24/7 EEG SubQ Link

Instructions for use

UNEEG™ medical

1 INTRODUCTION

This instruction guides you on how to use and maintain the 24/7 EEG SubQ Link (hereinafter: the Link software). Please read all instructions before you begin using the Link software.

2 PRODUCT DESCRIPTION

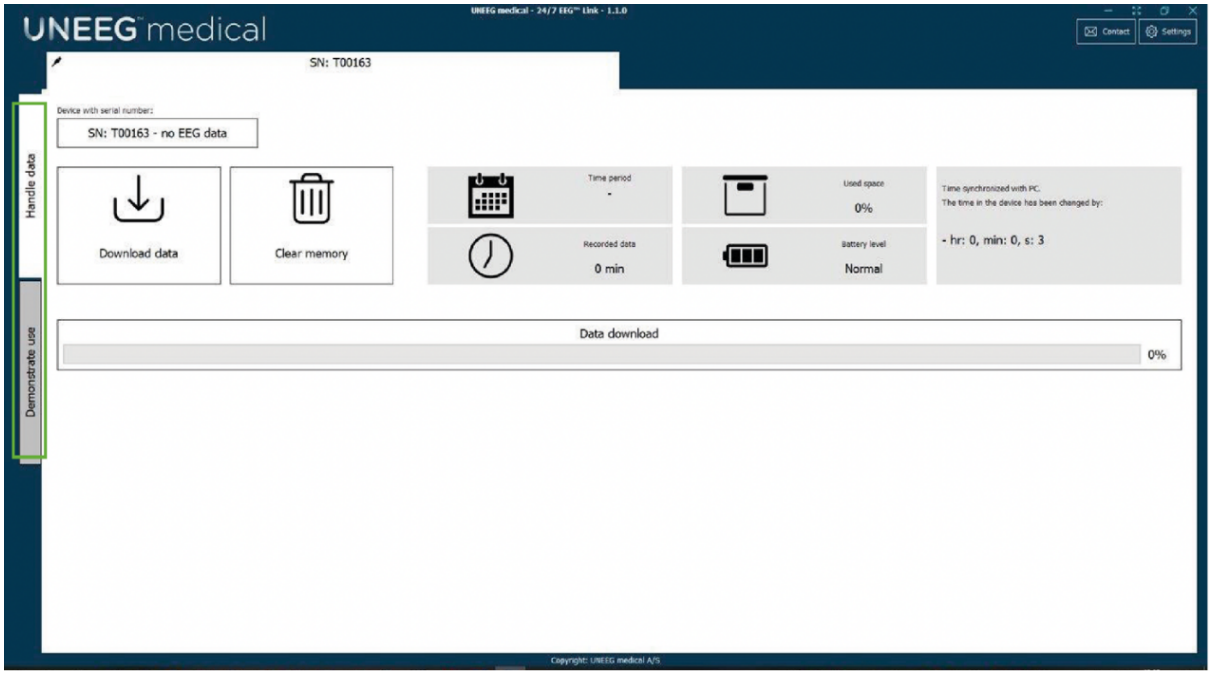
The Link software can download data from a UNEEG recorder (Figure 1: Handle Data module) and demonstrate UNEEG recorder functions (Figure 1: Demonstrate Use module).

The data stored on a UNEEG recorder are downloaded via the Link software, which parses the data to standard EDF+ format. EDF+ format is a widely used open-source EEG data-recording format that can be imported by third-party software to view EEG data.

The Demonstrate Use module allows the healthcare professional to demonstrate to the patient sounds, lights and feedback patterns from the UNEEG recorder.

The Link software is supplied to the healthcare professional electronically.

Figure 1



2.1 PRODUCT VARIANTS

CATALOGUE NUMBER	PRODUCT NAME	DESCRIPTION
20025	24/7 EEG SubQ Link	Software application

2.2 DESCRIPTION OF COMPONENTS

24/7 EEG SubQ Link consists of software only.

2.3 PRODUCT COMPATIBILITY

The Link software is to be used only with UNEEG products.

CATALOGUE NUMBER	PRODUCT NAME	DESCRIPTION
UNEEG Recorder		
20011	24/7 EEG™ SubQ Recorder, M1	For attachment via magnet
20013	24/7 EEG™ SubQ Recorder, C1	For attachment via clip
Connector cable		
20020	Connector cable	20 cm
20018	Connector cable	150 cm

The listed products may not be available in all countries. Please contact your local sales representative.

