1   Connection to computer networks (Lokomat)

1.1 Introduction

The availability of this feature depends on your system configuration. This section is intended for the person assigned by the RESPONSIBLE ORGANIZATION to connecting the Lokomat (Lokomat System, LokomatPro, LokomatNanos) to a computer network. It is assumed that the person has professional knowledge of medical device and IT technology and regulations, especially electrical safety and computer network operation.

This section covers information according to IEC 60601-1:2005 for Lokomat as a medical device. Conformity to additional local or regional regulations for medical devices has to be ensured by the RESPONSIBLE ORGANIZATION. Similarly the RESPONSIBLE ORGANIZATION has to ensure conformity with applicable regulations and standards for protection of classified health information and data security. The sole responsibility for connecting the Lokomat to a computer network lies with the RESPONSIBLE ORGANIZATION and not with HOCOMA as the Lokomat manufacturer. If the constraints described in this document are met, the Lokomat may be connected to a computer network via the insulated connector under the ramp (see operating instructions for details).

The RESPONSIBLE ORGANIZATION has to ensure that only authorized and trained persons connect the Lokomat to a computer network.

The Lokomat does not require network connection to achieve its INTENDED USE. All data are stored on the local hard disk. The Lokomat database must not be stored on a remote or network drive because delays or loss of data might make the Lokomat inoperable.

Please note that any configuration changes incl. driver installation might be lost in a system recovery of the Lokomat, in the rare case that this is needed. These configuration changes incl. driver installation will have to be repeated in order to re-establish the networking functionality. It is suggested to document the configuration changes incl. driver installation and keep these records. Service actions by Hocoma or your responsible Hocoma service organization that are caused by incompatible configuration changes by the RESPONSIBLE ORGANIZATION or its agents may be charged.

This section also covers the case of remote support via a cellular USB modem, e.g. via GPRS/UMTS.

1.2 Acceptable usage of computer network
1.2.1   Backup

Backup of the Lokomat data by creating a copy of the corresponding folder on the local drive to a network or external drive is acceptable, provided the copying action does not take place while the Lokocontrol software, especially a training, is running, the network or external drive is virus free.

If in doubt, backup the data by copying to a bus-powered, virus-free USB-drive while the Lokocontrol software is stopped.

1.2.2   Printing

Printing through a network enabled printer, e.g. printing of reports, is acceptable provided only Hocoma supplied software is used for printing, no additional software, e.g. office software, is installed.

Connection to the printer may be achieved through a computer network to which both the Lokomat and the printer are attached or alternatively by a direction connection between Lokomat and the printer. The selection of the appropriate printer driver and its installation are responsibilities of the RESPONSIBLE ORGANIZATION. Service actions by HOCOMA that are caused by inappropriate selection, installation or use of drivers not supplied by HOCOMA may be charged.

1.2.3 Virus scanning

Running virus scans of the Lokocontrol-PC supported by update of virus signatures via the computer network is acceptable provided

- system scans do not take place while the Lokocontrol software, especially a training, is running.
- awareness that the customer accepts responsibility of all actions (such as installation, update, scanning…) which are taking place in reference to virus scanner

Note that many virus scanners start system scans at regular time intervals. This has to be prevented, because it could degrade the response time for file access during Lokomat training, thus possibly degrading software-implemented safety mechanisms.

1.2.4 Remote support by Hocoma

Remote support by Hocoma or your responsible Hocoma service organization is acceptable provided

- no patient is attached to the Lokomat,
- a trained user is present while the connection is established,
- this user stays at least 1.5m away from moving parts of the Lokomat, and
- a continuous audio connection between the support technical and the user is available, e.g. via telephone.

In order to prevent intrusion to your Lokomat and misuse of the device (which might lead to serious injury):

- Start the Hocoma Support software (on your desktop) only after being explicitly instructed by Hocoma or your responsible Hocoma service organization.
- Never provide the displayed ID or password to anyone except Hocoma or your responsible Hocoma service organization.
- Close the Hocoma Support software immediately after the end of your service session.
- Never run the Hocoma support software while a patient is in the Lokomat.

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

2 Connecting the Lokomat to a network

An insulated RJ-45 connector (Label: "Ethernet") for connection to an Ethernet computer network is located under the ramp.

By default, this port is configured to use DHCP and uses the standard firewall settings of Microsoft Windows XP or Windows 7 depending on your device configuration. The firewall should be only opened as far as necessary, preferably not at all, in order to minimize intrusion risk.

