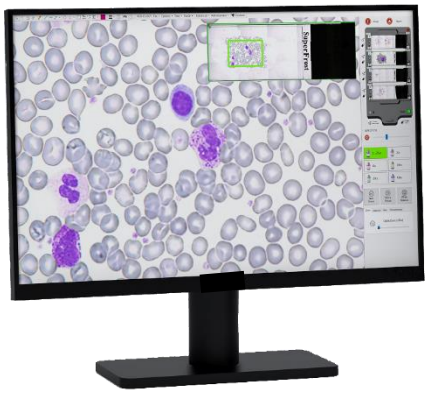
NANOTECH PROJECTS
DIGITAL IMAGING

User safety manual of NED.Micro System

v. 3.0 of 2023

NED DP MICRO

NED DH MICRO



SUMMARY

PREAMBLE

We are constantly trying to improve our tools and adapt them to the demands of modern research techniques and analysis methods. This involves changes to the mechanical structure and optical design of our devices. Therefore, all descriptions and illustrations in this user manual, including all specifications, are subject to change without notice.
The devices comply with EU Regulation 2017/746 relating to in vitro diagnostic/medical devices.

1. SAFETY CAUTION SYMBOLS

Safety precautions are found throughout this manual to indicate different levels of potential risk, as defined below:

Symbol	Explanation
	It indicates the need to follow the instructions to avoid the danger of damage to the operator and/or to the instrumentation (including objects placed nearby).
	It indicates the need to follow the instructions to avoid damage to the equipment.
I	It indicates that the main switch is on (ON).
O	InIt indicates that the main switch is off (OFF).
✞	Optional functions only on request.
▯	Tips / Warnings

 **Do not remove or change lenses. The installed lenses are calibrated specifically for the instrument.**

Do not attempt any unauthorized repairs or modifications.

➔ **NED.MICRO works using a standard PC keyboard and a standard mouse and a monitor with minimum resolution of 1920x1200px, preferably high definition. To use these accessories, refer to the specific riferirsi allo specifico manuale d'uso.**

2. INTENDED USE

NED-MICRO is a digital microscope intended to be used for in vitro diagnostic and qualitative analyses. The high-resolution image is displayed on a computer screen in real time. Samples used in analysis can be tissues, formalin-fixed tissues, paraffin-embedded specimens, frozen sections, cytological, hematological, and/or biological materials in general, on glass slides with a glass or film coverslip. If the glass slides do not have coverslips, specific lenses should be applied. The slide holder of the NED-MICRO can contain up to 4 slides.

NED-MICRO allows an interaction operation similar to a standard optical microscope. One of its main advantages is the ability to view streaming images remotely. In addition, users can manage different kinds of movement of the device: moving the specimen (X/Y), focusing (Z), changing the magnification. The NED-MICRO for digital pathology (NED-DP) has lenses with different magnification powers, namely 1.25X, 2X, 4X, 10X, 20X and 40X. The NED-MICRO for hematology (NED-DH) has lenses with magnifications of 1.25X, 20X, 40X and 100X. The 40X lens and the 100X lens of the NED-DH must be of the DRY type. Therefore, in order to use the NED-DH the glass slide must not have the coverslip and oil.

After inserting glass slides, NED-MICRO captures a panoramic image (minimap) of each glass slide, including imaging of their labels. The minimaps allow users to move and observe different samples.

Similar to the light microscope, NED-MICRO does not have analytical capabilities.

The final diagnosis is made by the user; the device itself does not independently identify any pathology.

NED-MICRO complies with the following standards:

- EN 61010-1 Safety requirements for electrical equipment for measurement, control and laboratory use - General requirements;
- EN 61010-2-101 Safety requirements for electrical equipment for measurement, control and laboratory use - Particular requirements for in vitro diagnostic (IVD) medical equipment;
- EN 61326-1 - Electrical equipment for measurement, control and laboratory use – EMC requirements - General requirements;
- EN 61326-2-6 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular Requirements - In vitro diagnostic (IVD) medical equipment.

These standards meet the requirements of **EU Regulation 2017/746** on in vitro diagnostic medical devices regarding electrical safety and electromagnetic compatibility.

The manufacturer assumes no responsibility for damages caused by or for risks deriving from the use of microscopes for purposes other than those for which they were intended or not used in the specifications of NTP Nano Tech Projects srl. In such cases the declaration of conformity ceases to be valid.

3. INSTALLATION INFORMATION

The device is classified as Class A in accordance with the relevant standard on EMC requirements.

Installation should be done only by a person that is qualified to the device installation. The NED-MICRO instrument must be properly installed to ensure proper operation and maintenance.

Before operating the NED-MICRO instrument, one should read this user manual carefully and strictly follow all instructions.

As is true with all electronic equipment, exposure to excessive humidity and temperature for a long time should be avoided. Temperature and humidity must be kept relatively constant to achieve the highest degree of operational stability (see 18. Technical specifications).

The device should be placed in a well-ventilated area, avoiding exposure to corrosive vapors, direct drafts, or extreme temperatures. It should not be exposed or closed to sunlight, open windows, sinks, ovens, open flames, hot plates, radiators and dry ice baths. It should be kept away from high voltage or current consuming equipment, including large refrigerators and ovens.

