

Medical		Senai Medical		Deviation Form	
Creation					
Deviation Information					
DE Number:	DE-SEN-00000080	Status:	Implementation		
Creation Date:	12/28/2018				
Site:	Senai Medical	Customer Name (Local):	WATERS CORP - SUBASSY		
Business Group:	High Reliability Solutions	Customer Local (Code):	WAT02M		
Segment:	Medical	Customer Name (Global):	WATERS		
Originator:	Bernard Retutas Pamplona	Customer Global (Code):	C000002303		
Deviation Owner:	Swee Thai Ng	Product Name:	N/A		
Deviation Owner Manager:	N/A	Deviation Type:	Process		
Deviation Summary:	To omit Y1 frequency test from the ICT Test.				
Deviation Creation					
Affected Item(s)					
File Name	Creation Date	Extension	File Size	User	Activity
No data available in table					
Document Number:	SEN-MFG2004-00	Document Name:	Deviation Procedure		
Document Revision:	A	Document URL:	https://qdms.flex.com/flexmedical/SenWeb=1		
Deviation Condition:	Before Shipping				
Description of Deviation:	Omit Y1 testing in the ICT coverage.				
Deviation Limitation:	Date				
Start Date:	12/28/2018	End Date:	03/29/2019		
Reason Why Deviation is Needed:	Due to urgent shipment, Flex Senai Omit Y1 testing in the ICT coverage temporary due to internal hardware (testware frequency measuring module board) faulty, as Flex Senai unable to fix the problem immediately.				
Training Requirements:	Training record will be provided on this Deviation after approval.				
Customer Approval Required?	Yes				
DE Approvals					
Quality Manager:	Mohd Faizal Abdul	Deadline:	12/28/2018		
Document Manager:	Ku Aini binti Ku Faizal	Deadline:	12/28/2018		
Additional Approver:	Jamaliah Binti Mohd, DisplayName: Narendran Sevoo Al Muniyandy, DisplayName: Ramon Anthony Vinas Regino, DisplayName: Chun Wei Kho	Deadline:	12/28/2018		
Customer Approver:	Muthiah @ Muthu Al Regupathi	Deadline:	12/28/2018		
DE Assignee					
Reviewer:	Azrul Bin Naim	Deadline:	12/28/2018		
Request to Void this process?	NA				
	Name	Date	Signature		
Decided by:	Bernard Retutas Pamplona	12/28/2018 3:31:35 AM	Digitally signed in FlexQ Medical Reason: Date and Time: 12/28/2018 3:31:35 AM		
Review and Evaluation					
Deviation Review and Evaluation					
Does the deviation apply to any devices shipped to customer?	No				
If yes, was the customer notified?	NA				
Customer Notification Date:	N/A				
Customer Feedback:	N/A				
Customer Facility:	N/A				
Customer Contact Name:	N/A				

Does the deviation apply to any products not yet shipped?	Yes		
If yes, what is the impact evaluation?	Low impact-The Y1 components will still tested in downstream process at functional test as simulation done and confirm able to detect wrong & faulty crystal.		
Are other products/processes impacted by the Deviation?	No		
Result of Risk Assessment:	Low Risk-The Y1 components will still tested in downstream process at functional test as simulation done and confirm able to detect wrong & faulty crystal		
Review and evaluate the deviation per Verification & Validation Procedure. Is the Verification & Validation Required?	No		
If No, specify rationale remark:	Not applicable since it's not medical product		
Customer Approval Required?	Yes		
CAR Needed?	☐		
NCMR Needed?	☐		
Implementation Designator:	Bernard Retutas Pamplona	Deadline:	03/29/2019
Request to Void this process?	NA		
	Name	Date	Signature
Reviewer:	Azrul Bin Naim	12/28/2018 3:51:19 AM	Digitally signed in FlexQ Medical Reason: Verified Date and Time: 12/28/2018 3:51:19 AM

