ER-214™ DATA SHEET

AUTOMATIC SYSTEM TO ASSIST THE MANUAL WASHING OF FLEXIBLE AND SEMI-RIGID ENDOSCOPES

PRODUCT

ER-214™

DESCRIPTION

The washing pump for endoscopes **ER-214** is a bench-top instrument that works in combination with sinks normally used for the instruments washing or with devoted automatized sinks (Washing pump for endoscopes ER-214/LV or ER-214-B/LV). This process guarantees the complete traceability and automation of the manual washing of endoscopes, relieving operators form executing daily risky operations which can cause carpal tunnel inflammations and osteoarticular diseases.

The washing pump for endoscopes ER-214 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 phase, **flushing** and rinsing of endoscopes channels, **organic residual test**, **auto-sanification cycle**, paper and digital report to **trace** cycles.

INTENDED USE:

Automatic support system for the pre-washing phases of flexible and semi-rigid endoscopes (**gastroscope, colonoscope, bronchoscope, etc**.).

MODELS:

CODICE	DESCRIZIONE
ER-214™	Washing pump for endoscopes equipped with printer, barcode reader (for all kind of endoscopes except little instruments (bronchoscopes, cystoscopes and similar)
ER-214/LV™	Automated washing pump for endoscopes equipped with printer, barcode reader. It operates with sink LV-215/LV-220 or with counters already on site. For all kind of endoscopes except little instruments (bronchoscopes, cystoscopes and similar)
ER-214/B™	Washing pump for endoscopes designed for bronchoscopes/cystoscopes and similar. Equipped with printer and barcode reader
ER-214-B/LV™	Automated washing pump for endoscopes designed for bronchoscopes/cystoscopes and similar. Equipped with printer, barcode reader. It operates with sink LV-215/LV-220 or with counters already on site

MAIN FEATURES:

- **Double-check leak test carried out at start-up and throughout the washing cycle, eliminating the possibility of instrument infiltration;**
- **Automatic dosage of the detergent chemical product 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;
- **Traceability** of cycle data managed via integrated printer and USB port or via Bluetooth (optional) or direct Ethernet connection (optional) via dedicated software (optional);
- **Barcode reader as standard or Integrated Barcode (optional) or RFID (optional)** for reading **instrument IDs and operators IDs;**
- **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;**
- **Soluscope's adapters;**
- **Reporting of any possible malfunctions (lead test fail, low/high flux, channel obstruction, …)** through the display, with acoustic and visual alarms and on printouts;
- **4" Color graphic display** that guides the operator following him step by step in the pre-washing 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 carried out in endoscope washing machines;**
- **Possibility of fixing the machine to the wall with an appropriate dedicated bracket (optional);**
- **Possibility of carrying out a cycle for the verification of protein residues;**
- **Support for the detergent / decontaminant bottle (wall / counter - optional);**
- **Possibility of carrying out up to two rinsing phases;**
- **Possibility of carrying out a channel clearing phase;**
- **Acid resistant pump for self-disinfection cycles with peroxides or peracetic.**

USABLE CHEMICAL PRODUCTS:

