SIEMENS Healthineers

ACUSON ABVS

Safety-Related Tests Report Service

ABVS Electrical Safety Test Report - Forms4Mobile

This document has been redacted. The original document is available upon deposit.

Customer:	[redacted]
Address:	[redacted]
	[redacted]
Fax / E-Mail:	
Fax / E-Mail:	

Department:		**Room:**	
Material-No.:	[redacted]	**Serial-No.:**	[redacted]
Contract-No.:		**Expire date:**	
Order-No.:	[redacted]	**System - ID:**	[redacted]

The instructions US15-101.833.01.01.XX are required for this protocol

Final Evaluation

☐ **Initial Measurement** ☑ **Repeat Measurement**

The evaluation was performed after completing all work steps.

☐ No deficiencies

☑ Slight deficiencies that require corrective measures: These must be recorded under Remarks.

☐ Significant deficiencies: The safety of the system is no longer assured. If these deficiencies are not corrected, there is a **"risk for patients, users or third parties"**.

Signature:

Date: 15-Dec-2017 Tester: [redacted]

If required by country-specific regulations:

The customer or a representative has taken note of the result of the evaluation of the system condition.

Signature:

Date: 15-Dec-2017 Name: [redacted]

Remarks:

Plastic shroud surrounding transducer cracked.

Will schedule for replacement.

Remarks regarding the Protocol

The chapter numbers refer to the chapters in the instruction, which is referenced on the cover page.

All pages have to have the serial number of the system and the date of maintenance in the page header.

The assignment n.a. (not applicable) indicates that the checkpoint or measured value is not used for this system.

On page 2 the completeness and the results of the maintenance work is confirmed.

Explanation of Abbreviations in the Report

Abbrev.	Explanation		Abbrev.	Explanation
SI	Safety Inspection		SIE	Electrical Safety Inspection
SIM	Mechanical Safety Inspection		CSE	Customer Service Engineer

Measuring Equipment and Measuring Instruments Used

Measuring instruments and measuring devices (phantoms, MR coils, etc.) may not be entered in the table if they have already been entered in the mobile device.

Measuring equipment / -instruments	Serial No.	Date Used

OK not OK n.a.

1 General Information

1.1 General Requirements

2 Electrical Checks

2.1 Test Results

2.1.1 Part 1: Visual Inspection

		OK	not OK	n.a.
SIE	Visual inspection of system	☑	☐	☐
SIE	System - safety-relevant damages	☑	☐	☐
SIE	Visual inspection of transducers	☑	☐	☐
SIE	Transducer - safety-relevant damages	☑	☐	☐

2.1.2 Part 2: Protective Ground Continuity Test

2.1.2.1 First Measurement Point

SIE	At the first measurement point the protective ground continuity wire has to be <200 mΩ	☑	☐	☐

Measured value: 0.112 ohms

2.1.2.2 Second Measurement Point

SIE	At the second measurement point the protective ground continuity wire has to be <200 mΩ	☑	☐	☐

Measured value: 0.160 ohms

2.1.2.3 Third Measurement Point

SIE	At the third measurement point the protective ground continuity wire has to be <200 mΩ	☑	☐	☐

Measured value: 0.118 ohms

2.1.3 Part 3: Alternative Equipment Leakage Test

SIE	Alternative equipment leakage current, the maximum Main PE Leakage is <600 µA.	☑	☐	☐

Measured value: 218 uA

2.1.4 Part 4: ECG Leakage Current Test

2.1.5 Part 5: Transducers

2.1.5.1 Transducer 1

Description:	14L5BV
Material No.:	10041852
Serial No.:	53734005

		OK	not OK	n.a.
SIE	Maximum leakage 50 µA	☑	☐	☐

Measured value: ok

2.1.6 Part 6: Functional Test

SIE	ACUSON ABVS boots up and the ACUSON ABVS POD Assembly operates properly.	☑	☐	☐

