CLINICAL EVALUATION REPORT

Product Name:	Nerve and Muscle Stimulator
Product Model	XFT-2003EA
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Prepared by:		**Date:**
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Approved by:		**Date:**

Revision History

Revision Record			
Ver.	Revision description	Reviser	Date
C	The first edition	Li Fei	
C1	Adjust file format	Li Fei	

Content

1 Summary

The current clinical evaluation of Pelvic Muscle Trainer (Model XFT-2003EA) is conducted according to MEDDEV 2.7/1 revision 4, June 2016, “CLINICAL EVALUATION: A guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC”. The clinical evaluation is submitted to the MDD as amended by directive 2007/47/EC.

The risks of XFT-2003EA are predetermined by their plans, requirements, design, laboratory documentation and clinical trial reports. Please refer to the Risk management report for details.

The XFT-2003EA is not designed and developed using new technologies, but in line with the current level of the state of the art.

2 Scope of the clinical evaluation

2.1 General information

Product Name:	Nerve and Muscle Stimulator
Product Models:	XFT-2003EA
Name of Manufacturer:	Shenzhen XFT Medical Limited
Address of Manufacturer:	Room 203 Building 1, Biomedicine Innovations Industrial Park, #14 Jinhui Road, Pingshan District, Shenzhen, China
Software version:	Embedded：V 1.1.0 APP:V1.1.3
Product Size:	134mm（±0.3mm）*91mm（Ref）*82mm（Ref）
Accessories:	Charger
Regulatory status	☐Being developed ☑-Undergoing initial CE-marking ☐CE-marked

Market information	☑ The device is currently on the market in Europe or in other countries. ☑The device is currently not listed in the EU and its member states, and is only listed in the People's Republic of China.

2.2 Product description

XFT-2003EA detects and monitors the EMG muscle activity signal of a patient and delivers an electrical stimulation pulses according to EMG signal strength to stimulate the patient in order to achieve a muscle contraction. With multiple training modes and interactive gaming applications patients can actively participate in the rehabilitation process and receive treatment with greater enjoyment and customization. The device is also equipped with an evaluation function to establish baseline data and threshold levels as well as track rehabilitation progress to help medical professionals customize evidence based, objective and effective rehabilitation treatment programs for each patient.

2.3 Intended use/indications for use

Functional Electrical Stimulation (FES)

Improvement of hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury.

Neuromuscular Electrical Stimulation (NMES)

1）Increase or maintain hand range of motion

2）Reduce muscle spasms

3）Retard muscle atrophy

4）Reeducate muscles

5）Increase local blood circulation

2.4 Contraindications

- Patients with heart disease, severe hypertension and skin disorder are forbidden to use this product.

- ❖ Patients with epilepsy are forbidden to use this product.
- ❖ Patients with active hemorrhage, acute purulent Inflammation, malignant neoplasms, thrombophlebitis, sepsis and cardiopulmonary failure are forbidden to use this product.

2.5 Safety classification

- ✶ Shock proof type :Class II, internal power device
- ✶ Shock proof degree: BF device
- ✶ Degree of protection by the host enclosure: IP67

2.6 Construction

The device XFT-2003EA consists of the host, Stimulator, Power Adapter ,charging cable and APP (optional).

1. Power/Mute

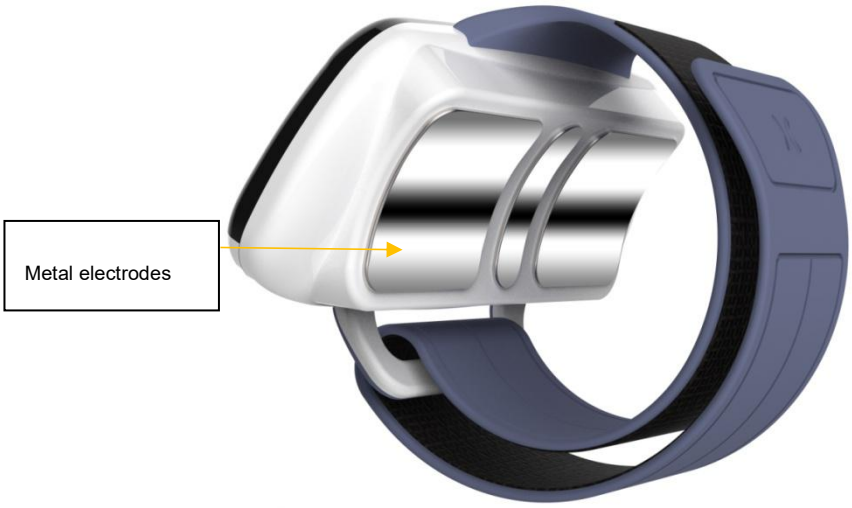
Product Parts, Icon and Buttons

Stimulator

Parts

Power Adapter charging cable

3.2.1 Operation button instruction



This device has 5 buttons and 1 charging port.

- Power Button: Press and hold for 1 second to turn on / turn off the stimulator.
- Mode Button:

  a) Switch among the Modes.

  b) Press and hold the mode button for 2 seconds to switch the language. The product serial number and software version will display at the same time.

  c) Turn on the Stimulator, when the logo displays, press and hold both power button and mode button for 5 seconds to restore factory setting.
- Play/Pause Button: press to start or pause the treatment, or confirm the language
- Intensity Buttons: Adjust the stimulation intensity during operation. User can feel the stimulation when increasing the intensity.

  At 0-10mA, the current will increase in 1mA increment;

  At 10-30mA, the current will increase in 0.5mA increment;

  For more than 30mA, the current will increase in 0.1mA increment;
- Magnetic charging port: For battery charging.

2.7 Claims on clinical performance and clinical safety foreseen by XFT

The XFT-2003EA Nerve and Muscle Stimulator has got been CE marketed, either do other markets. And the adverse event reports related with Nerve and Muscle Stimulator were seldom found in MAUDE adverse events database.