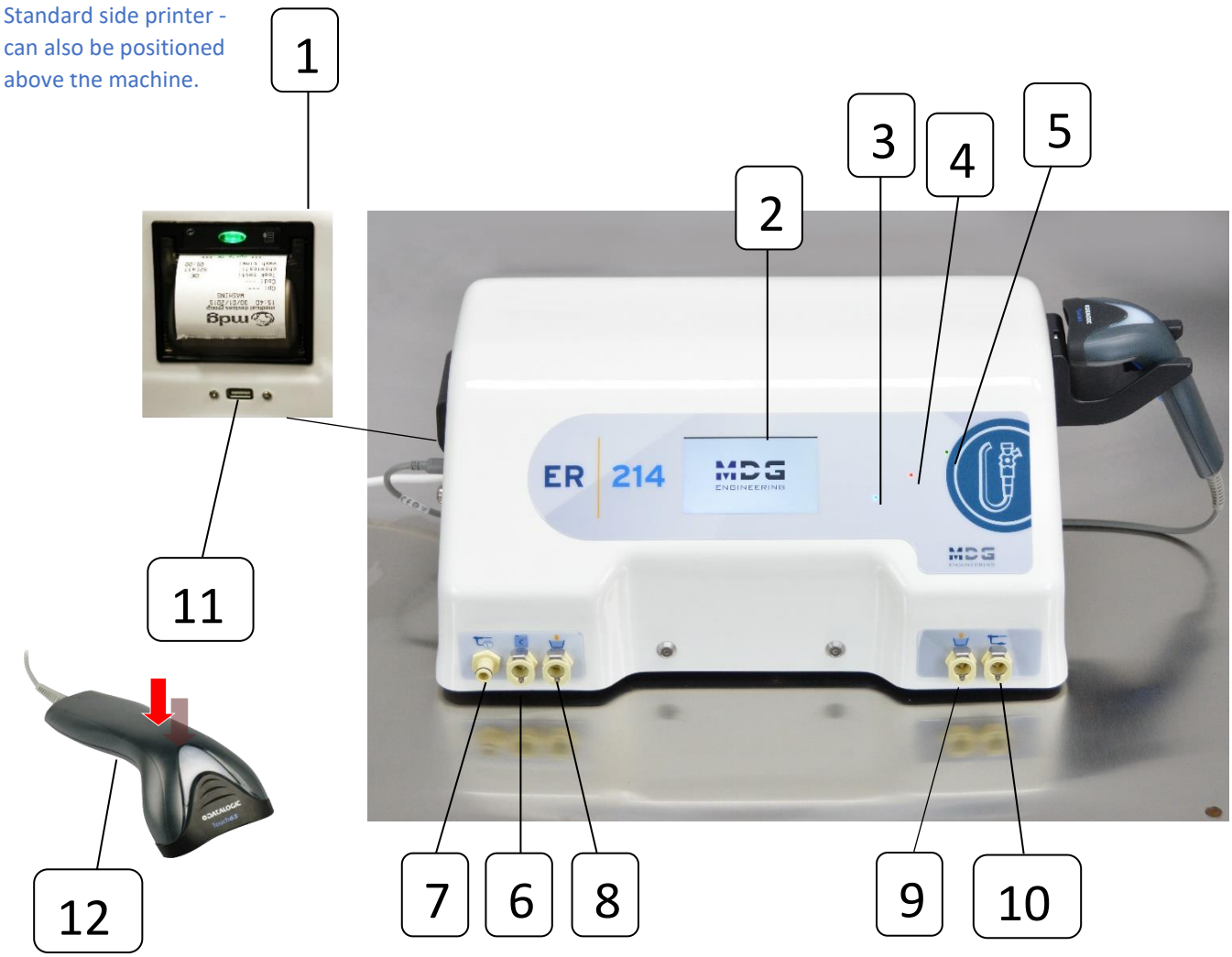
The following chemicals can be used with the ER-214™ Endoscope Flush Pump (all models):

- Detergent and decontaminant **Aniosyme XL3™** manufactured by LABORATOIRES ANIOS
- Detergent **Aniosyme X3™** manufactured by LABORATOIRES ANIOS
- Detergent **Aniosyme Synergy 5** manufactured by LABORATOIRES ANIOS
- Detergent and decontaminant **Aniosyme XL3™ diluted to 2%** for autosanification cycle by LABORATOIRES ANIOS
- Detergent and decontaminant **Steranios 2%** manufactured by LABORATOIRES ANIOS
- Detergent and decontaminant **Aniosyme 1000™** manufactured by LABORATOIRES ANIOS
- Detergent and decontaminant **Aniosyme 1000 LD™** manufactured by LABORATOIRES ANIOS
- Detergent and decontaminant **OPASTER™** manufactured by LABORATOIRES ANIOS

