1- Internal Audit information:

Activities Audited	**Measurement, analysis and improvement.** **Medical device adverse events and advisory notices.** ISO 13485:2016: 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.2.1, 7.1, 7.2.3, 7.3.9, 7.4.1, 7.5.2, 7.5.4, 7.5.6, 7.5.7, 8.1, 8.2.1, 8.2.3, 8.2.6, 8.3.1, 8.3.2, 8.3.3, 8.4, 8.5, 8.5.1, 8.5.2, 8.5.3, CMDR 1, 34, 57, 58, 59-61.1, 61.4-61.6, 63-65.1, TG(MD)R Sch3 P1 1.4(3)(a),(b),(c), (5)(b)(iii), (f), TG(MD)R Sch3 P1 2, 1.4(3)(a),(b), (5)(b)(iii),(f), TG(MD)R Sch1 P1 2, TG(MD)R Sch1 P1 2; Sch3 P1 1.5(4), 21 CFR 820.70(b), 820.75(c), 820.100(a)(2), (3), (4), (5), (6), (7), 820.100(b), 820.30(i), 820.30(g), 820.90(a), 820.100(a), 810.198, 21 CFR 803, 21 CFR 806, MDR2017/745 Chapter VII, Section 1, Article 83, MEDDEV 2.12/1, Rev. 8 MDSAP Chapter 3, Tasks 1 – 16)
Audit Date(s)	2024-06-10/11
Audit Date scheduled (*as per Audit schedule*)	June 10, 11, 13, 2024
Internal Auditor(s)	Gordon Forest, VL Solutions Inc.
Employees audited	Étienne Lefort, Fatima Chaouki, Tabitha Jaramillo
Department Manager	Étienne Lefort

2- Audit Summary:

Measurement, analysis and improvement activities: I verified that the management representative ensures that the requirements of the QMS are effectively defined, documented, implemented and maintained and that information related to the QMS is collected and analysed to identify actual and potential problems are investigated, and appropriate and effective corrective actions are taken.

Thorasys has documented and implemented procedures for measurement, analysis and improvement. The process described in QP12, Rev. 10.0 Servicing and Complaints Handling monitors feedback from customers, including customer complaints to provide early warning of quality problems and for input into the corrective and preventive action process.

Management review for MAI: There are three reviews conducted during the year and a final management review conducted yearly. The latest management review was conducted 3/5/2024 and 10/5/2024: Management Review No: REG-103450, Rev. 1.0. There were 14 action items issued for this review. Action item no. 1 - Retraining for Europe and India sales team on two- person approval requirement as per SOP-2 Ver.2 Sales and Purchasing. Due date 21/06/2024. This action is still pending.

Action items are tracked in a log:

Example: Update QP08 Nonconforming Product to update the risk classification timeframe objective with alternative risk-based process performance metrics that align with our

organization. Completed 16/05/2024. In the quarterly review completed in March 2024, reviewed the action item for updating QP08 Nonconforming Product to update the risk classification timeframe objective. This item is identified as ongoing and as such, has been accepted by management. I have determined the delay in the completion date for this action item was adequately addressed and was approved by management.

The total number of complaints for the current period (Oct 2022 – Sept 2023) was 183. There were 162 C-110 (including software) complaints out of 440 distributed (cumulative 2280), and 4 C2 complaints out of 29 distributed (cumulative 29). Considering that 582 devices were put on the field during the period (C100), and a total installation base of 1,840, the number of complaints per installed base was 5.0%. Since there was a significant increase in the number of complaints due to the larger install base, a negative trend was detected compared to previous periods.

Adverse trends were detected in 23 complaints for motor deactivated and Calibration Device Error (32).

Investigations are being conducted to confirm if there are any trends for trapped flat ribbon cable and mishandling.
There were important delays in the review and closure of complaints due to the changing role of the service manager and new manager, a greater number of total complaints, and the lack of ownership of the complaint investigation or investigation not adequately documented in the complaint report. Since September 2022 improvements are being made with regular complaint meetings.

I confirm that Thorasys has determined the control and actions to be taken on nonconforming products detected after delivery or use, commensurate with the risk associated with a product failure.

Investigation of Nonconformity

During the audit, I verified:

Case TS-528: 2023-08-29 – Santair Medical (Greece) reported a device "Motor Deactivated" error. The device could not pass calibration and could not be used for testing. Customer Service conducted an online inspection with the client and was able to replicate the issue. Customer Service triggered an RMA to get the device returned for Investigation and repair. Immediate/interim Risk Control Actions:

The "motor deactivated" issue does not expose the end-user to any safety-related hazards or hazardous situations; the device could not pass Field calibration and in turn could not perform any Patient test.

Reportability assessment: For Europe and the US (because the product is legally marketed in the US). Refer to procedure QP22, Rev. 1.0 Medical Device Reporting Procedure – Europe. Form QF22-1, Rev. 1.0 European Medical Device Reporting (NDR) Decision Assessment

Form. The form was filled out for complaint TS-528 and it was determined that the event was not reportable as the event was not a serious incident that directly or indirectly led, might have led or might lead to any of the following:

a. the death of a patient, user or other person,
b. the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
c. a Serious Public Health Threat (see QP22 definition)

Completed: 13/02/2024

During the management review the trend analysis indicate that CAP-100097 (loose screws causing motor deactivation) and CAP-100099 (inadequate soldering causing motor deactivation) were opened, and actions implemented:

CAP-100097 - Preliminary investigation for the common cause of the loose screws in the complaint cases points at incorrect torque applied to them during assembly, or a possible deviation from the specification where the wrong length of screws was used.

Corrections/Corrective/Preventive Action Plan (including further Immediate Actions)

Action #	Description	Responsible(s)	Due Date
1	Update the Risk assessment record (RSK-102133 rev 14) to cover pneumotach pressure port getting loose	Brandon Wong Ping Lun	31/01/2023
2	Mention of the torque for pneumotach pressure port will be added in the specification drawing 101337 (pneumotach base assembly) and inspection protocol INP-100343-TH. Specification drawings 100503 (motor assembly), 100343 (FOT electromech module assembly), 101397 (pre-calibration), 100506 (CU electronics assembly), and inspection protocol INP-101397-TH will also include mention of required torque for screws that were found to be loose.	Brandon Wong Ping Lun	31/01/2023

Description of how the actions address the problem, the root causes, the risks, and correlate to the Investigation:

The actions taken will ensure that assemblies and sub-assemblies are assembled according to their approved specifications thereby reducing the risk of screws becoming loose again in the future.

