

Restricted

Siemens Healthineers
Business Area Ultrasound

Title: TPS (Transducer Product Specification): 9VE4 Endocavity Transducer for COMPASS system

Part Number: 11289564-ASH-001-02

Revision Data

Rev	ECO #	Change Description	Printed Name
01	N/A	Not Used to align with TPRS and material revision.	Chris Na
02	695433	Initial Release	Chris Na

This document is under Engineering Change Order control. The official ECO released document is maintained in SAP. Per Change Control Procedure 08266240, any printed or electronic document external to SAP is reference copy only and must be confirmed in SAP as the most recent version or if still active. Employees, supervisors, and managers own this responsibility for documents they own or use.

Transducer Product Specification
9VE4

Doc. No. : P9EV4COM-4

Confidential

Transducer Product Specification

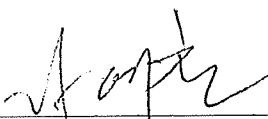
Real Time Mechanical Transducer for 2D and 3D/4D Endovaginal Imaging

9VE4

Approvals

SIEMENS Approval :

Transducer Product Manager :


Chris Na

Aug 11, 2020
Date

KONICA MINOLTA

Approved by :

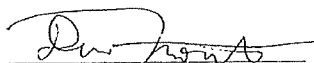
Manager of Sales Department


K. Haruki

Aug. 8, 2020
Date

Approved by :

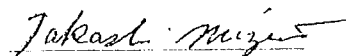
General Manager of Engineering Department


D. Morita

Aug. 8, 2020
Date

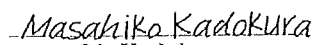
Checked by :

Manager of Transducer Engineering Section


T. Mizuno

Aug 7, 2020
Date

Originator :


M. Kadokura

Aug. 7, 2020
Date

Information contained herein is proprietary to KONICA MINOLTA INC. and should not be distributed or reproduced without the expressed written consent of KONICA MINOLTA INC., Japan.

Confidential

Revision History

Rev.	Description	Originator	Date
Draft 0	Draft Initial Release	J.Takeda	2016/2/15
Draft 1 (Rev. 0)	Update 1.1 Siemens Part Number 1.1 KONICA MINOLTA Part Number 1.5 Transducer ID 1.7 Sheath 2.0 ACOUSTICAL / ELECTRICAL PARAMETERS (Add parameters with inductor and Drive condition) 3.5 Tuning Coil 4.1 Dimension and Weight 4.3 Housing (Grip) 4.7 Connector Housing 4.9 Strain Reliefs (Connector side) 4.10 Labels 4.11 Packaging(Add section) 6.0 MECHANICAL 4D TRANSDUCER INTERFACE 7.1 Environment 7.2a Cleaning: 7.2b Chemical disinfection: 7.3c Electric Breakdown Appendix B : Circuit Block Diagram Appendix C : Appearance Appendix D : Caution Label A Appendix E : Identification Label Appendix F : Name Label Appendix G: Caution Label B Appendix H : Packaging Label (1) Appendix I : Packaging Label (2) Appendix J : Packaging Label (3) Appendix K : Temperature Label Appendix L : ORIGINAL PACKING Label Appendix M : Packaging Appendix N : Schematic Diagram for Production Line Measurement of Leakage Current Appendix O : Schematic Diagram for Production Line Measurement of High Pot Test	J.Takeda	2017/4/18
Rev.1	1.4 Transducer Name 2.2 Element Acoustical / Electrical parameters 3.5 Tuning Coil	J.Takeda	2018/3/30
Rev. 2	1.1 Transducer Part Number 1.5 Transducer ID 4.1b Weight of Transducer 4.7 Connector Housing 6.1 Operating Current Worst Case 6.2 Inrush Current Worst Case Appendix C : Appearance Appendix D : Caution Label A Appendix E : Identification Label Appendix F : Name Label Appendix H : Packaging Label (1) Appendix I : Packaging Label (2) Appendix J : Packaging Label (3)	M.Kadokura	2018/11/26

Transducer Product Specification 9VE4		Doc. No. : P9EV4COM-4	
		Confidential	
Rev.3	2.1 Physical Parameters 2.2 Element Acoustical / Electrical parameters 2.3 Array Acoustical / Electrical Parameters 4.9 Strain Reliefs (Connector side) 4.10 Labels 5.1.4 Motor profile spec and tolerance 5.3 Motor / Housing Zero Position 5.4 Probe Initialization Time 5.5 Motor Output Position Data 7.2 Cleaning/Disinfection/Sterilization 7.3 Safety 7.4 RoHS Directive Appendix C : Appearance Appendix D : Caution Label A Appendix E : Identification Label Appendix G : Caution Label B Appendix H : Packaging Label (1) Appendix I : Packaging Label (2) Appendix J : Packaging Label (3) Appendix K: Temperature Label Appendix L : ORIGINAL PACKING Label Appendix M : Packaging Appendix P : List of Compatible Chemicals	M.Kadokura	2020/2/12
Rev.4	Update 1.1 Transducer Part Number 1.7 Attachments 5.1.4 Motor profile spec and tolerance 5.4 Probe Initialization Time* 5.5 Motor Output Position Data* 6.3 FAST Bus Protocol 6.7 I ² C Timing added 7.2 Cleaning/Disinfection/Sterilization 7.4 RoHS Directive Appendix C : Appearance Appendix D : Caution Label A Appendix E : Identification Label Appendix H : Packaging Label (1) Appendix I : Packaging Label (2) Appendix M : Packaging Appendix P : List of Compatible Chemicals	M.Kadokura	2020/8/7

Confidential

1.0 CLASSIFICATIONS

- | | |
|----------------------------|---|
| 1.1 Transducer Part Number | : Siemens = 11289564 (Rev.02)
: KONICA MINOLTA = AA05 |
| 1.2 Exchange Part Number | : Siemens = N. A. |
| 1.3 Transducer Type | : Curved Array Transducer |
| 1.4 Transducer Name | : 9VE4 |
| 1.5 Transducer ID | : 11289564 (Dec) |
| 1.6 Application | : This transducer is envisioned as a transducer for
endovaginal OB/GYN examinations. |
| 1.7 Attachments | |
| a Biopsy Guide | : Yes – To be provided by Civco in future (Disposable TYPE) |
| b Water Path | : N.A. |
| c Sheath | : Yes – CIVflex or Latex Cover (Outside vender) |

