# *Second Opinion*® CADe Software System - Client

Computer-Aided Detection for Dental Radiographs

## CLIENT USER MANUAL & LABELING

Software Version 2

CE 0459

MD

**Manufacturer - Pearl Inc.**
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USA

UDI

Basic UDI-DI: ++D087SECONDOPINION2H8
UDI-DI – (01)00860003567920
Labeler Identification Code (LIC): D087
Model Identifier: SECONDOPINION2
Check Character: H8

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# 1. Manual Information

## 1.1. Version

This manual is intended for correct and safe utilization of *Second Opinion*® v2. The GTIN Barcode denoting the version number of the software to which this manual pertains is displayed below:


## 1.2. Purpose

This manual provides instructions for operation of the *Second Opinion*® Client software device in accordance with its function and intended use.

## 1.3. Intended Audience

This manual is intended for any person who uses, maintains, or troubleshoots the *Second Opinion*® Client software device.

## 1.4. How to obtain a paper copy of this manual

To receive a paper copy of this manual, please send a request to Pearl Inc. at support@hellopearl.com that includes your organization name, full address, name of the product for which you are requesting a manual and its software version. Pearl Inc. will send a printed version of the manual to you via the postal service.

## 1.5. Regulatory Compliance

*Second Opinion*® complies with the regulatory requirements of the following:

- EN ISO 13485:2016 - Medical Devices – Quality Management Systems.
- Quality Management Systems Requirements for regulatory purposes, FDA 21 CFR Part 820 entitled Quality System Regulation (QSR).
- EU Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Device (MDR)
- Australian Therapeutic Goods (Medical Devices) Regulations 2002
- Canadian Medical Devices Regulations SOR 98-282
- Medicines and Healthcare products Regulatory Agency (MHRA) UK MDR 2002 & Medicines and Medical Devices Act 2021
- Brazilian Health Regulatory Agency (ANVISA)
- Switzerland Medical Devices Ordinance (MedDO)
- The Health Insurance Portability and Accountability Act (HIPAA)
- General Data Protection Regulation (EU) 2016/679 (GDPR)

# 2. Second Opinion® Device Labeling

## 2.1. Brief Device Description

*Second Opinion*® is a computer-aided detection (CADe) software device intended to assist dental healthcare professionals read intraoral radiographs. A proprietary software application, it has been designed to process intraoral radiographs and automatically locate presumptive evidence of five pathologic and five non-pathologic features which may present therein.

*Second Opinion*® consists of three components:

- In-office application or Client User Interface (“Client”)
- Application Programing Interface (“API”)
- Computer Vision Models (“CV Model”, “CV Models”)

The Client resides in the clinician’s office. The API and CV Models reside in a cloud

computing platform hosted by Amazon Web Services Inc. (“AWS”), where radiograph processing takes place.

Results are displayed on a computer monitor in the clinician’s office for review by a dental practitioner. The user is instructed to first evaluate each radiograph in the conventional visual manner and then re-examine the radiograph utilizing *Second Opinion*® prior to making a final diagnosis.

## 2.2. Indications for Use

*Second Opinion*® is a computer aided detection ("CADe”) software to identify and mark regions in relation to suspected dental findings which include Caries, Bone loss, Discrepancy at the margin of an existing restoration, Calculus, Periapical radiolucency, Widened Periodontal Ligament, Crown (metal, including zirconia & non-metal), Filling (metal & non-metal), Root canal, Bridge and Implants. For pediatric patients (ages 4-11), Second Opinion® is intended only for the detection of caries.

It is designed to aid dental health professionals as a second reader in the review of:

- Bitewing and periapical radiographs for patients 4 years and older with primary or permanent teeth (primary or mixed dentition) and are indicated for dental radiographs, and
- Bitewing, periapical, and panoramic radiographs of permanent teeth in patients 12 years of age or older as a second reader.

## 2.3. Contraindications

Not to be used with patients under the age of 4 years.

## 2.4. Prerequisites

***2.4.1.*** *To operate Second Opinion® safely and according to its intended purpose, the following prerequisites must be met:*

- The user has read and understood the Intended Use, Warnings, and Operating Instructions included in this User Manual.
- 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 Reference Information section below.
- Second Opinion® has been correctly installed according to the instructions in Section 4 of this User Manual.

## 2.5. Warnings

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

- *Second Opinion*® is to be used with visual and tactile oral examination and patient risk assessment.

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

- Users should regularly confirm that the *Second Opinion*® Client software has been updated with the latest security patches.

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

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

- *Second Opinion*® 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 non-pathologic features warranting clinical attention are present in radiographs processed by *Second Opinion*®.

- Effectiveness and safety have been established only for detections in bitewing, periapical and panoramic radiographic images. Any features detected and highlighted on radiograph types other than bitewing, periapical and panoramic cannot be used by the clinician to assist in radiographic evaluations. *Second Opinion*® deploys a CV Model that classifies submitted radiographs into types: bitewing, periapical, panoramic and Other. If an image is categorized as Other, the *Second Opinion*® Client will display a message to the user indicating

that the image type is not supported.

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

## 2.6. Adverse 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 non-pathologic features that present in radiographs (false negative detections); and (b) that the device may detect pathologic or non-pathologic features that do not 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. The *Second Opinion*® 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.

## 2.7. Intended Use

The *Second Opinion*® is a cloud-based, stand-alone software that analyses radiograph images using machine learning techniques to detect, categorize, and highlight suspicious regions of interest (ROI). Any suspicious ROI detected by the *Second Opinion*® is assigned to one or more pathologic or non-pathological features. The device is intended for use as a concurrent reading aid for dental clinicians and should not be used as a standalone device.

## 2.8. Intended User Population

The intended users of *Second Opinion*® 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.

*Second Opinion*® 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.

## 2.9. Intended Patient Population

The device may be used to evaluate radiographs of dental patients, aged 4 and over, with permanent or mixed dentition teeth.

