

Hygiene Plan Sonata / Scala / Samoa

1 General

The diagnosis systems Sonata, Scala and Samoa including accessories are re-usable medical devices. In terms of hygienic treatment, the Sonata, Scala and Samoa as well as the accessories are assessed and classified as non-critical medical devices because it comes only into contact with intact skin.

The cleaning and disinfection for the Sonata, Scala and Samoa including accessories must be done manually. The disinfection has been successfully validated in terms of applicability and material compatibility in 100 application cycles per product. Additionally, testing was carried out to verify the reduction of the number of bacteria after disinfection.

2 Procedure for Cleaning and Disinfection

Cleaning and disinfection of the Sonata, Scala and Samoa must be carried out after every patient change, on the basis of the following indications. Before cleaning the charging and data cable must be disconnected.

After disinfection the Sonata, Scala and Samoa as well as the accessories must be stored in a dust-protected place until further use. There are no special requirements on packaging.

2.1 Cleaning

Cleaning of the Sonata, Scala or Samoa as well as the accessories is only required to remove coarser dirt, adhesive residue, odours and the like. The cleaning must be carried out with a slightly damp cloth. After cleaning the Sonata, Scala and Samoa including the accessories must then be dried in the open air before proceeding the disinfection.

2.2 Disinfection

The verification of the performance of the disinfection was carried out in accordance with the standard DIN EN ISO 11737-1. A reduction of the number of bacteria of ≥ 5 log-levels was observed. According to EN 1040 a disinfection could be demonstrated.

The performance of disinfection by manual immersion disinfection was also verified. The requirements of the reduction of the number of bacteria of ≥ 5 log-levels have been fulfilled or rather exceeded.

2.2.1 Wipe Disinfection with mikrozid® universal wipes premium

The disinfection for the Sonata, Scala and Samoa including the appropriate accessories has been validated with regard to surface compatibility and microbiological effectiveness with disinfectant wipes of the type mikrozid® universal wipes *premium* manufactured by Schülke & Mayr GmbH. The application the dosage, the exposure times and any protective measures to be taken for the disinfection are stated in the manufacturer's information¹. All surfaces of the Sonata, Scala and Samoa including accessories must be thoroughly cleaned. It must be ensured that no liquids enter the Sonata, Scala, Samoa or the plug-connections.

The above information regarding to the wipe disinfection with mikrozid® universal wipes premium is valid for the following products.

Article no. Description

925220	PAP adapter hose for oxygen mask
925395	Abdomen sensor, complete , 1 pressure pad, connection hose
925396	Abdomen sensor, complete , 1 pressure pad with flexible connection tube and lengthened tube
929010	Samoa patient recorder with Display
929011	Samoa patient recorder without Display
929140	Thorax sensor, complete , 2 pressure pads, flexible connection tubes
929150	Thorax sensor, complete , 2 pressure pads with flexible connection tubes and lengthened tube for positioning Samoa near child
929250	Carrying console for Samoa patient recorder

¹ <https://www.schuelke.com/intl-en/products/mikrozid-universal-wipes-premium.php>

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Article no. Description

929302	Shoulder bag cloth bag with shoulder strap for carrying the Samoa
930010	Sonata sleep diagnosis - Patient recorder incl. radio module
930020	Sonata sleep diagnosis - Neuro module for Sonata
930040	Scala sleep diagnosis – Patient recorder (24 channels) incl. radio module
930041	Scala sleep diagnosis – Patient recorder (24 channels) without radio module
930200	Sonata Base
930226	USB Cable for data transmission between Sonata/Scala and Sonata Base, 3m
930236	Adapter cable Redel – Hirose , for data transmission between Sonata/Scala and Sonata Base, 25 cm
930237	USB cable Redel – Redel , for data transmission between Sonata/Scala and Sonata Base, 2.7 m
930238	USB cable Redel – Redel , for data transmission between Sonata/Scala and Sonata Base, 3.6 m
930250	Carrying console for Sonata/Scala patient recorder
930251	Carrying console for Neuro module
930252	Carrying console V-form for patient recorder and Neuro module
930253	Shoulder bag cloth bag with shoulder strap for carrying the Scala
930393	Effort sensor, short, complete , 2 pressure pads with flexible connection tubes
930394	Effort sensor, long, complete , 2 pressure pads with flexible connection tubes
930395	Effort sensor for children, complete , 2 pressure pads with flexible connection tubes for positioning the device behind the child
930397	Effort sensor, short, complete, 2 m , 2 pressure pads with flexible connection tubes for positioning the device behind the patient
930398	Effort sensor, long, complete, 2 m , 2 pressure pads with flexible connection tubes for positioning the device behind the patient

2.2.2 Wipe Disinfection with mikrozid® AF wipes

The disinfection of other accessory products has been validated with regard to surface compatibility and microbiological effectiveness with disinfectant wipes of the type mikrozid® AF wipes manufactured by Schülke & Mayr GmbH. The application, the dosage and any protective measures to be taken for the disinfection are also stated in the manufacturer's information². All surfaces of the accessories must be thoroughly cleaned. During disinfection the surfaces must be kept moist. A contact time of two minutes must be observed to achieve the required disinfection performance.

