Status Page

PROTOCOL 14-485

Closed to New Accrual

Closure Date: May 8, 2017

No new subjects may be enrolled in the study as described above. Any questions regarding this closure should be directed to the study's Principal Investigator

DANA-FARBER CANCER INSTITUTE
DANA-FARBER / HARVARD CANCER CENTER

Office for Human Research Studies

Protocol Front Sheet

DFCI Protocol No.: 14-485

1. PROTOCOL INFORMATION

Title: Use Feasibility of the iThermonitor in Pediatric Patients on Myelosuppressive Therapies for Acute Leukemia and other Childhood Cancers
Phase: Feasibility/Pilot **Sponsor Study Number:**

2. DF/HCC STUDY CONTACT INFORMATION

Primary Study Contact: Amanda Centi **Email:** acenti@partners.org **Phone:** 617 724 2158

INVESTIGATORS: (List only those under DFCI IRB, *i.e.*, from institutions listed in Section 6 below)
Overall PI: Stephen Agboola MD, MPH **Phone:** 617-643-0291 **Institution(s):** MGH
Site Responsible PI: **Phone:** **Institution(s):**

3. DRUG / DEVICE INFORMATION N/A:

☐ **Drug(s), Biologic(s)**:
Provided by:
IND Exempt: ☐ -or-
IND#: **Holder Type:** [pull down]
IND Holder Name:

☒ **Device(s) Name**: iThermonitor
Provided by: Raiing Medical Company
IDE Exempt: ☒ -or-
IDE #: **Holder Type:** [pull down]
IDE Holder Name:

4. PROTOCOL COORDINATION, FUNDING, MODE

Regulatory Sponsor:
DF/HCC Investigator

CTEP Study: No

Funding/Support (check all that apply):
☒ Industry: Raiing Medical Company
☐ Federal Organization:
Grant #:
☐ Internal Funding:
☐ Non-Federal:
☐ Other:

Protocol Involves (check all that apply as listed in the protocol document, even if not part of the research but is mandated by the protocol document):

☐ Chemotherapy
☐ Immunotherapy
☐ Surgery
☐ Bone Marrow/Stem Cell Transplant
☐ Cell Based Therapy
☐ Gene Transfer (use of recombinant DNA)
☐ Radiation Therapy
Hormone Therapy
☐ Vaccine
Data Repository
☐ Exercise/Physical Therapy
Genetic Studies
☐ Human Material Banking
☐ Human Material Collection
☒ Medical Record Review
☒ Questionnaires/Surveys/Interviews
Radiological Exams
☐ Required Biopsy Study
Human Embryonic Stem Cell
☐ Quality of Life
☒ Other: use of study device

5. SUBJECT POPULATION (also applies to medical record review and specimen collection studies)

Total Study-Wide Enrollment Goal: 25 dyads **Greater than 25% of the overall study accrual will be at DF/HCC:** ☒ Yes ☐ No
Total DF/HCC Estimated Enrollment Goal: 25 dyads **Adult Age Range:** 18+ **Pediatric Age Range:** 2-17
Will all subjects be recruited from pediatric clinics? ☒ Yes ☐ No
If enrolling both adults and pediatric subjects, anticipated percent of pediatric subjects: 50% (1/2 of each dyads)
Retrospective Medical Record Reviews only (Please provide date range): from to

6. DF/HCC PARTICIPANTS UNDER DFCI IRB (check all that apply)

☐ Beth Israel Deaconess Medical Center (BIDMC)
☐ Boston Children's Hospital (BCH)
☐ Brigham and Women's Hospital (BWH)
☐ Dana-Farber Cancer Institute (DFCI)
☒ Massachusetts General Hospital (MGH)
☐ Beth Israel Deaconess Medical Center – Needham (BIDMC-Needham)
☐ Dana-Farber/New Hampshire Oncology-Hematology (DFCI @ NHOH)
☐ Dana-Farber at Steward St. Elizabeth's Medical Center (DFCI @ SEMC)
☐ Dana-Farber at Milford Regional Cancer Center (DFCI @ MRCC)
☐ Mass General/North Shore Cancer Center (MGH @ NSCC)
☐ Mass General at Emerson Hospital – Bethke (MGH @ EH)
☐ New England Cancer Specialists (NECS)
☐ DF/BWCC in Clinical Affiliation with South Shore Hospital (DFCI @ SSH)

7. NON-DF/HCC PARTICIPANTS UNDER DFCI IRB (check all that apply)

☐ Cape Cod Healthcare (CCH)
☐ Lowell General Hospital (LGH)
☐ New Hampshire Oncology-Hematology-P.A. (NHOH)
☐ Newton-Wellesley Hospital (NWH)
☐ Broad Institute
☐ Lawrence & Memorial Cancer Center in affiliation with Dana-Farber Community Cancer Care (LMCCC)

8. DF/HCC INITIATED STUDIES ONLY - INSTITUTIONAL PARTICIPANTS UNDER OTHER IRB (N/A:)

DF/HCC Multi-Center Protocols: (list institution/location)

DF/PCC Network Affiliates: (list institution/location)

Protocol Number: 14-485

Approval Date: 03/09/2015 (IRB meeting date when protocol/consent approved or conditionally approved)

Activation Date: 04/16/2015 (Date when protocol open to patient entry)

Approval signatures are on file in the Office for Human Research Studies, tel. 617-632-3029.

Date Posted	Revised Sections	IRB Approval Date	OHRS Version Date
07/06/15	Consent Form, Protocol, Front Sheet, Appendix table of contents, Appendix 1.4, Appendix 3.1, Appendix 3.3, Appendix 4.1, Appendix 5.2, Appendix 6.0 replaced due to Amendment #2	05/01/15	06/30/15
01/08/16	Consent Form replaced due to Amendment #5	01/06/16	01/07/16
Date Posted	**Revised Sections**	**IRB Approval Date**	**Oncore Version Date**
03/07/16	Study renewal/Consent Form footer replaced due to Continuing Review #1 (Note: 6 month approval only from date of IRB Review)	02/08/16	03/07/16
03/16/16	Protocol, Consent Form and Front Sheet replaced due to Amendment #7	02/18/16	03/15/16
05/31/16	Permanent Site Closure to New Accrual: DFCI site closing to accrual; Site PI no longer wishes to participate in the study (effective date:04/18/16; Amendment #9)	04/19/16	N/A
05/31/16	Protocol, Local Appendices, Consent Form and Front Sheet replaced due to Amendment #10	05/06/16	05/31/16
07/06/16	Study renewal/Consent Form footer replaced due to Continuing Review #2	07/06/16	07/06/16
05/08/17	Permanent Closure to New Accrual: Objective(s)/ Accrual Met (effective date: 5/8/2017; Amendment #11)	5/8/2017	N/A
06/21/17	Study renewal due to Continuing Review # 3 (Note: Consent form removed due to Data Analysis only phase)	06/15/17	N/a

Recruitment	• Solicit participation of pediatric oncology team at the MGH Cancer Centers • Potential subjects identified from the MGH Cancer Centers
Enrollment	• Study staff meets with subject/caregiver for consent • Enrollment procedures, baseline data collection and initial set-up
During the study	• Subjects continue care as usual • Use the iThermonitor
Close-out	• Complete final questionnaires and other closeout procedures

Use Feasibility of the iThermonitor in Pediatric Patients on Myelosuppressive Therapies for Acute Leukemia and other Childhood Cancers

Stephen Agboola, M.D., M.P.H.

Detailed IRB protocol

Table of Contents

6.0 iThermonitor Informational Material
6.1 Partners Broadcast Ad

1.0 Introduction

1.1 Overview

This is a pilot study to evaluate the use feasibility of the iThermonitor, a continuous temperature monitoring device, as a clinical support and patient self-management tool in the management of pediatrics patients on myelosuppressive therapies for acute leukemia and other childhood cancers.

1.2 Background and Rationale

Since 1975, the incidence rate of childhood cancers has been steadily increasing by an average of 0.6% every year.[1] Based on 2014 data, it is estimated that 1 in 285 children will be diagnosed with cancer before age 20 years.[1] Cancer is also expected to be the cause of death in about 1,960 children in 2014 making it the second leading cause of death in children. [1] This rise in cancer rates corresponds with increased rates of four childhood cancers: acute lymphocytic leukemia, acute myeloid leukemia, non-Hodgkin lymphoma, and testicular germ cell tumors.[1]

Specifically, acute lymphocytic leukemia is the most common childhood cancer, accounting for 26% and 80% of all cancers and leukemia respectively in children aged 0-14years.[1] Due to improvement in treatment strategies, the 5-year survival rate has increased from 57% in 1975 to about 90% in 2009.[1] In general, the treatment of ALL is in three phases over 2-3years: remission induction, consolidation and maintenance. Patients who relapse may be eligible for stem cell transplantation. Patients undergoing treatment for acute leukemia are particularly prone to profound neutropenia due to intensive chemotherapy during the induction phase.[2]This neutropenic state is expected to last about 10 days during intensive phase of treatment.[2] Similarly, patients undergoing allogeneic stem cell transplantation and other myelosuppressive therapies are also at high risk for neutropenia.

Neutropenia predisposes patients to significant risk for infectious complications which increases morbidity and mortality.[2] Usually, fever is the first clinical sign of the inflammatory response to the infective process; and early detection is an indication for empiric antimicrobial therapy and further evaluation to determine risk for sepsis. Today, broad-spectrum antimicrobial therapy at the first detection of fever has helped significantly decreased the mortality associated with neutropenia in the intensive phase of chemotherapy.[2]
Therefore, early detection of fever, through regular temperature monitoring, in a neutropenic patient is critical to improved clinical outcome. Vigilance on the part of care providers and care givers is crucial to early detection. Traditionally, this is simply done through episodic oral or axillary monitoring of temperature. In this study, we propose to test the use feasibility of an innovative device that continuously monitors body temperature as a clinical decision support tool in pediatric patients undergoing myelosuppressive therapies for acute leukemias and other childhood cancers.