Since NED-MICRO is a precise optical instrument, it should be installed on a very stable and solid working surface. The environment should preferably be free from vibrations and shocks that could affect the quality of images.

The instrument should be located near an electrical source that meets the specific electrical requirements (voltage and amperage) on the identification label on the back of the instrument. The socket should be grounded and should be, if possible, a dedicated, clean and quiet line equipped with an uninterruptible power supply.

Ensure that the selected installation location provides sufficient space to properly use the instrument including the monitor, keyboard and mouse and any other accessories provided.

Unauthorized modifications to the device or non-conforming use void all rights to any warranty claims.

4. SAFETY WARNINGS

4.1. SYSTEM

The system is built with high-precision components and therefore should be handled with care, avoiding exposure to sudden and violent shocks.

4.2. INSTALLATION

Install the instrument on a stable and flat surface.

UNLOCKING THE INTERNAL MOVEMENTS

The X and Y movement axes of the instrument are protected and locked by sealing bands and they must be removed before turning on the device.

The left side of the device is equipped with a door (♊ Figure 1) with a closing lock (♋ Figure 1).

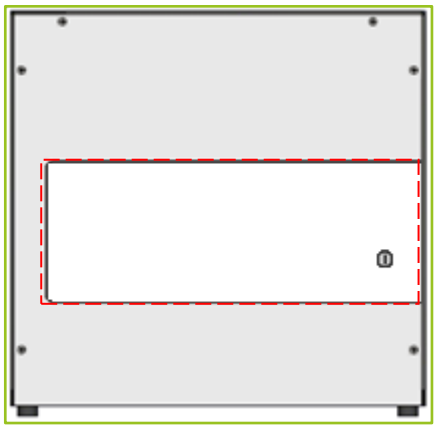


Figure 1 Left door appearance

Before performing any operation, it is necessary to open the door with the supplied key and remove the sealing bands.

The bands can be recognized by a red label similar to the one described in Figure 2.

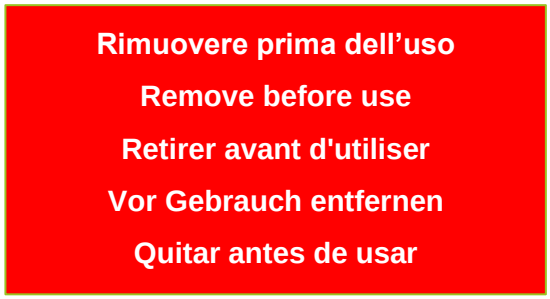


Figure 2 Movement block label placed on the bands

4.3. POWER CORD

Before connecting the power cord to the socket, please make sure that the main switch of the instrument is at "O" (OFF). Connect the power cord and ensure that the grounding terminals of the power supply and the wall socket are properly connected.

If the instrument is not grounded, NTP Nano Tech Projects cannot guarantee the electrical safety and proper operation of the equipment.

4.4. OPENING OF THE STRUCTURE

Do not open, disassemble or modify the structure of the instrument. Do not occlude the opening passages of the ventilation located under the bottom of the instrument.

⚠ **The device is incompatible with flammable and explosive atmospheres.**

⚠ **Do not use the device if it has been damaged.**

The damaged device should only be repaired by a qualified and authorized person. Contact the assistance office (for obtaining our assistance contacts see section 15. Troubleshooting).

4.5. CYBERSECURITY

To ensure an adequate level of cybersecurity, it is recommended to:

- Use the device only for its intended purposes.
- Limit the use of USB drives to activities related to the intended use of the device to prevent the introduction of external threats (viruses, etc.) and the improper data retrieval.
- Choose usernames and passwords with a high level of security and avoid disclosing them to others. Always follow the instructions of the system administrator for changes to credentials.
- Refer to the system administrator (if not provided, to the manufacturer/distributor) for any necessary updates to the operating system of the device.
- Do not install third-party software and/or apps without the approval of the system administrator.
- Use only accessories compatible with the device (refer to the system administrator for specifications).
- Promptly notify the system administrator and/or manufacturer/distributor of any suspicious event related to cybersecurity aspects (e.g., unusual and/or warning messages, etc.).

Improper use of the device could damage the device itself, as well as performance degradation due to the use of incompatible assets and/or external threats.

5. FRONT PANEL

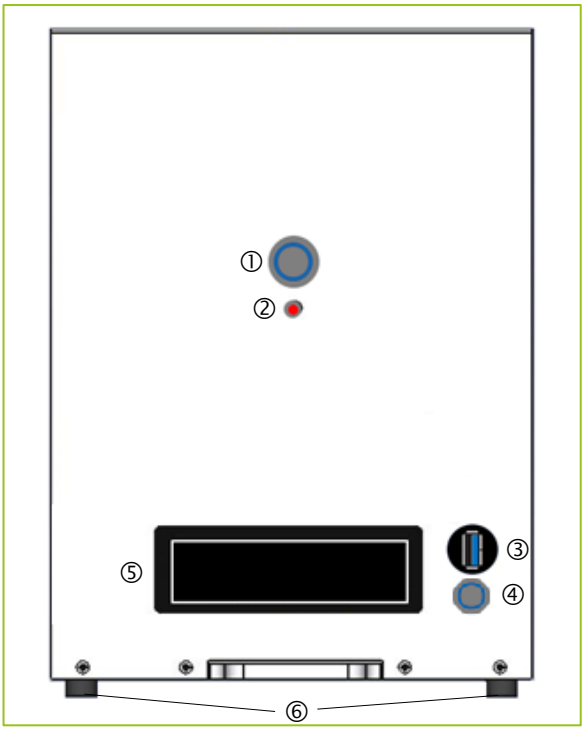


Figure 3 Front panel appearance

① Power or standby button.

