Clinical Evaluation Report

Edited by:Du Shi Gui

Reviewed by: Vicky Wang

Approved by:Yi Hui

1. Summary

This clinical evaluation report which is drafted in conformance with MEDDEV 2.7/1 revision 4 aims to evaluate the clinical safety and clinical effectiveness of JPD-FR100+、JPD-FR200、JPD-FR202、JPD-FR300、JPD-FR301、JPD-FR302、JPD-FR400、JPD-FR401、JPD-FR402、JPD-FR408、JPD-FR203、JPD-FR409、JPD-FR410 and JPD-FR412 infrared thermometer (referred to as thermometer in the following) which is a measurement instrument that uses the infrared receiving principle to measure the temperature of ear, forehead or object. User only need to place the temperature probe at the correct position, and press the measurement key to quickly and correctly measure the temperature.

The thermometer intends to be used by a medical department or a family to measure the body temperature. The temperature of a measured object is displayed by measuring thermal radiation of the thermal radiation of the measured part.

Through systematic evaluation in accordance with ISO 14971 and MEDDEV 2.7/1 revision 4, the benefit/risk profile in the intended target groups and medical indications is acceptable based on the state of the art in the medical fields concerned. There are no residual risks through implementation of control measures. Therefore both risk/benefit analysis and evaluation of residual risks are unnecessary.

2. Scope of the Clinical Evaluation

In accordance with 93/42/EEC as amended by directive 2007/47/EC, the product is classified into Class IIa.

2.1 Device Information

- Product Name: Infrared Thermometer
- Product Model and General Information: see table 1.
- Safety Classification:  BF
- Manufacturer Name: Shenzhen Jumper Medical Equipment Co., Ltd
- Manufacturer Address: D Building, No. 71, Xintian Road, Fuyong Street, Baoan, Shenzhen, Guangdong, China

Table 1 Procut Model and General Information

	JPD-FR100+	JPD-FR200	JPD-FR300	JPD-FR301	JPD-FR302
Length（mm）	155	160	150	150	150
Width(mm)	40	56	40	40	40
Height(mm)	38	46	38	38	38
Weight(g)	85.5	97.4(including two	85(including two AAA	85(including two	85(including two

		AAA batteries)	batteries)	AAA batteries) earcap box: 37.5 g	AAA batteries) earcap box: 37.5 g

	JPD-FR202	JPD-FR408	JPD-FR400	JPD-FR401	JPD-FR402
Length (mm)	150	157.5	155	155	150
Width(mm)	88.2	39	48	48	40
Height(mm)	40.6	36.5	48	48	38
Weight(g)	109.5(including two AAA batteries)	86.9(including two AAA batteries)	85.0(including two AAA batteries)	85.0(including two AAA batteries)	85.0(including two AAA batteries)

	JPD-FR203	JPD-FR409	JPD-FR410	JPD-FR412
Length (mm)	151.8	155.2	149.3	155.9
Width(mm)	36.2	39.6	38.1	40.2
Height(mm)	35.3	49.1	43.4	49.2
Weight(g)	79.0(including two AAA batteries)	101.0(including two AAA batteries)	86.7(including two AAA batteries)	90.0(including two AAA batteries)

2.2 Post-marketing Information and Device History

a) Post-marketing Information

The device which is CE-marked has been marketed in Europe ,USA and China for several years. Sales situation is shown in the table below:

Countries	Since When	Sales Volumes
Europe	2014	700,000PCS
U.S.	2014	1,000,000pcs
China	2014	500,000pcs
Others	2015	300,000pcs

b) Device History

Since the last report, the devices have not been modified.

2.3 Device Description

2.3.1 Intended Purpose of the Device

1) Intended Use

This product intends to be used by a health care professional or a lay person in a medical department or a family to measure the body temperature. It is applicable to individuals older than three months. And you can also use it for testing object temperature, such as milk-bottle. The temperature of a measured object is displayed by measuring thermal radiation of the thermal radiation of the earhole or forehead. During the use, the temperature probe will be inserted into the auditory meatus or aim at forehead and it will only take one second for the measurement. It is a reusable instrument and the earcap is disposable which can avoid cress infection.

2) Contraindications

The models used to measure temperature of eardrum can not be used for an individual having diseases such as otitis media and ear fester.