通过在国家食品药品监督管理总局发布的《医疗器械不良事件信息通报》、《医疗器械警戒快讯》、《医疗器械召回》，美国食品药品管理局申请人与用户机构设备使用数据库（MAUDE），英国医疗器械通过同品种医疗器械的临床研究数据集、投诉和不良事件数据集与临床风险相关的纠正措施数据集的分析总结，可知同品种医疗器械生物刺激反馈（型号：SA9800 或 T9800）有较好的临床有效性，且无相关安全问题记录或报道，其临床使用收益大于风险，因此可证实该同品种医疗器械生物刺激反馈仪（型号：SA9800 或 T9800）是安全有效的。警报（MDA）等未找到相关的投诉和不良事件数据。

2.8 Data sources and types of data

Clinical data for XFT-2003EA is from the following three sources:

1) Adverse event report from LE Medical;

2) Literatures searched;

3) Clinical data from demonstrated equivalence device.

2.9 PMS activity

PMS activity's plan:

- Regularly update the clinical evaluation report.
- Record feedback from customers in "Customer Information Record", and keep up to date the Customer's service record.
- In case of any abnormity, or potential abnormity, the product should be reviewed according to its risk severity as well as its components and materials, even its contribution approach should be traced for investigation.
- Regularly summarize the record data from customer's questionnaire.

PMCF study：

- The data collected should be reviewed and determined if a post-market clinical follow-up study is necessary. If after analysis, the new data will not lead to new risks, and will not affect the acceptance level or occurrence frequency of existing risks, it is considered that a PMCF study is not necessary to conduct. If the new data will lead to new significant risks, or lead to significant changes in acceptance level or occurrence frequency of existing risks, which is considered that a PMCF study should be considered to conduct. The PMCF study should be designed on the basis of the new collection data.

3 Clinical background, current knowledge, state of the art

Stroke is one of the three major diseases that currently cause death in humans. Among them, 70% to 80% of stroke patients become disabled, and they lose their independent living ability and work ability to varying degrees, which brings a heavy burden to society and families. In order to reduce the disability rate, rehabilitation therapy has become an indispensable part. Early rehabilitation training can reduce the disability rate and improve the quality of life, which is an important means to promote the recovery of the life ability of stroke patients. The electromyography feedback technique was successfully developed in 1967 by American psychologist Miller, who believed that through exercise, people can control the activities of their organs at will, thus changing their pathological state and gradually recovering their healthy functions.

Functional disorders caused by stroke are mainly caused by motor dysfunction, which seriously affects patients' ability of daily living activities, and causes a heavy burden on families and society. Operational electromyography biofeedback therapy is a relatively new rehabilitation therapy technology, which has been gradually applied in the rehabilitation of motor function after stroke in recent years. This technique uses Nerve and Muscle Stimulator to convert EMG signals generated by human activities into visual and auditory signals in real time, and feedback to the cerebral cortex so that people can

understand the movement of the nervous system to muscles in time. Control the situation, compare the intentional motion output with the exercise program, guide or correct the exercise, and gradually learn to control and adjust it freely. Many foreign studies have confirmed that the application of this therapy to post-stroke motor function recovery has a positive effect.

3.1 Brief summary of literature searching

We obtained may data related to the device through some literatures, which are listed in the following Table 1, and categorized them according to whether the data address performance or safety of the device. And we conducted appraisal for literatures on methodology and scientific validity, and data's relevance and contribution according to the appraisal criteria defined in Table 2, 3, 4 in Clause 3.1.1, for details, please refer to Clause 4.5.

Table 1 Selected literatures

No	Title of Literature	P/S	Imp.	Remarks
A1	Effects of biofeedback treatment on gait in children with cerebral palsy	P	L1	Clinical literature
A2	Muscle Recruitment and Coordination following Constraint-Induced Movement Therapy with Electrical Stimulation on Children with Hemiplegi	P	L1	Clinical literature
A3	Neuromuscular electrical stimulation in neurorehabilitation	P	L1	Clinical literature
A4	The effects of training using EMG biofeedback on stroke patients upper extremity functions.	P+S	L1	Clinical literature
A5	Powered muscle stimulator and biofeedback device 510K 053266	/	L1	Clinical literature
A6	Upper extremity motor training of a subject with initially motor complete chronic high tetraplegia using	P	L1	Clinical literature

No	Title of Literature	P/S	Imp.	Remarks
	constraint-induced biofeedback therapy			

3.1.1 Appraisal criteria

1) Appraisal Criteria for methodological quality of work and scientific validity of the information

Table 2 Criteria for MV

Suitability Criteria	Description	Grading system
Adequacy of the sample size and power calculation	Yes	1
	Can't answer or no	0
	Not applicable	0.5
Adequacy and relevance of follow-up period	Yes	1
	Can't answer or no	0
	Not applicable	0.5
Adequacy of applied controls	Yes	1
	Can't answer or no	0
	Not applicable	0.5
Adequacy of inclusion and exclusion criteria, and of stratification of patients	Yes	1
	Can't answer or no	0
	Not applicable	0.5
Distribution of prognostic factors	Yes	1

Suitability Criteria	Description	Grading system
	Can't answer or no	0
	Not applicable	0.5
Blinding of patients	Yes	1
	Can't answer or no	0
	Not applicable	0.5
Reliability of the methods used for quantifying symptoms and outcomes	Yes	1
	Can't answer or no	0
	Not applicable	0.5
Adequate recording and reporting of serious adverse events and device deficiencies	Yes	1
	Can't answer or no	0
	Not applicable	0.5
Adequate handling of medications and concomitant interventions	Yes	1
	Can't answer or no	0
	Not applicable	0.5
Adequacy of procedures for retrieving complete information	Yes	1
	Can't answer or no	0
	Not applicable	0.5

1) Criteria for determining the relevance of the information to the clinical evaluation

Table 3 Criteria for R

Suitability Criteria	Description	Grading System
To what extent is the data generated representative of the device under evaluation?	- device under evaluation - equivalent device - benchmark device	3
	- other devices and medical alternatives	2
	- data concerning the medical conditions that are managed with the device	1
What aspects are covered?	- pivotal performance data - pivotal safety data	3
	- claims - identification of hazards - estimation and management of risks	2
	- establishment of current knowledge/ the state of the art - determination and justification of criteria for the evaluation of the risk/benefit relationship - determination and justification of criteria for the evaluation of acceptability of undesirable side-effects	1
	- determination of equivalence - justification of the validity of surrogate endpoints	1
Are the data relevant to the intended purpose of the device or to claims	- representative of the entire intended purpose with all patient populations and all claims foreseen for the device under	3

Suitability Criteria	Description	Grading System
about the device?	evaluation	
	- concerns specific models/ sizes/ settings, or concerns specific aspects of the intended purpose or of claims	2
	- does not concern the intended purpose or claims	0

2) Criteria for contribution of each data set

Based on their scientific validity and relevance, the data should be weighted according to their relative contributions. In the clinical evaluation report, data contribution is defined as scientific validity x relevance.

