



# Instructions for Use

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## 1.1 Regulatory Standards

The following standards have been applied in development of this product: ISO 9001:2008, ISO 13485:2003. This product conforms to European Medical Device Directive, Health Canada requirements for Class II Medical Devices in accordance with Medical Device Regulations, Section 36 and 21 CFR Part 820, US FDA Quality System Regulations.

## 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.

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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.

## 1.4 Indications for Use

The Oasis system is indicated for the processing and review of scintigraphy data and other related diagnostic medical images produced by DICOM based multimodality sources. These sources may include, but are not limited to, radiological diagnostic systems, picture archive computers (PACS), and processing workstations.



Oasis is capable of processing and displaying the medical image data in traditional formats, as well as pseudo three-dimensional renderings, and in various forms of animated sequences showing kinetic attributes of the imaged organs. The Oasis system displays the processed images using an integrated computer. Oasis provides manual and automatic report creation plus the ability to view these reports remotely. Oasis also provides patient scheduling tools. This device is not used in the primary diagnosis of mammography images.

## 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

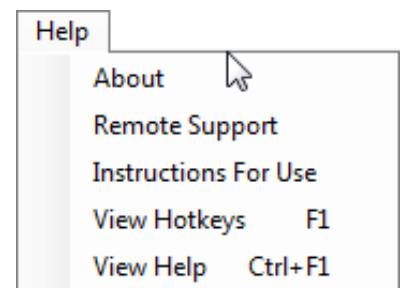
- Because the Oasis display is customized automatically for each protocol, the number of screens, pages, and viewports rendered will vary, depending upon the clinical application protocol in use.

### 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.