Quick Guide

Neon

1.3

This Quick Guide contains important information on your MetaSystems Neon software. Please familiarize yourself with its content prior to using Neon.

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Change History

Rev. no.	Reason for change	valid from
1.0	New document – for Neon 1.3 (US version).	2024-04-23

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1. Symbols Used

Symbol	Title / Remarks
Symbols According to ISO 15223-1:2021 (in alphabetical order of titles)	
⚠	*Caution* Text boxes marked with the standardized *Caution* symbol followed by the term **CAUTION!** indicate a potentially hazardous situation that, if not avoided, may interfere with the integrity of the software installation itself or data generated with the medical device. Text boxes marked with the standardized *Caution* symbol followed by the term **ATTENTION!** should be read with great care to prevent any problem with software or connected standard hardware.
📖	*Consult Instructions for Use (IFU) / Consult electronic Instructions for Use (eIFU)*
GE	*Country of Manufacture* *Country of Manufacture – Germany (two-letter country code according to ISO 3166-1)*
	Date of Manufacture
	Distributor
	Importer
IVD	*In Vitro Diagnostic Medical Device*

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	Manufacturer
	Translation – This symbol is accompanied by the name and address of the entity that is responsible for the translation activity.
UDI	*Unique Device Identifier* *Unique device identifier information.*

Additional Symbol

i	Text boxes marked with this information sign contain important technical information or hints on new or revised software features or settings.

2. General

Instructions for Use (IFU)

Instructions for Use for Neon 1.3 compromise of two types of documents:

IFU	Definition
Quick Guide	Concise Instructions for Use (IFU): product descriptions including Intended Use, safety instructions, notes on setup and operation, and basic instructions for use, and troubleshooting. Quick Guides are provided as PDF files, which can be viewed and printed with an appropriate reader software (not a MetaSystems product).
Manuals/ Help Files	Comprehensive Instructions for Use (IFU): product Descriptions including Intended Purpose, safety instructions, and extensive instructions for use and configuration. Manuals and Help Files for one software version have identical contents (except for minor format-specific alterations): ⧉ Manuals are provided as PDF files, which can be viewed and printed with an appropriate reader software (not a MetaSystems product). ⧉ Help Files are provided as CHM files, which can be opened directly from Neon No separate viewer software is required.

⚠ **ATTENTION! Consistency of versions!** Please check that the version of the IFUs match the version of the MetaSystems software you are using.

Additional Copies

Additional copies of this Quick Guide are available as PDF files on the MetaSystems website: *Support - Downloads – Certificates, Documents, and Forms - Quick Guides*. You can also send a request by e-mail to MetaSystems. Please mention the document number (see front page) in your request.

Assumptions on Previous Knowledge

The IFU assumes you have:

- Basic computer literacy, including a general understanding of data storage, file transfers, and copying and pasting.
- Sufficient knowledge of applicable laboratory techniques to interpret images generated by MetaSystems Neon software.

How to Obtain More Information and Support

MetaSystems Representatives

MetaSystems is an international company with offices in Germany (headquarters), in Argentina (Buenos Aires), in Hong Kong, in India (Bangalore), in Italy (Milano) and in the U.S.A. (Boston). Additionally, MetaSystems is proud to have a global network of partners, which is covering the local business in almost all regions of the world. Please refer to the front page of this Quick Guide for contact details of your local MetaSystems representative or visit *www.metasystems-international.com*.

Errors and Suggestions

You may submit electronic comments and suggestions on the IFU at any time for company consideration to MetaSystems (see footer). Comments may not be acted upon by MetaSystems until the document is next revised or updated.

Reporting Serious Incidents

If any serious incident occurs in relation to Neon 1.3, the incident shall be reported to MetaSystems and the FDA.

3. Product Description

Intended Use

The Neon software is intended to be used for collecting, organizing, managing, and displaying images and associated metadata obtained from other MetaSystems software to enable search, navigation, workflow management, and reporting. Neon can be used to import metadata from other systems and to export images and associated metadata to other systems.

