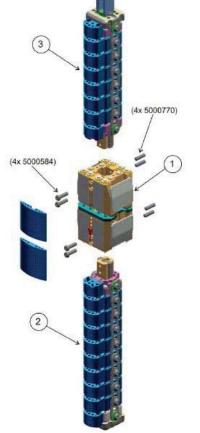
# Flex PLI GTR meeting actions

Informal Group GTR9 PH2









28-29 March 2012 Mark Burleigh

### Content (Actions from Last meeting)

- Legs manufactured, build level
- ► Change control/record documentation
- ► CFC 180 to 600 comparison
- ► Access to front leg attachment screws
- ► Update to manual status



### Legs Manufactured

- ► 3 prototypes (SN01, SN02, SN03)
- ► 3 internal legs (SN04, SN05, eng leg)
- ► 24 legs sold
- ► See appendix A for individual leg build details
- ► Build status cannot be controlled by Humanetics after delivery unless notified e.g. replacement bone



### Build Phases

Date	Phase	Changes
5/12/2008	Prototype	
12/02/2010	Phase 2	<ul> <li>Connector blocks removed to allow 24 DAS on-board channels</li> </ul>
		String pots made into separate units
		Rubber flesh extended down 146 mm
		Extra Velcro tie added
		<ul> <li>Bone PCBs now shrink wrapped and ribbon wire used for gage connection to PCB</li> </ul>
		Groove in bone spacer deepened to 7.5 mm to clear PCB
		Outer Neoprene skin widened by 15 mm to help fit
		• Segment impactors hole tolerance changed from 10.7 to 10.5 dia
		Bonded end bone buffer in end segments to ensure correct position
25/06/2010	Phase 3	All previous changes
		<ul> <li>Strain gage glue changed to similar 2 part epoxy high strain glue</li> </ul>
		<ul> <li>Pendulum test now with flesh fitted stopper bock removed from rig</li> </ul>
		• MCL and LCL string pot bushes made 1 mm longer, knee tibia block also modified 1
		mm deeper to suit
		• Sub assembly calibration loading changed from 325 to 400 Nm
		• Stopper cable clearance 9mm for femur and 10.3mm for tibia
/ /		Metal collars added to protective end caps to improve durability
14/07/2010		• All previous changes
		•Removed neoprene from bone loading test
	ative Solution	• Corridor change to reflect loading

# Part or Process change - Documentation History

- ► All changes are made through an ECO (Engineering Change Order) document process. See appendix B for front page of ECO.
- ▶ Before any drawing or documentation change can be implemented affected departments must sign off to the change. The engineer responsible will either initiate the ECO or check the action request.
- ▶ Questions like mating parts, effect on performance, affect on process, measurement change and affect to sales documents or manual are questioned.
- The system will also check parts in process to ensure they are updated or scrapped.
- ► The reason for the change is recorded along with a detailed description of the change and what there was before.
- ► The ECO is given a log number and this is recorded on the drawing or the process document. The drawing will also describe the change in the revision block and a revision letter will go next to the change on the drawing so that it can be easily identified.



#### Comparison Between 180 and CFC 600 Filter

- ► Humanetics reprocessed a pendulum and an inverse test to look at affect on results
- ► See appendix C for full detail
- ► The moment and ligament channels were not greatly affected but the accelerometer on pendulum was. Therefore if considered necessary (not an injury channel) it may be an idea to use CFC 600 on accelerometers as their amplitude is being reduced by the 180 filter.



#### Effect of CFC180 - 600 filter classes Inverse

Parameter Description
Pre Impact Velocity
Peak Moment @ Tibia Gauge 1
Peak Moment @ Tibia Gauge 2
Peak Moment @ Tibia Gauge 3
Peak Moment @ Tibia Gauge 4
Peak ACL Elongation
Peak MCL Elongation
Peak PCL Elongation
Temperature
Humidity

CFC 180	CFC 600
Result	Result
11.15	11.15
242.88	243.52
229.58	229.06
178.64	178.29
99.92	99.65
8.63	8.61
18.13	18.10
5.31	5.32
21.90	21.90
26.00	26.00