Verification and effectiveness 23/10/2023 -

Review of complaints since action implementation on 21-04-2023 showed no complaints regarding loose screw:

A total of 93 C100 complaints were initiated (21-04-2023 to 03-10-2023); as per attached «CAP-100097 Complaint Log»:

72 complaints related to devices manufactured before 21-04-2023: the Serial Number (SN) of these devices confirmed that they were manufactured before device SN141684 (first device manufactured on 21- 04-2023: TCO-103159 Release date);

17 complaints related to the software issue;

2 complaints related to the test loads;

2 complaints: TS-486 (TremoFlo not connecting) and TS-517 (Compensated calibration check fail) where SN device is not provided yet by the customer; Customer Service Manager and Engineering confirmed that these complaints are not related to the loose screw.

As there are no complaints regarding loose screw since action implemented, 21/04/2023, this CAPA is considered effective and can be closed.

CASE TS 582 – (3/01/2024) occurred in Denmark – customer reported a calibration error. Nowus Healthcare reported a device calibration error on TremoFlo unit SN 121193. Customer Service conducted an online inspection and could not troubleshoot the issue. The device could not pass calibration with the Test Load 15cm SN 414769 from the customer and also with a replacement Test Load 15cm SN ^43823. The attached Field Calibration reports were showing calibration gains between 27% and 30%. Customer Service triggered an RMA to get the device returned for Investigation and Repair.

Not a serious health risk.

Investigation:

Upon the retrieval of the device (5N139869) through RMA00330, the device was tested, and the issue «Compensated Calibration Check Fail" was reproduced with both customer's and production test loads. For further inspection, the device was opened and multiple defects directly relating to this issue were seen:

DEVICE MANUFACTURING DATE: 06/02/2020

Loose pressure ports (3 out of 3) in the PFT: Loose Pressure ports will lead to air leaks. Air leaks will cause a high gain triggering the "Compensated Calibration Check Fail" error. The root cause for the loose ports is insufficient tightening of the pressure ports. The PFT assembly was done as per SPEC- 101337 Rev. 4. This spec had no checks for tightening the pressure ports flush. This issue was addressed as per CAP-100097 and corrected through TCO-103159 which was effective on 21/04/2023 which was after the device manufacturing date.

Broken O-ring on the PFT: The root cause of a broken O-ring is caused by the deterioration of the O-ring which will happen due to the following:

- A small portion of the O-ring would sometimes be lodged between the pressure port threads and the inside of the heater ring threads which will cause the ring to break eventually leading to leaks and thus calibration failure.
- The assembly step and checks for installing the O-ring and pressure ports are qualitative and not Quantitative (when tightening the pressure ports to seal). This can lead to slight variations in the assembly step and checks for installing the O-ring and pressure ports are qualitative and not quantitative (when tightening the pressure ports to seal). This can lead to slight variations in acceptable criteria depending on the technician. Should too much

force be applied to the O-ring, this can lead to the O-ring deteriorating and cracking earlier than expected leading to leaks and thus calibration failure.

This issue has been previously observed as per NCR-100125, and the resolution is ongoing.

Damaged and Dusty PFT Mesh:

The root cause for a **damaged mesh** is due to customer mishandling. The damage on the mesh is caused by using incompatible or wrong filter. The user manual warns not to use a different or wrong filter. The damage on the mesh could also occur in case of poking when cleaning or using. The user manual instructs on the cleaning and handling of the device. A dusty mesh will lead to an increase of resistance and therefore a higher gain. The root cause for **dusty mesh** is also customer mishandling. The user manual states the use of a dust cap in case the device is not being used or in transportation.

Customer mishandling was addressed as per **CAP-100123** action no.3 which was completed on
25/10/2023.

Dusty Piston Mesh: A dusty piston mesh will cause an increase in the resistance, which will lead to higher gain and thus contribute to the issue.

The device could not pass daily calibration, therefore, could not be used on any patient. This implies no risk to the operator or the patient but a delay in the patient's treatment. The safety failure "Compensated Calibration Check Fail" was triggered successfully and prevented the use of the device.

No changes are required for RSK-102133 rev 20 because the risk associated with this root cause is acceptable and covered under risk ID OPR3A.

No changes are required for RSK-103324 rev 1 because the risk associated with this root cause is acceptable and covered under risk ID P12 and P13.

☒ No, provide rationale: Know issues:

- The broken O-ring change is ongoing.
- Loose pressure ports addressed as per CAP-100097 and corrected through TCO-103159 which was effective on 21/04/2023
- Customer mishandling was addressed as per CAP-100123 action no.3, completed on 28/10/2023.

Change order associated with broken O-ring
TCO-8

1. Proposed Changes

TCO Title:	Pressure Port O-Ring Removal				
TCO Coordinator :	Brandon Wong Ping Lun				
Product:	tf C-100 Pneumotach Base Assembly tremoflo C-100 FOT Module Assembly Torque Wrench Connecting Tool Heater Ring - Pressure Port Installation Checker Tool			DHF Number:	003
Product Part Number:	101337 102188 102197	Rev	6 NA NA	REF Number: UDI Number:	N/A N/A
	☐ [illegible]			☑ Other: PN 101337 is a sub-assembly of	

Specification drawing 101337 will be updated to remove the use of the pressure port o-rings (PN 101266) and will include a note that specifies the torque value for the pressure ports. This change will help to reduce the occurrences of o-rings cracking over time due to assembly errors and will add additional preventative measures to ensure that the pressure ports are adequately tightened.

Is design validation testing required (e.g. performance and usability testing)?	☑ **Yes**: Verification of the device's safety and performance following the removal of the pressure port o-ring is documented as part of the test report DES-103317. ☐ **No**: N/A
Is the product's compliance to applicable regulatory requirements affected? (example: FDA, CE, CMDR, TGA, EU Essential Requirements or GSPRs)	☑ **Yes**: This proposed change is subject to design verification testing as per test protocol DES-103316 and test report DES-103317 to ensure the product's compliance to applicable safety and performance requirements and essential requirements as per REG-102202 - CE Essential Requirements Checklist. ☐ **No**: N/A

The change has not been implemented and is pending approval.

The changes will also be implemented on devices that have been returned for repair.