Please note that, depending on your device, the IP-range of the attached network must not overlap with the IP-range 10.10.10.x or 192.168.157.x which are used for the internal network of the Lokomat device. Such connections would degrade software safety mechanisms and might lead to serious injury of the patient or the operator.

LokomatPro devices with a reference number on their device label (see below) must not be connected to networks that overlap with the IP range 192.168.157.x.

LokomatPro devices without a reference number on their device label, as well as LokomatNanos V1.0, must not be connected to networks that overlap the IP range 10.10.10.x.
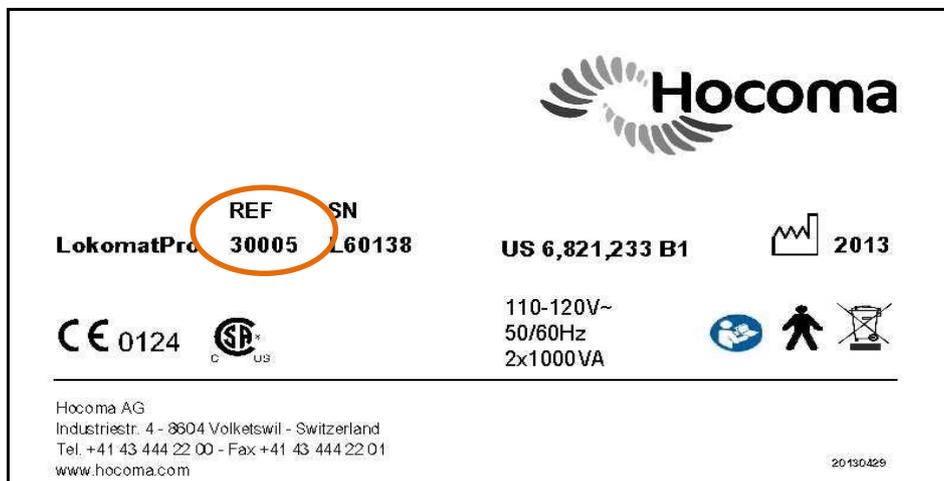

Figure 1: Example of a device label. The device label is on the base of the Lokomat. The reference number is marked.

In any case the Lokomat must not be connected to the internet without an appropriate external firewall because intrusions might modify software settings thus degrading the safety of the system.

If appropriate steps have been taken to

- prevent intrusions from sources within the local network or the internet,
- prevent virus or similar infections from sources within the local network,
- prevent virus or similar infections from the internet, especially instructions to personnel restricting the use of internet browsing, and
- limit and restrict network communication to the Lokomat from within the local network or the internet as far as possible,

it is acceptable that the network connection remains connected and active continuously. Otherwise, the connection has to be unplugged during operation of Lokocontrol software, especially during the training.

The user account "Lokomat" on the Lokocontrol-PC requires local administrator privileges for proper operation of the device.

Deviation from these guidelines can lead to

- corruption of data or software, or
- loss of processing power for Lokocontrol software,

which can degrade software safety mechanisms necessary to prevent serious injury of your patients.
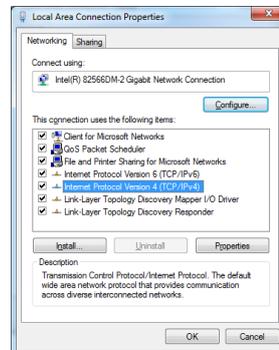
2.1 Setting the IP-address on the Lokomat

► Switch to Windows using <Alt>+<Tab>

► Open the Network and Sharing Center (Start->Control panel->Network and Sharing Center)

► Click "Change adapter settings" (see screenshot)

► Double-click "Local Area Connection"
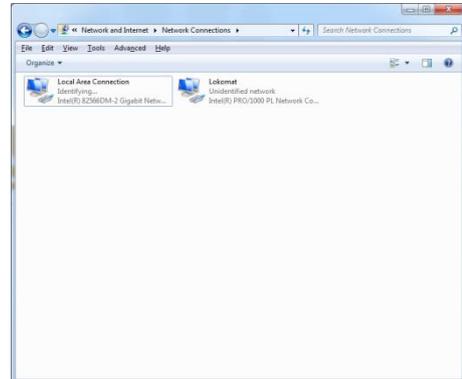
► Click Properties
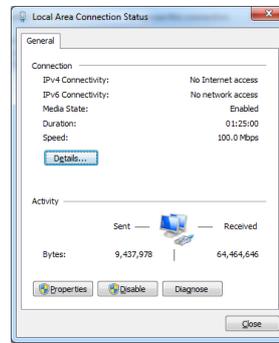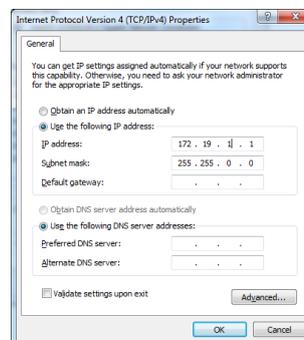
► Select "Internet Protocol Version 4 (TCP/IPv4)

► Set IP-address and subnet mask in the corresponding fields (see screenshot).

