koios™

Koios DS™ Breast & Thyroid

Introduction and Activation Playbook for Technology Managers

This document covers system function, system requirements, deployment process, and the information needed by Koios Medical to ensure a smooth activation of a Koios DS module in your technical infrastructure.

For Research and Production Versions 3.2.X or later

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koios™ STUDY LIST | JANE T. DOE (23456789)

Study | Levels | Zoom | Pan | Play | CINE | Reset | Clear | Scroll Lock | Koios ROI | Screenshot | Layout | More▾   Koios DS

Study:
Nov 21, 2018: ▾
(No Description)

1.5   HNR
2.5cm 17fps
◄▣ Fr445
SIEMENS

Save   Summary

F1   🗑 +

1 Benign
No FNA
0 pts   4.39 cm

TI-RADS® DESCRIPTORS
Spongiform   0 ▸
Hyperechoic Or Isoechoic   1 ▸
Wider-Than-Tall   0 ▸
Smooth   0 ▸
Large Comet-Tail Artifacts   0 ▸

Koios AI Adapter   -2 ▾
-2   -1   0   +1   +2
      TR1   TR2   TR3

POSITION & SIZE
R   X   L

1.5   HNR
Finding 1
RT LNG_
INF 2
2.5cm 17fps
◄▣ Fr578
SIEMENS
〇=14.6 mm
Img: 2 of 2

Save   Summary

F1   🗑 +

4 Moderately Suspicious
Follow
5 pts = 6 pts -1   1.44 cm ≥ 1 cm

TI-RADS® DESCRIPTORS
Spongiform   0 ▸
Very Hypoechoic   3 ▸
Wider-Than-Tall   0 ▸
Smooth   0 ▸
Large Comet-Tail Artifacts
Punctate Echogenic Foci   0 ▸
                                   3

Koios AI Adapter   -1 ▾
-2   -1   0   +1   +2
      TR4   TR5

POSITION & SIZE
R   X   L

POSITION: Lower Pole ▾
SIZE (CM):   1.16 X 1.44 X 0.89

Summary of Findings

Finding 1

1 Benign
No FNA
0 pts   4.39 cm

TI-RADS® DESCRIPTORS
Spongiform   0
Hyperechoic Or Isoechoic   1
Wider-Than-Tall   0
Smooth   0
Large Comet-Tail Artifacts   0

Koios AI Adapter   -2
-2   -1   0   +1   +2
      TR1   TR2   TR3

R   X   L
Left lobe
Upper Pole position
4.39 × 3.71 × 2.59 cm

Finding 2

4 Moderately Suspicious
Follow
6 pts = 4 pts +2   1 cm ≥ 1 cm

TI-RADS® DESCRIPTORS
Solid Or Almost Completely Solid   2
Hypoechoic   2
Wider-Than-Tall   0
Ill-Defined   0
None   0

Koios AI Adapter   +2
-2   -1   0   +1   +2
      TR2   TR3   TR4

R   X   L
Right lobe
Upper Pole p
1 × 0.66 × 0.5

What is Koios DS Breast & Thyroid?

Koios DS (Decision Support) is AI software that assesses the risk of malignancy of breast lesions & thyroid nodules shown in ultrasound images. It provides physicians on-demand "second opinions" as well as automated determination and reporting of lesion and nodule characteristics.

Its purpose is to improve diagnostic accuracy and increase physicians' productivity and clinical confidence, with the delivery of higher-quality patient care as the end result.

How do you use Koios DS Breast & Thyroid?

A physician or ultrasound technician selects patient images on a workstation and defines regions of interest (ROIs), which are rectangular selections that fit tightly around a nodule. Users draw ROIs manually around orthogonal views of the breast lesion or thyroid nodule for analysis. For breast, users may click the center of the lesion to autosegment the ROI using our SmartClick feature.

Analysis is triggered by clicking the "Analyze" button. The Koios DS AI engine will process the image data using proprietary models and return a system-generated quantitative likelihood of malignancy aligned to BI-RADS® for Breast or to Thyroid TI-RADS® or ATA reporting guidelines. For Breast, specific lesion characteristics such as shape and orientation are populated by the AI engine. For Thyroid, the classification is based on two separate outputs generated by the core AI engine using the bounding-box ROI data: Nodule Descriptors and the AI Adapter.

