深圳讯丰通医疗股份有限公司
Shenzhen XFT Medical Limited

Biocompatibility Evaluation

受控正本

Product Name:	Nerve and Muscle Stimulator
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Related Documents		
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Revision Record

Version	Description of the Revision	Revised by	Effective Date
C	Initial issued	Li Fei	2020. 7. 28

1 The product name and model

Trade name: Hand Rehab System
Product name: Nerve and Muscle Stimulator
Model: XFT-2003EA

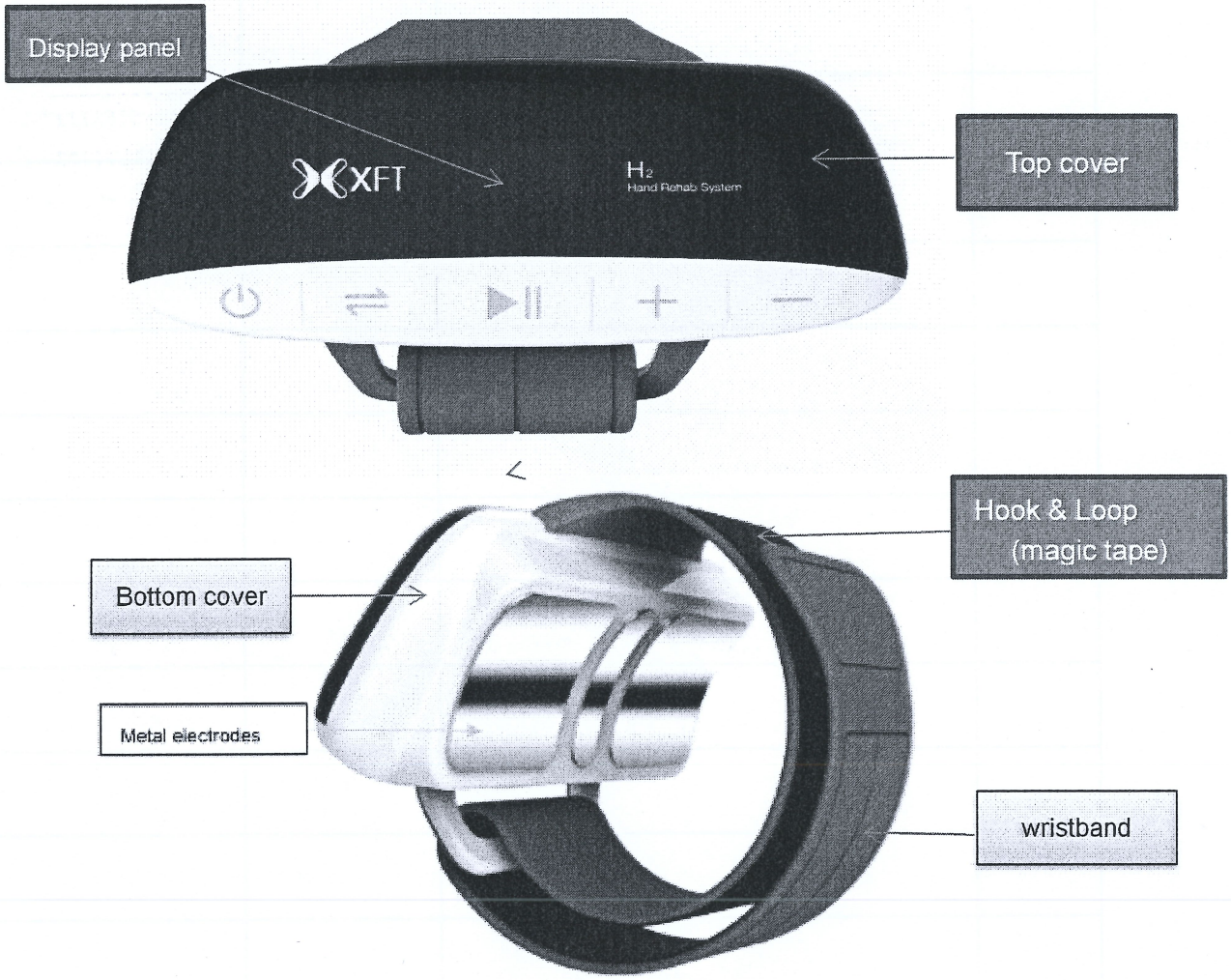
2 The purpose of evaluation

Nerve and Muscle Stimulator (Model: XFT-2003EA) is the final product which need perform as intended and be safe for human use, especially including a biological evaluation according to FDA guidance- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process.