The iThermonitor, a FDA class II device, is a high accuracy device that continuously captures body temperature and automatically delivers the data wirelessly (via blue tooth or wi-

fi) to mobile devices or for cloud storage. It has the capacity to store 10 days worth of recorded temperature data. The device can be used to effortlessly monitor patients on a continuous basis during the intensive phase of chemotherapy as opposed to the usual episodic oral or axillary measurements. It is also able to generate and deliver out-of-range temperature alerts on a mobile application for care givers or providers. It also provides care providers an opportunity to remotely monitor their patients' temperature in the immediate period after discharge from the hospital. Therefore, we hypothesize that the iThermonitor can serve as a feasible clinical decision support in the management of pediatric patients undergoing intensive treatments for acute leukemia and other childhood cancers. The device hasn't been previously tested for use in pediatric patients and finding from this study could generate useful data for future studies.

Proposed Study

This study will be implemented as a pilot study to test the use feasibility of the iThermonitor as a clinical decision support for continuous temperature monitoring in a dyad of 25 pediatrics patients, (aged 2yrs – 17yrs) on myelosuppressive therapies for acute leukemia and other childhood cancers at the MGH Pediatric Hematology and Oncology group and their caregivers. The iThermonitor will be used by patients and their caregivers for 14 days of data collection. There will be up to be two study visits: study enrollment and study closeout. Participants will be given the option to complete study closeout online via RedCap. REDCap is a secure, web-based application for building and managing on line surveys. The REDCap version offers a more convenient means for survey administration and eliminates the need for an in-person closeout visit. Should the participant choose this option, a member of the study staff will email a link to the RedCap survey via RedCap's secure email system.

We have chosen to implement this study as a feasibility study because our goal is to determine if continuous temperature monitoring by the iThermonitor can work in home settings. This is in keeping with the definition for feasibility studies proposed by the National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre (NETSCC), which states that "feasibility studies are pieces of research done before a main study in order to answer the question 'can it work?'"[3] Bowen et al further suggests that they could be used to answer the questions – "does it work and will it work?" and that they are used to determine whether an intervention is appropriate for further testing.[4] Based on the paper by Bowen et al describing the diverse types of feasibility studies funded by the National Cancer Institute, this study meets the criteria for conducting feasibility studies. According to them, one of the indications for a feasibility study is when "there are few previously published studies or existing data using a specific intervention technique".[4] To our knowledge, we are not aware of any previous research exploring continuous temperature monitoring in pediatric oncology patients on myelosuppressive therapies. Therefore, findings from this study have the potential to advance knowledge about the management of fever in pediatric patients on myelosuppressive therapies.

2.0 Objectives

2.1 Hypothesis

We hypothesize that at least 80% of study subjects will be able to successfully use the iThermonitor to continuously monitor their body temperature. A subject must be able to view temperature data on the provided iPad mini at least 80% of the time in the study to be considered successful. “Time in the study” here is defined as the number of days the subject spends in the study which is expected to be 14 days.

2.2 Primary and Secondary aims:

2.21 The primary aim of this trial is to assess the use feasibility of the iThermonitor as a clinical decision support tool in the management of patients on myelosuppressive therapies for acute leukemia and other childhood cancers. We will consider the iThermonitor as a feasible clinical decision support tool if it successfully captures body temperature data, transmit and displays the data on the iPad mini in at least 80% of the study subjects. We will also assess the ability of the device to alert the caregiver if the temperature falls outside of pre-set range which is defined for all patients as temperature less than or equal to 96 and greater than or equal to 100.

2.22 Secondary outcomes:

- Usability, acceptability and satisfaction with the iThermonitor.
- Caregiver engagement with the iThermonitor.
- Effect of the study on caregiver anxiety.

3.0 Research Subject Selection

Pediatric patients undergoing myelosuppressive therapies for acute leukemias and other childhood cancers at the Massachusetts General Hospital Cancer Center and their caregivers will be eligible to participate in this study. Eligible patients and their caregivers will be enrolled to participate in this study as a dyad.

3.1 Inclusion/Exclusion

All male and female patients, regardless of ethnicity, are candidates for enrollment in this study if they meet all of the inclusion and exclusion criteria listed below.

3.1a Inclusion criteria - Child:

- Pediatrics patients aged 2-17 years undergoing myelosuppressive therapies for acute leukemias and other childhood cancers.
- If applicable, willingness of the patient to shave axillary (armpit) hair.
- Ability of patient (if old enough) to read and speak English
- Has a caregiver, ≥ 18 years of age that is willing to participate in the study

3.1b Inclusion criteria – Caregiver/Parent:

- Caregivers (parents or legal guardians) must give informed consent
- Ability of caregiver to read and speak English

3.1b Justification of inclusion criteria:

- The iThermonitor is recommended for use only in children aged 2 years and above.
- Shaving is recommended for older children who have attained puberty because the device works best when in contact with flat and smooth skin.
- Participation of caregivers is needed because they will be required to monitor temperature data on the provided iPad mini and also to help answer questions pertaining to the usability of the iThermonitor.
- Fluency in English is required because the study materials will be administered only in English.
- No study procedure will be performed without informed consent from the parents or legal guardians of patients.

3.1c Exclusion criteria

- Patients with history of allergy to hydrogel dressing or ongoing skin diseases.
- Patients with ongoing febrile illness or documented infectious disease.

3.1d Justification for exclusion criteria

- We are excluding patients with history of allergy to hydrogel dressing or skin diseases to limit the possibilities of adverse skin reactions.
- We are excluding patients with ongoing febrile illness or documented infectious disease to decrease the chances of study-related adverse effects.

4.0 Research Subject Entry

4.1 Recruitment and Enrollment

All pediatric patients undergoing myelosuppressive therapies for acute leukemias and other childhood cancers at Massachusetts General Hospital Cancer Center and their caregivers will be considered potential candidates for this pilot study. Recruitment information will be posted through the following online channels: Partner's Healthcare and MGH research broadcast email services (Appendix6.1). These broadcasts are sent out to members enrolled in the broadcast at either Partners Healthcare or MGH. Additionally, the investigators will work directly with pediatric oncologists at the MGH Cancer Center to recruit their patients for this study. The hematology-oncology team, led by Dr. Howard Weinstein at Massachusetts General Hospital Cancer Center will help identify potential subjects for

the study. Identified candidates could either be on hospital admission for chemotherapy or have an upcoming clinic visit for chemotherapy.

For identified candidates with upcoming hospitalization or clinic visit for chemotherapy, the research team will send out letters and study consent forms prior to the hospital visit. The letters will briefly describe the study and the study commitments. The letter will explain that a research assistant (RA) will be approaching the candidate and caregiver during their upcoming hospital visit for chemotherapy. The letter will clearly explain to the patient that if s/he does not wish to be approached by study staff, s/he should call the study line and inform the research team. If we do not hear from patients after one week of sending the recruitment letter, study staff will contact them by phone to tell them more about the study and answer any questions they may have about their participation. Additionally, study staff will leave the study informational flyers (appendix 6.0) in the pediatric oncology clinics so that oncologists will be able to introduce the study to their patients and their families. This group of patients who are directly informed about the study by their oncologists will not be sent recruitment letters.

During the clinic visit, the research assistant will provide the patient with further detail regarding the study. If the patient is interested, the RA will aim to enroll the patient during the clinic visit or a day before hospital discharge for those on hospitalization. For those patients that are already on hospital admission, the oncologist will introduce the study staff to the patient and caregiver. Before commencing study related activity, the study staff will inform patients and their caregivers about the study and give them a consent form for them to review and consider participating in the study. Study staff will return after about 30 mins – one hour to confirm their willingness or unwillingness to participate in the study.

For the interested patient-caregiver dyad, the research assistant will aim to enroll them in the study at the clinic visit or one day prior to hospital discharge by going through the consent form with the subject and caregivers to ensure adequate comprehension of study protocol. After, explaining study details and procedures, subjects and their caregivers will be given sufficient time to review the consent form and will be encouraged to ask questions. Patients who fulfill the eligibility criteria and their caregivers will be enrolled together as a dyad after the parents/legal guardians' consents to their participation. The parents/legal guardians will sign two copies of the consent form – one for the subject and the other for the study team. However, patients aged to 10 -17 years will also be required to confirm their willingness to participate in the study by signing the assent box. All enrollment procedures, including the informed consent process, will be done by research assistants. While enrollment procedures will occur during the clinic visit for chemotherapy or prior to hospital discharge, patients will not begin to use the iThermonitor until they get back home. We will also make it clear that participation in this study does not preclude participation in other research studies.

If for any reasons some patients or their caregivers needs more time to consider participating in the study, we will leave them a copy of the consent form so that they can further review the study details. No patient-caregiver dyad will be coerced into participating. We will emphasize that participation is voluntary and their non-participation will not affect their treatment. They will be asked to contact the study staff by phone if they do decide to participate. After the informed consent process, the RA will then perform all other enrollment procedures.

5.0 Study Design and Materials

5.1 Study Design: This study will be implemented as a pilot study to evaluate the use feasibility of the iThermonitor as a clinical decision support tool for the continuous temperature monitoring in pediatrics patients (on myelosuppressive therapies for acute leukemia and other childhood cancers at the MGH Cancer Center) and their caregivers over a 2-week study period upon the start of device use. This will ensure that 14 days of data is collected. Apart from the enrollment and closeout procedures that will be occur in the hospital settings, all other procedures will be performed at home. The iThermonitor will only be used by the patient-caregiver dyad at home for 14 days of data collection (starting from the next day post-chemotherapy) to monitor the patient's temperature. For hospitalized patients, their 14 days will start from the first day after hospital discharge.