2.0 ACOUSTICAL / ELECTRICAL PARAMETERS

2.1 Physical Parameters

- | | |
|---|---|
| a Array Type | : Curved Array |
| b Number of Elements | : 192 Elements |
| c Element Pitch (at outside of outermost matching layer) | : 0.1382 mm ± 0.005 mm |
| d Element height (normal to scan direction) | : 6 mm ± 0.12 mm |
| e Acoustic Focus (1-way, -3 dB) * | : 21 mm ± 5 mm |
| f Footprint (defined as diameter of window) | : 24.0 mm ± 0.4 mm |
| g Acoustic Radius of Curvature (at outside of outermost matching layer) | : 10.04 mm ± 0.075 mm |
| h Wobble Radius of Curvature (at outside of outermost matching layer) | : 10.04 mm ± 0.075mm |
| i Window Radius of Curvature (measured at the outer side of window) | : Scan direction: 12 ± 0.2 mm
: Sweep direction: 12 ± 0.2 mm |

2.2 Acoustical / Electrical parameters

Conditions: KM new pulser (mode: 30/200 Ω), 2.7 uH tuned
Measurements are average of all elements within the array

- | | | |
|--|----------------------|---|
| a -6 dB Center Frequency | Average | : 5.85 MHz ± 0.59 MHz |
| b -6 dB Low Frequency | Average | : ≤ 3.75 MHz |
| | Standard deviation * | : ≤ 0.12 MHz |
| c -6 dB High Frequency | Average | : ≥ 7.80 MHz |
| d -20 dB Low Frequency | Average | : ≤ 3.20 MHz |
| e -20 dB High Frequency | Average | : ≥ 9.60 MHz |
| f Relative sensitivity (element 4-189) | | |
| Average | | : -3.4 dB ± 2.5 dB |
| Range | | : ≤ 5.6 dB |
| Standard deviation | | : ≤ 1.2 dB |
| Standard deviation (over any 10 adjacent elements) | | : ≤ 1.5 dB |
| g -6 dB Pulse Length | Average | : ≤ 0.28 μs |
| h -20 dB Pulse Length | Average | : ≤ 0.9 μs |
| i -30 dB Pulse Length | Average * | : ≤ 1.4 μs |
| j Time of Flight Variation (Elements 4 to 189) | | : ≤ 100 ns |
| k Acceptance Angle (1-way, -3 dB at fc) * | | : ≥ 22.0 degrees |
| l Crosstalk (over -20 dB FBW) * | | : ≤ -20.0 dB |
| m Multiple Echo Decay Suppression * | | : ≤ -16.0 dB |
| n Allowable dead elements | | : Maximum of 2. Allowed combinations are element 0 only,
191 only, 0&1, 190&191, and 0&191 |

Confidential

*:Not being inspected for all transducers on manufacturing process.

Refer to the transducer test procedures document for definitions and test methodology.

Note: Please drive acoustic elements by bi-polar voltages which uses positive and negative voltages.

3.0 ELECTRICAL SPECIFICATION

3.1 Motor Specification

a Method : Step motor

3.2 Position Detection

a Method
 A, B ch. :Photo Encoder
 Z ch. echo origin : HALL sensor
 A, B, Z , echo origin : TTL level
 A, B ch. : 400 pulse / rev. of each
 Z ch. :1 C/T
 echo origin :1pulse/T

b Encoder Signal

c Number of Encoder Pulse

3.3 Connector

a Manufacturer : TE Connectivity
 b Part Number : TE P/N 2822672-1
 c Total Number of Contact : 456 contacts
 d Contacts Configuration : See Appendix A

3.4 Cable

a Core : AWG42 Shield Cable for I/O and XGS
 & AWG 32 for Motor control

I/O

b Capacitance (at 1 kHz) : 60 pF/m (Nominal)
 c Impedance (at 10 MHz) : 70 Ohms (Nominal)

XGS

d Capacitance (at 1 kHz) : 90 pF/m (nominal)
 e Impedance (at 10 MHz) : 55 Ω (nominal)

3.5 Tuning Coil

: 2.7 μ H \pm 5 % Series

3.6 Circuit Block Diagram

: See Appendix B

4.0. MECHANICAL DESCRIPTION

4.1 Dimension and Weight

a Appearance of Transducer : See Appendix C
 b Weight of Transducer : Approx. 270 g
 (Excluding Cable and Connector)
 : Approx. 1 200 g (Including Cable and Connector)

4.2 Housing (Shaft)

a Material : Polyphenylene-Oxide-based plastics
 NORYL® Grade SE100V
 (SABIC JAPAN LLC)
 b Color : White (SIEMENS Standard Cool Gray 2)

Confidential

4.3 Housing (Grip)

- a Material : Polyphenylene-Oxide-based plastics
 NORYL® Grade SE100V
 (SABIC JAPAN LLC)
- b Color : Gray (SIEMENS Standard Soft Gray)
- c Frequency Identification Color : N.A.
- d Scanning Direction Identification : Scanning start direction identification is marked on
 transducer housing. (See Appendix C)

4.4 Band

- a Material : Fluorosilicone
- b Color : Gray (SIEMENS Standard Cool Gray 9)

4.5 Acoustic Window

- a Material : Polymethyl pentene TPX™
- b Color : Milky White

4.6 Cable

- a Material of Jacket : Polyvinyl chloride
- b Color : White (SIEMENS Standard Cool Gray 2)
- c Length : 2.4 m +0.1 / -0.0 m (Excluding Strain Relief)
- d Diameter : Approx. 8.8 mm

4.7 Connector Housing

- a Material : 380 ALUMINUM ALLOY
- b Color : SIEMENS SIGNAL WHITE
- c Siemens Part Number : 11269133 / 11269134

4.8 Strain Relief (Transducer side)

- a Material : Silicone Rubber Grade KE-961U (Shin-Etsu Chemical)
- b Color : White (SIEMENS Cool Gray2)

4.9 Strain Reliefs (Connector side)

- a Material OUT MOLD : PVC
- INSERT : ALUMINUM 7075-T6
- b Color : SIEMENS Cool Gray 2
- c Siemens Part Number : 11268743

4.10 Labels

- a Caution Label A : See Appendix D
- b Identification Label : See Appendix E
- c Name Label : See Appendix F
- d Caution Label B : See Appendix G
- e Packaging Label (1) : See Appendix H
- f Packaging Label (2) : See Appendix I
- i ORIGINAL PACKING Label : See Appendix L

4.11 Packaging

: See Appendix M
 Reference Siemens documents are Systems, Transducers and Accessories Label Specification and Packaging and Barcode Label Specification.