3 Changes to Previous Version

3.1 Changes to Previous Version

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ACUSON / SONOLINE

Maintenance Protocol System

Maintenance Protocol

Customer:	[redacted]
Address:	[redacted]
	[redacted]
Fax / E-Mail:	
Fax / E-Mail:	

Department:		**Room:**	
Material-No.:	10041461	**Serial-No.:**	[redacted]
Contract-No.:		**Expire date:**	
Order-No.:	400301237094_0001	**System - ID:**	[redacted]

This document is valid for all products listed in the Maintenance Instructions US00-000.831.01.XX.02
The instructions US00-000.831.01.18.XX are required for this protocol

Evaluating the Condition of the System

The system has no deficiencies. *	☐
The system has slight deficiencies that have no effect on continued operation of the system. The deficiencies should be corrected preventively. *	☑
The system has serious deficiencies. For safety reasons, continued operation of the system is permitted only after successfully correcting the deficiencies.	☐

*) For imaging systems: The result of the image quality check shows no deviation from the reference values.

The evaluation was performed after completing all work steps.

Signature:

Date: 15-Dec-2017 Name: [redacted]

If required by country-specific regulations:

The customer or a representative has taken note of the result of the evaluation of the system condition.

Signature:

Date: 15-Dec-2017 Name: [redacted]

Remarks:

Cracked plastic shroud surrounding ABVS transducer.

Will schedule to replace.

Remarks Regarding the Protocol

The chapter numbers refer to the chapters in the instruction, which is referenced on the cover page.

All pages have to have the serial number of the system and the date of maintenance in the page header.

The assignment n.a. (not applicable) indicates that the checkpoint or measured value is not used for this system.

On page 2 the completeness and the results of the maintenance work is confirmed.

Explanation of Abbreviations in the Protocol

Abbrev.	Explanation		Abbrev.	Explanation
SI	Safety Inspection		PMF	Preventive Maintenance, Operating Value Check, Function Check
SIE	Electrical Safety Inspection		Q	System Quality, Image Quality
SIM	Mechanical Safety Inspection		QIQ	Image Quality
PM	Preventive Maintenance		QSQ	System Quality Check
PMP	Periodic Preventive Maintenance		SW	Software Maintenance
PMA	Preventive Maintenance Adjustments		CSE	Customer Service Engineer

Measuring Equipment and Measuring Instruments Used

Measuring instruments and measuring devices (phantoms, MR coils, etc.) may not be entered in the table if they have already been entered in the mobile device.

Measuring equipment / -instruments	Serial No.	Date used

1 Planned Maintenance

1.1 Affected Systems

1.2 Introduction

1.3 Required Tools, Materials, and Documents

1.4 Preparations

		OK	not OK	n.a.
PM	Discuss Customer Concerns	☑	☐	☐
PM	Maintain the Patient Database	☑	☐	☐
PM	Perform Disk Maintenance	☐	☐	☑

1.5 Performing Maintenance

PM	System History Analysis	☑	☐	☐
PM	Perform System Diagnostics Checks	☑	☐	☐
PM	Perform System Calibration (where applicable)	☐	☐	☑
PM	Clean the System	☑	☐	☐
PM	Clean and Inspect Transducers	☑	☐	☐
PM	Clean Air Filters	☑	☐	☐
PM	Clean the Trackball	☑	☐	☐
PM	Check Monitor / Flat Panel Display (FPD)	☑	☐	☐
PM	Perform Monitor Optimization Procedure	☐	☐	☑
PM	Check Movement of User Controls	☑	☐	☐
PM	Check Mechanical Operation	☑	☐	☐

Maintenance of this section was performed by:

Signature: _____

Date: Name:

1.6 Safety Checks

SI	Check Wheels and Wheel Locks	☑	☐	☐
SI	Check Cooling Fans	☑	☐	☐
SI	Check the Power Cable	☑	☐	☐
SI	Check Electrical Safety	☑	☐	☐

