

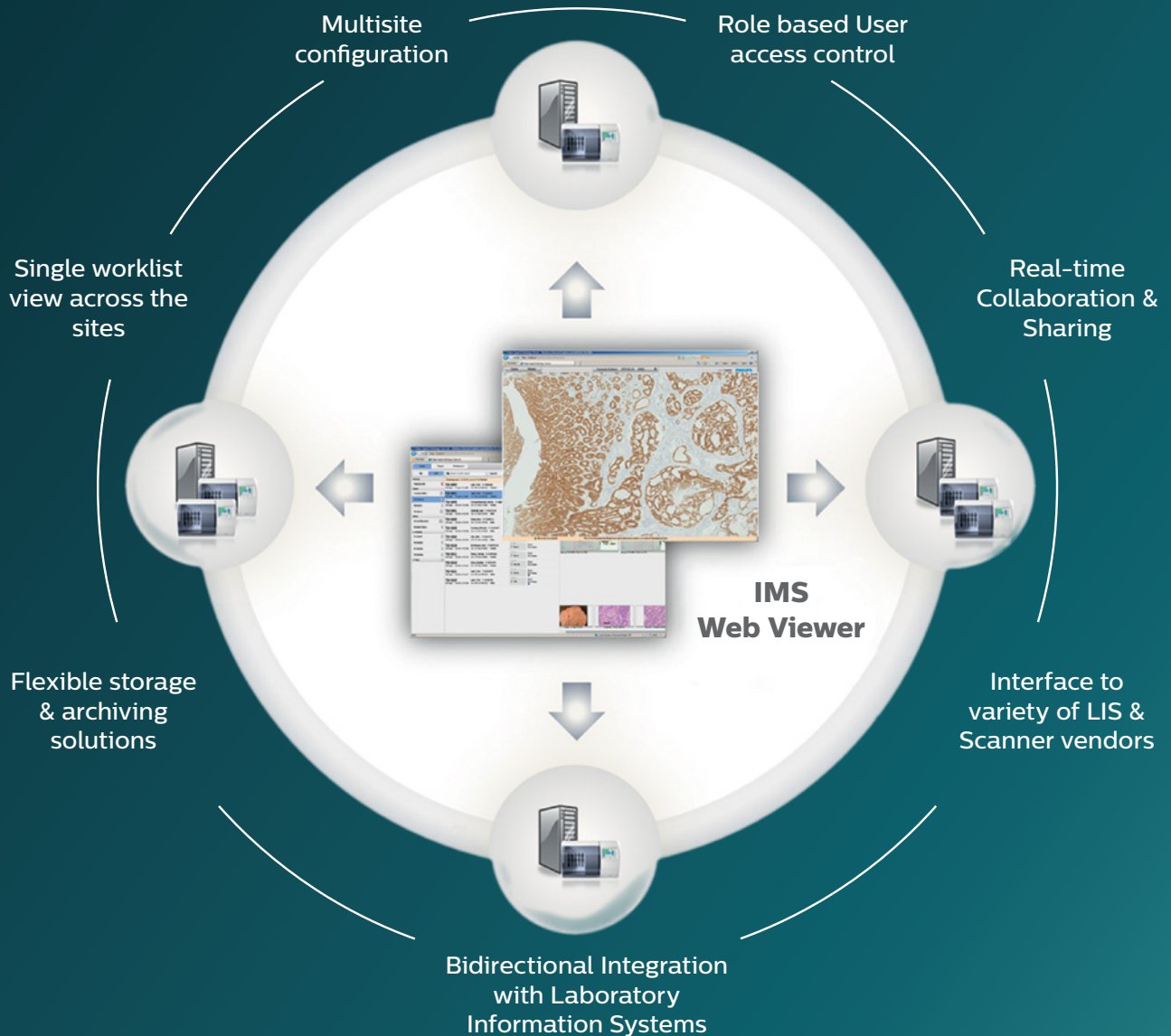
**PHILIPS**

Pathology Solution

IVD – US



**Philips IntelliSite  
HER2/neu IHC  
Digital Manual Read**



The intelligent Philips IntelliSite Pathology Solution Image Management System (IMS) is an element in setting up virtual network(s) and has 2 components, a viewer and an enterprise solution. The viewer is designed for **speed and ease of use**; It aims to support **fast and efficient workflow** with smart image-processing. Capable of running with the LIS in the lead, the workflow driven system allows fast slide-to-slide transitions to enable signing out cases quickly with configurable options for **bi-directional integration** with the LIS.