Confidential

5.0 MECHANICAL WOBBLING SPECIFICATION

5.1 Wobbling Angle and Speed

- 5.1.1 Maximum wobbling angle : 150 degrees
5.1.2 Minimum wobbling angle : 10 degrees
5.1.3 Maximum wobbling speed : 10 volume/s at 150 degrees
: 40 volume/s at 10 degrees

- 5.1.4 Motor profile spec and tolerance : The transducer shall comply with the motor control specifications ads shown in the Motor Profile Table Document No:US0103-V-UP4008D.

5.2 Vibration*

Wobbling Angle	Wobble rate	Acceleration
10 degree	40 Volume/sec	$\leq 2.5 \text{ m/sec}^2$
150 degree	10 Volume/sec	$\leq 2.5 \text{ m/sec}^2$

Maximum acceleration, after ISO 5349 weighting function is applied.

*:Not being inspected for all transducers on manufacturing process.

- 5.3 Motor / Housing Zero Position : +/- 1.0 degree (Adjusted with images on the system)
Notes) Does not include the slice fluctuation of the system image.

- 5.4 Probe Initialization Time* : $\leq 2.5 \text{ sec}$ (From turning on the power of transducer to going to the origin position after simple self-test)

*:Not being inspected for all transducers on manufacturing process.

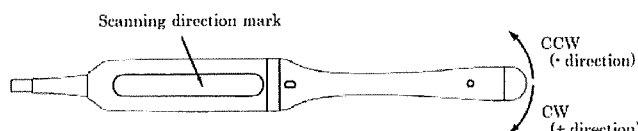
By design, there is no variability in manufacturing for Probe Initialization Time.

- 5.5 Motor Output Position Data* :The motor position must always monotonically increase or decrease except reversal of direction at the two edges.

*:Not being inspected for all transducers on manufacturing process.

By design, there is no variability in manufacturing for Motor Output Position Data.

- 5.6 Wobbling direction : Refer to the figure below for the definition of the wobbling Direction



6.0 MECHANICAL 4D TRANSDUCER INTERFACE

- 6.1 Operating Current Worst Case : P1.85V Supply $\leq 0.3 \text{ A}$ total
: P3.3V Supply $\leq 0.5 \text{ A}$ total

*2.5 V is generated from the 3.3 V power supply.

- : P5V Supply $\leq 0.3 \text{ A}$ total
: P12V Supply $\leq 1.0 \text{ A}$ total

- 6.2 Inrush Current Worst Case : P3.3V Supply $\leq 3.0 \text{ A}$ for 50 msec
: P12V Supply $\leq 1.0 \text{ A}$ for 50 msec

- 6.3 FAST Bus Protocol : Meets the FAST Bus specification in SMS P/N: "10855714-EPH-001-01".
Notes) It does not support multi-command.

Confidential

- 6.4 Position Resolution: : 0.18 degrees
6.5 Position Accuracy : $\leq \pm 0.225$ degrees
6.6 Position Angle unit (degrees) : 0.09 degree at Array

For additional information on wobbler interface and control, refer to KM document number MCB-SPEC-002-HH, "Motor Control Specification (4D Transducer for the Compass/K2 System)"

- 6.7 I²C Timing : Devices with I²C interfaces must have timing and logic margins within specification UM10204 from NXP for Fast Mode devices.
Logic margin V(IL) is 0.4V for bus master.

7.0 MISCELLANEOUS

7.1 Environment

- | | | |
|-----------------------------|-----------|-----------------------|
| a Ambient temperature | Operating | : +20 °C ~ +40 °C |
| | Storage | : - 5 °C ~ +50 °C |
| b Humidity (non-condensing) | Operating | : 10 % ~ 80 % |
| | Storage | : 10 % ~ 90 % |
| c Altitude | Operating | : 700 hPa ~ 1 060 hPa |
| | Storage | : 700 hPa ~ 1 060 hPa |

Caution: Do not use in the high-oxygen environment.

7.2 Cleaning/Disinfection/Sterilization

a Cleaning :

Wash the transducer with water or soapy water and remove dirt, gel.

A soft gauze can be used to wash the transducer. Do not use any hard brush.

And wipe off water on the transducer using soft cloth or gauze after washing. Do not dry the transducer by heated air.

KM shall test the first priority chemicals for user manual release in Appendix P. KM should be able to test additional chemicals after product release with important market needs. The chemical already tested and approved are marked "✓".

b Chemical disinfection:

Transducer has been tested and shown compatible with the disinfectants in Appendix P.

KM shall test the first priority chemicals for user manual release in Appendix P. KM should be able to test additional chemicals after product release with important market needs. The chemical already tested and approved are marked "✓".

c Rinsing:

Wash the transducer with sterile water to remove disinfectant on the transducer.

And wipe off water on the transducer using sterile soft cloth or gauze after rinsing.

Do not dry the transducer by heated air.

d Immersibility : IPX8

Transducer immersibility is from window surface to cable , excluding connector, strain relief of connector part and Caution Label. See Appendix C.

e Sterilization :

This transducer can not be sterilized.

f Acoustic coupling to patient :

Transducer is intended to be coupled to patient using water-based gel e.g., Aquasonic™ .

Caution : Do not use abrasive cleaning agents, organic solvents, or cleaning agents containing organic solvents to disinfection transducer. These substances can damage the transducer.