1.7 General System Maintenance

PM	Check Modules and Cables	☑	☐	☐

		OK	not OK	n.a.
PM	Check Mandatory/Non-Mandatory System Modifications	☑	☐	☐

1.8 Functional System Check

QSQ	Check the System	☑	☐	☐
QSQ	Check Image Quality and Transducers	☑	☐	☐
QSQ	Check Air Filter	☑	☐	☐

1.9 Network Setup Check

PMF	Verify Network Settings (if applicable)	☑	☐	☐

1.10 Peripheral Devices Check

QSQ	B/W and Color Video Printers	☐	☐	☑
QSQ	VCR and/or DVR	☐	☐	☑

1.11 Concluding the Maintenance

PM	Check System / Preset Data (Backup)	☑	☐	☐
PM	Concluding the Maintenance	☑	☐	☐

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SIEMENS Healthineers

ACUSON S Family

Maintenance Protocol Service

S Family Maintenance Protocol

Customer:	[redacted]
Address:	[redacted]
	[redacted]
Fax / E-Mail:	
Fax / E-Mail:	

Department:		**Room:**	
Material-No.:	10041461	**Serial-No.:**	[redacted]
Contract-No.:		**Expire date:**	
Order-No.:	400301237094_0001	**System - ID:**	[redacted]

The instructions US15-102.831.01.05.XX are required for this protocol

Evaluating the Condition of the System

The system has no deficiencies. *	☐
The system has slight deficiencies that have no effect on continued operation of the system. The deficiencies should be corrected preventively. *	☑
The system has serious deficiencies. For safety reasons, continued operation of the system is permitted only after successfully correcting the deficiencies.	☐

*) For imaging systems: The result of the image quality check shows no deviation from the reference values.

The evaluation was performed after completing all work steps.

Signature:

Date: 15-Dec-2017 Name: [redacted]

If required by country-specific regulations:

The customer or a representative has taken note of the result of the evaluation of the system condition.

Signature:

Date: 15-Dec-2017 Name: [redacted]

Remarks:

Plastic shroud surrounding ABVS transducer cracked.

Will schedule to replace.

Remarks Regarding the Protocol

The chapter numbers refer to the chapters in the instruction, which is referenced on the cover page.

All pages have to have the serial number of the system and the date of maintenance in the page header.

The assignment n.a. (not applicable) indicates that the checkpoint or measured value is not used for this system.

On page 2 the completeness and the results of the maintenance work is confirmed.

Explanation of Abbreviations in the Protocol

Abbrev.	Explanation		Abbrev.	Explanation
SI	Safety Inspection		PMF	Preventive Maintenance, Operating Value Check, Function Check
SIE	Electrical Safety Inspection		Q	System Quality, Image Quality
SIM	Mechanical Safety Inspection		QIQ	Image Quality
PM	Preventive Maintenance		QSQ	System Quality Check
PMP	Periodic Preventive Maintenance		SW	Software Maintenance
PMA	Preventive Maintenance Adjustments		CSE	Customer Service Engineer

Measuring Equipment and Measuring Instruments Used

Measuring instruments and measuring devices (phantoms, MR coils, etc.) may not be entered in the table if they have already been entered in the mobile device.

Measuring equipment / -instruments	Serial No.	Date used

1 S Family Planned Maintenance

		OK	not OK	n.a.

