exocad

03/2019

exocad GmbH

Performance Specifications Dental Software

exocad.com

I. DentalCAD

General

Intended use

DentalCAD is a software device intended to support the design of dental restorations such as inlays, onlays, crowns, copings, veneers, bridges, pontics, provisionals, and dental appliances such as bite splints via a 3D CAD tool. The design is based on suitable 3D scans of the patient's dental anatomy produced by a compatible scanner. The software generates the geometrical output of the design for manufacturing on compatible CAM systems. DentalCAD is intended to be used by trained professionals such as dental technicians in dental labs and dental practice labs and is not to be used for any purpose other than the design of dental restorations or dental appliances.

Initial Activation

The software has to be activated initially. "Initial Activation" is the activation of the software for an individual software license, which is protected by a USB Dongle. The software generally needs to be activated by the customer or the respective user ("Licensee") before initial usage. This activation is done via the license server from exocad ("Licensor").

License validation for perpetual licenses

It is highly recommended to have a valid internet connection while using the software. In certain cases, e.g. when the software was not used for an extended period or the configuration of the computer has changed, a confirmatory activation process (which will require an internet connection) may be triggered automatically for the computer and its USB Dongle.

License validation for subscription-based licenses (i.e. flex licenses)

The software will require a technical license validation every two weeks (which will require an internet connection) to ensure that the user's sub-license for a specific computer is still valid. The technical requirements for this validation are the same as for the initial activation. It is highly recommended to have a valid internet connection while using the software. In certain cases, e.g. when the software was not used for an extended period, the configuration of the computer has changed or the software was not used for a period of two weeks or longer, a confirmatory activation process (which will require an internet connection) may be triggered automatically for the computer and its USB Dongle.

Software version

The Performance Specifications for DentalCAD in this document refer to version DentalCAD 2.3 Matera Release.

Data management

The database module ("DentalDB") manages patient and design data using a file-based database. The parameters for a treatment are defined and saved here in a database, and also exported as a . dentalProject file for further processing with a compatible scan and design software. Furthermore, parameters dependent on materials and design (such as minimum thickness) can be saved here. The entered case can be exported to pdf or printed.

After the case is entered and all treatment parameters are defined, the DentalDB software can invoke programs like a scanner, CAD or CAM software through configurable buttons.

An FTP upload of files in the project folder (e.g. scans or designs) can be performed via the database software (for data transfer to a manufacturing center). This upload is encrypted if the FTP server used for the upload is compatible with an encrypted transfer. In this regard, the Licensee is to take note of the license for the OpenSSL encryption library used, which contains the following clause:

All advertising materials mentioning features or use of this software must display the following acknowledgment: 'This product includes software developed by the OpenSSL Project for use in the OpenSSL Toolkit. (http://www.openssl.org/)'.

Similar to the FTP upload, a local copy to a windows network folder is also possible.

Additionally, a cloud-based file transfer called "dentalshare" by exocad can be integrated by configuration options into DentalDB and is optionally available to end users based on a dedicated dentalshare end user license agreement (not part of this contract).

Data preparation

Input data

The correct function of the software, as well as quality and the fitting accuracy of the software data output, are limited by the quality of the (digital) dental impression and the topological and geometric properties of the associated 3D scans.

The input data for the software are 3D scans of dental impressions or intra-oral situations available in its triangulated form in a uniform coordinate system represented as open binary .STL, .OFF, .PLY or .OBJ files. Vertex colored or 2D textured scan data is also supported using the standard specification of the binary .PLY or .OBJ file format.

As one of the first steps in the software, the user must define the scan data orientation for each case. The software can be configured to always skip that step if the scanner is able to meet the requirement of having a pre-defined consistent z-axis for each patient case.

Each tooth or tooth stump to be processed and each jaw part to be considered must be present in these data (with the file names specified according to the .dentalProject specification) as a continuous triangular mesh (Euler characteristic = 1) without holes or tunnels. In each of these triangular meshes, each inner triangular edge must lie in exactly two triangles. The geometry here may have neither multiple surfaces nor surfaces not contained in the physical dental impression nor other gross deviations, nor may it deviate more than a maximum of 0.1 mm or an average of 0.05 mm from the associated dental impression.