Medical device reporting/vigilance report trends and corrections and removal actions
There were no reportable events including no Foreign Risk Notifications to Health Canada.

Device recalls

Since the last audit, a recall was initiated for product distributed in Australia based on an internal finding. CAP-100126 Initiation date: 19/0/2022.

1. **Source of CAPA Request reference (NC#, complaint#, KPI source, Audit report# etc.):**

   NCR-100123

2. **Description:**

   On 24-07-2023 we identified the following labels were incorrectly printed and affixed on the tremoflo C2 Support Arm (p/n: 101688 Rev1), lot number 142168:

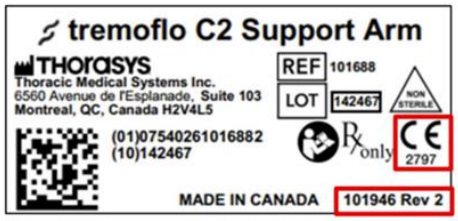
   1. p/n: 102119 Rev 1 – tf C2 Support Arm Label

   Additionally, we identified inconsistencies between the following label specifications as per the DMR and as found on Odoo:

   1. p/n: 102119 Rev 1 – tf C2 Support Arm Label
   2. p/n: 102000 Rev 1 – tf C2 Support Arm packaging label

   The differences between the label specifications are indicated below in red:

As the result of improper label transfer to production, there were discrepancies in the labeling:

Odoo:	**DMR:**
p/n: 102119 Rev 1 – tf C2 Support Arm Label	
 *Note: Lot Number 142467 is indicated next to the 'LOT' symbol and proceeding the (10) in the UDI for reference only.*	
Differences: The differences in the tf C2 Support Arm Label (p/n: 102119 Rev 1) is the presence of a CE (2797) symbol, and the label specification part number and revision featured at the bottom right hand corner.	

There were 16 C2 Support Arms under recall. The recall (in-field correction) was done where the customers were sent the new labels.

Containment and Corrections:

The following TremoFlo C2 Support Arm (p/n: 101688 Rev 1) are in inventory: 142168 (lot number).

The inventory was transferred to nonconforming product quarantine by T Jaramillo on 24/07/2023 as per NCR-100123.

Additionally, label specifications p/n: 102119 Rev 1 - tf C2 Support Arm Label, and p/n: 102000 Rev 1 - tf C2 Support Arm packaging label specification on Odoo will be corrected to aligned with the DMR.

Additionally, there are no labels in inventory as they are printed and affixed during production, and in turn, no containment actions are required.

Document the review of the issue information with those directly responsible for assuring the quality of the related product or the prevention of the related problems:

The following personnel contributed to gathering information pertaining to the issue described above: L. Posada, G. Chaib

A product Defect Correction RC-2023-RN-00979-1 was issued to the Sponsor who further issued it to all the customers who received these products.

The labels on the product and on the packaging were issued for replacement by the customers.

Corrective Action:

CAPA#: CAP-100126

Part 2: Investigation, Root Cause and Risk Analysis and Action Plan

1. Investigation & Root Cause Analysis:

Describe investigation including investigation methods and identification of root causes results. Determine if other variants (Thorasys products) may have the same or similar issue; Include document references when applicable.

2. Risk Analysis:

Describe Risk Analysis and provide rational for Risk Classification below. Include where applicable reviewed Risk Management file per Risk Management procedure. Include document references when applicable.

3. Documentation Review:

Review of any new issue information per (1) & (2) above as compared to that in the Request subsection with those directly responsible for assuring the quality of the related product or the prevention of the related problems:

Action #	Description	Responsible(s)	Due Date
1	Verify all specifications as per TCO-103039 were correctly transferred to the eDMR.	Albert Mouawad Ghania Chaib	22/09/2023
2	Update the following documentation to include or correct reference to p/n: 102119 Rev 1.0 – tf C2 Support Arm Label and/or p/n: 102000 Rev 1.0 – C2 Arm Shipping ID Label as per QP15 Technical Change Order: • 101688 Rev1 – tf C2 Support Arm Assem • 102023 Rev 1 – tremoflo C2 Support Arm Packaging Assembly • WI-103036 Rev 1 – tf C2 Order Preparation and Packing Procedure	Lucas Posada Brandon Wong	29/09/2023
3	Document INP-101688-TH and release the inspection protocol to production as per QP15 Technical Change Order.	Lucas Posada Brandon Wong	29/09/2023
4	Document an inspection protocol for the C2 Support Arm packaging labels and transfer to production as per QP15 Technical Changer Order.	Lucas Posada Brandon Wong	29/09/2023
5	Update QP15 Technical Change Order Process to include controls that all labels have an associated inspection protocol as required by QP06 Manufacturing Control.	Tabitha Jaramillo	31/10/2023
6	Update QP06 Manufacturing Control to indicate labels must be verified against the DMR by QA prior to application or prior to final packaging.	Tabitha Jaramillo	15/11/2023

Training on revised procedure QP06, Rev. 6.0 was provided:
The training is managed through Qualio.

Approvers
- Etienne Lefort approved at Mar 19 2024 1:43 PM
- Fatima Chaouki approved at Mar 11 2024 3:42 PM
- Ghania Chaib approved at Mar 11 2024 3:46 PM
- Jefferson Da Silveira approved at Mar 13 2024 4:16 PM
- Kim Chow
- Matthew De Bruyn approved at Mar 11 2024 4:16 PM
- Nasri Baghdadi approved at Mar 13 2024 10:20 AM
- Omar Dandan approved at Mar 12 2024 8:58 AM
- Victor Lanzo

The above are individuals who have approved their training records.
The training was reading and understanding with competency confirmed by the QA Manager.

Status of nonconforming product and review of nonconforming product trends

Between 2022-11-01 and 2023-09-30, 33 nonconformities were opened, and all were closed. Brandon and Omar are sharing this responsibility, and both have been interviewed during this audit and the expected improvement in closing the non-conformances has been achieved.

During the audit I verified the following NC 100113 C2 Main Unit Screen not sticking (22/03/2023) PN 101106 - Based on the dimensions of the screen (PN 101672) and the top shell (PN 101667), it was determined that the issue was caused by a design flaw in the top shell which prevented the screen from being able to be fully seated into its cut-out.

Other C2 units have already been shipped, however are unaffected by this issue due to the manufacturing tolerancing whereby enough space existed for the screen to be placed and fit into the slot.