5.2 Selection of instruments:

- An enrollment survey that will gather information regarding the dyad's demographic info and their technology use (Appendix 4.3)
- This study will use usability and satisfaction questionnaires specifically designed for this study. (Appendix 4.1)
- We will also assess caregiver anxiety with the Generalized Anxiety Disorder Questionnaire (GAD-7) (Appendix 4.2).

5.3 Description of intervention:

The iThermonitor is an electronic device that continuously monitors body temperature and connects to a receiver (iPad mini) via Bluetooth to display body temperature data in real time. The iThermonitor is attached to the skin by a hydrogel dressing which can be changed as needed. It captures data even without connection to a receiver and it can establish connection to a paired receiver device (the iPad mini) within a range of three meters. The provided iPad mini will be pre-loaded with the iThermonitor app which will be used to pair the receiver with the iThermonitor device. If a caregiver prefers to use their own smart device such as an iPad, iPad mini or iPhone, study staff will install the iThermonitor app to the caregiver's device for the duration of the study. The iThermonitor monitors body temperature every four seconds and is able to store 10 days' worth of data that can be offloaded as soon as it establishes connection with a receiver. It is able to measure temperature in the range of 25-45 degrees Celsius. Users are able to set temperature limits at which alerts for which out-of-range temperature can go off. However, for this study, the range will be fixed at less than or equal to 96°F and greater than or equal to 100°F as recommended by the pediatric oncology team at MGH. This alert can be audio or visual and will be displayed on the receiver. In the event of an out-of-range temperature alert, we will encourage subjects/caregivers to confirm the alert with their usual methods of temperature monitoring or personal thermometers before notifying their care providers. In the case of a true fever, we will emphasize during the enrollment visit that subjects/caregivers should continue to monitor patients' temperature through usual care methods and also to follow usual care protocols in managing fever as recommended by their care providers. If the out-of-range temperature alert is not confirmed by their usual

temperature monitoring methods, we would encourage them to disregard the alert and log it as a false alarm.

Caregivers who have smartphones can also view their children's temperature data on their personal smartphones (in addition to the iPad mini provided) if they wish. To be able to view temperature data on their smartphones, caregivers will have to download the iThermonitor from the Apple App and Google Play stores. The iThermonitor app is available for iPhone and Android users and there is no cost to downloading it on their phones. User manuals to guide use will be given to all subjects. (Appendices 1.4,)

5.4 Data Collection

- The use feasibility data will be collected by a daily event monitoring log designed specifically for this study which will be recorded manually by subjects everyday throughout the study period.
- Data collected by the iThermonitor is automatically uploaded to a paired receiver within a range of five meters for cloud storage. These data will be downloaded on a weekly basis and stored in the Partners Healthcare network of computer files available to only the IRB approved study staff at the Partners Connected Health Innovation. Partners Connected Health Innovation is an established leader in the creation and implementation of effective healthcare delivery strategies supported by patient-centric technology. At PCHI, we leverage information technology – mobile phones and apps, remote monitoring tools, personal health trackers, sensors, computers and networked devices – to help providers and patients manage chronic conditions, maintain health and wellness, and improve adherence, engagement and clinical outcomes.
- We will collect information about the participant's type of cancer, stage of disease and treatment regimens from a review of the electronic medical records.
- Enrollment, usability and satisfaction data will be collected by questionnaires designed specifically for this study.

Outcome data will be stored in computer network files that are accessible only to IRB approved study staff. Outcome data will be linked to each subject by a unique number, which will not have any identifying information. All data collected will be analyzed at the end of the study period.

A summary of data points to be assessed in this study is summarized in the table below:

Assessments	At entry	During the study	Close out (+/- 5days)
Enrollment questionnaires	X		
Temperature measurements via device	X	X	
Daily event monitoring log		X	X

Number of out-of-range temperature episodes detected		X	
Usability and satisfaction questionnaires and other closeout surveys			X
GAD-7	X		X

5.5 Risks and Privacy Concerns:

We do not foresee any significant risks for subjects/caregivers:

- Participants will continue to receive usual treatments including having their temperature monitored by their clinical team and caregivers according to standard care protocols.
- Participants are free to leave the study at any point without restriction.
- While we do not expect the iThermonitor to fail, the risk involved revolves around failure to appropriately notify subject/caregiver of a true fever episode or the generation of a false out-of-range temperature alert. Therefore, we will emphasize that subjects/caregivers should continue to monitor their temperature as recommended by their care providers. In the event of an out-of-range temperature alert, we will encourage subjects/caregivers to confirm the out-of-range temperature with their personal thermometers before notifying their care providers.
- Although subjects/caregivers are asked to complete questionnaires at the start and at the end of the study they will be instructed that they can choose not to answer any question(s) they do not wish to answer.
- The study team members responsible for completing chart reviews to gather the required information will be CITI certified and well-versed in HIPAA requirements. These team members will be trained and familiarized with the process of obtaining the required data points and will minimize viewing of any non-essential information.

Data security and privacy will be maintained through:

- Separation of participant names from all study data will be done through the use of unique identifiers. Only Study ID numbers will be used on the iThermonitor Application.
- The record review will be done by IRB approved study staff and will be focused only at collecting pre-specified information namely, temperature data while on hospitalization, type and stage of cancer and treatment regimens.
- Any information transferred via the internet will be done using 128 bit SSL encryption.
- Virus and password protected facilities within the Partners Healthcare network of computers will be provided for the research team.
- To safeguard confidentiality, access to all collected data will be limited to only the IRB approved study staff. Study subjects will be referred to by a unique study number and not by name.
- All communications via telephone or other media with subjects/caregivers will be stored in their study file.

- At the end of the study, all identifiable information will be destroyed and the study data will be maintained for at least two years after the completion of the study.
- Only de-identified outcomes data will be shared with study sponsors at the end of the study.
- Identifiable information will not be used or disclosed except as required by law, for authorized oversight of research, or for other research for which the use and disclosure would be permitted.

5.6 Description of Study Process:

Each subject/ caregiver dyad will participate in this pilot study for 2 weeks starting from the next day after the onset of chemotherapy. There are two study visits involved:

5.61 Enrollment visit:

This will take place during the clinic visit for chemotherapy or on the day before discharge for hospitalized patients.

- Enrollment into the study by signing the informed consent form. This will be done before performing any study procedures.
- Rescreening to confirm eligibility as described above. A screening checklist will be provided to guide the RA.
- Complete all enrollment surveys. Caregivers will be required to complete the GAD-7
- The research assistant will explain and demonstrate how to use the iThermonitor and also leave subjects with user manuals. (Appendices 1.4,)
- Subjects who wish to use their own smartphones, in addition to the provided study iPad minis, will be instructed to download the iThermonitor's app on the app store.
- Finally, study staff will emphasize that the iThermonitor is not a replacement for usual temperature monitoring protocols and will instruct participants to continue to receive medical care from their physicians as usual.

5.62 Registration Procedures

General Guidelines for DF/HCC and DF/PCC Institutions

Institutions will register eligible participants with the DF/HCC Quality Assurance Office for Clinical Trials (QACT) central registration system.

An investigator will confirm eligibility criteria and a member of the study team will complete the QACT protocol-specific eligibility checklist.

Registration Process for DF/HCC and DF/PCC Institutions

The QACT registration staff is accessible on Monday through Friday, from 8:00 AM to 5:00 PM Eastern Standard Time.

The registration procedures are as follows:

- Obtain written informed consent from the participant prior to the performance of any protocol specific procedures or assessments.

- Complete the QACT protocol-specific eligibility checklist using the eligibility assessment documented in the participant's medical record and/or research chart. **To be eligible for registration to the protocol, the participant must meet all inclusion and exclusion criterion as described in the protocol and reflected on the eligibility checklist.**

- Fax the eligibility checklist(s) and all pages of the consent form(s) to the QACT at 617-632-2295. For Phase I protocols, attach participant dose level assignment confirmation from the sponsor.

- The QACT Registrar will (a) review the eligibility checklist, (b) register the participant on the protocol, and (c) randomize the participant when applicable.

- An email confirmation of the registration and/or randomization will be sent to the Overall PI, study coordinator(s) from the Lead Site, treating investigator and registering person immediately following the registration and/or randomization.

5.63 During the study:

- If the study team does not receive data from the iThermonitor by the second day after study enrollment, study staff will follow-up (telephone call) with subjects to ensure that they are able to correctly set-up the device. We will encourage participants to continue to receive medical treatment and adhere to other management protocols as recommended by their physicians as usual. We will emphasize that the iThermonitor does not replace usual temperature monitoring protocols.

- Use the iThermonitor everyday to monitor the patient's temperature continuously until final study closeout.

- Complete the event monitoring log every day.

- In the event of a hospital admission during the study period, the hospitalized subject will stop using the device. If the subject has contributed less than 50% of data (i.e. used the device for less than 7 days) prior to hospitalization, they will be dropped from the study and another subject will be recruited to make up the enrollment

target. However, subjects who have contributed at least 50% of data prior to hospitalization will stop using the device but will be included in final analyses.

5.64 Close out visit:

- This visit will occur 2 weeks post-chemotherapy. If possible, subjects will schedule their final study visit at the enrollment visit. Study staff will also send an appointment reminder letter in the mail 3 days prior to the scheduled visit. They will also receive a reminder phone call to confirm the appointment a day before the final study visit. If participants would like, they can complete close-out surveys online via RedCap and return study devices during their next doctor visit or via a provided pre-paid FedEx envelope.

Participants will:

- Complete all close-out surveys
- Return the provided iPad mini devices.
- Be instructed to continue their medical care as usual.

5.65 Instrument administration

All study questionnaires will be administered by research assistants.

5.66 Intervention administration

At enrollment, study staff will demonstrate how the device works to subjects. They will also be available to answer questions or help subjects troubleshoot their devices. Subjects will receive user manuals to guide them for subsequent set-up and use. (Appendices 1.4,) They will be encouraged to use the iThermonitor to monitor the patient's body temperature continuously for the 2-weeks study period.