If there is an antagonist scan, it must be aligned correctly in the desired relationship with the opposing scan (typically in "centric position" for crown & bridge cases). Corresponding to the real situation, there must be no intersection present between teeth, except from the possible scanner deviations defined in the previous paragraph.

In the database module (i.e. in the .dentalProject file), prior to beginning the design, it must be correct and completely determined which teeth or jaw parts are included in the scan data used and which reconstructions are to be carried out for these.

A subsequent change of the reconstruction type in the CAD software is made possible to enable full anatomical crowns/pontics to be changed to reduced crowns/pontics and vice versa.

Preparation margin detection

The user must draw the preparation margin manually on the triangulated 3D scans. Optionally – but only if the preparation margin is clearly visible and convex in each area - the user may select points on the preparation margin to let the software estimate the margin automatically. The quality of the automatically selected preparation margin depends on the quality and the visibility of the margin in the input data. Especially in intraoral scan data with subgingival preparations, manual drawing is usually required.

Generating the inside of the crown

For all crown restorations (full crowns and anatomical crowns) and other indirect restorations designed on prepared dentition e.g. inlays, onlays, veneers, the inside of the crown is generated automatically with predefined parameters. Manual changes are generally possible and recommended for achieving the best results. The following are taken into account in the process:

- The cement gap parameters set by the user (thickness of the cement gap, beginning, and end).
- The minimum internal radius to ensure that milling is possible (diameter of the milling cutter can be set).
- Undercuts are blocked out if desired.

- A crown border can be added with preconfigured parameters (horizontal and vertical width as well as angle width).

Designs supported

Crowns with anatomical chewing surfaces

The design of crowns with full anatomical chewing surfaces takes place based on a library of model teeth.

In single crown cases, the model tooth will in many cases be automatically loaded over the crown stump and positioned automatically (taking into account the neighboring teeth, for example). If the software cannot find the suitable scan data parts automatically, the software will ask the user to indicate the mesial and distal teeth in the scan data to allow placing the model tooth.

In cases of more than one crown, each model tooth is loaded roughly over the crown stump and positioned automatically.

The user has the possibility of manually correcting the model tooth position, which can always be necessary in difficult patient situations (particularly with mispositioning of teeth which are still healthy, when the scan data orientation is not according to the typical standard or in cases where one or both neighboring teeth are partially or completely missing).

After the model tooth placement is finished, the software will adapt it to the preparation with consideration of the specified minimum thickness. This concludes the automatic generation of the proposed design for the crown. The user is given the opportunity to edit the suggestion manually as desired. (See the section on tools for manual post-processing.)

Subgingival preparations are generally also supported if the scan has full visibility of the preparation margin but might require special care with additional user interaction of the subgingival preparation margin area (e.g. using the virtual wax stylus or smoothing).

Minimum thickness above the preparation: The set minimum distances from the area lying on the preparation are maintained except for the usual transition area in the immediate vicinity of the preparation margin.

Due to the diversity of possible preparations, different characteristics of input data, and the complexity of the operation procedure, the Licensor does not guarantee the correct function of the crown generation in each case.

A library of 16 model teeth (8 each for the upper and lower jaws) is provided by the Licensor and supplemented by dental information (such as the equator, cervical edge, and approximal contacts). In addition, the Licensor provides a library tooth editor which may also be used with the CAD software.

Anatomical copings

Anatomical copings are designed by reduction of the model teeth (also known as “reduced crowns” or “framework crowns”). Configurable parameters are the shrinkage thickness (the place provided for the ceramic veneer). The material-dependent minimum thickness set by the user is also maintained.

The complete crown is shrunken by default. Alternatively, the user can mark particular areas for reduction.

Minimum thickness above the preparation: The set minimum distances from the area lying on the preparation are maintained except for the usual transition area in the immediate vicinity of the preparation margin.

Primary telescopes

Simple primary telescopes can be designed. The height at which the friction surface begins and ends and its angle of inclination can be set. These parameters can be configured separately for various sides of the tooth (buccal, lingual, mesial, distal). The user can interactively modify the primary telescope and herby also define some parts that shall not be frictional surface but instead represent a full anatomic restoration.