## 2.10. Compatible Radiological Data Sources

*Second Opinion*® can process intraoral radiographs. These radiographs can be acquired on a wide range of dental radiograph systems from different manufacturers. The radiographs are stored on clinical office network servers using digital storage systems. The system currently supports several common image formats, including JPEG, RVG, DCM, TIFF, PNG, and DIC.

## 2.11. Hardware Requirements

| | **Computer Requirements** |
|---|---|
| *Processor architecture* | Intel |
| *Minimum processor* | Pentium 4 |
| *Minimum internal memory* | 2 Gigabytes |
| *Minimum disk space* | 250MB |
| *Operating system* | Microsoft<br>Windows 10 or above |

The relationship of *Second Opinion*® to local and networked components within the dental office and cloud is illustrated in *Figure 1*, below.

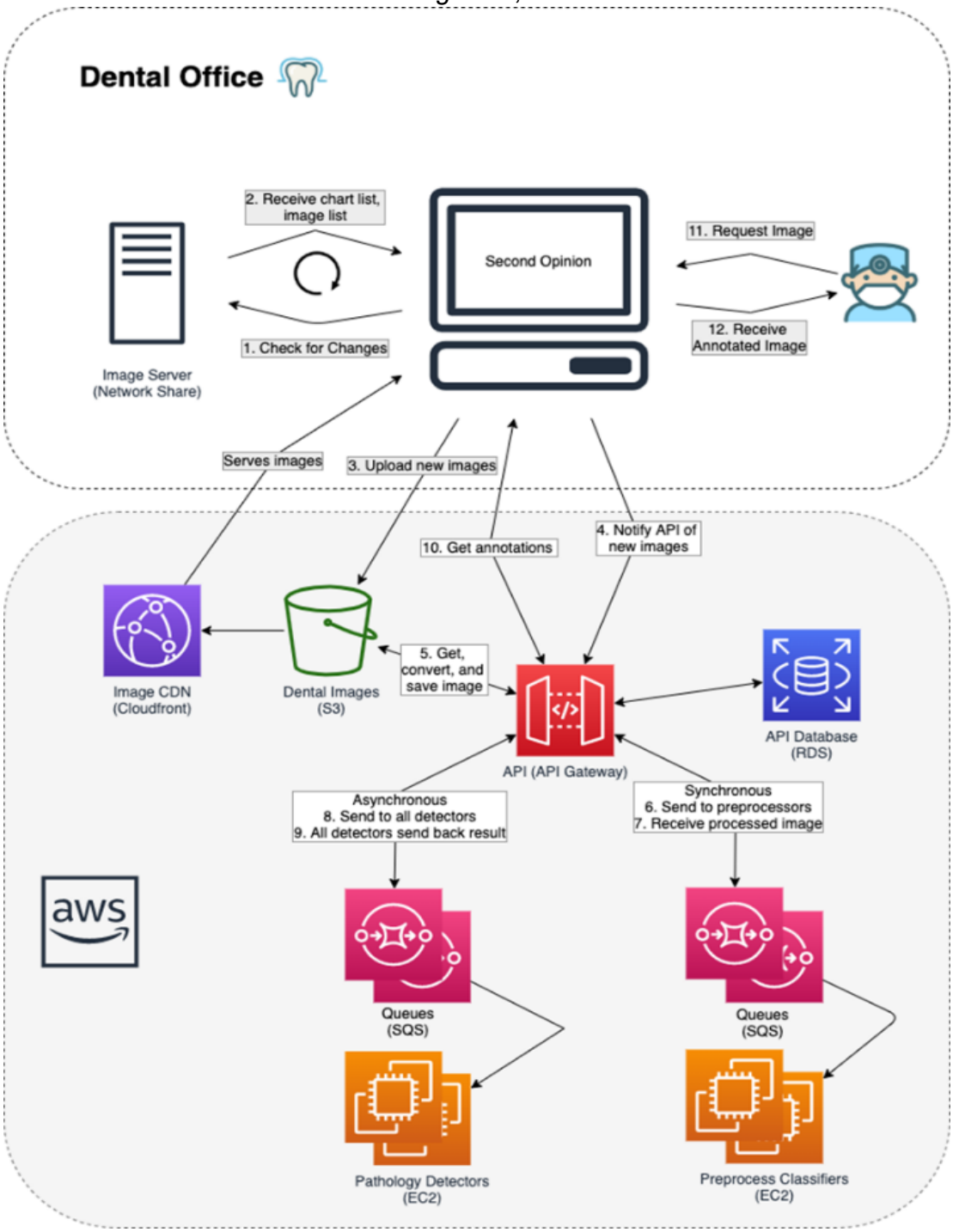



Figure 1

# 3. Product Information

## 3.1. Product Contents

*Second Opinion*® Client.

## 3.2. Principles of Operation

After installation, the *Second Opinion*® Client connects to the cloud based *Second Opinion*® API. To submit exams to the device, radiographic images are first selected in the *Second Opinion*® Client. To process the radiographs, *Second Opinion*® Client needs to be connected to the internet. The *Second Opinion*® Client sends the radiographs securely over the internet to cloud servers for processing. A result report and associated detections are then immediately generated by the API. The detections can then be viewed in the *Second Opinion*® Client user interface. To perform an analysis, the *Second Opinion*® Client must be authorized with valid account login credentials (username and password), which would have been configured at sign up.

# 4. *Second Opinion*® Installation Instructions

**Warning:** Pearl recommends that installation and system changes be performed by individuals familiar with the IT systems on which the *Second Opinion*® is running.

## 4.1. System Requirements

To use the *Second Opinion*® device, you will need the following:

- A computer running Microsoft Windows 10 or newer.
- A working internet connection.

Specific computer hardware requirements can be found in Section 2.11 of this User Manual.

## 4.2. Installation

Download & configuration of the *Second Opinion*® installation package occurs at http://secondopinion.hellopearl.com

## 4.3. Registration

To use *Second Opinion*®, a username and password combination is required. Successful purchase of *Second Opinion*® will have resulted in account creation.

After installation, the *Second Opinion*® can be started by launching the "**Second Opinion Desktop.exe**" file in the installation folder.

The client will start up and ask for a valid username and password. Fill in the credentials in the appropriate fields then press "OK". An internet connection is required for the *Second Opinion*® Client to verify the credentials.