5.67 Special Concerns

One special concern in this study is that the intervention may increase the sensitivity of detection of fever which may prompt caregivers to alerts care providers and hence increase the reporting of fever. We will instruct caregivers to confirm out-of-range temperature alerts with standard thermometers before notifying their care providers. We will emphasize that this intervention does not replace their usual care protocols.

5.68 Remuneration

Each patient-caregiver dyad will receive a Partners-issued check of $100 after completing the final study visit and returning the study iPad mini. The check will be mailed at the end of the study. No additional remuneration or reimbursement will be provided.

5.7 Adverse Reactions and their Management:

There is minimal chance for adverse effects directly from this study. However, because the iThermonitor is attached to the skin a hydrogel dressing patch, we cannot rule out the possibility of a skin reaction to the adhesive surface of the device. After discharge from the hospital, we will instruct caregivers to continue monitoring patients as recommended by their care providers. While we do not expect the iThermonitor to fail, we will emphasize that caregivers are to continue all standard protocols care for each patient.

5.71 Reporting Adverse or Unanticipated Events

The Investigator will ensure that all adverse events AEs that occur during the study period are well documented and reported timely to the IRB.

Documentation of AEs includes: date and time of onset and resolution of AE, intensity, frequency, seriousness, related interventions, and outcome. The Investigator will also evaluate the probability of a causal relationship of the AE to the study intervention as being: “definite, probable, possible, unlikely, or unrelated.” Intensity of adverse events will be graded as mild, moderate, or severe according to the following criteria:

Mild: symptoms that are easily tolerated and transient in nature with minimal or no impairment of normal activity

Moderate: symptoms that are poorly tolerated, are sustained, and interfere with normal activity

Severe: symptoms that are incapacitating and render the subject unable to work or participate in many or all usual activities

All AEs will be reported to the IRB according to the IRB’s requirements, regardless of causality.

5.72 Anticipated Reactions

We do not anticipate any adverse reaction consequent to participating in this study. This study is not invasive and does not prescribe medications nor recommend new treatment protocols. The iThermonitor only helps to timely detect the onset of out-of-range temperature. Participants will be advised to contact their physicians if they experience any problems with their medications or medical illness

5.73 Reaction Management

Should an AE be encountered, the first step in the process, after any actions required for patient stabilization, will be to record the event on the adverse event reporting log and also notify the principal investigator. The event will be classified base on the relatedness, severity and whether it is an anticipated or not. The AE will be reported and managed based on relatedness to the use of the iThermonitor, seriousness and whether it was anticipated or unanticipated. The principal investigator will in turn notify the IRB and the subject’s physician. All AEs will be monitored until resolution

or until, in the investigator's judgment, they are stable. If an emergency situation should occur, appropriate medical emergency measures should be taken to stabilize the subject.

6.0 Statistical Analysis

This study will be implemented as a pilot study to evaluate the use feasibility of the iThermonitor as a clinical decision support tool for continuous temperature monitoring in a dyad of 25 pediatrics patients (aged 2-17yrs) on myelosuppressive therapies for acute leukemia and other childhood cancers at the MGH Cancer Center and their caregivers over a 2-week study period.

6.1 Primary and secondary endpoints

6.1a Primary outcome measurement: use feasibility of the iThermonitor will be assessed by ability of the device to successfully capture, transmit and display the patient's body temperature data on the study iPad mini. To limit recall bias, subjects will be required to log (Appendix 5) the ability to view the temperature data on the iPad mini once a day for the entire duration of the study. The device will be deemed a feasible continuous temperature monitoring tool if at least 80% of study subjects are able to successfully use the iThermonitor to monitor their body temperature. A subject must be able to view temperature data on the provided iPad mini at least 80% of the time in the study to be considered successful. "Time in the study" here is defined as the number of days the subject spends in the study which is expected to be two weeks.

6.1b Secondary outcomes: secondary outcomes which will be assessed at the end of the study include:

i. Usability, acceptability and satisfaction with the iThermonitor. This will be assessed by questionnaires specifically designed for this study. We will be assessing ease of use, acceptability, connection and use problems like the device falling off the skin, usefulness of out-of-range temperature alerts and adverse reactions. We will also assess to see if the device helps to build caregiver self-efficacy skills in caring for the patient.

ii. Caregiver engagement with the iThermonitor. This will be assessed by time to first measurement and upload from the time of discharge and also by the frequency of logins to the iThermonitor app.

iii. Caregiver anxiety will be assessed using the GAD-7 questionnaire.

6.2 Sample size and statistical power or precision associated with the sample size: The length of time required to accrue an adequate number of subjects to the study should be indicated.

We will be able to estimate a feasibility success rate of 80% to within a 95% confidence interval of +/- 16% with a sample size of 25 evaluable patients. This is in keeping with a

recommendation of sample size of at least 24 subjects for feasibility studies.[5] Therefore, a dyad of 25 pediatric patients and their caregivers will be enrolled in the study. Based on estimates from the Partners Healthcare Research Patient Data Registry, about 101 pediatrics patients with hematologic malignancies alone were seen in 2013 at the MGH Cancer Center. We envisage that we would be able to accrue enough subjects over 12 months after the enrollment of the first subject.

6.3 Stratification factors and intervention allocation plan for randomized studies

This is not a randomized trial and we will not be stratifying on any variable.

6.4 Stratification factors and their impact on design

None.

6.5 Early stopping rules, if appropriate

None.

6.6 Unevaluable/ineligible participants

Our aim is to evaluate how the device is used in home settings. Therefore, subjects who become hospitalized will stop using the device. If the hospitalized subject has contributed less than 50% of data (i.e. used the device for less than 7 days) prior to hospitalization, they will be dropped from the study and another subject will be recruited to make up the enrollment target. However, subjects who have contributed at least 50% of data prior to hospitalization will stop using the device but will be included in final analyses. We estimate that less than 20% of subjects enrolled in the study might be inevaluable.

6.7 Analysis plan

Data collected will be verified before analysis, which will be done with Data Analysis and Statistical Software: STATA, version 13 with an alpha of 0.05 set a priori. All participants will be followed up for two weeks and we will summarize their baseline demographic and technology use characteristics.

To address the primary aim, the feasibility success rate will be calculated as the number of evaluable patients who meet the criteria for 'success' (per section 6.1) divided by the total number of evaluable patients. A 95% confidence interval will be calculated on this proportion. If the upper limit of the 95% confidence interval is less than 80%, then we will consider the iThermonitor not to be a feasible clinical decision support tool.

Descriptive analyses will be performed on all baseline data. Endpoints for all study outcomes are defined in section 6.1 above. All continuous variables will be computed as means with standard deviations, median and ranges while categorical variables will be computed as frequency distributions and percentages. The binomial test of proportion will be used to our dichotomous outcome of successfully using the iThermonitor. Paired t-test will be used to

analyze pre- and post- GAD-7 scores measured as a continuous variable. All other outcome variables will be summarized with descriptive statistics.

6.8 Handling of missing data in the analysis

We have adopted simple data collection techniques to limit missing data for this trial. Since this is largely exploratory work with descriptive statistics, a complete case analysis approach will be adopted for this study. .

7.0 References

1. American Cancer Society. Cancer facts & figures 2014. Atlanta: American Cancer Society; 2014.
2. Neuburger S, Maschmeyer G. Update on management of infections in cancer and stem cell transplant patients. Ann Hematol. 2006 Jun;85(6):345-56.
3. National Institute for Health Research. Feasibility studies, in NIHR NETSCC glossary. http://www.nets.nihr.ac.uk/glossary/feasibility-studies
4. Bowen, Deborah J., et al. "How we design feasibility studies." *American journal of preventive medicine* 36.5 (2009): 452-457.
5. Julious SA. Sample size of 12 per group rule of thumb for a pilot study. Pharm Stat 2005;4:287-291

8.0 Appendices

Appendix 1: Device

1.1 Premarket notification 501(k) summary

1.2 Biocompatibility statement

1.3 Device Technical specifications

1.4 Quick Manual for Parents

Appendix 2: Provider contact

2.1 iTherm letter to oncologists

2.2 Enrollment notification

Appendix 3: Parent contact

3.1 Parent Telephone Script

3.2 iThermonitor_appt_reminder

3.3 Parent Recruitment Letter

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4.2 GAD-7

4.3 Enrollment survey

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Use Feasibility of the iThermonitor in Pediatric Patients on Myelosuppressive Therapies for Acute Leukemia and other Childhood Cancers

JUL 0 8 2014

Section 3 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR-Section 807.92.

The assigned 510(k) Number: K132761

1. Prepared Date: Aug. 26, 2013

2. Sponsor Identification

Raiing Medical Company
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Establishment Registration Number: 3010052175

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3. Submission Correspondent

Mr. Wu Wei
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Email: tjww@raiing.com
Tel: 86-10-64118658
Fax: 86-10-80115555 ext. 776445
Raiing Medical Company
21 Huoju St, Beijing, China

4. Proposed Device Identification

PrOposed Device Name: Wireless Thermometer
Proposed Device Common Name: Thermometer

Regulatory Information:
Classification Name: Clinical Electronic Thermometer;
Classification: II;
Product Code: FLL;
Regulation Number: 21 CFR 880.2910;
Review Panel: General Hospital;

Intended Use Statement:
The Wireless Theimometer is/a battery-operated electronic device with intended use of measuring and monitoring human armpit temperaturcontinuously via wireless signal transmission of the measuring result. This system is reusable and intended for armpit temperature monitoring for persons over two years old.

5. Predicate Device Identification

510(k) Number: Kl21696
Predicate Device Name: Wireless Thermometer WTM-BT30-l
Manufacturer: Raling Medical Company

6. Device Description

The wireless thermometer, WT701, which is the combination device of thermometer and Bluetooth communication unit intended to be worn at axilla.to m nitor the annpit temperature continuously.