Solution Stack and Interfaces

Koios DS is an ASP.NET web application deployed on an on-site IIS Web Server (on a physical or virtual machine) in a Windows operating system environment including SQL Server. The application communicates with other systems as follows:

* Koios DS begins its analysis by receiving images for studies from your PACS system via a DICOM interface. Users may access studies through a study-context URL trigger from PACS or utilize a worklist within Koios to access the appropriate study. ROIs are then drawn for analysis by the Koios AI engine. Results returned by Koios may then be pushed back by the User to the PACS system via DICOM Secondary Capture to include Koios' result within the original image series in PACS. All major PACS systems are supported.

System Diagram and Workflow

Legend:
- SSL/HTTPS/TLSv1.2
- DICOM Protocol (C-FIND, C-MOVE, C-STORE)
- SQL Server Read/Write
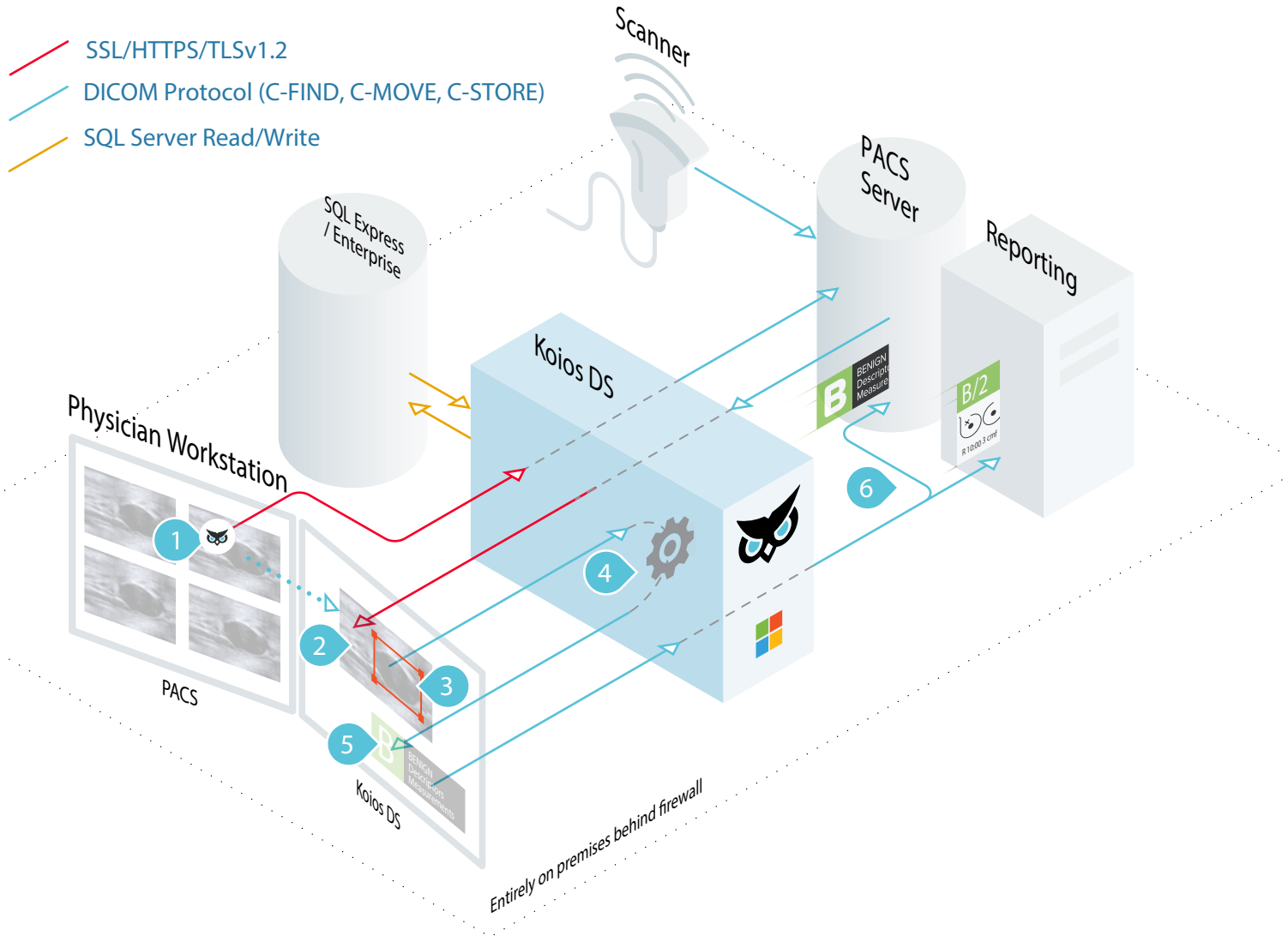
1. Launch patient case in Koios DS via URL triggering from PACS