If the button is illuminated in blue, the device is working.

If the button is illuminated in green, the device is on standby mode.

If the button is off, the device is off.

② LED Blue indicates that the instrument is powered.

LED Off indicates that the instrument is not powered.

③ USB 3.0 port.

④ Open/close button for slide holder insertion door.

⑤ Slide holder insertion door.

⑥ Height-adjustable support feet.

6. BACK PANEL

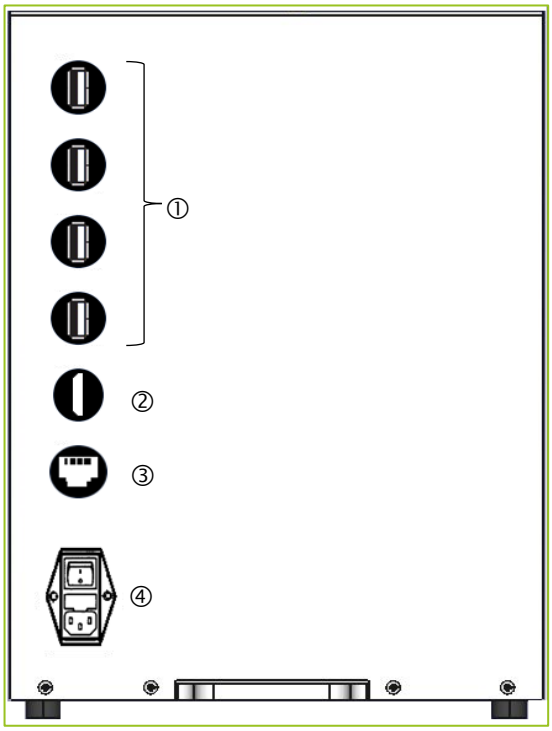


Figure 4 Back panel appearance

① USB 2.0 ports allow the following accessories connected to the device:

a. Mouse and keyboard
b. Joystick (optional)
c. Scanner (optional)
d. Webcam (optional)
e. External keyboard (optional)

② HDMI port for monitor connection. The system is calibrated for a 24” 2MP (1920x1200) monitor.

③ RJ45 Ethernet networking connection port.

④ Power cable socket with I/O ON/OFF switch.

7. CONNECTING THE POWER CORD

Before connecting the power cord, make sure the main switch (④ Figure 4), is on “**O**” (OFF).

Always use the power cord supplied with the instrument. If the power cord is not included in the supply, choose a suitable one by referring to section 16. Choosing of power cord at the end of this manual.

Connect the plug of the power cord to the AC socket (④ Figure 4).

Connect the power cord to an insulated 3-conductor socket and make sure that the grounding terminals of the power supply and wall socket are properly connected. If the instrument is not grounded, NTP Nano Tech Projects Ltd. cannot guarantee electrical safety and proper operation.

Plug the power cord into the available power outlet.

8. CONNECTIONS TO CONTROL SYSTEMS

The control systems for the handling functions of the NED-MICRO are: keyboard, mouse and a joystick (optional). The vision system consists of a monitor with HDMI connection.

The keyboard, mouse and joystick are connected to the USB 2.0 ports (① Figure 4) while the monitor is connected to the HDMI port (② Figure 4).

9. POWER ON

Before powering the instrument, make the connections as described in section 5 and section 6.

The NED-MICRO has two power switches. The general switch (④ Figure 4) must be in the position **"I"**. The button (① Figure 3) allows the device to pause (standby), the system is powered and the blue LED (② Figure 3) is displayed.

When the power button ① Figure 3 is on (light blue) and the LED ② Figure 3 (blue light) is displayed, you can proceed to use the software controls to manage the NED-MICRO.

10. CREATION OF USER PROFILES

→ **Only authorized technical personnel can access this procedure.**

Before accessing the NED-MICRO use and control software, it is necessary to create user profiles that can have access to the instrument according to three different statuses: "User," "Advance," or "Administrator".

→ **User:** user who can change only subjective usage parameters such as light intensity, X/Y movement speed, macro and micro metric focus sensitivity range, etc.

→ **Advance:** is a user with additional permissions. Advance accounts can set typical functions of the working routine predetermined for the instrument. It can set, for example, automatic extraction of the slide holder at power-up, automatic white balance, automatic connection to the network, etc.

➔ **Administrator:** provides the most control over the instrument. Administrators can set calibrations, autofocus, slide holder alignment, and all specific functions.

This activity is allowed only to authorized persons who can manage factory settings.

➔ The profile creation allows you to save some setting parameters related to a particular user. **It is therefore recommended that this profiling activity should be carried out in the presence of the user so that the desired variables can be set.**

The profile creation program is preinstalled in the system and is named "NTP.NED.Micro.UserProfiler.exe".

Please refer to the document "User Profiler User Manual" for the operation and use of this program.