3 INTENDED PURPOSE

3.1 INTENDED USE

The 24/7 EEG SubQ Link is intended to transfer EEG data from a UNEEG recorder.

3.2 INDICATION FOR USE

The indication is to aid in monitoring and diagnosis of diseases or conditions that alter EEG.

3.3 CONTRAINDICATIONS

There are no known contraindications with the use of 24/7 EEG SubQ Link.

4 HOW TO USE THE LINK SOFTWARE

4.1 INSTALLATION

The software is delivered with an installation program that guides the installation process and installs the software on the user's PC. The PC administrator must grant the user sufficient access rights to install the software.

1. Download **Setup – 24/7 EEG SubQ Link**
2. Launch the installer **Setup – 24/7 EEG SubQ Link** by double-clicking the downloaded file.
3. The installer will guide you through the installation process.
4. Once the installation has finished, launch the Link software by clicking the icon on your desktop.

4.2 SYNCHRONISE THE RECORDER TO YOUR LOCAL TIMEZONE

Always synchronise the recorder before providing it to the patient in order to ensure that the recorder data display the correct time.

Connect the recorder to the PC using the Connector cable (Figure 2). Synchronisation will start automatically. You can see the adjusted time in the module **Handle data** (Figure 3).

Note: To prevent any time drift and to ensure that data are correctly time-stamped, it is recommended that the clock be synchronised within 30 days prior to the start of data collection.

Note: Ensure that the PC's clock is correct when the recorder is connected to the PC.

Figure 2

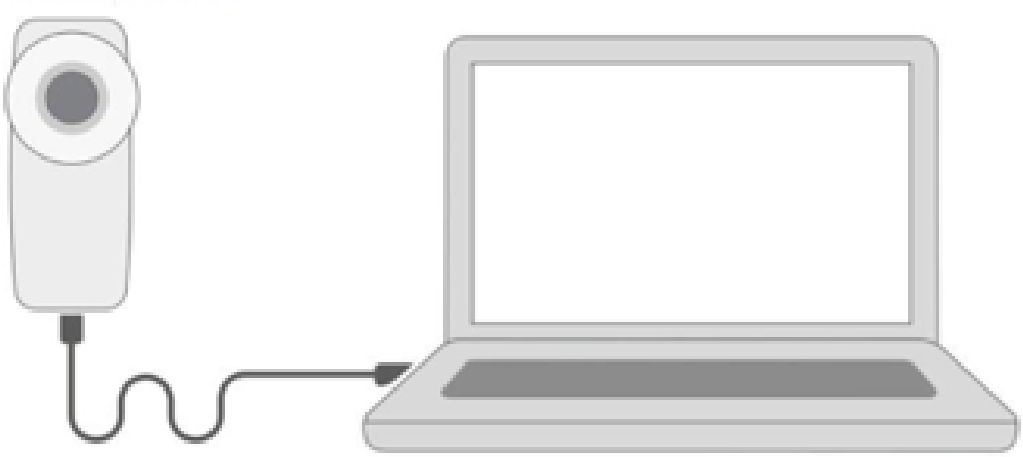
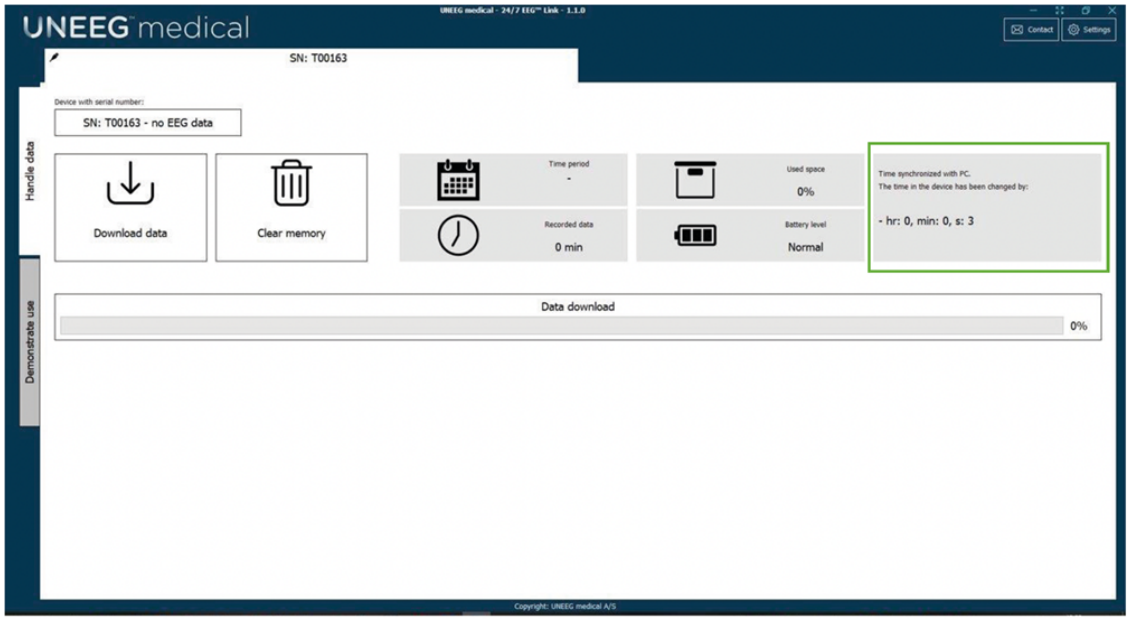