3) Precautions

a) This thermometer is applicable to indoor environments. There should be no strong cross-ventilation between the instrument and a measured object during measurement (for example, a fan, an air-conditioner, and a heater blow against each other).

b) This thermometer is sensitive to the environment temperature; do not hold the thermometer for a long time.

c) Keep the temperature probe clean and unblocked before using the thermometer.

d) Before measuring the temperature of the ear, keep the auditory meatus clean; otherwise, the measurement result may be incorrect.

e) Do not have emotional outbursts or take acute exercise before measurement.

f) Make measurement 30 minutes later after taking the thermometer into the measurement environment, if there is a temperature difference between the storage environment and the measurement environment.

g) The measured individual is advised to take a more than 10 minutes rest before measurement, if the individual enters the measurement environment from an environment and there is a temperature difference between the two.

2.3.2 General Description

2.3.2.1 Physical Description

As an instrument used for temperature measurement of human body, the thermometer is not a sterile or a radioactive device. And it incorporates no medicinal substance, animal tissue, or blood components.

a) Product Structure

This product mainly consists of a casing, a liquid crystal display, a press key, a buzzer, an infrared sensor, and a microprocessor.

b) Schematic Diagram of Appearance

JPD-FR100+	JPD-FR200	JPD-FR300	JPD-FR301	JPD-FR302
				
JPD-FR202	JPD-FR408	JPD-FR400	JPD-FR401	JPD-FR402

				
JPD-FR203	JPD-FR409	JPD-FR410	JPD-FR412	
				

2.3.2.2 Materials Coming in Contact with Human

JPD-FR100+, JPD-FR300, JPD-FR301, JPD-FR302, JPD-FR400, JPD-FR401, JPD-FR402, JPD-FR408, JPD-FR409, JPD-FR410 and JPD-FR412 may contact human body during use. The only applicable part coming in contact with earhole of patients directly is the disposable earcap. The earcap has been performed biocompatibility test in accordance with ISO 10993-5 and ISO 10993-10. It is believed the material contacting with human body is safe.

2.3.2.3 Operating Principle

Thermometer is a measurement instrument that uses the infrared receiving principle to measure the temperature in the tympanic membrane of the earhole or on the forehead.

It only need to insert the temperature probe into the earhole and place it at the correct position or aim at the forehead, and press the measurement key to quickly and correctly measure the ear temperature.

The infrared thermometer uses the infrared temperature sensor to receive infrared energy emitted by heat generated in the tympanic membrane of the earhole or forehead. The energy penetrates through the lens and becomes concentrated, and is further converted into a temperature value by using the thermopile and measurement circuit.

2.3.2.4 Technical Specifications

See Table from 4.2

2.4.1 Claims on Clinical Performance and Clinical Safety

Infrared technique originating from 19th century has been widely applied to many devices, including thermometer. Based on this mature technique, the manufacturer lays a claim on the clinical performance and clinical safety.

3. Clinical background, current knowledge, state of the art

3.1 Development Context

Measurement of body temperature is one of the oldest known diagnostic methods and still remains an important indicator of health and disease, both in everyday life and in medical care. Body temperature depends on the type of thermometer and the area of the body used for taking the measurement. Human body temperature varies depending on the site from which the reading was taken - these differences are actually no more than an approximation of the true value that is being estimated. Oral and rectal thermometers are invasive and poorly tolerated, while axillary thermometers require to hold the thermometer in the axilla for 30 seconds or longer. Infrared tympanic thermometers are easier to use, but can be inaccurate due to ear wax or insufficient straightening of the ear canal. Non-contact infrared thermometers (NCITs) are designed to measure temperature rapidly and non-invasively with negligible cross-infection risk. This update compares the accuracy and utility of NCITs with conventional thermometers in children. The accuracy and utility of non-contact infrared thermometers is the critical clinical question.