Table 4 Contribution of each data set

Data's contribution (R×MV)	Criteria
75~90	Prior accept
50~74	Accept
≤50	Refuse

3.2 Applicable standard and guidance

Table 5 List of applicable standards and guidance

No.	Standard's code	Guidance/Standard's title
01	IEC 60601-1:2005+A1:2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

02	IEC 60601-1-2:2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard - Electromagnetic disturbances - Requirements and tests
03	IEC 60601-1-11:2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
04	MEDDEV 2.7/1 rev.4	GUIDELINES ON MEDICAL DEVICES CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
05	MEDDEV 2.12.1 rev.8	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM
06	MEDDEV 2.12.2	GUIDELINES ON MEDICAL DEVICES POST MARKET CLINICAL FOLLOW UP STUDIES A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
07	EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
08	EN 1041:2008	Information supplied by the manufacturer of medical devices
09	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007- 10-01)
10	EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011)

		EN ISO 14155:2011/AC:2011
11	IEC 62304:2015	Medical device software - Software life-cycle processes
12	IEC 62366-1:2015	Medical devices - part 1:Application of usability engineering to medical devices
13	IEC 60601-1-6:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
14	ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
15	ISO10993-5：2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
16	ISO10993-10：2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
17	IEC 60529:2013	Degrees of protection provided by enclosures
18	IEC60601-2-10：2016	Medical electrical equipment -- Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
19	IEC 60601-2-40:2016	Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment

3.3 Clinical risk identification

Clinical hazards identified are listed as below:

Table 6 Clinical risk identification

Classification	No.	Hazard identified during Risk Management process	**Risk control**
Safety	12.1	Inappropriate energy supply	The instructions indicate that it is Nallowed to modify the product

Classification	No.	Hazard identified during Risk Management process	**Risk control**
			without authorization. User's Manual XFT-2003EA-A
	8.1.2	Electrical stimulation output exceeds the set value	The product inspection procedure stipulates that the electrical stimulation output detection method and the passing standard are tested in the production process of the product. Inspection work instruction (Q-WI-131)
Biocompatibility	7.1.1 7.1.2 7.1.3	Cototoxicity, irritation or allergy to skin may happen.	Metal electrode with medical grade material and random biocompatibility test. Biocompatibility test report： SDWH-M201900697-1（E） SDWH-M201900697-2（E） SDWH-M201900697-3（E） SDWH-M201900697-4（E） SDWH-M201900697-5（E）
	5.1	Risk of re-infection or cross-infection	Clean and disinfect before using the device again. User's Manual XFT-2003EA-A
Performance	8.1.1	Electrical stimulation output is lower than the set value	The product inspection procedure stipulates that the electrical stimulation output detection method and the passing standard are tested in the production process of the product.

Classification	No.	Hazard identified during Risk Management process	**Risk control**
			Inspection work instruction (Q-WI-131)
	8.1.2	Electrical stimulation output exceeds the set value	The product inspection procedure stipulates that the electrical stimulation output detection method and the passing standard are tested in the production process of the product. Inspection work instruction (Q-WI-131)
	8.1.3	Loss of electrical stimulation	The product inspection procedure stipulates that the electrical stimulation output detection method and the passing standard are tested in the production process of the product. Inspection work instruction (Q-WI-131)
	8.1.4	No electrical stimulation output	The product inspection procedure stipulates that the electrical stimulation output detection method and the passing standard are tested in the production process of the product. Inspection work instruction (Q-WI-131)
	8.2.1	EMG display value is low	The Product Inspection Procedure stipulates that the detection method of the EMG display value and the passing standard are tested in the production process of the product.

Classification	No.	Hazard identified during Risk Management process	**Risk control**
			Inspection work instruction (Q-WI-131)
	8.2.2	EMG display value is too large	The Product Inspection Procedure stipulates that the detection method of the EMG display value and the passing standard are tested in the production process of the product. Inspection work instruction (Q-WI-131)
	201.7.9.2.101 e）	The device’s performance will not be stable.	Instructions for use increase the warning that the high frequency device will cause the electrode to burn out or the machine is damaged. Use the User's Manual to increase the use of the product near shortwave or microwave (eg 1m), which may cause a warning of unstable output. Instructions for use increase warnings near the chest that increase the risk of heart fibrillation User's ManualXFT-2003EA-A
Performance +safety	17	The device has electromegnetic disturbance to other equipments surrounded.	Product EMC meets the requirements of electromagnetic compatibility standards. EMC test report number: TR1810150201

4 Device under evaluation

4.1 Type of evaluation

The current clinical evaluation is based on:

- Scientific literatures currently available;
- Clinical data in literatures related with demonstrated equivalence device;
- Adverse events report from MAUDE databse

4.2 Demonstration of equivalence

Comparison between XFT-2003EA and the equivalent device:

Table 7 Comparison between XFT-2003EA and Powered muscle stimulator and biofeedback devicer manufactured by Thought Technology Ltd

NESS H200 Wireless Hand Rehabilitation System by Bioness, Inc.