Additional Information

Every MetaSystems Ikaros 6.3, Isis 6.3 or Metafer 4.3 software license is accompanied by a Neon 1.3 software license.

License Protection and Software Feature Control by Hardware Token

MetaSystems software requires the presence of hardware copy protection modules, also known as 'dongles', to be started and executed. Failure to plug in the dongle will result in the software not running. A MetaSystems' dongle does not only work as a security key, but also as a physical license key, which enables particular features in the MetaSystems software.

- Each dongle has an individual serial number.
- Only features enabled by the license key are available in the respective software. All other software features are disabled but can be enabled after purchasing the respective license and reprogramming the dongle.
- The software periodically performs checks for a valid dongle and license key.
- The required **Update Expiry Date** for Neon 1.3 is *June 2021* (*0621*).

4. Safety Information

General Precautions

For professional laboratory use only. Using this product in a manner not specified in the user documentation may result in personal injury or damage to the instrument or device.

Table: General Precautions

⚠	**CAUTION: Power Point!** The computer running Neon 1.3 shall be connected only to properly grounded electrical outlets. Also consult the safety instruction in the product information supplied with all electric instruments and components.
⚠	**CAUTION: Operation by qualified personnel only!** The software must be operated only by qualified and trained laboratory personnel.
⚠	**CAUTION: Risk of Ineffective Safety Measures!** If it is determined that protective measures are no longer effective, the device must be taken out of service and secured against inadvertent operation, to avoid the risk of injury. Contact MetaSystems or its representative to have the device repaired.
⚠	**ATTENTION! Consult Laboratory Safety Guidelines and Instructions for Use for all installed hardware components!** Before using Neon, it is essential to familiarize yourself with all applicable laboratory safety guidelines and regulations in their latest versions, and the instructions for use (IFUs) of all installed hardware components. Please study the IFUs supplied with the components.

Protection of Personal Data

MetaSystems guarantees confidentiality of all medical or patient related data and herewith confirms to fulfil the requirements according to European Union Regulation (EU) 2016/679 *On the protection of natural persons with regard to the processing of personal data* (General Data Protection Regulation) as follows:

Personal data will be:

- Processed lawfully, fairly and in a transparent manner in relation to the data subject.

- Collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes.

- Adequate, relevant, and limited to what is necessary in relation to the purposes for which they are processed.

- Kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed.

- Processed in a manner that ensures appropriate security of the personal data, including protection against unauthorized or unlawful processing and against accidental loss, destruction, or damage, using appropriate technical or organizational measures.

If you have any questions concerning the MetaSystems' Privacy Policy statement, please contact MetaSystems.

Cybersecurity

Supported Operating System

⚠ **ATTENTION!** Neon 1.3 has been developed and tested exclusively for use with the Windows™ 10/64-bit and Windows™ 11/64-bit operating system (OS).

Microsoft™ has discontinued the support for all operating system versions prior to Windows™ 10. These versions do not receive updates and security patches any longer and bear a high level of vulnerability against cybersecurity threads. We explicitly recommend running our software only on computers with Windows™ 10/64- bit or higher.
Although our software may technically be able to run on older operating systems (for example Windows™ 7), this will be entirely at your own risk. MetaSystems does not take any responsibility for errors arising due to the use of non-approved operating systems.

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User Access

MetaSystems offers different levels of user login modes. Depending on the security policies of the institution where Neon 1.3 is installed, user access modes can be selected from low to high security. For details on the login modes, please refer to the product help or manual.

Local Mode

If network resources hosting the case data or shared configuration folder are (temporarily) not accessible, Neon 1.3 can be operated in a 'local emergency mode'. This mode allows to continue to work with data stored on the local computer. After the normal operation mode has been restored, data can be manually transferred to the preferred data storage location.

