



## Installation manual

Date of issue: **23/03/2022**  
Revision number: **v1.2**  
Applicable software version: **v8.\*.1.\***

# Mediadent V8 Installation Manual

## 1 Installation instructions

Prior to installing Mediadent software, please verify whether your system and environment satisfies the **Minimum System Requirements**. This information is part of the Instructions For Use ("user manual"), which can be downloaded from [www.imagelevel.com](http://www.imagelevel.com).

Typically, the Mediadent installation is performed by a competent technical support engineer. Please consult your local Distributor for installation and configuration services.

You will find **2 USB sticks** in the package :

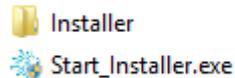
- The **Imagelevel Software USB stick** : this stick contains the Mediadent software
- The **Safenet USB stick** : this is the security dongle

To start the installation of Mediadent :

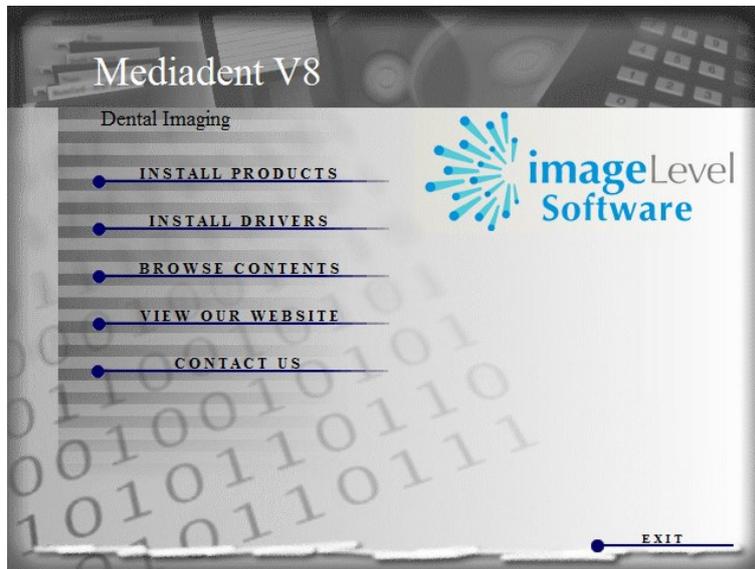
**Step 1:** Insert the **Imagelevel Software USB key** into the PC and navigate with the File Explorer to the USB drive.



Double click on the **start\_installer.exe** to launch the installation menu.



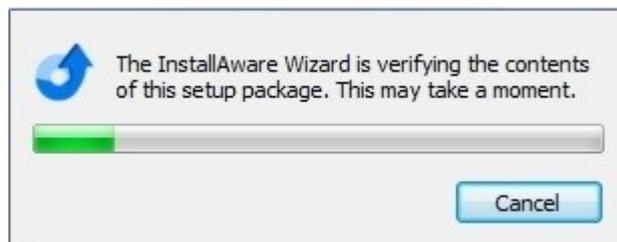
The installation menu will launch:



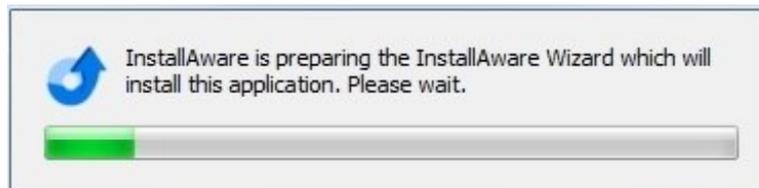
**Step 2:** Click on 'Install Products'.



