

Status: Draft Version: 2.1

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Project: QMS

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Version: 2.1 Status: Draft

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Paragit*

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Flex Adapter Sub-System

Structural overview diagram

Requirement coding format

See the **QMS** Requirement Format Procedure.

System Traceability Matrix

User needs folder	Requirement Code	Requirements Folder	Description
PXS User needs	S	PXS Design Input	Paragit PX System

	Design Input	Design Outpu t	Design Verification (Incl. protocol w. acc criteria)	Design Valida tion (Incl. protoc ol w.	V&V Record s					
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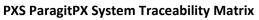


rupted	budget outlined in this requireme nt	PHR001, PS PS- PHR005, PEA PEA- PHR001, PFA PFA- PHR001				
	PXS S- PHR004 The ParagitPX system shall adhere to the size budget outlined in this requireme nt	Identified in subsystem requirements/verific ation: PRU PRU-B-PHR002, PRU PRU-B-PHR003, PRU PRU-C-PHR002, PRU PRU-C-PHR003, PRU PRU-C-PHR003, PRU PRU-C-PHR004	PX Usabili ty Test Report			
W UN003 - As a user wearin g the device, I expect it to withsta nd daily activiti es, allowin g for prolon ged use withou t the need for	Covered by PX S- ST005 The system shall comply with EN 60068-2- 27:2009, as confirmed by accredited test centre	N/A				





replace ment.							
<u>W</u> <u>UN004</u>	PX S- UR002 The system shall have the means to be turned on/off	Identified in subsystem requirements/verific ation: PRU PRU-C-FR001 The casing shall be equipped with one button, PRU PRU-PCB-PHR002 The PCB shall have a button, PRU PRU-FR003		PX Usabili ty Test Report , PX PXS- VEPRO T003			
- As a wearer , I want to easily turn the device on/off, so that I can use it easily during my day	PX S- PHR007 The Paragit PX system shall be operable using low amounts of force, allowing easy use for users with movemen t disorders	Identified in subsystem requirements/verific ation: PRU PRU-C-UR001 The button embedded in the casing shall activate with a force of 0.5 to 2 Newtons (+/- 0.1)	PX Usabili ty Test Overvi ew, test realiza tion 12	PX Usabili ty Test Report			
	PX S- PHR008 The ParagitPX System shall be designed for	Identified in subsystem requirements/verific ation: PRU PRU-C-UR002 The button embedded in the casing should be raised at least		PX Usabili ty Test Report			



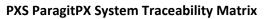


	<u>optimal</u>	0.8mm from their					
	usability,	sorroundings					
	ensuring	<u>sorroundings</u>					
	that all						
	user						
	interface						
	componen						
	ts are						
	easily						
	accessible						
	and						
	distinguish						
	able by						
	touch.						
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<u>UN005</u>							
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		subsystem					
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		PRU PRU-C-UR003,					
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<u>l can</u>		emitting a brightness					
<u>I can</u> <u>confir</u>	to the	emitting a brightness of at least 40 mcd,					
<u>I can</u> <u>confir</u> <u>m</u>		of at least 40 mcd,					
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l can confir m wheth er it is	to the						
l can confir m wheth er it is operati	to the						
l can confir m wheth er it is	to the						
easily unders tand the current state of the device,	PX S- UR005 The ParagitPX system shall have features to communic ate status and errors	Identified in subsystem requirements/verific ation: PRU PRU-C-UR003, PRU PRU-PCB-FR004 The PCB shall be equipped with an LED capable of	PX Usabili ty Test Overvi ew, test realiza tion 6	PX Usabili ty Test Report			





W UN006 - As a wearer , I want to easily wash and disinfe ct the device, so that I can mainta in proper hygien e	PX S- OR002 The ParagitPX System shall be constructe d such that only the componen ts in contact with the skin must be able to withstand a minimum of 10 wash cycles at 30 degrees Celsius with less than 5% degradati on EMG signal to noise ratio.	Identified in subsystem requirements/verific ation: PS PS-FR002 The sleeve shall be able to withstand a minimum of 10 wash cycles at 30 degrees Celsius with less than 5% degradation in EMG signal to noise ratio.	PX Usabili ty Test Overvi ew, test realiza tion 4	PX Usabili ty Test Report					
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Risk Manag ement, R-CY- 01	PX S-OR003 The ParagitPX system should store all data offline, locally on the device	Identified in subsystem requirements/verific ation: PRU PRU-PCB-FR005, PRU PRU-FW-FR005, PRU PRU-FW-SR001	N/A				
W UN008 - As a wearer , I want the device to be easy to rechar ge, so that I can use it contin uously withou t inconv enienc e	PX S-FR005 The ParagitPX System shall be able to recharge from 0% to 100% via USB-C in a maximum of 6 hours	Identified in subsystem requirements/verific ation: PRU PRU-B-FR002, PRU PRU-B-FR003, PRU PRU-C-FR002, PRU PRU-PCB-FR003 The PCB shall allow a USB-C connection to be established	PX Usabili ty Test Overvi ew, test realiza tion 12	PX Usabili ty Test Report , PX PXS- VEPRO T003			
R UN001 - As a researc her, I want to measu re the effect	PX S- FR002 The system shall quantify impedanc e changes of at least 100 ohm in order to	Identified in subsystem requirements/verific ation: PRU PRU-PCB-FR001, PRU PRU-PCB-PR003, PRU PRU-PCB-PR010, PRU PRU-FW-PR005, PRU PRU-FW-PR006,	PX Clinical Evalua tion Plan (signe d)	PX Clinical Evalua tion Report (signed)			



	l	
<u>of</u>	<u>estimate</u>	PS PS-PHR006, PS PS-
<u>sweat</u>	<u>the</u>	FR004 The sleeve
<u>on</u>	amount of	shall feature one
<u>biopot</u>	<u>accumulat</u>	reference electrode
<u>ential</u>	ed sweat	to evaluate
signals,	<u>between</u>	impedance changes,
so that	<u>the</u>	PEA PEA-FR003, PFA
<u>I can</u>	<u>electrodes</u>	PFA-FR003
quantif		
<u>y its</u>		
<u>impact</u>		
<u>to</u>		
improv		
e the		
<u>accura</u>		
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<u>my</u>		
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<u>analysi</u>		
<u>s</u>		
<u>R</u>	PX S-	Identified in
UN002	FR003 The	subsystem
- As a	system	requirements/verific
researc	shall	ation:
her, I	<u>measure</u>	ation:
want	3D	PRU PRU-PCB-PR004,
to	accelerati	PRU PRU-PCB-PR006,
<u>measu</u>	on	PRU PRU-PCB-PR008,
	accurately	PRU PRU-PCB-PR009,
<u>re</u> accurat	in ranges	PRU PRU-FW-PR004
	typical for	The Firmware
<u>e</u> move	human	subsystem shall
move ment	movemen	measure 3D
ment data in	t during	acceleration at a
data in		sample rate between
<u>3D</u>	daily	95 and 105 hz
space,	activity	
so that	PX S-	Identified in
<u>l can</u>	FR004 The	subsystem
<u>quantif</u>	<u>system</u>	requirements/verific
¥	<u>shall</u>	ation:
move	<u>measure</u>	
ment	<u>3D</u>	PRU PRU-PCB-PR007,
<u>activity</u>	rotation	PRU PRU-PCB-PR013,
÷	accurately	PRU PRU-PCB-PR014,





	in ranges typical for human movemen t during daily activity	PRU PRU-PCB-PR015, PRU PRU-FW-PR002				
R UN003 - As a researc her, I want to measu re muscul ar functio n, so that I can accurat ely quantif Y muscul ar activity .	PX S- PR011 The system shall measure bio- potential signals accurately in ranges typical for human movemen t during daily activity [OHz - 500 Hz]	Identified in subsystem requirements/verific ation: PRU PRU-PCB-PR001, PRU PRU-PCB-PR005, PRU PRU-FW-FR001, PRU PRU-FW-PR001, PS PS-FR003, PEA PEA-FR002, PFA PFA-FR002				
R UN004 - As a researc her, I want the system to measu re on differe nt parts	PXS S- PHR006 The system must be designed to be universally wearable, accommo dating placement on any	Identified in subsystem requirements/verific ation: PRU PRU-C-PR001, PRU PRU-C-FR003 the casing shall be able to connect with the sleeve subsystem, PRU PRU-C-FR004 The casing shall be be able to connect with the electrode adapter				





