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Comments to JAMA presentation GTR9-7-06c and Proposed Changes, Flex PLI GTR Manual

IG GTR9-PH2 8TH MEETING

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Content

- Review of JAMA comments GTR9-7-06c
- Proposal further additions/changes to manual

Comment to sheet 1

The result of manual review of FlexPLI

NO.	Item number	Page	Comment
1	1.2 Tools Required	12～14	Please consider disclosing specialized maintenance tools for drawing.
2		-	Is the statement of the name of the maker to a manual permitted? Humanetics,DTS,M-BUS,Kyowa,etc….
3	7.6 Data Processing	91	The display method of each rated value of a ligament corridor is not unified.

setting tool drawings have now been supplied but should these be regulated?

We agree this could be a problem should DAS section be removed and put in none regulated document?

GTR Pendulum Dynamic Calibration Results	Peak Moment @ Tibia Gage 1	Peak Moment @ Tibia Gage 2	Peak Moment @ Tibia Gage 3	Peak Moment @ Tibia Gage 4	Peak ACL Elongation	Peak PCL Elongation	Peak MCL Elongation
Unit	Nm				mm		
Upper	272	219	166	111	10.5	5	24
Lower	235	187	139	90	8	3.5	20.5

Agreed

All values should have 1 decimal place as well?

10.5 5.0 24.0
8.0 3.5 20.5

Comment to Sheet 2

<table>
<tr><td>4</td><td>8.7 Data Processing</td><td>96</td><td>The display method of each rated value of a ligament corridor is not unified.
<table><tr><th>GTR Inverse Dynamic Calibration Results</th><th>Peak Moment @ Tibia Gauge 1</th><th>Peak Moment @ Tibia Gauge 2</th><th>Peak Moment @ Tibia Gauge 3</th><th>Peak Moment @ Tibia Gauge 4</th><th>Peak ACL Elongation</th><th>Peak PCL Elongation</th><th>Peak MCL Elongation</th></tr><tr><td>Units</td><td colspan="4">Nm</td><td colspan="3">mm</td></tr><tr><td>Upper</td><td>272</td><td>252</td><td>192</td><td>108</td><td>10.0</td><td>6</td><td>21</td></tr><tr><td>Lower</td><td>230</td><td>210</td><td>166</td><td>93</td><td>8.0</td><td>4</td><td>17</td></tr></table>All values should have 1 dec place as well?
10.0 6.0 21.0
8.0 4.0 17.0
Agreed</td></tr>
<tr><td>5</td><td>2.1 Standard 12 Channel instrumentation</td><td>15</td><td>Both ACL and PCL(s) which are indicated in Table 2 are not Monitoring but Injury Assesment.
Agreed</td></tr>
<tr><td>6</td><td>3.1 Femur Exploded View</td><td>48,49</td><td rowspan="2">133-5516 The collar which fixes END COVER has escaped from the block diagram and the table.
This part is molded into 133-5516 so no need to show</td></tr>
<tr><td>7</td><td>3.3 Tibia Exploded View</td><td>61,62</td></tr>
</table>

Comments to Sheet 3

8	2.3.2 Signal Polarity, Sensor function check	25	In the examination of Fig. 16, the output of ACL and PCL is minus in the state of the place where a bend angle in the knees is small. Therefore, you should make a judgment of the output signal of ACL and PCL in the state where a bend angle in the knees is to some extent large. Therefore, for performing the output judging of ACL and PCL, it is necessary to enlarge a knee bend angle to some extent. Refer to the separate attachment diagram.
9	Figure 85	81	The unit of the horizontal axis of the graph of Fig. 85 is not mm but N.

Suggest we add note - "For low bending angles ACL and PCL outputs will be negative when manipulated manually. In the diagram below (fig 16) they are shown as positive. To obtain a positive signal the bend angle would have to be more significant.

Agreed

Further Changes Proposed

- In the overview 1.1 we would like to add a short description of the main components and DAS options. We would also like to add a brief structure of the manual
- In section 1.2 we would like to add an overview list of screw torques with pictures and a list of abbreviations like BHCS, Button Head Cap Screw. We would also like to add a list of recommended spares.
- In section 3 we would like to start with disassembly rather than assembly as this seems more logical for users.
- Propose we change Section 3 to:-
- 3.1 Introduction
- 3.2 Leg disassembly and assembly
- 3.3 Femur disassembly and assembly
- 3.4 Knee disassembly and assembly
- 3.5 Tibia disassembly and assembly
- 3.6 Flesh assembly and disassembly
- This will include some new pictures

Further Changes Proposed

- Before table 10 in section 5 - Weight Specification add note:- The Flex-PLI assembly mass and tolerances are given in table 10. For dynamic certification tests, pendulum and inverse, as well as regulatory vehicle tests, the leg must comply to the given limits.
- Add a table showing regulation dimensions
- Table 11 sensor weight. we propose we remove this table, not relevant
- Add note in introduction in pendulum and inverse that leg should be certified with it's on board DAS

Thank You