Confidential

7.3 Safety

- a. Classification of ME Equipment : CLASS II ME EQUIPMENT
- b Leakage Current : $\leq 50 \mu\text{A}$ leakage at 264 V [AC rms] / 60 Hz
See Appendix N
- c Electric Breakdown : No Breakdown to 4 000 V [AC rms] (current limited to 2 mA) for 60 s.
See Appendix O
- d Compliance : FDA 510(k), UL60601-1, IEC60601-1, IEC60601-1-2, CSA C22.2
No.601.1-M90, IEC 61157 and IEC 62359 in conjunction with
Siemens Sequoia/Redwood Ultrasound System.
- e Biocompatibility : ISO 10993-1:2018
- f Acoustic output power : Upper limit is insured by Siemens Sequoia/Redwood Ultrasound System.
The power consumption below 15VA of the transducer is insured by
Siemens Sequoia/Redwood Ultrasound System.
- g Surface Temperature : Upper limit is insured by Siemens Sequoia/Redwood Ultrasound System.

7.4 RoHS/PREP Requirements : This transducer shall comply with the latest requirements of Directive
EU RoHS and Shall comply to Siemens PREP Design Requirements, PN
10044285

Transducer Product Specification 9VE4

Doc. No. : P9EV4COM-4

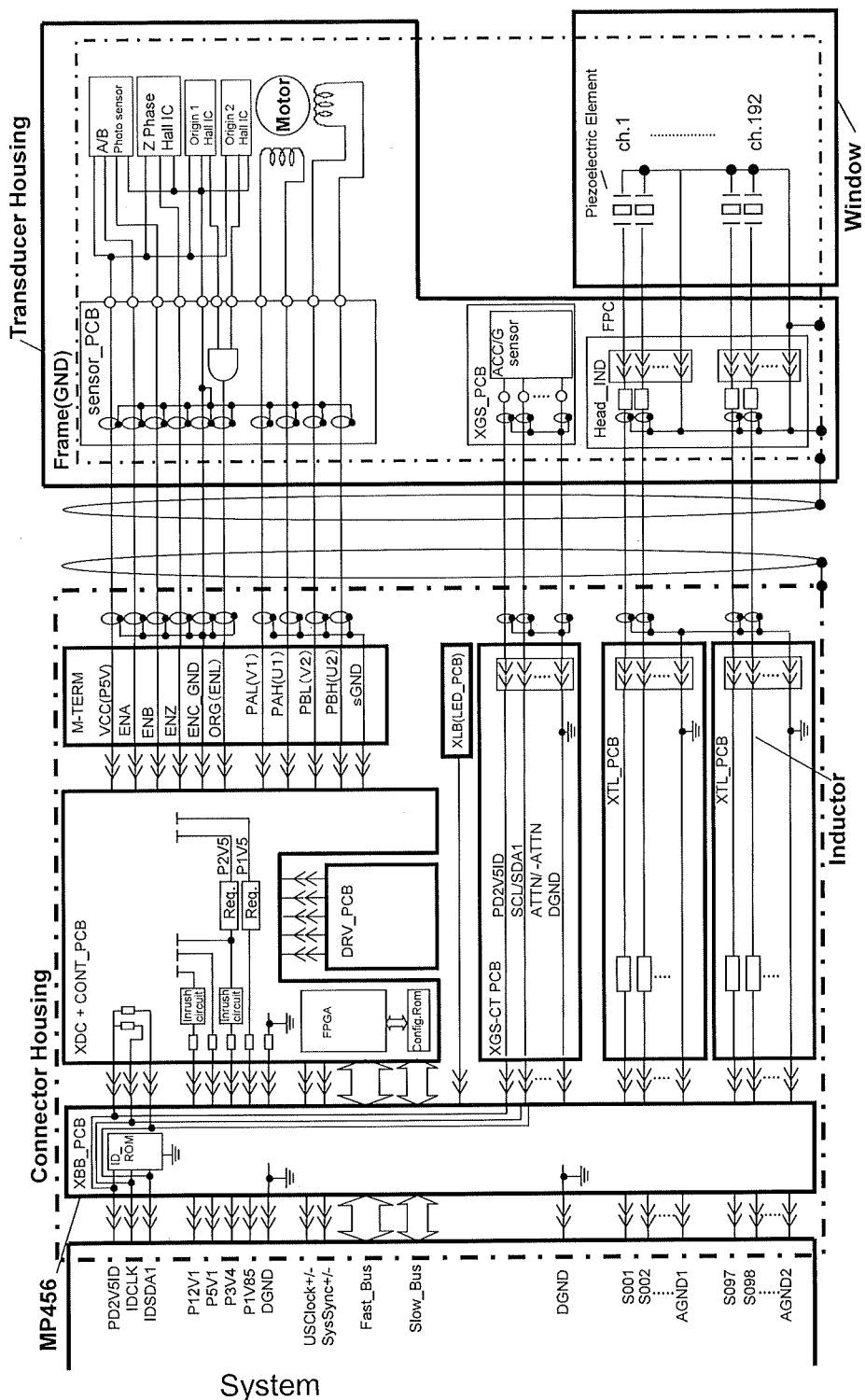
Confidential

MPX456 Pinout with 192-Element Transducer Numbers

	A	B	C	D	E	F	G	H	J	K	L	M
1	Rf Return	Rf Return	Rf Return	Rf Return	GND	GND	GND	GND	Rf Return	Rf Return	Rf Return	Rf Return
2	E023	E047	E071	E095	GND	PORT_N3V 4	PORT_P12 V1	PORT_N12 V1	E119	E143	E167	E191
3	E022	E046	E070	E094	PORT_P3V 4	PORT_N3V 4	PORT_P12 V1	PORT_N12 V1	E118	E142	E166	E190
4	Rf Return	Rf Return	Rf Return	Rf Return	PORT_P3V 4	GND	PORTMOTO RRETURN	PORTMOTO RRETURN	Rf Return	Rf Return	Rf Return	Rf Return
5	E021	E045	E069	E093	PORT_P3V 4	GND	PORTMOTO RRETURN	PORTMOTO RRETURN	E117	E141	E165	E189
6	E020	E044	E068	E092	PORT_P3V 4	SlowBusP rom	Reserved	Reserved	E116	E140	E164	E188
7	Rf Return	Rf Return	Rf Return	Rf Return	PORT_P3V 4	SlowBusP rom	Reserved	Reserved	Rf Return	Rf Return	Rf Return	Rf Return
8	E019	E043	E067	E091	PORT_P3V 4	GND	Reserved	Reserved	E115	E139	E163	E187
9	E018	E042	E066	E090	GND	SlowBusC s	Reserved	Reserved	E114	E138	E162	E186
10	Rf Return	Rf Return	Rf Return	Rf Return	GND	SlowBusC s	GND	GND	Rf Return	Rf Return	Rf Return	Rf Return
11	E017	E041	E065	E089	GND	SlowBusR ead	FastBusF rm	STIM	E113	E137	E161	E185
12	E016	E040	E064	E088	PortTemp +	SlowBusR ead	FastBusF rm	STIM	E112	E136	E160	E184
13	Rf Return	Rf Return	Rf Return	Rf Return	PortTemp +	SlowBusC lk	GND	GND	Rf Return	Rf Return	Rf Return	Rf Return
