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OR1 31 1.1 02/2018-E

White Paper KARL STORZ SCB control NEO

WHITE PAPER

STORZ
KARL STORZ — ENDOSKOPE

Foreword

This document is supplied by KARL STORZ in order to provide to the responsible organization/hospital necessary information to be used for the integration of KARL STORZ SCB control NEO software 200900 01-46 into the hospital IT-network. This document was generated based on our current knowledge of IT-networks and is subject to change as conditions in this area change/advance. Since framework conditions, installations, and the operation of the network are the responsibility of the operator, we cannot fully guarantee failure-free operation. The responsible organization/department must ensure the protection, safety, and reliability of the IT-network through the responsible organization's own risk management procedures in accordance with IEC 80001.

Introduction

Product Description:

KARL STORZ SCB control NEO system is a medical device system for control of medical devices in the operating environment for minimally invasive surgery.

Medical Device Classification:

According to the Medical Device Directive 93/42/EEC (MDD) Class IIb.

Device Intended Use (IEC 80001):

KARL STORZ SCB control NEO system allows the display as well as the central and sterile centralized control of almost all parameters of the SCB-devices connected to the KARL STORZ SCB control NEO system.

Electrical Specifications Overview:

See KARL STORZ OR1™ control NEO 20097120-1.
(see user manual ref. 96206575EN)

Purpose of the KARL STORZ Medical Device Connection to an IT-Network (IEC 80001):

The KARL STORZ SCB control NEO system does not access the hospital network in any way.

Modifying the appliance through electrical and/or software additions may void the manufacturer's declaration of conformity and may result in the operator bearing full responsibility for the altered device. Such modifications include, among other things, installing additional software of any type, such as antivirus software, or updating or patching components such as the operating system.

The KARL STORZ SCB control NEO system does not have any connection to the hospital network.
However, it has interfaces to the following other KARL STORZ OR1™ products:

- AIDA™ compact NEO
- KARL STORZ OR1 FUSION®

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1. Using KARL STORZ SCB control NEO system with KARL STORZ AIDA® compact NEO

This configuration requires a KARL STORZ OR1™ 8-Port Ethernet Switch W21499 which connects the KARL STORZ SCB control NEO system with the KARL STORZ AIDA® compact NEO. This KARL STORZ OR1™ 8-Port Ethernet Switch W21499 shall not be connected with the hospital network. Therefore, no requirements of the norm IEC 80001 must be adhered.
Please refer to the document "DICOM Conformance Statement AIDA™ compact NEO" from the KARL STORZ website http://www.karlstorz.com (Service / Interface Descriptions / DICOM Conformance Statement) for further details.

2. Using KARL STORZ SCB control NEO system with KARL STORZ OR1 FUSION®
Please refer to the document "White Paper KARL STORZ OR1 FUSION®" for further details. (Ref. no. 96202074E)

IT-Network Requirements

1. Requirements

The KARL STORZ SCB control NEO system does not access the hospital network.

2. Hazardous Situations

- Hazard by cyber-attack
  - KARL STORZ SCB control NEO software is only accessible within the operating theater it is located in.
    - Connected medical devices, which should be controlled by the KARL STORZ SCB control NEO software, are only accessible within the operating theater they are located in.
- Hazard by incompatible software
  - KARL STORZ OR1™ control NEO's BIOS is password-protected and therefore the preconfigured operating system cannot be bypassed.
- Hazard of violation of the privacy policy
  - The KARL STORZ SCB control NEO software does not contain any patient data which shall be archived.
- Hazard of data loss
  - The loss of preset data is bearable.

Note: Connection of the KARL STORZ SCB control NEO system to a network/data coupling that includes equipment that is not validated for use with the KARL STORZ equipment could result in previously unidentified risks to patients, or operators. The operator should identify, analyze, and control such risks. This includes any subsequent changes to the network/data coupling introducing new risks and requiring new analysis. Examples of pertinent changes to network/data coupling include:

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

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Software Installation

No separate software installation by the operator is required or necessary to connect the device to the network.

Licensing Model

No licensing model via network is defined and implemented.