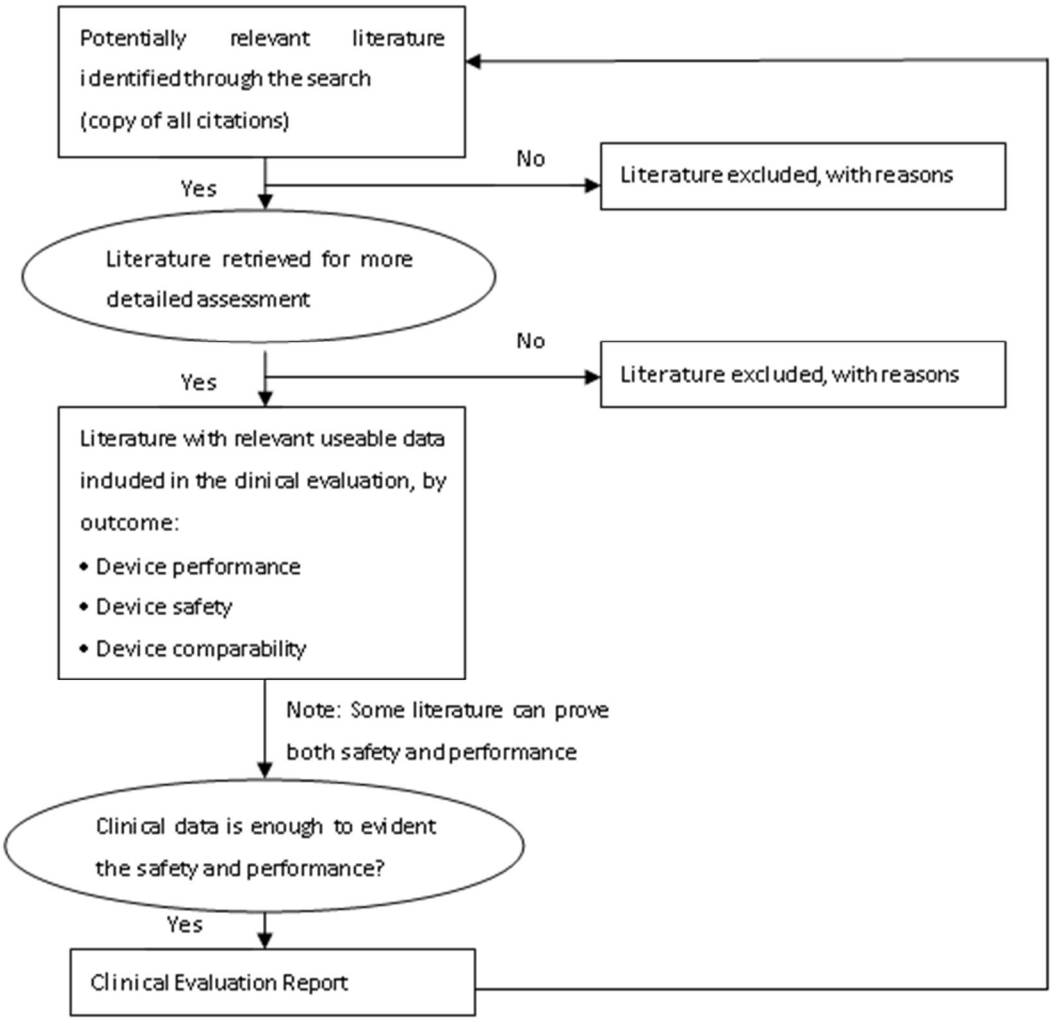
3.2 Literature Search Strategy

In accordance with MEDDEV 2.7/1 revision 4 and the CE-marked devices, the literature search strategy is applied to demonstrate the safety and effectiveness of the devices.

- Scientific Literature Databases
  - MEDLINE
  - PubMed
  - Wanfang
- Internet Searches
  - harmonised standards and other standards applicable to the device in question and containing information on clinical performance and clinical safety.
  - Field safety corrective actions for the equivalent and/or other devices.
  - Documents available in systematic review databases
  - Expert documents produced by professional medical associations that are important for assessment of current knowledge/ the state of the art, including clinical practice guidelines and consensus statements.
  - Identification of studies via the WHO International Clinical Trials Registry Platform (ICTRP) and ClinicalTrials.gov.
- Non-published data
  - The label and IFU of equivalent device

- Test report sponsored by manufacturer

- Search Questions: Accuracy
- Search Terms: (Infrared thermometer AND ear) OR (Infrared Tympanic thermometer) OR (Infrared Forehead thermometer)
- Selection Criteria: Selection is conducted in accordance with the content of the literature and scope of the clinical evaluation.
  - Age: all ages
  - Operating Principe: Infrared
  - Measuring part: forehead and earhole
- Quality Control Measures: Initial selection is conducted in accordance with the title and abstract of the literature. Those irrelevant with Auto CPAP are extruded at first. While those cannot be determined are included temporarily. Check the rest literature to decide if the article is appropriate.
- Results:
  - Attach copies of literature citations retrieved from each database search
  - Data selection process



- Number and Type of Literature:
  - Scientific Literature: 6
  - Internet Searches: 0
  - Non-published data: 5

3.3 Applicable standards and guidance documents

See list of applicable standards.