## 4.4. Updates

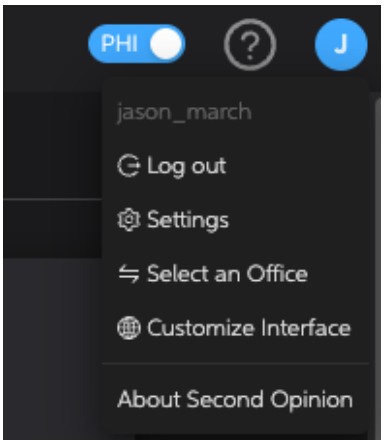
Every time the *Second Opinion*® Client starts, or every three minutes, the software checks if a software update is available. When an updated version of the software has been found, *Second Opinion*® Client will automatically download the new software and alert the user.

To install the update close and restart the application.

## 4.5. Accessing the manual and viewing the product label

*Second Opinion*® comes loaded with an up-to-date electronic copy of the user manual, which can be accessed by clicking the "Help" button in the application's toolbar, located at the upper right corner of the application's viewer. The "Help" button is denoted with a question mark icon inscribed in a circle.

*Second Opinion*® has an official product label that can be viewed from the user profile menu in the upper right-hand corner of the application, then by selecting "About *Second Opinion*®".




# 5. *Second Opinion*® Operating Instructions

## 5.1. Description of User How *Second Opinion*® Operates.

The *Second Opinion*® system consists of three parts: in-office application ("*Second Opinion*® Client*"*) or User Interface ("UI"), Application Programing Interface ("API"), and Computer Vision

The *Second Opinion*® Client is continually monitoring a local (or networked) resource where dental radiographs (refer to Section 2.5 for list of supported image types) are stored. Once new imagery is discovered, the *Second Opinion*® Client invokes cloud-based APIs which submit the imagery to Computer Vision Models ("CV Model", *"*CV Models") for processing. The metadata that these CV Models produce describe the nature and location of detected pathologic or non-pathologic features that may appear in the radiographs.

This metadata information is then sent back to the *Second Opinion*® Client, which renders it for visual display and review within the Client's user interface. Any potential pathologic or non-pathologic features detected will appear as color-coded masks overlaid on the original radiograph.

The entire process outlined above takes five to ten seconds to complete.

*Second Opinion*® CADe detects potential pathologic or non-pathologic features based on their visual appearance. Features are detected because they closely resemble known features present in the radiographs used to train the *Second Opinion*® CV Models.

The system can assist the clinician in minimizing observational oversights by identifying regions that may warrant a more meticulous review.

The *Second Opinion*® software may be used only as an aid for detecting certain potential pathologic or non-pathologic features that can appear in bitewing, periapical, and panoramic radiographs. It is not for use as an aid in radiographic diagnosis or interpretation.

## 5.2. Getting Started

Follow the instructions below to begin using the *Second Opinion*® Client.

### 5.2.1. Launch Application

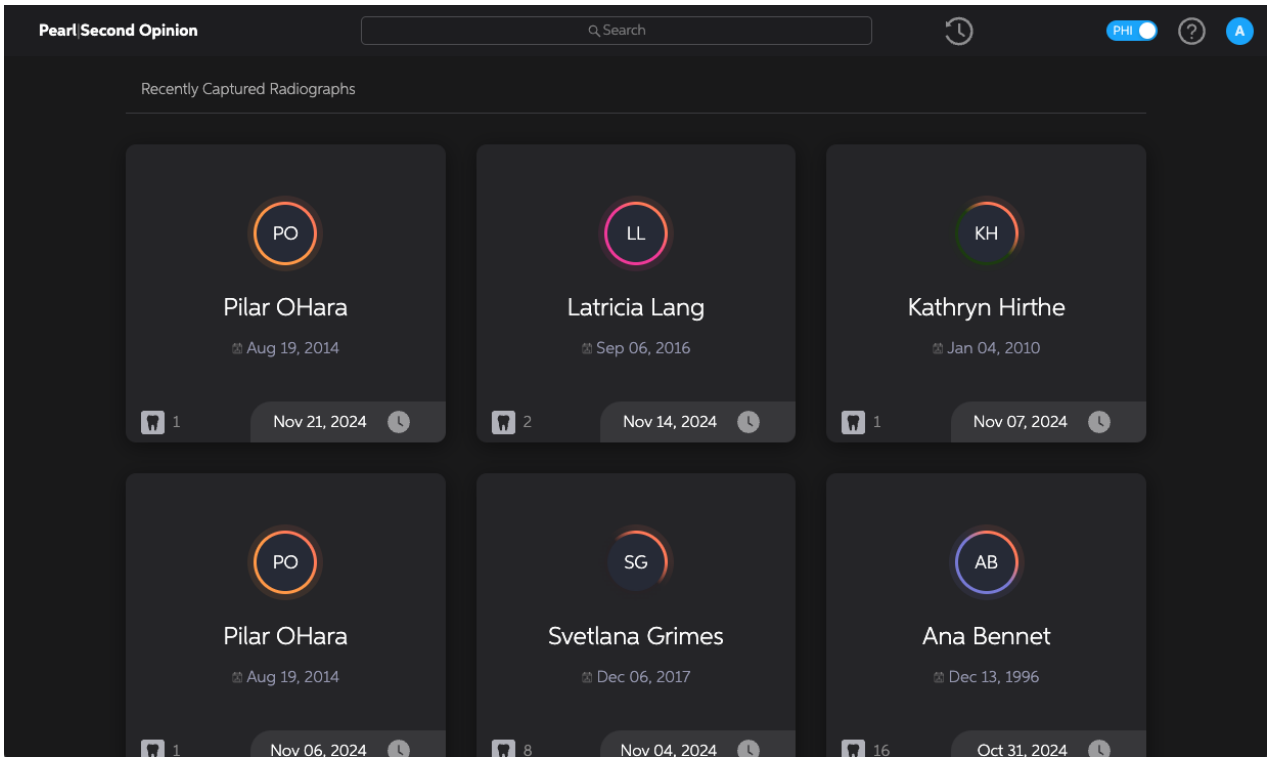
To launch the *Second Opinion*® Client, open the operating system's Start menu and click the All programs/All apps button to display a list of all installed applications. Click on the *Second Opinion*® application to open it.