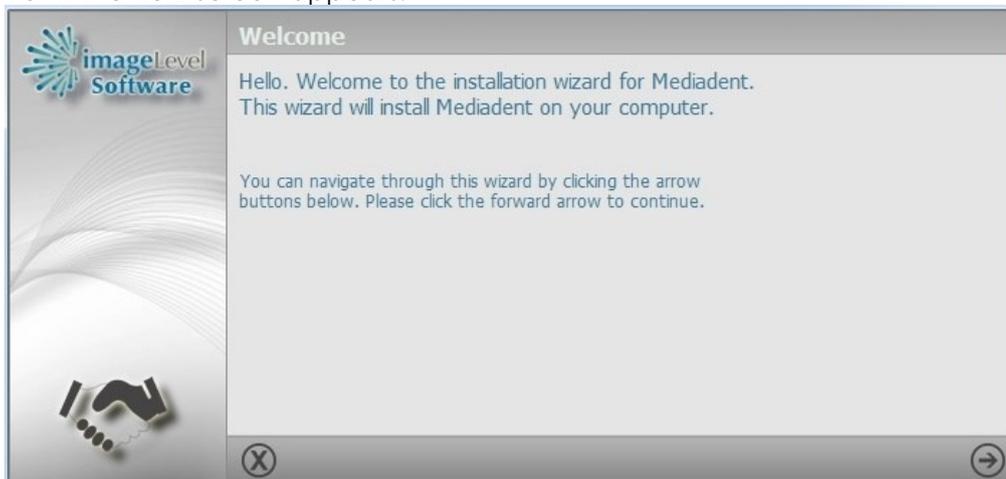
**Step 3:** Click on 'Install Mediadent V8'  
The installation of Mediadent will now start.  
The following window will appear:



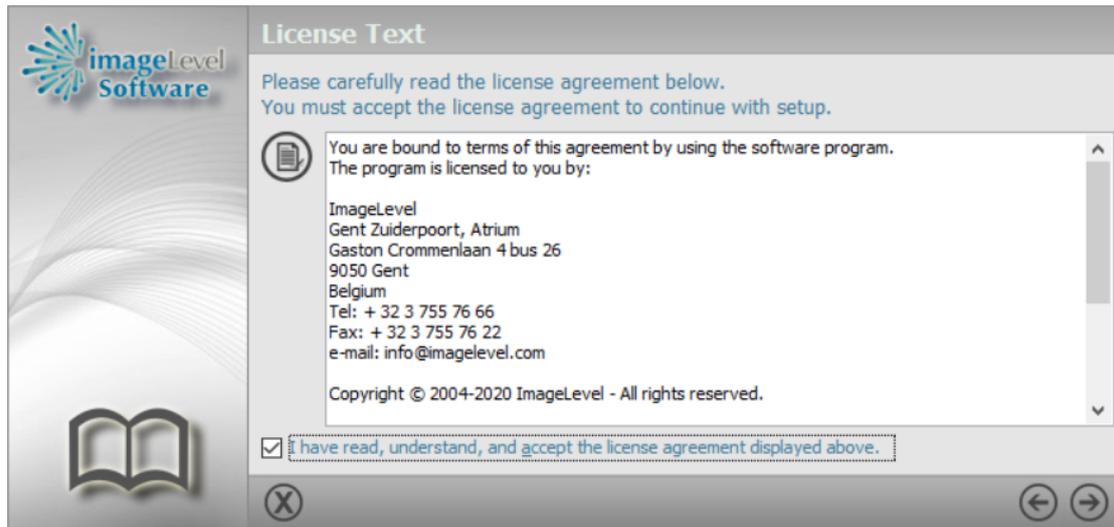
After verifying the contents of the package the installer continues showing:



Wait until the next screen appears:



**Step 4:** To continue click 



**Step 5:** After reading the license agreement, check 'I have read, understand, and accept the license agreement displayed above' and click 



**Step 6:** If there is a Safenet USB key connected to your computer it will be detected and you will have to **remove** it. The installer will continue automatically. Note: If there is no Safenet USB key connected to your computer, this step will be skipped.



The installer is now installing the local key drivers on the system.