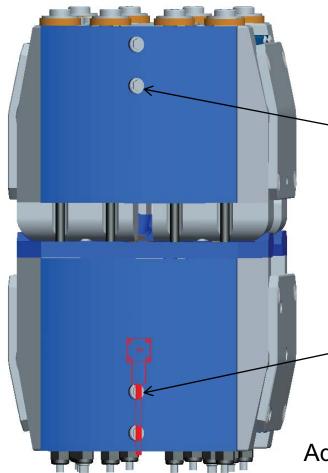
#### Effect CFC180 -> 600 filter classes pendulum

CFC 180 CFC 600

Parameter Description	Result	Result
Peak Acceleration at knee	69,68	82.08
Peak Moment @ Femur Gauge 1	182.68	182.67
Peak Moment @ Femur Gauge 2	133.62	133.63
Peak Moment @ Femur Gauge 3	86.50	86.51
Peak Moment @ Tibia Gauge 1	250.98	250.99
Peak Moment @ Tibia Gauge 2	203.09	203.10
Peak Moment @ Tibia Gauge 3	155.39	155.39
Peak Moment @ Tibia Gauge 4	105.10	105.12
Peak ACL Elongation	9.89	9.89
Peak MCL Elongation	23.30	23.30
Peak LCL Elongation	2.04	2.04
Peak PCL Elongation	4.44	4.44
Temperature	21.40	21.40
Humidity	22.00	22.00



#### Access to Tighten Front Leg Screws



4x 7 mm diameter holes could be drilled into plastic front covers

Problem on this hole if accel is fitted as wire will obstruct screw

Adding holes to the femur block would prevent the need to remove cover to tighten screws. However tibia block would still need to be removed as accelerometer wire blocks access



### Manual (PADI) Status

- Current manual is at issue C
- ► Manual will be updated after RR testing
- ► Known updates from IG not yet in manual
  - Guide lines on when to dismantle
  - 2. Further maintenance guidelines
  - 3. Torque update to 3 Nm (segment and shoulder screws)
  - 4. Speed measurement???
  - 5. Potential updates after round robin
  - 6. Other issues?



## Annex A sheet1 (build level)

Date	S/N	Bone Batch latest known	Bone Stiffness status inside corridor	Changes and Comments	Onboard DAS Y/N		Pendulum
GTR05/12/20 08	SN01	ТВС	Vinylester tibia high	Pendulum test without flesh, buffer on rig. Tibia updated to Vinylester Nov 2009. Refubished for RR 2012	Y	ТВС	
05/12/2008	SN02	Polyester	Polyester	Polyester bones and no updates, has old terminal block	Υ		
05/12/2008	SN03		Vinylester tibia high Sept 2009	Sept 2010 femur updated to Vinylester and knee block updated for new DAS arrangement. Refurbished for RR 2012	Y	TBC	
26/03/2009	SN04	B1	Mid stiffness both bones	Vinylester bones, Started grinding bones to meet mid bone corridor	Υ		
10/06/2009	SN05	B4 and B5	ТВС	Bones updated March 2012	Υ		
12/02/2010	AC4180		Cross ref bone S/N to data base	•Connector blocks removed to allow 24DAS channels total •String pots made into separate units •Rubber flesh extended down 146 mm •Extra Velcro tie added •Bone PCBs now shrink wrapped not potted and ribbon wire used for gage connection to PCB •Groove in bone spacer deepened to 7.5 mm to clear PCB •Outer Neoprene skin widened by 15 mm to help fit •Segment impactors had hole tolerance changed from 10.7 to 10.5 dia to tighten fit over button head screws •Bonded end bone buffer in end segments to ensure location and not be lost on disassembly			Pass
12/03/2010	AC5024	B1	Cross ref bone S/N to data base		Y		
17/03/2010	AC4689	B1	Cross ref bone S/N to data base		Y		
22/03/2010	AC5025		Cross ref bone S/N to data base		Y		