### 5.2.2. Logging On

At the login window, enter Username and Password, then press Enter.
*Note: For security reasons, the password is issued by the system administrator.*

### 5.2.3. Opening Screen

When the application launches, the home screen will display in the user interface window.




To search for a patient's X-rays a search bar is provided. To return to recent radiographs you may select the "Recents" icon (circular arrow) to the right of the search bar.

### 5.2.4. Customized Interface

The available language and date formats for the Second Opinion® application are located within the Customize Interface section, which is available from the user profile dropdown when hovering over the user's initial in the upper right-hand corner of the application.

### 5.2.5. Navigating Patient Records

To load images from a patient visit, click on the patient record.

Charts are groups of images captured for a specific patient identifier on a specific date. The Chart List is populated in chronological order. Newly captured radiographs are

accessible from the top left of the list. Images that are recognized as the same image type may be automatically stacked by the application when being imported into Second Opinion®.

### 5.2.6. Finding Specific Charts

The search bar above the Chart List can be used to search charts by patient identifier, date, or combination thereof.

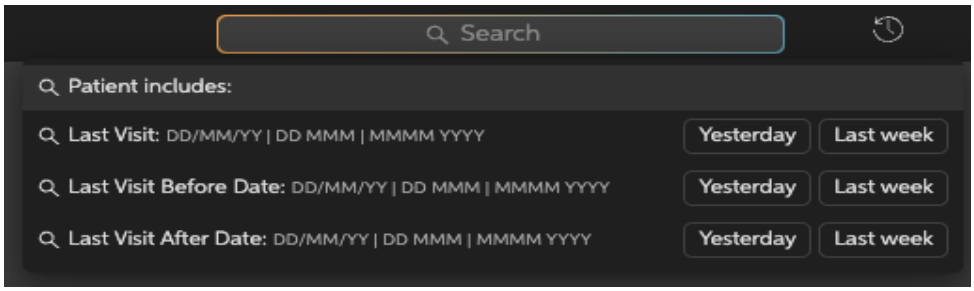



***Image 4***. Using search to find all radiographs for a specific patient identifier.

### 5.2.7. Typical Image Display

When you select a patient chart, a radiograph from the most recent imaging session will automatically display full-size. Additional radiographs taken on the same date will appear as thumbnail images in the left-hand filmstrip for easy selection. Radiographs captured on earlier dates will be grouped by date of radiographic capture and accessible through tabs across the top of the screen.

Radiographs in the radiograph display pane will be scaled to fit within the pane. To the right of the radiograph display screen, the Conditions index presents a list of all potential pathologic and non-pathologic features that *Second Opinion*® has detected.

Within the radiograph display pane, annotated detections are overlaid on the original radiograph to indicate regions where detected features appear. To highlight the region where a feature has been detected, the user can hover the cursor over the detection. Users can also highlight a region containing a detected feature by hovering the cursor over the corresponding feature in the Conditions index.


Users can limit which detected features are displayed and listed using the sensitivity/specificity slider, the pathology/non-pathology toggles above the conditions index, and the checkboxes adjacent the labels. These functionalities will be discussed further later in this User Manual.

To quickly access and load a different chart, users can use the search bar, press the recent charts icon (to the right of the search bar) or press the back arrow adjacent the current chart's name to go back to prior results.

A vertical toolbar along the upper right side of the radiograph display pane includes five tools for manipulating the appearance of the radiograph in the radiograph display pane. Listed from top to bottom as they appear in the toolbar, these tools and their corresponding icons are:

- **Full Screen** ( ): Expand image to full viewport
- **Reset** ( ): Reset Image Controls
- **Edit Mode** ( ): Toggle Edit Mode
- **Measurements** ( ): Toggle Display of Measurements
- **Measurement Tool ( ):** Measure distance between two points
- **Affected ( ):** Toggle display of Affected Tooth overlay
- **Tooth Parts** ( ): Toggle Display of Tooth Parts Overlay
- **Brightness** ( ): Adjust brightness
- **Contrast** ( ): Adjust contrast
- **Zoom** ( ): Zoom in and out

- **Invert** ( ◑ ): Invert colors
- **Rotate** ( ⟳ ): Rotate image orientation
- **Flip (⇔):** Flip image orientation
- **Pearl Enhanced View** ( 👁 ): Sharpen or Unsharpened Imagery

To access one of these tools, simply use the mouse to click on its icon using the mouse. This User Manual explains these image adjustment functionalities in greater detail later.

### 5.2.8. Comparison (A/B)

The comparison tool (A/B) allows the user to view two images from the same patient simultaneously (side by side) to compare for clinical analysis and education. When in comparison mode, you will have the capability of viewing and interacting with each individual image.

### 5.2.9. Image Selector Filmstrip

When a chart is loaded, all radiographs in the patient record are presented to the left of the radiograph display pane in a thumbnail filmstrip. Each date of radiographic capture serves as an expandable folder and notes the number of images contained within.

To select an image for display in the radiograph display pane, use the mouse to click on its thumbnail in the filmstrip. Users can also move between images by pressing the keyboard's up and down arrow keys.

### 5.2.10. How to Read Results

*Second Opinion*® applies bounding boxes or segmentations around all potential pathologic and non-pathologic features that it detects. These detections are color coded according to the system's confidence in a detection's accuracy. Users should understand how *Second Opinion*® evaluates the accuracy of a detection in order to make informed use of its detection capabilities.

The system's confidence is determined by the specificity of discernment required to make a detection. Detections that the system is most confident in are those made when a high specificity of discernment is required to flag a detection. Naturally, the system makes fewer detections when it approaches them with a high specificity requirement.

When the specificity requirement is relaxed, the system will make more detections, but it will be less confident in their accuracy. In other words, when specificity requirements are lowered, the system will be more sensitive to the presence of potential pathologic and non-pathologic features in a radiograph, at the risk of flagging features that are not present (false positive detections).