The 6 nonconforming top shells and 29 additional top shells from lot 141601 will be reworked as per the following:

- Using a Dremel to create a chamfer on the upper portion of the top shell's screen slot.
- Visually inspect before placing the screen to ensure that there is minimal residual material sticking out or left over which could reduce the effectiveness of the screen's glue.
- Inspect as per INP-101709-TH Rev 1.0.

The NC was approved and closed 10/11/2023.

Post-market surveillance

QP25, Rev. 3.0 is used as a post-production feedback system for product safety and performance input to the analysis of data and management review processes to provide early warnings of quality problems, to provide input to maintain risk management data up to date, to provide input and maintain clinical data and the CER for products in the EU, and for input into the corrective action process.

The sources of post-market surveillance information are derived from:

• Information concerning serious incidents from complaints, including from recalls, and PSURs.
• Active supervision by customer monitoring
• Feedback from sales representatives
• Inquiries of users and patients
• Literature reviews
• Internal testing
• PMCF
• Information about competitor devices
• Trending in key performance indicators
• User reaction during training programs
• Media and trade shows
• Suppliers' related issues

• Review of regulatory authorities' databases on similar incidents
• Audit reports etc.

A **Post-Market Surveillance Report** (Doc. # REG-103376, Rev. 1.0) for TremoFlo C100 Airway Oscillometry System was issued for the period 2022-08-01 to 2023/05/26 and issued 30/12/2023 and a PSUR (Doc. # REG-103282) was prepared in accordance with article 86 of MDR 2017/745 to cover the requirements of the EU PSUR. The period covered 2021-05-266 to 2023-05-255. The report was issued 30/12/2023.

The TremoFlo C100 Airwave Oscillometry System is a legacy device and is the first PSUR as required under the MDR. There are no prior applicable NB actions and no changes to the collection period (e.g. first PSUR).

Based on the analysis of the collected data, it is concluded that the benefit-risk profile of the TremoFlo C100 Airwave Oscillometry System has not been adversely impacted and remains unchanged.

The **Post-Market Clinical Follow-Up Report** (Doc. # 103298) was issued on 2023-12-30 and covered the period from Aug 6, 2022, to May 26, 2023. Section 4 of the "TremoFlo C100 PMCF report where the exact same PMS and Risk Management Inputs were collected, assessed, summarized, and concluded upon. It refers to REG-103289 Post-Market Clinical Follow-Up report where the exact same PMS and Risk Management inputs were collected, assessed, summarized, and concluded upon.

This report includes the following assessments:

- previously unrecognized hazards or hazardous situations are present,
- an estimated risk arising from a hazardous situation is no longer acceptable,
- the overall residual risk is no longer acceptable in relation to the benefits of the intended use; or
- the generally acknowledged "state of the art" has changed.

Only CAP-100119 identified new risks which triggered an update to the risk management file (see RSK-102133 Rev 17, Risk ID SOF37). This newly identified risk involves the low likelihood possibility of inaccurate pulmonary assessment similarly as with other database errors. It was already possible but was not previously identified. It was found to be acceptable and is within the present established risk benefit profile of the product. All other CAPAs did not identify new risks and in turn, the risk-benefit profile of the product is unchanged.

Information generated by the supply chain: Over the subject period (2022 August 1st to 2023 May 26th), there were a total of 8 NCs related to supplier issues that were opened - see Appendix 8 for list of supplier NCs. Per the list, although some of the root cause investigations are not yet completed on all, the issues (NCs) were all given specific instances of supplier component failure issues which were identified per supplier controls (receiving inspection and all units are performance tested before being released) and quarantined without underlying any new risks or

undue performance specification issues for systems and components that do meet specifications and are conforming.

Therefore, the results support meeting the aims (a), & (d) below:

(a) confirming the continued safety and performance of the device throughout its expected lifetime - no issues identified for components and systems meeting specifications,

(d) ensuring the continued acceptability of the benefit-risk ratio - no change to benefit-risk profile.

Conclusions

The PMS activities over the Aug 1, 2022, to May 26, 2023 that were completed as planned as part of the PMCF Plan were completed and the results support the following main objectives:

a) confirming the safety and performance of the device throughout its expected lifetime,
b) Identifying previously unknown and monitoring these side-effects and contraindications - none were identified,
c) identifying and analyzing emergent risks on the basis of factual evidence - none were identified,
d) ensuring the continued acceptability of the benefit-risk ratio, and
e) identifying possible systematic misuse or off label use of the device, with view to verifying that the intended purpose is correct - none were identified.

In addition, per the Clinical Literature data, and the unchanged applicability of the ERS Guidelines for Airwave Oscillometry and the applicable External Standards, the current State of Art for Airwave 'Oscillometry is relatively unchanged since the original CER although increasing uses are being demonstrated and increasing clinical data is being made available for both the TremoFlo as well as the Resmon equivalent device.

A **CER** for TremoFlo C2 (Doc. # REG-1022728, Rev. 3.0 was issued on 30/12/2023. The scope of the CER was:

- Products Scope,
- Classification
- Description & Technology
- Indications for Use (as per current labelling for EU - e.g. User Manual)
- C2 Marketing Status (main countries)
- Claims (same as CI00 as per REG 102899 rev 2.0)

Medical Fields Concerned/ Relevant Medical Conditions:

FOT devices such as the present TremoFlo are intended for use in the general field of respiratory care as a diagnostic tool to evaluate quantitatively the respiratory impedance characteristics of a patient's airways and lungs. These provided impedance measurement are intended to provide the clinician with indications of possible respiratory diseases and changes in these on the basis of comparisons to normative data as well as over time in the individual patient.

The results validated that the tremolo meets the present state of the art and the General Safety and Performance Requirements (GSPR) #1 and 8 of the current MDR 2017/745 with respect to:

- the requirements of the safety of patients and users (GSPR 1),
- the requirements of an acceptable benefit-risk profile (GSPR 1),
- the requirements of adequate performance (GSPR 1),
- the requirements of acceptability of side effects (GSPR 8).

Conclusions

In conclusion, the present clinical data assessment, which included numerous post market studies for both the TremoFlo as well as the Resmon equivalent devices, the demonstration of substantial equivalence between the TremoFlo and the Resmon products, and also PMS data for the TremoFlo collected by Thorasys since its initial release in 2013, supports compliance with the Essential Requirements #1,3, and 6 with respect to safety of patients and users, the acceptability of the risks whereby the benefits outweigh the risk, the achievements of the claimed benefits, and that there are no undesirable side effects.