1.3 Evaluating the System Condition

QSQ	Discuss Customer Concerns	☑	☐	☐

1.4 System Tests and Diagnostics

PMF	System History Analysis	☑	☐	☐
PM	Perform System Diagnostics Checks	☑	☐	☐
PM	Perform Monitor Optimization	☐	☐	☑

1.5 Safety Inspection

SIM	Inspect Wheels and Braking System	☑	☐	☐
SI	Inspect Rear Card Cage Cover	☑	☐	☐
SIE	Perform Electrical Safety Tests on System and Transducers	☑	☐	☐
SIE	[For ACUSON S2000 ABVS Only] Perform Electrical Safety Test on S2000 ABVS	☑	☐	☐
SIM	Test Cooling Fans	☑	☐	☐

1.6 Inspect and Clean the System

PM	Clean the Flat Panel Display (FPD)	☑	☐	☐
PM	Clean and Inspect the Control Panel and Trackball	☑	☐	☐
PM	Clean and Inspect the Air Filters	☑	☐	☐
PM	Clean and Inspect System Covers	☑	☐	☐
PM	Clean and Inspect OEM Peripheral Devices	☐	☐	☑
PM	Clean and Inspect Transducer Holders	☑	☐	☐
PM	[For ACUSON S2000 ABVS Only] Clean and Inspect the ABVS POD	☑	☐	☐

1.7 Inspect System Mechanical Operation

PM	Inspect Flat Panel Display (FPD)	☑	☐	☐
PM	Inspect Control Panel Movement	☑	☐	☐
SI	[For ACUSON S2000 ABVS only] Permanent Mounting Fixtures	☑	☐	☐
SI	[For ACUSON S2000 ABVS only] Mechanical Operation	☑	☐	☐
PMF	[For ACUSON S2000 ABVS Only] Calibrate the ABVS LCD	☐	☐	☑

1.8 Final Functional System Inspection

QSQ	Verify System Functionality	☑	☐	☐
QSQ	Verify Standby Functionality	☑	☐	☐
QSQ	Inspect Image Quality and Transducers	☑	☐	☐
PMF	Verify Network Settings (if applicable)	☑	☐	☐

		OK	not OK	n.a.
PMF	Verify SRS Connection (if applicable)	☐	☐	☑

1.9 Peripheral Devices Inspection

QSQ	Inspect BW or Color Printers	☐	☐	☑
QSQ	Inspect DVR	☐	☐	☑

1.10 Concluding the Maintenance

PM	Check System / Preset Data (Backup)	☑	☐	☐
PM	Concluding the Maintenance	☑	☐	☐

1.11 Documentation Requirements

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ACUSON S Family

Safety-Related Tests Report System

Electrical Safety Test Report - Forms4Mobile

Customer:	[redacted]
Address:	[redacted]
	[redacted]
Fax / E-Mail:	
Fax / E-Mail:	

Department:		**Room:**	
Material-No.:	10041461	**Serial-No.:**	[redacted]
Contract-No.:		**Expire date:**	
Order-No.:	400301237094_0001	**System - ID:**	[redacted]

The instructions US22-101.833.01.01.XX are required for this protocol

Final Evaluation

☐ **Initial Measurement** ☑ **Repeat Measurement**

The evaluation was performed after completing all work steps.

☐ No deficiencies

☑ Slight deficiencies that require corrective measures: These must be recorded under Remarks.

☐ Significant deficiencies: The safety of the system is no longer assured. If these deficiencies are not corrected, there is a **"risk for patients, users or third parties"**.

Signature:

Date: 15-Dec-2017 Tester: [redacted]

If required by country-specific regulations:

The customer or a representative has taken note of the result of the evaluation of the system condition.

Signature:

Date: 15-Dec-2017 Name: [redacted]

Remarks:

Plastic shroud surrounding ABVS transducer cracked.

Will follow up. Otherwise, system checkout satisfactory.

Remarks regarding the Protocol

The chapter numbers refer to the chapters in the instruction, which is referenced on the cover page.

All pages have to have the serial number of the system and the date of maintenance in the page header.

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SIM	Mechanical Safety Inspection		CSE	Customer Service Engineer

Measuring Equipment and Measuring Instruments Used

Measuring instruments and measuring devices (phantoms, MR coils, etc.) may not be entered in the table if they have already been entered in the mobile device.

Measuring equipment / -instruments	Serial No.	Date Used

OK | not OK | n.a.