	Application products	Equivalent device	Equivalent device	**Evaluation**
	Nerve and Muscle Stimulator	NESS H200 Wireless Hand Rehabilitation System	MyoTrac Infiniti System	
Manufacturer	Shenzhen XFT Medical Limited	Bioness, Inc.	Thought Technology Ltd	NA
	❶ **Clinical aspects**			

Intended use	**Functional Electrical Stimulation (FES):** 1）Improvement of hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury. **Neuromuscular Electrical Stimulation (NMES)** ● 2）Increase or maintain hand range of motion ● 3）Reduce muscle spasms ● 4）Retard muscle atrophy ● 5）Reeducate muscles ● 6）Increase local blood circulation	**Functional Electrical Stimulation (FES):** - Improvement of hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury **Neuromuscular Electrical Stimulation (NMES):** - Maintenance and/or increase of range of motion - Prevention and/or retardation of disuse atrophy - Increase of local blood circulation -Reduction of muscle spasm -Muscle re-education	The MyoTrac Infiniti system is indicated or the ongoing treatment of the following conditions: Relaxation of Muscle Spasms, Prevention or retardation of disuse atrophy, increasing local blood circulation, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, Maintaining or increasing range of motion and Stroke Rehab by Muscle re-education. ● It is also used for Biofeedback, Relaxation & Muscle Re-Education purposes.	The intended use of the proposed device is identical to that of NESS H200 Wireless Hand Rehabilitation System .

Target population	Patients with hemiplegia due to stroke or other central nervous system injured.	Patients with hemiplegia due to stroke or other central nervous system injured.	Patients with motor function caused by stroke or other central nervous system injury.	Identical
Application area	Upper limbs	Upper limbs	Upper limbs, head and neck, abdomen, back, lower limbs, pelvic floor	The anatomical Sites of the proposed device is identical to that of NESS H200 Wireless Hand Rehabilitation System .
Adaptation di sease	Patients with Motor dysfunction	Patients with Motor dysfunction	Patients with Motor dysfunction	Identical
	❷ **Technical aspects regarding device equivalence**			
Product components	Stimulator (metal electrode, batteries included), Battery charger or power adapter,	• H200 Wireless Orthosis • H200 Wireless Control Unit • System Charger Set (with Y Cable)	skin conductance, temperature sensor, powerful multimedia biofeedback software and stress control kit	Identical

		• Control Unit Neck Strap • Control Unit Wrist Strap • Control Unit Belt Pouch • Orthosis Wrist Strap • H200 Wireless Cloth Electrodes • Cloth Electrode Mesh Bag • H200 Wireless FPL Panel • Large Thenar • Wrist Inserts • H200 Wireless User's Guide		
working principle	The electrical stimulation is triggered according to the intensity o sEMG signal which also means the intensity of	The H200 Wireless System is designed to treat the complications associated with	Combined neuromuscular electrical stimulation, sEMG triggered electrical stimulation,	Identical

	muscle strength, it stimulates the patient's muscle contraction function , and helps their limbs to achieve the voluntary contraction movement,as well as to train and repair patient's limb movement function, for preventing their muscle from atrophy. With a variety of modes of training, treatment of interactive game software, to improve patient treatment fun, enhance patient confidence for rehabilitation.. The product also has a medical assessment function of rehabilitation progress	upper limb impairment caused by stroke and other disorders of the central nervous system. The H200 Wireless System delivers electrical stimulation to the nerves of the muscles that control the hand. The H200 Wireless System may help to improve hand function and assist with tasks of daily living.	multimedia biofeedback therapy, psychotherapy, and surface EMG assessment to provide you with a high-level, all-round integrated solution.	

	and training level, which helps doctors to develop scientific and effective rehabilitation training and treatment programs for each patient.			

Working Mode	1. NMES 2. PAS 3. ETS 4. EMG 5. Multimedia Biofeedback FES	Stimulate（NMES、FES）	1.EMG 2.SEMG 3.STIM 4.EMG Trigger Stim	STIM and NMES express the same meaning. ETS and EMG-STIM have the same meaning. They all stimulate the patient's muscle contraction function by collecting electromyographic (EMG) signals to trigger electrical stimulation, so as to achieve the patient's muscle autonomic contraction movement, for training and repairing the patient's muscle motor function. . The game mode is connected to

				the external IPAD, which has no effect on the performance of the device. Therefore, it can be considered that the working modes of the two are equivalent.

Stim+EMG Biofeedback	Yes	NO	Yes	The proposed device is identical to that of MyoTrac Infiniti System (T9800).
EMG Ranges in μV	10-1000	NA	0-5, 0-10, 5-10, 0-20, 5-20, 10-20, 0-50, 10-50, 0-100, 50-100,0-200, 50-200, 100-200, 0-500,100-500, 0-1000, 0-2000	Not Identical
EMG Bandwidth	20-500Hz	NA	20-500Hz	The proposed device is identical to that of MyoTrac Infiniti System (T9800).
EMG Detection	Bipolar	NA	Bipolar	The proposed device is identical to that of MyoTrac Infiniti System (T9800).
Frequency	2Hz -100Hz（±10%）	20–45 Hz, 5-Hz resolution	2Hz – 100Hz	Not Identical

Wave form	Bidirectional symmetric balanced wave	symmetrical	Asymmetric balanced pulse	Identical
Pulse width	50μs～450μs（±10%）	100μs，200μs，300μs	50～400μs	Similar. This part of the equipment technical indicators have been tested, the use of equipment safety and effectiveness of no effect.
Intensity	0—60mA (load 500Ω)	80mA (load 500Ω)	0 - 100mA at 500ohms	Not Identical
Power	1、DC 5V AC Power Adaptor 2、Rechargeable lithium battery 7.4V	Rechargeable Li-Ion 3.7 V, 280–350mAh	4AAA batteries, single use alkaline or Rechargeable battery pack 6V Medical Grade AC wall adaptor	Identical
Safety class	BF type application part	BF type application part	BF type application part	Identical