In order to offer a comprehensive list of features potentially warranting the user's attention, *Second Opinion*® is designed to approach the detection process with varying degrees of specificity.

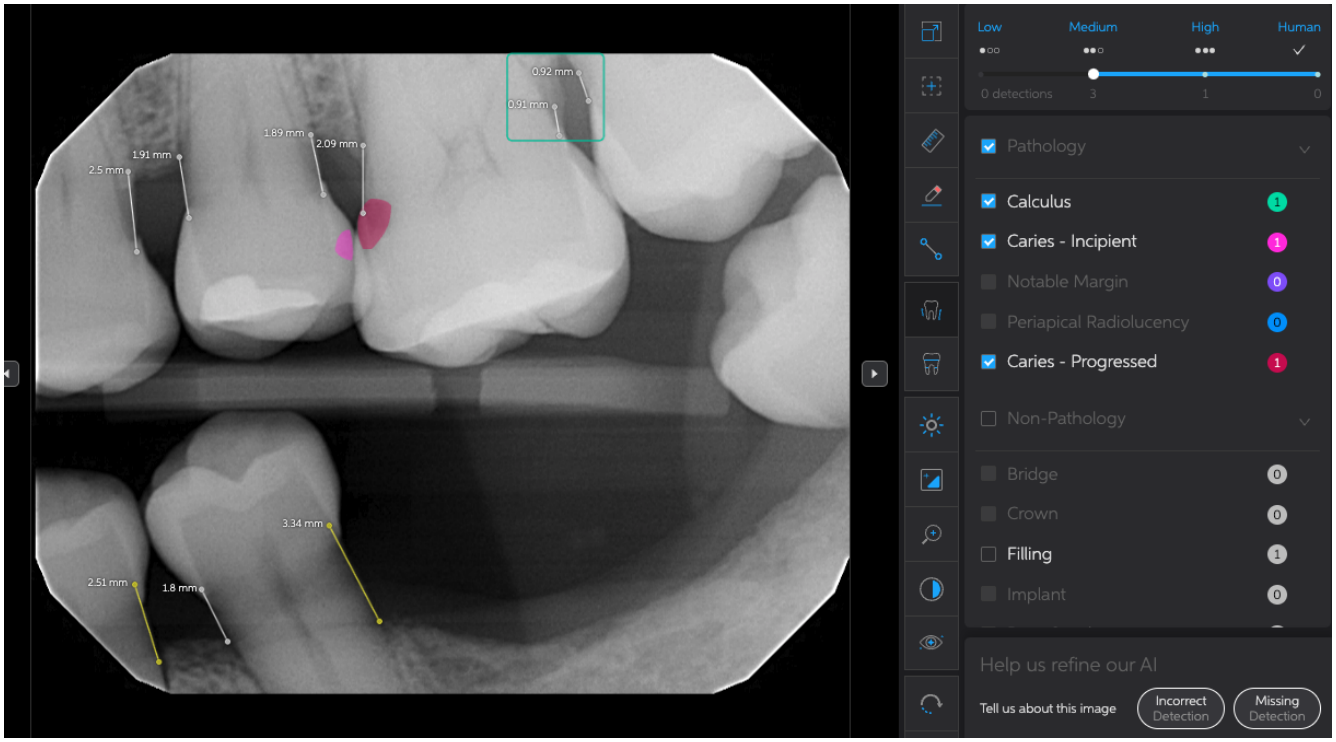
The detections presented by the *Second Opinion*® Client are color coded to allow users to understand whether the detection is the product of a) a specificity-first detection approach, b) a sensitivity-first detection approach, or c) a detection approach that balances specificity and sensitivity.

Users should consider every *Second Opinion*® detection in light of the shading of the three dots next to the detected features name in the label (or the shading of the three dots next to the detected feature's name in the Condition index). The detection dot codes are as follows:

- **3 Filled Dots**: The system is highly confident in the detection's accuracy.
- **2 Filled Dots (1 Unfilled)**: The system is moderately confident in the detection's accuracy.
- **1 Filled Dot (2 Unfilled)**: The system has low confidence in the detection's accuracy.

*Second Opinion*® users should move the Confidence Slider (found at the top of the Conditions index) between the low, medium, and high positions to gain a fuller understanding of the qualitative character of the *Second Opinion*® detections prior to taking any *Second Opinion*® detections into consideration.

Explanation of the Confidence Slider functionality is included in Section 5.2.11 of this User Manual.




### 5.2.11. How to Use the Confidence Slider

The Confidence Slider (found at the top of the Conditions index pane of the Detection screen) allows users to limit which detections are displayed based on the system's confidence in the detections' accuracy. By moving the slider from left to right (low to high, sensitive to specific), users can hide low and medium-confidence detections from display in both the radiograph display pane and the Conditions index. Low- and medium-confidence detections are less likely to be accurate because less specificity of discernment was required to spot them. The slider allows users to display detections based on the following confidence thresholds:

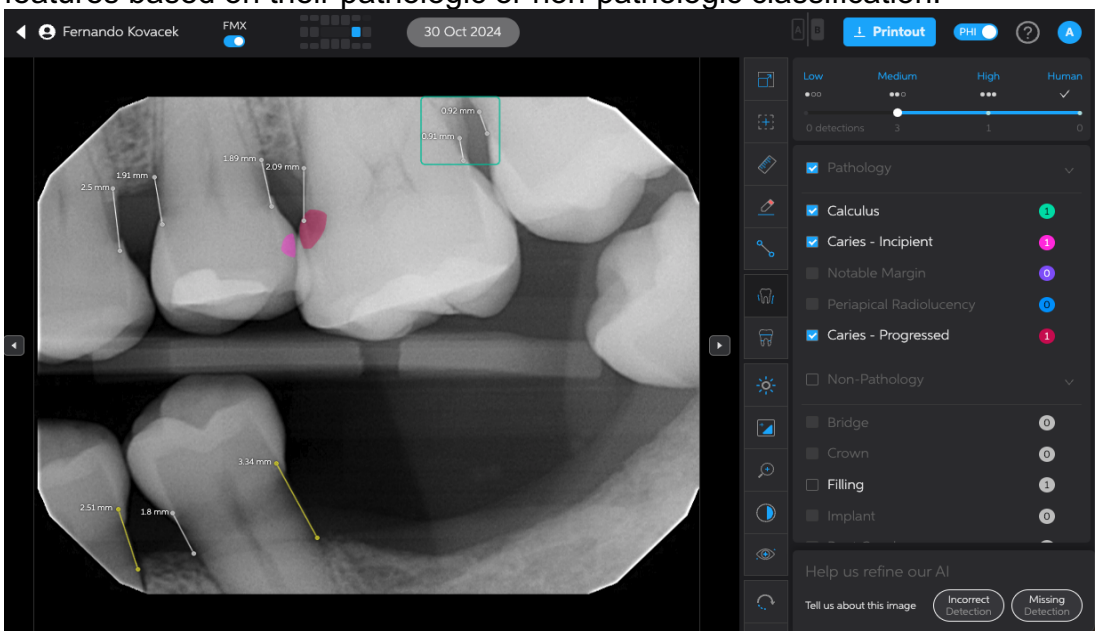
- **✓:** Only human affirmed or added detections will be displayed.
- **High (more specific):** Only the high confidence (and human) detections will be displayed.
- **Med**: The high, medium, and human confidence detections will be displayed.
- **Low (more sensitive)**: High, medium and low confidence detections will be displayed as well as human affirmed or added detections.

Users should view *Second Opinion*® detections at all three confidence threshold

settings before taking any detections into consideration.

### 5.2.12. Selective Display of Potentials Detections

Located below the Confidence Slider are two checkboxes labeled “Pathology” and “Non-Pathology.” Users can select these checkboxes to show or hide detected features based on their pathologic or non-pathologic classification.




*Detection screen with the Confidence Slider set to Medium*

As detections are identified, a filled checkbox will appear next to the detection. Unchecking the box off will temporarily hide results of that class. If the box is inactive then there are no results of that class to hide or show.

### 5.2.13. How to Use Image Adjustment Controls

To improve the viewability of a radiograph in the radiograph display pane, *Second Opinion*® offers image adjustment tools located in a toolbar on the upper right-hand side of the radiograph display pane. These tools can be used as follows:

- **Brightness** ( ☼ ): Use this slider to adjust image brightness. Move the slider to the left to decrease image brightness. Move the slider to the right to increase image brightness. Midpoint is default (and original) brightness.
- **Contrast** ( ◪ ): Use this slider to adjust image brightness. Move the slider to the left to decrease image contrast. Move the slider to the right to increase image contrast. Midpoint is default (and original) contrast.
- **Zoom** ( 🔍 ): Use this slider to zoom in and out of the image. When the slider is the far-left position, the full un-zoomed image fills the radiograph display pane; this is the default position. Moving the slider to the right will zoom in to magnify the image. When zoom is applied the image may be moved around via click and drag.
- **Invert** ( ◑ ): Select this toggle button to invert coloration of the radiograph. Black

regions of the original image will become white. White regions of the image will become black.

- **Rotate** ( ): Select this button to rotate the radiograph. Rotation can occur either clockwise or counterclockwise. Each time the button is clicked, the radiograph will rotate 90 degrees.
- **Pearl Enhanced View** ( ): Use this slider to deactivate or strengthen a sharpening of the image. Select 0 for no adjustments to the image or between 1-20 for increasing strength of sharpening.

### 5.2.14. End User Controls to Add or Remove Detections

In order to provide the end user with ability to over-rule the AI detections, *Second Opinion*® employs a remove detections option and an edit mode. The option to remove detections will appear as an Eye icon when hovering on detections. Once a detection has been removed, it can be restored in Edit Mode.

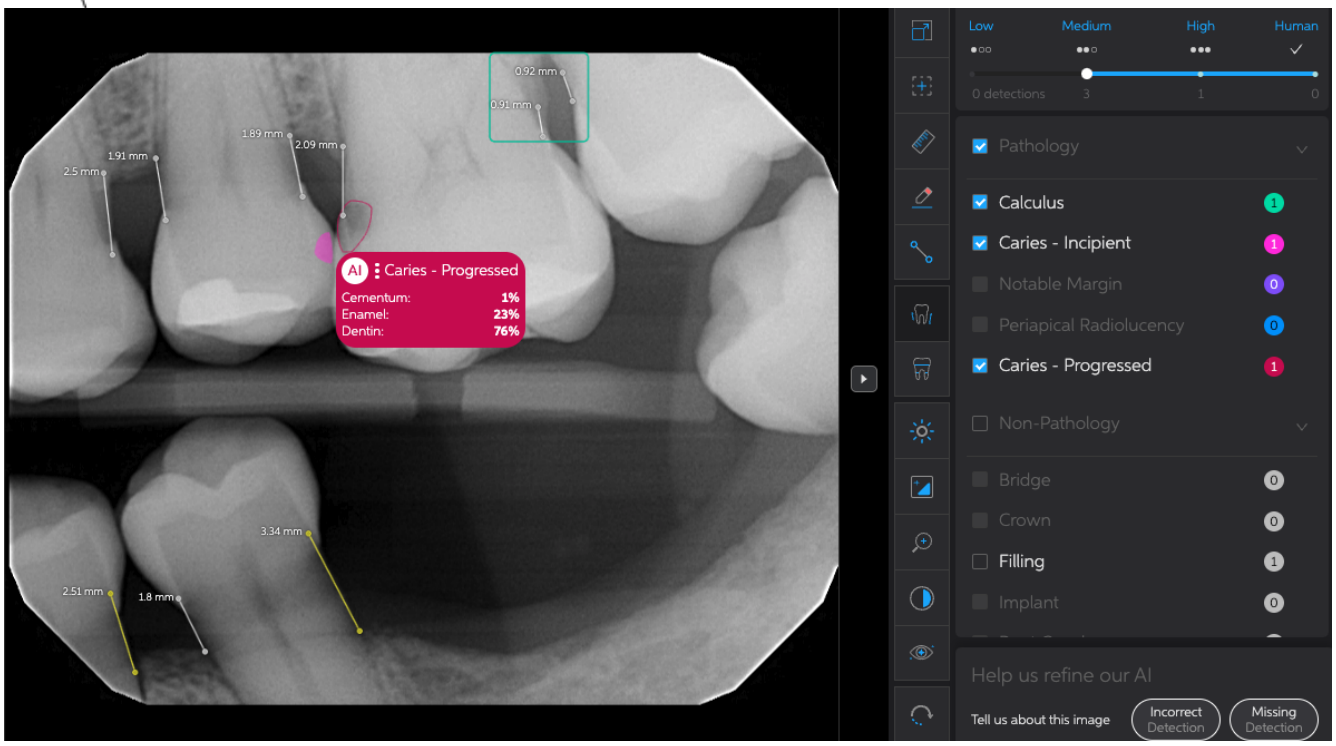
Edit Mode is accessible via a pencil icon in the toolbar. Once activated, edit mode allows the user to restore an annotation (by way of the crossed-out Eye icon adjacent the label), or draw their own annotation (by way of click and drag a rectangle) and provide it a label (by way of a drop-down selection). The status of a detection may be understood by iconography in the label.