# Philips IntelliSite HER2/neu IHC Digital Manual Read

The Philips IntelliSite HER2/neu IHC Digital Manual Read (further referred to as Philips IntelliSite Her2/neu) 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. Philips IntelliSite HER2/neu IHC Digital Manual Read is based on the Philips Pathology Solution, which is an automated digital slide creation, management, viewing and analysis system.

**Designed with pathologists, for pathologists** the Philips IntelliSite Her2/neu consists of the Philips IntelliSite Pathology Solution Ultra Fast Scanner (UFS) and the web-based Philips IntelliSite Pathology Solution Image Management System (IMS). The solution aims to increase the efficiency and productivity of laboratory workflow.

The Philips IntelliSite Her2/neu is an **open and scalable system** that enables virtual networks across pathology labs to grow, simply by adding new locations and new users. This system easily interfaces with multiple Laboratory Information Systems and functions with all kinds of hardware fulfilling the minimal specified hardware requirements.

The Philips IntelliSite Her2/neu is a **turnkey solution** that includes advanced workflow features, LIS integration and extensive training and aims to support to facilitate the seamless conversion to this new way of working.

The Philips IntelliSite 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.

## Key advantages

- Integrated workflow solution
- Designed with pathologists, for pathologists
- The Philips IntelliSite Her2/neu is an open and scalable system
- A turnkey solution that includes advanced workflow features

# Design princip

# Philips

With the aim to enable efficiency and productivity improvements, the Philips IntelliSite HER2/neu is built on 4 design pillars:



## Workflow driven

The Philips IntelliSite HER2/neu is seamlessly embedded in the pathology workflow and aims to provide:

- Intuitive workflow with user-specific worklists across all sites.
- Interactive and real-time multi-user case discussion capabilities.
- Content export to LIS supporting existing reporting workflows.
- Customizable panels to maximize viewing area.
- Digital tools unavailable in conventional pathology, such as automatic registration of multiple cuts from the same block on a single screen, with side-by-side or stacked display.
- Innovative panning and zooming solutions such as the magnifier zoom navigation and clickless panning for comfortable navigation of images.



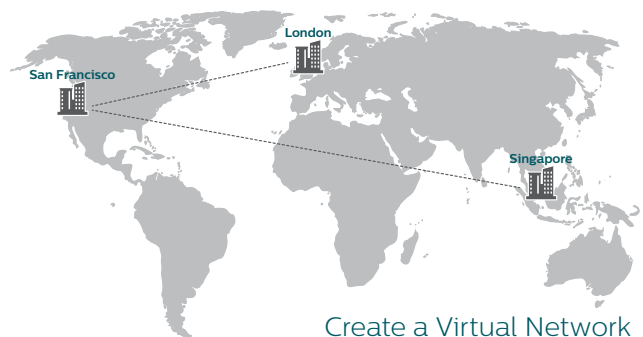
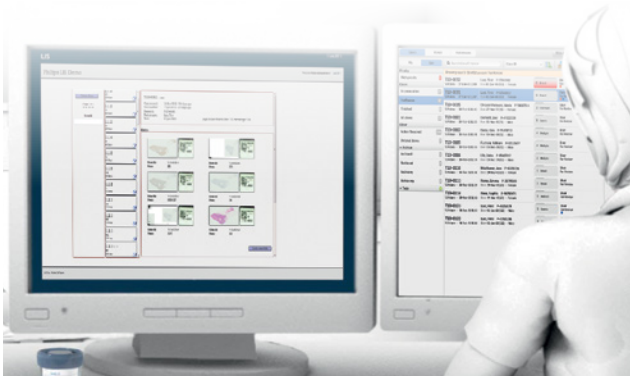
## High Performance