The results are consistent with the current state-of the art, and with the current risk management assessments and measures adopted for TremoFlo and supports that the system can and does meet its intended use as labelled.

Date of the next clinical evaluation: in 4 years.

Health Canada Summary Reports (QP-25, Rev,) section 7 Summary Report (Canada only)

THORASYS shall prepare Summary Reports corresponding to each Thorasys medical device licence from Health Cans every two years (as of the effective date of amendment SOR/2020-262 i.e. 23/12/2021) for Class II device licences.

Using Form F25-08 – Summary Report

REG-103377 (issued 30/12/2023) Rev..1.0 First version: for tf C-100 and C2 2023.

Listing of countries where devices were sold, and the quantity sold in each country.

Changes: There were 13 TCOs completed in the period. The changes included minor production/inspection changes related to design changes, documentation changes, minor product changes, and minor label changes and corrections. Some of the changes corrected given product issues in relation to given CAPAs and NCs (see CAPA and NC sections below). None involved new risks or otherwise adversely impacted existing hazards.

Notifications and/or Amendments to the Devices to Health Canada

Licence Amendments:

1. 2021-07-30: correction to indication for use (remove home use), various updates to identifier - see Appendix 1

2. 2022-05-25: update to add C2 variant including change to licence name (remove C100 in name) and added device IDs for C2 version - see Appendix 2
3. 2023/01/18: addition of software version 1.9 and correction to component part number - see Appendix 3

Possible adverse effects associated with the device

The main potential risk directly related to the use of this technology is that the measurements are inaccurate, not reproducible and/or standardized per the presently established ERS guideline specifications (e.g., such as to allow the establishment and use of normative data).

Complaints and customer feedback

These are all considered low risk complaints, and none involved new risks or otherwise adversely impacted existing hazards or the benefit-risk profile.

Conclusions

Assessment and Conclusion of Risk-Benefit Determination

This includes o determination of whether a change to the benefit or risks has occurred during the reporting period. Clearly state whether there has been a change to the risks and/or benefits of the devices within scope of the report, re- "Change" in the present instance means that, per the above analysis that the device may no longer meet the applicable requirements (sections 10 to 20 of the SOR 98-282 Regulations).

In summary none of the above post-market information and assessment indicated any change whereby the given products no longer meet the applicable Health Canada requirements ((sections 10 to 20 of the Regulations). The minor class III recalls noted above did not involve any changes to the risk benefit profile. There were minor updates to the risk documentation, but no new risks were identified outside of the product known risk benefit profile.
As supported by the above information, there is **no change in the benefits or risks of the device within the scope of this report.**

Preventive or Corrective Actions

Include CAPA actions that have been considered or implemented or those that are planned as a result of the identified change.

If the actions have already been implemented and Health Canada has already been notified during the reporting period indicate here that any Accessary preventive or corrective actions were already taken in relation to the identified change to the benefits and/or risks of the device, and that Health Canada has already been notified (recall notification or submission of a licence amendment application)

Not Applicable (i.e. since no change to benefits or risks as per the above data and assessments)

Date of the Next Summary Report

In 2025 after and to cover the next Period May 26, 2023, to May 25, 2025 (to align with the Periodic Safety Update Report for EU).

Verification of closed nonconformities and CAPAs in response to deficiencies identified by BSI during their las audit.

CAP-100128 – Inadequate documentation:

2378373-202308-NI, "The General Requirements of the QMS are incomplete and not fully effective. The reference to UKCA is not mentioned in the scope, the quality manual and some regulatory processes."

Thorasys implemented QP27 Rev 1.0 Medical Device Reporting UK and included UK specific requirements in QP20 Rev 4.0 General Recall Process & Specifics for Canada - USA - European Union - UK. QP00 Rev 10.0 Quality Manual and QP16 Rev 7.0 Regulatory Processes were verified and found that they inadequately implement applicable UK MHRA regulatory requirements.

Action proposed:
2378373-202308-NI, "The General Requirements of the QMS are incomplete and not fully effective. The reference to UKCA is not mentioned in the scope, the quality manual and some regulatory processes."

Corrections/Corrective/Preventive Action Plan (including further Immediate Actions)			
Action #	Description	Responsible(s)	Due Date
1	Update QP00 Rev 10.0 Quality Manual to include reference to UK MHRA medical device regulation.	Tabitha Jaramillo Fatima Chaouki	15/12/2023

Under section 5-2 Applicable Standards of QP00, Rev. 11 it is noted: UK MHRA medical device regulations 2002. This became effective on 15-02-2024.

2378373-202308-N4, "The control of measuring equipment is not fully effective. The procedure does not indicate how to re-evaluate the validity of product when equipment is found out of tolerance."

Action Proposed:
Update QP07 Rev 3.0 Equipment Calibration Process to include process requirements to evaluate the validity of product measured with equipment found to be out of calibration.

I verified
QP07, Rev. 4.0 Add in section 10, the requirement to evaluate the validity of the products measured with the equipment found out of calibration since the last equipment calibration which was found within specification (CAP- 100128 action 2). This revision had been made.

Training was done on QP7, Rev. 4.0: Evidence: Training record from May 8 and June 30, 2024. Everyone implicated by the change was trained by June 11, 2024.

3	Update QP14 Rev 8.0 Document and Record Control to include process requirements for transferring the following documentation to our Authorized Representative in the case of bankruptcy or termination of business activities: 1. The EU declaration of conformity, 2. Documentation referred to in the fifth indent of Section 2.1 of Annex IX and in particular the data and records arising from the procedures referred to in point (c) of the second paragraph of Section 2.2 of Annex IX of EU MDR 2017/745, 3. Information on the changes referred to in Section 2.4 of Annex IX of EU MDR 2017/745, 4. Documentation referred to in Section 4.2 of Annex IX of EU MDR 2017/745, and 5. The decisions and reports from the notified body as referred to Annex IX of EU MDR 2017/745.	Tabitha Jaramillo	23/02/2024

I verified QP14, rev. 9.0 and the following was added: (13-03-2024)

1) Per CAP-100128 (Action no.3) added §17 Bankruptcy or Termination of Business Activities
2) "or SOP-X" and "Where X is automatically assigned on Qualio" in Annex A: Document Identification
3) "or FRM-X" and "Where X is automatically assigned on Qualio" in Annex A: Document Identification
4) "or QI-X" and "Where X is automatically assigned on Qualio" in Annex A: Document Identification
5) "Additionally, we preserve access and retain the information available on myThorasys and the Thorasys website for the same retention period. Electronic information is backed up and retained as per Thorasys Backup Policy (refer to ISO 27001 ISMS)" to §13 Document and Records Retention, Disposition and Retrieval.

