

## ER-WD223™ DATA SHEET

**AUTOMATED CLEAN-UP COUNTER TO ASSIST THE MANUAL WASHING OF FLEXIBLE ENDOSCOPES**

**(gastrosopes, colonoscopes, bronchoscopes and similar)**

### PRODUCT

**ER-WD223™**



### DESCRIPTION

The clean-up counter for endoscopes **ER-WD223™** is a Class I Medical Device that assists the manual washing of flexible endoscopes. The device guarantees the complete traceability and automation of the manual washing of endoscopes, relieving operators from executing daily risky operations which can cause carpal tunnel inflammations and osteoarticular diseases.

The system is validated according to EN ISO 15883:2021 part 5, Annex F to remove the microbial biofilm. The automated counter for endoscopes **ER-WD223™**, performs the washing in a fast and safe way automatically, that means operators need only to clean instruments externally and brush the channels. It performs automatically: leak testing at the beginning and during the entire cycle, chemical and water dosage during the washing, flushing and rinsing of endoscopes channels, discharge and purging of endoscopes channels, organic residual test, auto-sanification cycle, paper and digital report to trace cycles. It can be connected to MDG's software datatrace or Soluscope's one by Ethernet. (optional).

#### INTENDED USE:

Automatic support system for the manual pre-washing phases of flexible endoscopes (**gastrosopes, colonoscopes, bronchoscopes and similar**).

#### MODELS:

| CODE        | DESCRIPTION                                                                                                                                                                                                                                                                                                      |
|-------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ER-WD223™   | <p>Washing pump for endoscopes equipped with printer, barcode reader (for all kind of endoscopes except little instruments (bronchoscopes, cystoscopes and similar) – 1 position with recirculating chemical detergents.</p>    |
| ER-WD223/2™ | <p>Washing pump for endoscopes equipped with printer, barcode reader (for all kind of endoscopes except little instruments (bronchoscopes, cystoscopes and similar) – 2 positions with recirculating chemical detergents.</p>  |
| ER-WD223/3™ | <p>Washing for endoscopes equipped with printer, barcode reader (for all kind of endoscopes except little instruments (bronchoscopes, cystoscopes and similar) – 3 positions with recirculating chemical detergents.</p>      |

#### MAIN FEATURES:

- Double-check **leak test** carried out at start-up and throughout the washing cycle, decreasing the possibility of instrument infiltration;
- **Automatic dosage of the detergent chemical** thanks to the internal membrane pump, the device doses the right amount of concentrated detergent to be diluted in the tank, reducing the risk of waste and damaging overdosing for the instruments;
- **Flushing of the mixed detergent/decontaminant** through a special connection kit in all channels of the endoscope in full immersion way;
- **Traceability** of cycle data managed via integrated printer and USB port or direct Ethernet connection (optional) via dedicated software (optional);
- **Barcode reader** as standard or Integrated Barcode (optional) or RFID (optional) for reading instrument ID and operators ID;

- **Paper report** containing date, time of start and end of cycle, operator ID and endoscope ID or endoscope serial number, washing phase data including pause for manual brushing if activated, rinsing phase, progressive ID, endoscope sampling operator (if activated) and serial number of the equipment;
- **Connectors** for all major endoscope brands and models;
- **Reporting of any possible malfunctions** through the display, with acoustic and visual alarms and on printouts;
- **4" Colour graphic touch screen display** that guides the operator following him step by step in the phases. The display shows all the information necessary for the operator regarding the status of the machine: phase of the cycle in progress and the time remaining at the end of the cycle and of the single phase;
- **Possibility of connecting the medical device to the traceability software or to the hospital system** (optional);
- **Labels applicable on endoscopes** and compatible with the sterilization cycles;
- **Automatic** carrying out up **rinsing** phases;
- **Automatic** carrying out channel **clearing** phase;
- **Acid resistant pump and components** for self-disinfection cycles with peroxides or peracetics.