Availability

KARL STORZ cannot make any statements regarding the safety and availability of devices that the operator has modified without authorization, for instance, by installing printer drivers, additional software, etc.

Remote Maintenance

Currently, there is no remote maintenance possible for the KARL STORZ SCB control NEO system.

Patch Management of the Operating System (OS)

The closed operating system is maintained by KARL STORZ and therefore does not require any efforts by the operator. Furthermore, the KARL STORZ SCB control NEO system is not connected to the hospital network.

Malware Defense

The closed KARL STORZ operating system prevents any installation of third-party software such as malware protection software.

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Data Protection

The software component Data Logger records, if enabled and configured, patient data (i.e. last name, first name and the date of birth) besides device data during a preset and stores them on the hard disk. Please export these data recordings according to the procedure described in the instruction manual before sending the device in for service.

For removing any Personally Identifiable Information (PII) create dummy data recordings with dummy PII so that the existing data recordings are overwritten by these dummy ones.

Data Backup and Recovery

Only presets are stored as data on the device.
As these presets do not contain any medical relevant information, no archiving of the data is required.
In case a recovery is required after a full system failure, a dedicated KARL STORZ service engineer has to be contacted.

Network Load

The network load generated by the KARL STORZ SCB control NEO software is minimal in the dedicated and independent network infrastructure, which is not connected to the operator's network infrastructure.

Conformity Assessment

The following standards/approvals are fulfilled:

- CE
- CB
- FDA
- 93/42/EEC (MDD)
- IEC 60601-1
- IEC 60601-1-2
- 2011/65/EU RoHs II

DICOM Conformance Statement

DICOM is neither used by nor required for KARL STORZ SCB control NEO software.

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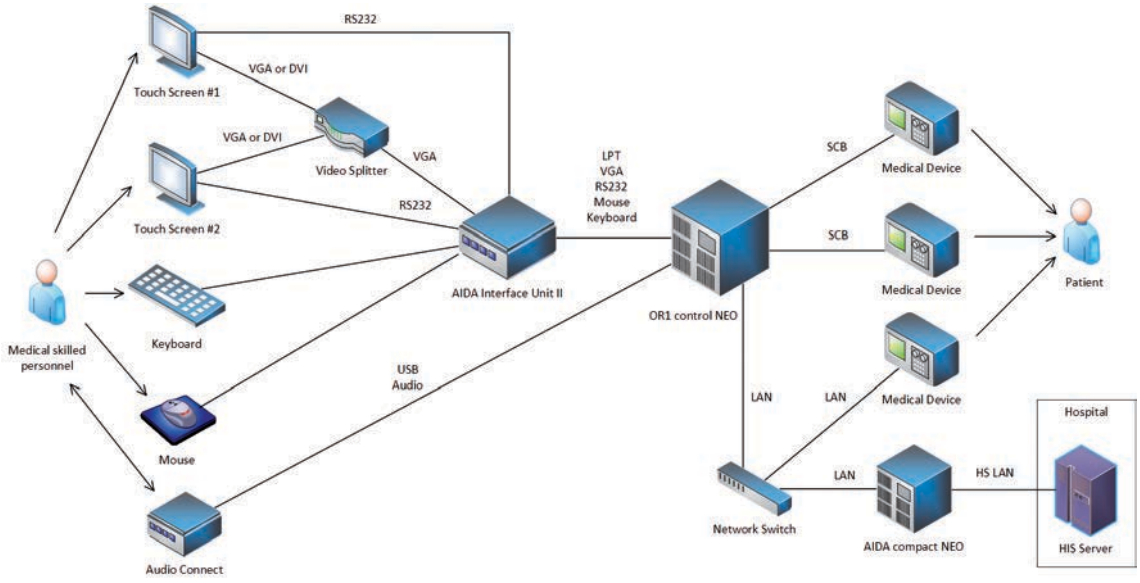
System Schematic

1. Using KARL STORZ SCB control NEO system with KARL STORZ AIDA® compact NEO



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Notes

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It is recommended to check the suitability of the product for the intended procedure prior to use.

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