2378373-2023Q8-N7, "The reporting to the notify body is not fully compliant because the method of reporting is not clearly documented."

2378373-202308-N7, "The reporting to the notify body is not fully compliant because the method of reporting is not clearly documented."
QP12, Rev. 10.0 was revised (06-06-2024).

In addition, in the case of an adverse event which was determined as reportable in any given country/area the Registrar/Notified Body BSI must also be notified of such events and provided with copies of the applicable MDRs.

Use the Manufacturer's Incident Report (MIR) Version 7.2.1 available electronically on the BSI Portal to inform BSI of the reportable event. If the BSI Portal is unavailable, send the MIR to vigilancereports@bsigroup.com.

The records related to the above activities including any rationales, including MDR decision trees, MDRs, and notifications to BSI, are to be included in the complaint report file.
When section 2 is completed, the QA/RA print, sign and file this section as per section 8.

I have verified the above action plans and found them to be effective in eliminating the observed nonconformances.

CAP-100131: the risk management process was not fully effective. The risk management file does not evaluate the effect of risk arising from risk control measures.

Proposed Action:

Corrections/Corrective/Preventive Action Plan (including further Immediate Actions)			
Action #	Description	Responsible(s)	Due Date
1	Update the following QFs to include an evaluation of the risk control measures: - QF17-01 Rev 4.0 – Product FMEA - QF17-04 Rev 1.0 – Usability FMEA - QF17-05 Rev 1.0 – Hardware FMEA - QF17-06 Rev 1.0 – Process FMEA - QF17-07 Rev 1.0 – Software FMEA	Tabitha Jaramillo Étienne Lefort	30/11/2023
2	Update the following C-100 and C2 risk management documentation in accordance with the new QF as per Action no.1: • RSK-102612 – C2 Risk Assessment Record	Lucas Posada Brandon Wong	31/01/2024

Updating of the forms QF17-01 through QF17-07 to include an evaluation of the risk control measures.

I verified the following sample: QF17-05, Rev. 2.0 Hardware FMEA. (29-09-2023)

Added: 1. 'Other Risks or Impact to Existing Risks? (Refer to Risk ID or N/A)' column Updated: 1. 'Maximum Residual Risk Rating' to 'Maximum Residual Rating' 2. 'Maximum Residual Risk Category' to 'Maximum Residual Risk Level' 3. 'Initial Risk Rating' to 'Initial Rating' 4. 'Initial Risk Category' to 'Initial Risk Level' 5. 'Related Requirement' to 'Related Requirement/Design/Process ID' 6. 'Risk Control Verification of Effectiveness' to 'Risk Control Measures' and 'Risk Control Verification of Effectiveness (Refer to applicable test procedure and specific section' 7. 'Acceptable' to 'Acceptable or Unacceptable' 8. 'Residual Risk Category' to 'Residual Risk Level' 9. 'Software/Hardware/Usability' to 'Risk Control Category: (e.g. Software/Firmware/Hardware/Usability)' Removed 10. 'Comments/Reference' column	02-Oct-2023

This column was added to the form:

Other Risks or Impact to Existing Risks? *(Refer to Risk ID or N/A)*

The product risk management documentation was updated. Example RSK-101612 – C2 Risk Assessment Record, Rev. 5.0 was effective on 05-12-2023. QF17-01 Rev. 5.0 is indicated in the footer of the Product FMEA (RSK-102612, Rev., 5.0.
CAP-100134 C2 Mold Enclosure Validation.

During VOE of CAP-100114, we identified the corrective actions implemented were ineffective in preventing the recurrent of the problem. The verification demonstrated mold validation activities prescribed in the Process Validation Master Plan Schedule were not completed by the defined timeline. This means C2 injection molding processes were not validated.

The injection refolding process validation for the TremoFlo C2 mold enclosure was due June 2023 according to the Process VMPS June 2022.

Processes are validated according to QI06-05 Rev 1.0 Process Validation and in turn, by not fulfilling the obligations of the Process Validation Master Plan Schedule, the C2 did not comply with all applicable process requirements.

Proposed actions:

Corrections/Corrective/Preventive Action Plan (including further Immediate Actions)			
Action #	**Description**	**Responsible(s)**	**Due Date**
1	Validated injection molding processes for the tremoflo C2 in accordance with QI06-05 Process Validation.	Lucas Posada Albert Mouawad	30/03/2024
2	Update the Process VMPS to reflect the new due date associated with Action Item no.1	Tabitha Jaramillo	27/10/2023
3	Update QP03 Design Control to include reference to QI06-05 Process Validation under design transfer process requirements.	Tabitha Jaramillo	31/01/2024

QP3, Rev. 9.0 Design Control.
Under section 7.7 Design Transfer : process validation activities are performed as per QI06-06 Process Validation.

CAP-100135 The data analysis is not fully effective because the process is not properly documented.

Planned actions:

	7. Audits 8. Suppliers 9. Post-market surveillance 10. Nonconformance related to advisory notices Analysis methods must use valid statistical techniques, where applicable. Additionally, the methods must permit the identification of existing and potential causes of nonconforming product or other quality problems that may require corrective or preventive actions.		

Corrections/Corrective/Preventive Action Plan (including further Immediate Actions)			
Action #	**Description**	**Responsible(s)**	**Due Date**
1	Document a stand-alone procedure for Data Analysis that describes how to collect and analyze the following sources of quality data: 1. Customer Complaints 2. Nonconformances 3. Corrective and Preventive Actions 4. Feedback 5. Servicing 6. Returned Product	Tabitha Jaramillo Fatima Chaouki	28-06-2024

VoE Plan			
Action #	Description	Responsible(s)	Due Date
1	Verify the compliance of the quality procedure through Internal Audits.	Tabitha Jaramillo	31/07/2024
2	Verify sources of quality data which serve as an input to management review were collected and analyzed in accordance with the implemented Data Analysis procedure during a quarterly or annual Management Review.	Tabitha Jaramillo	31/10/2024

QP-30 Data Analysis Ver. 1.0 (13-06-2024).