of the body, body. C-FROO5 The casing shall be able to connect with the flex adapter subsystem. R UNOO5 -As a researc her, I want the shall be raw designed data, to ensure so that compatibil interopera sthem linter perast sthem linter perast sthem party computing party						
so that Lcan achieve adapter subsystem of the compact with the flex adapter subsystem of the compact with the flex adapter subsystem of the compact with the co						
Can achiev ea multi-dimens ional insight. R UN005 -As a researc her, I want her shall be raw designed data, to ensure so that billity with in any standard third- external party computing progra devices m and for data ensure managem the ent accura purposes. Cy of my data analysi Connect with the flex adapter subsystem Connect with the flex adapter s		body.				
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ional insight. R UN005 -As a researc her, I want PX S- to FR006 The extract system the shall be raw designed data, to ensure so that Ican ity and proces interopera sthem billity with in any standard third- external party computing progra devices m and for data ensure managem the ent accura purposes. Cy of my data analysi	<u>multi-</u>					
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<u>UN006</u>	PR005:		
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<u>researc</u>	<u>ParagitPX</u>		
<u>her, I</u>	<u>system</u>	Identifie	d in
<u>want</u>	shall be	subsyste	
<u>to</u>	<u>able</u>		nents/verific
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day to	<u>minimum</u>		
<u>identif</u>	<u>of 24</u>		
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<u>lies in</u>	PX S-		
move	PR006 The		
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thorou	least 24		
<u>gh</u>	hours of		
<u>analysi</u>	<u>data</u>		
<u>S</u>			
<u>R</u>			
<u>UN007</u>	PXS S-		
<u>- As a</u>	PR007 The		
researc	<u>system</u>	PRU-	
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<u>want</u>	the	<u>15000</u>	
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<u>acquir</u>	<u>of</u>	<u>Design</u>	PX PXS-
e low-	<u>sensitive</u>	<u>Files</u> ,	VEPROT003
noise	EMG (>30	PRU-	
<u>data</u>	dB)	FW DBI 00	
withou +	without	DRL00	
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<u>cumbe</u>	<u>manual</u>		
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COTUR			





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<u>R</u>		
<u>UN008</u>		
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to be		
able to		
see		
releva	PX S-	
nt	FR007 The	
metad	system	
ata for	shall allow	Identified in
my	the user	subsystem
<u>recordi</u>	to see	requirements/verific
ngs, so	when a	ation: PRU PRU-FW-
that I	recording	FR008
can	was	
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	and ended	
<u>track</u> <u>of</u>	and ended	
<u>when</u>		
and have		
how		
<u>my</u>		
<u>data</u>		
was		
collect		
<u>ed</u>		





R UN009 - As a researc her, I want to the device to be portabl e, so that I can perfor m my researc h in differe nt setting s	Covered by PXS S- PHR003	N/A			
R UN010 - As a researc her, I want to be able to record key timest amps so that I can correla te the data with design ated points of interes t	PX S- UR007 The system shall be capable of accurately logging events with precision to the second	Identified in subsystem requirements/verific ation: PRU PRU-PCB-PR011, PRU PRU-PCB-PCB-PR012	Verified in subsystem verification (technical user needs)		





Standa rd Review of ISO109 93	PXS S- ST001 CYTOTOXI CITY System materials in touch with the skin, shall be made of biocompat ible materials in accordanc e with ISO10993- 5 PXS S- ST002 IRRITATIO N System materials in touch with the skin, shall be made of biocompat ible materials in touch with the skin, shall be made of biocompat ible materials in touch with the skin, shall be made of biocompat ible materials in accordanc e with ISO10993- 23	QMS EN ISO 10993- 1:2020, PX Biological Compatibility Evaluation Plan	N/A	PX Biologi cal Evalua tion, PX Biologi cal Risk Assess ment, PX Biologi cal Evalua tion					
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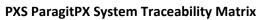


	PXS S- ST003 CHEMICAL CHARACTE RIZATION System materials in touch with the skin, shall be made of biocompat ible material in accordanc e with ISO10993- 18 PX S- ST004 The system shall						
Review of applica ble standa rds	comply with EN 60068-2- 64:2008, as confirmed by accredited test centre	PRU-C Design Outpu t, PRU- PCB Design Outpu t, PRU-	PX EN 60068-2- 64:2008, EN 60068- 2-27:2009 EN 60529:1991	PX EN 60068- 2- 64:200 8, EN 60068- 2- 27:200 9 EN 60529:			
Review of applica ble standa rds	PX S- ST005 The system shall comply with EN 60068-2- 27:2009, as confirmed by	E FRO- FW Design Outpu	+ A1:2000 + A2:2013, IP22	1991 + A1:200 0 + A2:201 3, IP22			





	100					
	<u>accredited</u>					
	test					
	<u>centre</u>					
	PX S-					
	ST007 The system					
Review	<u>shall</u>					
of	comply					
applica	with IP22,					
ble	as					
standa	confirmed					
rds	by					
	<u>accredited</u>					
	<u>centre</u>					
	PX S-					
	ST008 The					
	<u>system</u>					
Review	<u>shall</u>					
of	comply		<u>PX IEC</u>			
applica	with IEC	QMS IEC	<u>60601-</u>			
ble	60601-2-	60601-2-	<u>2-40</u>			
standa	<u>40, as</u>	<u>40:2016</u>	<u>Part 2-</u>			
rds	<u>confirmed</u>		<u>40:</u>			
	<u>by</u>					
	<u>accredited</u>					
	test					
	<u>centre</u>					
	<u>PX S-</u> <u>ST009 The</u>					
	system					
	shall					
Review	comply					
of	with IEC	QMS IEC	PX IEC			
applica	<u>60601-1,</u>	60601-	60601-			
ble	as	1:2006/A2:	<u>1</u>			
standa	confirmed	<u>2021</u>				
rds	<u>by</u>					
	accredited					
	<u>test</u>					
	<u>centre</u>					
Review	PX S-	QMS IEC	PX IEC			
of	ST010 The	60601-1-	60601-			
applica	<u>system</u>	6:2010+AM	<u>1-6</u>			
ble	<u>shall</u>					





standa	comply		D1:2013+					
rds	with IEC 60601-1-		AMD2:2020					
	<u>6, as</u>							
	<u>confirmed</u> <u>by</u>							
	<u>accredited</u>							
	<u>test</u>							
	centre PX S-							
	ST011 The							
	<u>system</u> <u>shall</u>							
Review	comply		0.46.150					
of applica	with IEC		<u>QMS IEC</u> 60601-1-		<u>PX IEC</u>			
ble	60601-1- 11, as		11:2015/A1		60601- 1-11			
standa rds	<u>confirmed</u>		:2020		<u></u>			
Tus	<u>by</u>							
	accredited test							
	centre							
Review	PX S- ST020 The	Identifie	d in					
of	system	subsyste			<u>PRU</u>			
applica ble	<u>shall</u>		nents/verific		PRU-B-			
standa	comply with IEC	SR003	RU PRU-B-		<u>SR003</u>			
rds	62133							
	PX S- ST021 The	PRU-C						
	system	<u>Design</u>						
Review	<u>shall</u>	Outpu t, PRU-						
of	comply with IEC	<u>PCB</u>	QMS IEC		PX IEC			
applica ble	60601-1-	<u>Design</u> Outpu	60601-1- 2:2015/A1:		60601-			
standa	2, as confirmed	t, PRU-	2021		<u>1-2</u>			
rds	<u>by</u>	<u>FW</u> <u>Design</u>						
	<u>accredited</u>	<u>Outpu</u>						
	<u>test</u> <u>centre</u>	<u>t</u>						
Risk	PX S-		d in subsysten					
manag	PR008 The	requirer	nents/verificat	ion: <u>PRU I</u>	PRU-B-			



