathologic features that do in fact present in radiographs (false positive readings). These possibilities are clearly explained in the warnings section included in the labeling of the device. Proper operation of the device is explained in the directions for use printed in this manual.DTSO output is one of several inputs that physicians employ in their decision making; final diagnostic decisions represent physicians' assessments and judgments derived from these several inputs.

5.6 Storage

DTSO is not a consumable device and thus has no shelf lifetime. The device lifetime is ongoing as long as the technology is applicable for the clinical need.

6. Installation

CAUTION!
The device must be properly installed according to the installation instructions. Dentail recommends that installation and system changes be performed by individuals familiar with the IT systems in which DTSO is running.

DTSO is intended for installation at dental clinics, dental service organization offices and dental insurance providers on off-the-shelf computer systems running Microsoft Windows 7+ or through integration of an API with third-party practice management systems and X-ray sensor software.

Before the product may be put to clinical use, it must be installed properly according to the installation instructions.

Installation is performed on one or several computers in a network. All computers may or may not connect to a common server that stores the X-ray software's database with patient

information and images. Each computer in a treatment room is a workstation with connected equipment such as sensors and cameras as well as third party software such as drivers. In Muntra, settings are stored centrally. Each workstation may have additional settings that may be different between computers.

6.1 Software Requirements

- Windows 7 or newer. The user should always strive to use the latest available version (not beta / development / early access / versions).
- A working internet connection.

6.2 Hardware Requirements

- Intel Core i5 or better,
- 4 GB RAM or higher,
- Display 23-24" with resolution 1920-1080. For optimum experience, a higher-quality display is recommended with a so-called IPS, PVA panel type instead of TN. The larger and better the screen, the better the user experience.