1 General Information

1.1 General Requirements

2 Electrical Checks

2.1 Test Results

2.1.1 Part 1: Visual Inspection

		OK	not OK	n.a.
SIE	Visual inspection of system	☑	☐	☐
SIE	System - safety-relevant damages	☑	☐	☐
SIE	Visual inspection of transducers	☑	☐	☐
SIE	Transducer - safety-relevant damages	☑	☐	☐

2.1.2 Part 2: Protective Ground Continuity Test

2.1.2.1 First Measurement Point

SIE	At the first measurement point the protective ground continuity wire has to be <200 mΩ	☑	☐	☐

Measured value: 0.067 ohms

2.1.2.2 Second Measurement Point

SIE	At the second measurement point the protective ground continuity wire has to be <200 mΩ	☑	☐	☐

Measured value: 0.079 ohms

2.1.2.3 Third Measurement Point

SIE	At the third measurement point the protective ground continuity wire has to be <200 mΩ	☑	☐	☐

Measured value: 0.164 ohms

2.1.2.4 Fourth Measurement Point

SIE	At the fourth measurement point the protective ground continuity wire has to be <200 mΩ	☑	☐	☐

Measured value: 0.079 ohms

2.1.3 Part 3: Alternative Equipment Leakage Test

SIE	Alternative equipment leakage current, the maximum Main PE Leakage is <400 µA.	☑	☐	☐

Measured value: 125 uA

2.1.4 Part 4: ECG Leakage Current Test

SIE	ECG leakage current does not exceed 10 µA.	☐	☐	☑

Measured value: NA

OK | not OK | n.a.

2.1.5 Part 5: Transducers

2.1.5.1 Transducer 1

Description:	14L5
Material No.:	10789396
Serial No.:	53428012

SIE Maximum leakage 50 µA ☑ ☐ ☐

Measured value: 1.5 uA

2.1.5.2 Transducer 2

Description:	18L6
Material No.:	10789400
Serial No.:	60502036

SIE Maximum leakage 50 µA ☑ ☐ ☐

Measured value: 219 uA

2.1.5.3 Transducer 3

Description:	9L4
Material No.:	10789393
Serial No.:	53531043

SI Maximum leakage 50 µA ☑ ☐ ☐

Measured value: 6.6 uA

2.1.5.4 Transducer 4

Description:	
Material No.:	
Serial No.:	

SIE Maximum leakage 50 µA ☐ ☐ ☑

Measured value: NA

OK not OK n.a.

2.1.5.5 Transducer 5

Description:	
Material No.:	
Serial No.:	

SI Maximum leakage 50 µA ☐ ☐ ☑

Measured value: NA

2.1.5.6 Transducer 6

Description:	
Material No.:	
Serial No.:	

SIE Maximum leakage 50 µA ☐ ☐ ☑

Measured value: NA

2.1.5.7 Transducer 7

Description:	
Material No.:	
Serial No.:	

SIE Maximum leakage 50 µA ☐ ☐ ☑

Measured value: NA

2.1.5.8 Transducer 8

Description:	
Material No.:	
Serial No.:	

SIE Maximum leakage 50 µA ☐ ☐ ☑

Measured value: NA

OK | not OK | n.a.

2.1.5.9 TEE Transducer 1

Description:	
Material No.:	
Serial No.:	

SIE Maximum leakage 300 µA ☐ ☐ ☑

Measured value: NA

2.1.5.10 TEE Transducer 2

Description:	
Material No.:	
Serial No.:	

SIE Maximum leakage 300 µA ☐ ☐ ☑

Measured value: NA

2.1.5.11 TEE Transducer 3

Description:	
Material No.:	
Serial No.:	

SIE Maximum leakage 300 µA ☐ ☐ ☑

Measured value: NA

2.1.6 Part 6: Functional Test

SIE System boots to imaging and generates a normal B-mode image ☑ ☐ ☐

3 Changes to Previous Version

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