

# Exa® PACS/RIS 1.4.30

**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
<u>~</u>	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

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

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**

- Added the ability to require a document review process for selected document types, and an associated study flow status.
- Users can now view and edit the VIP status of patients.
- Users can now add facility notes when configuring a facility.
- Users can now add a merge field for facility notes to templates and forms.
- Added Facility Fax Number and Facility Email merge fields for use in templates and forms.
- Users can now assign both a referring and ordering physician to orders.
- When scheduling appointments, users can now extend the duration of the appointment by a preset amount of time.
- Exa PACS/RIS can now immediately auto-retrieve priors upon receiving an order from an external PACS.
- Users can now adjust a claim balance to paid in full with a single short procedure.
- Users can now view a list of studies whose location/contact billing type is Census, and edit the census type.
- Users can now add the following merge fields to selected templates and forms: Non-Proprietary Name, Amount Used, and Route.
- Users can select a Global option for a census study to create a single claim.
- Users can now split claims to process technical and professional charges separately.
- Users can now process census claims by facility.
- Exa PACS/RIS now warns users if they attempt to change an accession number to one that is already in use.
- When scheduling back-to-back appointments, users can now filter the selectable time slots by a maximum amount of wait time between them.
- For specified ordering facilities, claims are now split automatically into a technical fee claim and a professional fee claim.
- Users can set an ordering facility location to different types that determine default responsible payers, billing statuses, and fee schedules.
- In Canadian configurations, Exa PACS/RIS now supports alternate patient identifiers, such as the ULI.
- In the USA configuration, claims can now be automatically split for selected insurance providers into technical fees and professional fees.
- Users can now specify whether the issue of PID for an AE is static (user selected) or dynamic (updated by the system based on inbound information).
- In the USA configuration, mobile billing can now be enabled, and a user right is now available for accessing the Census screen.
- Users can now add the supervising physician to an order.
- In the Ontario configuration, added a Health Card Number merge field for forms and templates.

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### **Customer Requested Improvements**

#### Summary

- OpalForwarder can now be configured to receive from and send to multiple sources and destinations.
- Redesigned the OpalForwarder UI to make it easier to configure DICOM edit functions.
- OpalForwarder can now send all images in a specified folder and its subfolders.
- Users can now easily compare studies of the same or different patients in a dedicated instance of the Exa PACS/RIS viewer.
- In the Alberta configuration, users can now work with diagnosis code pointers.
- When DICOM-printing, overlay text now scales to match the size and number of images in the layout.
- Users can now search, sort, and create filters for the claims screen by modality.
- Users can now create lifecycle management rules to enable automatic purging of selected information after a specified number of days.
- In the Technologist screen, users can now change the status of one or all studies within an order to Unread.
- Users can now exclude specific facilities from appearing on portals.
- Users can now apply authorization rules to one, multiple, or all facilities.
- Users can now apply multiple modalities to an authorization rule.
- Patient search results are now restricted by the user's regional access.
- Added configuration to support encoding for OrthoView and other third-party tools.
- Users can now modify NDCs from the edit study screen.
- Users can now add NDCs to CPT/Charge codes from the Charge/Payments screen.
- Exa PACS/RIS can now pass the Study UID to an external (third-party) tool.
- In the Ontario configuration, users can now submit claims belonging to only one radiologist at a time.
- In the edit study and other screens, Exa PACS/RIS now determines which fee to display in the same manner as in Billing.
- In the Ontario configuration, the program can now differentiate between Exa-original claims and claims migrated from other systems, and process them accordingly.
- In the Ontario configuration, claims that failed to be submitted are now accompanied by a red exclamation point, which users can click to view the reason for failure.
- In the Ontario configuration, when configuring facilities, users can now set an SLI code for professional fees.
- In the Ontario configuration, when configuring procedure codes, users can now specify the charge type (such as Technical or Professional).
- In the Ontario configuration, made various improvements to handling of claims based on charge type, facility, specialty code, and other parameters.
- In the Ontario configuration, payments against professional provider claims are now made to the providers themselves instead of a parent organization.
- When faxing HL7 reports to a primary referring provider, Exa PACS/RIS now also faxes the reports to the CC providers.

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- In Canadian configurations, Exa Document now dynamically imports to studies or patients depending on the document's associated accession and account numbers.
- Providers and attorneys are now prevented from viewing studies that they did not refer, or to which they
  are not associated.
- The Technologist Productivity Report can now include a Facility column.
- New fields can now be required to create pre-orders.
- Users can now search, sort, and filter the worklist by the referring physician's report delivery method.
- On the Dispatching Dashboard, the confirmation screen now only appears if any orders failed to be dispatched, and users can select to Schedule Anyway in such cases.
- Improved window management and scheduling operations in the dispatching dashboard.
- Uses can now double-click studies in the Dispatching Dashboard to open them.
- Removed default filtering criteria from the Dispatching Dashboard, and now search criteria are retained when users leave and return to a tab.
- Mobile users can now assign types to ordering facilities.
- In addition to clicking the Search button, users can now search for ICDs in the New Appointment screen by pressing the Enter key.
- In the Ontario configuration, provider numbers now appear in the edit claim screen for reference.
- Users can now group data in the Monthly Recap report by insurance class or service facility.
- Users can now create multiple locations or contacts within a facility.
- Users can now assign credentialed technologists to ordering facility locations, thereby controlling which technologists can be assigned to studies.
- Users can now export a list of completed mobile billing studies for which patient billing statuses have not
  yet been received.
- Users can now configure ordering facilities (in addition to non-ordering facilities) for auto billing.
- When configuring a new insurance provider, Exa PACS/RIS can now automatically assign an insurance provider code.
- Improved back-to-back scheduling by streamlining the way available time slots are presented to the user.
- Users can now enable and disable adding of modality types to an existing appointment type code.
- If Exa PACS/RIS fails to send a fax, and the fax remains in the Queued status, the program now automatically retries the sending at set intervals.

### **Other Improvements**

#### Summary

- Various improvements to the UI and for performance.
- Added the option to show or hide the Attorney Portal button on the sign-in screen.
- To support mobile sites, the Monthly Recap report now tracks the service facility rather than the scheduling facility.
- Ad hoc chat rooms are now titled with a default name or a user-specified name.
- The DICOM print preview now more closely matches the actual printed output.
- Mobile customers can now save the start date of their contract with an ordering facility.

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- Exa PACS/RIS now supports the ZIP+4 code in relevant parts of the program.
- Made security enhancements to OpalForwarder.
- The appointment end times now appear on appointment cards on the schedule book.
- Users can now change the date and time of a quick block without having to delete and recreate it.
- Administrators can now reset users' 2FA secrets.
- Exa PACS/RIS now supports DICOM printing of multi-frame images.
- When users add a fax or office fax number to a provider contact, the fax or office fax field now becomes mandatory.
- When importing appointment types, Exa PACS/RIS now also imports "additional time."
- When manually authorizing insurance, users can now see the authorization status of each insurance level.
- When rescheduling a study, inactive reschedule reasons are no longer available to select.
- The physician's portal now uses the same required fields for creating pre-orders as the main area of Exa PACS/RIS.
- To better support 3D iCAD annotations, the manufacturer DICOM tag is now ignored, and case score values are always displayed, if available.
- The Diagnostic Use warning on the sign-in screen of mobile devices now conforms to FDA specifications.
- Temporarily disabled auto-linking of new patient portal accounts.
- For Philips studies that use ctns units, and where no scale factor or concentration tags are present, Exa PACS/RIS viewer now attempts to convert to bq/ml and display SUV values with those units.

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