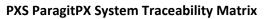


ement,	system	PR001 and system requirement: PX S-			
RP-02	shall be	PR010			
111 02	designed	THOTO			
	to ensure				
	consistent				
	operation				
	al				
	performan				
	ce and				
	reliability				
	over a				
	<u>minimum</u>				
	service life				
	<u>of three</u>				
	<u>years</u>				
	<u>under</u>				
	normal				
	<u>usage</u>				
	conditions				
	PX S-	Identified in subsystem			
	SR004 The	requirements/verification: PRU PRU-B-			
	system	SR004, PRU PRU-B-SR005, PRU PRU-B-			
Risk	shall be	SR006, PRU PRU-B-SR007, PRU PRU-			
manag	designed	PCB-SR002 The PCB must include a NTC			
ement,	to manage	that shuts down operations if the			
RP-03	power	temperature of the battery exceeds 45			
	efficiently	degrees during charing			
	and safely				
	allu salety				
	PX S-				
	PR010 The				
	<u>system</u>	Identified in subsystem			
	shall be	requirements/verification: PRU PRU-C-			
Diele	<u>durable</u>	OR001 The casing shall be able to			
Risk	enough to	withstand 1.095 matings with the			
manag	withstand	connector (PS/PEA/PFA) while			
ement,	connectio	maintaining the ability to connect, PRU			
RP-07	<u>n life</u>	PRU-PCB-FR002, PS PS-FR001, PEA			
	cycles	PEA-FR001, PFA PFA-FR001			
	through				
	the				
	lifetime				
Risk	PX S-	Identified in subsystem			
manag	SR009 The	requirements/verification: PRU PRU-C-			
manag	SINUUS THE	requirements, verification. Fito Fito-C-			





ement, RM-07	system shall be designed to ensure safe and reliable maintena nce through controlled service procedure s	SR002, PRU PRU-C-SR003			
Risk manag ement, RM-07	PX S- SR010 The system shall be designed to ensure secure and error- free integratio n of all electrical componen ts.	Identified in subsystem requirements/verification: PRU PRU-B-SR008, PRU PRU-PCB-SR003			
Risk Manag ement, RU-06	PX S- OR004 The ParagitPX system shall be able to withstand appropriat e cleaning during its lifetime without performan ce degradati on	Identified in subsystem requirements/verification: PRU PRU-C- OR002, PS PS-FR002 The sleeve shall be able to withstand a minimum of 10 wash cycles at 30 degrees Celsius with less than 5% degradation in EMG signal to noise ratio.			





Risk Manag ement, RU-14	PX S- OR005 The ParagitPX system shall be active only when it is disconnec ted from the charger	requirer	Identified in subsystem requirements/verification: PS PS-SR002, PFA PFA-SR002, PEA PEA-SR002					
Risk manag ement, RU-17	PXS S- SR001 The Paragit PX system shall have soft edges with a radius of at least 2mm to avoid injury	requirer	ed in subsysten ments/verificat <u>PS PS-SR001</u> , <u>P</u> SR001	tion: PRU				
Review of app licable standa rds	PX S- ST022 The ParagitPX labels shall adhere to the standards outlined in this requireme nt	PX Produ ct Label	QMS EN ISO 13485:2016 /A11:2021	N/A	PX LVE24 0424 Label Verific ation Eviden ce			
Review of app licable standa rds	PX S- PHR009 The ParagitPX system shall be able to withstand	PX Packag ing Instruc tion	QMS EN ISO 13485:2016 /A11:2021	N/A	PX VARPT 24042 5 Validat ion Record for			



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appropriat	<u>Packin</u>
<u>e</u>	g and
<u>transporta</u>	<u>Transp</u>
<u>tion</u>	<u>ort</u>

Recording Unit Sub-System

Requirement Code	Requirements Folder	Description
PRU	PRU Design Input	Paragit Recording Unit Subsystem

Parent	Design	Design	Design Verification (Incl.	Verification
requirement	Input	Output	protocol w. acc criteria)	Records

Battery Sub-System

Requirement Code	Requirements Folder	Description
PRU-B	PRU-B Design Input	Paragit Recording Unit Battery Subsystem

Parent requirement	Design Input	Design Output	Design Verification (Incl. protocol w. acc criteria)	Verification Records
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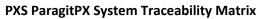


PXS S-PR005: The				
ParagitPX system shall be able actively collect data over a minimum of 24 hours continuously	PRU PRU-B- FR001 The battery shall have a minimum capacity of 300 mah PRU PRU-B- SR003 The		IEC 62133-2:2017 + AMD1:2021	PRU PRU-B- VE001 IEC 62133
PX S-ST020 The system shall comply with IEC 62133	battery shall comply with IEC 62133, as confirmed by accredited test centre			
PXS S-PHR003 The ParagitPX system shall adhere to the weight budget outlined in this requirement	PRU PRU-B- PHR001 The battery shall weigh a maximum of 25 grams	PRU PRU-B DNK- LP402535	PX PXS- VEPROT001	PX PXS- VEPROT001
PXS S-PHR004 The ParagitPX system shall adhere to the size budget outlined in this requirement	PRU PRU-B- PHR002 The battery shall have a maximum length of 4 cm PRU PRU-B- PHR003 The battery shall have a maximum width of 2,5 cm PRU PRU-B- PHR004 The battery shall have a maximum thickness of 0,4 cm		Ruler	PRU PRU-B DNK- LP402535
PX S-FR005 The ParagitPX System shall be able to recharge from 0% to 100% via	PRU PRU-B- FR002 The battery shall have a charge voltage of 4.2V		PX PXS- VEPROT003	PX PXS- VEPROT003





USB-C in a maximum of 6	PRU PRU-B- FR003 The		
hours	battery shall		
TIOUIS	recharge from		
	0% to 100% in a		
	maximum of 6		
	hours		
	PRU PRU-B-		
PX S-PR008 The	PRO01 The		
system shall be	battery should		
designed to	maintain at least		
ensure consistent	80% of its initial		
<u>operational</u>	capacity after	PRU PRU-B DNK-	PRU PRU-B DNK-
performance and	undergoing 156	<u>LP402535</u>	LP402535
reliability over a	cycles, with one	<u>LF 402333</u>	<u>LF402333</u>
minimum service	cycle occurring		
<u>life of three years</u>	each week over a		
<u>under normal</u>	period of three		
usage conditions	years		
PX S-SR004 The system shall be designed to manage power efficiently and safely	PRU PRU-B- SR004 The battery shall have over charge protection PRU PRU-B- SR005 The battery shall have over discharge protection PRU PRU-B- SR006 The battery shall have over current protection PRU PRU-B- SR007 The	IEC 62133-2:2017 + AMD1:2021	PRU PRU-B- VE001 IEC 62133
	battery shall have short		
	protection		
	protection		





PX S-SR010 The system shall be designed to ensure secure and error-free integration of all electrical components.	PRU PRU-B- SR008 The battery shall include a poco connection that ensures proper connection and correct polarity alignment	PRU-B LP402535 B	PRU-B LP402535 Battery Connector	
Review of applicable standards	PRU PRU-B- ST001 The battery shall comply with EN 55032:2015+A11, as confirmed by accredited test centre			PRU PRU-B- VE002 EN 55032:2015+A11,
Review of applicable standards	PRU PRU-B- ST002 The battery shall comply with EN EN 55035:2017+A11, as confirmed by accredited test centre	PRU PRU-B DNK- LP402535	EN 55032:2015+A11	EN 55035:2017+A11, EN IEC 61000-3- 2:2019+A1, EN 61000-3- 3:2013+A1
Review of applicable standards	PRU PRU-B- ST003 The battery shall comply with IEC 61000-3- 2:2019+A1, as confirmed by accredited test centre			



Casing Sub-System

Requirement Code	Requirements Folder	Description
PRU-C	PRU-C Design Input	Paragit Recording Unit Casing Subsystem

Parent require ment	Design Input	Design Output	Design Verificat ion (Incl. protocol w. acc criteria)	Verification Records
PXS S-PHR006 The system must be designe d to be universa lly wearabl e, accomm odating placeme nt on any part of the body.	PRU PRU-C- PR001 The PRU- casing subsyste m shall have an attachm ent/det achmen t mechani sm allowing it to be mechani cally connect ed to its adapter.	PRU-C Plastic Enclosur e, PRU-C Assembl y Screws STP3202 00060E, PRU-C Protecti ve Foam, PRU-C PA2200 Datashe et	PX PXS-VE	PROT002