- ( ) AI Detection without User Involvement
- ( ) User created annotation
- ( ) Eye Icon
- ( ) Crossed-Out Eye Icon

### 5.2.15. Tooth Parts Segmentation Overlay, Affected Overlay & Labeling of Caries

*Second Opinion*® makes use of AI Segmentation to ascertain the composition of a radiograph amongst ***tooth parts*** (e.g. Enamel, Dentin, Pulp, etc.). The ***tooth parts*** overlay may be activated by the toggle at right of the radiograph providing a semi-transparent colored overlay and explanatory legend.

*Second Opinion*® displays an ***affected tooth*** percentage that is calculated by adding the portions of tooth composed of existing restorations and caries. Together, these are represented as a percentage of healthy crown. The ***affected tooth*** overlay may be activated using the toggle to the right of the radiograph. When active, colored radials will appear on each tooth with an ***affected tooth*** value. Additionally, a legend will display at the bottom with an explanation of each radial color and how calculations are made. There is also a disclaimer explaining usage limitations.




### 5.2.16. Bone Height Measurement

*Second Opinion*® provides estimated measurements from the CEJ to the bone crest. These are represented as line segments with millimeter measurements alongside for reference.

## 6. Summary of *Second Opinion*® Clinical Study Outcomes

To determine whether human readers' diagnostic accuracy improved when they used *Second Opinion*® to aid in their detection of certain pathologic and non-pathologic features that can appear in dental radiographs, *Second Opinion*® was clinically tested as a standalone device and in a fully-crossed multi-reader multi-case (MRMC) reader study. A supplemental CADe vs. Unaided Reader study was also conducted.

Both a consensus-based ground truth (GT) dataset and a forced-adjudication-based GT dataset – developed in parallel from the same geo- and pathology-enriched pool of over 2000 dental radiographs of permanent teeth – were applied in each of the three study designs. After post hoc analysis revealed higher levels of agreement among consensus GT readers than forced-adjudication GT readers, results based on consensus GT were given precedence across all studies.

The standalone studies evaluated readers' accuracy in detecting the nine dental features included in the Indications of use for *Second Opinion*®, as well as one additional feature

not supported by *Second Opinion*®:

- Caries
- Margin Discrepancies
- Calculus
- Periapical Radiolucency
- Crowns
- Bridges
- Implants
- Root Canals
- Filling
- Bone Loss
- Widened Periodontal Ligament

The MRMC studies evaluated impact on reader performance in detection of only the five pathologic features in that list. To test device performance at different user-selectable detection specificity/sensitivity settings, the MRMC studies were broken into three sub-studies with specificity/sensitivity settings locked at the low, medium, or high for each. In total, 81 qualified readers participated in the MRMC studies.

For the supplemental CADe vs. Unaided Reader studies, the diagnostic performance of *Second Opinion*® was compared against the accumulation of all unaided reader responses produced in the MRMC studies.

The Weighted Alternative Free-Response Receiver Operating Characteristic (wAFROC) paradigm was used as the metric of efficacy for all studies. The studies were conducted as retrospective, unblinded open-label, multi-site trials that produced clinically useful information on the potential application of this device in a dental office setting.

The performance of *Second Opinion*® met expectations in both standalone and MRMC studies. In the standalone study, the *Second Opinion*® CADe exhibited comparable performance to unaided readers in detecting the five pathologic features that were tested in the MRMC.

The performance of *Second Opinion*®-aided readers across the three slider settings collectively – reflecting the holistic effect of the device when users can freely move between slider settings as intended – demonstrated statistically significant improvement over the performance of unaided readers for caries, margin discrepancy, calculus, and periapical radiolucency.