14	E015	E039	E063	E087	PortTemp -	SlowBusC lk	FastBusC lk	Txcl	E111	E135	E159	E183
15	E014	E038	E062	E086	PortTemp -	SlowBusD ata	FastBusC lk	Txcl	E110	E134	E158	E182
16	Rf Return	Rf Return	Rf Return	Rf Return	GND	SlowBusD ata	GND	GND	Rf Return	Rf Return	Rf Return	Rf Return
17	E013	E037	E061	E085	USClock+	GND	FastBusD t0	FastBusD 4	E109	E133	E157	E181
18	E012	E036	E060	E084	USClock+	SysSync+	FastBusD t0	FastBusD 4	E108	E132	E156	E180
19	Rf Return	Rf Return	Rf Return	Rf Return	USClock-	SysSync+	FastBusD t1	FastBusD 5	Rf Return	Rf Return	Rf Return	Rf Return
20	Rf Return	Rf Return	Rf Return	Rf Return	USClock-	SysSync-	FastBusD t1	FastBusD 5	Rf Return	Rf Return	Rf Return	Rf Return
21	E011	E035	E059	E083	GND	SysSync-	FastBusD t2	FastBusD 6	E107	E131	E155	E179
22	E010	E034	E058	E082	PortTgc+	GND	FastBusD t2	FastBusD 6	E106	E130	E154	E178
23	Rf Return	Rf Return	Rf Return	Rf Return	PortTgc+	PortInt	FastBusD t3	FastBusD 7	Rf Return	Rf Return	Rf Return	Rf Return
24	E009	E033	E057	E081	PortTgc-	PortInt	FastBusD t3	FastBusD 7	E105	E129	E153	E177
25	E008	E032	E056	E080	PortTgc-	/PortRes et	GND	GND	E104	E128	E152	E176
26	Rf Return	Rf Return	Rf Return	Rf Return	GND	/PortRes et	FastBusR ead	Reserved	Rf Return	Rf Return	Rf Return	Rf Return
27	E007	E031	E055	E079	IDAttn	/TxDis	FastBusR ead	Reserved	E103	E127	E151	E175
28	E006	E030	E054	E078	IDAttn	/TxDis	GND	GND	E102	E126	E150	E174
29	Rf Return	Rf Return	Rf Return	Rf Return	IDSDA2	TPSPARE	FastBusA ttn	GND	Rf Return	Rf Return	Rf Return	Rf Return
30	E005	E029	E053	E077	IDSDA2	TPSPARE	FastBusA ttn	PORT_P1V 85	E101	E125	E149	E173
31	E004	E028	E052	E076	GND	GND	GND	PORT_P1V 85	E100	E124	E148	E172
32	Rf Return	Rf Return	Rf Return	Rf Return	IDSCL	GND	GND	PORT_P1V 85	Rf Return	Rf Return	Rf Return	Rf Return
33	E003	E027	E051	E075	IDSCL	PORTHVPO WERP	PORT_P5V 1	PORT_P1V 85	E099	E123	E147	E171
34	E002	E026	E050	E074	IDPower	PORTHVPO WERP	PORT_P5V 1	PORT_P1V 85	E098	E122	E146	E170
35	Rf Return	Rf Return	Rf Return	Rf Return	IDPower	GND	PORT_P5V 1	PORT_P1V 85	Rf Return	Rf Return	Rf Return	Rf Return
36	E001	E025	E049	E073	IDSDA1	PORTHVPO WERN	PORT_P5V 1	GND	E097	E121	E145	E169
37	E000	E024	E048	E072	IDSDA1	PORTHVPO WERN	GND	GND	E096	E120	E144	E168
38	Rf Return	Rf Return	Rf Return	Rf Return	GND	GND	GND	GND	Rf Return	Rf Return	Rf Return	Rf Return

