Instructions for Use

ARKON Data Bridge

Philips Option

SW 1.00.00

Page intentionally left blank.

Typographic conventions

- ● Bullet points represent lists of options, objects or data.
- ⇨ In safety instructions and warnings, this arrow represents the options for avoiding the hazard.
- **1** Numerals in illustrations represent elements that are referred to in the text.
- **A** Consecutive letters represent actions. A new sequence of actions starts again from A.
- ► The triangle represents the outcome of an action.

Brand names

Brand name	Owner of the brand
IntelliVue	Philips
IntelliBridge	Philips
MIRUS™	Technologie Institut Medizin GmbH (TIM)
Incides®	Ecolab®
Sani-Cloth®	Ecolab®
Mikrozid®	Schülke & Mayr GmbH
Cleanisept®	Dr. Schumacher GmbH

0 Table of contents

1 Introduction

1.1 Intended use

ARKON Data Bridge is a device for transferring data signals from a medical device, e.g. the TIM MIRUS™ Controller, to a Philips IntelliVue patient monitor with an internal or modular IntelliBridge EC10 interface.

During operation, measurements and alarms are transferred unencrypted and unmodified, and the following functions are supported:

- Display of parameter data ($etCO_2$ and etVA)
- Signalling of certain high-priority alarms
- Transfer of device settings (MACset)

1.2 Operator and user qualification

Clinical professionals for installation
The Data Bridge must only be installed by personnel with expertise in connecting devices to IT networks.

Preparation personnel
Hygienic preparation should only be carried out by personnel with expertise in the preparation of medical devices.

1.3 Areas of use

The Data Bridge is intended for stationary use in hospitals and rooms used for medical purposes.

2 Safety information

2.1 Basic safety instructions

2.1.1 Safe operation

If the Data Bridge is not used as described in these Instructions for Use, it may result in personal injury or damage to property.

⇨ Before operating the Data Bridge for the first time, the user must familiarise themselves with these Instructions for Use.

⇨ Only use the Data Bridge for the purpose described under Intended Use.

⇨ Follow these Instructions for Use and the instructions for all other devices that are used together with this device.

⇨ Keep these Instructions for Use in an accessible place.

2.1.2 Symbols and product labels

If symbols and product labels are not observed, it may result in personal injury or damage to property.

⇨ Observe symbols and product labels.

2.1.3 Place of use

If the Data Bridge is used in a poorly ventilated environment, or if it is covered, this may result in malfunctions and damage to property due to the inside of the device overheating. Data may not be transferred correctly or data transfer may fail.

⇨ Use the Data Bridge in a well ventilated environment.

⇨ Do not cover the housing.

If the Data Bridge is not positioned as described in these Instructions for Use, it may fall down, causing damage. Data may not be transferred correctly or data transfer may fail.

⇨ When in use, the device should be placed on a stable, flat surface and secured against falling down.

2.1.4 Before every use

Checks before using the device
Parts of the Data Bridge may be damaged during cleaning, by wear and tear, and incorrect storage, and this may affect its function.
Ensure the following requirements are met before operating the device:

⇨ All parts of the device are free from cracks and sharp edges.

⇨ All cables are undamaged and correctly connected.

⇨ Replace the device if it is clearly malfunctioning.

2.1.5 Electrical supply

If the Data Bridge is operated with a voltage that is not intended for this device, it may result in damage to property.

⇨ Ensure that the supply voltage is the same as shown on the identification plate of the ARKON Data Bridge.

If the Data Bridge is operated with a faulty mains adapter, or one that is not approved by the manufacturer, this may result in a short-circuit, possibly causing personal injury or damage to property.

⇨ Only operate the Data Bridge with the original mains adapter.

⇨ Ensure that the protective earthing of the electrical installation is working properly.

2.1.6 Connected devices

The Data Bridge has been tested for compatibility with the MIRUS Controller. If an external anaesthetic vaporiser other than the MIRUS Controller is connected to the Data Bridge, it may result in malfunctions of both devices. Proper functioning of the anaesthetic vaporiser may be affected, possibly resulting in personal injury or damage to the Data Bridge and the anaesthetic vaporiser.