Working environment	Temperature: 5℃ -- 40 ℃ Relative humidity: ≤80%HR Atmos.: 86Kpa ~ 106Kpa	• Operating conditions temperature: 5°C to 40°C (• Operating conditions relative humidity: 15% to 93% • Charging temperature: 5°C to 40°C	/	Similar. This part of the equipment technical indicators have been tested, the use of equipment safety and effectiveness of no effect
Storage Environment	Temperature : -20℃ -- 55 ℃ Relative humidity : ≤93%HR Atmos : 70Kpa ~ 106Kpa	Transport and storage temperature: -25°C to +70°C; • Shipping pressure: 30 kPa (equivalent to approximately 9,100 meters above sea-level) for up to 10 hours	Store in its original case at up to 90% humidity / 30C°	
Product certified to the following standards	IEC 60601-1、 IEC60601-1-2、 IEC 60601-2-10、 IEC 60601-2-40	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	IEC 60601-1、 IEC60601-1-2、 IEC 60601-2-10、 IEC 60601-2-40	
	❸ **Biological aspects regarding device equivalent**			

Contact with the patient	Use biocompatible electrode pads，which to be contact directly with human skin surface	H200 Wireless Cloth Electrodes	K874469A AxelGaard for EMG or Stim. K935213 Electrodes Uni-Gelfor EMG only K903497A Triode Electrodes for EMG only K903497A Single Electrodes for EMG only	Not Identical
Relevant Standard	ISO 10993-5; ISO 10993-10;	ISO 10993-5; ISO 10993-10;	ISO 10993-5; ISO 10993-10;	Identical
	❹ **CE Marking**			
CE Marking	No	Yes C0086	Yes CE0413	--

Analysis:

Substantial Equivalence Discussion

EMG Ranges

The EMG ranges of the Nerve and Muscle Stimulator is within the range of for the predicate device of MyoTrac Infiniti System (SA9800). This modification does not raise any safety or effectiveness issues.

Power Source(s)

The power source is 7.4V rechargeable lithium battery compared to the power source of the predicate devices are Rechargeable Li-Ion 3.7 V, 280-350mAh of NESS H200 Wireless Hand Rehabilitation System and 4 AAA batteries, single use alkaline or Rechargeable battery pack of MyoTrac Infiniti System (SA9800). The 7.4V rechargeable lithium battery has been validated, this modification does not raise any safety or effectiveness issues.

Number of Output Modes

The Number of Output Modes of NESS H200 Wireless Hand Rehabilitation System is single output mode,the predicate device of MyoTrac Infiniti System （SA9800）) is Two output modes.the Nerve and Muscle Stimulator is three output modes.The waveform of the Nerve and Muscle Stimulator is the same as NESS H200 Wireless Hand Rehabilitation System, this modification does not raise any safety or effectiveness issues.

Max Output Current

The measured peak current at 500 ohms of the predicate device are 80mA and 100mA compared to 60mA r.m.s for the proposed device. The r.m.s current level for the proposed device is actually less than the predicate device. The Max Output current of the proposed device is 50mA r.m.s at 2K ohms and 10mA r.m.s at 10K ohm, the modification does not raise any safety or effectiveness issues since it meets the applicable requirements of IEC60601-2-10 "Particular requirements for the safety of nerve and muscle stimulators" specification of 80mA r.m.s Max.

Frequency(Pulses per second)

The Frequency of the proposed device are 2-100Hz (±10%) in NMES & ETS modes and 18Hz (±10%) in PAS mode.The Frequency of the predicate device are 20-45Hz and 2-100Hz.The Frequency of the Nerve and Muscle Stimulator is within the range of for the predicate device of MyoTrac Infiniti System (T9800). This modification does not raise any safety or effectiveness issues.

Pulse width

The Pulse width of the proposed device is 50-450μS compare to 50-400μS for the predicate device. The Pulse width of the Nerve and Muscle Stimulator is within the range of for the predicate device. This modification does not raise any safety or effectiveness issues.

Burst Mode

The Frequency of the proposed device are 2-100Hz (±10% or±2Hz) in ETS modes.The Pules width of the predicate device are 50-450 μ s(± 10%).The Output intensity of the predicate device are 0-60mA(± 10% or ± 2mA).The Frequency of the Nerve and Muscle Stimulator is within the range of for the predicate device of MyoTrac Infiniti System (T9800). This modification does not raise any safety or effectiveness issues.

Wireless communication

The proposed device use Blue tooth 4.0 to enable the communication of components compare to RF communication for the predicate device. The Bluetooth 4.0 has been validated, this modification does not raise any safety or effectiveness issues.

Substantial Equivalence Conclusion

This comparison of the specifications demonstrates the functional equivalence of the products.

The differences discussed in this section do not raise new issues of safety and effectiveness.

Verification and Validation testing demonstrated that no adverse effects have been introduced by these differences.

Based on the above information regarding the equivalent intended use and similar technological characteristics, Shenzhen XFT Medical Limited believes that the Nerve and Muscle Stimulator is as safe and effective, and performs in a substantially equivalent manner to the predicate device. The modifications do not raise any safety or effectiveness issues and meet the applicable requirements of IEC60601-2- 10 "Particular requirements for the safety of nerve and muscle stimulators." We conclude that the proposed Nerve and Muscle

Stimulator is substantially equivalent to the MyoTrac Infiniti System (T9800).

Equivalent equipment refers to the clinical use and clinical literature of products , which already on the market that are equivalent in terms of basic principles, structural composition, manufacturing materials, production processes, performance requirements, safety evaluation, standards compliance, and intended use.

When the company conducts clinical evaluation of the declared product through the clinical data of the equivalent equipment medical device, it demonstrates the equivalence between the declared product and the equivalent equipment.

To compare the declared products with equivalent equipment and detail the similarities and differences between the two. The comparison project should include, but is not limited to: the items listed in Annex 1, and the comparison includes qualitative and quantitative data, verification and validation results. It is recommended to provide comparative information in a list (Table 1). When the difference between the declared product and the same product has no effect on the safety and effectiveness of the declared product, the two are considered to be equivalent. Whether the difference between the declared product and the same product has an impact on the safety and effectiveness of the declared product can be verified and/or confirmed by non-clinical studies and/or clinical trials conducted outside China.

4.3 Clinical data generated and held by the manufacturer

Because the technology used to design Nerve and Muscle Stimulator has been very mature, there is no need about clinical investigation for the device, so there is no clinical data from the manufacturer.