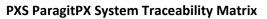


<u>PRU</u>
PRU-C-
FR003
the
<u>casing</u>
shall be
able to
connect
with the
<u>sleeve</u>
<u>subsyste</u>
<u>m</u>
<u>PRU</u>
PRU-C-
FR004
<u>The</u>
casing
shall be
be able
to
<u>connect</u>
with the
electrod
<u>e</u>
<u>adapter</u>
<u>subsyste</u>
<u>m</u>
<u>PRU</u>
PRU-C-
FR005
<u>The</u>
casing
shall be
able to
connect
with the
flex
adapter
<u>subsyste</u>
<u>m</u>





PXS S- PHR003 The ParagitP X system shall adhere to the weight budget outlined in this require ment	PRU PRU-C- PHR001 The casing shall weigh a maximu m of 25 grams	PX PXS-VEPROT001
PXS S- PHR004 The ParagitP X system shall adhere to the size budget outlined in this require ment	PRU PRU-C- PHR002 The casing shall have a maximu m length of 10cm	PRU-C Plastic Enclosure
	PRU PRU-C- PHR003 The casing shall	





	have a maximu m width of 3cm					
	PRU PRU-C- PHR004 The casing shall have a maximu m height of 0,9 cm					
PX S- UR002 The system shall have the means to be turned on/off	PRU PRU-C- FR001 The casing shall be equippe d with one button					
PX S- PHR007 The Paragit PX system shall be operabl	PRU PRU-C- UR001 The button embedd ed in the	PRU-C UR- VEPROT	PRU-C UR	-VEPROT00	1 button fo	rce (Newton)
e using low amount s of force, allowing easy use for users with movem	casing shall activate with a force of 0.5 to 2 Newton s (+/- 0.1)	001 button force (Newton)		PX S-PHR008 The ParagitP X System shall be designe d for optimal	PRU PRU-C- UR002 The button embedd ed in the casing should	PRU-C Plastic Enclosure





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	<u>PRU</u>				
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	<u>UR003</u>				
	<u>The</u>				
	casing				
	must				
PX S-	include				
<u>UR005</u>	<u>a</u>				
<u>The</u>	<u>transpar</u>				
<u>ParagitP</u>	ent,				
<u>X</u>					
<u>system</u>	uncover				
<u>shall</u>	ed, or				
have	<u>transluc</u>				
features	<u>ent</u>				
<u>to</u>	section				
<u>commu</u>	<u>that</u>				
<u>nicate</u>	<u>allows</u>				
	an LED				
<u>status</u>	on the				
and	PCB to				
errors to	visibly				
the user	indicate				
	the				
	device's				
	status to				
	the				
	user.				





PX S-FR005 The ParagitP X System shall be able to recharg e from 0% to 100% via USB-C in a maximu m of 6 hours PX S-FR006 The system shall be designe d to ensure compati bility and interope rability with standar d external computi ng devices for data manage ment purpose s.	PRU PRU-C- FR002 The casing must feature a precisel Y aligned opening that allows access to the USB-C port on the PCB	PX PXS-VEPROT003		





PX S- ST007 The system shall comply with IP22, as confirm ed by accredit ed centre	PRU PRU-C- ST001 The casing must comply with IP22, as confirm ed by accredit ed test centre PRU	Applicab le standar d	PX EN 60068-2-64:2008, EN 60068-2-27:2009 EN 60529:1991 + A1:2000 + A2:2013, IP22
PX S- PR010 The system shall be durable enough to withstan d connecti on life cycles through the lifetime	PRU-C- OR001 The casing shall be able to withstan d 1.095 matings with the connect or (PS/PEA /PFA) while maintai ning the ability to connect	PX PXS-VE	EPROT002





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	PRU C	
	PRU-C-	
	SR002	
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	casing	
	<u>shall</u>	
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	<u>cal</u>	
	locking	
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PX S-	securely	
<u>SR009</u>	<u>enclose</u>	
<u>The</u>	and seal	
<u>system</u>	the PCB	
shall be	<u>and</u>	
<u>designe</u>	battery.	
<u>d to</u>	PRU	
<u>ensure</u>	PRU-C-	
safe and	<u>SR003</u>	PRU-C Plastic Enclosure, PRU-C Assembly Screws
<u>reliable</u>	<u>The</u>	<u>STP320200060E</u>
<u>mainten</u>	casing	
<u>ance</u>	shall be	
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controll	<u>with</u>	
<u>ed</u>	screws	
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PX S- OR004 PRU The PRU-C- ParagitP OR002 X The system casing shall be able to withstan d d 1.095 appropri cleaning TODO TODO	
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The PRU-C- ParagitP OR002 X The system casing shall be shall be able to withstan d d 1.095	
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PCB Sub-System

Requirement Code	Requirements Folder	Description
PRU-PCB	PRU-PCB Design Input	Paragit Recording Unit PCB Subsystem

Parent requirement	Design Input	Design Output	Design Verification (Incl. protocol w. acc criteria)	Verification Records
PX S-PR011 The system shall measure bio-potential signals accurately in ranges typical for human movement during daily activity [0Hz - 500 Hz]	PRU PRU-PCB-PR001 The PCB subsystem shall be equipped with a high-precision analog-to-digital converter (ADC) with a minimum resolution of 14 bits	PRU-PCB DRL002	N/A	PRU-PCB DRL002
	PRU PRU-PCB- PR005 The PCB subsystem shall			
	have an ADC capable of sampling EMG signals at a			





PX S-FR002 The system shall quantify impedance changes of at least 100 ohm in order to estimate the amount of accumulated sweat between the electrodes	PRU PRU-PCB-FR001 The PCB subsystem shall have the capability to output two individual DAC signals into the EMG circuit PRU PRU-PCB-PR003 The PCB subsystem shall have a DAC capable of outputting signals at an amplitude within 1-10mV PRU PRU-PCB-PR010 The PCB subsystem shall feature a DAC capable of outputting signals at an amplitude within 1-10mV PRU PRU-PCB-PR010 The PCB subsystem shall feature a DAC capable of outputting signals at a rate of at least 2000 Hz		
PX S-UR007 The system shall be capable of accurately logging events with precision to the second	PRU PRU-PCB-PR011 The PCB subsystem shall feature an external crystal that is accurate within at least 10 ppm	PRU-PCB DRL003	PRU-PCB DRL





	PRU PRU-PCB- PR012 The PCB subsystem shall feature an external crystal that oscillates at 32,768 kHz		
PX S-FR003 The system shall measure 3D acceleration accurately in ranges typical for human movement during daily activity	PRU PRU-PCB-PR004 The PCB subsystem shall have an IMU capable of measuring 3D acceleration data at a sample rate of at least 200 Hz	PRU-PCB DRL001	PRU-PCB DRL001



PRU PRU-PCB-
PR006 The PCB
subsystem shall
have an IMU
capable of
measuring 3D
acceleration
within a range of
±4 · 9.81 m/s² (4
g)
PRU PRU-PCB-
PR008: The PCB
subsystem shall
include an IMU
capable of
measuring 3D
acceleration with
an offset
accuracy of
±480.5 mm/s ²
(±50 milli-g)
across the PRU's
operating
<u>temperature</u>
range
PRU PRU-PCB-
PR009: The PCB
subsystem shall
include an IMU
capable of
measuring 3D
acceleration with
a sensitivity of at
least ±4.905
mm/s ² (±0.5
milli-g) across the
PRU's operating
temperature
<u>range</u>
range