Purpose

This standard operating procedure describes how to collect and analyse sources of quality data to assess the conformity of the product and the quality management system. This procedure describes the criteria used to evaluate if Improvement is required by identifying existing and potential nonconformities.

Scope

This standard operating procedure describes the statistical techniques used for collecting, measuring, and analysing sources of quality data.

The next quarterly review will have to be performed using the analysis methods described in SOP-30.

A complete evaluation of the effectiveness cannot be done at this point, other than to confirm that the documentation has been approved (June 13, 2024) and will be implemented by the end of July 2024.

CAP100136 Reporting to regulatory authorities is not fully effective.

2390187-202309-N2: *Reporting to regulatory authorities is not fully effective because the recalls reporting in Australia is not properly documented.*

2390187-202309-N3: *Documented QMS - Quality Management System is not fully compliant in relation to Notification of Changes to Marketed Devices or to the QMS to Australia and also that their Regulatory Plan has not been updated as documented under their QMS.*

2390187-202309-N4: *Design and development validation is not fully compliant in relation to Clinical Evaluation Procedure.*

Action Plans:

3	Update QP24 Rev 2.0 – Recall Procedure – Australia to include the following process requirement: • Notification requirements to Sponsor with respect to recall activities performed in Australia. • Notification requirements to regulatory authorities with respect to recall activities performed in Australia.	Tabitha Jaramillo	30/04/2024

QP-24 Recall Procedure Australia, Rev. 3.0 (02/02/2024)

3.0	Per CAP-100136, add a new section as section 7.2 « Notifying Regulatory Authorities and Sponsor» and change the section that was previously in 7.2 «Investigation of the problem» to section 7.3. Upadate recall contacts.

Section Added: 7.2 Notifying Regulatory Authorities and Sponsor

THORASYS shall inform the Sponsor of the need for a recall as soon as we become aware (but no later than 24 hours after becoming aware of the need for a recall). It is the Sponsor's responsibility to notify the Australian Regulatory Authorities following notification from Thorasys.

8.5 TGA (Australia)

Inform our Australian Sponsor of a planned substantial change. The Sponsor applies for the substantial change and notifies the TGA on our behalf.

Complete the *Substantial change notification applicable* on the TGA Business Services (TBS) portal in collaboration with the Sponsor.
Additionally, if the product under change was authorized for distribution in Australia under a valid EU MDD or MDR certificate, then both the European and Australian authorities must be notified of the change.

2	QP16 Rev 9.0 Regulatory Processes (effective 14/03/2024) was updated to include the clinical evaluation requirements with respect to the Australian regulation. QP16 Rev 8.0 Regulatory Processes (24/04/2024) was updated to include the following requirements: 1. Notification requirements to Auditing Organization with respect to substantial changes. 2. Specify when updates to the Regulatory Plan are required.	24/04/2024

9.3 TGA CER (Australia)

Document a Clinical Evaluation Plan and a Clinical Evaluation Report (CER) in accordance with the Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3 (Conformity Assessment Procedures), Part 8 (Clinical Evaluation Procedures). The Clinical Evaluation Plan and Clinical Evaluation Report must be updated throughout the lifecycle of the product and demonstrate the

product's continued compliance to the Essential Principles as per the Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 1 (Essential Principles).

Sections 9.3.1 Clinical Evaluation Plan and 9.3.2 Clinical Evaluation Report were also updated in the procedure.

The next time the CER is executed, it will be done in accordance with these updates.

CAP 100137 Design and development transfer not fully compliant in relation to Quality Procedure for Design Transfer not having been followed.

Because two design transfers hardware and software could be applicable, there was no link from one to the other.

Action Plan;

Action #	Description	Responsible(s)	Due Date
1	Update QP03 Rev 8.0 – Design Control to include reference QP04 – Software Development Life Cycle in design transfer controls.	Étienne Lefort	31/01/2024

QP03 Design Control Rev. 9.0

Software transfer activities are performed as per QP04 Software Development Lifecycle and process validation activities are performed as per QI06-05 Process Validation.

CAP 101138 Medical Device file not fully compliant in relation to labelling specifications. The IFU did not reference the most current Authorized Representative.

Actions planned:

1	Update the European Authorised Representative in the following User Manuals: • 101648 Rev 16.0 – tremoflo C100 User Manual • 101960 Rev 1.0 – tf C100 Support Arm IF • 101652 Rev 10.0 – tremoflo C100 Manual D'Utilisateur • 102578 Rev 2.0 – tremoflo C100 via ERT MasterScope User Manual • 102588 Rev 9.0 – tremoflo C100 User Manual Tremoflo Swedish	Lucas Posada Brandon Wong	29/02/2024
2	Update QP16 Rev 7.0 – Regulatory Processes to include processes requirements for assessing the impact to product identification and accompanying documentation if a change to the European Authorized Representative occurs.	Tabitha Jaramillo	29/03/2024

TCO-3 obsoleted the Swedish and the French IFU because they were chronically out-of-date. They are no longer available for use.

I verified IFU 101648, Rev. 17.0 TremoFlo C100 User Manual

17	Updated EC REP address. Added test load activation steps.	TCO-103299	Refer to previous version

Represented in Europe by

OMC NI Medical Limited
Unit-763 Moat House Business Centre
54 Bloomfield Avenue
Belfast, Northern Ireland
BT5 5AD

IFU 102578 tremoFlo via ERT Master Scope

Change History		
Revision	Description of Change	Reference
3	Updated: 1. Copyright year to 2024 (from 2017) 2. From "represented in Europe by **THORASYS Europe GmbH** Tscheulinstr. 21, D-79331 Teningen, Germany" to "Represented in Europe by **OMC NI Medical Limited** Unit-763 Moat House Business Centre, 54 Bloomfield Avenue, Belfast, Northern Ireland, BT5 5AD".	TCO-103410

Represented in Europe by

OMC NI Medical Limited
Unit-763 Moat House Business Centre
54 Bloomfield Avenue
Belfast, Northern Ireland
BT5 5AD

3- Non-Conformities:

- **NC#ID:** NCxx
- **Category:** Minor ☐ Medium ☐ Major ☐
- **NC Description** (including reference and evidence):

No non-conformities were detected for this process.