11. SYSTEM CONFIGURATION

NED-MICRO can be used as an observation emplacement instead of an optical microscope. In this case, our device can be used independently from a network connection. The control systems, keyboard, mouse and joystick (optional), 24" HDMI HD monitor, will be connected directly to the NED-MICRO. The configuration may look as in Figure 5 (images for illustration purposes only).

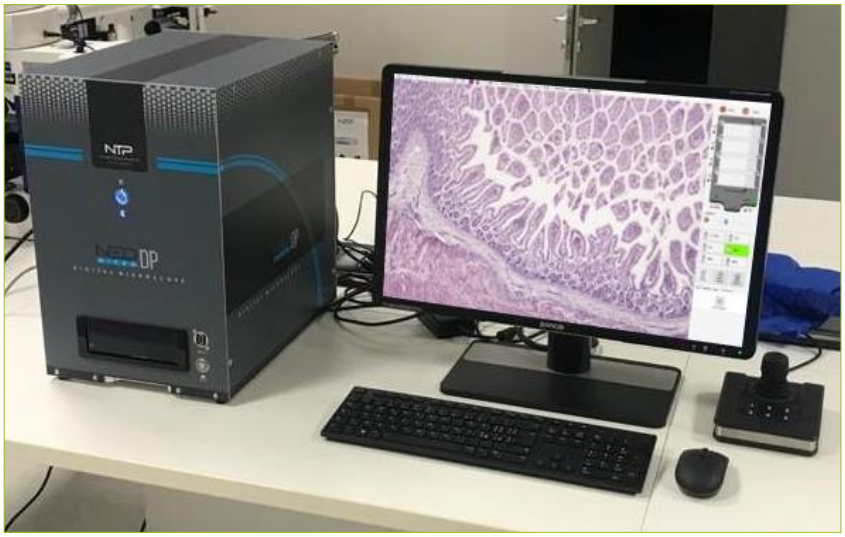


Figure 5 Example of configuration of the local NED-MICRO station

The NED-MICRO is also designed for real-time image transfer and remote control of all functions through an Internet/Intranet connection. The system configuration in this case takes a structure similar to the one presented in Figure 6 (image for illustrative purposes only).

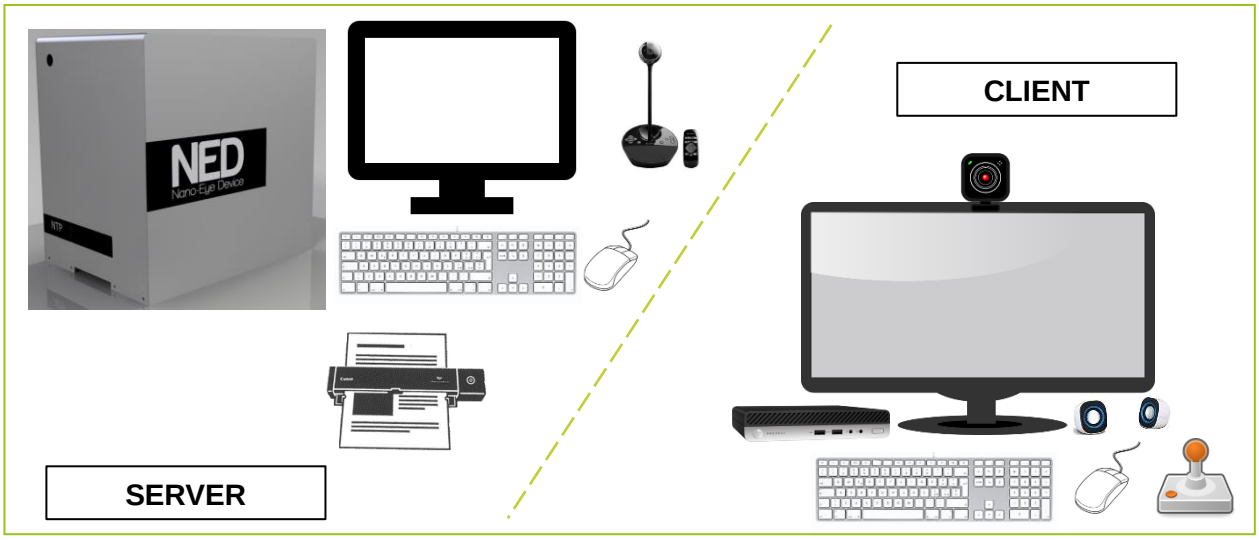


Figure 6 Example of configuration of the local NED-MICRO station and the remote NED-MICRO station

In the configuration shown in Figure 5, the NED-MICRO can execute not only its specific digital microscope functions but also acts as a SERVER for CLIENT to connect remotely.

In this case a possible configuration (Figure 6) could include HDMI monitor (also HD type if required), keyboard and mouse. Webcam and scanner (optional) for the SERVER station, while for the CLIENT station it is preferable to use a 24" HD monitor, keyboard and mouse. Other components such as Webcam, joystick and audio speakers are optional. The CLIENT station can be equipped with a PC to connect to the network.

For information purposes, Figure 7 shows a network in which several clients access a NED-MICRO server.