And in the view of adverse event report from MAUDE database, there is nearly none adverse event reports related with Nerve and Muscle Stimulator. So such clinical data can not be used to evaluate the device's safety and performance.

4.4 Clinical data from literature

The data from literatures were obtained Pubmed and Medline, Clinicaltrials, etc. which produced the equivalent or similar products.

4.4.1 Literature search strategy

The scope of the literature search is consistent with the scope of clinical evaluation, involving the available pre and post market clinical data considering the intended use of the device, including data on clinical safety, benefit/risk, performance and side-effects.

a. Design features of the device or target treatment populations that require specific attention. In determining what kind of literatures need to be searched, the following aspects need to be considered:

- The design features that pose special performance or safety concerns (i.e. presence of medicinal, human or animal origin composition)
- The intended purpose and application of the device (i.e. target treatment group and disease, proposed warnings, contraindications and method of application) and
- The specific claims made by LE Medical about the clinical performance and safety of the device.

b. Determining whether data from equivalent devices can be used to support the safety and/or performance of XFT-2003EA.

c. Duration of search

March-April, 2018

d. Name of persons undertaking the literature search

Zhang Pande: evaluator of the clinical evaluation report

e. Period covered by search

f. Period covered by search

Jan. 2006~April. 2020

g. Literature sources used to identify data:

- Pubmed NCBI
- https://www.ncbi.nlm.nih.gov/pubmed/
- Clinicaltrials

http://ClinicalTrails.gov

The searching engines used are “Baidu”, “Binging”, or “Google”, the key words used for search are “surface electromyography biofeedback”, “upper limb dysfunction”, etc. The literatures selected involve data on performance, safety, side effect and risk.

h. Literatures after search outcome:

Table 8 List of literatures searched

No	Title of Literature	P/S	Imp.	Searched by
A1	Effects of biofeedback treatment on gait in children with cerebral palsy Search source: https://www.ncbi.nlm.nih.gov/pubmed/	S	L1	**Pub Med**
A2	Muscle Recruitment and Coordination following Constraint-Induced Movement Therapy with Electrical Stimulation on Children with Hemiplegic Cerebral Palsy: A Randomized Controlled Trial Search source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4599892/.	P	L1	**Pub Med**
A3	Neuromuscular electrical stimulation in neurorehabilitation Search source: https://www.ncbi.nlm.nih.gov/pmc/,	P+S	L1	**Pub Med**
A4	The effects of training using EMG biofeedback on stroke patients upper extremity functions. Search source: https://www.ncbi.nlm.nih.gov/pmc/	/	L1	**Pub Med**
A5	Powered muscle stimulator and biofeedback device 510K 053266	/	L1	**FDA**
A6	Upper extremity motor training of a subject with initially motor complete chronic high tetraplegia using constraint-induced biofeedback therapy. Search source：	P		**Pub Med**

No	Title of Literature	P/S	Imp.	Searched by
	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5798912/			

Note: 1) P/S means performance or safety;

2) Imp means importance;

3) L means level, and L1 means the most important.

4.5 Summary and appraisal of clinical data

As described above, we obtained many data related to the device through some literatures, which are listed in Table 1 in Clause 3.1, and appraised their methodology and scientific validity, and data's relevance and contribution. Please refer to the following appraisal process for details.

4.5.1 Appraisal process

1) Sub-process of appraisal for methodological quality and scientific validity (MV)

Suitability Criteria	**Description**	**Sub-score (MV)**					
		A1	**A2**	**A3**	**A4**	**A5**	**A6**
Adequacy of the sample size and power calculation	Yes	/	1	/	/	/	1
	Can't answer or no	0	/	/	0	0	/
	Not applicable	/	/	0.5	/	/	/
Adequacy and relevance of follow-up period	Yes	/	1	/	/	/	1
	Can't answer or no	0	/	0	0	0	0
	Not applicable	/	/	/	/	/	/
Adequacy of	Yes	1	1	1	1	1	1

Suitability Criteria	Description	Sub-score (MV)					
		A1	A2	A3	A4	A5	A6
applied controls	Can't answer or no	/	/	/	/	/	/
	Not applicable	0.5	/	/	/	/	0.5
Adequacy of inclusion and exclusion criteria, and of stratification of patients	Yes	1	1	1	1	/	1
	Can't answer or no	/	/	/	/	0	/
	Not applicable	/	/	/	/	/	/
Distribution of prognostic factors	Yes	/	/	/	/	/	/
	Can't answer or no	0	0	0	0	0	0
	Not applicable	/	/	/	/	/	/
Blinding of patients	Yes	1	1	/	/	/	/
	Can't answer or no	/	/	/	0	0	/
	Not applicable	/	/	0.5	/	/	/
Reliability of the methods used for quantifying symptoms and outcomes	Yes	1	1	/	/	/	1
	Can't answer or no	/	/	0	0	0	/
	Not applicable	/	/	/	/	/	/
Adequate recording and reporting of serious adverse events and device	Yes	1	/	1	/	1	1
	Can't answer or no	/	0	/	0	/	/
	Not applicable	/	/	/	/	/	/

Suitability Criteria	Description	Sub-score (MV)					
		A1	A2	A3	A4	A5	A6
deficiencies							
Adequate handling of medications and concomitant interventions	Yes	1	1	1	1	1	1
	Can't answer or no	/	/	/	/	/	/
	Not applicable	/	/	/	/	/	/
Adequacy of procedures for retrieving complete information	Yes	1	1	/	1	/	1
	Can't answer or no	/	/	0	/	0	/
	Not applicable	/	/	/	/	/	/
Score (MV)		7.5	8	5	4	3	8

2)Sub-process of appraisal for relevance of data (R)

Suitability Criteria	Description	Sub-score (R)					
		A1	A2	A3	A4	A5	A6
To what extent is the data generated representative of the device under evaluation ?	- device under evaluation - equivalent device - benchmark device	/	1	/	/	/	1
	- other devices and medical alternatives	/	2	2	/	/	2
	- data concerning the medical conditions that are managed with the device	1	/	/	1	1	/