4- Opportunities For Improvement:

No opportunities for improvement were detected in this process.

Documented /Approved by	Name:	Signature:	Date:
Department Manager	Etienne Lefort		25-Jul-2024 EDT
Quality Assurance	Etienne Lefort Signer ID: HFBIXXRYNS... 25 Jul 2024, 12:16:54, EDT Signing Reason: I approved this document Tabitha Jaramillo Signer ID: INFXWXQWVX... 25 Jul 2024, 13:33:23, EDT Signing Reason: I approved this document	Tabitha Jaramillo	25-Jul-2024 EDT

Signature Certificate

Envelope Ref:ae760810abfcc5823fe393328b35ea5440733f21

Author:	Fatima Chaouki	Creation Date:	10 Jul 2024, 10:16:07, EDT	Completion Date:	25 Jul 2024, 13:33:23, EDT

Document Details:

Name: Internal Audit Report Design and Development Process - June 2024

Type:

Document Ref: 00d44092572e1fb9fb07cdf5ba25d88e0d6699e1cd1809f8b301e7a7fe7b36b7

Document Total Pages: 11

Name: Internal Audit Report Marketing Authorization - June 2024

Type:

Document Ref: 35eb680dbd1a9232d0e91a198247763e268c61b1c634d9ec53b5fb604075316e

Document Total Pages: 7

Name: Internal Audit Report Measurement Analysis and Improvement - June 2024

Type:

Document Ref: e4f0153e6e3c3983e69298f095766af5a9edc0186eb98890e26a801d6182ef54

Document Total Pages: 24

Name: Internal Audit Report Medical Device Adverse Events and Advisory Notice Reporting Process - June 2024

Type:

Document Ref: a991dc4e3d45975521036c90e3cb066ce56e374b6512a415b0681e0196aae39f

Document Total Pages: 3

Name: Internal Audit Report Production and Service Controls Process - June 2024

Type:

Document Ref: da29b0d0922bc5d491f9358586b448d4323c44c7e35008e429784ee251eb0262

Document Total Pages: 10

Name: Internal Audit Report Sales and Purchasing Process - June 2024

Type:

Document Ref: 3beba510df6a925fba7b5cc05328469b029c11dd914b9e48865470d09bb93668

Document Total Pages: 7

Name: Internal audit summary report - 2024 - Corrected

Type:

Document Ref: 65a58bb305e79723c1455ccd94b23e43245f0676fa0470540254f32710f5c6d5

Document Total Pages: 2

Document Signed By:

Name: Tabitha Jaramillo
Email: tabitha.jaramillo@thorasys.com
IP: 104.221.20.56
Location: MONTREAL, QC (CA)
Date: 25 Jul 2024, 13:33:23, EDT
Consent: eSignature Consent Accepted
Security Level: Email, Account Login Password Authentication

Tabitha Jaramillo
Signer ID: INFXWXQWVX...
25 Jul 2024, 13:33:23, EDT
Signing Reason: I approved this document

Name: Etienne Lefort
Email: etienne.lefort@thorasys.com
IP: 70.53.167.187
Location: KIRKLAND, QC (CA)
Date: 25 Jul 2024, 12:16:54, EDT
Consent: eSignature Consent Accepted
Security Level: Email, Account Login Password Authentication

Etienne Lefort
Signer ID: HEBIXXRYNS...
25 Jul 2024, 12:16:54, EDT
Signing Reason: I approved this document

Name: Ghania Chaib
Email: ghania.chaib@thorasys.com
IP: 197.204.13.234
Location: ALGIERS, 16 (DZ)
Date: 25 Jul 2024, 09:27:10, EDT
Consent: eSignature Consent Accepted
Security Level: Email, Account Login Password Authentication

Ghania Chaib
Signer ID: DOT5CSV9JP...
25 Jul 2024, 09:27:10, EDT
Signing Reason: I approved this document

Name: Lucas Posada
Email: lucas.posada@thorasys.com

Lucas Posada
Signer ID: VURHTIJKP1...
11 Jul 2024, 15:51:33, EDT
Signing Reason: I approved this document

IP:	69.70.57.54
Location:	MONTREAL, QC (CA)
Date:	11 Jul 2024, 15:51:33, EDT
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Security Level:	Email, Account Login Password Authentication

Document History:

Envelope Created	Fatima Chaouki created this envelope on 10 Jul 2024, 10:16:07, EDT
Invitation Sent	Invitation sent to Lucas Posada on 10 Jul 2024, 11:22:41, EDT
Invitation Accepted	Invitation accepted by Lucas Posada on 10 Jul 2024, 12:55:04, EDT
Signed by Lucas Posada	Lucas Posada signed this Envelope on 11 Jul 2024, 15:51:33, EDT
Invitation Sent	Invitation sent to Ghania Chaib on 11 Jul 2024, 15:51:33, EDT
Invitation Accepted	Invitation accepted by Ghania Chaib on 11 Jul 2024, 15:52:23, EDT
Signed by Ghania Chaib	Ghania Chaib signed this Envelope on 25 Jul 2024, 09:27:10, EDT
Invitation Sent	Invitation sent to Etienne Lefort on 25 Jul 2024, 09:27:10, EDT
Invitation Accepted	Invitation accepted by Etienne Lefort on 25 Jul 2024, 12:08:41, EDT
Signed by Etienne Lefort	Etienne Lefort signed this Envelope on 25 Jul 2024, 12:16:54, EDT
Invitation Sent	Invitation sent to Tabitha Jaramillo on 25 Jul 2024, 12:16:54, EDT
Invitation Accepted	Invitation accepted by Tabitha Jaramillo on 25 Jul 2024, 13:32:31, EDT
Signed by Tabitha Jaramillo	Tabitha Jaramillo signed this Envelope on 25 Jul 2024, 13:33:23, EDT
Executed	Document(s) successfully executed on 25 Jul 2024, 13:33:23, EDT
Signed Document(s)	Link emailed to lucas.posada@thorasys.com
Signed Document(s)	Link emailed to ghania.chaib@thorasys.com
Signed Document(s)	Link emailed to etienne.lefort@thorasys.com
Signed Document(s)	Link emailed to tabitha.jaramillo@thorasys.com
Signed Document(s)	Link emailed to fatima.chaouki@thorasys.com