For the monitoring operation, switch the thermometer on and stick the thermometer in the user's axilla. The thermometer will make a Bluetooth connection between the thermometer and the receiver automatically (User should setup Bluetooth properly on receiver). Then the thermometer starts to measures the body temperature by means of testing the NTC resistor's resistance value and calculates the body temperature every 4 seconds continuously and sends the temperature data to the receiver through

Bluetooth connection.

The wireless thermometer uses a CR2032 battery for operation. When the battery is low, internal circuit will detect the low battery condition automatically and send "low battery" signal through Bluetooth **communication unit to receiver.**

7. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verifY that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test· results demonstrated that the proposed **device complies with the following standards:**

IEC60601-1:2005 Medical electrical equipment Part 1: General requirements for basic safety and **essential performance**

IEC 60601-1-2:2007 Medical electrical equipment- Part 1-2: General requirements for basic safety and **essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests**

FCC Part 15 Subpart C test FCC Part 15.247

ASTM Elll2-00: 2006 Standard Specification for Electronic Thermometer for Intermittent **Determination of Patient Temperature.**

EN 12470-4: 2000+AI:2009 Clinical thermometers Part-4: performance of electrical thermomet-'rs for **continuous measurement.**

And the proposed device also conducted the performance test, which include Dimension Test, Weight **Test, and accuracy transmission test under a complex electromagnetic environment.**

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 3-1 Comparison of Technology Characteristics

ITEM	**Proposed Device** WT701	**Predicate Device** K121696
Product Code	FLL	FLL
Regulation No.	880.2910	880.2910
Class	Class II	Class II

Intended Use	The **Wireless Thermometer** is a battery-operated **electronic device with intended use of measuring and monitoring human an"ll.pit temperature continuously via wireless** signal **transmission of the measuring result.** This system is reusable and intended **for armpit temperature monitoring f?r persons over two years old.**	The Wireless **Thennometer,** model WTM-B530-J, is a battery-operated elected **electronic device** with intended use of **measuring** and **monitoring human armpit temperature continuously via wireless** signal **transmission of the measuring result.** This **system** is reusable and is **intended** for armpit **temperature monitoring for persons over two years** old.
Display Unit Specification	iOS device Display	.LED and iOS device Display
Working voltage	DC3V	DC3.7V
Battery	The button battery 3.0 V, 2 IOmAh	Internal 3.7V, IOOmAh Li Battery
Measurement range	25 ·c-45 ·c	,2s ·c-45 ·c
Accuracy	±o.o5 ·C(35 ·C-38.5'CJ ±O.I'C(25'C-34.99'C and 38.5I'C-45'C)	±O.I'C
Temperature unit	·c or 'F	·c or 'F
Signal transmission	Wireless 2.4G Bluetooth BLE	Wireless 2.4G Bluetooth 3:0
Receiver	iPhone 4S, iPhone 5, iPad(3rd generation), iPad(4th generation), iPad mini, iPod touch(5th generation)	iPod touch 4, iPhone 4, iPhone 4S, iPad, iPad 2, The new iPad
Valid transmission distance	Up to 5 meters	Upto *5* meters
Operating Temperature!	5'C-40 'C	5'C-40. 'C
Operating Humidity	15-85%	15-85%

Based on the compafison and analysis abov, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.

DEPARTMENT OF IIEAL**Til** & IIUMAN SERVICES

Public Ileahh Scr\'iCc

Food and Dntg Administration
10903 New Hampshire Avenue
Document Control Center- W066·G609
Silver Spring. MD 20993-0002

July 8. 2014

Raiing Medical Company
Mr. Wei Wu
General Engineer
No.I l Huatong Rd
Beijing
CHINA

Re: Kl32761
Trade/Device Name: Wireless Thermometer, Model WT70l
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: Class ll
Product Code: FLL
Dated: June 3, 2014
Received: June 6, 2014

Dear Mr. Wu:

We have reviewed your Section 51 O(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for usc stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the geneml controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you. however, that device labeling must be truthful and not misleading.

If your device is classified (sec above) into either class ll (Special Controls) or class Ill (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, fDA may publish lt1rthcr announcements concerning your device in the federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801}, please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicaiDevices/ResourcesforYoullndustry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicaiDevices/Safetv!ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division ofPostmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division oflndustry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou!Jndustry/default.htm.

Sincerely yours,

MaryS. Runner -5

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910.0120
Expiration Date: January 31, 2017
See *PRA Statement below.*

510(k) Number *(if known)*
KJ32761

Device Name
Wireless Thermometer, Model WT701

Indications for Use *(Describo)*
The Wireless Thermometer is a battery-operated electronic device with intended use of measuring and monitoring human annpit temperature continuously via wireless signal transmission of the measuring result. This system is reusable and intended for armpit temperature monitoring for persons over two years old.

Type of Use (Select *one or both,* as *applicable)*

D Prescliption Use (Part 21 CFR 801 Subpart D) l:8l Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center *tor* Devices and Radiological Health (CDRH) *(Signatural*

Digitally signed by Richard C. Chapman -S
Date: 2014.07.08 11:26:01 -04'00'

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Exhibit #8 Biocompatibility Statement

Biocompatibility Statement

The material of Double coated medical tape and Shell, is identical to that of the wireless thermometer as it was approved in k121696 in Oct. II, 2012, in formulation, and processing, and no other chemicals have been added (e.g., plasticizers, filers, color additives, cleaning agents, mold release agents, etc.).

Wu Wei

Authorized Signature

Wu Wei

General Engineer

Raiing Medical Company

Aug. 26, 20 13

Section 9 Biocompatibility

1. Patient--Contact Material Identification

The patient--contact components and materials are presented as follows:

Table 9--1 Patient Contact Material Identification

Components	Material	Contact Level	Contact Duration
Double coated medical tape	Medical Tape	Surface	Short--term (<24h)
Shell	ABS	Surface	Short--term (<24h)

NOTE: The contact level and contact duration are determined according to Annex A of ISO 10993--1:2009 Biological evaluation of medical devices — Part 1 Evaluation and testing within a risk management process.

2. Biocompatibility

The patient contact material(s) of the proposed device as identified is(are) identical device to that(those) of the legally marketed device, wireless thermometer , as cleared in K121696 at date Oct. 11, 2012. Biocompatibility Statement is provided in Exhibit #8 Biocompatibility Statement.

3M Health Care
Skin and Wound Care Division

3M Center
St. Paul, Minnesota 55144-1000
651-733-1110

May 23, 2012

Dear Valued 3M Customer:

This letter is in response to your request for composition information on the products listed below.

You requested information regarding the following 3M products:

3M™ Spunlace Nonwoven Tape 2476 and 2476P

3M Skin and Wound Care Division does not add animal derived materials or tissues to these products during manufacture. We are not aware that the suppliers for the ingredients used to make these products add or use animal derived materials or tissues during their operations. Since the products do not contain any animal derived material they are compliant with US and EU regulations for Bovine Spongiform Encephalopathy (BSE) or Transmissible Spongiform Encephalopathy (TSE) control.

This information was prepared based on the best knowledge and understanding of the Skin and Wound Care Division and, in part, on other information provided by 3M suppliers.

In the event any product listed above is proven not to conform with 3M's certification, then to the extent permitted by law, 3M's entire liability and Buyer's exclusive remedy, will be at 3M's option either: (i) replacement of Product with a conforming product, or (ii) refund of the purchase price paid by Buyer for each non-conforming Product, within a reasonable time after written notification of said non-conformance and return of said Product to 3M. 3M shall not under any circumstances be liable for direct, incidental, special, or consequential damages (including but not limited to loss of profits, revenue, or business) related to or arising out of this certification, including, the use, misuse or inability to use the Product. Unless stated otherwise in writing, the foregoing language cannot be waived, modified, or supplemented in any manner whatsoever.

If you have other related questions or need further information you may contact me at 651-733-0257.

Sincerely,

Tammy Johnson
3M Skin and Wound Care Division
Product Responsibility
3M Company
3M Center, Bldg. 275-5W-06
St. Paul, MN., 55144-1000
e-mail: tljohnson1@mmm.com

Preliminary Technical Information Sheet
Product Number #2476P [formerly MSX-6935B]
3M™ Single Coated Nonwoven Medical Silicone Adhesive Tape on Premium Liner
Effective: March 2013
Supersedes all previous versions

Proposed Features and Benefits:

- Hypoallergenic Silicone Pressure Sensitive Adhesive
- Flexible, Conformable
- Excellent Initial Skin Adhesion
- No Natural Rubber Latex
- EtO Sterilization Compatible Only
- Premium Clear Polypropylene Liner

Current Composition:

Tape Caliper	14.6 mil [0.37 mm] single-coated Film Tape on Clear Polyester Liner
Backing	10.6 mil [0.27 mm] White Polyester Spunlace Nonwoven/Film Laminate
Adhesive	4 mil [0.10 mm] Medical Grade Gentle 3M Silicone Adhesive
Release Liner	3.5 mil [0.09mm] Clear Polypropylene Film, one side Fluoropolymer Release

Preliminary Properties[+]:

Adhesion to Stainless Steel, 180q Peel	4.5 oz/inch [128 gms/25.4 mm] [1.25 N/25.4 mm]
Typical Liner Release, 180q Peel	10 gm/inch width [10 gms/25.4 mm width]
Moisture Vapor Transmission Rate, MVTR	800 gms/sq m/24hrs

+ 3M test methods are available upon request.
1 Preliminary results based on limited run data. Subject to change.

Proposed Roll Description: Tape supplied on 3 inch (76 mm) diameter cores.

Length, Maximum	100 yds [91.4 meters]
Width, Maximum	12 inches (30.5 cm)

Packaging and Recommended Storage:
Product as supplied in original packaging will maintain stated properties for a period of two years from date stamped on shipping container when stored at temperatures of 50-80qF (10-27qC) and relative humidity between 40-60 percent.