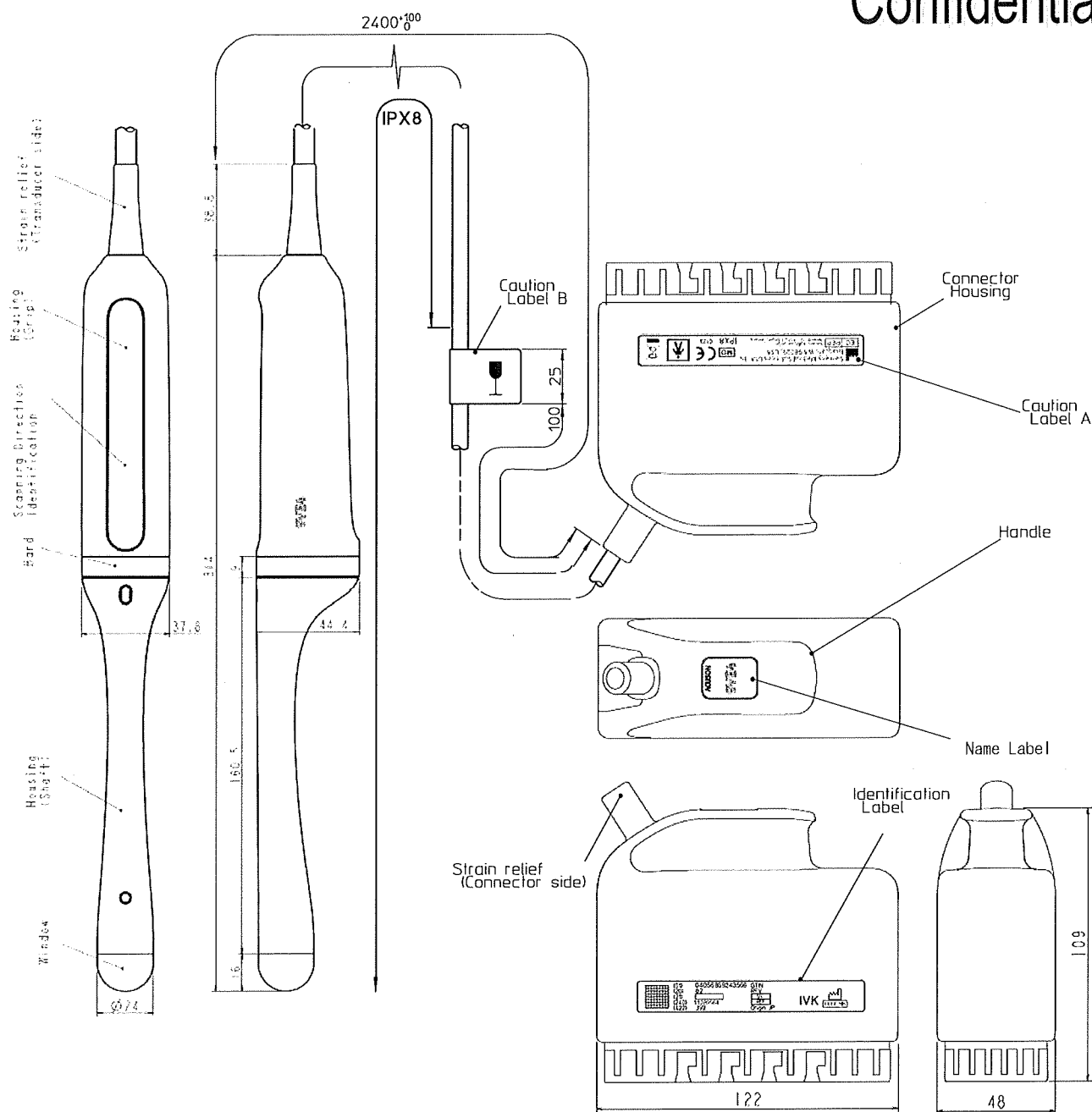
Appendix A : Contacts Configuration

Confidential



Appendix B : Circuit Block Diagram

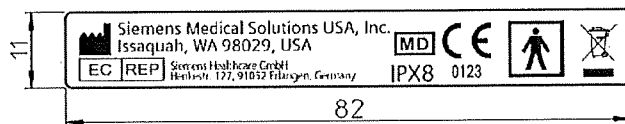
Confidential



[Unit : mm]

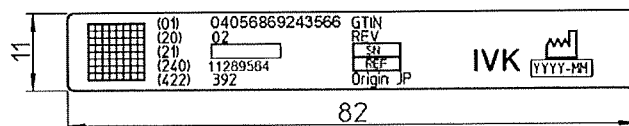
Appendix C : Appearance

Confidential



[Unit : mm]

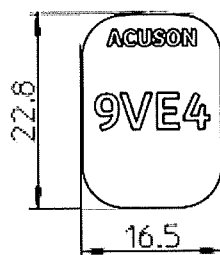
Appendix D : Caution Label A



* Serial header is "BT"

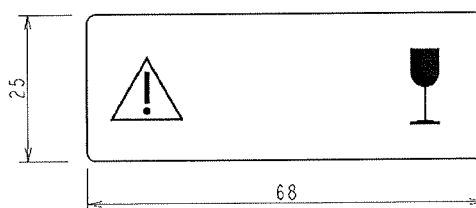
[Unit : mm]

Appendix E : Identification Label



[Unit : mm]

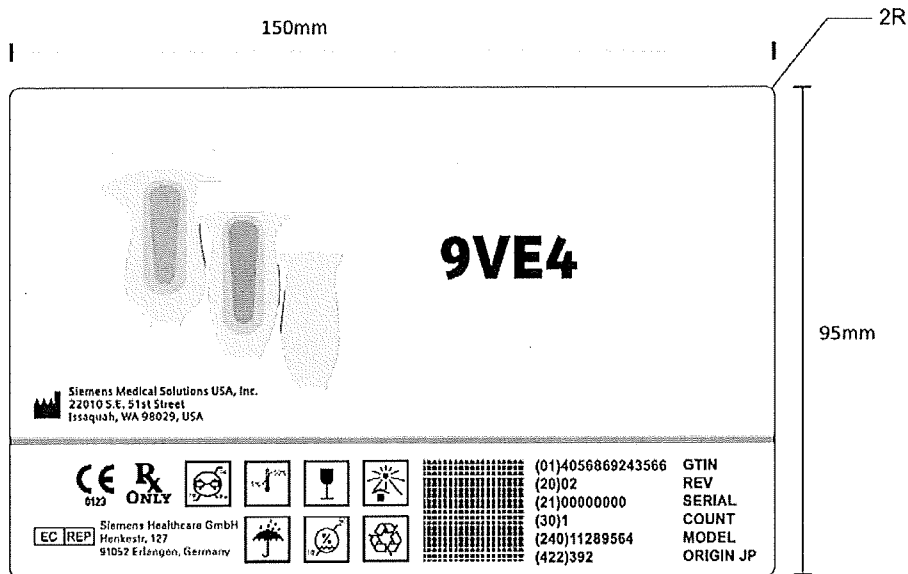
Appendix F : Name Label



[Unit : mm]

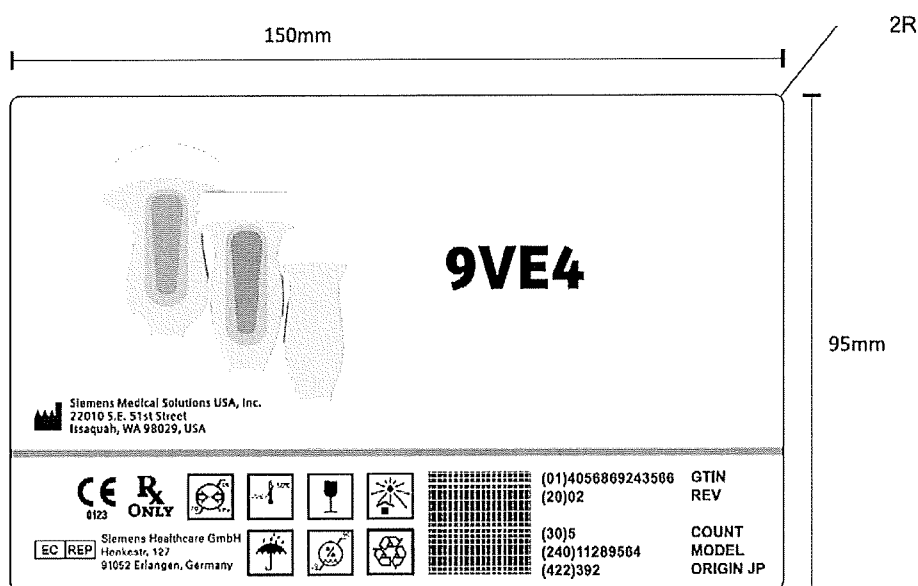
Appendix G : Caution Label B

Confidential



[Unit : mm]