Figure 3

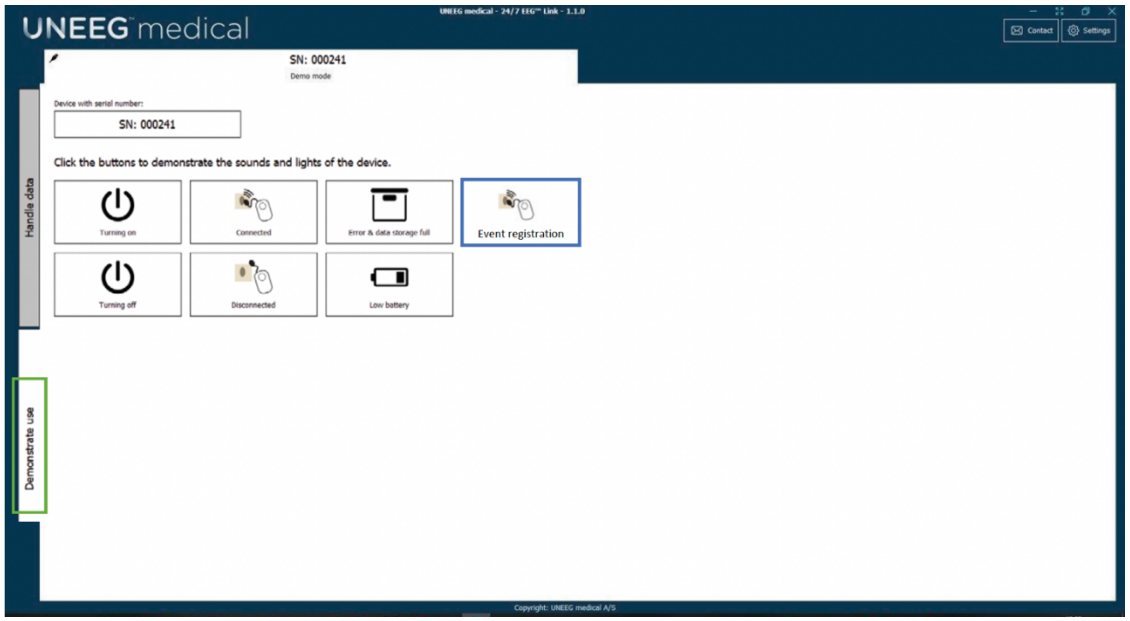


4.3 DEMONSTRATION MODULE TO SUPPORT PATIENT USE

The recorder may be demonstrated using the module **Demonstration use** (Figure 4). To use the demonstration module, the recorder should be connected to the PC (Figure 2).

Click on the icon to choose the function that you wish to demonstrate. The recorder will then vibrate, play a sound and flash.