3 Evaluation of medical device

3.1 Materials/components in contact with the human body

3.1.1 Illustration of accessible components



3.1.2 List of patient contact components

Model#	Components	Patient contact material	Body Contact Location	Contact duration
XFT-2003EA	Top cover	ABS920	Indirect contact, patient hand may contact it during operation	More than 30days
	Bottom cover	PC+SUS316	Indirect contact, patient hand will contact it during operation	More than 30days
	Metal electrode	SUS316	Direct contact, patient hand will contact it during operation	More than 30days
	Wristband	ABS920+TPE(534 U)+SUS316	Direct contact, patient hand will contact it during operation	More than 30days
	Hook & Loop (magic tape)	Imported nylon non-scratch 6210 Velcro, Imported nylon non-scratch 6210 Velcro	Indirect contact, patient hand may contact it during fasten the cuff.	More than 30days
	Display panel	PC	Indirect contact, patient hand will contact it during operation	More than 30days

Note: The above materials are very common in daily life, these materials have the characteristic of has a high performance due to its high resistance to mechanical damage and protection from environmental factors. So, they have been widely used an applied in the medical industry recent years.

3.2 According to the description of section 3.1.1 and 3.1.2 in this document, the device can be considered as a surface device and contact with the intact skin of the body, the contact duration is less than 24 hours. Therefore, the device is categorized as "A" in according to Table A.1 of FDA guidance- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process. The risk of adverse reaction such as in vitro cytotoxicity, skin irritation and skin sensitization should be considered.

Table A.1: Biocompatibility Evaluation Endpoints

Medical device categorization by			Biological effect												
Nature of Body Contact		Contact Duration													
Category	Contact	A – limited (≤24 h) B – prolonged (>24 h to 30 d) C – permanent (> 30 d)	Cytotoxicity	Sensitization	Irritation or Intracutaneous Reactivity	Acute Systemic Toxicity	Material-Mediated Pyrogenicity	Subacute/Subchronic Toxicity	Genotoxicity	Implantation	Hemocompatibility	Chronic Toxicity	Carcinogenicity	Reproductive/Developmental Toxicity#	Degradation@
Surface device	Intact skin	A	X	X	X										
		B	X	X	X										
		C	X	X	X										
	Mucosal membrane	A	X	X	X										
		B	X	X	X	O	O	O		O					
		C	X	X	X	O	O	X	X	O		O			
	Breached or compromised surface	A	X	X	X	O	O								
		B	X	X	X	O	O	O		O					
		C	X	X	X	O	O	X	X	O		O	O		
External communicating device	Blood path, indirect	A	X	X	X	X	O				X				
		B	X	X	X	X	O	O			X				
		C	X	X	O	X	O	X	X	O	X	O	O		

3.3 Evaluation endpoints for consideration

Model	Components	Material	Corresponding Bio-compatibility Test		
			In Vitro Cytotoxicity	Skin Sensitization	Skin Irritation
XFT-2003EA	Top cover	ABS920	ISO10993-5: 2009 Biological evaluation of medical devices -Part 5: Tests for in vitro cytotoxicity	ISO10993-10: 2010 Biological evaluation of medical devices -Part 10: Tests for irritation and delayed-type hypersensitivity	ISO10993-10: 2010 Biological evaluation of medical devices -Part 10: Tests for irritation and delayed-type hypersensitivity
	Bottom cover	PC+SUS316			
	Metal electrode	SUS316			
	Wrist band	ABS920+TPE(534 U)+SUS316			
	Hook & Loop (magic tape)	Imported nylon non-scratch 6210 Velcro, Imported nylon non-scratch 6210 Velcro			
	Display panel	PC			

4 Biological Safety Testing Results

Model	Test Item	Test Report Number	Test Result
XFT-2003EA	In Vitro Cytotoxicity	SDWH-M201900697-1（E）(007_ In Vitro Cytotoxicity Test)	The result showed that the test article has no potential toxicity
	Skin Sensitization	SDWH-M201900697-3（E）(007_ Skin Sensitization Test Using Sesame Oil Extract); SDWH-M201900697-2（E）(007_ Skin Sensitization Test Using 0.9% Sodium Chloride Injection Extract)	The results showed that the test article has no significant evidence of causing skin sensitization
	Skin Irritation	SDWH-M201900697-5（E） Amd01(E) (007_Skin Irritation Test Using Sesame Oil Extract); SDWH-M201900697-4（E）(007_Skin Irritation Test Using 0.9% Sodium Chloride Injection Extract)	The test results showed that the response of the test article extract was categorized as negligible under the test condition

5 Conclusion

The biocompatibility test result shows that the materials which used for the device did not have any potential toxicity, skin sensitization and skin irritation. In

conclusion, the biocompatibility of the Nerve and Muscle Stimulator (Model: XFT-2003EA,) conforms to the intended use and regulation requirement.