	DDLI DDLI DCD		
	PRU PRU-PCB-		
	PR007 The PCB		
	subsystem shall		
	have an IMU		
	capable of		
	measuring 3D		
	rotation within a		
	range of ±2000		
	<u>°/s</u>		
	PRU PRU-PCB-		
	PR013 The PCB		
	subsystem shall		
	have an IMU		
	capable of		
	measuring 3D		
	rotation data at a		
PX S-FR004 The	sample rate of at		
system shall	least 200 Hz		
measure 3D	PRU PRU-PCB-		
otation	PR014 The PCB		
accurately in	subsystem shall		
ranges typical for	include an IMU		
human	capable of		
movement	measuring 3D		
during daily	rotation with a		
activity	zero-rate level		
	accuracy of ±0.75		
	dps across the		
	PRU's operating		
	<u>temperature</u>		
	<u>range</u>		
	PRU PRU-PCB-		
	PR015 The PCB		
	subsystem shall		
	include an IMU		
	capable of		
	measuring 3D		
	rotation with a		
	sensitivity of at		
	<u>least ±105</u>		
	mdps/LSB across		
	the PRU's		
	operating		





	tem rang	<u>oerature</u> <u>e</u>					
Risk management, RE-05	PRU SROO shall with resis conr signo to en	PRU-PCB- 01 The PCB be equipped serial	PRU-PCB 1500001E Design Files			PRU- 1500 Files	0001E Design
PX S-SR010 The system shall be designed to ensure secure and error-free integration of all electrical components.	PRU SROO shall way conr PCB batt	PRU-PCB- 03 The PCB have a safe	PRU-PCB Pico- EZmate Plus PCB Header, 1.00mm Pitch, Single Row, Gold (Au) Plating, 2 Circuits 538- 212134-0002			EZm Head Pitch Gold 2 Cir	-PCB Pico- ate Plus PCB der, 1.00mm n, Single Row, I (Au) Plating, cuits 538- 134-0002
adhere to the weight		PRU PRU-PCB-PHR001 The PCB shall weigh less than 25 grams		PRU-PCB 1500001E Design Files	N/A		PX PXS- VEPROT001
PXS S-PHR004 The ParagitPX system shall adhere to the size budget outlined in this requirement PRU PCB widt PRU PCB		PRU PRU-PCE PCB shall hav width of 2.5 c	B-PHR004 The re a maximum Cm B-PHR005 The re a maximum	PHR004 The a maximum PRU-PCB 1500001E STEP drawin PHR005 The a maximum		drawing	
thickness of (3-PHR002 The					





PX S-UR004 The ParagitPX system shall have haptic feedback of at least 0.00196newtons of force	PRU PRU-PCB-FR006 The PCB shall feature a vibration motor capable of generating at least 0.00196 newtons of force	PRU-PCB Vibration Motor, SMD, 12x6.8mm BLT-4312GC
PX S-UR005 The ParagitPX system shall have features to communicate status and errors to the user	PRU PRU-PCB-FR004 The PCB shall be equipped with an LED capable of emitting a brightness of at least 40 mcd	PRU-PCB LED IN-S66TFT5R5G5B datasheet
PX S-OR003 The ParagitPX system should store all data offline, locally on the device PX S-PR006 The system shall be able to store data corresponding to at least 24 hours of data	PRU PRU-PCB-FR005 The PCB shall feature local storage capabilities of 2 GB or more	PRU-PCB Alliance Memory NAND Flash AS5F38G04SND-08LIN Datasheet
PX S-FR005 The ParagitPX System shall be able to recharge from 0% to 100% via USB-C in a maximum of 6 hours PX S-FR006 The system shall be designed to ensure compatibility and interoperability with standard external computing devices for data management purposes.	PRU PRU-PCB-FR003 The PCB shall allow a USB-C connection to be established	PRU-PCB 1500001E PX PXS- PX PXS- STEP VEPROT003 VEPROT003
PX S-SR004 The system shall be designed to manage power efficiently and safely	PRU PRU-PCB-SR002 The PCB must include a NTC that shuts down operations if the temperature of the battery exceeds 45 degrees during charing	PRU-PCB NTC Leaded 10k 1% B3936 NXFT15XV103FEAB025



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	PRU PRU-PCB-FR002 The PCB			
PX S-PR010 The system	must maintain its integrity			
shall be durable	through 1.095 connection	PRU-PCB		
	cycles, ensuring that the	3 Pins	PX PXS-	PX PXS-
enough to withstand	electromyography (EMG) data	Connector	VEPROT002	VEPROT002
connection life cycles	quality, specifically the signal-	data sheet		
through the lifetime	to-noise ratio (SNR), does not			
	deteriorate (tolerance +/- 5%)			

Firmware Sub-System

Requirement Code	Requirements Folder	Description
PRU-FW	PRU-FW Design Input	Paragit Recording Unit Firmware Subsystem



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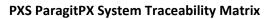


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PXS S-UR001 The ParagitPX system shall only provide
<u>user feedback</u> <u>when prompted</u>
by the user

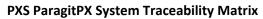
PRU PRU-FW-FR002 The firmware shall ensure that feedback is only provided when the device is prompted by the user

PRU-FW 1.0.5prod source code PXS PRU-FW-VEPR OT00 1



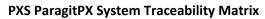


	PRU PRU-FW-
	PR005 The
	<u>Firmware</u>
PX S-FR002 The	subsystem shall
system shall	output two
quantify	individual DAC
<u>impedance</u>	signals within the
changes of at	1110-1120Hz and
least 100 ohm in	1210-1220Hz
order to estimate	range
the amount of	PRU PRU-FW-
accumulated	PR006 The
sweat between	Firmware
the electrodes	subsystem shall
	have a DAC
	amplitude within
	1-10mV
PX S-FR003 The	
system shall	PRU PRU-FW-
measure 3D	PR004 The
acceleration	<u>Firmware</u>
accurately in	subsystem shall
ranges typical for	measure 3D
	acceleration at a
<u>human</u>	sample rate
movement	between 95 and
during daily	<u>105 hz</u>
activity	
PX S-FR004 The	DD11 DD11 EW/
system shall	PRU PRU-FW-
measure 3D	PR002 The PRU
rotation	<u>Firmware</u>
accurately in	subsystem shall
ranges typical for	measure 3D
<u>human</u>	rotation within a
movement	range of ±2000
during daily	<u>°/s</u>
activity	
PX S-PR011 The	PRU PRU-FW-
system shall	FR001 The PRU
measure bio-	<u>Firmware</u>
potential signals	subsystem shall
accurately in	<u>sample</u>
ranges typical for	electromyograph
<u>human</u>	y (EMG) signals
ranges typical for	electromyograph



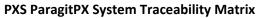


movement	at a minimum	
during daily	resolution of 14	
activity [0Hz -	<u>bits</u>	
500 Hz]		
	PRU PRU-FW-	
	PR001 The PRU	
	Firmware	
	subsystem shall	
	sample EMG	
	signals at a rate	
	between 2505	
	and 2510 Hz	
	PRU PRU-FW-	
DVC C DDOOF, The		
PXS S-PR005: The	PR003 The PRU	
ParagitPX system	<u>Firmware</u>	
shall be able	subsystem shall	
actively collect	adhere to the	
data over a	total power	
minimum of 24	consumption	
hours	specifications	
continuously	(defined in this	
	<u>requirement)</u>	
PX S-UR007 The	PRU PRU-FW-	
system shall be	FR010 The	
capable of	<u>firmware shall</u>	
accurately	allow the user to	
logging events	log a point of	
with precision to	interest	<u>PX</u>
the second	timestamp in the	PXS-
the second	<u>metadata</u>	<u>VEPR</u>
	PRU PRU-FW-	<u>OT00</u>
PX S-UR002 The	FR003 The	<u>3</u>
system shall have	<u>firmware must</u>	
the means to be	allow the PCB	
turned on/off	<u>button to</u>	
turned on/on	activate on/off	
	<u>operations</u>	





PX S-UR005 The ParagitPX system shall have features to communicate status and errors to the user	PRU PRU-FW-FR004 The firmware shall adhere to the guidelines in this requirement for communicating errors and status to the user	PXS PRU FW VEF	<u>J-</u> ' <u>-</u> PR
PX S-OR003 The ParagitPX system should store all data offline, locally on the device	PRU PRU-FW- FR005 The firmware shall store all data offline, locally on the device	<u>OT(</u> <u>1</u>	<u>00</u>
PX S-OR003 The ParagitPX system should store all data offline, locally on the device	PRU PRU-FW- SR001 The firmware shall not store personal data		
PX S-FR006 The system shall be designed to ensure compatibility and interoperability with standard external computing devices for data management purposes.	PRU PRU-FW-FR007 The firmware must configure the local storage to function as a USB drive when the device is connected to a PC with Windows operating system.	PXS PRU FW VEF OTO 1	<u>J-</u> '- PR
PX S-FR007 The system shall allow the user to see when a recording was	PRU PRU-FW-FR008 The firmware shall log start and end	P X P X S-	P X P X S-

