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ANALYSIS INFUSION PUMP CALIBRATION RESULTS MERK TERUMO TYPE TE-112

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ABSTRACT

The infusion pump functions to periodically control and regulate the administration of substances that are liquid nutrients or drugs at the right dose into the patient's body in a certain amount through the blood vessels with moderate precision. The use of an infusion pump for a long time will affect the accuracy and accuracy of the tool, which can result in compression and thus disrupt the flow rate regulation. For this reason, the Infusion Pump must be calibrated periodically. Infusion Pump calibration is carried out using a direct measurement method by testing the parameters of the physical condition and function of the tool, measuring electrical safety and its flow rate. Based on the results of the research and analysis of the calculation of the uncertainty of the measurement, the parameters of the physical condition and function of the tool as well as the electrical safety are in 100% good condition, while the flow rate parameter is in a condition of 66.67%. After reviewing the calibration results of the three parameters, the total value was 83.33%. So that the Infusion Pump tool is in a USAGE-worthy status.

Keywords: infusion pump, calibration, flow rate

INTRODUCTION

Infusion pump is a medical device that functions to control and regulate periodically the administration of substances that are liquid nutrients or drugs with the right dose into the patient's body in a certain amount through the blood vessels[1]. Infusion pump is one of the most effective tools for injecting fluids into the body[2]. This tool is also used in the administration of drugs with moderate precision[3]. Flow rate and volume are the parameters used in the working principle of an infusion pump[4]. The working principle of this tool uses a main controller system using an Arduino microcontroller that controls the control of the tool[5]. The needle that is inserted into the blood vessel will be connected to the hose as a place for flowing fluid[6]. The hose is an important accessory for infusion pumps, where the hose factor is very influential on drip control[7]. Using an infusion pump for a long time will affect the precision and accuracy of the tool, which can result in compression due to the presence of air bubbles, causing disruption to the flow rate setting[8]. When administering fluids into the veins, air is not allowed to enter and there is no compression of the tube. If there are air bubbles, the air bubbles will enter the blood vessels, which can cause health problems such as stroke[9]. If the flow rate is not controlled, it

cannot maintain fluid balance so that it can cause a decrease in glomerular filtration rate and renal vein congestion[10]. Therefore, efforts can be made to test the feasibility of an infusion pump in avoiding various cases of flow blockage, one of which is by calibrating the Infusion Pump tool. In order to avoid mistakes when giving fluids to the patient's body, it must be calibrated regularly and at least once a year so that the infusion pump can function in good condition and is safe to use[11]. Calibration is carried out to compare the correctness and accuracy of measuring instruments such as the Infusion Pump with standard measuring instruments[12]. Standard measuring instruments or those used to calibrate measuring instruments are also known as calibrators. The calibrator used to calibrate the Infusion Pump tool is the Infusion Device Analyzer (IDA) as shown in Figure 1[13]. One of the tools used to calibrate the infusion pump is Flow Rate[14].

Figure 1. IDA and Infusion Pump Equipment (Kemenkes, 2018)

Calibration is very important to ensure the function and accuracy of this Infusion Pump tool. Thus the health service process can run well. For this reason, this research will discuss the feasibility of the Infusion Pump tool with the Terumo Type TE-112 brand.

RESEARCH METHODS

In general, the research procedure for analyzing the results of the calibration of the Terumo Infusion Pump Brand is divided into 3 analyses:

a. Analysis of the physical examination test and the function of the infusion pump tool with a measurement contribution of 10% of the total test.
b. Analysis of electrical safety measurements with a measurement contribution of 40%.
c. Analysis of tool performance measurement based on the flow rate parameter with a measurement contribution of 50%.

If the total measurement contribution is more than 70% then this Infusion Pump tool can be said to be suitable for use, if the total measurement contribution is less than 70% then this tool is declared not suitable for use.

The flow of research on the calibration analysis of the Infusion Pump tool can be seen in Figure 1. This research starts from Document Preparation, by preparing reference procedures and making work mechanisms as a reference for conducting testing and/or calibration, what must be prepared are work methods, work instructions, worksheets and labels. Next prepare the infusion pump tool and all its accessories. Preparation of calibrators, namely Infusion Device analyzer (IDA), electrical safety analyzer (ESA) and thermohygrometer.

The next step is the administrative data collection of the tool, recording the tool to be tested. Measurement of environmental conditions, in measuring environmental temperature and humidity using a thermohygrometer. Physical examination and function of the tool, namely carrying out a physical examination and function of the tool to be tested. Electrical safety testing, using the ESA refers to the Electrical Safety Testing Work Method. Performance measurement, the parameters to be tested are flow rate and congestion test using IDA. Data processing, analyzing the uncertainty of all data sets obtained, finally drawing conclusions, is about whether or not it is appropriate to use the Terumo Brand Infusion Pump tool. After drawing conclusions, a normality check is carried out on the tool before it is returned to the user. Confirmation checks consist of the completeness of tool accessories and the functioning of the tool.