INSTRUCTION FOR USE

Refer to End-user Manual

LAYOUT WASHING PUMP ER-214:



REF.	DEVICE	REF.	DEVICE
1	Printer	**8**	Dosed chemical outlet
2	4” Color display	**9**	Tank liquid suction
3	Reset button	**10**	Instrument washing connection
4	Stop button	**11**	USB port
5	Start button	**12**	Barcode reader
6	Leakage test		

TECHNICAL SPECIFICATIONS:

External Dimensions (WxDxH)	440x260x200mm
Materials	Made of ABS and 304L stainless steel. Other components made with materials resistant to the action of aggressive chemical detergents.
Power supply and maximum absorbed power	230V – 50 Hz/ maximum absorbed power: 3 A
IP protection degrees	Class IP54 (CEI EN 60529)
Operating temperature range	- 5°C ÷ + 50 °C
Relative humidity range	20-90% without condensation
Sound level indication	< 45 dB (A)
Weight	10 Kg

COMPLIANCE WITH STANDARD:

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 60601-1-2:2015 (Electromagnetic compatibility);
- CEI EN ISO 14971:2019 (Application of risk management to medical devices);
- CEI EN ISO 13485:2021
- CEI EN 62366-1:2015
- IEC 62304:2006
- ISO 10993-1:2020
- CEI EN ISO 15223-1:2021
- MEDDEV 2.12/2 rev.2
- ISO 15883-5 annex F
- EN 61010-1:2010/A1:2019
- EN 61010-2-040:2015
- 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. 9th June 2010
- DM 15th novembre 2005

CND, RDM e GMDN

Device - code	CND	RDM	GMDN
Washing pump for endoscopes ER-214™	G0380	2456370	66649
Washing pump for endoscopes ER-214/B™	G0380	2459992	66649
Washing pump for endoscopes ER-214/LV™	G0380	2460007	66649
Washing pump for endoscopes ER-214-B/LV™	G0380	2460005	66649

CONNECTION BASE B-01 (OPTIONAL)

The washing pump ER-214 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-214 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).

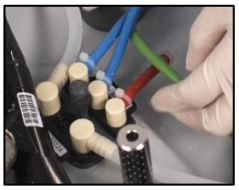
Advantages from using the B-01:

- 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)

ER-214
ER-214/B
ER-214/LV
ER-214/B-LV

SOLUSCOPE BASE B-01



SOLUSCOPE CONNECTION KIT

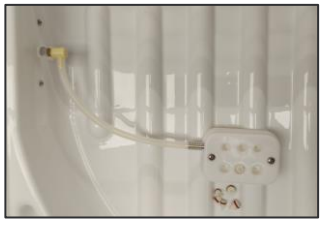
LV-215

LV-220

SOLUSCOPE 3

SOLUSCOPE CONNECTION KIT

SOLUSCOPE 4



DS-01462

DRS-222

DRS-218/S/VP

DRS-215

DRS-215-B5

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

The washing pump ER-214 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-214 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)

ER-214
ER-214/B
ER-214/LV
ER-214/B-LV

E-01595

SOLUSCOPE CONNECTION KIT

LV-215

LV-220

SOLUSCOPE KIT S1

SOLUSCOPE S1

DS-01555

Kit SOLUSCOPE S1

DRS-222

DRS-218/S/VP

DRS-215

DRS-215-B5

ACCESSORIES

The washing counter dedicated to the automatic washing pump system for endoscopes ER-214/LV™ or ER-214-B/LV™ for the reprocessing of endoscopic canals, allows the automatic loading / unloading of the water and the dosage of the chemical necessary for the correct washing of the instrument channels in a separate tank.

This configuration can be combined with the decontaminant Aniosyme XL3 validated for the removal of the microbial biofilm.