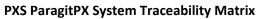




started and ended	time for a recording	V E P R O T O 0	V E P R O T O O 3
PX S-FR009 The system shall provide the user with the exact (+/- 0.1 Hz) sample rate that was used during a recording	PRU PRU-FW-FR009 The firmware shall log the the exact (+/- 0.1 Hz) sample rate that was used during a recording to the metadata	PXS PRI FW VEI OT	<u>U-</u> <u>/-</u> PR
PX S-FR005 The ParagitPX System shall be able to recharge from 0% to 100% via USB-C in a maximum of 6 hours	PRU PRU-FW-FR011 The firmware shall ensure that the battery is charged with 0,15 - 0,2 ampere	PX: PX: VEI OT: 3	PR

Sleeve Sub-System

Requirement Code	Requirements Folder	Description
PS	PS Design Input	Paragit Sleeve Subsystem





Parent requirement	Design Input	Design Output	Design Verification (Incl. protocol w. acc criteria)	Verification Records
PXS S-PHR001 The ParagitPX system shall be wearable for at	PS PS-PHR002 The Sleeve shall return to its original size when stretched to less than 50% beyond its original size		PXS verification tex	<u>ktile</u>
least 95% of users	PS PS-PHR004 The Sleeve shall be available in 4 sizes (defined within this requirement)		PXS verification tex	<u>ktile</u>
PXS S-ST001 CYTOTOXICITY System materials in touch with the skin, shall be made of biocompatible materials in accordance with ISO10993-5	PS PS-ST001 CYTOTOXICITY the Sleeve shall be made of biocompatible materials in accordance with ISO10993-5	PS Explosive Design Drawing	QMS EN ISO 10993-1:2020, PX Biological Compatibility Evaluation Plan	PX Biological Evaluation, PX Biological Risk Assessment, PX Biological Evaluation
PXS S-ST002 IRRITATION System materials in touch with the skin, shall be made of biocompatible materials in accordance with ISO10993-23	PXS S-ST002 IRRITATION System materials in touch with the skin, shall be made of biocompatible materials in accordance with ISO10993-23		QMS EN ISO 10993-1:2020, PX Biological Compatibility Evaluation Plan	PX Biological Evaluation, PX Biological Risk Assessment, PX Biological Evaluation





PXS S-ST003 CHEMICAL CHARACTERIZATI ON System materials in touch with the skin, shall be made of biocompatible material in accordance with ISO10993-18	PS PS-ST003 CHEMICAL CHARACTERIZATI ON The sleeve shall be made of biocompatible material in accordance with ISO10993-18		QMS EN ISO 10993-1:2020, PX Biological Compatibility Evaluation Plan	PX Biological Evaluation, PX Biological Risk Assessment, PX Biological Evaluation
PXS S-PHR003 The ParagitPX system shall adhere to the weight budget outlined in this requirement	PS PS-PHR005 The Sleeve's weight shall not exceed 25 grams.		PXS verification tex	<u>ktile</u>
PXS S-PHR004 The ParagitPX system shall adhere to the size budget outlined in this requirement	PS PS-PHR004 The Sleeve shall be available in 4 sizes (defined within this requirement)	PS non- conductive base textile		
Risk management, RU-05	PS PS-UR001 The Sleeve should contain a mark guiding the user on how place it correctly	PS Explosive Design Drawing	N/A	





PX S-OR002 The		
ParagitPX System		
shall be		
constructed such		
that only the		
components in		
contact with the		
skin must be able		
to withstand a	PS PS-FR002 The	
minimum of 10	sleeve shall be	
wash cycles at 30	able to withstand	
degrees Celsius	a minimum of 10	
with less than 5%	wash cycles at 30	PS Gecko Electrodes
degradation EMG	degrees Celsius	13 decko Liectiodes
signal to noise	with less than 5%	
<u>ratio.</u>	degradation in	
PX S-OR004 The	EMG signal to	
ParagitPX system	noise ratio.	
shall be able to		
<u>withstand</u>		
<u>appropriate</u>		
cleaning during		
<u>its lifetime</u>		
without		
<u>performance</u>		
degradation		
PX S-FR002 The	PS PS-PHR006	
system shall	The sleeve shall	
quantify	exclusive feature	
impedance	electrodes with a	PS Gecko Electrodes
changes of at	<u>maximum</u>	
least 100 ohm in	impedance of	
order to estimate	250 kilo ohm	
the amount of		
accumulated		
sweat between		
the electrodes		





	PS PS-FR004 The sleeve shall feature one reference electrode to evaluate impedance changes	PS Explosive Design Drawing
PX S-PR011 The system shall measure bio-potential signals accurately in ranges typical for human movement during daily activity [OHz - 500 Hz]	PS PS-FR003 The sleeve shall feature at least two electrodes for one bi-polar measurement of EMG	
PXS S-PHR006 The system must be designed to be universally wearable, accommodating placement on any part of the body.	PS PS-FR005 The sleeve shall be designed to fit on lower limbs (arms and legs)	PS non-conductive base textile

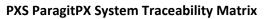


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PX S-PR010 The system shall be durable enough to withstand connection life cycles through the lifetime	PS PS-FR001 The Sleeve must maintain its integrity through 365 connection cycles, ensuring that the electromyograph y (EMG) data quality, specifically the signal-to-noise ratio (SNR), does not deteriorate (tolerance +/- 5%)	PS Sleeve Adapter PS Connector Disc	PX PXS-VEPROT002
PX S-OR005 The ParagitPX system shall be active only when it is disconnected from the charger	PS PS-SR002 The sleeve shall ensure that the PRU cannot be charged while connected to the sleeve	PS Sleeve Adapter	
PXS S-SR001 The Paragit PX system shall have soft edges with a radius of at least 2mm to avoid injury	PS PS-SR001 The connector on the sleeve have soft edges with a radius of at least 2mm to avoid injury		

Electrode Adapter Sub-System

Requirement Code	Requirements Folder	Description
PEA	PEA Design Input	Paragit Electrode Adapter Subsystem





Parent requirement	Design Input	Design Output	Design Verification (Incl. protocol w. acc criteria)	Verification Records
PXS S-PHR003 The ParagitPX system shall adhere to the weight budget outlined in this requirement	PEA PEA-PHR001 The electrode adapter shall weight less than 25 grams	PEA Design Drawing	PX PXS-VEPROTOO:	<u>1</u>
PXS S-PHR004 The ParagitPX system shall adhere to the size budget outlined in this requirement	PEA PEA-PHR002 The electrode adapter shall have a maximum length of 15 cm PEA PEA-PHR003 The electrode adapter shall have a maximum width of 3 cm PEA PEA-PHR004 The electrode adapter shall have a maximum width of 1,5 cm			
PX S-FR002 The system shall quantify impedance changes of at least 100 ohm in order to estimate the amount of accumulated sweat between the electrodes PX S-PR011 The system shall measure biopotential signals accurately in ranges typical for human	PEA PEA-FR003 The electrode adapter shall feature at least one snap-on button for a reference gel electrode to evaluate impedance changes PEA PEA-FR002 The electrode adapter shall feature snap-on button for at least 2 gel electrodes for bi-	PEA Design Drawin	ng	





movement	polar					
during daily	measurement of					
activity [OHz -	EMG					
	EIVIG					
500 Hz]	DEA DEA EDOOE					
	PEA PEA-FR005					
	The electrode					
	adapter shall					
	<u>feature snap-on</u>					
	buttons for gel					
PXS S-PHR006 The system must be designed to be universally wearable,	<u>electrodes</u>					
	embedded in a					
	<u>fixed based for</u>					
	flexible body					
	placement					
	PEA PEA-FR004					
accommodating	The electrode					
placement on	adapter must be					
any part of the	capable of					
	bending up to 45	DEA Design Drawing				
body.	degrees and then					
	returning to its	PEA Design Drawing				
	original shape to					
	<u>facilitate</u>					
	placement on					
	various parts of					
	the body					
	PEA PEA-FR001					
	The electrode					
	adapter must					
	maintain its					
	integrity through					
PX S-PR010 The	365 connection					
system shall be	cycles, ensuring					
durable enough	that the					
to withstand	electromyograph	PEA Design	PX PXS-	PX PXS-		
connection life	y (EMG) data	Drawing	VEPROT002	VEPROT002		
cycles through	quality,					
the lifetime	specifically the					
are meane	signal-to-noise					
	ratio (SNR), does					
	not deteriorate					
	(tolerance +/-					
	<u>5%)</u>					