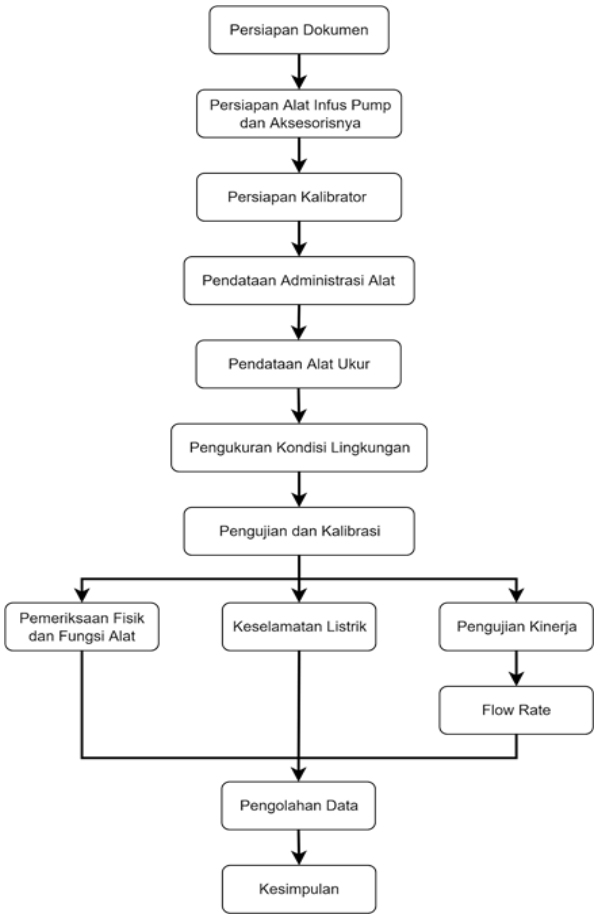

Figure 2. Research Flowchart

For calibrating the flow rate, the test method is a direct calibration method, where the correction to the flow indication at UUT (C) is a subtraction of the measured flow rate value at standard (Fstd) with the flow rate value displayed by UUT (Fuut). As for the analysis of measurement uncertainty calculations, it pays attention to the parameters of type A measurement parameters and type B measurement parameters. For type A, the influential parameter is repeated observation, the sensitivity coefficient is 1 and the degree of freedom is 4 for 5 measurements. Whereas for type B, pay attention to the standard uncertainty value from the calibration certificate of the calibrator, UUT resolution and standard drift. Calculation of combined uncertainty, effective degrees of freedom and uncertainty stretch refers to the Uncertainty Budget. Evaluation of flow rate testing based on tolerance of ± 10%.

RESULTS AND DISCUSSIONS

The results of the research are written down and presented in table form. Table 1 contains data collection on tool administration. The Infusion Pump brand used in this study is Terumo with type TE-112, along with its accessories such as hoses, infusion sets and consumables such as distilled water.

Table 2 contains data on measuring instruments consisting of IDA, ESA and Thermohygrometer. These three tools are often referred to as calibrators. The IDA brand used is Bio-tek Instruments with type IDA-1, while the ESA brand is Metron with type QA-90, then a thermohygrometer with type 303.

Table 3. Interprets the measurement conditions before calibration and after calibration. The parameters measured were room temperature and room humidity. The room temperature before calibration was obtained at 27.2 °C and at the end of the calibration it increased by 1 °C, namely 28.8 °C. Meanwhile, the humidity in the room decreased from 49% to 45%.

Table 1. Administrative Data Collection Tool

Merk	Terumo
Type/Model	TE-112
Nomor Seri	1202000110
Aksesoris	Aquades, selang,infusion set

Table 2. List of measuring instruments

No.	Nama Alat	Merk	Model/Type	No. Seri
1	Infusion Device Analyzer	Bio-tek Instruments	IDA-1	10457
2	Electrical Safety Analyzer	Metron	QA-90	9390
3	Thermohygrometer	Thermo-hygrometer	303	N/A

Table 3. Measurement of Environmental Conditions

Measurable	Parameter	
	Room Temperature	Room Humidity
Early	27.2 ℃	49 %
finish	28.8 ℃	45 %