3.4 Hazards and Risk

See risk management report.

4. Device under Evaluation

4.1 Type of Evaluation

In view of the mature technique and the previous similar devices, the clinical evaluation of the device under evaluation which has been place on market for

several years is based on previous clinical accuracy and repeatability test, safety and performance test report and risk analysis of manufacturer and scientific literature currently available.

4.2 Demonstration of Equivalence

In this clinical evaluation, JPD-FR400 is determined as the typical device which has all the types of measurement and functions compared with other models(JPD-FR100+、JPD-FR200、JPD-FR202、JPD-FR300、JPD-FR301、JPD-FR302、JPD-FR401、JPD-FR402、JPD-FR408、JPD-FR203、JPD-FR409、JPD-FR410、JPD-FR412). All models have the following similarities:

- Same intended use;
- Same operating principle;
- Same technology;
- Same biological, chemical, physical characteristics.

It has clinically difference in the performance of the device in measurement site. In these models. JPD-FR400 which can measure both forehead and ear, besides it has a large broad of measurement range from 0.0°C－100.0°C with the ear measured function. So the safety and effectiveness of JPD-FR400 can represent all the other models. And the clinical data of JPD-FR400 can be considered as the clinical support.

As for the detailed comparison table of technical specifications among these models, please refer to the file 'Technical specifications.xlsx' from CE Technical Files.

4.3 Clinical Data Generated and Held by the Manufacturer

4.3.1 Pre-market clinical investigation

To evaluate the Accuracy and Repeatability, a pre-market clinical investigation of JPD-FR400 is performed in 3 groups (see clinical data of JPD-FR400): Group I - Infants, Group II – Children, Group III – Adults from difference distances.

Evaluate criteria and/or statistical method:

- Clinical Bias: △**cb**

$$\Delta_{cb} = \frac{\sum_{i=1}^{n}\left(t_{TUT,i} - t_{RCT,i}\right)}{n} \quad \text{(equation 1)}$$

i is the index number for an individual subject;

n is the total number of subjects per MEASURING SITE and age group;

t TUT, *t*RCT are the observed OUTPUT TEMPERATURES from the JPD-FR400 and the *t*RCT

- Standard Deviation: $\sigma_{\Delta_{cb}}$

$$\sigma_{\Delta cb} = \sqrt{\frac{\sum_{i=1}^{n}\left[\left(t_{TUT,i} - t_{RCT,i}\right) - \Delta cb\right]^2}{n-1}}$$ (equation 2)

where

i is the index number for an individual subject;

n is the total number of subjects per MEASURING SITE and age group;

t TUT, *t*RCT are temperatures indicated by the JPD-FR400 and the RCT respectively;

△**cb** is the CLINICAL BIAS as calculated in Equation (1).

- Clinical Repeatability: $\hat{s}_R$

$$\sigma_j = \sqrt{\frac{\sum_{i=1}^{m}\left(t_{TUTi} - \overline{t_{TUTj}}\right)^2}{m-1}}$$ (equation 3)

where

$\overline{t_{TUTj}}$ is the average of the output temperatures on subject j; and

m is the number of output temperature measurements on the subject.

Then calculate a pooled standard deviation (the CLINICAL REPEATABILITY),

$$\sigma_r = \sqrt{\frac{\sigma_1^2 + \sigma_2^2 + \ldots + \sigma_j^2 + \ldots + \sigma_N^2}{N}}$$ (equation 4)

where

N is the total number of subjects of all age groups in a study.

a) Group I

In group I, 35 subjects (female=18; male=17; age range: 3 months – 12 months; fieber: 6, fieber%: 17.1%) are measured by the device in equivalence.

