



PHILIPS

Pathology Solution

IVD - US

Designed to meet the needs of high volume laboratories

Philips IntelliSite HER2/neu IHC Digital Manual Read

Philips Pathology Solution

The Philips IntelliSite HER2/neu IHC Digital Manual Read product is based on the Philips IntelliSite Pathology Solution technology platform which comprises the Philips IntelliSite Pathology Solution Image Management System (IMS) and the Philips IntelliSite Pathology Solution Ultra Fast Scanner (UFS).

The Philips IntelliSite HER2/neu IHC Digital Manual Read is intended for in vitro diagnostic use as an aid to the pathologist in the display, detection, counting and classification of tissues and cells of clinical interest based on particular color, intensity, size, pattern and shape. The Philips IntelliSite HER2/neu IHC Digital Manual Read is based on the Philips IntelliSite Pathology Solution platform, which is an automated digital slide creation, management, viewing and analysis system, designed to meet the needs of high volume labs and expand to create virtual networks across multiple pathology labs.

The Philips HER2/neu IHC Digital Manual Read is intended for use as an accessory to the Dako HercepTest™ to aid in the detection and semi-quantitative measurement of HER2/neu (c-erbB-2) in formalin-fixed, paraffin-embedded neoplastic tissue immunohistochemically stained for HER-2 receptors on a computer monitor. When used with the Dako HercepTest™, it is indicated for use as an aid in the assessment of breast cancer patients from whom HERCEPTIN® (Trastuzumab), PERJETA® (Pertuzumab) or KADCYLA® (Ado-Trastuzumab Emtansine) treatment is being considered. Note: The actual correlation of the Dako HercepTest™ to Herceptin®, Perjeta®, or Kadcyla®, clinical outcome has not been established. Note: The Philips IntelliSite HER2/neu IHC Digital Manual Read is for evaluation of digital images of immunohistochemically stained slides that would otherwise be appropriate for manual visualization by conventional microscopy. It is the responsibility of a qualified pathologist to employ appropriate morphological studies and controls as specified in the instructions for Dako HercepTest™ to assure the validity of the scores obtained using Philips IntelliSite HER2/neu IHC Digital Manual Read.

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Philips IntelliSite Pathology Solution Ultra Fast Scanner (UFS) 1.6



Philips IntelliSite Pathology Solution Image Management System (IMS) 2.4

Workflow driven

Ease of use

With a 2-step “Load & Scan” operation; scanning starts automatically, saving time, technician training simplified

Continuous processing

Add/remove slides without interrupting the scanning process

Full barcode integration

With LIS/IMS for slide/ case association

High performance

High throughput

- A storage capacity of 300 slides
- 60 seconds per slide at 40x equivalent (15 x 15 mm scan area)
- High image quality through continuous autofocus

Ease of use

- Auto tissue detection; eliminating extra steps, saving valuable time
- Automated “walk away” scanning

Collaboration made easy

Workflow / smart features

- Image alignment automatically aligns multiple serial tissue sections for synchronized panning and zooming
- Tissue detection automatically suggests bookmarked area for single click slide navigation
- Smart navigation via a combination of intuitive workflow oriented shortcuts keys and novel clickless panning for comfortable navigation of images

Speed

The IMS aims to improve efficiency and effectiveness of pathology labs to get pathologists through cases as fast as possible. Case centric work list helps organize workload

- Fast workflow navigation for next slide and case
- Advanced navigation tools incl. magnifier zoom and bookmarks
- Performance design for handling > 1,000,000 cases
- Performance and capacity based storage architecture for enhanced viewing performance

Enhanced tools for interaction and remote viewing with the aim to improve information sharing and simplify connectivity.

- One unified case list over different locations
- Simple case sharing via secure web link
- Simultaneous viewing with real-time collaboration
- Non-intrusive notifications with single click access to a shared session directly from the image viewer

Seamless Integration

Seamless integration with workflow and information systems. LIS can remain the central system to drive the workflow for case dispatching and reporting.

- Role-based access with secure user login
- Customizable bi-directional LIS connectivity and communication

Technical specifications

Philips IntelliSite Pathology Solution Ultra Fast Scanner

Slide capacity	300 slides (15 racks each hold 20 slides)	Slide rack	Winlab LS-20/Winlab LSM-20, Sakura 4768 20-slide basket
Total handling and imaging time per slide	60 seconds at 40x equivalent (15x15 mm scan area)	Barcode support	DataMatrix(recommended), Code 39, Code 128
Scanning method	TDI line scanning	Operating temperature	10 to 35° (for performance)
Microscope objective	Olympus, NA of 0.75 Plan Apo	Relative humidity (no condensation)	20 - 80% (for performance)
Focus method	Continuous auto focus	Dimensions of scanner	993 x 656 x 587mm (LxWxH)
Pixel size/resolution	0.25 µm/pixel	Weight of scanner	129 kg
UFS output format	iSyntax Philips proprietary file format with either RAW or iSyntax compression	Power supply	110-230 VAC, 50/60 Hz, 150 Watts
Compliance to standards	EN 61010-2-101:2002, EN 61326-2:2006, CAN/CSA-C22.2 No 61010-2-101.04, UL 61010-2-101, FCC Part 15	UFS connectivity ports	USB2.0, with 2 x RJ45 connectors, Ethernet cable for 10GB and/or 1G/100MB

Philips IntelliSite Pathology Solution Image Management System Viewer – minimum hardware requirements

CPU	Dual-core @3GHz	Operating system	Any operating system supporting a browser with Microsoft Silverlight® 5
RAM	3GB of physical RAM memory	Other software	A PDF reader (e.g. Adobe Acrobat Reader)
Monitor BARCO MDCC2121	2 Megapixel Resolution: 1600 x 1200 Brightness: 300cd/m2 Colordepth: 24-bit Contrast: 750:1	Connectivity	100Mbit or 1Gbit Ethernet connection to internet/intranet
Browser	Internet browser supporting Microsoft Silverlight® 5		

Philips IntelliSite Pathology Solution Image Management System Application Server & storage – options

Storage capacity	Flexible and extendable storage configurations from Terabytes to Petabytes
Configuration options	Single and multi site
LIS interface	HTTP/XML, or HL7 via LIS broker
Browser	Internet browser supporting Microsoft Silverlight® 5

How to reach us:

Philips Digital Pathology Solutions North America

North America
345 Scarborough Road
Briarcliff Manor, NY 10510
United States

Manufacturing address:

Philips Electronics Nederland BV
Philips Digital Pathology Solutions
Veenpluis 4-6, 5684 PC Best,
The Netherlands

General access

Phone: +800 PHILIPSH (+800 74454774)*

U.S.A. +1 844 7570 939

Email: digitalpathology@philips.com

*Please use the alternate number if the +800 number is not supported locally

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Printed in the Netherlands
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4522 207 27501 * NOV 2015