Table 4. is the result of a physical examination and function of the Infusion tool Pump. Physical inspection and the functioning of this tool is carried out by examining the body and surfaces, device contacts, main supply cables, safety fuses, switch and control buttons, displays and indicators. Examination refers to the inspection limits that have been set. The results of the physical examination and the functioning of the infusion pump, all parameters are in the good category. Each examination in a good category is indicated by the number 1 so that a percentage of the results of the examination is 100%. Table 4. Is the result of electrical safety measurements with the measurement parameters as recorded in the table. Table 6. Is the result of measuring the performance of the flow rate on the infusion pump, where the measurement is carried out at a device setting of 10, 50, 100 ml/day with 6 repetitions for each point of measurement. The allowable deviation in this measurement is ±10%, then data processing is carried out using the uncertainty analysis contained in table 7. In the uncertainty analysis there were results that did not pass at the 10 ml/day setting. Analysis of measurement uncertainty in the flow rate performance test obtained a score of 66.67%. Table 8 is a total calculation of the 3 parameters, physical measurement parameters and tool function contributing 10%. For the electrical safety test it contributes 40% and for performance measurement results it contributes 33,333% so that the overall value obtained is 83,333%.

Table 4. Electrical Safety Testing

No.	Parameter	Measurable	Threshold	Results
1	Insulation Resistance	>200 MΩ	NL	Good
2	Earth Leakage Current Normal Condition	10.2 µA	500	Good
3	Patient Leakage Current Normal Condition	0.00 µA	≤100 (B&BF) or ≤10 (CF)	Good
4	Enclosure Leakage Current Normal Condition	µA	100	

5	Protective Earth Resistance	mΩ	>200	
6	Current Consumption (switch On)	A	NL	
	Current Consumption (switch Off)	A	NL	
7	Voltage L1 - L2	204.5 Vac	NL	Good
	Voltage L1 – GND	0.61 Vac	NL	Good
	Voltage L2 – GND	100.7 Vac	NL	Good
8	Class: I II III	-	-	-
9	Applied Part Type: B BF CF NA	-	-	-

Table 5. Flow Rate Performance Measurement

Tool Setting	Standard Designation						Permissible Deviation
(ml/hr)	1	2	3	4	5	6	
10	9.20	9.50	9.20	7.90	7.90	9.70	± 10 %
50	51.00	51.00	53.00	51.00	51.00	52.00	
100	104.00	103.00	106.00	107.00	104.00	102.00	

Table 6. Results of Measurement Uncertainty of Flow Rate Performance

Tool Setting (ml/hr)	Flat	Correct	%KTPS	Tolerance	Results	Score
10	9.116666667	-5.331139687	38.41483065	10	No Pass	
50	51.33333333	-3.604639435	3.95706914	10	Pass	66.67
100	104.3333333	-7.666666667	4.706855288	10	Pass	

Table 7. Review Calibration Results

No.	Bobot	Parameter	Score	Weight Results	Total Result	Tool Function	Technical Review
1	10%	Physical and functional examination	100	10	83,333	Good	Within Tolerance Limits
2	40%	Electrical safety testing	100	40			
3	50%	Flow rate	66,667	33,333			

In calibrating the Infusion Pump device, the room temperature must meet the standards set in the Infusion Pump testing work method, namely 25º C ± 5º C. Table 3 shows the results of measuring room temperature during calibration of 27.2º C -28.8º C. The temperature value this is still within the tolerance of measuring limits ± 5º C. Likewise with the room humidity value of 49% RH - 45% RH where the standard is set at 55% RH ± 20% RH so this value is still within tolerance limits. Physical examination of the Infusion Pump equipment such as the enclosure is intact, clean, tightly fitted to one another and there are no signs of being hit by liquid or other disturbances, no loose contact of the device, power supply cables, safety fuses, buttons, switches and displays and indicators are in good condition. So that the physical examination and function test of this tool get a score of 100. If multiplied by the weight, it gives a test contribution of 10%. Parameters of electrical safety measurements starting from physical inspection, insulation resistance and leakage current are all in the good category. The value of this electrical safety measurement gets a score of 100 and contributes 40%. Measuring the performance of the flow rate of the device at a setting of 10 ml/day did not pass the results, while those at 50 and 100 ml/day were in good condition or passed the test. If you look at the average measurement results at a setting of 10 ml/day, it is seen that it is still within the allowable deviation limits, but after taking into account the results of the analysis of the uncertainty of flow rate measurements based on Type A and Type B, the measurement uncertainty is 38.14%, where this value exceeds the allowable tolerance value of 10%.

CONCLUSION

For this reason, it is recommended for device owners to reset the special infusion pump device to a setting of 10 ml/day. The results of this flow rate performance measurement contributed a value of 66,667 so that it contributed 33,333% of all tests. Overall the calibration assessment for the Infusion Pump tool gets a value of 83.333%. This value has exceeded the standard set in the conclusion method, which is 70%. Based on the results of a technical review of the Terumo brand Infusion Pump calibration with the TE-112 type, it obtained a score of 83.333% so that it can be concluded that this tool is usable and recalibrate according to a regular schedule.

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