Note: Product should be stored in the original packaging out of direct sunlight or high-intensity indoor lighting.

Please see reverse side for important product, safety and warranty information.

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Tel: 886-2-2704-9011
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3M Turkey
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3M Ukraine
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3M Health Care Ltd.
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Venezuela
3M Manufacturera Venezuela
Tel: 58-241-8391911
Fax: 58-241-8391928

Viet Nam
3M Viet Nam Ltd.
Tel: 84 8 640986
Fax: 84 8 641024

3M Medical Specialties
3M Center, Building 275-5W-05
St. Paul, MN 55144-1000 USA
Tel.: 800 228-3957

ISO 9001
ISO 13485
EN 46001
CERTIFIED
BSI
REGISTERED
FM 14552

TECHNICAL SPECIFICATIONS

Product name
Wireless Thermometer

Model
WT701

Size
51.9mmx31.6mmx6.5mm

Weight
6g (without battery)

Battery
CR2025

Receiver
iPhone 4s+,iPad 3+,
iPad mini+,iPad Air,iPod touch 5+
Android Devices
(with 4.3+ system and Bluetooth 4.0;for more details about Android support,please see our website}

Battery life
120 days at 8 hours per day
Note: frequent synchronization of data may deplete power more quickly

Operating conditions
Temperature: S·C - 40'C
Humidity:15% - 85%
Barometric pressure: 86kPa - 106kPa

Valid transmission distance
Up to 5 meters

Temperature unit
·C or 'F

Measurement range
25'(-45'(

Accuracy
±0.OS'C (35'C-38SC)
±OI''C (25'C-34.99" C and 38.51" C-45"C)

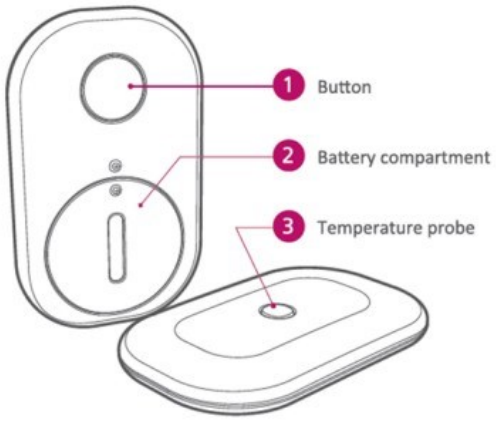
Appendix 1.4 User Manual – to be sent home with subjects

raising

iThermonitor

Wireless Thermometer

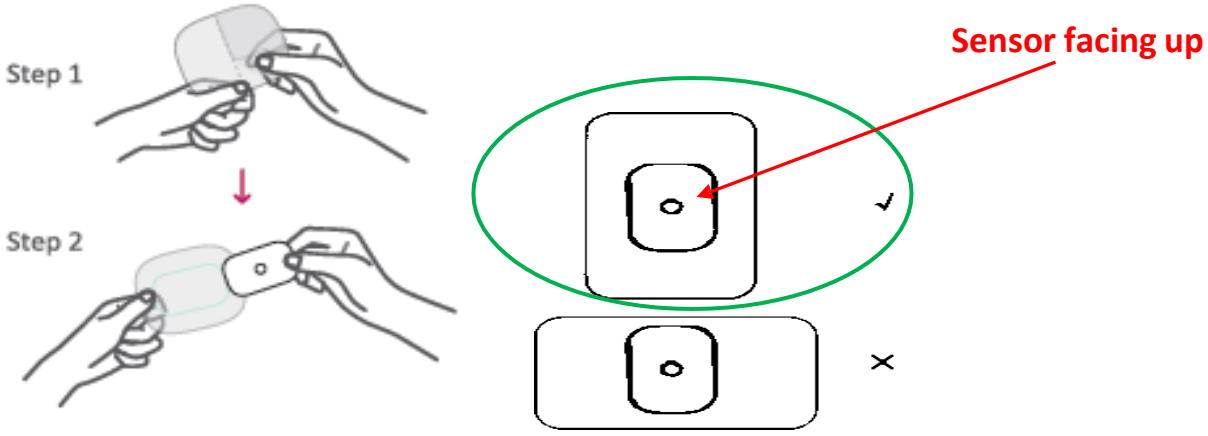
QUICK MANUAL



iThermonitor Instruction Guide

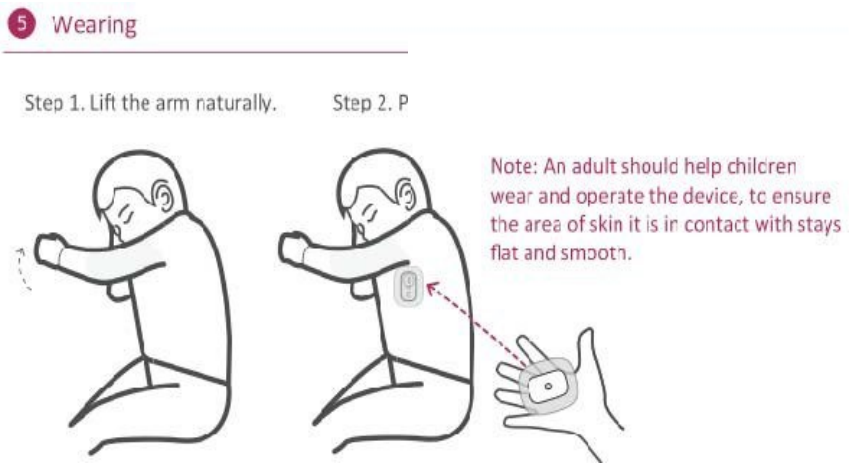
Preparation of the iThermonitor

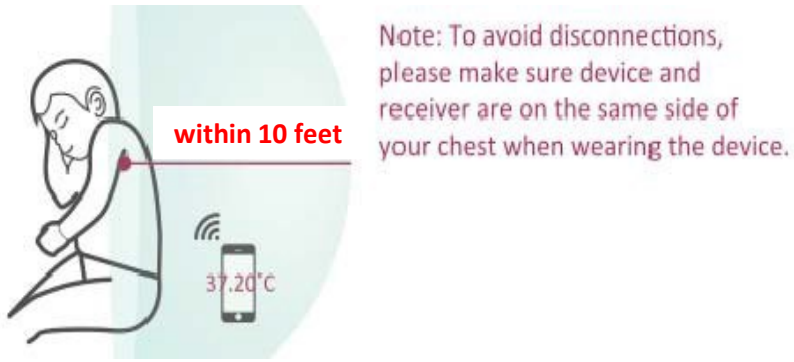
- Remove the cover of the patch. The patch is the sticky adhesive.
- Face the temperature sensor up and stick the other side with the button to the patch. Make sure the device is in the center of the sticker.
- The iThermonitor should be aligned vertically with the patch



Wearing the iThermonitor

- Lift the child's arm naturally.
- Paste the device facing vertically into the armpit. Try to get the device as close to the most inner part of the armpit.
- Make sure that the device is laying flat and smooth against the skin



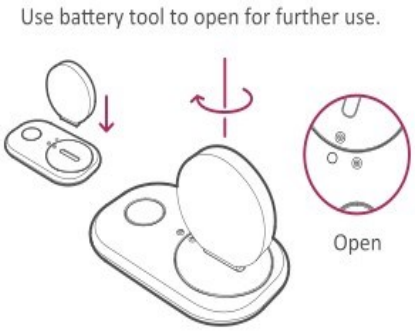


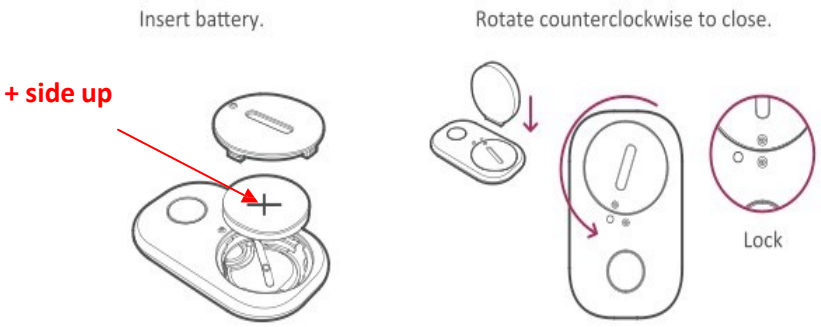
- If the connection is lost, the sensor will continue recording and storing temperature data for maximum 10 days. The data will be automatically synced with iPad once the connection is back.

Changing the battery

Your device will come with a battery installed. This battery should last throughout the two-week study. If you believe the battery has died, please follow the instructions below to install the replacement battery, which was given to you at enrollment.

- Use the battery tool and rotate clockwise to open.
- Remove the old battery.
- Insert the new battery (+) side up.
- Replace battery cover and rotate counterclockwise to close.





If you want to download on your own iOS device, please use the following link:

http://doc.raiing.com/enterprise/mgh.html

Using and maintaining the iThermonitor

- Charge the iPad regularly and keep the iThermonitor app open. Do not log out of the app.
- Make sure the Bluetooth is in the on position.
    - If you have a Wi-Fi connection in your home, connect the iPad to the Wi-Fi to allow the iThermonitor to sync for data collection.
- DO NOT change settings of the iPad or the iThermonitor app.
- DO NOT get the iThermonitor wet (shower, bath swimming, etc).
- DO NOT wear the iThermonitor at one side for more than 24 consecutive hours. Change sides everyday to wear it for continuous monitoring.
- If your child feels unwell (uncomfortable or allergic) when using the patch, replace it with another type of adhesive dressing based on your doctor's advice. A fully-covered patch larger than 76mm×62mm should be used.
- Do not reuse the patches. If a patch is already folded over, a new patch is required.

- Shave armpits in advance. Make sure the area of skin in contact with the patch is flat and smooth.
- For the most accurate results, make sure the iThermonitor has been at room temperature for at least 5 minutes before using it.