Suitability Criteria	Description	Sub-score (R)					
		A1	A2	A3	A4	A5	A6
What aspects are covered?	- pivotal performance data - pivotal safety data	1.5	1.5	3	/	/	1.5
	- claims - identification of hazards - estimation and management of risks	1	/	1	1	/	1
	- establishment of current knowledge/ the state of the art - determination and justification of criteria for the evaluation of the risk/benefit relationship - determination and justification of criteria for the evaluation of acceptability of undesirable side-effects	1	1	1	1	1	1
	- determination of equivalence - justification of the validity of surrogate endpoints	/	/	1	/	/	/
Are the data relevant to the intended	- representative of the entire intended purpose with all patient populations and all	/	3	3	/	/	3

Suitability Criteria	Description	Sub-score (R)					
		A1	A2	A3	A4	A5	A6
purpose of the device or to claims about the device?	claims foreseen for the device under evaluation						
	- concerns specific models/ sizes/ settings, or concerns specific aspects of the intended purpose or of claims	/	/	/	/	/	/
	- does not concern the intended purpose or claims	0	/	/	/	0	/
Score (R)		4.5	7.5	11	3	2	9

3) Sub-process of appraisal for data's contribution (C)

Data's contribution (R×MV)	Criteria	Score (C)					
		A1	A2	A3	A4	A5	A6
75~90	Prior accept	/	/	/	/	/	
50~74	Accept	/	60	51	/	/	60
≤50	Refuse	33.75	/	/	12	6	/

Conclusion: according to the score of each literature evaluated above, the literature A2 and A3.A6 are qualified to support the device in question both on performance and safety.

4.6 Analysis of the clinical data

4.6.1 Requirement on safety

According to the literature A2 "Muscle Recruitment and Coordination following Constraint-Induced Movement Therapy with Electrical Stimulation on Children with Hemiplegic Cerebral Palsy: A Randomized Controlled Trial".The MyoTrac Infiniti dual-channel neuromuscular electrical stimulation in the literature is the same as Equivalent device by our company. Frequencies were set at 50Hz, pulse rate 30 pulses per second with 300μs of amplitude, and the amplitude to a maximum of 100mA. ON time was set to 12 seconds with 1 second of rise and decay consistent with our company. The test subjects chose patients with upper extremity dyskinesia. The results of the trial are statistically significant to demonstrate the safety and efficacy of biofeedback therapy.

According to the literature A3 "Neuromuscular electrical stimulation in neurorehabilitation" .This paper is a review of clinical applications, demonstrating the role of NMES in sports re-learning, reducing hemiplegia, muscle recovery, preventing muscle atrophy, and preventing venous thrombosis. These are consistent with our intended use. The literature cites a large number of clinical examples to demonstrate the effectiveness of these functions, and the results of clinical strength are statistically significant, which can prove the safety and effectiveness of NMES.

4.6.2 Requirement on acceptable benefit/risk profile

In the literature A3 "Neuromuscular electrical stimulation in neurorehabilitation", at the beginning of the study, the investigator had identified the risk factors at first, and considering the risk management process during the whole clinical trial procedure. And the type of device has lower risk grade, and during XFT-2003EA risk management process, all the risk identified have all been controlled into ACC region after risk control measures have been taken, and benefit-risk analysis has been performed for each hazard identified and has been judged acceptable.

4.6.3 Requirement on performance

In the literature A2 "Muscle Recruitment and Coordination following Constraint-Induced Movement Therapy with Electrical Stimulation on Children with Hemiplegic Cerebral Palsy: A Randomized Controlled Trial", the investigators has indicated that "The results of this study demonstrated that the use of CIMT plus electrical stimulation, CIMT and traditional OT could strengthen muscle recruitment and coordination of the involved hand, and the bimanual isolated movement control. Pearson's analysis indicated that the global functional improvement of the involved arm and hand was associated strongly with the increase of muscle recruitment. The results also suggest that surface EMG is an effective method in evaluating hand function in children with hemiplegic CP. The CIMT plus electrical stimulation

showed a superiority over the CIMT alone and traditional OT,." At the beginning of the literature, and after the whole procedure of the trial stated in the literature, the investigator gave the conclusion "Constraint-induced movement therapy plus electrical stimulation is likely to produce the

best outcome in improving muscle recruitment and coordination in children with hemiplegic cerebral palsy compared to constraint-induced movement therapy alone or traditional occupational therapy."

In the literature A3 "Neuromuscular electrical stimulation in neurorehabilitation", the investigator mentioned "The principal goal of rehabilitation management of persons with UMN paralysis is to maximize quality of life. NMES systems bypass the injured central circuitry to activate neural tissue and contract muscles to provide function to what is otherwise a nonfunc-tioning limb or structure. Recent advances in clinical medicine and biomedical engineering make the clinical implementation of NMES systems to en-hance the mobility and function of paralyzed person more feasible. Hand neuroprosthesis systems can signifificantly enhance the upper-limb function of persons with tetraplegia. The application of this technology for persons with hemiplegia is in its infancy and must await further technical and scientifific developments if it is to be applicable to the broader stroke population ".

4.6.4 Requirement on acceptability of side-effects

Not only from the investigation of adverse event reports related with other devices has the same intended use, but also from the appraisal process of selected literatures, all the clinical data searched can be demonstrated that there were no side effects happened on the market history of so many Nerve and Muscle Stimulator, and the technology of the device is very mature, so the device can be acceptable on such aspects.

5 Conclusions

Through the above XFT-2003EA Nerve and Muscle Stimulator clinical evaluation process, we think that XFT-2003EA Nerve and Muscle Stimulator with the same variety of products are basically the same.

Through the retrieval and analysis of the clinical data of the same kind of products in the market, it can be proved that XFT-2003EA Nerve and Muscle Stimulator is safe and effective.