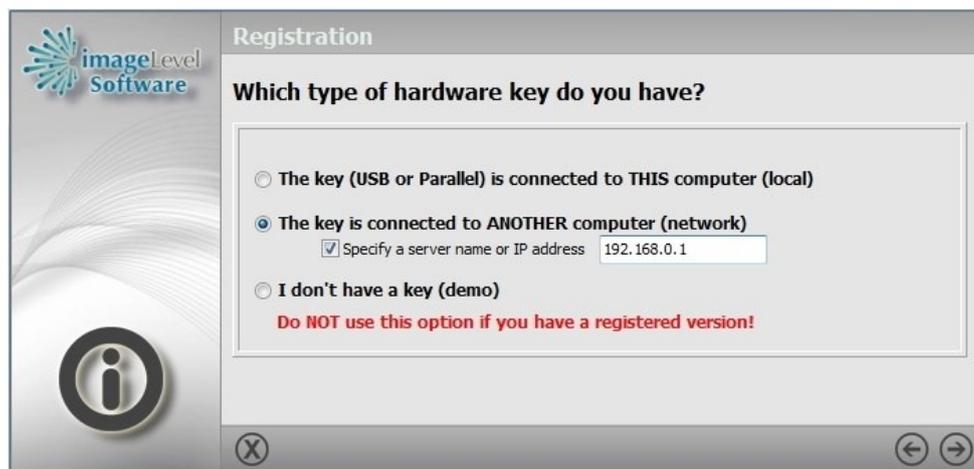


**Step 7:** If you have a Safenet USB key, **plug it in** a USB port. The installer will detect the key and continue. If you do not have a USB key, or there is a network key on another station click 



If the USB key is plugged in, the installer will detect it. You can continue with **Step 9**.

If you don't have a key or it is installed on another computer in the network the installer will show the following window:



If the key is connected to **another computer**, Select: **'The key is connected to ANOTHER computer (network)'**. If you know the IP address of your computer sharing your key you can specify it by clicking **'Specify a server name or IP address'** and entering its IP (computer network name is not recommended). Specifying the IP address is not required, however it can be helpful if the installer cannot find the shared key on the network. Using the IP address implies that you work with fixed IP addresses.

Continue with **Step 9**.

If you don't have a key, the installer will continue at step 9.

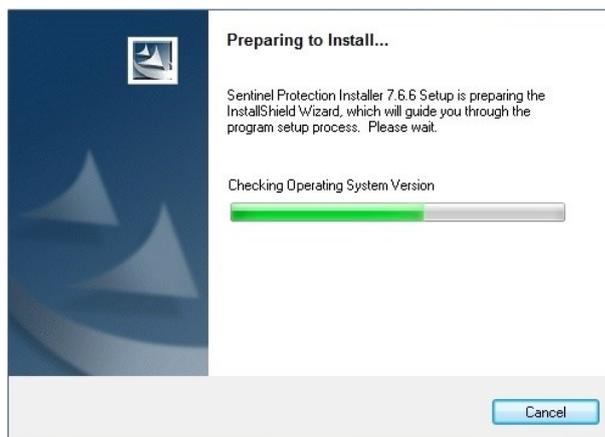


**Step 8:** If you don't have a network key please continue with **Step 9**. However if you do have a network key, the installer will detect it and offer you to install the server application to **share** your key on the network.

**Step 8.1:** Navigate to the setup of your **firewall** and **manually** allow the indicated port (the installer cannot change your firewall settings). Then check **'Yes, install the server application'** and click 



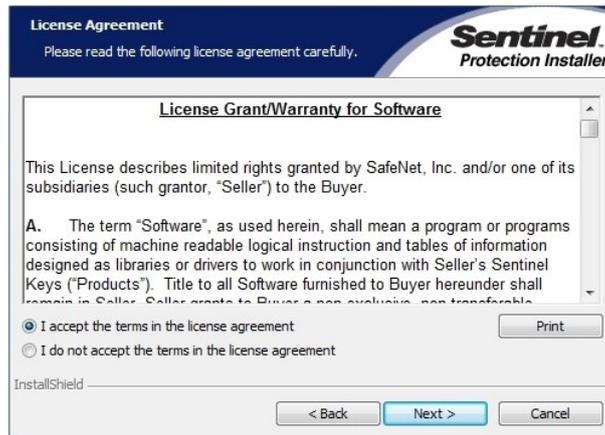
**Step 8.2:** Remove your USB key from the computer. Once you have removed it, the installer will continue automatically.



The network application installer will launch, wait for the next window:



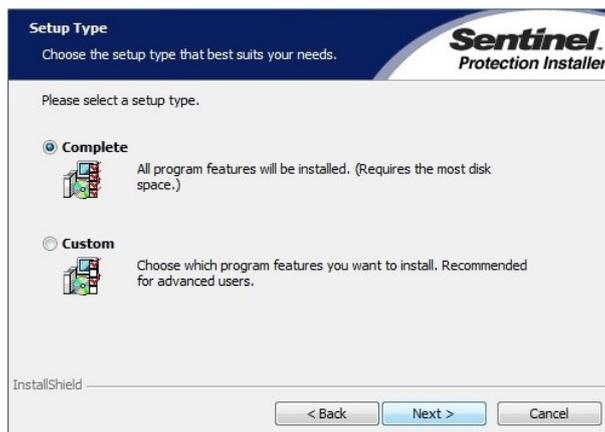
**Step 8.3: Click Next**



**Step 8.4: After reading the license agreement, check 'I accept the terms in the license agreement' and click 'Next'**



**Step 8.5: Click 'No'**



**Step 8.6: Select 'Complete' and click 'Next'.**



**Step 8.7:** You can continue clicking 'Install'.



The installer will install the network application.  
Afterwards the following window will appear:



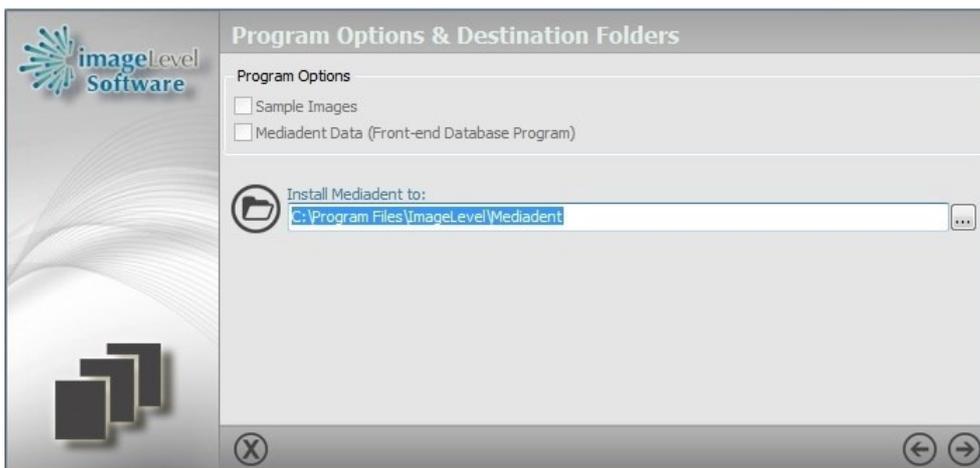
**Step 8.8:** Click 'Finish'. The installation of the network application is complete, the main installer will now continue.



**Step 8.9:** If you have a USB key, plug it in the USB port. The installer will detect the key and continue. If you do not have a USB key, click on 



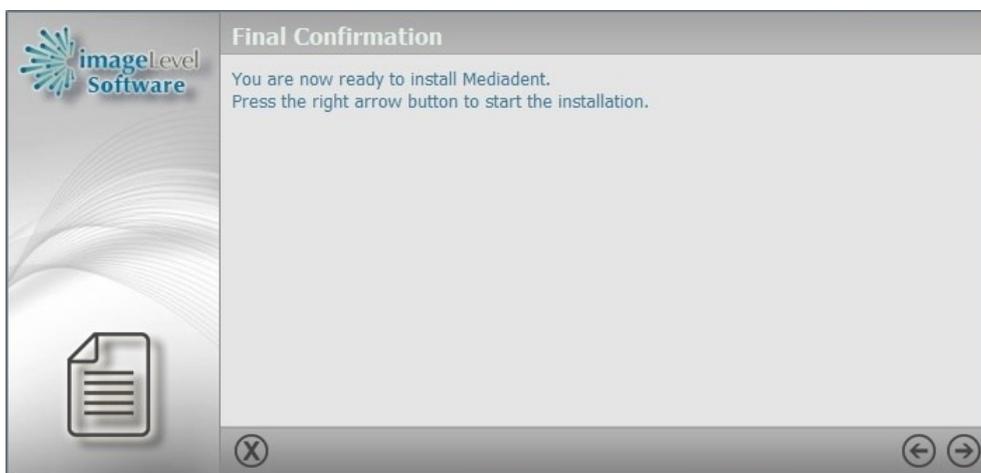
The installer will detect your key and continue automatically.