Minimum thickness above the preparation: The set minimum distances from the area lying on the preparation are maintained with the exception of

the usual transition area in the immediate vicinity of the preparation margin.

Design based on loaded 3D objects ("Waxup Scans")

The design of dental restorations can also be based on 3D scans represented by the same formats as the scan data can be loaded into the design software to be used as design templates (for example to generate a crown or bridge from one modeled in wax). Hereby, excess material in the 3D scans that are not supposed to be in the final dental restoration must be manually trimmed by the user. The waxup scan must be very high quality because most parts of it are directly used as the dental restoration. The same input data requirements as the for jaw scans also applies to waxup scans. Designing bridges using waxup scans is only possible when either the waxup scan is connecting all related teeth, or when each tooth is individually scanned as a separate waxup. This also means that it is not possible to generate additional bridge connectors between waxup scans when one of the waxup scans by itself already represents a bridge.

These 3D scans can then either be used directly instead of using tooth library models for generating a dental restoration (so-called "waxup scans"), or alternatively used as visual template e.g. a "pre-op scan" where a semi-automatic adaptation of the tooth library model towards the loaded 3D scan is also possible (see section "Pre-operative model scan").

Due to the diversity of possible shapes which can be loaded, we do not guarantee that adaptation, shrinking or bridge generation will function correctly for each case.

Pre-operative Model Scans

An additional pre-operative model scan represented by same formats as normal scan data can be loaded into the software that reflects the pre-operative patient situation for visualization purposes. Additionally, parts of the anatomically designed surfaces can be adapted to the pre-operative model scan semi-automatically.

Due to the diversity of possible pre-operative situations, different characteristics of input data, and the complexity of the operation procedure, the Licensor does not guarantee the correct function of the pre-operative adaptation in each case. Especially in the approximal or gingival area, the manual post processing by the user will be required using the smoothing or virtual wax stylus tools.

Design of bridges

To design bridges, predefined model teeth can be loaded as bridge elements, so-called "pontics". In the typical application scenario, pontic forms are loaded with anatomical chewing surfaces.

These are first placed automatically, with manual correction possible.

Reduction of full anatomical pontic models is also possible if the pontic is defined as reduced pontic. Furthermore, it is possible to adapt the base of the pontic to the gingiva if there is a suitable scan of it available (sufficient size, correctly scanned and without rupture edges).

The optional generation of bridge connectors takes place after definition in the data management (tab). They will be generated between adjacent pontics and crowns if preset in the data management section. The software first presents an automatic design suggestion for the bridge connector which can later be changed by the user. Parameters which can be selected are the minimum cross-section and the shape (which can be chosen from various standard shapes). Furthermore, the position of the interfacial surface can be adapted to the crown or coping with a click.

Various bridge elements (except for scan-based wax-up designs) can be combined into a single mesh (so-called "merging"), and hereby optionally also be connected to form a single closed mesh e.g. for further manual freeforming and to improve compatibility for later SLM/3D printing.

Inlays, Onlays, and Veneers

Similar to anatomic crowns, anatomical inlay, onlay or veneers can be designed from tooth library models. Hereby, a manual tooth placement and size correction is crucial for best results. Also in some

cases, the manual segmentation of scan data between two neighboring reconstructed inlay teeth might be required. Due to the diversity of possible inlay, onlay and veneer preparations, different characteristics of input data, and the complexity of the operation procedure, the Licensor does not guarantee correct function of the inlay, onlay or veneer adaptation to complex preparation shapes in each case.

Offset copings

The option is provided to design a simple coping with a uniform wall thickness.

Framework bridges

Framework bridges can be designed by placing bridge connectors between anatomic copings, offset copings and/or reduced pontics, or alternatively by shrinking anatomic waxup scans in the software. Also, framework bridges can be designed in combination with pre-reduced pontic tooth model libraries, e.g. so-called "thimble crowns" (availability depends on the used pontic tooth library).