#### USABLE CHEMICAL PRODUCTS:

The following **detergents** can be used with the ER-WD223™ Endoscope Flush Pump (all models):

- Anyosime XL3
- Anyosime X3
- Aniosyme Synergy 5

#### INSTRUCTION FOR USE

Refer to End-user Manual



#### TECHNICAL SPECIFICATIONS:

|                                                  |                                                                                                                                                     |
|--------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>External Dimensions (WxDxH)</b>               |                                                                                                                                                     |
| <b>ER-WD223™</b>                                 | W800xD700xH1050mm (bench height 950 mm)                                                                                                             |
| <b>ER-WD223/2™</b>                               | W1550xD700xH1050mm (bench height 950 mm)                                                                                                            |
| <b>ER-WD223/3™</b>                               | W2300xD700xH1050mm (bench height 950 mm)                                                                                                            |
| <b>Materials</b>                                 | Made of tempered glass and 304L stainless steel.<br>Other components made with materials resistant to the action of aggressive chemical detergents. |
| <b>Power supply and maximum absorbed current</b> | 110V to 230V – 60/50 Hz/ maximum absorbed current: 5A                                                                                               |

|                             |                             |
|-----------------------------|-----------------------------|
| Operating temperature range | - 5°C ÷ + 50 °C             |
| Relative humidity range     | 20-90% without condensation |
| Sound level indication      | < 50 dB (A)                 |
| Weight                      |                             |
| ER-WD223™                   | 60Kg                        |
| ER-WD223/2™                 | 110Kg                       |
| ER-WD223/3™                 | 150Kg                       |

#### COMPLIANCE WITH STANDARDS:

Product classification in accordance with the requirements of Directive (EU) 2017/745 (MDR) concerning **Class I** medical devices:

- MEDICAL DEVICES REGULATION (EU) 2017/745 (MDR)
- CEI EN ISO 14971:2022(Application of risk management to medical devices);
- CEI EN ISO 13485:2021
- CEI EN 62366-1:2015
- IEC 62304:2006
- ISO 10993-1:2021
- CEI EN ISO 15223-1:2021
- MEDDEV 2.12/2 rev.2
- ISO 15883-5:2021
- BS EN 60601-1-2:2015/A1:2021
- EN 61010-1:2010/A1:2019
- EN 61010-2-040:2020
- Directive 2012/19/UE 4th July 2012
- CEI EN ISO 20417:2021
- Med Dev 2.12.1 rev. 8th January 2013
- Med Dev 2.12.2 rev 2nd January 2012
- Med Dev 2.4 part 1 rev. 9<sup>th</sup> June 2010
- DM 15th novembre 2005

## CND, RDM e GMDN

| Device - code | CND   | GMDN  | RDM     |
|---------------|-------|-------|---------|
| ER-WD223™     | G0380 | 66649 | 2462966 |
| ER-WD223/2™   | G0380 | 66649 | 2463019 |
| ER-WD223/3™   | G0380 | 66649 | 2463035 |

## ACCESSORIES: CODES

|           |                                                                                                     |
|-----------|-----------------------------------------------------------------------------------------------------|
| 000102S   | Ethernet module + traceability software                                                             |
| 000105S   | 50 instrument tags and 20 operator tags                                                             |
| 000ER-O   | Olympus connection 140-180 series                                                                   |
| 001ER-O   | Olympus connection 190 series                                                                       |
| 002ER-P   | Pentax connection 30-80 series                                                                      |
| 003ER-P   | Pentax connection 90 series                                                                         |
| 023ER-PB  | Pentax videobronchoscope connection series 30/80                                                    |
| 024ER-PB  | Pentax videobronchoscope connection series k90-j10                                                  |
| 004ER-F   | Fujinon connection 200 series                                                                       |
| 005ER-F   | Fujinon connection 400 – 600 series                                                                 |
| 006ER-S   | Storz connection                                                                                    |
| 007ER-F   | Fujinon connection 700 series                                                                       |
| E-01119   | Bacteriological filter leak test (every 6 months)                                                   |
| ANIOSYME  | Aniosyme XL3                                                                                        |
| AN2633036 | Aniosyme X3                                                                                         |
| B-01      | Interface base for connecting the washing kit / connecting the Soluscope endoscope washing channels |
| 000108S   | 10" Bacteriological filter (below the sink)                                                         |
| 000109S   | Point of use bacteriological filter (mixer tap) - optional                                          |
| 000114S   | Water spray reader provided with universal kit (the reader is supplied instead of the standard one) |

|         |                                                    |
|---------|----------------------------------------------------|
| 000117S | Standard water spray gun with stainless steel hose |
| 000118S | Standard water spray gun with PVC hose             |

### **CONNECTION BASE B-01™ (OPTIONAL)**

The washing pump ER-WD223™ and all its versions can be used with a multi-channel unique connector that can be adapt to Soluscope's washer disinfectors models S3 or S4. (optional)