Clinical data analysis in this group:

	Forehead	Ear
Clinical Bias Δ_{cb}	-0.043	-0.011
Standard Deviation $\sigma_{\Delta cb}$	0.154	0.123
Clinical Repeatability σ_r	0.144	0.074

b) Group II: Children

In group II, 35 subjects (female=17; male=18; age range: 1 year – 5 year; fieber: 10, fieber%: 28.6%) are measured by the device in equivalence.

Clinical data analysis in this group:

	Forehead	Ear
Clinical Bias Δ_{cb}	-0.022	-0.028
Standard Deviation $\sigma_{\Delta cb}$	0.173	0.125
Clinical Repeatability σ_r	0.119	0.060

Conclusion:
In this year group of “children”:
- the repeatability and standard deviation are according with EN ISO 80601-2-56-2009.

c) Group III
In group III, 35 subjects (female=18; male=17; age range: ≥5 years; fieber: 7, fieber%: 20%) are measured by the device in equivalence.

Clinical data analysis in this group:

	Forehead	Ear
Clinical Bias Δ_{cb}	-0.029	-0.006
Standard Deviation $\sigma_{\Delta cb}$	0.145	0.119
Clinical Repeatability σ_r	0.136	0.057

Conclusion:
In this year group of “adult”:
- the repeatability and standard deviation are according with EN ISO 80601-2-56-2009.

Pooled standard deviation (the CLINICAL REPEATABILITY)

$$\sigma_r = \sqrt{\frac{\sigma_1^2 + \sigma_2^2 + \ldots + \sigma_j^2 + \ldots + \sigma_N^2}{N}} = 0.13341 \text{ (forehead)}$$

$$\sigma_r = \sqrt{\frac{\sigma_1^2 + \sigma_2^2 + \ldots + \sigma_j^2 + \ldots + \sigma_N^2}{N}} = 0.00411 \text{ (ear)}$$

$$\sigma_r = \sqrt{\frac{\sigma_1^2 + \sigma_2^2 + \ldots + \sigma_j^2 + \ldots + \sigma_N^2}{N}} = 0.10466 \text{ (forehead+ ear)}$$

4.3.2 Data from Clinical Experience

The product has been placed on the EU market for several years. From the customer feedback, it is in good clinical use. And so far, no adverse event is available.

4.3.3 Pre-clinical study

See test report and risk analysis report

4.4 Clinical Data from Literature

a) Objective

The objective of the literature retrieve is to identify all favorable and unfavorable data related to the device under evaluation.

b) Sources Used

- Scientific Literature Databases
  - MEDLINE
  - PubMed
  - Wanfang
- Internet Searches
  - harmonised standards and other standards applicable to the device in question and containing information on clinical performance and clinical safety.
  - Field safety corrective actions for the equivalent and/or other devices. This is found on manufacturer's website, internet sites of European Competent authorities, FDA website and CFDA website.
  - Expert documents produced by professional medical associations that are important for assessment of current knowledge/ the state of the art, including clinical practice guidelines and consensus statements.
  - Identification of studies via the WHO International Clinical Trials Registry Platform (ICTRP) and ClinicalTrials.gov.
- Non-published data
  - The label and IFU of equivalent device
  - Test report
  - Product analysis report

c) Search Questions: Accuracy and body site

d) Search Terms: (Infrared thermometer AND ear) OR (Infrared Tympanic thermometer) OR (Infrared Forehead thermometer)

e) Selection Criteria: Selection is conducted in accordance with the content of the literature and scope of the clinical evaluation.

- Age: all ages
- Operating Principe: Infrared
- Measuring part: forehead and earhole

f) Quality Control Measures: Initial selection is conducted in accordance with the title and abstract of the literature. Those irrelevant with Auto CPAP are extruded at first. While those cannot be determined are included temporarily. Check the rest literature to decide if the article is appropriate.