Overpress crowns

On top of a reduced crown or reduced pontic, an additional "overpress" surface can be generated, which represents the difference of the full anatomic surface minus the reduced surface. The overpress part is supposed to be produced in wax to represent the designed chewing surface on top of a coping or framework bridge for manual post-processing. Therefore it does not necessarily cover the entire tooth and is NOT meant to be used as dental reconstruction directly. In the area of the chewing surface, a minimum thickness for the overpress crown can be defined.

Tools for manual post-processing

An interactive "freeform tool" is available for manual change of the designed surface.

Anatomical deformation

Individual parts of tooth library models can be selected by clicking and can then be reshaped interactively (for example, cusp, tooth above the equator, and the mesial, distal, buccal or lingual side of the tooth).

Virtual wax stylus

The virtual wax stylus simulates the application and removal of material.

Smoothing

The surface to be edited is smoothed.

Visual representation

Distances and overlaps (with respect to antagonists and adjacent teeth) can be displayed visually if desired. Spacing and material thickness can be measured.

Attachments

Attachment parts can be applied to bridges or individual bridge elements. The attachment must be present as a waterproof mesh without any self-intersections. It is loaded in the software by the user, then positioned manually so that it touches exactly one bridge part or exactly one merged bridge (no intra- or inter-coronal attachment). Hereby only the primary attachment part is designed. Similarly, the user can also add or subtract attachment parts from the designed surface in the "freeform tool" of the designed dental restoration. In any case, in the area where the attachment part shall be applied to the dental restoration, the user must make sure that the dental restoration is waterproof without self-intersections or open boundaries in that area. In some cases depending on the material and surface type, the "freeform tool" on waterproof meshes offers a "3D text attachment" tool to add 3D text into the designed dental restoration or designed dental appliance e.g. with the purpose to recognize the part after production.

Output format

Design data are output in the open binary .STL file format (except for closed system where reseller uses dedicated encrypted formats). Additional information to support processing on milling machines (e.g. tooth axis, the position of the preparation margin) is saved in the open .constructionInfo XML format.

Graphical user interface

The software provided to Licensee has a standard graphical user interface developed by the Licensor, which is not exclusively for Licensee. It is operated using expert menus or a wizard as desired.

User help is available in German or English; further languages (initially only those written from left to right) can be added by the customer by adapting a translation file in XML format. The customer can also adapt icons or the color representation of 3D elements simply by editing the configuration files in the XML format and replacing graphics files. Changes to the GUI are possible beyond that and can be the subject of a separate agreement (at additional cost).

Automated sending of error reports

To ensure software quality and detect errors at an early stage, in the case of an error (if technically possible) an error ("exception") report will be sent automatically. The transmission takes place only after the customer has been informed via a dialog and has given permission. No data related to persons is sent.

Prerequisites

Minimum hardware configuration to run DentalCAD:

CPU: Quad-Core and 2.8 GHz; RAM: 4GB; Graphics: Nvidia or AMD Radeon dedicated GPU with at least 1 GB graphics memory, OpenGL 4, DirectX 11.1, Shader Model 5 and a graphics driver dated August 2017 or newer; Screen resolution: 1080p (1920x1080, or higher); Power: 450 Watt.

Software requirements for DentalCAD, one of the following operating systems installed:

Microsoft Windows 7 with at least SP1, 64-bit version; Microsoft Windows 8.1 64-bit version; Microsoft Windows 10 (Versions 1607, 1703 or 1709) 64-bit version.

Note: Some modules might have additional requirements, see module specification below.

.Net requirements:

Microsoft .NET Framework 2.0; Microsoft .NET Framework 3.5 SP1 and later; Microsoft .NET Framework 4.5.2 or 4.6.1 or 4.6.2 or 4.7.1; Be advised that in Windows 8 and 10, the installation of the .NET 3.5 SP1 framework cannot be done via Installer .NET 3.5 SP1 due to Microsoft restrictions. To perform the installation properly, please check the Framework checkboxes in the Features menu of your operating system. For more information, please visit https://msdn.microsoft.com/en-us/library/hh506443(v=vs.110).aspx

Peripherals/Human Interface devices (HID):

Standard computer keyboard required; Standard computer mouse required; Multitouch screen (10 Finger-Touch capacitive) optional/supported; Certain 3D mice from 3dconnexion and SpaceControl are supported. Please be advised that any special LED/display-powered 3D mouse macros/buttons are not supported.