⇨ Only use MIRUS Controller as external anaesthetic vaporiser with the Data Bridge.

The Data Bridge has been tested for compatibility with the patient monitors listed in the “Technical Data” section. If other patient monitors are used with the Data Bridge, it may result in malfunctions of both devices. Proper functioning may be affected, possibly resulting in damage to property.

⇨ Always follow precisely the instructions for all connected devices or device combinations before operating the Data Bridge for the first time.

2.1.7 Delays in transmission

Signals of measurements and alarms from the MIRUS Controller may be delayed before being transferred to a patient monitor. This delay time may vary depending on the conditions in which the Data Bridge is working. For this reason, specified delay times cannot be provided.

⇨ Only use the MIRUS Controller as the primary source for alarms and for viewing measurements.

⇨ Refer to the manufacturer's instructions regarding patient monitor delay times.

2.1.8 Deviations in transmission

The data transferred to a patient monitor may be displayed incompletely or incorrectly on the monitor.

Alarms
The various alarm priorities may be displayed differently on the patient monitor than on the MIRUS Controller connected via the Data Bridge.

⇨ Check which alarms are assigned to which alarm priorities.

⇨ Only use the MIRUS Controller alarm system as the primary alarm source.

Measurements
In certain cases, there may be differences between the measurements displayed on the patient monitor and the measurements displayed on the MIRUS Controller connected via the Data Bridge.

⇨ Only use the MIRUS Controller as the primary source for viewing measurements.

2.1.9 Modifications to the device

Modifications to this device may lead to malfunctions and unforeseeable hazards, possibly causing personal injury or damage to property.

⇨ Do not modify this device.

2.1.10 Accessories

The Data Bridge has been tested for electromagnetic compatibility with the accessories on the accessories list. The Data Bridge's electromagnetic emissions may be increased, and the interference immunity may be reduced, if accessories not included on the accessories list are used. Moreover, the proper functioning of the Data Bridge may be affected, possibly resulting in personal injury or damage to property.

⇨ Only use the accessories specified by the manufacturer.

⇨ Other accessories may only be used if they do not affect the electromagnetic compatibility.

2.1.11 Electromagnetic compatibility (EMC)

Medical electrical devices are subject to special precautions regarding electromagnetic compatibility (EMC). They must be installed and operated in accordance with the EMC instructions contained in the accompanying documentation.

Electrostatic discharges
If no protective measures are taken against electrostatic discharges, malfunctions may occur in certain situations, possibly resulting in personal injury.

In order to avoid malfunctions, comply with the following measures and train the personnel involved:

⇨ Observe the ESD protective measures.
These measures may include wearing antistatic clothing and shoes, touching a potential equalization bolt before and during connection, or using electrically insulated and antistatic gloves.

⇨ Comply with the requirements for the electromagnetic environment.

⇨ Only use approved electronic accessories, e.g. mains adapter.

Electromagnetic disturbances
If devices that emit electromagnetic radiation (e.g. mobile telephones or medical electrical devices, such as defibrillators or electrosurgical units) are used near to the Data Bridge, its proper functioning may be affected by electromagnetic disturbances.

⇨ Maintain a distance of at least 0.3 m (1.0 ft) between the Data Bridge and radio communication devices to make sure that the Data Bridge can function optimally.

2.1.12 Infection risk

In order to avoid an increased infection risk for patients and users from a contaminated device, the Data Bridge must be cleaned.

⇨ Comply with the hygiene regulations of the location where the Data Bridge is being used (e.g. Intensive Care), including the cleaning interval and cleaning method.

⇨ Clean the Data Bridge as descripted in chapter 7.

⇨ Clean the Data Bridge before maintenance and before it is returned for repair purposes.

2.2 Warnings in these Instructions for Use

Warnings highlight safety-relevant information.
In the Instructions for Use, the warnings are located before an action that may lead to the endangerment of people or objects.