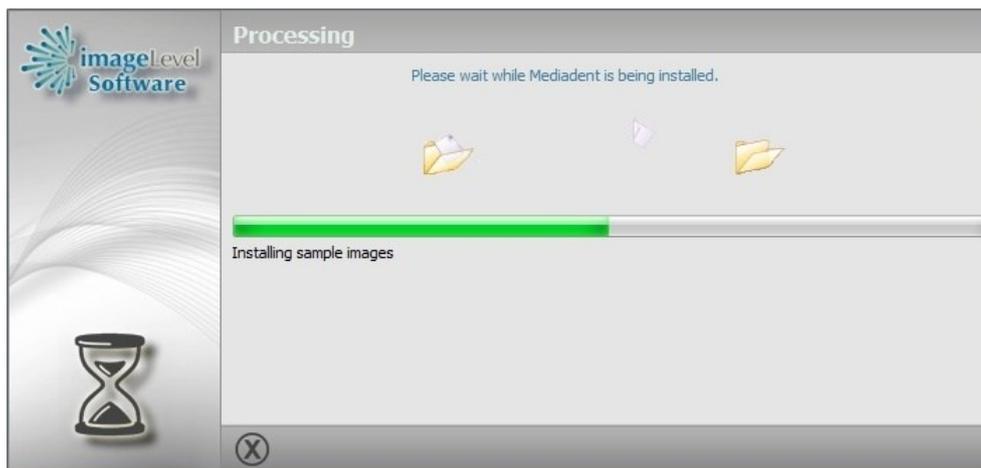
**Step 9:** Select the program options you want to install, then click  Note: If you like to install Mediadent Data and/or Sample Images, please check the boxes. The additional installation directories will be shown:



You can change the destination folder for Mediagent, Mediagent Data and the sample images. However the **default location** is recommended.

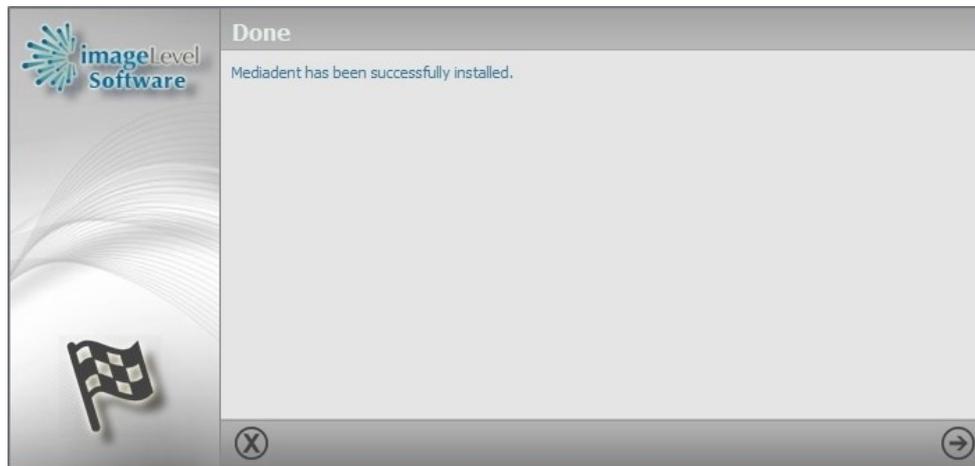


**Step 10:** If everything is set please click  to continue the installation.



The installer will copy the files to your computer, it is possible that some pop-ups will appear and disappear. Just let the installer take care of it.

When the installation is complete it will be shown:



**Step 11:** The installation is now complete, click  to finish the setup.

**Step 12:** The installation can be considered successful if all of the following conditions apply:

- The installer executed successfully,
- No errors were displayed during the installation,
- Mediadent software starts without any errors displayed during the installation,
- Mediadent software does not start in DEMO-mode (if so: there might be a problem with the security dongle).

**Step 13:** We refer to the “Mediadent Setup” instructions, part of the Instructions For Use (“user manual”) for further configuration of the Mediadent software. In case of questions, don’t hesitate to contact your Dealer for technical assistance.

## 2 Uninstallation instructions

Mediadent can be uninstalled, similar to any other Windows program.

### Uninstall from the Start menu

1. Select Start and look for *Mediadent* in the list shown.
2. Press and hold (or right-click) on *Mediadent*, then select Uninstall.

### Uninstall from the Settings page

1. Select Start , then select Settings > Apps > Apps & features.
2. Select *Mediadent* and then select Uninstall.

### Uninstall from the Control Panel (for programs)

1. In the search box on the taskbar, type Control Panel and select it from the results.
2. Select Programs > Programs and Features.
3. Press and hold (or right-click) on *Mediadent* and select Uninstall or Uninstall/Change. Then follow the directions on the screen.