<u>The dimensions of the sink counter and its washing tanks can be customized.</u>

STANDARD

- Counter entirely made of 15/10 stainless steel, designed to optimize ergonomics in favour of the operator and endoscopic instruments.
- Worktop including a tank for the dilution of the chemical from mm. 200 × 400x300 and a washing tank of mm. 500x500x200; complete with an ac / af mixer dispenser unit and equipped with a compressed air or water reader.
- Rear upstand from mm. 100.
- Special surface for positioning the ER-214/LV™ or ER-214-B/LV™ Endoscope Flushing Pump.
- Closed front with sliding doors on PVDF wheels.

CHEMICAL DOSING TRAY

Image 1:

Standard LV-215 endoscopy wash counter (1700x 950x850) prepared for automated control of the ER-214/LV™ or ER-214-B/LV™ endoscope wash pump.

Image 2:

Standard LV-220 endoscopy wash counter (200x 950x850) prepared for automated control of the ER-214/LV™ or ER-214-B/LV™ endoscope wash pump.

KIT FOR AUTOMATION OF SINKS ALREADY PRESENT IN THE WARD

The Kit provides for a hydraulic adaptation to the sink benches already existing in the ward connected to the automatic washing pump system for ER-214/LV ™ or ER-214-B/LV ™ endoscopes for the reprocessing of endoscopic channels. This kit allows the automatic loading / unloading of the water and the dosage of the chemical necessary for the correct washing of the instrument channels in recirculation conditions using the existing washing tank.
The modification involves permanent adaptations on the sink.

CODES:

CODE	DESCRIPTION
ER-214	Washing pump for endoscopes complete with printer and barcode reader (for all endoscopes except small instruments - bronchoscopes, cystoscopes and similar).
ER-214/LV	Automated washing pump for endoscopes complete with printer, barcode reader; it can be interfaced with the sink cod. LV-215 / LV / 1-215 or with sinks already present on site, for all endoscopes except small instruments (bronchoscopes, cystoscopes and similar).
ER-214/B	Washing pump for endoscopes, device dedicated to bronchoscopes / cystoscopes and similar, complete with printer and barcode reader.
ER-214-B/LV	Automated washing pump for endoscopes, device dedicated to bronchoscopes / cystoscopes and similar, complete with printer, barcode reader, interfaceable with sink cod. LV-215 / LV / 1-215 or with the sinks already present on site.
000100S	RFID reader + 50 instrument tags and 20 operator tags
000101S	Bluetooth module + traceability software
000102S	Ethernet module + traceability software
000103S	50 instrument tags and 20 operator tags
000105S	50 instrument tags and 20 operator tags
000106S	Stainless steel wall bracket for ER-214
000107S	Kit for hospital sink automatization
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

CODE	DESCRIPTION
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

AUTOMATIC SINKS

Cod. LV-215	Washing counter designed for the automated control of the ER-214 endoscope wash pump with 24L dosing tank and standard 500mmx500mmH200mm wash tank W1700mm x D850mm x H950
Cod. LV-220	Washing counter designed for the automated control of the ER-214 endoscope washing pump with 2 dosing tanks of 24L and 2 washing tanks of 500mmx500mmH200mm standard W2000mm x D850mm x H950top x 1400mm integration of washing pump.

NOTE: the sizes of the sinks can be customized.

LV-215 AND LV-220 OPTIONALS

CODE	DESCRIPTION
000106S	Stainless steel wall bracket to support the device
000108S	10” Bacteriological filter (below the sink)
000109S	Point of use bacteriological filter (mixer tap)
000110S	Point of use bacteriological filter (shower mixer tap)
000111S	Point of use filter (only filter – every 3 months)
000112S	Shower mixer tap filter (only filter – every 3 months)

CODE	DESCRIPTION
000113S	10” bacteriological filter (only filter – every 6 months)
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
E-01499	Control unit for sink height adjustment managed by 4 independent servomotors (+150 mm)

Manufacturer:

MDG ENGINEERING s.r.l., Carraia Baruzzi, 4/M - 48123 Mezzano (RA), Italia
VAT number 02637160397 - www.mdg-engineering.com