Approval							
Approver							
Process Number	Name	Description	Creation date (UTC-00:00)	Close date	Status	Approver	Comments
DE-Approver-SEN-00000172	DE-Approver	Approve Deviation	12/28/2018	12/28/2018	Approved	Mohd Faizal Abdul	
DE-Approver-SEN-00000173	DE-Approver	Approve Deviation	12/28/2018	01/03/2019	Approved	Ku Aini binti Ku Faizal	
DE-Approver-SEN-00000174	DE-Approver	Approve Deviation	12/28/2018	12/28/2018	Approved	Narendran Sevoo Al Muniyandy	Approved, as per impact assessment done the risk is slight.
DE-Approver-SEN-00000175	DE-Approver	Approve Deviation	12/28/2018	12/28/2018	Approved	Jamaliah Binti Mohd	In total wips affected 61pcs
DE-Approver-SEN-00000176	DE-Approver	Approve Deviation	12/28/2018	12/28/2018	Approved	Ramon Anthony Vinas Regino	Approve
DE-Approver-SEN-00000177	DE-Approver	Approve Deviation	12/28/2018	12/28/2018	Approved	Chun Wei Kho	
Approval Date:		01/03/2019					

Customer Approval			
Approved by:	Muthiah @ Muthu AI Regupathi	Approval Date:	01/07/2019
Business Title:	Program Management Manager	Department:	5200 PROGRAM MGMT
Customer Comments History:	approve Commented by Muthiah @ Muthu AI Regupathi - 01/07/2019 07:40:44 (UTC-00:00)		
	Name	Date	Signature
Customer:	Muthiah @ Muthu AI Regupathi	1/7/2019 7:40:49 AM	Digitally signed in FlexQ Medical Reason: Date and Time: 1/7/2019 7:40:49 AM

Implementation	
Implementation Activities:	N/A

Deviation Limitation:	Date		
Start Date:	12/28/2018	End Date:	03/29/2019
Initiate early expiration:	NA		
Reference with existing Deviation Workflow?	☐		
Deviation Expiration Assignee			
Expiration Confirmation:	N/A	Deadline:	N/A

List of Attachments

File Name	Creation Date	Extension	File Size	User	Activity
Risk assessment.pdf	12/28/2018 3:46:45 AM	application/pdf	27.63 KB	Azrul Bin Naim	DEReview
img-Z28185012-0001.pdf	1/7/2019 7:40:11 AM	application/pdf	0.10 MB	Muthiah @ Muthu AI Regupathi	CustomerApproval
WAT-SBR0040.zip	1/7/2019 7:40:16 AM	application/x-compressed	12.81 MB	Muthiah @ Muthu AI Regupathi	CustomerApproval
SBR# 600SNI_signed.pdf	1/23/2019 7:20:29 AM	application/pdf	42.74 KB	Bernard Retutas Pamplona	DEImplementation
Serial Number_REV00.pdf	1/23/2019 7:20:29 AM	application/pdf	0.38 MB	Bernard Retutas Pamplona	DEImplementation

Affected Item(s)

Attachments

Risk assessment.pdf



Board P/N information: WT210000562

Date: 28-December-2018.

SUMMARY REPORT FOR THE RISK ASSESSMENT

Purpose: To assess the risk of any potential Y1 component related issue once omitted from ICT test.

Background: On 27-Dec-18 Flex Senai encountered model WT210000562 ICT Fixture frequency measuring module bad.

Risk Assessment: The crystal Y1 frequency test will be temporary omitted from the ICT test and the Y1 component will still tested in the downstream process with simulation at functional test as below :

- 1) By removing the crystal the board will failed at the LCD display test.
- 2) By replace with the different crystal (25Mhz), it will failed at External Pump Motor control test.

Conclusion: The assessment based on the changes made for the process of WT210000562 is assessed against the following categories.

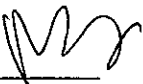
The outcome for each are as follows:

1. Process – There will be a process change by temporary removing Y1 Test on ICT to proceed ICT Testing until the Fixture is fixed.
2. Product – There are no product changes, other than the added process.
3. Materials – There is no change in material.

Base on the conclusion above:

Deviation will be raise until fixture frequency measuring module replace.