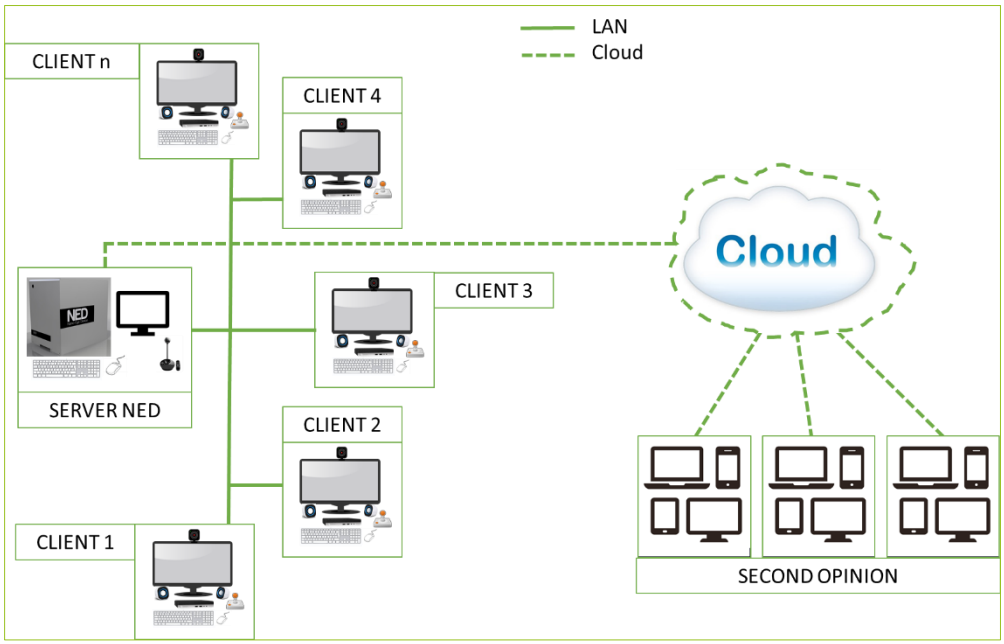


Figure 7 Example of a network configuration with multiple clients and a NED-MICRO server

The number of available CLIENTs is configured in the system installation requirements.

Among all CLIENTs, if a SECOND OPINION task is enabled, only one is allowed to take the MASTER role while the others can take the VIEWER role. If required, it is also possible to use the system outside a physical network through a Cloud service. In this case it will be possible to use tablets or

smartphones in addition to PCs. The tablet and smartphone versions are not yet available as of the release date of this manual.

➔ **For the best performance of the system, Chrome® browser is required.**

Similar to the network described in Figure 7, it is also possible to have more SERVERs with one or more CLIENTS (Figure 8).

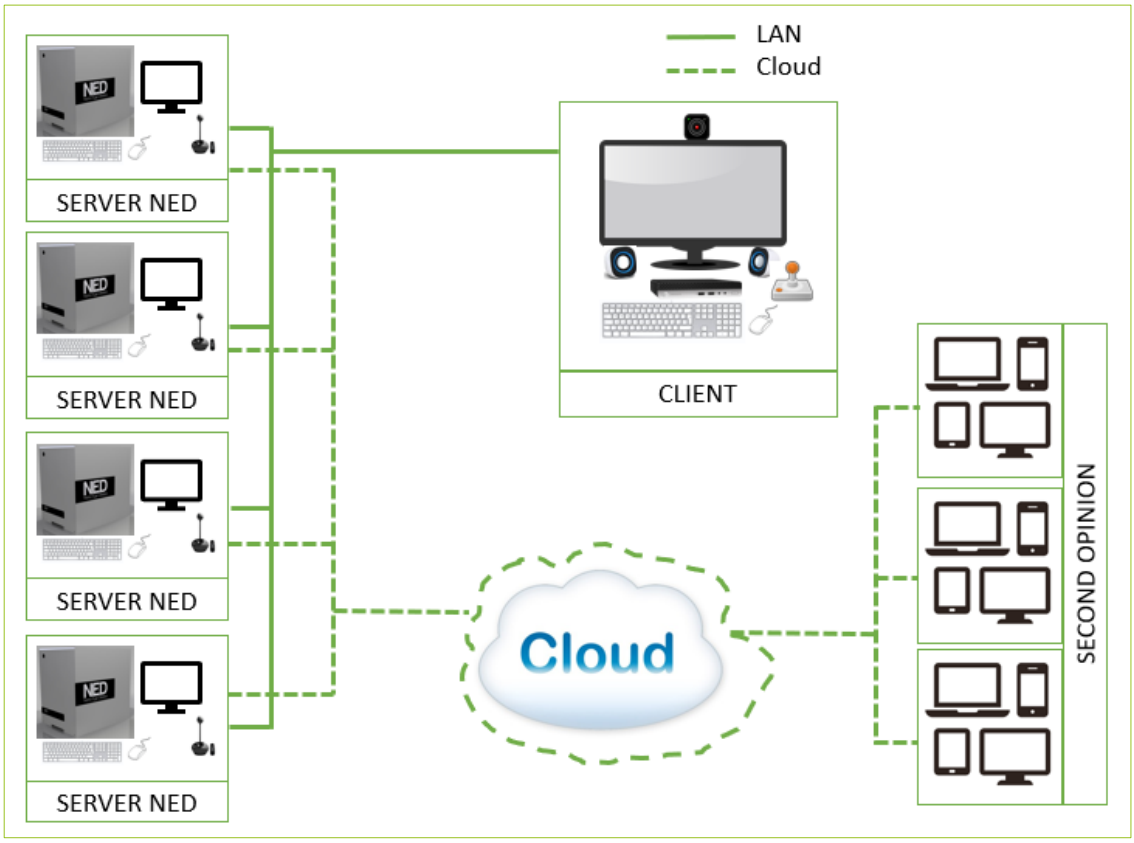


Figure 8 Example of network configuration with one or more clients and more NED-MICRO servers

Figure 8 shows a possible network with more than one NED-MICRO SERVERs and CLIENTS.

