# D2P®

# From DICOM to PRINT

This document contains the basic 'Instructions for Use' of D2P Software. Detailed instructions can be found in the 'User Guide/ User Manual'. English is the language used in the D2P software interface.

## Description

The D2P® is a stand-alone modular software package that is aimed for use by medical personnel for the creation of 3D digital models. It addresses and consolidates all 3D model preparation steps into a single workstation while relying on unique automatic segmentation tools and functions that will minimize the effort and time associated in the creation of a model.

Patient specific models that are created using the software can be exported in the form of several digital output files for use in a wide variety of applications including 3D printers, virtual reality devices, and CAD software.

## Intended Purpose

The D2P software is intended for use as a software interface and image segmentation system for the transfer of DICOM imaging from a medical scanner to an output file. It is also intended as pre-operative software for surgical planning.

## Indications For Use

### Software

The D2P software is indicated for any medical condition in which the use of computer-assisted planning and surgery may be appropriate, including cardiovascular, craniofacial, gastrointestinal, genitourinary, neurological, and/or musculoskeletal applications.

## Output File

The output file may be used to produce a physical replica. The physical replica is intended for adjunctive use along with other diagnostic tools and expert clinical judgment for diagnosis, patient management, and/or treatment selection of cardiovascular, craniofacial, gastrointestinal, genitourinary, neurological, and/or musculoskeletal applications.

# Precautions, Warnings, and Contraindications

## Precautions

- For vasculature, it is recommended to use slice thickness up to 3 mm. In addition, it is recommended to use scans of 512x512 or 1024x1024 resolution (columns x rows) and pixel spacing of 0.5-1 mm. Not following the recommended CT protocol may result in inaccuracies. For narrower structures such as used in neuro intervention, it is recommended to use slice thickness of up to 0.85mm. In addition, it is recommended to use scans of 512x512 or 1024x1024 resolution (columns x rows), Beam collimation 8-10mm, pixel spacing of 0.5mm. Scans should use standard contrast according to radiology department policy. Not following the recommended CT protocol may result in inaccuracies.
- The application should not be used in cases where following the standard CT scanning protocol or suboptimal CT data prevents the creation of accurate 3D model segmentation.
- Information provided by the system is intended to serve as an adjunct to information available from relevant patient data imaging sources. The information presented by the system is not intended for use as the sole base decision of planning and therapeutic use. In case of discrepancy between relevant patient imaging data and system results, the user should use the original imaging data.
- Where system results are to be used for supporting a decision regarding diagnosis or treatment, they should be interpreted only by or under the supervision of a competent medical professional.
- Prior to using this system, all operators must carefully read the operating instructions and be familiar with product operation.

- The determination of the working projection is subjected to the same patient position as during image acquisition. Failing to follow this requirement may result in an inaccurate projection orientation labels.
- Results generated by the application rely on user markings. If the guidelines in this guide are not followed strictly and accurately, the results provided by the application could be unreliable. Large deviations from expected results are usually the result of faulty user input or procedure.
- Since the software is designed to be able to use sub pixel values, the 3D reconstruction calculation has a maximal error of 1/2 pixel size.
- Editing of the digital 3D model directly affects its form and dimensions. Make sure you verify all changes made to the digital model with the patient's imaging data.
- Medical imaging may include the risk of radiation exposure to the patient. It is the responsibility of a qualified physician to determine if the benefits of using the D2P software outweigh such risks.

## ⚠ Warnings

- The Virtual Reality (VR) Implementation is not intended for diagnostic use.
- It is recommended to use the software within the hardware and/or network environment in which the cyber security controls have been implemented. Examples of controls include, but are not limited to, anti-virus, anti-malware, firewalls, and user login protections.
- It is recommended to use hard drive encryption solutions (e.g. BitLocker) to protect against data loss due to theft or unauthorized access.
- It is recommended to use the minimum hardware requirements referenced in Chapter 2, Instructions for Use, Minimum System Requirements to ensure D2P software functions as intended.
- It is recommended to follow VR manufacturer setup and operation instructions and that Headset positioning and sensors must be setup according to the manufacturer's directions to ensure best visualization comfort and image sharpness.

## Contraindications

There are no known contraindications to the use of D2P Software.

# Installing D2P

Start the installation by launching the **D2P installer**. Run the installer with administrator privileges. One way to do this is right-click the **D2P installer** icon and select **Run as administrator**. If you encounter any problems with this step, ask from your local IT Team for assistance. The **D2P Application Setup** will start. Follow the prompts. Once the installation is complete, the **Installation Complete** screen is displayed. Click **Next** to continue. Click **Finish** to exit the installation. D2P is now installed on your computer and a start icon appears on your Desktop.

# Minimum System Requirements

**To run D2P segmentation**

| Software | Hardware |
|---|---|
| Windows 10-64 bit | Intel Core i7 or equivalent<br>Intel CPU only. D2P does not currently support AMD CPUs |
| PDF viewer | NVIDIA GTX1060 or equivalent with ≥3GB memory<br>NVIDIA GPU only. D2P does not currently support AMD GPUs |
| DirectX 11 | ≥16GB RAM |
| | ≥500GB free hard disk space |
| | Screen resolution 1920x1080 |

**To run VR (Mesh and Volume)**

| Software | Hardware |
|---|---|
| Windows 10-64 bit | Intel Core i7 or equivalent<br>Intel CPU only. D2P does not currently support AMD CPUs |

| | |
|---|---|
| PDF viewer | NVIDIA GTX1080 or equivalent with ≥8GB memory<br>NVIDIA GPU only. D2P does not currently support AMD GPUs |
| DirectX 11 | ≥16GB RAM |
| | ≥500GB free hard disk space |
| | Screen resolution 1920x1080 |

## Recommended System Requirements

**To run D2P segmentation and VR**

| Software | Hardware |
|---|---|
| Windows 10-64 bit | Intel Core i7 or equivalent |
| DirectX 11 or higher | NVIDIA GTX1080 VR ready, equivalent or higher with ≥8GB memory |
| PDF viewer | ≥32GB RAM |
| | SSD ≥256GB for the software installation |
| | >500GB extra available disk space to store data |
| | Screen resolution 1920x1080 |

It is recommended to use the software within the hardware and/or network environment in which the cyber security controls have been implemented. Examples of controls include, but are not limited to, anti-virus, anti-malware, firewalls, and user login protections.

It is recommended to use hard drive encryption solutions (e.g. BitLocker) to protect against data loss due to theft or unauthorized access.

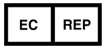
# Symbol Description

*Caution*
Symbol indicates a situation that the user must take into consideration to ensure the safe and effective operation of the equipment and associated accessories.

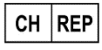

**Unique Device Identifier**
Indicates a carrier that contains unique device identifier information

**Manufacturer**

**Consult Instruction for Use**




**European Authorized Representative**




**Switzerland Authorized Representative**

**CE Marking Symbol**


**UKCA Marking Symbol**


**Medical Device Symbol**
The symbol was developed specifically to meet the GSPR 23.2 (q) “an indication that the device is a medical device”

Contact customer service (contact information provided below) to request a paper copy or digital download of the user guide. Paper copies will be provided within 7 calendar days at no additional cost.

## Company Contact Information

**The legal manufacturer is:**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