Prepared by:

NG SWEE TAY  Date: 28 Dec 2018

(Name and Signature)

Reviewed and approved by:

SUA SIN JEC  Date: 28/12/18

(Name and Signature)

Reviewed and approved by:

AKRUL BIN NAIM  Date: 28/12/18

(Name and Signature)

img-Z28185012-0001.pdf

SPECIAL BUILD REQUEST FORM (PCBA / Sub Assembly / Box Build)																																																				
Date Initiated: <u>27-Dec-18</u>	SBR# <u>599SNI</u>																																																			
TO :	Narendran Sevoe Al Muniyandy, Jamaliah Binti Mohd, Ramon Anthony Vinas Regino, Sulasyah Binti Haradi, Ezrul Azura Binti Sam																																																			
CC :																																																				
CUSTOMER :	Saludod Hamlet Jr, Azrul Bin Naim, Sui Sin Jett, Amelia Binti Siman																																																			
PROJECT # :	Waters																																																			
PURPOSE :	WATH-WT-210000562-G To run evaluation on PCBA WATH-WT-210000562-G 9pcs as per attached S/N by unit Y1 (WATH-WT-338000161) testing in the ICT coverage. The component Y1 (WATH-WT-338000161) will still be tested in the downstream process at Flex Sengal Functional test. Flex Kallang to share the top level result and determine if there is any impact to Waters top level product accordingly.																																																			
DETAILS OF SPECIAL BUILD :																																																				
BUILD QUANTITY	: 9pcs (ZWTF004243)																																																			
BUILD DATE	: 27-Nov-18																																																			
SHIPMENT DATE	: 28-Nov-18																																																			
PROCESS FOR EVALUATION	: NA																																																			
PCA/SUB ASSY/BOX BUILD IDENTIFICATION	: WATH-WT-210000562-G																																																			
CARTON-BOX IDENTIFICATION	: SBR Build																																																			
ECO (Special Requirement)	: ☐ Yes ☒ No If Yes, please specify below:																																																			
REMARKS																																																				
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Handwritten:
MEOWDY Y4 28/12/2018
SQE
Low risk as per reviewed by CFT team. Y1 able to capture in Final Test.

Melody Yu

From: Joel Mamalateo Deduyo
Sent: Friday, December 28, 2018 3:57 PM
To: Chun Wei Kho; Amy Xu Xia Jie; Azrul Bin Naim; Kar Chuon Chan; Melody Yu; Narendran Sevoo Al Muniyandy; Sua Sin Jein; Swee Thai Ng; Yew Wah Pang; Yoganandhan Duraisamy
Cc: Nallajanula Phani Bhushan; Pratheush Paleri; Michelle Koh Sai Noi
Subject: RE: Waters ICT fixture faulty - model 210000562
Attachments: WAT070800 Rev 6 515 Final Test Station.pdf; 710000562rA SCHEM, PCB 515 CONTROLLER.pdf

Team,

TSP: WAT070800 Rev 6

RISK ASSESSMENT: 515 Final Test Station Procedure

If pcba 210000562 having Y1 with condition as below:

1. Missing component
2. Defective Component
3. Tilted / No Solder on the pcba

The Unit Under test will fail on 515 Final Test Station Procedure such as :

1. Ramp and Decay Test Fail
Specs: Total decay from 6000 psi over 3 minutes (≤ 250 psi) , 3rd minute decay (≤ 50 psi)
2. Ripple Test
Specs: Ripple at 1000 psi backpressure at 1 ml flow (≤ 2 %)
3. Flow Test
Specs: Flow error % @ 1000 psi back pressure @ 1 ml flow for 5 minutes ($\leq .5$ %)

Basic Electronics:

Y1 supplying 12MHZ frequency to U15 IC Processor Microcontroller and U8 CPLD (Complex Programmable Logic Device) having above condition makes UUT INOPERABLE and is ABLE to capture at 515 Final Test Station.

RISK: LOW

For Your Update,



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SBR# 600SNI_signed.pdf

MELODY YU
SSE
29 DEC 2018