A free USB-Slot is required to connect the required USB license copy protection Dongle (HID-Device). Internet connection is generally recommended. For subscription-based licenses, a permanent internet connection is required.

For current hardware requirement specification please visit http://wiki.exocad.com/wiki/index.php?title=Hardware_Requirements

Disclaimer

The Licensee is aware that the accuracy of the overall result depends to a great extent on the accuracy of the input data, the measurement and production process used, and the precision of the CAM system used for production. A particular accuracy of the output data is explicitly not warranted.

The software supports the work of dental technicians or properly trained professionals in dental labs or dental practice labs; the designs generated automatically are suggestions using parameters preset by the user or provider. There is no check for medical or technical correctness. The scope of

options given enable the user to shape the design freely; thus, responsibility for the final result lies with the user.

For further details about the specification, requirements, and limitations of the specific version the release notes and the user manual of the related products apply additionally.

II. Modules

Disclaimer:

For any module, the Licensee is aware that the accuracy of the overall result depends to a great extent on the accuracy of the input data, the measurement and production process used, and the precision of the CAM system used for production. A particular accuracy of the output data is explicitly not warranted.

Module "Virtual articulator"

The virtual articulator enables simulation of movements of a real articulator using the software. It provides the following functionality:

- Calculation of movement paths, taking into account the dental models loaded (upper and lower jaw scans) as well as articulator parameters set by the user (such as condylar path inclination). Four standard directions of motion are calculated (protrusion, retrusion and left/right laterotrusion)
- Visual representation of the calculated movement
- Visual representation of overlaps between tooth reconstructions and teeth of the opposing jaw part (from scan data) contained in the design
- Adaptation of the shape of designed teeth, taking into account the scan of the opposing jaw part and the calculated path of movement

Requirements for Virtual Articulator:For correct predictable results, the input scan data from the 3d dental scanners must already be aligned correctly relative to the software's standard coordinate system for the selected supported articulator. In other cases, the software can semi-automatically predict an average position for the scan data relative to the articulator which the user must then correct manually. Additionally, the scan data of both jaws must not intersect each other. In case of very small (less than 0.05 mm) and simple intersections, the software might be able to correct those automatically by adjusting the scan data while using the virtual articulator. Since the virtual articulator relies on a (simplified) physical simulation, any remaining intersection might lead to wrong results of the simulations of jaw movements. Similarly, unrealistic distances between both jaw scans might also lead to unrealistic results, e.g. when both original scanned jaw models are supposed to be in contact, then both the 3d scan data should have contact or at least not have a distance bigger than 0.05mm, because the virtual articulator is supposed to bring both jaw scans into contact if possible.

Module "Implant module"

The implant module enables the design of tooth reconstructions supported by implants, e.g. for custom abutments, screw-retained crowns, or screw-retained bridges. It offers the following functionality:

- Determination of the position of implants from 3D scan data of markers (scan abutments) and a marker library, where the user must select the correct implant system for each tooth from the supported implant library systems.
- Design of the emergence profile of the implant-supported construction, with consideration of 3D scan data of a gingival mask as required
- Design of custom abutments and screw-retained bridges using previously determined implant positions as well as geometries stored in the library, which describe the contact area for the interface (e.g. titanium base) or the implant (not available in all markets depending on local medical device regulations).
- Alternatively, the position of implants in the 3D scan data can be estimated by manually defining the screw channel position and direction in the scan

data as well as the margin of the scanned titanium base or a scanned abutment. However, this approach without markers is generally not recommended due to the lower precision and unreliable results.