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	PEA PEA-SR002	
PX S-OR005 The	The electrode	
ParagitPX system	adapter shall	
shall be active	ensure that the	
only when it is	PRU cannot be	
disconnected	charged while	
from the charger	connected to the	
	<u>adapter</u>	PEA Design Drawing
PXS S-SR001 The	PEA PEA-SR001	
Paragit PX	The electrode	
system shall have	adapter shall	
soft edges with a	have soft edges	
radius of at least	with a radius of	
2mm to avoid	at least 2mm to	
<u>injury</u>	avoid injury	

Flex Adapter Sub-System

Requirement Code	Requirements Folder	Description
PFA	PFA Design Input	Paragit Flex Adapter Subsystem

Parent requirement	Design Input	Design Output	Design Verification (Incl. protocol w. acc criteria)	Verification Records
PXS S-PHR003 The ParagitPX system shall adhere to the weight budget outlined in this requirement	PFA PFA-PHR001 The flex adapter shall weigh less than 25 grams	PFA Design STEP file	PX PXS-VEPROTOO:	<u>1</u>



PXS S-PHR004 The ParagitPX system shall adhere to the size budget outlined in this requirement	PFA PFA-PHR002 The flex adapter shall have a maximum length of 5 cm	PFA Design STEP file





	PFA PFA-PHR003
	The flex adapter
	shall have a
	maximum width
	of 3 cm
	PFA PFA-PHR004
	The flex adapter
	shall have a
	maximum
	thickness of 1,5
	<u>cm</u>
PX S-FR002 The	
system shall	PFA PFA-FR003
quantify	The flex adapter
impedance	shall feature at
changes of at	least 1 snap-on
least 100 ohm in	button for a gel
order to estimate	electrode to
the amount of	evaluate
accumulated	impedance
sweat between	measures
the electrodes	
PX S-PR011 The	
system shall	PFA PFA-FR002
measure bio-	The flex adapter
potential signals	shall feature at
accurately in	least 2 snap-on
ranges typical for	buttons for gel
human	electrodes for bi-
movement	polar
during daily	measurement of
activity [0Hz -	EMG
500 Hz]	
PXS S-PHR006	PFA PFA-FR004
The system must	The flex adapter
be designed to	shall exclusively
be universally	feature snap-on
wearable,	buttons
accommodating	connected to a
placement on	base via wires
any part of the	
body.	





PX S-PR010 The system shall be durable enough to withstand connection life cycles through the lifetime	PFA PFA-FR005 The flex adapter shall feature a strap to support flexible body placement PFA PFA-FR001 The flex adapter must maintain its integrity through 365 connection cycles, ensuring that the electromyograph y (EMG) data quality, specifically the signal-to-noise ratio (SNR), does not deteriorate (tolerance +/-5%)	PFA Design STEP file	PX PXS- VEPROT002	PX PXS- VEPROT002
PX S-OR005 The ParagitPX system shall be active only when it is disconnected from the charger	PFA PFA-SR002 The flex adapter shall ensure that the PRU cannot be charged while connected to the adapter	PFA Design STEP fil	l <u>e</u>	
PXS S-SR001 The Paragit PX system shall have soft edges with a radius of at least 2mm to avoid injury	PFA PFA-SR001 The flex adapter shall have soft edges with a radius of at least 2mm to avoid injury			

Revision History



Version: 2.1 Status: Draft

The table below presents the major changes and tasks for this document.

Version	Date	Change/Action	Author
1.0	2024-03- 05	Create	Mathias Stephensen (MAST)
1.1	2024-03- 05	Update	Mathias Stephensen (MAST)
1.2	2024-03- 05	Update	Mathias Stephensen (MAST)
1.3	2024-03- 05	Update	Mathias Stephensen (MAST)
1.4	2024-03- 05	Update	Mathias Stephensen (MAST)
1.5	2024-03- 05	Update	Mathias Stephensen (MAST)
1.6	2024-03- 05	Update	Mathias Stephensen (MAST)
1.7	2024-03- 05	Update	Mathias Stephensen (MAST)
1.8	2024-03- 08	Update	Mathias Stephensen (MAST)
1.9	2024-03- 08	Update	Mathias Stephensen (MAST)
1.10	2024-03- 08	Update	Mathias Stephensen (MAST)
1.11	2024-03- 08	Update	Niklas Sarup-Lytzen (NISA)
1.12	2024-03- 08	Update	Mathias Stephensen (MAST)
1.13	2024-03- 08	Update	Mathias Stephensen (MAST)
1.14	2024-03- 08	Update	Mathias Stephensen (MAST)
1.15	2024-03- 08	Update	Mathias Stephensen (MAST)
1.16	2024-03- 08	Update	Mathias Stephensen (MAST)
1.17	2024-03- 08	Update	Mathias Stephensen (MAST)
1.18	2024-03- 08	Update	Mathias Stephensen (MAST)
1.19	2024-03- 08	Update	Mathias Stephensen (MAST)



1.21	2024-03- 08	Update	Mathias Stephensen (MAST)
1.22	2024-03- 08	Update	Mathias Stephensen (MAST)
1.23	2024-03- 08	Update	Mathias Stephensen (MAST)
1.24	2024-03- 08	Update	Mathias Stephensen (MAST)
1.25	2024-03- 08	Update	Mathias Stephensen (MAST)
1.26	2024-03- 08	Update	Mathias Stephensen (MAST)
1.27	2024-03- 08	Update	Niklas Sarup-Lytzen (NISA)
1.28	2024-03- 08	Update	Niklas Sarup-Lytzen (NISA)
1.29	2024-03- 08	Update	Mathias Stephensen (MAST)
1.30	2024-03- 08	Update	Mathias Stephensen (MAST)
1.31	2024-03- 12	Add pcb requirement for new researcher user need	Niklas Sarup-Lytzen (NISA)
1.32	2024-03- 12	Add DAC frequency requirement	Niklas Sarup-Lytzen (NISA)
1.33	2024-03- 12	Update	Mohammad Filfil (MOFI)
1.34	2024-03- 15	Update	Mohammad Filfil (MOFI)
1.35	2024-03- 19	Update	Mohammad Filfil (MOFI)
1.36	2024-03- 19	Туро	Niklas Sarup-Lytzen (NISA)
1.37	2024-03- 19	Update	Niklas Sarup-Lytzen (NISA)
1.38	2024-03- 19	Update	Niklas Sarup-Lytzen (NISA)
1.39	2024-03- 19	Update	Niklas Sarup-Lytzen (NISA)
1.40	2024-03- 19	Update	Niklas Sarup-Lytzen (NISA)
1.41	2024-03- 20	Update	Mohammad Filfil (MOFI)
1.42	2024-03- 20	Update	Niklas Sarup-Lytzen (NISA)