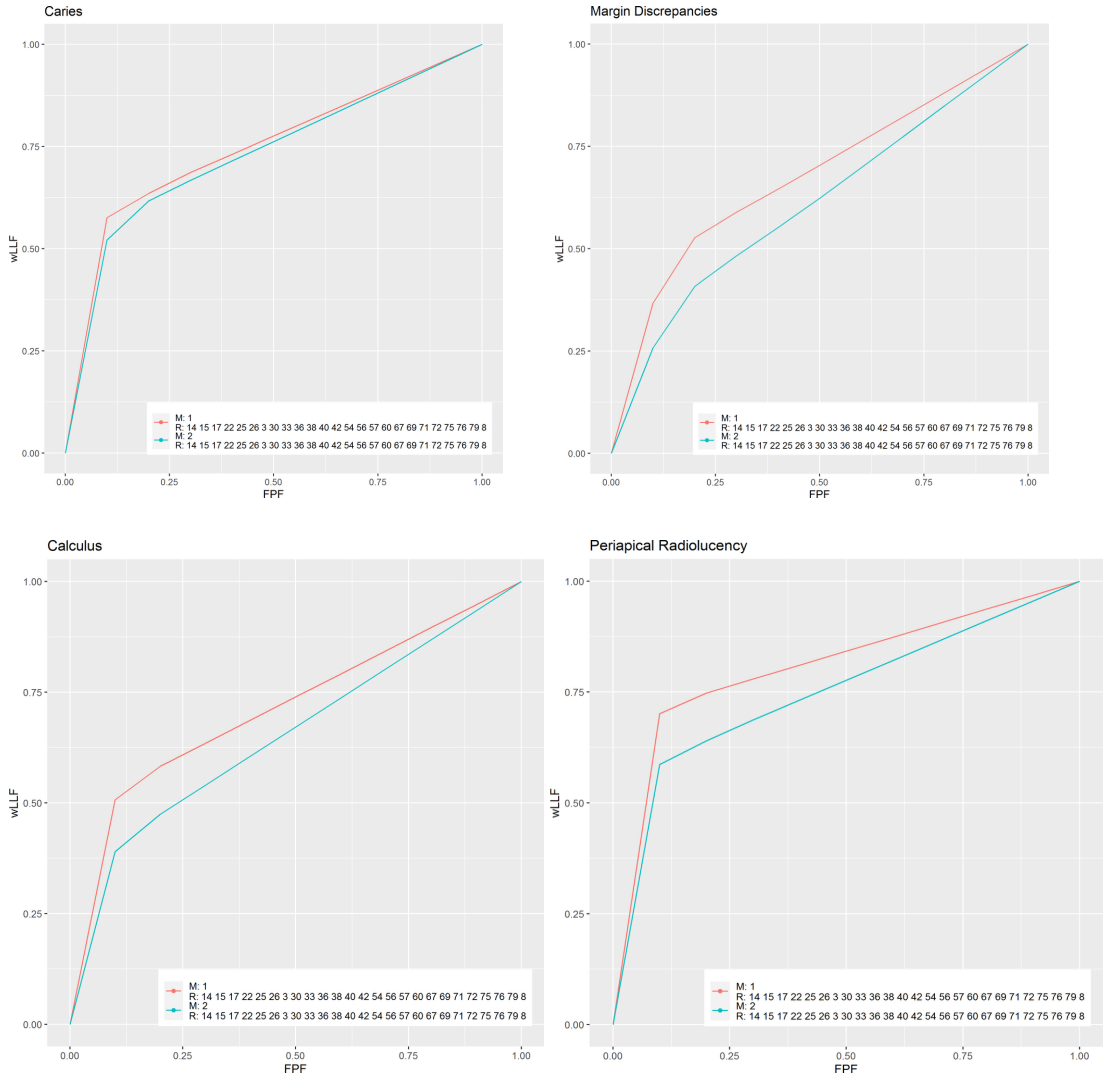



*Figure 1.* wAFROC-FOMs for aided readers (red) and unaided readers (teal) when using *Second Opinion® fixed at the High setting*.

No statistically significant reductions in performance were observed when readers used *Second Opinion®* as an assistive aid.

As expected, based on the intended function of the device's variable sensitivity-specificity slider settings, *Second Opinion®* improved reader sensitivity when its slider was fixed at the Low setting and improved reader specificity when its slider was fixed at the High setting.

Analysis of study results for geographic region of image capture, patient age and patient sex confounders in the GT dataset demonstrated improvement in *Second Opinion®*-aided

reader performance that was consistent with that observed across the studies in general. Vis-à-vis imaging device generalizability requirements, a similar concordance with overall study results was also observed in the image acquisition device subgroup, where across the five image acquisition devices with sufficient representation in the GT dataset to yield statistically meaningful results, as well as for the remaining four image acquisition devices with limited representation, aided readers outperformed unaided readers.

The statistically significant gains in aided reader performance observed in the results of these clinical studies validate the efficacy of *Second Opinion*® as an aid to dental health professionals in their detection of pathologic features dental of permanent teeth.

# 7. Second *Opinion*® Troubleshooting

The information contained in this section provides steps that users may take to identify and solve basic problems that may occur while using the *Second Opinion*® Client. Any issues determined to be beyond the scope of these basic user troubleshooting instructions should be communicated to Pearl Customer Support.

A monitor, keyboard and mouse are required for troubleshooting.

| Problem | Cause and Solution |
|---|---|
| Images or Results Fail to Load | Ensure that the computer is connected to the local network.<br><br>Ensure that the local network is connected to the internet.<br>Ensure that the networked image drive where radiographs are stored (if utilized) is connected to the network.<br><br>Quit and restart *Second Opinion*®<br><br>If the problem persists, contact *Second Opinion*® Customer Service. |

| | |
|---|---|
| Unable to Log In | Verify that credentials are correct.<br><br>Ensure that the computer is connected to the local network.<br><br>Ensure that the local network is connected to the internet.<br><br>Quit and restart *Second Opinion*®<br><br>Utilize forget password link to reset password. |
| Images Missing | Ensure that the date filter in the chart search function is configured correctly. |

| | |
|---|---|
| | Ensure that the computer is connected to the local network.<br><br>Ensure that the local network is connected to the internet.<br><br>Ensure that the networked image drive where radiographs are stored (if utilized) is connected to the network.<br><br>Ensure that the radiograph storage file location settings are correctly configured |
| Application Crashes | Restart application. Restart the computer.<br><br>If the problem persists, contact *Second Opinion*® Customer Service. |

# 8. Service and Maintenance

*Second Opinion*® is not independently user serviceable. When service is needed, Pearl will release an updated version of *Second Opinion*®. The update will be downloaded and installed automatically. See Section 4.4 of this User Manual for more information about software updates.

# 9. Technical Assistance

*Second Opinion*® Customer Service is available to answer questions about business, pricing, upgrades, customization and order status.

Technical Support is available to answer questions about technology, integration, and troubleshooting. Contact us at:

In-App: Users may receive support through the in-app chat tool in the bottom right corner of the *Second Opinion*® app. Clicking on the chat icon will open a live chat session with Pearl support.

- Support Chat Icon - 

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