g) Results

1) Wenbin Chung, Chiachung Chen, Evaluation of Performance and Uncertainty of Infrared Tympanic Thermometers, Sensors (Basel) 2010; 10(4): 3073–3089. Published online 2010 Mar 31. doi: 10.3390/s100403073, PMCID: PMC3257961
2) Sara Sollai, Carlo Dani, Elettra Berti, Claudia Fancelli, Luisa Galli, Maurizio de Martino, Elena Chiappini, Performance of a non-contact infrared thermometer in healthy newborns, BMJ Open. 2016; 6(3): e008695. Published online 2016 Mar 16. doi: 10.1136/bmjopen-2015-008695 PMCID: PMC4800130
3) ST-81 型数字体温计，秦钰、姚录成、余慧卿，1994-2010 China Academic Journal Electronic Publishing House., medical science journal
4) 电子体温计在儿科临床应用的准确性和可行性研究(The study on the accuracy and reliability of electronic thermometer in clinical usage of paediatrics). medical science journal
5) Fadzlin Mohd Fadzil, David Choon, Kulenthran Arumugam A comparative study on the accuracy of noninvasive thermometers Number and Type of Literature. medical science journal
6) 电子体温计与水银体温计在临床使用中的效果观察. medical science journal

4.5 Summary and appraisal of clinical data

4.5.1 Summary of clinical data

- Clinical data generated and held by the manufacture

  Test report of IEC 60601-1
  Test report of IEC 60601-1-2
  Test report of ISO80601-2-56
  Test report of EN/ISO10993-5
  Test report of EN/ISO10993-10
  IFU and label
  Risk analysis report

- Clinical Literature

1) Wenbin Chung, Chiachung Chen, Evaluation of Performance and Uncertainty of Infrared Tympanic Thermometers, Sensors (Basel) 2010; 10(4): 3073–3089. Published online 2010 Mar 31. doi: 10.3390/s100403073, PMCID: PMC3257961

   Infrared tympanic thermometers (ITTs) are easy to use and have a quick response time. They are widely used for temperature measurement of the human body. The accuracy and uncertainty of measurement is the importance performance indicator for these meters. The performance of two infrared tympanic thermometers, Braun THT-3020 and OMRON MC-510, were evaluated in this study. The cell of a temperature calibrator was modified to serve as the standard temperature of the blackbody. The errors of measurement for the two meters were reduced by the calibration equation. The

predictive values could meet the requirements of the ASTM standard. The sources of uncertainty include the standard deviations of replication at fixed temperature or the predicted values of calibration equation, reference standard values and resolution. The uncertainty analysis shows that the uncertainty of calibration equation is the main source for combined uncertainty. Ambient temperature did not have the significant effects on the measured performance. The calibration equations could improve the accuracy of ITTs. However, these equations did not improve the uncertainty of ITTs.

2) Sara Sollai, Carlo Dani, Elettra Berti, Claudia Fancelli, Luisa Galli, Maurizio de Martino, Elena Chiappini, Performance of a non-contact infrared thermometer in healthy newborns, BMJ Open. 2016; 6(3): e008695. Published online 2016 Mar 16. doi: 10.1136/bmjopen-2015-008695 PMCID: PMC4800130

   To evaluate the performance of a non-contact infrared thermometer (NCIT) in comparison with digital axillary thermometer (DAT) and infrared tympanic thermometers (ITT) in a population of healthy at term and preterm newborns nursed in incubators.

   Our results with Bland and Altman analysis demonstrate that NCIT is a very promising tool, especially in preterm newborns nursed in incubators

3) ST-81 型数字体温计，秦钰、姚录成、余慧卿，1994-2010 China Academic Journal Electronic Publishing House., medical science journal

   introduced the situation about the research and development and clinical usage of Model ST-18 digital thermometer, the 7 model ST_81 digital thermometers were conducted investigation respectively in 198TH DIVISION HOSPITAL OF BEIJING MILITARY REGION, 106TH AMBULANCE HOSPIITAL, 254TH HOSPITAL, PAEDIATRICS OF TIANJIN HEDONG HOSPITAL, the all tested patients were 221, and 520 man-time; The result revealed that Model ST-18 digital thermometers were not as prone to be break as Mercury thermometers, and the measuring results were consistent with Mercury thermometers.

4) 电子体温计在儿科临床应用的准确性和可行性研究(The study on the accuracy and reliability of electronic thermometer in clinical usage of paediatrics)

   introduced the situation about model MC-141W-HP made by OMRON, which was conducted investigation in Shanghai Fudan University Children's Hospital, and the total cases are 616. the conclusion is that the accuracy of electronic thermometer is same as Mercury and its safety is over Mercury.