Figure 4



4.4 DOWNLOAD DATA

Data from the recorder can be downloaded to the PC via the module **Handle data** as follows:

1. Click **Download data** on the left side of the screen (Figure 5).
2. Select the destination folder and supply a file-name prefix (patient-related) for the data (Figure 6).
3. Click **Start download** (Figure 6) and wait for the data to download. Ensure that the recorder is not disconnected, and that the PC is not turned off during the download.
4. Once the data are successfully downloaded, the recorder memory may be cleared (see section 4.6).

Figure 5

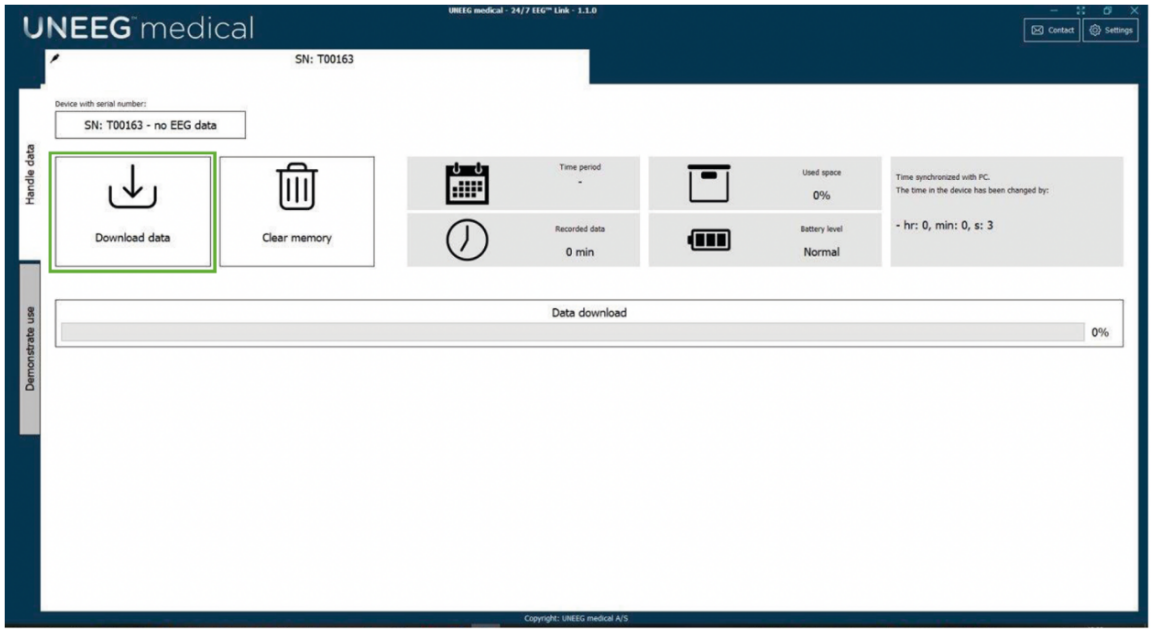
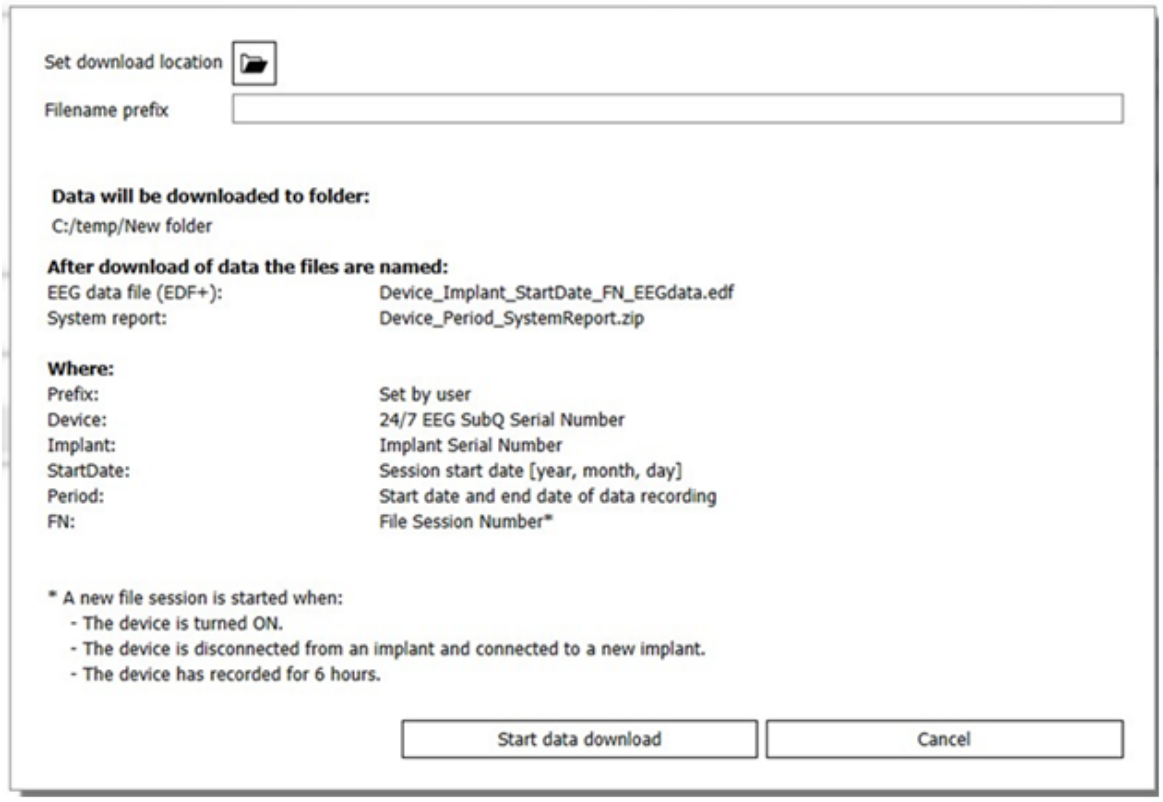