A warning contains information about a possible hazard and instructions on how to avoid the hazard. They are divided into different hazard levels, depending on the degree of the danger.

	**WARNING**	Denotes a hazard with a medium degree of risk. Failure to observe this warning can lead to severe, irreversible or fatal injuries.
	**CAUTION**	Denotes a hazard with a low degree of risk. Failure to observe this warning can lead to minor or moderate injuries.
	IMPORTANT	Denotes a harmful situation. Failure to observe this warning can lead to damage to property.

3 Overview

3.1 Package contents

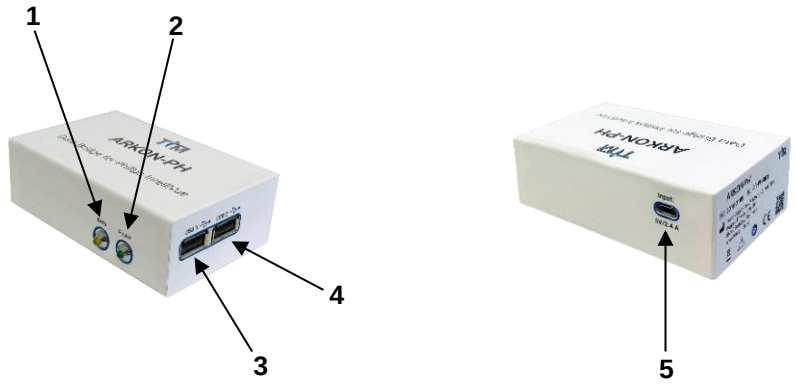
ARKON Data Bridge

Connecting cable (1) with USB 2.0 connector **(1.a)** and FireWire connector **(1.b)** for connecting the ARKON Data Bridge to the MIRUS Controller.

Connecting cable (2) with USB 2.0 connector **(2.a)** and RS232 connector **(2.b)** for connecting the ARKON Data Bridge to the patient monitor.

Mains adapter incl**. power cable (3)** with USB 2.0 connector **(3.a)** and micro USB connector **(3.b)** for connecting to the mains power supply.

3.2 ARKON Data Bridge - device description



No.	Description
1	**LED display (yellow):** Data communication
2	**LED display (green):** Mains power supply
3	**USB 1**: USB interface for connecting the MIRUS Controller
4	**USB 2**: USB interface for connecting the IntelliBridge EC5 module using the connecting cable (2)
5	**Input:** Micro USB port for the mains adapter power cable (5V/2.4 A)

3.3 Symbols on the device and packaging

Manufacturer

WEEE symbol, Directive 2012/19/EU
Device must not be disposed of in normal household waste.

Follow the Instructions for Use

Warning! Alerts the user to refer to the Instructions for Use for important safety information such as warnings and precautions.

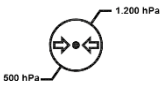
Regulation 2014/30/EU

Serial number

Article number

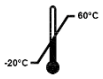
USB interface

Packaging can be recycled



Air pressure, limit (storage, transport)

Relative humidity, limit (storage, transport)



Temperature, limit (storage, transport)

Keep dry

Fragile, handle with care

4 Connecting the ARKON Data Bridge

WARNING **Patient hazard due to malfunctions and damage to the connected devices**

Incorrectly connected devices may malfunction or cause damage to the connected devices.

⇨ Follow the manufacturer’s instructions for the connected devices.

In order to use ARKON Data Bridge with a Philips IntelliVue patient monitor, the ARKON Data Bridge is connected to the integrated or modular IntelliBridge EC10 interface of the patient monitor by the IntelliBridge EC5 ID module.