1.43	2024-03- 20	Update	Niklas Sarup-Lytzen (NISA)
1.44	2024-03- 20	Update	Niklas Sarup-Lytzen (NISA)
1.45	2024-03- 20	Update	Niklas Sarup-Lytzen (NISA)
1.46	2024-03- 20	Update	Niklas Sarup-Lytzen (NISA)
1.47	2024-03- 20	Update	Niklas Sarup-Lytzen (NISA)
1.48	2024-03- 20	Update	Niklas Sarup-Lytzen (NISA)
1.49	2024-03- 20	Update	Niklas Sarup-Lytzen (NISA)
1.50	2024-03- 20	Update	Mohammad Filfil (MOFI)
1.51	2024-03- 20	Update	Mohammad Filfil (MOFI)
1.52	2024-03- 20	Update	Mohammad Filfil (MOFI)
1.53	2024-03- 20	Update	Mohammad Filfil (MOFI)
1.54	2024-03- 20	Update	Mohammad Filfil (MOFI)
1.55	2024-03- 25	Update	Niklas Sarup-Lytzen (NISA)
1.56	2024-03- 26	Update	Mathias Stephensen (MAST)
1.57	2024-03- 26	Update	Mathias Stephensen (MAST)
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1.63	2024-03- 26	Update	Niklas Sarup-Lytzen (NISA)
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1.69	2024-03- 26	Update	Mathias Stephensen (MAST)
1.70	2024-03- 26	Update	Mathias Stephensen (MAST)
1.71	2024-03- 26	Update	Mathias Stephensen (MAST)
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1.89	2024-03- 26	Update	Niklas Sarup-Lytzen (NISA)
1.90	2024-03- 26	Update	Niklas Sarup-Lytzen (NISA)
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1.108	2024-03- 26	Update	Mohammad Filfil (MOFI)
1.109	2024-03- 27	Update	Niklas Sarup-Lytzen (NISA)
1.110	2024-04- 04	Update	Nikola Stojanovic (NIST)



1.111	2024-04- 04	Update	Nikola Stojanovic (NIST)
1.112	2024-04- 05	Update	Niklas Sarup-Lytzen (NISA)
1.113	2024-04- 05	Update	Niklas Sarup-Lytzen (NISA)
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1.119	2024-04- 05	Update	Niklas Sarup-Lytzen (NISA)
1.120	2024-04- 05	Restore to united version	Niklas Sarup-Lytzen (NISA)
1.121	2024-04- 05	Update	Niklas Sarup-Lytzen (NISA)
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1.139	2024-04- 05	Update	Niklas Sarup-Lytzen (NISA)
1.140	2024-04- 05	Update	Niklas Sarup-Lytzen (NISA)
1.141	2024-04- 05	Update	Niklas Sarup-Lytzen (NISA)
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1.145	2024-04- 05	Update	Niklas Sarup-Lytzen (NISA)
1.146	2024-04- 10	Update	Mathias Stephensen (MAST)
1.147	2024-04- 10	Update	Mathias Stephensen (MAST)
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1.154	2024-04- 10	Update	Mathias Stephensen (MAST)



1.155	2024-04- 10	Update	Mohammad Filfil (MOFI)
1.157	2024-04- 15	Update	Niklas Sarup-Lytzen (NISA)
1.158	2024-04- 15	Update	Niklas Sarup-Lytzen (NISA)
1.159	2024-04- 15	Update	Niklas Sarup-Lytzen (NISA)
1.160	2024-04- 15	Update	Niklas Sarup-Lytzen (NISA)
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1.165	2024-04- 15	Update	Niklas Sarup-Lytzen (NISA)
1.166	2024-04- 15	Update	Niklas Sarup-Lytzen (NISA)
1.167	2024-04- 15	Update	Mohammad Filfil (MOFI)
1.168	2024-04- 15	Update	Niklas Sarup-Lytzen (NISA)
1.169	2024-04- 15	Update	Niklas Sarup-Lytzen (NISA)
1.170	2024-04- 15	Update	Niklas Sarup-Lytzen (NISA)
1.171	2024-04- 15	Update	Mathias Stephensen (MAST)
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1.174	2024-04- 15	Update	Niklas Sarup-Lytzen (NISA)
1.175	2024-04- 15	Update	Mathias Stephensen (MAST)
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1.178	2024-04- 15	Update	Mathias Stephensen (MAST)
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1.184	2024-04- 15	Update	Niklas Sarup-Lytzen (NISA)
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1.191	2024-04- 15	Update	Mathias Stephensen (MAST)
1.192	2024-04- 15	Update	Niklas Sarup-Lytzen (NISA)
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1.196	2024-04- 15	Update	Mathias Stephensen (MAST)
1.197	2024-04- 15	Update	Mathias Stephensen (MAST)
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1.199	2024-04- 15	Update	Mathias Stephensen (MAST)



1.200	2024-04- 15	Update	Mathias Stephensen (MAST)
1.201	2024-04- 16	Update	Niklas Sarup-Lytzen (NISA)
1.202	2024-04- 16	Update	Niklas Sarup-Lytzen (NISA)
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1.208	2024-04- 16	Update	Mathias Stephensen (MAST)
1.209	2024-04- 16	Update	Niklas Sarup-Lytzen (NISA)
1.210	2024-04- 16	Update	Mohammad Filfil (MOFI)
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1.225	2024-04- 16	Update	Niklas Sarup-Lytzen (NISA)
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1.229	2024-04- 16	Update	Niklas Sarup-Lytzen (NISA)
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1.256	2024-04- 17	Update	Mathias Stephensen (MAST)
1.257	2024-04- 17	Update	Mathias Stephensen (MAST)
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1.264	2024-04- 17	Update	Niklas Sarup-Lytzen (NISA)
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1.307	2024-04- 19	Update	Niklas Sarup-Lytzen (NISA)
1.308	2024-04- 19	Update	Mathias Stephensen (MAST)
1.309	2024-04- 19	Update	Niklas Sarup-Lytzen (NISA)



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1.314	2024-04- 19	Update	Mathias Stephensen (MAST)
1.315	2024-04- 20	Update	Mathias Stephensen (MAST)
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1.329	2024-04- 21	Update	Mathias Stephensen (MAST)
1.330	2024-04- 21	Update	Mathias Stephensen (MAST)
1.331	2024-04- 22	Update	Niklas Sarup-Lytzen (NISA)





1.332	2024-04- 22	Update	Niklas Sarup-Lytzen (NISA)
1.333	2024-04- 22	Update	Niklas Sarup-Lytzen (NISA)
1.334	2024-04- 22	Update	Mathias Stephensen (MAST)
1.335	2024-04- 22	Update	Mathias Stephensen (MAST)
1.336	2024-04- 22	Update	Mathias Stephensen (MAST)
1.337	2024-04- 22	Updated verification for the firmware	Mathias Stephensen (MAST)
1.338	2024-04- 22	Update	Mathias Stephensen (MAST)
1.339	2024-04- 22	Update	Mathias Stephensen (MAST)
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1.354	2024-04- 23	Update	Mathias Stephensen (MAST)
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1.358	2024-04- 23	Update	Mathias Stephensen (MAST)
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1.360	2024-04- 23	Update	Niklas Sarup-Lytzen (NISA)
1.361	2024-04- 23	Update	Niklas Sarup-Lytzen (NISA)
1.362	2024-04- 23	Update	Mathias Stephensen (MAST)
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1.374	2024-04- 23	Update	Mathias Stephensen (MAST)
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1.376	2024-04- 23	Update	Mathias Stephensen (MAST)
1.377	2024-04- 23	Update	Mathias Stephensen (MAST)
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1.381	2024-04- 24	Update	Mathias Stephensen (MAST)
1.382	2024-04- 25	Update	Mathias Stephensen (MAST)
1.383	2024-04- 25	Update	Nikola Stojanovic (NIST)
1.384	2024-04- 25	Update	Nikola Stojanovic (NIST)
1.385	2024-04- 25	Update	Nikola Stojanovic (NIST)
1.386	2024-04- 26	Ready	Mathias Stephensen (MAST)
1.386	2024-04- 26	TSK-1563 Reviewed	Niklas Sarup-Lytzen (NISA)
2.0	2024-04- 26	Publish	Niklas Sarup-Lytzen (NISA)
2.1	2024-06- 04	Update	Niklas Sarup-Lytzen (NISA)

Attached Files

The table below list the list of files which are attached to this document at the moment of export.

File Name	Upload Date	Size	SHA256
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Acceptance Tasks

The table below list the accomplished Acceptance tasks for this document.

Completion Date	Version	Completed by	Method	Description	
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Signatures Tasks



Version: 2.1 Status: Draft

The table below presents the accomplished Signature tasks for this document.