STÖRZ MEDICAL

V V T - Validation, Verification and Testing

SAMSUNG HS30

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Abbreviation

None

Definitions

None

References

/Ref_01/	DRE_PE_aea01-054_01_02	General requirements for usage of US devices in combination with Storz Medical shock wave devices. Revision 3.0

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1   General

The new ultrasound device SAMSUNG HS30 is used with STORZ MEDICAL lithotripters. Therefore, a special ultrasound probe for inline use and a software for crosshair display was developed by Samsung. The aim of this test is to prove that the generation of the crosshairs used for targeting the shock waves by the so called StorM Link data link is correct and not interrupted when using a RS232 to USB converter with a fibre optic cable for isolation.

Figure 1: SAMSUNG HS30

2   Device Data

2.1   Shock wave device or StorM-Link adapter/ILCU

a)   Model   MODULITH SLK (1L)
b)   Serial number   1L.1200_____
c)   Protection Class   I_____

	No test	Pass	Fail

2.2 Ultrasound device

a) Manufacturer   SAMSUNG

b) Model   HS30

c) Serial number   S1F0M3HM900031H

d) Version number of ultrasound device software 1.01.00 Build Date: 2019-11-13

e) CE marking at device   ☐ ☒ ☐

f) Notified body   n/a Prototype

g) Certificate of Conformity (existence of copy, apparent correctness)   ☐ ☒ ☐

h) Operating manual addendum describing the StorM link specific features and connectors (existence of copy, apparent correctness)   ☒ ☐ ☐

i) Service manual addendum describing the StorM link specific calibration and service actions (existence of copy, apparent correctness)   ☒ ☐ ☐

2.3 Ultrasound probe

j) Manufacturer   SAMSUNG

k) Name

l) Serial number

2.4 Adapter USB > Serial

m) Manufacturer   DELOCK

n) Model   Adapter USB 2.0 > 1 x Serial

o) Order number   29285

p) Chip set   FDTI

2.5 RS 232 LWL Cable

q) Manufacturer   W&T

r) Model   Interface KunststoffLWL<> RS232

s) Order number   26358

2.6 Inline Unit

t) Manufacturer   Storz Medical AG

u) Model   inline snap-in slk Samsung HS-30

v) Order number   29161

w) Serial number   0003

3   Assembly

3.1   Used material

- 2x 5088:   Cable clip: 2x item number: 5088
- 10033 (60mm): Velcro fastener: 6cm item number: 10033
- 30178:   Fiber optical converter cable 70cm (needs to be shortened to 60cm)
- 29285:   Adapter USB -> Serial

3.2   Procedure

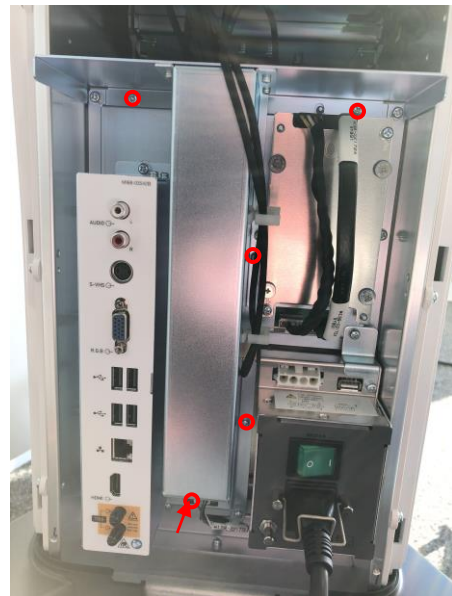Figure 1: USB Port for connection with RS232 adapter cable

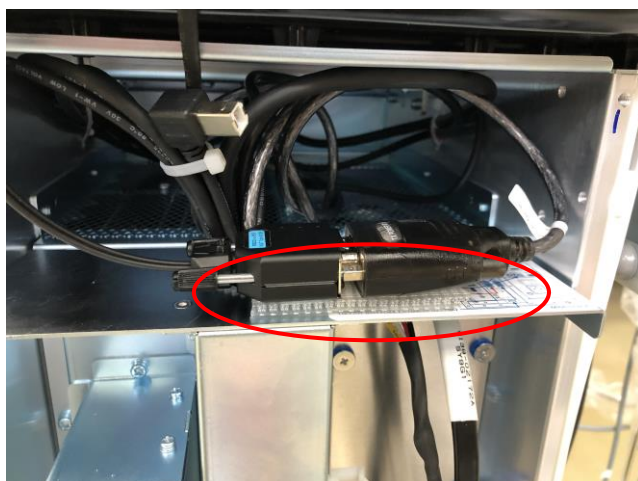Figure 2: cover fixed with 5 screws

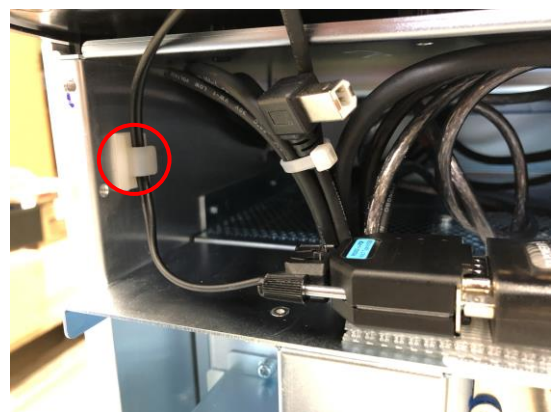Figure 3: RS232 Adapter to fiber optical converter fixed with a velcro fastener