2. Koios DS displays DICOM images from PACS

3. User requests Koios DS analysis on lesion

4. Koios DS analyzes images at the pixel level in ≤ 2 seconds and captures select BI-RADS descriptors automatically

5. Displays Koios DS results and findings that align with BI-RADS® for Breast or TI-RADS® or ATA for Thyroid categories

6. User can save findings as a secondary capture to PACS and/or export findings to reporting system
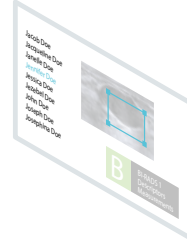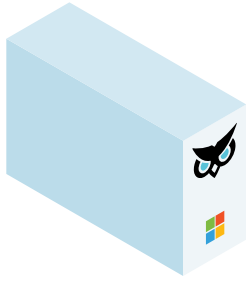
Server Requirements

Server

- Windows Server 2012
- Windows Server 2012 R2
- Windows Server 2016
- Windows Server 2019
- Windows 10
- Windows 11

Processor

- Intel i7/Xeon, 4-core or greater, 2.2 GHz clock speed or greater

RAM

- 8 GB minimum. 16 GB recommended.

Storage

- 256 GB or more

Network Access

- Network read-write access to PACS
- DICOM read-write access to PACS

Microsoft .NET Framework†

- .NET Framework v4.7.2 or v4.8

Microsoft SQL Server†

- Microsoft SQL Server Express 2012 or later
- Microsoft SQL Server 2012 or later
- Microsoft SQL Server Enterprise 2012 or later

Microsoft Internet Information Services (IIS)†

- Microsoft IIS v8.0 or later

Client Requirements

Web Browser

- Microsoft Internet Explorer 11 (including IE 11 Compatibility View)
- Microsoft Edge 79 or later
- Google Chrome 79 or later
- Mozilla Firefox 96 or later
- Apple Safari 13.1 or later

Network Access

- Network read-write access to Koios DS Server

Storage

- 256 GB or more

Monitor Resolution

- 1024 x 768 pixels or more

† Koios will install this software as part of deployment process. All off-the-shelf third-party solutions carry a free commercial-use license from Microsoft.

Setup and Updates

Koios DS requires the following setup to begin configuration:

- Virtual machine or physical server configured with Windows Server and IIS
- Microsoft SQL Server (Express, Standard or Enterprise)
- Koios web application installation
- PACS server access with opened port in firewall

Koios staff need remote access rights to perform software updates, configuration support, and to provide usage analytics and reports.

See the Deployment Checklist on the following pages for the full process of deployment and testing.

Monitoring and Tracking

Log files for the following are stored in SQL:

- User access – maintained indefinitely for audit capability
- Log/Event tracking data
- User account creation/modification – changes to access privileges, timestamps, ID of creating/modifying use, and account activation/inactivation

Application Access and Control

Enterprise Directory Services

- AD and LDAP ready for user authentication
- SSO requirements for unique accounts that leverage your password requirements, expiration intervals, histories, and minimum password age

Local Application Access

- Enforces unique user accounts
- Password requirements: 6-character minimum length

User Access Management

- Conducted by an Application Owner and/or System Administrator
- Koios's account provisioning supports RBAC (Role Based Access Control) when regulating access control.

Database, Data Transmission, Data and Event Tracking

Local Processing and Analytics

- Processing and analysis strictly occur on the Koios DS Server and remains local to the internal network. No data leaves your internal domain.

Clinical Data Storage

- Data related to lesion analysis is strictly stored in session memory and never in the database. No patient image or patient data is ever stored.