### 3 Medical Device Information

 <p><b>Corilus SA / NV</b> Gaston Crommenlaan 4 9050 Ghent, Belgium</p> <p>Tel: +32 3 755 76 66 Fax: +32 3 755 76 22 <a href="mailto:info@imagelevel.com">info@imagelevel.com</a> <a href="http://www.imagelevel.com">www.imagelevel.com</a></p>		<p>Mediadent is a registered Medical Device.</p>
		<p>The following Mediadent modules with a medical purpose in Mediadent are covered by the CE mark: Core, Viewport, Optimize, Calibration, Measurements, 3D Viewer and DFO.</p>
		<p>This document is also made available in other languages. Please contact your Distributor to obtain this document in your local language.</p>
<p><b>Intended purpose of Mediadent</b></p> <p>Mediadent is an imaging software for dental and maxillo-facial professional users only, i.e. licensed dentists, orthodontists, and dental assistants. Mediadent visualises, processes and saves digital or digitized images acquired with dental imaging devices. With Mediadent, images can be sent to various archiving and communication systems.</p> <p>The Mediadent software is to be used on a computer with a Windows operating system in the dentist's practice or the dentist work area (office).</p> <p>Mediadent proposes various digital image processing tools to improve the quality and diagnostic value of the acquired 2D and 3D images. It allows the user to magnify/reduce images, apply pre-defined filters such as image sharpness and contrast and to perform measurements on the images. The Dental Facial Orthopedics (D.F.O.) module permits the orthodontist and maxillo-facial surgeon to perform automated cephalometric analysis.</p> <p>Mediadent aims to facilitate image interpretation by providing the user a clear, enhanced view of the dental health of the patient and subsequently support diagnosis, treatment planning and follow-up.</p>		
<div style="display: flex; align-items: center;">  <div> <p><b>Warnings and precautions</b></p> <ul style="list-style-type: none"> <li>• Users of Mediadent should be dental healthcare practitioners qualified to perform and interpret dental imaging.</li> <li>• Introduction training on the use of Mediadent software is provided by your dealer during the installation process. Users also receive access to the full set of documentation, available via <a href="http://www.imagelevel.com">www.imagelevel.com</a>. In case of further questions regarding use, the user is requested to contact the dealer for support or to request a formal training to be scheduled.</li> <li>• This software is an aid to diagnosis only. You must apply your professional training and judgment before deciding a course of treatment.</li> <li>• Installations may only occur on environments that fulfill the minimal system requirements (Section 3.1). The user is responsible for the supporting infrastructure (e.g. computer maintenance, network connectivity, electrical power) and its stability.</li> <li>• The minimal system requirements (Section 3.1) inform the user that the use of virtualization is not officially supported. Please, contact your dealer if you have questions about the use of virtualization.</li> <li>• Radiographic images are not for diagnostic use when viewed on displays or monitors that do not meet minimum system specifications (Section 3.1).</li> <li>• Any connected devices must be present on the compatibility list (see our <a href="http://www.imagelevel.com">www.imagelevel.com</a> for the complete overview) to be officially supported.</li> <li>• The user remains responsible for verifying the quality of images and the associated meta-data while using Mediadent software and when importing to and exporting from Mediadent.</li> <li>• It is recommended that you do measurements or drawings only on calibrated images. Doing this on an image with no calibration information requires use of a reference segment of known length.</li> <li>• Annotations and measurements made in the software are under your own responsibility. A radiographic image is a two dimensional image of a three dimensional object, and measurements may be subject to errors.</li> <li>• Measurements are only informative and operations requiring precise positioning on the patient are under your own responsibility.</li> </ul> </div> </div>		

- Panoramic or OPG images, by their nature, contain distortions due to magnification both vertically and horizontally. Any calibrations on these image types must be seen as rough guides that apply only to the immediate vicinity of the calibration. Inserting objects of pre-determined length such as implant simulators provides approximative information.
- Patient orientation information is not provided for intraoral images, computed radiography (CR) images, cephalometric oblique images or color images. Orientation of these images depends on user manipulation and patient positioning.