Figure 6



4.5 FILE STRUCTURE

The downloaded data files will be named after this pattern:

- EEG data file (EDF+): Prefix_Device_Implant_StartData_FN_EEGdata.edf
- System Report: Prefix_Device_Period_SystemReport.zip

Where the following applies:

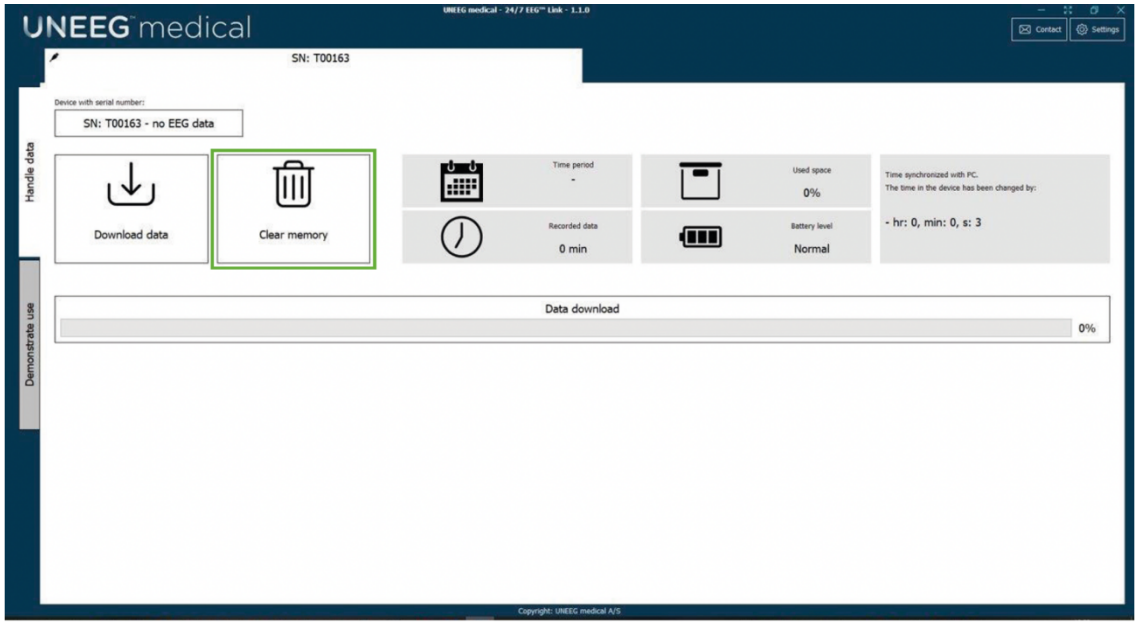
- Prefix: Set by user
- Device: Serial number of the recorder
- Implant: Serial number of the implant
- StartDate: Session start date [year, month, day]
- Period: Start date and end date of data recording
- FN: File Session Number
  Note: a new file section is started when the recorder is turned on or disconnected from an implant and connected again, or has recorded for 6 hours.