Data Transmission

- DICOM is used to handle and transmit information.

Purge of Clinical/PHI Data

- At the close of the user session, PHI and DICOM data are cleared out of the system.

Database Considerations

- Technical specifications for database configuration require that the IIS Application Pool account have read/write access to the database that the Koios DS web application creates.
- Initial database size is approximately 16MB.
- 5MB monthly growth is expected, assuming 40 active users with regular weekly use.
- No data files are stored other than User Access log and event data.

Koios Deployment Team

Your Koios Deployment team is at your disposal to guide and coordinate a smooth and successful activation of the Koios DS Breast solution in your technical environment. Bringing the proper blend of product knowledge, technical expertise, quality and customer-focus, your team stands ready to make working with Koios as hassle-free as any technical configuration you have ever experienced. Contact support@koiosmedical.com with any questions.

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Deployment Checklist

![koios logo]

✔	Server	PACS	Reporting
1	Provision virtual server/machine • Provision VM (≥ 256 GB hard disk, ≥ 8 GB RAM, ≥ 4 core CPU, Windows Server ≥ v.2012) • VM must have outbound internet access rights to https://console.koiosmedical.com/	**9** — Configure Regex Filters *Can be done in parallel to Steps 1-8* Provide Koios with keywords specific to your ultrasound study descriptions. This allows for the correct AI engine to be utilized for the requested study. Examples of keywords may include: • Breast • Breast Ultrasound • Breast Biopsy • Breast US • Thyroid • Thyroid Ultrasound • Thyroid Biopsy • Thyroid US	**10** — *Can be done in parallel to Steps 1–9* Provide Koios with reporting system configuration * This may include: • Vendor administrative service account in the reporting system • Reporting system URL • Reporting text generation fields/templates/macros • Custom reporting fields or mapping Koios outputs to existing custom fields. • DICOM SR AE Title, IP Address, Port for DICOM SR-enabled reporting systems. *For PenRad and MagView integrations, please contact us directly at support@koiosmedical.com.
2	Provide remote-access credentials to Koios • Access to VM through VPN or other access method		
3	Koios team installs Koios DS, SQL Server and IIS SQL Server Access – one of the following: • Provide Microsoft SQL Server database with admin credentials (customer) • Koios will install SQL Server Express on VM		
4	Provide SSL/TLS/HTTPS certificate for the Koios server • Install HTTPS/TLS/SSL certificate on the VM		
5		Provide DICOM connectivity information Provide PACS IP address, AE title, and port number for: • Called query/retrieve • Responding query/retrieve • Storage	
6		Configure PACS server Configure PACS for Koios: C-FIND, C-MOVE, C-STORE • Koios AE title: KOIOSDS • Port: 104 • IP address: same as VM	
7		Configure URL triggering launch per triggering requirements Additional instructions provided	
8	Provide Active Directory groups • AD groups for radiologists, technologists, and administrators • Enable Windows Authentication (if no AD, provide a list of all physician/tech names, emails for manual registration)		
11		Execute go-live testing checklist • Access: Successful login for each user or AD group • Data and analysis: Successful launch of study (ultrasound, mammography, cine loops, Analyze, Save) • View saved results in PACS • Export results to report; verify all custom fields and text templates/macros populate correctly	

Initial Setup Information

Please complete this PDF form and send it to deployment@koiosmedical.com.

Feel free to comment within your answers or in the comment field at the bottom.

Number of physician users
radiologists, oncologists, ob-gyn, etc.

Number of technician users
ultrasound sonographers, technologists,
healthcare workers

Annual diagnostic ultrasound volume
number of ultrasound studies per year

Primary PACS   Version
most frequently used vendor-provided system

Secondary PACS   Version
next most frequently used PACS, if any

Viewer app(s)   Version
vendor-provided app(s) for ultrasound viewing

EMR/EHR system   Version
e.g., Epic, Cerner, Athenahealth

Dictation and Thyroid reporting system   Version
e.g., Nuance PowerScribe, Fluency, etc.

Number of sites
facilities at which Koios will be deployed

Approved connected services
e.g., Citrix, VPN, or other preferred methods for
Koios to connect to customer network

**User administration method and
system for user management**
Koios DS supports Active Directory/LDAP
for user management and single sign-on

Comments