# ANNEX A sheet 2 (build level)

Date	•		Done Stiffiess status   Changes and Comments				
		latest known	inside corridor		DAS Y/N	Kg	
25/03/2010	AC5023	B1	Cross ref bone S/N to data base		Y		Pass
29/03/2010	AC5026	B1	Cross ref bone S/N to data base		Y		
30/03/2010	AC5027	B1	Cross ref bone S/N to data base		Y		
25/06/2010	DG0726	F B2, T B3	Both bones high	<ul> <li>Strain gage glue changed to similar 2 part epxoy high strain glue as old glue no longer available.</li> <li>Pendulum test now with flesh fitted buffer removed from rig.</li> <li>MCL and LCL string pot bushes made 1 mm longer.</li> <li>Sub assembly calibration loading changed from 325 to 400 Nm.</li> <li>Stopper cable clearance now 9 for femur and 10.3 for tibia.</li> <li>Metal collars added to protective end caps to improve durability.</li> </ul>	Y	13.04	Failed MCL
24/06/2010	DG1091	B2	Mid femur, mid to high tibia		Υ	13.06	failed MCL
28/06/2010	DG1090	B2	Cross ref bone S/N to data base		Y	13.02	failed ACL
14/07/2010	DG1096	B2	Mid to low femur, high tibia	From July 2010 removed neoprene from bone loading test and	Υ	13.01	failed MCL
15/09/2010	DG5934	B2	Mid stiff femur and tibia	corridor change to reflect loading	Y		Pass



### ANNEX A sheet 3 (build level)

Date	S/N	Bone Batch latest known	Bone Stiffness status inside corridor	Changes and Comments	Onboard DAS Y/N	Weight Kg	Pendulum
20/09/2010	DG6304	B2	Mid femur, mid stiff tibia		Y		
22/11/2010	DG8583	B2	Mid to low femur, mid tibia		Υ	13.15	failed MCL
08/11/2010	DG8090	B2	Both bones mid stiffness		Υ	13.16	Pass
31/03/2011	DH5644	Check Bone	Mid to high both bones	Femur top plate incorporates 2 M8 holes for new pendulum ballast wt. Femur top plate incorporates 2x M8 holes for	Y		
22/04/2011	DH5646	B2	Mid femur, mid to high tibia	pendulum ballast weight	Υ	13.22	Pass
02/05/2011	DH6791	F B2, T B3	Low femur medium tiba		Υ	13.0	Failed MCL
16/06/2011	Eng Leg	TBC	ТВС		Υ	TBC	
06/06/2011	DH8224	F B3, T B2	Both high		Y		Pass
11/9/2011	DJ2632	Check bone	Both mid to high		Y	13.16	Pass
11/10/2011	DJ0726	B4	Mid-High Femur, mid to high Tibia		Y		Pass
18/11/2011	DJ0027	Check bone	Mid to high femur, mid tibia	Stopper cable washer changed from 4 to 3 mm to allow engagement of locknut	Y	13.08	Pass
27/11/2011	DJ2040	B2	Mid femur, mid to high tibia		Υ	13.13	Pass
02/02/2012	DJ7773	Check bone	Mid to high femur, high tibia		Υ	13.154	Pass



# ANNEX B (ECO change record front sheet)

HUM	ive Solutions	_	Supervision Sign/Date	e:	
	125 ALC 16ALA	0	Part No.(s):	Clarification/Improvement	
	blem Description:			oduct or Engineering Recommendati	inn
Add probl	lem descriptio	n		estigation - Log No.:	
			Unit District Control	se Only:	
			ECO Lo		
			Start Da		
		Harrison Albert	Deviatio	n Source No.:	
CO Coordinat	or: Plymouth Source			document masters)	
Sites Affects			Dominican Republic	Field Office(s) Outside Ve	endor
		Buy	® No.	☐ Yes; Contact QM @ above s	200
	ange affect WIP, finis		ction, sales as appropr	ACCUSED TO STATE OF STREET	-
			roduction, sales as appropr		
" ye		existing inventor	_	® Scrap: O Use "as i	
ACT - 1011 - 11		The second second	® No.	Yes; Contact Mfg Eng Mg	_
May this cha	ange affect mating par	ts?	170.000		ш
Could this c	hange affect test perfo	rmance?	® No,	O Yes; Contact Lab Mgmt	
Could this c	hange increase cost >	10%?	■ No,	Yes; Contact Mfg Eng Mg	mt
Could this c	hange or alter process	conditions?	® No,	O Yes; Contact Mfg Eng Mg	mt
Could this o	hange affect QA meas	urament/criteria	2 ® No.	O Yes; Contact QA Mgmt	
	ange affect sales or ou		-	O Yes; Contact CustomerSe	rvice
			Maria III	- 100, 001000 0000110100	
lf an	ny above are yes, Eng	PM must be ass	signed:		
		Validation has been a	required □CAR Action (II What to and f	50 9001) PAR Action (ISO 900	1)
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## Appendix C (CFC 180-600 Inverse)