Besides, during the pre-clinical evaluations, the following tests have been performed, which contain:

Item	Applicable standard	Title of standard	Test Report	Test result
General safety	IEC 60601-1:2012	Medical electrical equipment – Part 1: General requirements for safety	TR1810150202	Pass
EMC	IEC 60601-1-2:2014	Medical Electrical Equipment – Part 1-2: General requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests	TR1810150201	Pass
product standard	IEC60601-2-10 ：2016	Medical electrical equipment -- Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators	TR1810150203	Pass
	IEC 60601-2-40:2016	Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment	GZES190101036601	Pass
Biocompatibility	ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	ENNE-2003EA-147	Pass
	ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	SDWH-M201900697-1（E）	Pass

	ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	SDWH-M201900697-2（E） SDWH-M201900697-3（E） SDWH-M201900697-4（E） SDWH-M201900697-5（E	Pass

And for each proposed clinical indication, the conclusions below stand by:

- The clinical data has demonstrated conformity with relevant Essential Requirements of MDD;
- The performance and safety of XFT-2003EA is claimed to be credible;
- The risks related to the use of XFT-2003EA are acceptable after Risk Control Measures taken, and risk/benefit weight has also been analyzed.

6 Date of the next clinical evaluation

According to the requirements of Article 6.2.3 of MEDDEV 2.7 / 1 revision 4, and Classification (excluding MDD, Annex IX), Nerve and Muscle Stimulator is classified into IIa, rule 9. The Nerve and Muscle Stimulato is low-risk and Improvement of hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury. When the data collected by the supervisory after the product is listed will affect the clinical evaluation or conclusion, CERs should be updated every five years. The next update date is July, 2025.

7 Dates and signatures

Evaluator: Approved by:

Date: Date:

8 Qualification of the responsible evaluators

Resume of evaluator:

Introduction about Dr. Zhang Pande

Dr. Zhang Pande graduated from the First Military Medical University in 1987. He worked in the Pearl River Hospital affiliated to the First Military Medical University from 1987 to 1997. He has worked in the First People's Hospital of Foshan since September 1997. In 1988, he participated in the national soft tissue injury class. In 1992, he graduated from the World Health Organization and the Hong Kong Rehabilitation Cooperative Center. He has participated in international conferences and studies in foreign countries and Hong Kong. Engaged in rehabilitation for 20 years, specializing in the rehabilitation of neurological diseases and the treatment of neck, shoulder, back and leg pain. He has participated in the compilation of five professional works such as "Practical Rehabilitation", "Modern Physical Therapeutics" and "Modern Rehabilitation Therapeutics", and published more than 20 papers in national journals.

He is currently the chairman of the Physical Medicine and Rehabilitation Branch of the Foshan Medical Association, the Standing Committee of the Physical Medicine and Rehabilitation Society of Guangdong Medical Association, the standing director of the Guangdong Rehabilitation Medical Association, and the Standing Committee of the Guangdong Community Rehabilitation Society. The editorial member of "International Journal of Physical Medicine and Rehabilitation Volume"

Honors

He has won the fourth prize of the military scientific and technological progress and the third prize of Foshan Science and Technology Progress.

Paper publicing

Resume of evaluator:

Introduction about **Li Fei project engineer**

李飞于 2005/09—2009/07　　毕业于：北京交通大学，电子科学与技术专业（集成电路设计方向）；

主修课程：数字/模拟集成电路设计　VLSI 电路设计　ASIC 原理及应用　IP 模块设计　半导体器件工艺学　数字/模拟电子技术基础　混合集成电路设计　微机原理与接口技术　集成电路可靠性设计　　射频电路的理论与应用　　半导体物理。

工作经历和科研经历

- 2015.8 至今**就业于深圳讯丰通医疗股份有限公司**，担任硬件工程师，主要从事生物反馈电刺激仪的元件选型、硬件电路原理设计、电路仿真及分析、PCB LAYOUT 设计、板卡调试及测试。

- 2013.3~2015.4 **就业于苏州朗众电子科技有限公司**，担任电子工程师，主要从事 DC/DC 转换器、电磁阀驱动电路的设计和仿真；混合动力汽车整车特性的仿真验证；使用 comsol 对电磁阀工作特性进行仿真验证。已完成 6V 转 12V 的 LVDCDC 转换器、300V 转 12V 的 HVDCDC 转换器的电路设计和仿真；完成带 PTO 的混合动力汽车的整车特性的仿真。熟练使用 Cadence&Simulink 进行电路设计和仿真，熟练运用 cadence 软件进行版图绘制；熟练运用 Protel99SE 进行电路图和 PCB 版图的绘制，熟悉开关电源各种拓扑、半桥&全桥整流电路、RLC 滤波电路等的电路设计和仿真，并编写仿真报告。

- 2009.4~2013.3 **就业于宁波比亚迪半导体有限公司**，担任器件工程师，主要从事器件特性测试和分析；新器件的特性、测试结构、测试方法、评价标准及模型架构和验证电路的研究和应用；各类器件模型的提取和验证，及时更新器件测试图形的版图；熟练运用 MBP\MQA 进行模型的提取，熟练运用 HSPICE\PSPICE\SPECTRE 软件进行各类器件模型验证和电路的仿真，熟练运用 Cadence 软件进行器件的版图绘制和电路图绘制，熟练运用 Protel99 软件进行电路图和 PCB 版图的绘制，完成模型数据文件的更新和生效，确保模型数据的准确性和及时性；协助客户进行电路设计，进行电路工作特性的仿真等。

科研能力

- **数字电路开发能力**，熟悉数字电路前端、后端设计流程，熟练掌握分立器件的各种特性，能熟练运用 Cadence 进行**版图绘制和电路仿真**，熟练运用 HSPICE&PSPICE 对电路进行仿真，可进行大规模集成电路版图绘制和电路开发；熟练运用 MBP 和 MQA 进行模型提取和验证，熟悉 verilog 语言编程，了解 QuartusII、Modlesim、Synplify、Tanner，Protel 等 EDA 软件。

- **动手能力和问题解析能力** ，具有较强的动手能力和思维能力。工作期间，积极进行器件的特性分析、结构设计、功能验证及问题解析、电路的仿真验证；在学期间，积极参加了电子电路课程设计、数字电子技术实验、模拟电子技术实验课程，并参加了北京交通大学电子电路竞赛。

9 References

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