

# 1 Connection to computer networks (Erigo)

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## 1.1 Introduction

This section covers important information on connecting the Erigo to a computer network, in conformity with the IEC 60601-1 standard, as well as on remote support via a cellular USB modem, e.g. via GPRS/UMTS.

The responsible organization shall also ensure compliance with other applicable regulations and standards, in particular for the protection of confidential health information and data security. It is solely accountable for connecting the Erigo to a computer network. This can be done using the isolated Ethernet port located on the base frame if the requirements described herein are met.

Only an authorized and trained person with the appropriate expertise is permitted to connect the Erigo to a computer network.

The Erigo does not require a network connection to achieve its intended use. All data are stored on the local hard disk. The Erigo database should not be stored on a remote or network drive because delays or loss of data might render the device inoperative.

- ① A system recovery of the Erigo might cause the loss of configuration changes, including driver installation. These changes will have to be repeated in order to restore network connectivity. We therefore recommend that you document them. Service actions by Hocoma or your Hocoma Service Center due to incompatible configuration changes may be charged.

## 1.2 Acceptable usage of a computer network connection

### Data backups

You can back up patient and training data from the Erigo by copying it from the internal memory stick to a network or external drive provided that:

- the Erigocontrol software is not running
- the network or external drive is free of viruses.

### Printing

You can print (e.g. reports) using a network-enabled printer provided that:

- only Hocoma-supplied software is used for printing
- no additional software (e.g. MS Office) has been installed.

The Erigo can be connected to a printer either directly or through a computer network. The responsible organization is accountable for selecting and installing the appropriate printer driver. Service actions by Hocoma due to inappropriate selection, installation or use of drivers not supplied by Hocoma may be charged.

### Virus scanning

You can run virus scans of the Erigo PC including virus signature updates via the computer network provided that:

- system scans do not take place while the Erigocontrol software is running
- you accept responsibility for all actions pertaining to the virus scanner (e.g. installation, update, scanning).
- ① Many virus scanners start system scans at regular time intervals. This has to be prevented to avoid degrading the response time for file access during training, thus possibly degrading software-implemented safety mechanisms.

## Remote support by Hocoma

Remote support by Hocoma or your Hocoma Service Center can be carried out provided that:

- no patient is on the Erigo
- a trained user is present while the connection is established
- the user stays at least 1.5 m (5 ft) away from moving parts of the Erigo
- there is a continuous audio connection (e.g. phone) between the support technician and the user.

In order to prevent intrusion and misuse (which could lead to serious injury):

- start the Hocoma Support software (on your desktop) only after being explicitly instructed to do so by Hocoma or your Hocoma Service Center
- never provide the ID or password displayed to anyone except Hocoma or your Hocoma Service Center
- close the Hocoma Support software as soon as the service session has ended
- never run the Hocoma Support software while a patient is on the Erigo.

Remote support and virus scanning are the only acceptable uses for connections via cellular (UMTS) modems.

## 2 Connecting the Erigo to a computer network

An isolated RJ-45 connector (Label: "LAN") for connection to an Ethernet computer network is located on the base frame.



The Ethernet port of the Erigo PC is configured to use DHCP by default and should therefore be compatible with most existing computer networks.



### **WARNING!**

#### **Risk of corrupted data/software and loss of processing power.**

Failure to follow these instructions could lead to a degradation of software safety mechanisms necessary to prevent serious injury to your patients.

A network connection may only be established via the isolated Ethernet port located on the Erigo's base frame. Connected devices have to comply with applicable IEC standards. By default, the isolated Ethernet port is configured to use DHCP as well as the standard firewall settings of Microsoft Windows XP. Open the firewall only as far as necessary, preferably not at all, in order to minimize the risk of intrusion.

Do not connect the external Ethernet port to a network that overlaps with the IP range 192.168.157.x (i.e. the class C network 192.168.157.0/24, mask 255.255.255.0), because this range is used for the internal network within the device. Such a connection would degrade software safety mechanisms and could result in serious injury to the patient or the user.

In any case do not connect the Erigo to the Internet without an appropriate external firewall, because intrusions might modify software settings and degrade the system's safety.

If appropriate, take preventive measures to:

- counter intrusions from sources within the local network or the Internet
- avoid virus or similar infections from sources within the local network or the Internet (e.g. by regulating Web browsing)
- restrict as much as possible network communication to the Erigo from within the local network or the Internet.

Provided that such measures have been taken, continuous network connection is acceptable. Otherwise, unplug the network isolator to disconnect the Erigo from the network during patient training.

The user account “Erigo” on the Erigo PC requires local administrator privileges for proper operation of the device.

## 2.1 Static IP address assignment



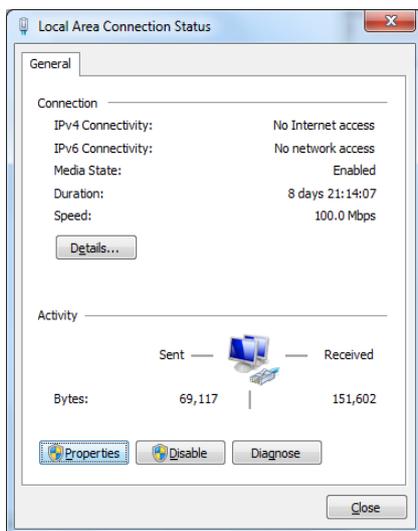
### WARNING!

Using IP addresses in the range of the internal network connections of the device could degrade software safety mechanisms and result in serious injury to the patient or the user.

If you need to assign a static IP address, proceed as follows.