#### **Product Validation Report**



**Humanetics - Plymouth ATD Certification Lab** 47460 Galleon Drive Plymouth, MI 48170

Cert ID: Test ID:

240945.01 01/09/2012 Test Date: Test Time: 10:46 AM

#### **Product Validation Report**



Humanetics - Plymouth **ATD Certification Lab** 47460 Galleon Drive Plymouth, MI 48170

Cert ID: Test ID:

240945.03 Test Date: 01/09/2012 Test Time: 10:46 AM

Test: Flex PLI-GTR, Leg Assembly, Inverse High Speed Impact

**ENGINEERING R&D** Customer:

Serial Number: DH-9331-3 Part Condition: R&D

Corridor Type:

GTR

Components Tested

Part Description Part Serial Number Part Model Number **Purchase Date** 

Parameter Description	Test Point	Unit	Low	Result	High	Unit	Result
Pre Impact Velocity	0.00		10.90	11.15	11.30	m/sec	Pass
Peak Moment @ Tibia Gauge 1	0.00		237.00	242.88	277.00	N-m	Pass
Peak Moment @ Tibia Gauge 2	0.00		223.00	229.58	269.00	N-m	Pass
Peak Moment @ Tibia Gauge 3	0.00		176.00	178.64	204.00	N-m	Pass
Peak Moment @ Tibia Gauge 4	0.00		98.00	99.92	120.00	N-m	Pass
Peak ACL Elongation	0.00		8.50	8.63	10.50	mm	Pass
Peak MCL Elongation	0.00		18.00	18.13	23.00	mm	Pass
Peak PCL Elongation	0.00		4.50	5.31	6.00	mm	Pass
Temperature	0.00		18.00	21.90	22.00	degC	Pass
Humidity	0.00		10.00	26.00	70.00	%	Pass

Test Setu	Details						
Channel	Channel Name	Sensor SN	Axis	Cal Due Date	Gain	Filter	Class
1	Velocity	FlexVane	None	04/15/2012	0.99	3000	None
2	Tibia Gauge 1	DH5255 TIBI	Mx	10/24/2012	49.08	3000	180
2	Tibia Gauge 2	DH5255 TIBI,	Mx	10/24/2012	49.62	3000	180
4	Tibia Gauge 3	DH5255 TIBIA	Mx	10/24/2012	49.66	3000	180
5	Tibia Gauge 4	DH5255 TIBIA	Mx	10/24/2012	50.06	3000	180
5 6	ACL Pot	10093448	None	05/26/2012	1.00	3000	180
7	MCL Pot	10103893	None	05/26/2012	1.00	3000	180
9	PCL Plot	11066518	None	07/14/2012	1.01	3000	180
8	Probe Accel	A003756	None	12/23/2012	49.88	3000	180
10	Femur Gauge 1	DI4865 FEMU	Mx	10/24/2012	50.74	3000	180
11	Femur Guage 2	DI4865 FEMU	Mx	10/24/2012	50.85	3000	180
14	Femur Guage 3	DI4865 FEMU	Mx	10/24/2012	50.53	3000	180
16	LCL Pot	10103894	None	05/26/2012	1.00	3000	180
15	Knee Accel	FU1550002	None	05/07/2011	201.36	3000	180

Test: Flex PLI-GTR, Leg Assembly, Inverse High Speed Impact

Serial Number: DH-9331-3 Corridor Type: GTR Part Condition: R&D

Components Tested Part Description Part Serial Number Part Model Number **Purchase Date** 

est Result Details Parameter Description	Test Point	Unit	Low	Result	High	Unit	Result
Pre Impact Velocity	0.00	Oilit	10.90	11.15	11.30	m/sec	Pass
Peak Moment @ Tibia Gauge 1	0.00		237.00	243.52	277.00	N-m	Pass
Peak Moment @ Tibia Gauge 2	0.00		223.00	229.06	269.00	N-m	Pass
Peak Moment @ Tibia Gauge 3	0.00		176.00	178.29	204.00	N-m	Pass
Peak Moment @ Tibia Gauge 4	0.00		98.00	99.65	120.00	N-m	Pass
Peak ACL Elongation	0.00		8.50	8.61	10.50	mm	Pass
Peak MCL Elongation	0.00		18.00	18.10	23.00	mm	Pass
Peak PCL Elongation	0.00		4.50	5.32	6.00	mm	Pass
Temperature	0.00		18.00	21.90	22.00	degC	Pass
Humidity	0.00		10.00	26.00	70.00	%	Pass