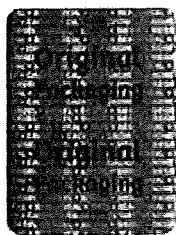
Appendix H : Packaging Label (1)



[Unit : mm]

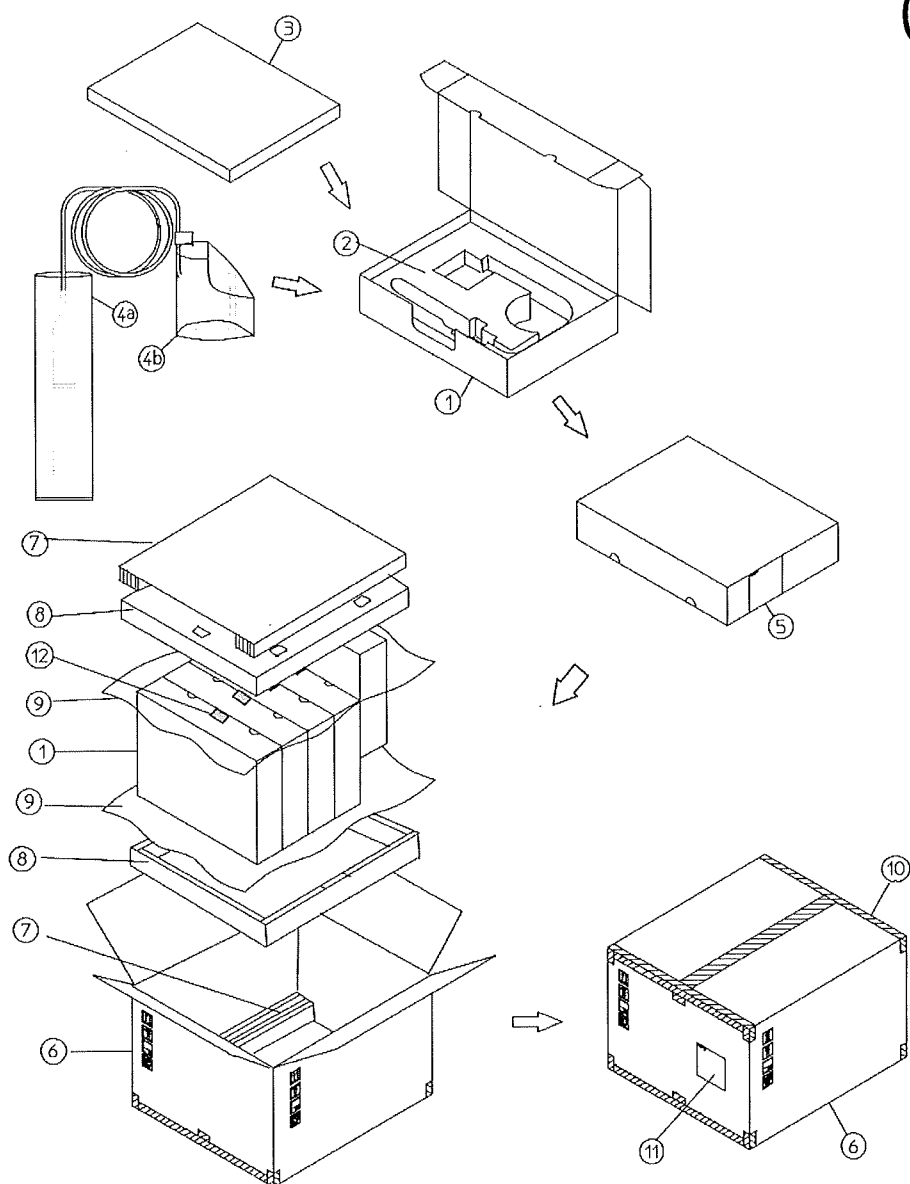
Appendix I : Packaging Label (2)