5) Fadzlin Mohd Fadzil, David Choon, Kulenthran Arumugam A comparative study on the accuracy of noninvasive thermometers Number and Type of Literature. medical science journal

   The methods are:

   The temperatures in degrees celsius were taken simultaneously using the four thermometers in 207 patients at the casualty department of a Malaysian hospital. The Bland Altman statistical test was used to assess the concordance by the 95% limits of agreement between the three newer thermometers and the mercury in glass thermometer.

   Results:The digital thermometer gave the best concordance (limits of agreement 0.48–0.59°C). The liquid crystal forehead thermometer gave the least concordance

(limits of agreement -1.14–0.98°C). The digital infrared tympanic was in between (limits of agreement -0.88–0.85°C).

And the conclusion of this study is:

Based on a sample of our population of cooperatives, predominantly adult patients from a Malaysian ED, the digital thermometer appears to be the best alternative to the traditional and time tested mercury in glass thermometers. It is reliable, safe, easy to use and cost effective. The infrared tympanic thermometers, though quick and easy to use, should preferably be used for children and the uncooperative patient. The liquid crystal forehead thermometer is best used at home and even so, readings must be interpreted with caution.

6) 电子体温计与水银体温计在临床使用中的效果观察. medical science journal introduced a comparison between brand 'YUYUE' glass thermometer and brand "OMRON" digital thermometer when using in Beijing JISHUITAN hospital, its conclusion is that the measuring result had no remarkable difference, and digital thermometer is safer than glass thermometer.

4.5.2 Appraisal for Suitability

Each piece of data is appraised in compliance with the criteria for suitability, and the data below corresponding to the statement of bold letters are screened.

Table D1 Appraisal Criteria for Suitability

Suitability Criteria	Description		Grading System
Appropriate device	Were the data generated from the device in question?	D1	**Actual device**
		D2	**Comparable device**
		D3	Other device
Appropriate device application	Was the device used for the same intended use (e.g., methods of deployment, application, etc.)?	A1	**Same use**
		A2	**Minor deviation**
		A3	Major deviation
Appropriate patient group	Were the data generated from a patient group that is representative of the intended treatment population (e.g., age, sex, etc.) and clinical condition (i.e., disease, including state and severity)?	P1	**Applicable**
		P2	Limited
		P3	Different population
Acceptable report/data collation	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1	**High quality**
		R2	Minor deficiencies
		R3	Insufficient information

Note: the device in question is compliance with the criteria in bold.

4.5.3 Appraisal Criteria for Data Contribution

Table D2 Appraisal Criteria for Data Contribution

Data Contribution Criteria	Description	Grading System	
Data source type	Was the design of the study appropriate?	T1	**Yes**
		T2	No
Outcome measures	Do the outcome measures reported reflect the intended performance of the device?	O1	**Yes**
		O2	No
Follow up	Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications?	F1	**Yes**
		F2	No
Statistical significance	Has a statistical analysis of the data been provided and is it appropriate?	S1	**Yes**
		S2	No
Clinical significance	Was the magnitude of the treatment effect observed clinically significant?	C1	**Yes**
		C2	No

Note: the device in question is compliance with the criteria in bold.

4.6 Analysis of the Clinical Data

Content in Appraisal	Cited Reference	Data Source	Description	Grading System
1 Electrical Safety	IEC 60601-1 Test Report ISO80601-2-56 Test Report	manufacturer	Were the data generated from the device in question?	■D1 Actual device □D2 Equivalent device □D3 Other device
2 EMC	IEC 60601-1-2 Test Report	manufacturer	Were the data generated from the device in question?	■D1 Actual device □D2 Equivalent device □D3 Other device
3. Biocompatibility	ISO 10993-5 test report ISO 10993-10 test report	manufacturer	Were the data generated from the device in question?	■D1 Actual device □D2 Equivalent device □D3 Other device
4 Residual and Potential Risk	Risk Management Report IFU and label	manufacturer	Were the data generated from the device in question?	■D1 Actual device □D2 Equivalent device □D3 Other device
5 Suitability and Clinical Application	电子体温计在儿科临床应用的准确性和可行性研究	Wanfang Database	Was the design of the study appropriate?	■ D1 Same intended use □ D2 Minor deviation □ D3 Major deviation
	电子体温计与水银体温计在临床使用中的效果观察	Wanfang Database	Was the design of the study appropriate?	■ D1 Same intended use □ D2 Minor deviation □ D3 Major deviation
	A comparative study on the accuracy of noninvasive thermometers Number and Type of Literature.	Wanfang Database	Was the design of the study appropriate?	■ D1 Same intended use □ D2 Minor deviation □ D3 Major deviation
	ST-81 型数字体温计	Wanfang Database	Was the design of the study appropriate?	■ D1 Same intended use □ D2 Minor deviation □ D3 Major deviation