Required equipment:

- Philips IntelliBridge EC10 interface
  (Philips article number: 865115 option A01, 101)
- Philips IntelliBridge EC5 ID module (open interface)
  (Philips article number: 865114 option 101)
- When connecting to patient monitor MX400/450: integrated IntelliBridge EC10 interface
  (Philips article number: 866060/866062 option J32)
- Philips power cable in the required length

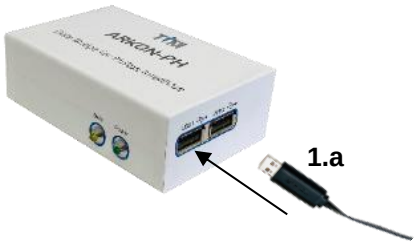
In order to use ARKON Data Bridge with a Philips information centre, the ARKON Data Bridge is connected to the information centre by the IntelliBridge EC5 ID module via the IntelliBridge EC40/80 hub instead of via the IntelliBridge EC10 interface. The procedure is the same as when connecting to a patient monitor.

Required equipment:

- Philips IntelliBridge EC40/80 hub, option H04 or H08
  (Philips article number: 865056)
- Philips IntelliBridge EC5 ID module (open interface)
  (Philips article number: 865114 option 101)
- Philips power cable in the required length

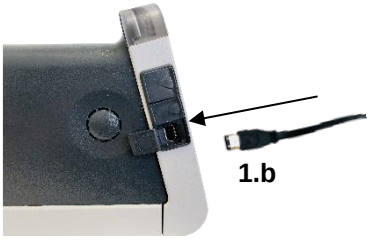
Comment: Additional information can be found in the patient monitor manufacturer's instructions.

A. Plug the USB connector **(1.a)** of the connecting cable **(1)** into the USB port 1 on the device.



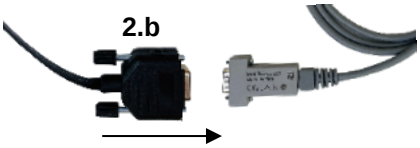
B. Plug the FireWire connector **(1.b)** of the connecting cable **(1)** into the serial data output for PDMS on the MIRUS Controller.

Connect the MIRUS Controller to the mains power supply.



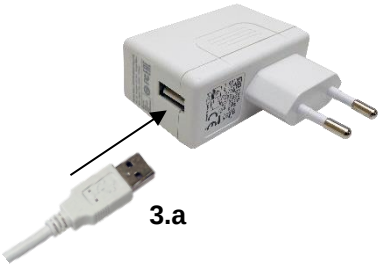
C. Plug the USB connector **(2.a)** of the connecting cable **(2)** into the USB port 2 on the device.

D. Plug the RS232 male connector of the IntelliBridge EC5 ID module (with the already connected power cable) into the RS232 female connector **(2.b)** of the connecting cable **(2)**.

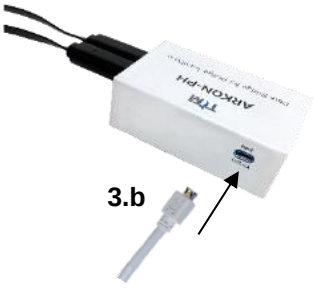


E. Connect the power cable to the corresponding input on the internal or modular IntelliBridge EC10 interface.

F. Plug the USB connector **(3.a)** of the power cable **(3)** into the mains adapter.



G. Plug the micro USB connector **(3.b)** of the power cable **(3)** into the micro USB port on the device.



H. Connect the device to the power supply using the mains adapter supplied.

► On the ARKON Data Bridge, the green LED for the mains power supply is illuminated.

I. The patient monitor set-up occurs automatically after the data communication between the two devices has been established (duration: approx. 5 minutes).

► Once the data communication is established, the yellow data communication LED on the ARKON Data Bridge is permanently illuminated.

5 Data signals from the MIRUS Controller

The following tables list the MIRUS Controller output signals provided by the ARKON Data Bridge that are visible on the patient monitor. The signal ranges and validity conform to the specifications of the MIRUS Controller.

5.1 Measurements

Measurements	Description	Unit
etDES	End-tidal concentration of the volatile anaesthetic	% v/v
etISO		
etSEVO		
etCO_2	End-tidal concentration of CO_2	mmHg

5.2 Settings on the MIRUS Controller

Value	Description	Unit
MAC	MAC target value	No unit

5.3 MIRUS Controller alarms

Certain high-priority alarms are transferred. The alarm notifications are displayed on the patient monitor in English.