Implant Data Provision

The module includes an "implant library" that contains the markers and the predefined geometries for supported implant systems. If the Licensee wishes an expansion of the implant library, then an inclusion of additional implant data can be effected in the software if the Licensee provides accordingly suitable input data. The Licensee assures the Licensor in this case that it is entitled to the permanent surrender of the input data in the scope necessary for the purpose and grants the Licensor with the delivery of the input data the corresponding right also to deliver the integrated data to other customers free of charge. Further technical and legal details for integration of implant library data is available on request and might be bound to a separate legal agreement ("Implant library integration contract"). For correct workflow of the implant module with implant library, the scanner used must be able to make multiple scans of the situation (with and without scan abutments, with and without gingival mask) and output these in a correctly registered form (i.e. in the same coordinate system as the jaw scan data). The same requirements described under "input data" for the scan data apply to the additional scan abutment scan.

Module "Jaw Motion Import"

The "Jaw Motion Import module" requires the Articulator Module as a prerequisite. It allows to import jaw motion records from compatible devices based on the Licensors standard jaw import XML file format and visualize them in a 2D user interface. To use the imported data for design, the 3d motion tracking device must either write the motion data in the correct coordinate system related to the 3d jaw scan data of the patient. Alternatively, a 3d "bite fork scan" must be performed in an external 3d scan software that allows the software to transfer the jaw motion data into the 3d jaw scan data coordinate system of the patient using semi-automatic registration (defining points and then best-fit registration). Hereby, parts of a standard "bite fork" (compatible to one supplied as library mesh in the software) must be contained in the additional "bite scan" as well as parts of the 3d jaw scan data of the patient, so the software is able to match both data sets. Once the jaw motion records were transferred to the 3D jaw scan data coordinate system successfully, the user is able to use these motion data instead of the virtual articulator generated motion data to visualize the jaw movement of the patient, as well as for adapting dental restorations occlusions to the dynamic antagonist simulation based on the recorded motion.

DISCLAIMER: The Module Jaw Motion Import is NOT a medical device and especially must NOT be used for diagnostic purposes. It is a pure visualization feature for helping while designing dental restorations by dental labs as an alternative patient specific method to using a virtual articulator. Hereby, the outcome of the dental restoration relies heavily on the quality of the measured input motion records of the jaw motion tracking device, as well as its relative positioning to the 3d jaw scan data and/or bite registration scan. The software cannot detect or correct possible errors in the jaw motion data, and it cannot correct or detect possible registration errors between jaw motion data and the 3d scan data (e.g. jaw scans).

Module "Bar"

The Module "Bar" allows designing dental bars between fixating teeth like crowns, copings, primary telescopes or simple cylindrical shapes i.e. the so-called "bar pillars". The bar design is also possible to be fixated on top of implants but then requires the "Implant Module". The shape of the dental bar is generated from a guiding user defined curved or straight center line and its outer shape is defined by simple standard 2D outlines from a library ("bar library"), whereas some shapes have interactive user adjustable parameters e.g. width and length. For each defined section of the dental bar, an individual shape of the dental base can be defined by the user. The dental bar has a user-defined "bar direction" that is used to align all shapes accordingly (e.g. the secondary insertion direction of a dental supra structure). If cylindrical bar pillars are designed by the

user, then the bar direction can be used to align the top level part of the bar pillars accordingly. The user can also add or subtract attachments to/from the designed dental bar, with the same requirements as the "Attachment" feature of the standard software. These attachments can also be aligned to the "bar direction" by the user. The user can also include manually placed and optionally reduced pontic tooth library models into the dental bar.

Module "Model Creator"

The „Model Creator" module allows the design of dental models based on 3d optical intraoral or impression scan data with the following additional requirement to the normal scan data input requirements: All scans must be unsegmented 3D surface scans without additional artificial geometric data e.g. ditching (note: especially scans of sectioned models are not supported). The purpose of these dental models is solely for visualization and handling purposes during the dental restorative process. Prior to designing dental models, the user must define preparation margins, and also define implants with the same tools that the Standard CAD software offers.