The above information regarding to the wipe disinfection with mikrozid® AF wipes is valid for the following products.

Article no. Description

925285	Thorax strap, XS
925286	Thorax strap, XXS
925287	Thorax strap, XXXS
925388	Abdomen strap, Size S
925389	Abdomen strap, Size M
925390	Abdomen strap, Size L
925393	Abdomen strap, XS
925397	Abdomen strap, XXS
925398	Abdomen strap, XXXS
926280	Carrying strap Thorax, Size M
926281	Carrying strap Thorax, Size S

² <https://www.schuelke.com/intl-en/products/mikroqid-AF-wipes.php>

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Article no.	Description
926282	Carrying strap Thorax, Size L
927370	RIP Belt for MiniScreen/Sonata/Scala, flexible, black, reusable
929320	Thermistor for Samoa, with fixation for flow prong reusable
930220	Sonata Intercom-Cable connection cable Sonata – Neuro module 8.5 cm
930221	Sonata Intercom-Cable connection cable Sonata – Neuro module, 60 cm
930224	USB Cable for data transmission to PC, 1.8 m
930260	Carrying strap for Sonata/Scala, flexible, blue, Size S
930261	Carrying strap for Sonata/Scala, flexible, black, Size M
930262	Carrying strap for Sonata/Scala, flexible, red, Size L
930263	Carrying strap for Sonata, flexible, blue, with connection to position sensor 930310, Size S
930264	Carrying strap for Sonata, flexible, black, with connection to position sensor 930310, Size M
930265	Carrying strap for Sonata, flexible, red, with connection to position sensor 930 310, Size L
930266	Carrying strap for children, flexible, black, with connection to position sensor 930310, Size XS
930267	Carrying strap for children, flexible, black, with connection to position sensor 930310, Size XXS
930268	Carrying strap for children, flexible, black, with connection to position sensor 930310, Size XXXS
930300	Finger sensor SpO₂ finger cuff with cable
930310	External position sensor , for Sonata
930320	Thermistor for Sonata/Scala, with fixation for flow prong, reusable
930321	Snoring microphone for Sonata/Scala, external, reusable
930324	RIP-Interface cable Thorax/Abdomen , for Sonata/Scala, with Key hole plug, 1m
930330	Actimeter für Sonata
930410	Extension cable 2-cables Sonata/Scala for cables with 1.5mm safety plug connections 94 cm

2.2.3 Immersion Disinfection with Gigasept® FF

The disinfection of the Pressure-Diff-Adapter must be carried out by immersion disinfection in a 6 % Gigasept-FF solution. The disinfectant is a concentrate of the company Firma Schülke & Mayr GmbH, which must be diluted with cold water to produce the desired application concentration. For example, 1 litre of a 6 % working solution corresponds to 940 ml of water and 60 ml of Gigasept FF.

The contaminated Pressure-Diff-Adapter must be immersed in the 6 % Gigasept FF solution for at least 15 minutes. The tubes of the Pressure-Diff-Adapter must be filled with the Gigasept-FF solution by means of disposable items like a 20 ml syringe and a cannula no. 1, to ensure complete covering and air removal of the surfaces.

Any protective measures to be taken for the disinfection are stated in the manufacturer's information³.

The above information regarding to the immersion disinfection with Gigasept® FF is valid for the following product.

Article no.	Description
930322	Pressure-Diff-Adapter for Sonata/Scala

³ <https://www.schuelke.com/intl-en/products/gigasept-FF-new.php>

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2.2.4 Wipe Disinfection with Mikrobac® Virucidal Tissues

The disinfection of the thermistor for Sonata, Scala and Samoa has been validated with regard to surface compatibility and microbiological effectiveness with disinfectant wipes of the type Mikrobac® Virucidal Tissues manufactured by BODE Chemie GmbH. The application the dosage, the exposure times and any protective measures to be taken for the disinfection are stated in the manufacturer's information⁴. All surfaces of the accessories must be thoroughly cleaned. It must be ensured that no liquids enter the device or the plug-connections.

The above information regarding to the wipe disinfection with Mikrobac® Virucidal Tissues is valid for the following product.

Article no.	Description
929320	Thermistor for Samoa, with fixation for flow prong, reusable
930320	Thermistor for Sonata / Scala, with fixation for flow prong, reusable

⁴ https://productcatalogue.bode-chemie.com/products/surface/mikrobac_virucidal_tissues.php

Information from Product Management Diagnostics

Addendum to hygiene plan Samoa lite/Samoa/Scala/Sonata Usage of compatible disinfection wipes

The following disinfectant wipes can be used for the steps of procedure 2.2.1 and 2.2.2 in hygiene plan Samoa/Scala/Sonata. Manufacturer's details in brackets.

- Mikroqid AF Wipes (Schülke & Mayr)
- Mikroqid Universal Wipes (Schülke & Mayr)
- Incidin Alcohol Wipes (Ecolab Healthcare)
- Descosept Sensitive Wipes (Dr. Schumacher)
- Meliseptol Acute Wipes (B. Braun)
- Bacillol Wipes, Bacillol AF Wipes (Paul Hartmann)

Bad Ems
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