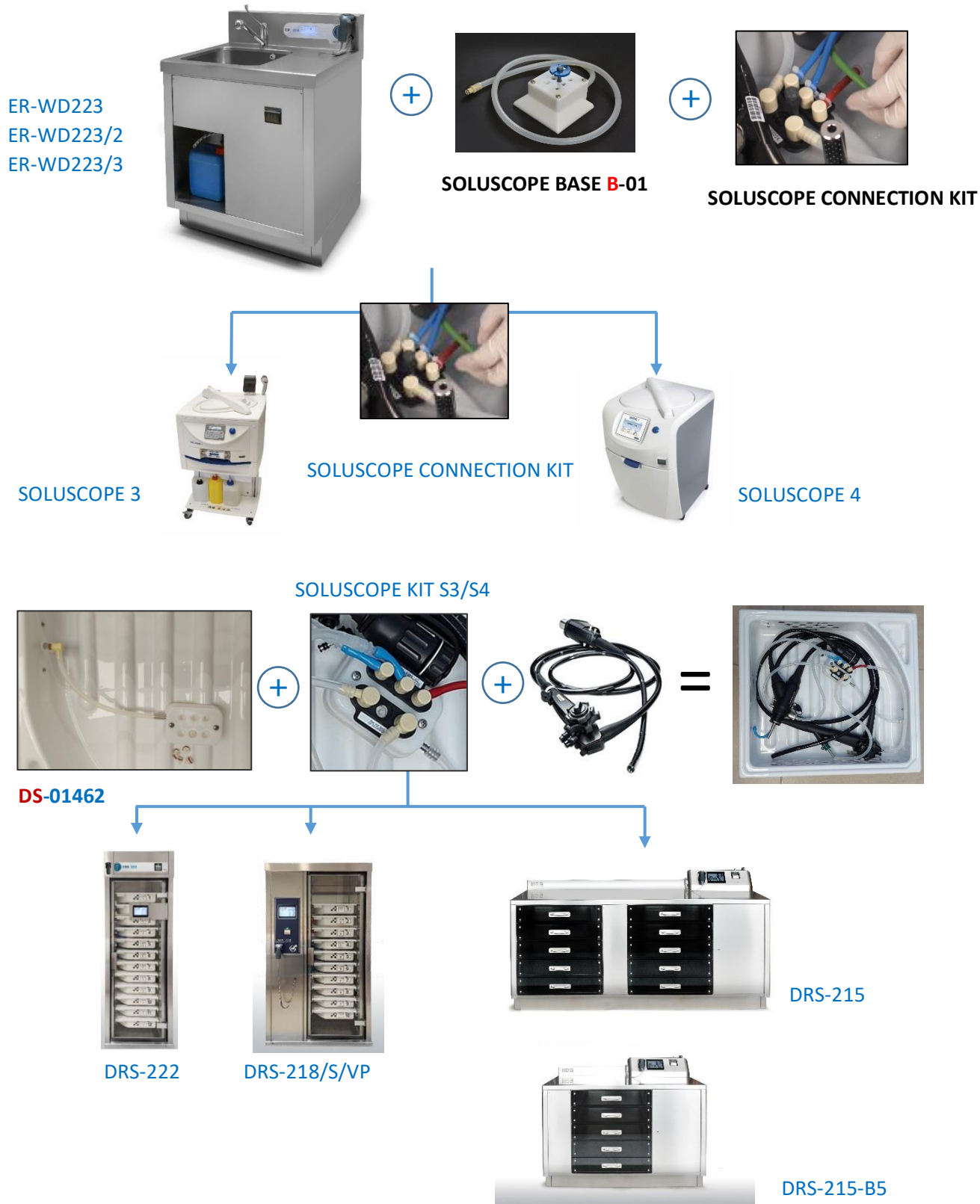
This B-01 connector is connected to one side of the washing pump ER-WD223™ through a direct connection to the pump or the washing basin if the sink is automated and on the other side all the endoscope connections.

The operator connects the instrument during the first manual washing and is being kept connected to the same connector for the entire reprocessing (manual washing, disinfection in Soluscope's AER, drying in dedicated drying cabinets).

Advantages from using the B-01:

- Less manipulation of endoscopes reducing risk of contamination
- Efficacy improving (gain of time for the operator)
- Easy connection operations (plug & play)
- No error during connection operations

**CONNECTION DIAGRAM B-01 BASE FOR SOLUSCOPE'S AER MODELS S3 AND S4:**  
(See dedicated technical data sheet)



#### **ADAPTER E-01595 TO USE KIT OF SOLUSCOPE'S AER MODEL S1 (OPTIONAL)**

The washing pump ER-WD223™ and all its versions can be used with a multi-channel unique connector that can be adapt to Soluscope's washer disinfectors models S1 (optional).

