

Exa® PACS/RIS 1.4.30_P2

Customer Release Notes

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Symbols

The following symbols may appear in the product documentation or on the product.

Symbol	Symbol Name	Symbol Description	Standard Number and Name	Symbol Reference Number
	Manufacturer	Indicates the name and address of the manufacturer	ISO 15223-1:2016	5.1.1
EC REP	Authorized Representative in the European Economic Area (EEA)	Indicates the Authorized Representative, responsible for the device in the European Economic Area (EEA).	ISO 15223-1:2016	5.1.2
سا	Date of Manufacture	Indicates the date when the device was manufactured.	ISO 15223-1:2016	5.1.3
\triangle	Caution	Indicates information that is important for preventing loss of data or misuse of the software.	ISO 15223-1:2016	5.4.4
LOT	Batch Code	Indicates the full Software Release / Version number	ISO 15233-1:2016	5.1.5
SN	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified	ISO 15233-1:2016	5.1.7
REF	Catalogue Number	Indicates the manufacturer's catalogue number so that the device can be identified	ISO 15233-1:2016	5.1.6
[]i	Consults instructions for use	Indicates the need for the user to consult the instructions for use	ISO 15233-1:2016	5.4.3
Rx only	Prescription Device	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner	21 CFR 801.109(b)(1) Prescription Devices	N/A

 $ISO\ 15223-1: 2016\ Medical\ devices\ -\ Symbols\ to\ be\ used\ with\ medical\ devices\ labels,\ labeling,\ and\ information\ to\ be\ supplied\ -\ Symbols\ be\ used\ with\ medical\ devices\ labels,\ labeling,\ and\ information\ to\ be\ supplied\ -\ Symbols\ be\ used\ with\ medical\ devices\ labels,\ labeling,\ and\ information\ to\ be\ supplied\ -\ Symbols\ be\ used\ be\$

Part 1: General requirements

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Indications for Use

EXA™ is a software device that receives digital images and data from various sources (i.e. CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources). Images and data can be stored, communicated, processed, and displayed within the system and or across computer networks at distributed locations. Lossy compressed mammographic images are not intended for diagnostic review. Mammographic images should only be viewed with a monitor cleared by FDA for viewing mammographic images. For primary diagnosis, post process DICOM "for presentation" images must be used. Typical users of this system are trained professionals, nurses, and technicians.

Training

Users of this software must have received adequate training on its safe and effective use before attempting to operate the product described in this Instructions for Use. Users must make sure they receive adequate training in accordance with local laws or regulations.

Regulatory and compliance

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New Features

Summary

• Exa PACS/RIS now better handles cases where the accession number of an inbound study already exists in the database.

Customer Requested Improvements

Summary

- Custom function for one customer: For selected facilities and study statuses, the program can now validate the primary insurance when scheduling orders and pre-orders.
- Patient Kiosk now prompts the user to enter secondary insurance, or skip.
- If a patient selects to sign a form in to Patient Kiosk, the patient's first and last name are now automatically populated.
- In the Ontario configuration, Exa Billing now supports the two-character health card province codes used when RMB is the insurance provider.
- In the Alberta configuration, AHS claim numbers now include a user-selected year and source code segment.

Other Improvements

Summary

- Users can now select SUV units and calculation sequences.
- When required fields are missing in the Find Slots screen, the program now provides a convenient method to enter the missing information.
- Exa PACS/RIS now displays default SUV values according to the user specified type, rather than the units stored in the DICOM values.
- You can now specify how pixels are selected for inclusion in an ROI.
- You can now configure Exa PACS/RIS to display the number of pixels and or slices selected when annotating an ROI or selecting with the freehand tool.
- iCAD 3D density and calcification certainty percentages ending in point zero (.0) now appear as whole numbers (without the point zero).
- Users can now specify when to clear the local cache by percentage of disk drive used space.
- Various improvements in performance and to the UI.

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