**i** The IP range of the connected network must not overlap with the IP range 192.168.157.x (i.e. the class C network 192.168.157.0/24, mask 255.255.255.0) which is used for the internal network of the device.

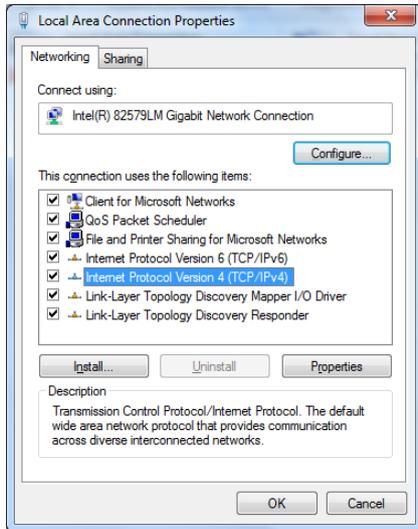
- Exit the Erigocontrol software using the [Go to Windows] button.
- Open the Windows Control Panel (Start > Control Panel).
- Open Network and Sharing Center.
- Open Change adapter settings.
- Open Local Area Connection.
- ➔ The Local Area Connection Status screen appears.



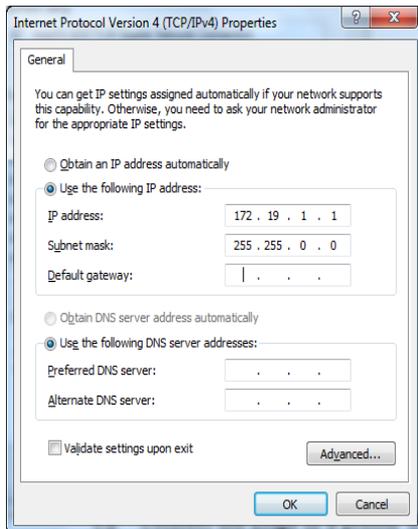
- Double-tap **[Properties]**.

➔ A dialogue box appears prompting you to enter your Administrator password, together with the on-screen keyboard.

**i** If you do not already have an Administrator password, please contact your Hocoma Service Center.



- In the Local Area Connection Properties screen, double-tap **[Internet Protocol Version 4 (TCP/IPv4)]**.



- In the Internet Protocol Version 4 (TCP/IPv4) Properties screen, enter the IP address and subnet mask in the corresponding fields.
- Tap **[OK]**.
- Close all windows.

### 3 Direct connection to a printer via a network cable

In case you only want to connect a printer to the Erigo, use the isolated Ethernet port located on the base frame. Connected devices have to comply with applicable IEC standards.

While many devices automatically select an appropriate IP address (by using link-local specifications), the Ethernet port can be configured to use a fixed IP address if needed (see Chapter 4, Section 1 for details).

If possible, use preinstalled printer drivers.

#### 3.1 Connection to a printer via a computer network

The Erigo uses default Windows network printing protocols and procedures. Refer to the Microsoft Windows documentation for details or contact your computer network's administrator.

If possible, use the preinstalled printer drivers (Windows 7 Professional). If no compatible printer driver is preinstalled, contact Hocoma Service at [service@hocoma.com](mailto:service@hocoma.com) for instructions on and approval of the changes required to your device.

### 3.2 Direct connection to a printer via a network cable

The installation and configuration of a printer may only be performed when no one is lying on the Erigo.

#### Printer requirements

- Network Ethernet connection, min. 100 Mbps
- Configurable IP address or dynamic configuration of link-local addresses according to RFC 3927
- Conformity with applicable regulations and standards, e.g. IEC 60950
- If possible, a Windows 7 preinstalled driver

The following printer has been tested successfully: Brother HL-3070CW (with dynamic configuration as well as static assignment; using the preinstalled drivers Brother HL-4040CN and Brother HL40-70CDW).

#### Basic network configuration

The Erigo has one Ethernet port available for external connections. It is configured to use DHCP by default. Most network printers support automatic configuration. We suggest that you first try the dynamic configuration described here and only if needed use static IP address assignment.

- ▶ Connect the printer to the Erigo using an Ethernet cable plugged into the network isolator as described above.
  - ➔ The Erigo and the printer should automatically configure the ports to appropriate IP addresses in the range of 169.254.x.y.

#### Advanced network configuration

If the automatic configuration of the IP addresses did not work, configure the Erigo's network interface using static IP address assignment as described in Section 2.1. We suggest the following configuration:

Device	IP address	Subnet mask	Gateway
Erigo	192.168.1.1	255.255.255.0	(leave empty)
Printer	192.168.1.2	255.255.255.0	(leave empty or use 192.168.1.1)

Refer to the printer's user manual for instructions on how to assign a static IP address on the printer.

#### Printer configuration

The Erigo uses default Windows network printing protocols and procedures. Refer to the Microsoft Windows documentation for details or contact your computer network's administrator.

If possible, use the preinstalled printer drivers (Windows 7 Professional). If no compatible printer driver is preinstalled, contact Hocoma Service at [service@hocoma.com](mailto:service@hocoma.com) for instructions on and approval of the changes required to your device.

## 4 Risk management

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Connecting the Erigo to a computer network that includes other equipment could result in previously unidentified risks to patients or users. The responsible organization shall identify, analyze, and control such risks, in accordance with IEC 60601-1 and other applicable regulations and standards.

Subsequent changes to the computer network could introduce new risks and must be correctly reevaluated. These include:

- changing the computer or data network configuration
- connecting additional items to the computer network
- disconnecting items from the computer network
- updating equipment connected to the computer network
- upgrading equipment connected to the computer network.