Appendix 1.4 User Manual- to be sent home with subjects

Appendix 1.4 User Manual- to be sent home with subjects

Appendix 2.1: Letter to oncologists requesting patient referrals

Dear Dr._____,

I am writing to share details about an upcoming study being conducted by Partners Healthcare Connected Health Innovation, a research division of Massachusetts General Hospital, in collaboration with the MGH Cancer Center and the Dana Farber Cancer Institute's Pediatric Oncology department. Stephen Agboola, MD, MPH is the PI on this project. The primary aim of this study (DFCI Protocol 14-485) is to assess the feasibility of the iThermonitor device as a clinical support tool in the management of pediatric patients undergoing myelosuppressive therapies. The iThermonitor is an electronic device that continuously measures the wearer's body temperature. It is secured to the skin via hydrogel dressing. Full technical details of the device and its functionality are included below.

A total of 25 dyads will be enrolled in this study. Dyads will include one pediatric cancer patient and his/her caregiver. The caregiver will be asked to use the iThermonitor device for a period of 2 weeks to monitor the child's body temperature. Upon registering and creating an account on the iThermonitor mobile application, the device will be paired with a wirelessly enabled iPad Mini or Smartphone receiver which should be within 3 meters of each other. Upper and lower temperature limits can be set on the device to alert users when temperatures are outside of pre-set range. However, for this study, the range will be fixed at less than or equal to 96 and greater than or equal to 100 as recommended by the pediatric oncology team at MGH. If you would like to review a more detailed description of the protocol, please let me know and I'll be happy to share that with you.

There will be 2 study visits (enrollment and closeout) and patient/caregiver dyads will receive a total of $100 for their participation. The eligibility criteria are as follows:

- Pediatric patient Aged 2- 17 years
- English speaking patient/caregiver (18 yrs or older)
- Undergoing myelosuppressive therapies for acute leukemia or other childhood cancers.
- If applicable, willingness of the patient to shave axillary (armpit) hair.

We are excluding patients who may have:
a history of allergy to hydrogel dressing or ongoing skin diseases, patients with ongoing febrile illness or documented infectious disease. We are contacting you to request your help identifying and referring eligible patients for this study. Upon physician approval, study staff will approach parents or legal guardians of eligible patients about recruiting them and their children for this study. Participation in this study will not interfere with their treatments nor does it preclude participation in other research studies.
Please let me know if you have any questions.
Thank you for your consideration.

Stephen Agboola, MD, MPH
Principal Investigator
Center for Connected Health,
25 New Chardon St., Suite 300
Boston, MA 02114
Phone: 617.643.0291
SAgboola@partners.org

Lisa Diller, MD
Principal Investigator
Dana Building, Dana Farber Cancer Institute
44 Binney St.
Boston, MA 02115
617.632.5642
LDiller@partners.org

Appendix 2.2: Enrollment notification letter to provider

Dear Colleague,

I am writing to inform you that your patient **name, DOB**, is now participating in the iThermonitor device study. Your patient's caregiver consented on behalf of **patient name** to enroll in a research study being conducted by the Partners Center for Connected Health, a research division of Massachusetts General Hospital.

The 2-week study is a use feasibility pilot of the iThermonitor device, which continuously measures body temperature. During your patient's enrollment in this study, s/he will wear this device and his/her consenting caregiver will be able to use the device to detect fever in the child.

This study does not interfere with your patient's medical care, and s/he should continue to receive usual medical care throughout the study.

If you have any new information that may jeopardize your patient's clinical condition due to his/her continued participation in this trial, please do not hesitate to share your concerns with me.

If you would like additional information about this study, please call or email me at 617-643-0291 or SAgboola@mgh.harvard.edu

Thank you.

Stephen Agboola, MD, MPH
Principal Investigator
Center for Connected Health,
25 New Chardon St., Suite 300
Boston, MA 02114

Phone: 617.643.0291
SAgboola@partners.org

Appendix 3.1: Parent phone script

Screener's Name_____ **Date:_____**

Section 1: Introduction

Hello, my name is_____, and I am calling from Partners Connected Health Innovation/Massachusetts General Hospital. May I speak with Mr./Mrs./Miss_____?

[If the person is unavailable, ask for a good time to call back and or leave a name and number for them to call you.]

[If the person is available to speak]

We are conducting a study to assess the use of a monitoring device, the iThermonitor, as a tool for parents caring for kids undergoing myelosuppressive therapies. We believe your child may be an eligible candidate for this study and I would like to tell you about the study.

The iThermonitor device is a thermometer that, when worn on the skin, can measure body temperature continuously. The device takes the wearer's temperature every 4 seconds and uploads this data to a mobile application on a smart device – like a smartphone. The device can then alert parents when a child's temperature goes above a certain limit or below a certain limit. The visit involves 2 study visits at the MGH or DFCI. The study lasts for 2-weeks and during this time, we'll ask your child to wear the iThermonitor device every day. You could receive up to $100 for your participation in the study.

Would you like to hear more about this study?

[If No]: Okay, thank you for speaking with me today. Have a nice day.

[If Yes]: Great, l'd be happy to tell you a little more about the study.

Section 2: Study Description

So during our first visit, we'll first review the consent form together. The consent form is a really important document that will explain all of the study details to you. If, after reviewing this consent form, you want to participate in this study, we'll sign the consent form together and that will officially begin your participation in this study.

Once the consent form has been signed, we'll have you fill out a couple surveys; then, the research assistant will give you the iThermonitor device and show you how it works. If you have a smartphone, we'll show you how to download the iThermonitor app so you can receive alerts from the device. If you do not have a smartphone, you can use a study-issued iPad mini during your child's enrollment in this study.

During the study, we'll ask you to have your child wear the iThermonitor device daily. You should change the location of the device every day. So you can take it off to give your child a bath and then put the device back on. Anytime your child is wearing the device, the device will be checking your child's

temperature. The app will alert you when your child has a fever and when his/her temperature is too low.

We'll ask you to have your child wear the device for 2-weeks. At the end of this time, we'll have you come back into MGH or DFCI for a close-out visit. During this visit, we'll ask you to fill out some surveys about how you liked using the device. At the end of the study you'll receive a $100 check for your participation in the study. If you've been using a study-issued iPad mini, you'll be asked to return this device and the iThermonitor before your check can be issued.

Please note we will have to ask for your social security number or tax ID number in order to issue the $100 check.

Before we continue do you have any questions? [Answer any questions]

Are you interested in participating in the study?

[If No]: Okay, thank you for your time.

[If Yes]: Great, when would you be available to meet?

Do you have any final questions? [Answer questions]

Thank you for taking the time to speak with me and for your interest in this study. I look forward to meeting with you on [Date, time, location]. Have a nice day.

Appendix 3.2: Appointment reminder letter to parents

[Date]

Dear _____,

Thank you for your participation in the iThermonitor study. This is a friendly reminder that your final study visit is scheduled for the following time:

Date: _____
Time: _____
Location: _____

Take along: **smartphone/provided iPad Mini**

At this study visit, we'll ask you to complete some surveys about your experience using the iThermonitor device. You will receive a $100 check for completing the study. If you have been using a study-provided iPod Touch, you will only receive this check upon returning the iPod Touch.

Please feel free to contact us with any questions or concerns at [###-###-####]. We look forward to seeing you!

Best Regards

_____

Study Staff
iThermonitor Study

Appendix 3a: Recruitment Letter to Patient

Date

Dear [Parent Name],

We are contacting you because your child, [CHILD NAME], is currently undergoing chemotherapy. This letter is to tell you about a research study being conducted by Partners Connected Health Innovation, a research division of Partners HealthCare and Massachusetts General Hospital. This research study is being conducted at the MGH Pediatric Oncology department as well as the Dana Farber Cancer Institute's Pediatric Oncology department. The Principle Investigator on this study is Stephen Agboola, MD, MPH. I think this study may be of interest to you.

The goal of the study is to assess the use of a monitoring device, the iThermonitor, as a tool for parents caring for kids undergoing myelosuppressive therapies. The iThermonitor device is a thermometer that, when worn on the skin, can measure body temperature continuously. The device can then alert parents when a child's temperature goes outside of a set temperature range. We hope to show that the iThermonitor device is successful in a home setting at continuously monitoring your child's temperature.

The study involves 2 study visits at your child's pediatric oncology clinic at the Massachusetts General Hospital or Dana Farber Cancer Institute. The visits will last no longer than 1-hour. The study lasts for 2-weeks and during this time, we'll ask your child to wear the iThermonitor device every day. You could receive up to $100 (Partners-issued check) for your participation in the study.

Taking part in this research study completely is voluntary and you can end your participation when you so desire.

The study phone number is ###-###-####. Please call this number if you have any questions about the study. The line is open Monday-Friday 9am-5pm. You can also call this number to tell us if you are not interested in participating in this study. If we do not hear from you after one week of sending this letter, a member of our research team will attempt to contact you by phone to tell you more about the study and answer any questions you may have. We look forward to speaking with you soon.

Thank you for your consideration.

Sincerely,

_____

Your MGH/DFCI provider

Appendix 4.1

iThermonitor Closeout Questionnaire

Study ID: _____

Date: _____

Thank you participating in the iThermonitor study. Please answer the following questions about your experience using the device to monitor your child's temperature.