The characteristics refer to what is described for the scheme in Figure 7.

➔ **System performance, real-time image transfer, and NED-MICRO operations are affected by the speed performance of the network to which the system is connected. Similar concerns are also applied for mobile type.**

12. CONTROLLO NED-MICRO CON COLLEGAMENTO IN LOCALE

The “local” connection allows the users to use NED-MICRO without being connected to a data network and perform all system functions via a direct connection to the instrument.

The NTP.NED.-MICRO application is pre-installed, and for its local use, please refer to the document "NED-DP Local System User's Guide".

The following are instructions and warnings that must necessarily be followed to avoid damage to the instrumentation.

Do not interrupt the initialization process of the NED-MICRO by not stopping the control procedure.

➔ **Slide labels should be placed on the right side of the holders as shown in Figure 9.**

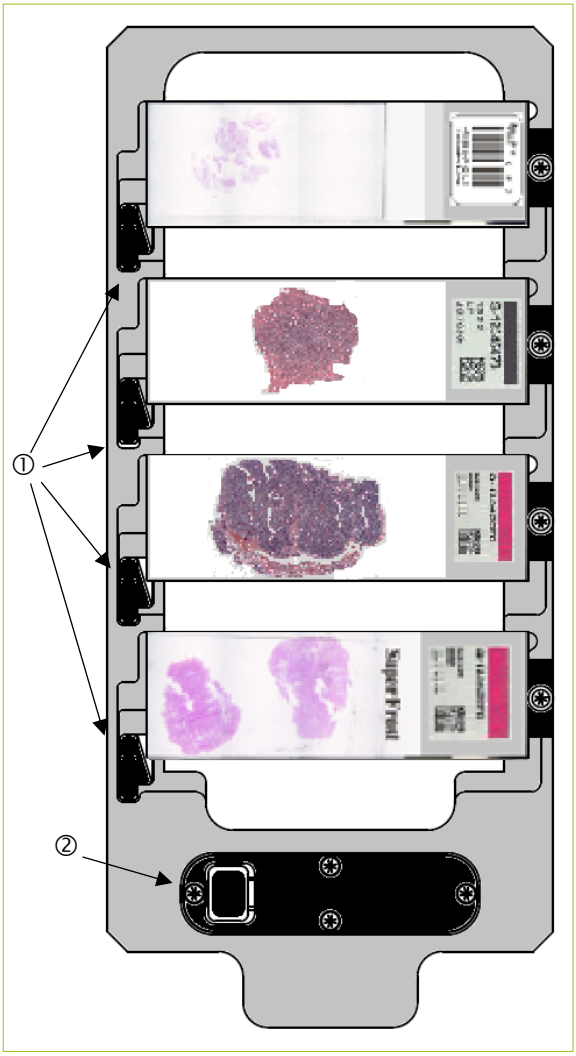


Figure 9 Illustration of the correct positioning of the slides in the slide holder

The NED-MICRO allows observation of slides to a maximum size of 76x26mm, mounted with 0.17mm coverslips. The specimen should be placed so that the coverslip always faces up. These are essential conditions for using the slide holder. Other conditions might be applied for applications other than those described in this manual.

➔ **When drawing or measuring functions are activated on the main image, the keyboard is temporarily disabled to allow writing. The keyboard will be back to active as soon as the drawing/measuring is finished.**

➔ **Each device has undergone a series of tests derived from which the factory settings are derived which are optimized for each individual machine.**

➔ **The factory settings can be changed only by Administrator profiles.**

➔ **When using the Measurements, Drawing and Writing functions, the live image is locked. The movements along axes X/Y/Z and magnification modification are not possible. This guarantees the reliability in measurements with proper overlap to the image.**

➔ **Measurements are calibrated according to the lens used for observation.**

➔ **Some settings define how to use the system that cannot be modified by USER users. It is recommended to define and agree in advance which functions to activate with respect to the preferred management process.**

The defined functions can be modified by only Advanced or more powerful users. Users should follow the procedures without manually intervening in the movements defined in this menu.

➔ **The choice of the value of light enhancement and gain when scanning the slide label must be made considering the nature of the label which can be more or less transparent to light. It is recommended to carry out some tests with the most frequently used slides to find the right value.**

➔ **It is recommended to set the "Auto white balance at start up" and "Lens focus storage" functions to activate.**

➔ **When changing lenses, the focus system automatically positions itself with respect to the characteristics of the selected lens. This function "Pre-focus" allows one to have an image in optimal focus conditions. Different conditions of specimens, slides and coverslips may affect the operation of "Pre-focus".**

13. NED-MICRO CONTROL WITH REMOTE CONNECTION

The NED-μ is designed to be connected to the internet and/or intranet to be managed in its movements and thus obtain real-time images that can be observed from any station connected to the network as explained in section 11. System configuration.