Confidential



Appendix L : ORIGINAL PACKING Label

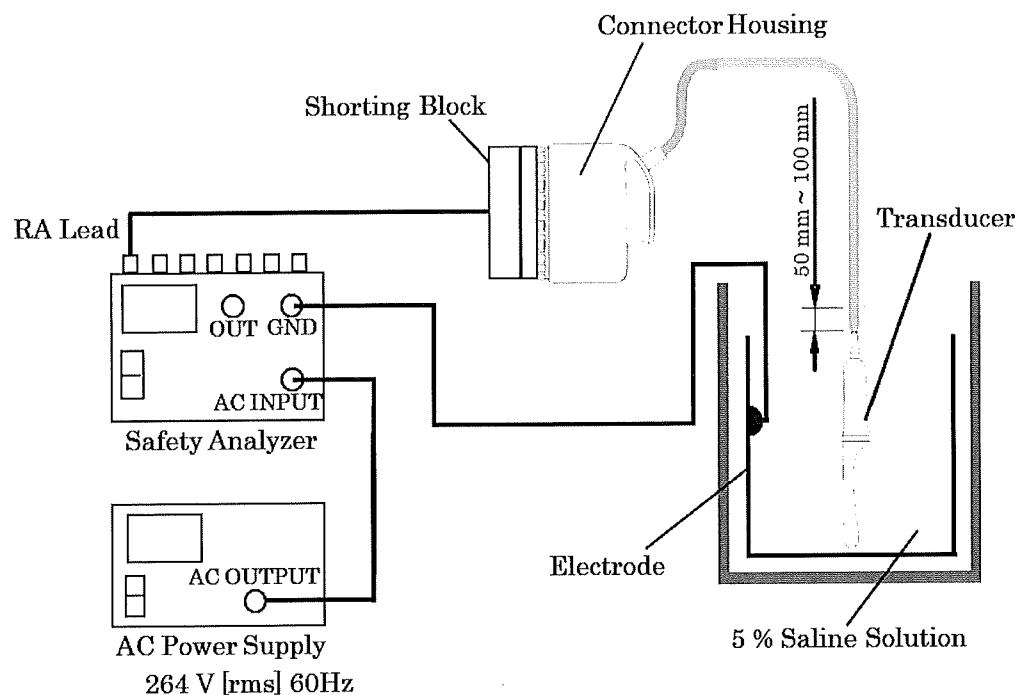
Confidential



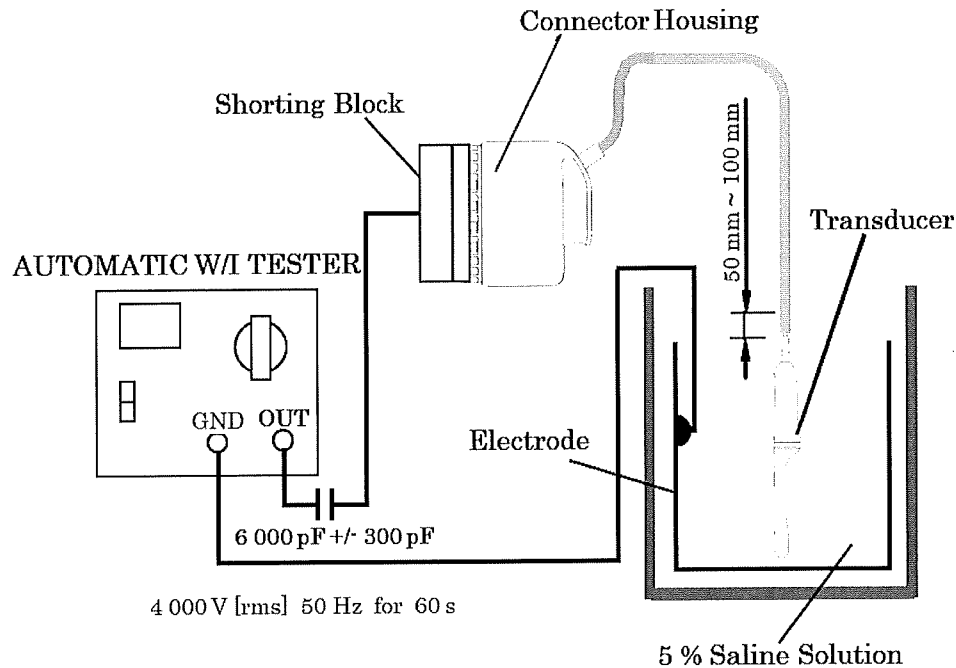
- | | |
|----------------------------|---|
| ① Shipping box | ⑥ Carton box |
| ② Transducer cushion | ⑦ Carton spacer |
| ③ Cushion | ⑧ Carton tray |
| ④a Plastic bag | ⑨ Poly sheet |
| ④b Plastic bag(ANTISTATIC) | ⑩ PP-tape or Sealing adhesive tape (material no.11372500) |
| ⑤ Packaging label (1) | ⑪ Packaging label (2) |
| | ⑫ ORIGINAL PACKING Label (material no.11372504) |

Appendix M : Packaging

Confidential



Appendix N : Schematic Diagram for Production Line Measurement of Leakage Current



Appendix O : Schematic Diagram for Production Line Measurement of High Pot Test

Confidential

Column A	
Priority	List of High Level Disinfectants
2	ANIOXYDE 1000 **
1	✓ CIDEX
1	✓ CIDEX OPA
1	✓ Gigasept FF(new)
2	✓ MetriCide OPA Plus
2	✓ Metricide Plus 30
3	Microcide PA *
3	✓ OPASTER'ANIOS
2	Rapicide PA **
3	Rely+On Perasafe **
1	✓ Revital-Ox RESERT HLD
2	Tristel Trio Wipes System **
2	✓ Trophon

Column B	
Priority	List of Low and Intermediate Level Disinfectants
3	✓ Anios Clean Excel D
3	✓ ANIOSYME X3
3	✓ CaviWipes and CaviCide
2	✓ CLEANISEPT WIPES
3	✓ CLEANISEPT WIPES forte
2	✓ Clinell Universe wipes
2	✓ Clorox Healthcare Bleach Germicidal Cleaner
3	✓ Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant
3	Mikrozyd PAA wipes **
3	✓ Oxivir Tb Wipes
3	✓ Protex Spray and Wipes
2	✓ Protex ULTRA Wipes
1	✓ Sani-Cloth AF3
2	✓ Sani-Cloth Bleach Germicidal Disposable Wipes
1	✓ Sani-Cloth HB
3	Sekusept easy **
3	✓ SONO Ultrasound Wipes
1	✓ Super Sani-cloth
3	✓ SURFA'SAFE Premium
3	✓ WIP'ANIOS Excel

Column C	
Priority	List of Cleaners
1	✓ ENZOL
2	✓ Metrizyme
3	HEXIANOS G+ R **
3	Matrix Wipes *
1	✓ Transeptic

1	First Priority for User Manual Release
2	Next Higher Priority for Testing
3	Tertiary Priority

Compatible of disinfectants and cleaners are tested by the substitutes that contain equal or more active ingredient content.

*) Active ingredient is not known. It cannot be compatible currently.

**) Content of the active ingredient can be not compatible currently.

Appendix P : List of Compatible Chemicals

SAP-EDM Signature Information
- generated automatically by SAP system P41 -

Page 1 of 1

Appendix to Document: 11289564 ASH 001 02 , ECO: 695433

Sheet generated at : 2020-09-04T16:03:28 UTC

Originator : SIEMENS Healthcare, P41

Signatures related to this document and performed in SAP:

Meaning	UTC date and time	surname, given name of signee
AUTHOR	2020-09-04T16:02:00	Culiac, Ruxandra
APPROVAL	2020-09-04T16:02:46	Culiac, Ruxandra