There are two main types of models available, so-called "plated models" (to be produced to fit on pre-manufactured model plates), and so-called "plateless models" (to be designed relative to a user-defined plane). In both cases, the user must manually align the scan data to the base plate ("plated models") or to the base plane ("plateless models"), watching carefully the size constraints of the 3d printer or the size of blanks in case of subtractive manufacturing. In the case of "plated models", the user can define removable sections using split planes typically orthogonal to the model plate (if necessary the split planes can be tilted). In the case of "plateless models", the user can define removable dies. For Inlays, Onlays, and Veneers, a special user definition for the removable or healthy tooth sections is required if the affected tooth shall be created as a removable die. For models with lab analogs, a compatible lab analog library is required. For those models with lab analogs, a removable gingiva section can be defined around the lab analogs. For plated models, the user can choose to convert the upper part of the model sections around lab analogs to be the removable gingiva mask. For plateless models, the user can define a spline/closed curve around the lab analog as the border of the removable gingiva mask.

In the case of plateless models, small dental model attachments can be added in a dedicated model attachment wizard step. In the case of plated models, the freeform model feature can be used to apply small attachments. In both cases, the requirements for the standard software "Attachment input data requirements" apply. Similar to dental model attachments also 3D text can be applied as attachments.

Abutments (from restoration design) can be used as detachable dies (currently for plateless models only).

DISCLAIMER: The quality, precision, and accuracy of the dental model rely heavily on the production system e.g. the 3d printer or milling machine and its materials. The software comes with some presets for some 3d printers, but in general, the reseller of the software or the production system or even end-user is supposed to calibrate his model manufacturing parameters for his specific printer to allow the best fitting. Since typical manufacturing systems for dental models are far from being highly precise or accurate, it is NOT recommended to use machine produced models as a tool to check the clinical fitting of restorations e.g. the crown's preparation margin or fitting of implants or abutments or screw retained crowns. Creating models with lab analogs requires the "Implant Module" to be activated. The models can only be calculated correctly by the software if the scan data is free from scan artifacts and only represents real patient data (note creating models from sectioned models is not supported). Any artifacts or excess scan data must be removed by the user, e.g. in the original scan software or using the mesh editor or freeform scan data tools available inside the Model Creator software.

Module "Provisional"

The "Provisional" module allows designing individual temporary crowns and bridges using the eggshell technique, i.e. thin shells where only the anatomic surface matters and which are "filled" later by the dentist with cement, glue or ceramics after preparation of the tooth to allow correct fitting to the

actual tooth preparation. Provisional pontics can similarly also be designed, whereas the generated shape simulates a tooth that is supposed to replace a later extracted patient tooth. The temporaries are created based on the scans of the pre-operative situation; the shape of the provisional crown/bridge can either be copied from the original anatomy (if the tooth is still in reasonable condition), or the tooth model library can be used.

Module "DICOM-Viewer"

The "Dicom-Viewer" module allows loading 3D volume data by dental CT/CBCT scanners that follow the DICOM CONFORMANCE STATEMENT and output the standard DICOM format. These DICOM files can be loaded either without any optical scan data or additionally loaded to optical scan data of the patient and registered using a simple 3D point registration. Hereby, the loaded DICOM-Data can be visualized using ISO surface mode with a user-defined threshold (ISO value) as a surface visualization, or by user-defined cut planes through the 3D volume data using grayscale colors. Furthermore, the ISO value surface visualization can optionally be converted to a surface mesh and stored to supported mesh file formats for visualization purposes. The intended use for the "DICOM-Viewer" module as part of the Licensors lab software package is only for visualization purposes while designing dental restorative case using the Licensors DentalCAD software. The module must NOT be used for any diagnostic or medical purposes.

Additional hardware requirements for that module: 6 GB of RAM and NVIDIA or AMD Radeon graphics card with 1,5GB video RAM or better.

Module "Bite Splint"

The "Bite Splint" module allows the design of night guards. Output files can both be milled or 3D printed if supported by the respective hardware (e.g. scanner, milling machine, and 3D printer). Responsibility to scan both jaws in suitable relation to each other lies with the user.

Module "TruSmile"

The "TruSmile" module allows a more realistic appearing visualization of dental restorations, especially for full anatomic teeth, as well as a more realistic visualization of reconstructions to be produced in metal e.g. for marketing purposes.