The remote stations will be appropriately set up by specialized and authorized personnel to be able to access the NED-MICRO which will assume the SERVICE function and will therefore be managed for loading the slides by suitably trained laboratory technicians.

As explained in section 10. Creation of user profiles, only registered users will be able to access the SERVER.

➔ **Some of the features in the local user interface are disabled when you are connected remotely. Other functions have different characteristics. These slight differences are due to the different settings that the system has to manage when connected to a WEB SERVER.**

For remote operation and use of the NED-MICRO, please refer to the document "Guida all'uso del sistema web NED-DP".

Below are instructions and warnings that must necessarily be followed to avoid damage to the instrumentation.

➔ **Remember that the password change can be regulated by the administrators of the data network according to pre-established policies. Changing your password frequently ensures better protection of your personal data.**

➔ **Remember that a strong password should be at least eight alphanumeric characters long, including both uppercase and lowercase and also special characters such as ! ? & @ #.**

➔ **In addition to physically exiting the program, the EXIT function can be used to disconnect, for example, from the MASTER function (which will be held by another user) and reconnect as a VIEWER user.**

14. CARE AND MAINTENANCE

⚠ **Disconnect the power supply before carrying out any type of work, cleaning, maintenance or checking of the internal moving elements. The opening of the device, internal checks, maintenance and any type of work must be carried out only by authorized personnel.**

14.1. CLEANING

Dust and dirt particles can be removed with a soft brush or a lint-free cotton cloth.

Adherent dirt can be cleaned with aqueous solutions and mildly aggressive detergents. To clean the coated parts, use a linen or soft cloth moistened with one of these substances or even alcohol.

Try cleaning solutions of unknown composition on a less visible area of the unit first.

14.2. CLEANING THE SLIDE HOLDER PROTECTION GLASS

The slide holder should be kept clean to minimize dust and contamination entering the instrument.

Remove dust on glass surfaces with a fine, dry cloth. Carefully remove stubborn dirt on the glass with a clean cloth moistened with water. If the dirt persists, use pure alcohol, chloroform or petrol.

➔ **The protective glass can be removed from its seat to allow for better cleaning. Be careful to handle the glass carefully.**

14.3. LENS CLEANING

The lenses and optical systems that make up the device must be checked and cleaned by specialized and authorized personnel. If you have a problem with dirt on the lenses, contact technical support personnel.

14.4. PREVENTIVE MAINTENANCE

In order to guarantee perfect functioning of the device over time, it is advisable to call in specialized personnel to carry out at least preventive maintenance.

Depending on the use of the system, it may be necessary to perform periodic maintenance procedures more frequently than recommended.

It is recommended to periodically repeat the electrical safety tests, in accordance with the reference legislation.

14.5. DISPOSAL

The device packaging made up of cardboard and plastic must be disposed of in a differentiated manner according to the regulations in force.

For the disposal of the device, the regulations regarding electrical devices must be followed, which are highlighted by the symbol (Figure 10) also placed on the label.

Figure 10 WEEE marking - disposal of electrical and electronic equipment

14.6. DEVICE HANDLING

The instrument must only be handled by authorized and previously trained personnel.

14.7. BIOLOGICAL RISK

The instrument is not at biological risk as indicated in the risk analysis document.

15. TROUBLESHOOTING

The following troubleshooting guide contains information relating to general problems you may encounter when using the NED-MICRO device. Under certain conditions the performance of the NED-MICRO system may be diminished by factors which cannot be considered defects. If problems occur, read this guide to remedy the problem.

Problem	Cause	Solution	Pag.
The instrument does not turn on.	The main switch is in the OFF (O) position. Switch to ON (I).	Set the switch to ON (I). Check fuses.	
The instrument is on but the illumination LED is off.	The LED intensity value is set to zero.	Set a non-zero value.	
The live image is not evenly focused.	Slide is not inserted correctly or not perfectly prepared.	Check the correct position in the slide holder.	
The monitor is on but nothing is displayed.	HDMI video cable is not connected properly.	Check the HDMI cable connection.	
Keyboard and/or mouse do not work.	USB connection is not connected.	Check USB connections. Check the batteries.	
Unable to capture images.	Damaged camera.	Contact Technical Assistance.	
The instrument does not connect to the data network.	Unplugged ethernet cable.	Connect the ethernet cable.	
The instrument does not connect to the data network.	No signal.	Contact the data network managers.	
The instrument is not perfectly stable.	The support feet are not adjusted correctly.	Adjust the support feet.	

If the problem persists after having checked all the documents accompanying the NED-MICRO, contact the technical assistance referred to in your purchase contract. Alternatively, consult the list of authorized distributors at www.ntpsrl.biz.

15.1. FUSE REPLACEMENT

⚠ **Before replacing the fuse(s) make sure that the instrument is switched OFF (O) and that the power cord is unplugged.**

Use fuses type T1,25A.