► Click "OK"

► Close remaining the open windows.

3 Connecting to a network printer

The Lokomat uses default Windows network printing protocols and procedures. Please consult the Microsoft Windows documentation for details or contact the system administrator of your computer network.

If possible, use the printer drivers preinstalled (Windows XP Pro SP3). If no compatible printer driver is pre-installed, please contact Hocoma Service at service@hocoma.com for instructions for and approval of the required changes to your device.

WARNING!

Possibility of connection to a network depends on the system you have. Please contact Hocoma Service.

WARNING!

Preventive actions for virus and intrusion need to been taken if there is a permanent connection to a network.

3.1 Connecting the Lokomat directly to a network enabled printer

Please note that installation and configuration must only take place if no person is in the Lokomat.

Requirements for the printer

- Network Ethernet connection, min. 100Mbps
- Configurable IP-address or Dynamic configuration of Link-Local addresses according to RFC 3927
- Conform to applicable regulations and standards, e.g. IEC 60950
- Ideally, compatible driver in Windows XP SP3 or Windows 7 Professional respectively.

Dynamic network configuration of the Lokomat and the printer (basic)

The Lokomat has one Ethernet port available for external connections. It is configured to use DHCP by default. Most network printers support automatic configuration such that no manual configuration is needed (so called LinkLocal technology). It is suggested that you first try dynamic configuration described here and only if needed, use static IP-address assignment described below.

- Connect the printer and the Lokomat using an Ethernet cable plugged into the appropriate port of the printer and the insulated RJ-45 connector of the Lokomat which is located under the ramp (Label: "Ethernet"). The Lokomat and the printer should automatically configure the ports to appropriate IP addresses in the range of 169.254.x.y.

Windows Printer configuration: Installation of drivers (basic)

Printer drivers supplied by the printer's manufacturer usually provide tools that automatically identify and locate attached network printers, if you select the appropriate drivers.

In the following two approaches are described. The easier approach described in this section, uses drivers supplied by the printer's manufacturer. The advanced approach described below, uses drivers preinstalled on the system.

Please remember that you are responsible for the correct selection and installation of additional drivers. Service actions by HOCOMA that are caused by inappropriate selection, installation or use of drivers not supplied by HOCOMA may be charged.

- Please follow the user manual of the printer to install the drivers. The printer is usually detected automatically during the driver installation and automatically configured (you may have to select peer-to-peer connected printer). If needed, follow the printer's user manual for manual configuration.

- If the printer's manufacturer supplied the drivers on CD/DVD-ROM, you connect a standard USB CD/DVD ROM drive to the Lokomat's USB port or use another computer to copy the contents of the CD/DVD to a USB removable drive that you then connect to the Lokomat. Many printer manufacturers provide the latest drivers on their websites for download. Please ensure appropriate virus scanning if using USB drives.

3.2 Advanced configuration

Network configuration using static IP- address assignment (advanced)

If the automatic configuration of the IP addresses described above did not work, change to static IP-addresses. We suggest the following configuration:

Device	IP-Address	Subnetmask	Gateway
Lokomat	172.19.1.1	255.255.0.0	(leave empty)
Printer	172.19.0.1	255.255.0.0	(leave empty, alternatively use 172.19.1.1)

4 Risk Management

Connection of the Lokomat to a computer network that includes other equipment could result in previously unidentified RISKS to PATIENTS, or OPERATORS. RESPONSIBLE ORGANIZATION should identify, analyze, and control such RISKS (refer to IEC 60601-1:2005 Chapter 14 section 13 and other applicable regulations and standards).

Subsequent changes to computer network could introduce new RISKS and require new analysis.

Changes to the computer network include:

- changes in computer or data network configuration
- connection of additional items to computer network
- disconnecting items from computer network
- update of equipment connected to computer network
- upgrade of equipment connected to computer network

The term computer network used here corresponds to the term network/data coupling in IEC 60601-1:2005.