1 Connection to IT networks (ArmeoPower, ArmeoSpring, ArmeoSpring Pediatric)

1.1 Introduction

This section covers important information on connecting the ArmeoPower, ArmeoSpring and ArmeoSpring Pediatric to an IT network, in conformity with the IEC 60601-1 standard, and information on remote support.

The responsible organization shall ensure compliance with other applicable regulations and standards, in particular for the protection of confidential health information and data security. Only an authorized and trained person with the appropriate expertise under the guidance of the responsible organization may connect the ArmeoPower, ArmeoSpring and ArmeoSpring Pediatric to an IT network. This must be done according to the requirements described in this section.

The ArmeoPower, ArmeoSpring and ArmeoSpring Pediatric do not require a network connection to achieve its intended use. All data are stored on the local hard disk. The ArmeoSpring database should not be stored on a remote or network drive because delays or loss of data might render the device inoperable.

ⓘ A system recovery of the ArmeoPower, ArmeoSpring or ArmeoSpring Pediatric 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 uses of connecting to an IT network
1.2.1 Sharing data locally (depending on model)

If configured, your ArmeoSpring (V2), ArmeoSpring Pediatric and ArmeoPower devices will synchronize patient settings, therapy plans and results. This will allow you to:
- have all training results from connected ArmeoSpring, ArmeoSpring Pediatric and ArmeoPower devices on every other connected device (e.g. in order to review training progress across devices and prepare comprehensive training reports)
- have the latest relevant settings and therapy plans available at all compatible devices irrespective of where you made the recent changes (as long as the devices are connected sufficiently long to the local network for them to synchronize).

1.2.2 Data backup

You can back up patient and training data from the ArmeoPower, ArmeoSpring and ArmeoSpring Pediatric by copying it from the local (internal) hard drive to a network or external drive provided that:

- the Armeocontrol software is not running
- the network or external drive is free from viruses.

1.2.3 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 ArmeoPower, ArmeoSpring and ArmeoSpring Pediatric can be connected to a printer either directly or through an IT network. The responsible organization is responsible 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.

1.2.4 Virus scanning

You can run virus scans of the ArmeoPower, ArmeoSpring and ArmeoSpring Pediatric PC including virus signature updates via the IT network provided that:

- system scans do not take place while the Armeocontrol software is running
- the responsible organization performs all actions pertaining to the virus scan (e.g. installation, updating, scanning).

⚠ **WARNING!**
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.

1.2.5 Remote support by Hocoma

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

- no patient is in the ArmeoPower, ArmeoSpring or ArmeoSpring Pediatric
- a trained user is present while the connection is established
- the user stays at least 1.5 m (5 feet) away from moving parts of the ArmeoPower, ArmeoSpring and ArmeoSpring Pediatric
- 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 in the ArmeoPower, ArmeoSpring or ArmeoSpring Pediatric.

2 Connecting the Armeo Device to an IT network

⚠ **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.

ArmeoPower: A network connection may only be established via the isolated Ethernet port located on the back of the ArmeoPower base module.

Figure 1: ArmeoPower isolated Ethernet port.

ArmeoSpring V2, ArmeoSpring Pediatric: A network connection may only be established using the network isolator (art. no. 11545 or 25642) supplied by Hocoma.

Figure 2: Network isolator for network connection on ArmeoSpring V2 and ArmeoSpring Pediatric.

Network components and other devices connected to the network have to comply with applicable IEC standards. By default, the Ethernet port is configured to use DHCP and the standard firewall settings of Microsoft Windows 7. Open the firewall only as far as necessary; this will minimize the risk of intrusion.

While it is possible to use a local network to have local connected data synchronization (only with Armeo devices and one Ethernet Switch, see Sharing data locally), it is recommended you use a managed network such that you can use all connectivity features. Creating a (virtual) subnet for medical devices is considered best practice.

Feature		Port	Destination
Local connected data	Required	TCP ports 52001, 52002, 52003	Subnet with the other Armeo devices
	Suggested	NTP time synchronization (UDP port 123)	Your local time server, usually your Primary Domain Controller
Data backup	Required	Depends on your backup concept.	Depends on your backup concept. Should not be an internet connection.
Printing	Required	Depends on your network setup.	Your printer or print server.
Virus scanning	Suggested	Depends on your virus scanner.	Depends on your virus scanner. Local cache recommended.
Remote support	Required	For details consult: http://www.teamviewer.com/docs/en/TeamViewer-Security-Statement-en.pdf	

ArmeoPower: Do not connect the external Ethernet port to a network that overlaps with the IP ranges 10.10.10.x or 192.168.157.x because these ranges are 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.

ArmeoSpring, ArmeoSpring Pediatric: not applicable

In any case do not connect the Armeo device 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 Armeo device from within the local network or the Internet.

Provided that such measures have been taken, continuous network connection is acceptable. Otherwise, unplug the network cable from the Armeo device (see Figure 1 and Figure 2) during patient training.

The computer name defined in the Windows settings must be changed from the default setting, "Armeocontrol-PC", to a unique name in order to prevent conflicts in network communication. Consider "Armeo-AO1234", where "AO1234" is the serial number of the device).

The devices can be integrated in Windows domains. However, service technicians of your Hocoma service partner usually require administrator access for maintenance, installations and troubleshooting. Please prepare access for them in a timely manner, because additional time waiting for access will be charged.

2.1 Direct connection of multiple Armeo devices to each other

In case you only want to connect multiple Armeo devices (ArmeoSpring V2, ArmeoSpring Pediatric and/or ArmeoPower) to each other in the same room, you can use Ethernet switches or routers that comply with applicable IEC standards.

> ⚠ **WARNING!**
>
> When connecting ArmeoSpring (V2) or ArmeoSpring Pediatric, the network isolator (art. no. 11545 or 25642 see Figure 2) supplied by Hocoma has to be used in order to in order to ensure electrical isolation against electric shock.

By default, the Windows 7 operating system is configured to automatically ensure appropriate configuration of the IP address (by using link-local specifications).

2.2 Direct connection to a printer via a network cable

ArmeoPower: In case you only want to connect a printer to the ArmeoPower, use the isolated Ethernet port located on the back of the ArmeoPower base module (see Figure 1). Connected devices have to comply with applicable IEC standards.

ArmeoSpring, ArmeoSpring Pediatric: In case you only want to connect a printer to your ArmeoSpring or ArmeoSpring Pediatric, use the network isolator (see Figure 2) supplied by Hocoma. 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 desired. If possible, use preinstalled printer drivers.

3 Risk management

Connection of an Armeo device to an IT network that includes other equipment could result in previously unidentified risks to patients, operators or third parties, the responsible organization should identify, analyze, and control such risks (refer to IEC 60601-1).

Subsequent changes to the IT network could introduce new risks and require new analysis.
Changes to the IT network include:

- Changes in computer or data network configuration
- Connection of additional items to the IT network
- Disconnecting items from the IT network

- Update of equipment connected to the IT network
- Upgrade of equipment connected to the IT network

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