4.6 CLEARING THE RECORDER MEMORY

The recorder memory can be cleared in the module **Handle data** as follows:

1. Click **Clear memory** (Figure 7).
2. The following window will display the last time data were downloaded. Be sure that all data are downloaded before clearing the recorder memory.
3. Click **Clear memory** and wait. Ensure that the recorder is not disconnected, and that the PC is not turned off while clearing the memory.
4. After the memory has been cleared you may disconnect the recorder.

Figure 7



4.7 UPDATE RECORDER FIRMWARE

If an update for the recorder is available, the Link software will automatically detect it. The recorder firmware can be updated as follows:

1. Be sure the data are downloaded and the recorder memory is cleared.
2. Once the memory has been cleared, the software will ask whether you wish to update the firmware. Click **Yes**.
3. Wait for the recorder to update. Ensure that the recorder is not disconnected, and that the PC is not turned off during the firmware update.
4. Once the update is complete, click **Continue**.

4.8 RESET RECORDER IN ERROR MODE

If the recorder is in Error mode or data storage is full, the Link software can be used to reset the recorder. The software can also be used to update the recorder firmware.

The recorder is reset as follows:

1. Connect the recorder to the PC using the Connector cable. If the recorder encounters an error, the software will display **An error has occurred** and the recorder must be reset.
2. Download data from the recorder.
3. Once data are successfully downloaded, click **Reset device** and wait.
4. Once the reset is complete, click **OK**.

Note: A system report (…Systemreport.zip) is automatically generated every time data are downloaded from the recorder (see section 4.4). If the recorder encounters an error, please send the system report to UNEEG medical.

4.9 SOFTWARE UPDATES

Updates to the Link software will be distributed via a secure link to the registered e-mail. Updates will be installed following the same procedure as a first-time installation (see section 4.1).

4.10 UNINSTALLATION

It is recommended to uninstall the Link software by using the Windows '*add or remove programs'* function under System Settings.

5 TECHNICAL PRODUCT INFORMATION

PRODUCT ATTRIBUTE	PRODUCT SPECIFICATION
Supported operating systems	Microsoft Windows 10 (64-bit)
Recommended hardware	CPU 2 GHz or faster processor 8 GB RAM (for 64-bit) Minimum 10 GB (Disk Space) USB port
Requirement for graphics driver	DirectX 9 compatible graphics device with WDDM 1.0 or higher

5.1 DATA PROTECTION

Please contact UNEEG medical if you discover any suspicious activities or suspect a data breach. If any breach related to data security is detected, UNEEG medical will inform you of how to act to ensure that data protection is restored.

Moreover, to fulfil further cybersecurity measures, UNEEG medical recommends the following:

- Keep your operating system, firewall and anti-virus software up to date.
- Do not run 24/7 EEG SubQ Link on Windows operating systems for which the support has been discontinued by Microsoft.
- Ensure that access to 24/7 EEG SubQ Link is limited to authorized personnel with administrator rights.
- Adopt best practices for setting usernames and passwords where 24/7 EEG SubQ Link is installed.

5.2 CYBERSECURITY BILL OF MATERIAL

The main off-the-shelf software components that are used in 24/7 EEG SubQ Link can be found on the UNEEG website.

6 TROUBLESHOOTING

If problems occur with the Link software, first try to reset the recorder (see section 4.8). If this does not work, contact UNEEG medical.

7 WARNINGS

No warnings have been identified.

8 PRECAUTIONS

No precautions have been identified.

9 SIDE EFFECTS

There are no known side effects related to the use of the Link software.

10 SERIOUS INCIDENCE REPORTING

Per European Regulations, report any serious incident that has occurred in relation to this product to the manufacturer and the competent authority of the EU Member State where the product was used.

11 SYMBOL EXPLANATION

SYMBOL	DESCRIPTION
	Catalogue number
	Manufacturer
	Medical device
	Unique device identifier
	Consult instruction for use

UNEEG™ medical

Borupvang 2
3450 Allerød
Denmark

www.uneeg.com

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