Figure 4: cable clip inside

Figure 5: cable clip outside

Figure 6: fiber optic converter to StormLink cable fixed with a cable clamp

4 Practical Test

Connect the ultrasound device to the lithotripter and place it in proximity of the shockwave source. During the release of the shockwaves no time out error should be displayed or no other incorrect behaviour of the device should be observed. The shockwave should be released at the highest energy level. A treatment was performed with 4000 shocks on highest energy level. Storm Link and transducer cable are tight together in parallel to simulate highest interference-prone.

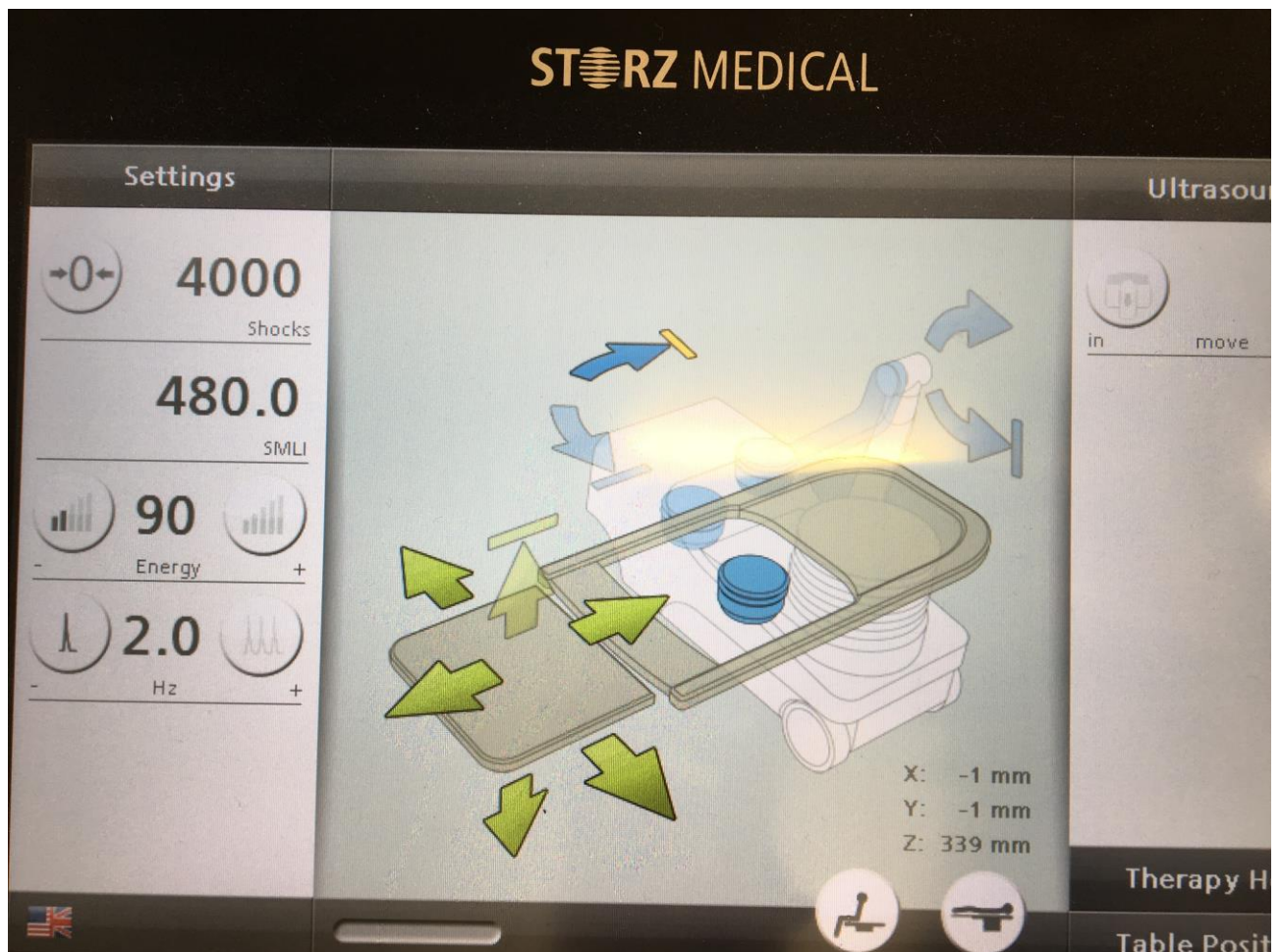|		No test	Pass	Fail
a)	No error message displayed on the US-device	☐	☒	☐
b)	No uncommon behaviour observed on the US-device	☐	☒	☐
c)	Crosshairs change position when probe is driven up or down	☐	☒	☐

Figure 7: total number of shockwaves

5 Conclusion

☒ The adapter of the above stated manufacturer can be combined with the ultrasound device SAMSUNG HS30 and the STORZ MEDICAL shock wave device used for lithotripsy. No interferences or communication breakdown was observed during the testing.

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