Hardware

Hardware Requirements

Table: Minimal Hardware Requirements for Computer Running Isis V6.3

Hardware Component	Description
PC	Standard PC (processor speed: 2 GHz, RAM size: 2 GB system memory, hard disk space: 32 GB, display: 1920 x 1080). Data are indexed automatically with the help of a software called NeonServer which runs as a Windows service. For all installations, except for a stand-alone computer, NeonServer should be installed on a separate PC with at least 4 cores, 16 GB RAM, and 100 GB disk space. Dedicated server hardware is not required but recommended. The computer network should allow fast data transfer (1 Gb/low-latency).
Monitor	Minimum resolution: Full HD (1920 x 1080)
Mouse	3-button mouse (or equivalent ergonomic input device)

For addresses of hardware component manufacturers, please refer to the Ikaros / Isis 6.3 Help / Manual or Metafer 4.3 Help / Manual.

5. Pre-Installation Requirements, Installation and Post-Installation

⌐ **Workspace and IT-infrastructure** - The workspace and IT-infrastructure requirements are identical to Ikaros, Isis, or Metafer. For further information consult the Ikaros 6.3, Isis 6.3, or Metafer 4.3 Quick Guides.

⌐ **Appoint 'Super-Users'** – Determine one or two persons among the users who are responsible for the systems and are available as our contact persons. These persons should be allowed to coordinate and communicate the requests and wishes of the users and to make short-term decisions regarding the system configuration.

⌐ **Provide IT Support** – Ensure that IT staff are available for the duration of the installation to respond quickly to any issues related to the IT infrastructure.

⌐ **Provide Temporary Administrator Account** – During the installation phase, our employees require temporary administrator access. This access can be deactivated after the installation and is used to carry out the necessary installations and to test the interoperability of the systems.

⌐ **Installation and Training by MetaSystems Personnel** – We offer installation and training of laboratory staff as a service.
We are aware that installation and training may interfere with your daily laboratory routine in one way or the other. Therefore, we suggest making appropriate arrangements which allow your personnel attend the training sessions. Together we can draw up a training plan in advance to address the general and particular training requirements for every operator of the Isis software.

⌐ **Training Scope Neon** – In brief, the training covers:

  ⌐ **Start and end Neon / user login**.
  ⌐ **Settings** – Data folders, paths, security settings, user groups, reporting.
  ⌐ **Navigation** – create case, case data import.
  ⌐ **Cases** – View, search, filter, sort, and group cases.
  ⌐ **Cases** – Rename, delete to 'trash', and restore from 'trash'.
  ⌐ **Case datasheet** – Enter data, customize data sheet.

- ꘎ **Case structure** – Hierarchical levels: case, scans, cells, culture, slide, region; data on each hierarchical level

- ꘎ **Case history**

- ꘎ **Cells** – Cell List, Cell Gallery, and Combined Karyogram

- ꘎ **Workflows** – Manual / automatic (triggered/conditional) workflow progression.

- ꘎ **Reporting** – Printing reports, different report types, customizing reports.

- ꘎ **Problems** – solve problems and report unsolvable problems (XReports).

- ꘎ **Get Help** – Look-up shortcuts, open / navigate / search Help file.

꘎ **Installation and Training Are Documented** – For your and our reference we will ask you to sign an Installation / Service Report after training is completed to document the trained software features. The same report is also used to document any service / maintenance work, if necessary.

꘎ **Software Installations Backups** – MetaSystems software comes with built-in routines to create backups of the current software installation. Backups are stored (*a*) locally on the computer running Neon, (*b*) on a network resource chosen by the customer, and (*c*) at MetaSystems. The latter backup copy helps us to look up configuration details, even if a remote support is not feasible.
Software installation can be restored from backups.

꘎ **Using Neon** – Please refer to the Neon 1.3 Manual / Help for detailed description of the case management, data management, and reporting options.