Test Setu	p Details							
Channel	Channel Name	Sensor SN	Axis	Cal Due Date	Gain	Filter	Class	
1	Velocity	FlexVane	None	04/15/2012	0.99	3000	None	
2	Tibia Gauge 1	DH5255 TIBL	Mx	10/24/2012	49.08	3000	600	
3	Tibia Gauge 2	DH5255 TIBL	Mx	10/24/2012	49.62	3000	600	
4	Tibia Gauge 3	DH5255 TIBL	Mx	10/24/2012	49.66	3000	600	
5	Tibia Gauge 4	DH5255 TIBL	Mx	10/24/2012	50.06	3000	600	
6	ACL Pot	10093448	None	05/26/2012	1.00	3000	600	
7	MCL Pot	10103893	None	05/26/2012	1.00	3000	600	
9	PCL Plot	11066518	None	07/14/2012	1.01	3000	600	
9	Probe Accel	A003756	None	12/23/2012	49.88	3000	600	
10	Femur Gauge 1	DI4865 FEMU	Mx	10/24/2012	50.74	3000	600	
11	Femur Guage 2	DI4865 FEMU	Mx	10/24/2012	50.85	3000	600	
14	Femur Guage 3	DI4865 FEMI	Mx	10/24/2012	50.53	3000	600	
16	LCL Pot	10103894	None	05/26/2012	1.00	3000	600/	
15	Knee Accel	FU1550002	None	05/07/2011	201.36	3000	600	



### Appendix C (CFC 180-600 pendulum)

#### **Product Validation Report**



Humanetics - Plymouth **ATD Certification Lab** 47460 Galleon Drive Plymouth, MI 48170

Cert ID:

Test ID: 241342.01 Test Date: 01/20/2012 Test Time: 04:24 PM

#### Test: Flex PLI-GTR, Leg Assembly, Pendulum Impact

Customer:

ENGINEERING DEVELOPMENT

Serial Number: Part Condition:

Components Tested

DH9331-3 R&D

Corridor Type:

GTR

Part Description	Part Serial Num	art Serial Number Part N		odel Number			Purchase Date	
Test Result Details								
Parameter Description	Test Point	Unit	Low	Result	High	Unit	Result	
Peak Acceleration at knee	0.00	200000	48.10	69.68	72.90	g	Pass	
Peak Moment @ Femur Gauge 1	0.00		176.89	182.68	220.30	N-m	Pass	
Peak Moment @ Femur Gauge 2	0.00		121.19	133.62	158.10	N-m	Pass	
Peak Moment @ Femur Gauge 3	0.00		82.10	86.50	100.40	N-m	Pass	
Peak Moment @ Tibia Gauge 1	0.00		235.00	250.98	272.00	N-m	Pass	
Peak Moment @ Tibia Gauge 2	0.00		185.00	203.09	211.00	N-m	Pass	
Peak Moment @ Tibia Gauge 3	0.00		135.00	155.39	160.00	N-m	Pass	
Peak Moment @ Tibia Gauge 4	0.00		94.00	105.10	108.00	N-m	Pass	
Peak ACL Elongation	0.00		9.00	9.89	11.00	mm	Pass	
Peak MCL Elongation	0.00		23.00	23.30	26.00	mm	Pass	
Peak LCL Elongation	0.00		2.00	2.04	4.50	mm	Pass	
Peak PCL Elongation	0.00		4.00	4.44	5.40	mm	Pass	
Temperature	0.00		20.60	21.40	22.20	degC	Pass	
Humidity	0.00		10.00	22.00	70.00	%	Pass	