1. With a flat screwdriver, open the door containing the fuses (Figure 11).

Figure 11 Illustration of the fuse door opening operation

2. Extract the fuse holder and replace it (Figure 12).

Figure 12 Illustration of the fuse extraction and replacement operation

3. Put the stand back in place and reconnect the power cord.

16. CHOOSING OF POWER CORD

A power cord must be certified by one of the agencies listed in Figure 13, including marked wiring, and bear at least one of the approval marks of an authorized agency.

If the power cable approved by one of the indicated bodies is not available in the country of use, spare parts approved by another equivalent and authorized body in the country of use must be used (Figure 13).

Paese	Ente	Marchio di certificazione	Paese	Ente	Marchio di certificazione
Argentina	IRAM		Irlanda	NSAI	
Australia	SAA		Italia	IMQ	
Austria	ÖVE		Norvegia	NEMKO	
Belgio	CEBEC		Paesi Bassi	KEMA	
Canada	CSA		Regno Unito	ASTA BSI	
Danimarca	DEMKO		Spagna	AEE	
Finlandia	FEI		Svezia	SEMKO	
Francia	UTE		Svizzera	SEV	
Germania	VDE		U.S.A.	UL	
Giappone	JET, JQA, TÜV, UL-APEX / MITI				

Figure 13 Table of power cord certification bodies

17. WARRANTY NOTES

For technical assistance contracts that can keep your instrument in excellent condition for a long time, please ask a representative of NTP Nano Tech Projects srl.

The warranty provisions may vary according to the different national legislations. More details can be found in the delivery documentation or from your dealer or representative.

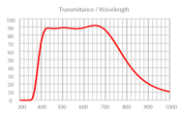
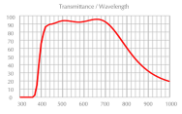
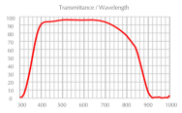
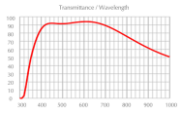
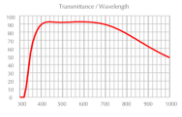
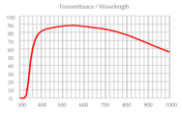
➔ **Please note that the guarantee may be invalidated if:**

- **This device has been modified in any way.**
- **Accessories and reagents are used that have not been approved by the manufacturer.**
- **If the instrument is not used or maintained in accordance with the instructions in the User Manual.**

18. TECHNICAL SPECIFICATIONS

Object	Technical specifications
Optical system	Infinity-corrected optical systems
Lighting	White LED: 18.000 cd/m2 to 35.000 cd/m2; average life around 100,000 hours.
Revolver of the lenses	Six-position revolver
Lens magnification	1,25X; 2X; 4X; 10X; 20X; 40X; 40X Dry NoCover lens; 100X Dry NoCover lens.
Power source and fuses	110-230Vac / 50-60 Hz PWR: 250W - Fuses 2X T1,25A
Dimensions and weight	Width 30; height 46; depth 42 cm – 22Kg
Environmental conditions of use for internal use	Maximum relative humidity 75% for temperatures up to 31°C, decreasing linearly to 50% for temperatures up to 40°C Room temperature 15 / 40° C Voltage swing not to exceed ±10%

NED-DP

Lens	Magnif.	N.A.	W.D. (mm)	C.S.	F.N. (mm)	Res. (⌈m)	T.W.
PLAPON	1.25X	0.04	5	-	26.5	8.39	
PLAPON	2X	0.08	6.2	-	26.5	4.20	
UPLFLN	4X	0.13	17	-	26.5	2.58	
UPLFLN	10X	0.30	10	-	26.5	1.12	
UPLFLN	20X	0.50	2.1	0.17	26.5	0.67	
UPLFLN	40X	0.75	0.51	0.17	26.5	0.45	

NED-DH

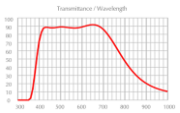
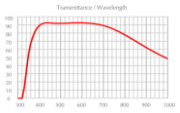
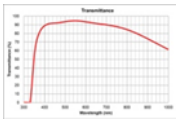
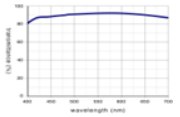
Lens	Magnif.	N.A.	W.D. (mm)	C.S.	F.N. (mm)	Res. (⌠m)	T.W.
PLAPON	1.25X	0.04	5	-	26.5	8.39	
UPLFLN	20X	0.50	2.1	0.17	26.5	0.67	
MPLFLN	40XDry	0.75	0.63	NO	26.5	0.45	
MPLFLN	100XDry	0.90	1	NO	26.5	0.25	

Table header legend:

N.A.. Numerical Aperture.
Performance index.
The optical resolution is in proportion to the value of N.A.

W.D. Working distance.
The distance between the surface of the coverslip and the front objective lens.

CS. Coverslip.
Coverslip thickness.

FN Field number.
Defines the dimension in which optical aberrations are corrected.

Res Resolution.
The minimum separation distance between two points of the object that can be distinguished.

T.W. Transmittance/Wavelength

NOTE

NOTE

Via Fortunato Zeni n. 8
38068 – Rovereto (TN)
Italy

Via Circonvallazione n.11/A
61048 - Sant'Angelo in Vado (PU)
Italy

www.ntpsrl.biz
info@ntpsrl.biz
+39 072288681