The Philips IntelliSite HER2/neu aims to offer high performance throughout the entire system:

- Easy-to-use system with automated “walkaway” scanning for signing off cases quickly, with the efficiency of single click slide/ case transitions.
- The UFS features continuous auto focus, a storage capacity of 300 slides and a total slide handling and imaging time of less than 60 seconds per slide at 40x equivalent (15 x 15 mm scan area).
- Going through cases quickly with fast slide to slide transitions slides. Real-time collaboration connects colleagues for case discussion at the click of a button.
- High image quality through continuous autofocus.
- Capacity based storage architecture with the aim for viewing performance and multi-scanner configurations.



# les of the Pathology Solution



Create a Virtual Network  
Invite remote Pathologists

## Seamless integration

Current Information Systems aggregate all required information and make it easily accessible, where the LIS drives the workflow:

- LIS can remain the central system to drive the workflow for case dispatching.
- When the LIS does not offer this, the IMS can provide these functionalities.
- Directly open images from thumbnails in the LIS or from the IMS itself.
- Easy access to and sharing of data among peers regardless of geographic location.
- Role-based access limits access to information when needed for privacy protection.
- Fully barcoded system for high-throughput labs.
- Flexible storage and archiving solutions with automated archiving policies.
- Single, unified case list over multiple locations.

## Collaboration

The Philips Pathology Solution is designed to easily facilitate knowledge sharing, consultation and workload distribution with:

- Instant case sharing via a secure web link. Simultaneous role based viewing and interactions to protect sensitive information.
- Role-based, user access control to select the information available for viewing.
- Smart algorithms, using features as automatic image alignment, tissue detection, tissue presentation and single-click navigation support.



# Engineered to **meet the** **needs** of today's digital pathology labs

Philips IntelliSite Pathology Solution Ultra Fast Scanner (UFS), the easy-to-use UFS combines **high image quality** with **high speed scanning** and **throughput**. This scanner features continuous auto focus, a storage capacity of 300 slides and a total slide handling and imaging time of less than 60 seconds per slide at 40x equivalent (15 x 15 mm scan area).

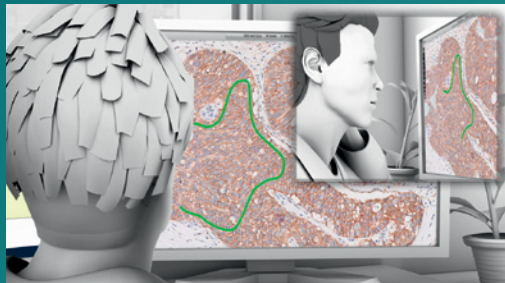
- When it comes to its user-friendly interface, the UFS does not require complex training thanks to its simplified and intuitive design.
- The scanner is designed without a start button, providing the “walk away” scanning capability.
- Based on an intuitive 2-step “load & scan” operation, scanning starts automatically by simply loading the slides and closing the door.
- In addition, the scanner enables the user to add/remove slides without interrupting the scanning process.



# A true enterprise solution

Philips IntelliSite Pathology Solution Image Management System, the system provides an open and scalable design that aims to offer optimal integration to the workflow and IT infrastructure environment by:

- Easily interfaces with multiple LIS.
- Offering the infrastructure to implement customer-specific archive strategies.
- Password protected access to pathology images directly from electronic health records.
- Securing and protecting access and sharing of informatics data.
- Providing LIS, radiology PACS, DICOM, and interoperability integration services.



Powerful slide/case sharing tools allow **real-time collaboration with role based access providing privacy when required**. From simple case sharing via a secure web link to simultaneous viewing with real-time interactions, the system connects colleagues anywhere in the world for instant consults and second opinions.



**Smart workflow algorithms** include automatic image alignment, tissue detection, tissue presentation and single-click navigation. The aim is to support a pathologist's work and streamline productivity while decreasing mouse clicks with innovative panning and zooming solutions.

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For In Vitro Diagnostic Use. Federal law restricts this device to sale  
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