#### **Serious incidents**

Please report any incidents relating to Mediadent software without delay to your dealer. Your dealer shall do what is necessary to fulfill their legal and contractual obligations and to help mitigate the incident as soon as possible.

You may also contact your local competent authority for vigilance. For EU, the list of contact details is available via their website.

#### **Residual risk**

Corilus would like to draw attention to the following residual risks associated with the use of Mediadent:

1. Software bugs are inherent to any software system, such as Mediadent. Corilus has processes in place to prevent, identify and resolve known bugs timely. Despite these efforts, the risk of an unknown bug in Mediadent, which could potentially lead to information being wrongfully processed or displayed incorrectly, is nonetheless inherently present.
2. Corilus attaches the greatest importance to safeguarding information security and data protection for its products and related services. Nevertheless, cybersecurity is a joint responsibility between Corilus and the users of the software and a security incident always remains a potential risk in a connected environment. As a user of Mediadent, we therefore strongly advise to protect your workstations by keeping your operating system and SDK/drivers up to date and by installing firewall and endpoint protection software (e.g. antivirus).
3. Mediadent relies on correct use by the user. To support correct use, a minimum requirements list (part of this user manual), training materials and user-documentation on Mediadent are made available and updated on a regular basis by Corilus and its Distributors. Yet, human error in the use of Mediadent cannot be ruled out and could possibly lead to erroneous output.
4. The user remains responsible for the dental imaging hardware's maintenance and configuration. Errors directly associated with a faulty dental imaging hardware might result in a risk in the Mediadent software (e.g. source image comes into Mediadent poorly calibrated). Mediadent can't be held responsible for any malfunction of the devices it interfaces with or any wrong images (e.g. not calibrated correctly) that are sent to Mediadent.
5. Corilus wishes to provide state of the art imaging software and best of class service and support. That is why, we have set up and maintain an effective Quality Management System, based on the ISO-13485 standard. Even though we continuously improve our quality processes, there is always a small chance that an error occurs which potentially impacts the product's performance or safety. In such a case, we ask the user to contact Corilus as soon as possible (via the Distributor, if relevant) so that we can identify the root cause and take the necessary corrective and preventive actions.

All identified risks are reduced as low as possible and none of these residual risks are deemed unacceptable. Undesirable side effects and contraindications for the use of Mediadent have not been identified.

#### **Clinical benefit**

Mediadent offers a wide range of state of the art image enhancement, processing and measurement tools to provide a positive impact on patient management by supporting accurate diagnosis, treatment planning and follow-up.

#### **Special considerations**

The Mediadent imaging software is always integrated in a Patient Management System (PMS).

All Patient Management Systems compatible with the use of the OLE interface are deemed compatible if they correctly implement the specifications of the "Embedding Mediadent" documentation.

The use of the command line-interface is not officially supported anymore, but that we assist on a best effort basis for backwards compatibility reasons. Please, contact your dealer if you have questions about this type of interface.

You will be able to launch Mediadent via the PMS system by clicking on the Mediadent icon.

The list of compatible hardware imaging devices can be found on our [www.imagelevel.com](http://www.imagelevel.com) website. In case you have questions about compatibility, please contact your Dealer Support.

**Symbols used in this document and on the label**

Symbol	Title	Description
	Manufacturer	Indicates to the name and address of the manufacturer.
	Date of manufacture	Indicates the date that the product was manufactured, expressed as four digits for the year ("YYYY") and two digits for the month "MM"). For software, this represents the production release date.
	Consult instructions for use	Indicates the need for the user to consult the instructions for use. The user manual (instructions for use) is supplied in electronic format. You may consult the user manual via the Help section of the Mediadent software via the Help-menu or by hitting the "F1"-shortcut key . Alternatively , you may also download a PDF copy via <a href="http://www.imagelevel.com">www.imagelevel.com</a> or request a printed copy free of charge by contacting our Customer Support. Paper manuals will be delivered at the latest within 7 calendar days.
	CE Marking	The letters 'CE' appear on many products traded on the extended Single Market in the European Economic Area (EEA). They signify that products sold in the EEA have been assessed to meet high safety , health, and environmental protection requirements.
	Medical Device	Indicates that the item is a medical device.
	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier ("UDI") information.
	Translation	To identify that the original medical device information has undergone a translation which supplements or replaces the original information.