Delay:
There is a delay of up to 15 seconds before the alarms sent from the MIRUS Controller are displayed on the screen of the patient monitor.

Patient alarms

ID of the alarm notification originating from the MIRUS Controller	Display of the alarm notification on the patient monitor	Condition
[04]	***LOW VT	Measured Vt_i is less than 200 ml
[09]	***ETVA LOW	The lower alarm limit for the etVA concentration was exceeded.
[10]	***ETVA HIGH	The upper alarm limit for the etVA concentration was exceeded.
[11] [13]	***$ETCO_2$ LOW	The lower alarm limit for the $etCO_2$ concentration was exceeded.
[12]	***$ETCO_2$ HIGH	The upper alarm limit for the $etCO_2$ concentration was exceeded.

Technical alarms

ID of the alarm notification originating from the MIRUS Controller	Display of the alarm notification on the patient monitor	Condition
[14] [15]	***OCCLUSION	A gas sampling or gas measuring line is blocked.
[16] [19]	***DOSAGE ERROR	A problem with the calculation was identified.
[20]	***UPS BATTERY LOW	UPS battery has dropped below 25% of its capacity. (2 minutes remaining)
[21]	***DEVICE INCLINED	Device is tilted.
[24]	***VA RES. EMPTY	Level is less than 45 ml.

ID of the alarm notification originating from the MIRUS Controller	Display of the alarm notification on the patient monitor	Condition
[25] [26] [27] [29] [30] [31]	***DEVICE FAILURE	A technical problem was identified.
[39]	***MR IFACE DISC.	Reflector connector was disconnected.

6 Faults

If faults cannot be repaired using the table below, stop using the device so as to avoid major damage.

Fault	Cause	Repair
Power supply LED not illuminated.	Device not connected to mains adapter.	Connect device to the mains adapter.
	Mains adapter not connected to the power supply.	Connect mains adapter to the power supply.
	Mains adapter or power cable is defective.	Replace mains adapter and power cable.
Data communication LED not illuminated.	Data communication cannot be established because the device is not connected to the MIRUS Controller or the patient monitor.	Connect device to the MIRUS Controller. Connect device to the EC10 interface on the patient monitor or the IntelliBridge EC40/80 hub of the information centre via the IntelliBridge EC5 ID module.
	Data communication cannot be established because the MIRUS Controller is not connected to the mains power supply.	Connect the MIRUS Controller to the mains power supply.
Data communication LED is flashing.	There is a problem with the data communication.	Ensure that the USB connectors of the two connecting cables are correctly inserted.
No data is displayed on the patient monitor.	Faults or errors in the patient monitor.	Refer to the instructions for the patient monitor.

7 Cleaning

⚠ **CAUTION** **Risk of harm to persons and damage to the device from incorrect use of cleaning and disinfecting agents**

⇨ Follow the product information provided by the manufacturer of the cleaning and disinfecting agents.

⇨ Perform the cleaning as described.

IMPORTANT **Damage caused by ingress of liquid**

If liquid enters the device, it may result in damage.

⇨ Disconnect the device from the power supply prior to cleaning.

⇨ Do not allow any liquid to get inside the device.

⇨ Only clean the device using a wipe disinfection method.

The surface disinfectants listed in the following table are suitable for wipe disinfection. These disinfectants have been tested by the device manufacturer and they demonstrated material compatibility at the time of the test. The composition of the cleaning and disinfecting agents is the responsibility of the manufacturer of these agents and may change over time.

Active ingredient	Name	Manufacturer
Alcohol	Incides® N wipes	Ecolab
Quaternary ammonium compounds	Sani-Cloth® active wipes	Ecolab
Quaternary ammonium compounds	Mikrozid® alcohol free liquid Mikrozid® alcohol free wipes	Schülke & Mayr GmbH
	Mikrozid® sensitive liquid Mikrozid® sensitive wipes	Schülke & Mayr GmbH
	Cleanisept® Maxi wipes	Dr. Schumacher
Peracetic acid	Mikrozid® PAA wipes	Schülke

Other surface disinfectants are used at your own responsibility.