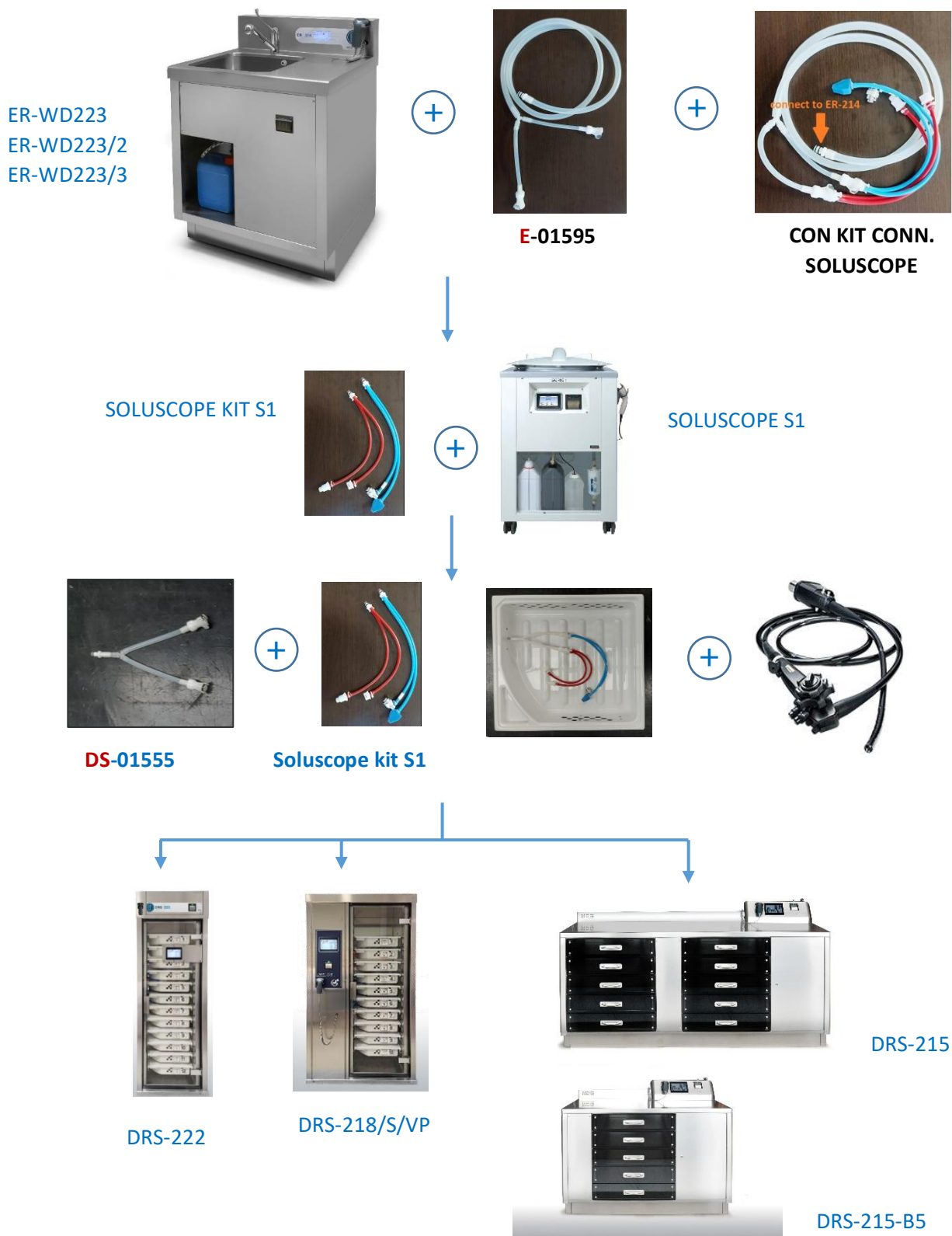
The **E-01595** connector is connected to one side of the washing pump ER-WD223™ through a direct connection to the pump or the washing basin if the sink is automated and on the other side all the endoscope connections.

The operator connects the instrument during the first manual washing and is being kept connected to the same connector for the entire reprocessing (manual washing, disinfection in Soluscope's AER, drying in dedicated drying cabinets).

Advantages from using the adapter E-01595:

- Less manipulation of endoscopes reducing risk of contamination
- Efficacy improving (gain of time for the operator)
- Easy connection operations (plug & play)
- No error during connection operations

**CONNECTION DIAGRAM E-01595 FOR SOLUSCOPE'S AER MODELS S1:**  
(See dedicated technical data sheet)



**Manufacturer:**

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