est Setup Details									
Channel	Channel Name	Sensor SN	Axis	Cal Due Date	Gain	Filter	Class		
1	Accelerometer	FU1550002	None	05/07/2011	492.54	3000	180		
2	Femur Gauge 1	DI4865 FEMU	Mx	10/24/2012	49.09	3000 /	180		
3	Femur Gauge 2	DI4865 FEMU	Mx	10/24/2012	49.62	3000	180		
4	Femur Gauge 3	DI4865 FEMU	Mx	10/24/2012	49.67	3000	180		
5 6	Tibia Gauge 1	DH5255 TIBIA	Mx	10/24/2012	50.07	3000	180		
6	Tibia Gauge 2	DH5255 TIBIA	Mx	10/24/2012	50.29	3000	180		
7	Tibia Gauge 3	DH5255 TIBIA	Mx	10/24/2012	49.50	3000	180		
15	Tibia Gauge 4	DH5255 TIBIA	Mx	10/24/2012	50.59	3000	180		
9	ACL Pot	10093448	None	05/26/2012	1.01	3000	180		
10	MCL Pot	10103893	None	05/26/2012	1.01	3000	180		
11	LCL Pot	10103894	None	05/26/2012	1.01	3000	180		
14	PCL Pot	11066518	None	07/14/2012	1.00	3000	180		

#### **Product Validation Report**



Humanetics - Plymouth ATD Certification Lab 47460 Galleon Drive Plymouth, MI 48170

Cert ID: Test ID:

241342.03 Test Date: 01/20/2012 Test Time: 04:24 PM

#### Test: Flex PLI-GTR, Leg Assembly, Pendulum Impact

Customer: Serial Number: Part Condition: CFC600 DH9331-3 R&D

Corridor Type:

**GTR** 

Components Tested Part Description Part Serial Number Part Model Number **Purchase Date** 

Test Result Details							
Parameter Description	<b>Test Point</b>	Unit	Low	Result	High	Unit	Result
Peak Acceleration at knee	0.00		48.10	82.08	72.90	g	Fail
Peak Moment @ Femur Gauge 1	0.00		176.89	182.67	220.30	N-m	Pass
Peak Moment @ Femur Gauge 2	0.00		121.19	133.63	158.10	N-m	Pass
Peak Moment @ Femur Gauge 3	0.00		82.10	86.51	100.40	N-m	Pass
Peak Moment @ Tibia Gauge 1	0.00		235.00	250.99	272.00	N-m	Pass
Peak Moment @ Tibia Gauge 2	0.00		185.00	203.10	211.00	N-m	Pass
Peak Moment @ Tibia Gauge 3	0.00		135.00	155.39	160.00	N-m	Pass
Peak Moment @ Tibia Gauge 4	0.00		94.00	105.12	108.00	N-m	Pass
Peak ACL Elongation	0.00		9.00	9.89	11.00	mm	Pass
Peak MCL Elongation	0.00		23.00	23.30	26.00	mm	Pass
Peak LCL Elongation	0.00		2.00	2.04	4.50	mm	Pass
Peak PCL Elongation	0.00		4.00	4.44	5.40	mm	Pass
Temperature	0.00		20.60	21.40	22.20	degC	Pass
Humidity	0.00		10.00	22.00	70.00	%	Pass

est Setu	Details						
Channel	Channel Name	Sensor SN	Axis	Cal Due Date	Gain	Filter	Class
1	Accelerometer	FU1550002	None	05/07/2011	492.54	3000	600
2	Femur Gauge 1	DI4865 FEMU	Mx	10/24/2012	49.09	3000	600
2	Femur Gauge 2	DI4865 FEMU	Mx	10/24/2012	49.62	3000	600
4	Femur Gauge 3	DI4865 FEMU	Mx	10/24/2012	49.67	3000	600
5 6	Tibia Gauge 1	DH5255 TIBIA	Mx	10/24/2012	50.07	3000	600
6	Tibia Gauge 2	DH5255 TIBI	Mx	10/24/2012	50.29	3000	600
7	Tibia Gauge 3	DH5255 TIBI,	Mx	10/24/2012	49.50	3000	600
15	Tibia Gauge 4	DH5255 TIBIA	Mx	10/24/2012	50.59	3000	600
9	ACL Pot	10093448	None	05/26/2012	1.01	3000	600
10	MCL Pot	10103893	None	05/26/2012	1.01	3000	600
11	LCL Pot	10103894	None	05/26/2012	1.01	3000	600
14	PCL Pot	11066518	None	07/14/2012	1.00	3000	600