꘎ **Allow Us to Support You Remotely** – For fast and professional online support, we offer a remote support software tool TeamViewer (branded as 'MetaSystemsQS'). Please note, that remote support by MetaSystems requires a signed Remote Support Agreement form, which is available on request (*Remote Support Agreement*).

TeamViewer is a highly secure remote maintenance solution using fully encrypted data channels. In its latest version, it includes encryption based on 2048 RSA private/public key exchange and AES (256-bit) session encryption. This technology is based on the same standards as https/SSL and meets today's standards for security. The key exchange also guarantees full client-to-client data protection. Access from outside requires a session token which is generated on startup of the QuickSupport module. This token is only valid during one single session; it is not possible to access the device from outside without it. Do not start the remote access module unless asked by a MetaSystems staff member to do so.
You can download the tool from the MetaSystems website:
1. *Scroll down to Support and a click on Online Support Tool; the download will start automatically.*
2. *Double-click the TeamViewerQS.exe to install. Follow the on-screen instructions.*

⌐ **Make sure that your device(s) is/are protected against malware and viruses** – Likewise, we support the installation and maintenance of anti-virus software through your IT department. You should also take all necessary measures to protect the device and your network from harmful influences (e.g., by a network firewall). Please note that the above measures are part of on-site network maintenance, and that MetaSystems assumes no responsibility for damage or data loss caused by inadequate protective measure.

⌐ **Software Updates Fixing Software Errors – Despite our thorough testing regime, certain software errors may remain undetected until after the initial release of a software version.** We are committed to fix known software errors.
For this purpose, we will release minor software updates, indicated by the third part of the version number (e.g., 1.3.0 -> 1.3.1).
Major issues compromising the proper operation of Neon must be reported by MetaSystems to the competent authority together with a plan for corrective actions. In this instance, you will be informed about the corrective measures.

⌐ **Pay attention to regular updates of security relevant drivers and software** – We strongly recommend updating computers regularly and to keep the drivers and operating system (OS) up to date. If we become aware of any OS patches that may compromise the intended operation of our software, we will inform you and recommend corrective actions.

⌐ **Service and Maintenance Plans** – Neon 1.3 does not require maintenance at fixed intervals.
MetaSystems and its distribution partners are offering service and maintenance service plans, which include installation of minor software updates. Please inquire.

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6. Troubleshooting

Problem	Potential Cause	Action
Software cannot connect to NeonServer	Computer running NeonServer is not on and/or not connected to the network. NeonServer is not properly installed 'as a service'. NeonServer service is not started.	Start computer running NeonServer with correct user account.
		Check, whether NeonServer is listed as 'Service' under Windows. If not, re-install NeonServer (requires admin rights).
		Start NeonServer service.
Software starts, but data folders are not accessible	Computer hosting data is not on and/or not connected to the network.	Ask your IT dept. to check, whether this computer is properly connected to the network domain and folders are shared correctly.
	Your Windows user account does not have read/write access to the respective network resources.	Ask your IT dept. to upgrade your user rights on the network accordingly.
Software indicated problems		Open Diagnostics (press [F10]) and check details on Problems.
		Check dongle for available licenses.
Software apparently	Software bug.	Create Exception Report (XReport) and forward it to MetaSystems (automatic transfer, if configured accordingly).
	Wrong configuration.	Open Diagnostics (press [F10]) and check details on Problems. Restart Isis. Restart computer. Rerun Neon installer package. Check program settings.
Cases seem to be missing in the Case List	Case List has been filtered.	Check, whether filter conditions are active for the Case List.
	Data are not fully indexed.	Refresh Case List. Check physical data folder for presence of case subfolder. Reindex data.
Scans / cells seem to be missing in a case	Case has been filtered.	Check, whether filter conditions are active for cells.
	Data are not fully indexed.	Reindex case.

If your problem is not listed here, please consult the help file and corresponding manuals before contacting your local MetaSystems distribution partner.