Module "Full Denture"

The "Full Denture" module provides a guided workflow for the design of full dentures with exactly 14 teeth for upper and 14 teeth for lower at the same time, based on the combination of specially adapted virtual premanufactured full denture tooth model libraries and virtual gingiva modeling. The purpose of the full denture tooth model library is to work with premanufactured full denture tooth libraries. Therefore, the loaded virtual tooth models cannot be re-scaled by the user, and some of their relations are also fixed in the software depending on the library. After the user carried out a digital model analysis by clicking point, drawing lines, or defining areas on the patients scan data, the software automatically suggests an initial set-up based on the analysis results and guides the user through the further design steps. Full dentures can be designed exclusively in edentulous jaws (no remaining teeth, preparations, implants etc.) and only for both jaws at the same time.

The input data (3D scan of the maxilla and mandible) must both be correctly positioned relative to each other, as well as correctly present in the articulator coordinate system specified by the Licensee. The result of the full denture design module for each jaw is a designed denture base which was optionally adjusted in a way, that the basal and approximal adapted premanufactured full denture tooth models can be inserted into it. For compatibility with a milling process, a milling tool diameter compensation can be performed on the full denture base, which creates spacing and reduces the virtual gingival model to allow physical insertion of the (adapted) premanufactured denture teeth. Alternatively, the designed denture base files are also suitable to be loaded into typical 3d printer software for further processing. Depending on the selected full denture tooth library, the virtually adapted full denture teeth

are not available as an output of the full denture module, because the virtual premanufactured full denture tooth models libraries are typically licensed by third-party tooth manufactures. Hence, they are not licensed for reproduction and are supposed to be encrypted at all times. In those cases, a compatible closed production system must be used. In no case, neither the Licensoee nor the user is allowed to use the full denture tooth model library to reproduce individual full denture teeth independent from an individual patient case, i.e. the full denture tooth libraries are only licensed to design patient-specific full denture cases.

Module "PartialCAD"

The "PartialCAD" software allows designing basic dental removable partial frameworks following a guided workflow suitable for 3d printing in soft materials. The user can design the dental partial framework mesh, major connector, clasps, lingual aprons, finish lines, and I-Bar retainers. The input scan data for "PartialCAD" shall be unsegmented jaw models and should have exactly one mesh per jaw in one of the supported mesh file formats: .STL, .OBJ, . PLY binary OFF. In combination with the DentalCAD software, pontic library models, anatomic copings, crowns, and primary telescopes can also be included as part of the final partial framework or as visualization object (requirement: use unencrypted tooth libraries and unencrypted open output file formats). Additional minimum hardware requirements for Module "PartialCAD": The software will work with NVIDIA and AMD Radeon graphics cards only. A minimum of 2GB graphics memory is required (3GB preferred). A minimum CUDA level of 3.0 or OpenCL 1.2 is also required (see the list of CUDA levels of different graphics cards). Older or entry-level NVIDIA chips might not work well, or will result in poor performance. Intel integrated graphics chips are not supported for Module "PartialCAD".

Module "In-CAD Nesting"

The "In-CAD Nesting" module allows the user to interactively place single- or multi-unit restorations in a suitable milling blank, and export that information for further processing in a separate or third-party CAM Software.

The responsibility of selecting a suitable milling blank lies with the user.

The module "In-CAD Nesting" together with the module "TruSmile" also offers multi-layered blank visualization. Only a single cylindrical milling support (also known as sprue) can be generated.

Note: Advanced nesting functionality requires the dedicated "Nesting" module.

Module "Nesting"

The "Nesting" module allows the user to interactively place designed restorations in a selected milling blank, define simple cylindrical milling supports (also known as sprues), and invoke a supported third-party tool path calculation software (not supplied by the Licensor) to generate tool paths, and then use a supported third-party machine control tool/API/ network protocol (not supplied by the Licensor) to send the tool path calculation file to a supported milling machine for production.

The "Nesting" module together with the "TruSmile" module also offers multi-layered blank visualization.

Module "Smile Creator"

The "Smile Creator" module allows the esthetic planning of restorations, using 3D scan data and photos. On load, photos will be converted to planar 3D objects, which can subsequently be viewed as part of the 3D scene, to provide an approximate preview of a possible prosthetic outcome, using a tooth library. During the smile design, the situation and tooth setup will be visualized from various angles. The "Smile Creator" module works only in combination with the "TruSmile" module.