Instructions for Use

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1.1 Regulatory Standards

The following standards have been applied in development of this product: ISO 13485:2016. This product conforms to European Medical Device Directive; Health Canada requirements for Class II Medical Devices in accordance with Medical Device Regulations Section 36; 21 CFR Part 820, US FDA Quality System Regulations; and ANVISA Resolution-RDC No 16 of March 28, 2013.

1.2 CE Conformity

This product is classified as Class IIa. Segami Corporation declares that this product meets the provision of the Council Directive 2007/47/EC for Medical Devices, and therefore bears the CE mark of conformity.
This product is manufactured by:

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1.3 Program Description

Oasis is an advanced visualization, quantification, and reporting software solution for nuclear medicine diagnostic imaging. It integrates multiple modalities — SPECT, PET, and CT — for the accurate interpretation of organ function and anatomy in a single, comprehensive environment. The intuitive, user-centered environment guides the user while providing configurable preferences for workflow personalization. The core functionality is to provide an accurate environment for quantification and display of nuclear medicine images and related other modalities. It supports a wide variety of study types, based on European and North American published standards and guidelines. Oasis provides a non-manufacturer specific solution for review of images from a wide variety of available scintigraphic cameras. Data may be passed to Oasis either from a connected or integrated Oasis server/database or from

various commercially available PACS system databases. The system is intended for use in imaging centers and hospitals by qualified nuclear medicine personnel trained in the use of the Oasis product.

Users without normal color vision should use select non-quantitative greyscale color tables and may require additional training.

1.4   Indications for Use

Oasis is indicated for processing and review of diagnostic medical images produced by DICOM based multi-modality sources; in other words it provides the physicians with a tool to get, format, store and display diagnostic image data in all traditional manners; to add three-dimensional and multi-planar renderings to the displays; to fuse multimodality images and to display certain kinetic attributes of the imaged organs and systems.

Analysis in Oasis is NOT intended to be used as a replacement for visual interpretation nor as a diagnostic tool without other clinical and laboratory information.

Oasis is not used to treat the patient, to monitor vital signs or to give a direct diagnosis of disease.

1.5   Using Oasis

Opening Oasis
- Double-click the Oasis icon on the desktop.
- Once the login screen appears, enter the username and password and click [Login]. The patient/study browser screen will appear.

Closing Oasis

- First, close any application currently in use by clicking in the top right of the screen.
- Then close the patient/study browser by selecting the File ► Logout menu or by clicking in the top right corner.
- Finally, click [Exit] in the login screen.
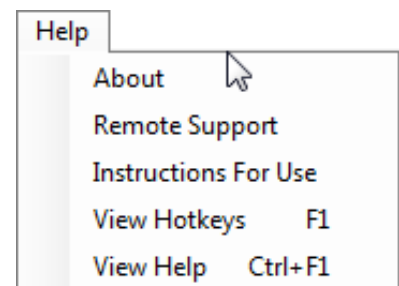
About Oasis Display
- Because the Oasis display is customized automatically for each protocol, the number of screens, pages, and viewports rendered will vary, depending upon the clinical application protocol in use.

Access to Oasis Server Web Services
- When successfully logged into Oasis client select Tools ► Administrative Tools to access the Oasis Server interface to perform operations such as Query/Retrieve, image or study deletion, and other data administration tasks.

Location of Help Files
- Press [F1] to display a list of keyboard shortcuts. Press [Ctrl]+[F1] or to view the User Manual.

1.6   Support

The product is distributed and supported only by Segami or its qualified sales representatives. Please contact your local sales representative. Select Help ► Remote Support to activate direct support from Segami qualified personnel.