	Performance of a non-contact infrared thermometer in healthy newborns	PubMed	Was the design of the study appropriate?	■ D1 Same intended use □ D2 Minor deviation □ D3 Major deviation
	Evaluation of Performance and Uncertainty of Infrared Tympanic Thermometers	PubMed	Was the design of the study appropriate?	■ D1 Same intended use □ D2 Minor deviation □ D3 Major deviation

The clinical data have been appraised to be appropriate on information on elementary aspects, numbers for statistical significance, statistical methods, control, collection of mortality, interpretation by the authors, activities. And no serious adverse events data are found.

4.7 Analysis of the clinical data

4.6.1 Conformity assessment with requirement on safety

MDD R1: The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

Conformity assessment with requirement on acceptable benefit/risk profile to R1:

The proof documents to R1:

All identified hazards Risk management documents are fully covered by harmonized standards. Please see risk management report for specify information.

4.6.2 Conformity assessment with requirement on acceptable benefit/risk profile

a) Evaluation of the description of the intended purpose of the device

The intended purpose of the device description provided in IFU correctly identifies those medical conditions and target groups for which conformity with the Essential Requirements R1 have been demonstrated.

b) Evaluation of the device's benefits to the patient

Based on the clinical investigation report and the test report all the risk is acceptable compared to the benefits to patient.

4.6.3 Conformity assessment with requirement on performance

MDD ER3: The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.

Based on the clinical investigation report and the test report the performance is achieved.

4.6.4 Conformity assessment with requirement on acceptability of undesirable side-effects

MDD ER6: Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.

Based on the clinical investigation report, device used experience. There is no side-effect occur.

5. Conclusion

The devices are evaluated from safety, benefit/risk, performance, side-effects which are shown to be in conformance with Essential requirements.
According to current knowledge/ the state of the art in the medical fields concerned and according to available medical alternatives, benefit/risk profile is acceptable.
Information materials supplied by the manufacturer are adequate.
Device, including its IFU, for the intended users and usability aspects are suitable.
Claims foreseen by the manufacturer is adequate.
Clinical data, information materials supplied by the manufacturer, the risk management documentation for the device under evaluation is consistent.
The documents above and the current knowledge/the state of art is consistency. There is no residual risk and uncertainties or unanswered questions. And it is not necessary to perform PMCF.
To draw a conclusion, the analysis and evaluation above indicate the performance and safety of the device are coincident with the intended use as claimed by manufacturer. The risks associated with the use of the device are considered to be acceptable through the risk evaluation and clinical evaluation when weighting against the benefit of the device to patients.

6. Date of the Next Clinical Evaluation

The clinical evaluation is actively updated:

• when the manufacturer receives new information from PMS that has the potential to change the current evaluation;

• if no such information is received, then

- every 5 years

And the updates are aligned with the timetable for surveillance audits and the renewal of the certificates.

Qualification of the Responsible Evaluator

1. General Information

- Name: Du ShiGui
- Education Background: Bachelor, mechanical design and manufacturing, University of Electronic Science and Technology of China

2.Knowledge:

research methodology: Medical Doppler ultrasound field

information management:

regulatory requirements: MDD93/42/EEC, IEC61266, IEC62304, IEC60601-1, IEC60601-1-2, IEC60601-1-4, IEC60601-1-6, IEC60601-1-8, IEC60601-1-11, IEC60601-2-37, ISO14971, ISO9919, ISO10993-1, ISO10993-5, ISO10993-10

medical writing:

The principle of ultrasonic piezoelectric micro robot.

3.Training and experience

a degree from higher education in the respective field and 5 years of documented professional experience; or
10 years of documented professional experience if a degree is not a prerequisite for a given task.
over 10 years medical Doppler ultrasound field work experience.

As can be seen from the basic experience and qualification above, the evaluator is seriously considered to qualify for the clinical evaluation.