Procedure

A. Disconnect the device from the power supply.

B. Remove all other connecting cables.

C. Carry out wipe disinfection.

D. Remove any remaining disinfectant after the exposure time.

E. Let the device dry.

F. Check the device for any visible damage.

8 Service

Service is comprised of measures to preserve the specified condition of the device. These include:

- Maintenance
  Preventive, recurring measures to keep the device in good condition and prevent technical malfunctions. These consist of inspection (assessment of the current condition of the device), replacement of wearing parts, and checking the functioning of individual device components.

- Repair
  Corrective measures to restore full functionality following failure of a device function.

Maintenance
The device does not require any maintenance.

Repair
To repair a defective device, and in the case of errors that you cannot rectify yourself, contact a manufacturer-authorized service organisation or the manufacturer.

9 Disposal

At the end of its service life (5 years), dispose of the device in accordance with statutory regulations.

For countries covered by the EU Directive 2012/19/EU
This device falls within the scope of the EU Directive 2012/19/EU (WEEE) on waste electrical and electronic equipment. To dispose of the device correctly, contact an authorised retailer or the manufacturer (TIM) to arrange for its return.

10 Sending the device

The device can be sent to a manufacturer-authorized service organisation or the manufacturer for repair or disposal at the end of its service life.

WARNING **Risk of infection**

The device may be contaminated with pathogens.

⇨ Before sending clean the device as described in chapter 7.

11 Spare parts list

Description	Part number
Connecting cable 1 (MIRUS data cable with USB 2.0 connector / FireWire connector)	MC-SC-DC-01
Connecting cable 2 (USB 2.0 connector / RS232 female connector)	AR-PH-002
Mains adapter including power cable (USB / micro USB)	AR-PS-001
ARKON Basic Unit	AR-PH-003
ARKON Unit Feet	AR-SC-12641

Comment: The instructions for use in digital form are provided via the manufacturer's website. The printed documents can be requested from the manufacturer.

12 Technical data

Specification	Device
Dimensions (W x H x D)	95 mm x 31 mm x 60 mm
Weight including supplied cables and mains adapter	450 g
Environmental conditions - operation: Temperature range Atmospheric pressure range Relative humidity	 +15°C to +35°C 700 to 1,100 hPa 30% to 75%, non-condensing
Environmental conditions - storage: Temperature range Atmospheric pressure range Relative humidity	 -20°C to +60°C 500 to 1,200 hPa 10% to 95%, non-condensing
Electrical supply - mains adapter Supply voltage Frequency Power consumption	 100 to 240 V_{AC} ± 10% 50 to 60 Hz ± 5% < 15 VA
Electrical supply - device Nominal voltage Current	 5V direct current 2.5 A max.
Electromagnetic compatibility (pursuant to EN 60601-1-2)	Test parameters and threshold values may be obtained from the manufacturer if required.
Compatible Philips monitors (via IntelliBridge EC10)	The Data Bridge is compatible with the following Philips patient monitors, provided that they are equipped with an integrated or modular IntelliBridge EC10 interface: • IntelliVue MP Series (SW version H.15 or higher) • IntelliVue MX Series (all SW versions)
Compatible Philips information centres (via IntelliBridge EC40/80)	The Data Bridge is compatible with the following Philips information centres, provided that they are directly connected via a Philips IntelliBridge EC40/80 hub: • PIIC iX Information Center (SW version B.0) • PIC Information Center (SW version C.0 or higher)
Compatible drivers	OpenInterface IB-ED101-A.6 or higher

Notes

Manufacturer

Technologie Institut Medizin GmbH (TIM)
August-Thyssen-Strasse 30
56070 Koblenz, Germany
Germany
Tel.: +49 261 899 689 00
Fax: +49 261 899 689 09
info@tim-gmbh.de
http://www.tim-gmbh.de

CE

This document

ARKON Data Bridge – Philips Option
Instructions for Use (en-GB)
Ident.no. 063-10108-A
Edition 2021-12
Printed in Germany