1. **The following are statements about your experience using the iThermonitor. Please rate how much the following statements concerning the iThermonitor are true for you.** (*Please circle the number of your answer)**:***

		Definitely NOT true	**A little bit true**	**Mostly true**	**Definitely true**
1)	Overall, I am satisfied with how easy it was to use the device	1	2	3	4
2)	It was easy learning to use the device	1	2	3	4
3)	I felt comfortable using the device	1	2	3	4
4)	I was able to easily monitor my child's temperature by using this device	1	2	3	4
5)	I feel more confident monitoring my child's temperature by using the device	1	2	3	4
6)	The device was helpful in starting discussions about my child's health with my doctor	1	2	3	4
7)	Using the device makes me feel more connected to my care team	1	2	3	4
8)	I found the mobile application very useful in monitoring my child's temperature	1	2	3	4
9)	I found the out-of-range temperature alert function very useful when my child's temperature was out of range	1	2	3	4
10)	I would recommend iThermonitor to a friend or family member	1	2	3	4
11)	The iThermonitor stayed on my child's body for most days during the study.	Yes		No	

iThermonitor Closeout Questionnaire

Study ID: _____

Date: _____

12)	I was able to view my child's temperature data on the provided iPad mini for most days during the study.	Yes	No

2. **Did you view your child's temperature on the iThermonitor app? (**Please circle <u>one</u> of these options)
   a. Yes
   b. No
   c. Prefer not to answer

3. **Did you use another device other than the provided iPad mini to monitor your child's temperature? (**Please circle <u>one</u> of these options)
   a. Yes
   b. No
   c. Prefer not to answer

4. **How often did you view the measurements?** *(Please circle **<u>one</u>** of these options)*

a. Hourly
b. 2-hourly
c. 4-hourly
d. Daily
e. 2-3 times per week
f. Once a week
g. never
h. other: _____

5. Was viewing measurements on the app useful in being able to better manage your child's health? *(Please circle **<u>one</u>** of these options)*

a. Yes
b. No
c. Prefer not to answer

6. Did viewing measurements on the app help you become more interested in your child's health? *(Please circle **<u>one</u>** of these options)*

a. Yes
b. No
c. Prefer not to answer

iThermonitor Closeout Questionnaire

Study ID: _____

Date: _____

7. Did you discuss the iThermonitor device with others?

*(Please circle **one** of these options)*

a. Yes
b. No
c. Prefer not to answer

8. Did you discuss the iThermonitor device with your doctor?

*(Please circle **one** of these options)*

a. Yes
b. No
c. Prefer not to answer

9. If you were given the choice would you like to continue using the iThermonitor device to monitor your child's health?

*(Please circle **one** of these options)*

a. Yes
b. No
c. Prefer not to answer

10. If the iThermonitor were for sale in a store, would you buy it?

(Please circle all that apply)

a. Yes, for my child.
b. No
c. Prefer not to answer
d. Yes, for someone else (please tell us who): _____

iThermonitor Closeout Questionnaire

Study ID: _____

Date: _____

11. How much do you like the components of the iThermonitor system below?
(Please circle the number of your answer)

	Not at all	A little bit	I like it	Very much
a) Continuous temperature monitoring	0	1	2	3
b) Viewing measurements on the app	0	1	2	3
c) Alerts when measurements are out of range	0	1	2	3
d) Other (please specify): _____ _____	0	1	2	3

12. Did you experience problems using the iThermonitor?
*(Please circle **one** of these options)*

a. Yes
b. No*
c. Prefer not to answer *

[If No or "Prefer not to answer", skip to question 14]

13. What problems did you experience?
*(Please circle **all that apply**)*

a. Problems keeping the device on my child's body
b. Problems linking the device with my smartphones
c. Problems with the iThermonitor battery
d. Problems setting out-of-range temperature alerts
e. Other problems: _____

iThermonitor Closeout Questionnaire

Study ID: _____

Date: _____

14. Please explain in detail the nature of the problem(s) you experienced as marked above:

_____
_____
_____
_____
_____

15. What else would you want added to the iThermonitor system to help to you better monitor your child's health?

_____
_____
_____
_____
_____

16. Did the iThermonitor alert you when your child's temperature was of out-of-range during the study period?

a) Yes
b) No
c) Prefer not to answer

***[If No** or "**Prefer not to answer"**, skip to question 17]*

17. How many times did the iThermonitor detect out-of-range temperatures? (If multiple times, please indicate number)

a) Once
b) Twice
c) 3 times
d) Other: ____times

18. We understand that this questionnaire may not fully capture your experiences participating in this study. Would you be interested in speaking with a research staff about your experiences in this research study?

a) Yes
b) No

Your answers are important to us. Please take a moment to check that you have answered all of the questions. Thank you for taking the time to complete this questionnaire!

Appendix 4.2 GAD-7

Subject ID: _____

Visit: _____

Date: _____

GAD-7

Over the last 2 weeks, how often have you been bothered by the following problems? *(Use "/" to indicate your answer)*	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0		2	3
2. Not being able to stop or control worrying	0		2	3
3. Worrying too much about different things	0		2	3
4. Trouble relaxing	0		2	3
5. Being so restless that it is hard to sit still	0		2	3
6. Becoming easily annoyed or irritable	0		2	3
7. Feeling afraid as if something awful might happen	0		2	3

(For *office coding: Total Score T*____= + + ____)

iThermonitor Enrollment Questionnaire

Study ID: _____

Date: _____

There are three sections in this form – A, B and C. Section A contains questions about your child. Sections B and C contains questions for the caregiver.

Section A: Child-specific information

Please answer the following questions about your child.

1. **What is your child's age?** _____**(Years) or** _____**(Months)**

2. **What is your child's gender?**
   (Circle the number of your answer.)
   1 Male
   2 Female

3. **Is your child Hispanic or Latino?**
   (Circle the number of your answer.)
   1 Yes
   2 No

4. **Which one or more of the following would you say is your child's race?**
   (Circle the number of your answers, more than one may apply.)
   1 American Indian or Alaska Native
   2 Asian
   3 Black or African American
   4 Native Hawaiian or other Pacific Islander
   5 White
   6 Other, please specify: _____

Section B: Caregiver-specific information

Please answer the following questions about yourself.

1. **What is your age?** _____ *(Write in number of years.)*

2. **What is your gender?**
   (Circle the number of your answer.)
   1 Male
   2 Female

3. **What is your marital status?**
   (Circle the number of your answer.)

1 Married
2 Living with partner
3 Divorced or separated
4 Widowed
5 Single, never been married

5. What is the highest grade at school or years in college that you have completed?
(Circle the number of your answer.)

1 1st – 8th grade
2 9th – 11th grade
3 12th grade, completed high school, or GED
4 1 to 3 years of college
5 4 or more years of college

6. Are you Hispanic or Latino?
(Circle the number of your answer.)

1 Yes
2 No

7. Which one or more of the following would you say is your race?
(Circle the number of your answers, more than one may apply.)

1 American Indian or Alaska Native
2 Asian
3 Black or African American
4 Native Hawaiian or other Pacific Islander
5 White
6 Other, please specify: _____

8. What is your current employment status?
(Circle the number of your answer.)

1 Employed full-time (includes self-employment)
2 Employed part-time (includes self-employment)
3 Unemployed
4 Homemaker
5 Student
6 Retired
7 Disabled
8 Other, please specify: _____

iThermonitor Enrollment Questionnaire

Study ID: _____

Date: _____

Section C: Technology Ownership and Use

1. **Do you ever go online to access the Internet or World Wide Web, or to send and receive email?** *(Circle the number of your answer.)*

   1 Yes

   2 No [skip to question 4]

2. **When you use the Internet, do you access it through…**
   (*For each item, please circle the number for your answer. You may answer "YES" to more than one question.***)**

	Yes	No
a. A regular dial-up telephone line.	1	2
b. Broadband such as DSL, cable or FiOS.	1	2
c. A cellular network (e.g., smartphone, 3G/4G)	1	2
d. A wireless network (Wi-Fi)	1	2

3. **Have you ever used the Internet to do any of the following things?**
   (*For each item, please circle the number for your answer.***)**

	Yes	No
a. Send or receive email.	1	2
b. Send or receive instant messages or chat online.	1	2
c. Upload pictures to share with others.	1	2
e. Look for health or medical information online.	1	2
f. Track weight, diet or exercise routine.	1	2
g. Track any other health indicators like blood pressure, sleep patterns, headaches, etc.	1	2
h. Check your bank account balance or do any online banking.	1	2
i. Use a social networking service like Facebook or MySpace.	1	2

iThermonitor Enrollment Questionnaire

Study ID: _____

Date: _____

4. Do you have any of the following devices?
(*For each item, please circle the number for your answer.*)

	Yes	No
a. A landline telephone.	1	2
b. A desktop computer.	1	2
c. A laptop computer or netbook.	1	2
d. A tablet computer like an iPad.	1	2

5. Have you ever used your cell phone or smartphone to do any of the following things?
(*For each item, please circle the number for your answer.*)

	Yes	No
a. Send or receive email.	1	2
b. Send or receive text messages.	1	2
c. Take a picture to share with others.	1	2
d. Access the Internet.	1	2
e. Look for health or medical information online.	1	2
f. Track weight, diet or exercise routine.	1	2
g. Track any other health indicators like blood pressure, sleep patterns, headaches, etc.	1	2
h. Check your bank account balance or do any online banking.	1	2
i. Use a social networking service like Facebook or MySpace.	1	2

iThermonitor Enrollment Questionnaire

Study ID: _____

Date: _____

6. How much do you agree or disagree with <u>each</u> of the following statements?
(*For each item, please circle the number for your answer.*)

	Strongly agree	Somewhat agree	Somewhat disagree	Strongly disagree
a. I am willing to try new technology.	1	2	3	4
b. I plan to make greater use of technology in the future to manage my health.	1	2	3	4
c. I generally feel confident using new technology.	1	2	3	4
d. I generally feel confident that I can use new technology to manage my medical condition.	1	2	3	4
e. I worry about security issues of sending health information by the Internet.	1	2	3	4
f. It is easy for me to follow instructions and set up new technology.	1	2	3	4
g. I have no difficulty setting up computers or Internet modems.	1	2	3	4
h. Learning how to use new technology is easy for me.	1	2	3	4
i. New technology can be useful in keeping me healthy.	1	2	3	4
j. I find using new technology to be a waste of time.	1	2	3	4

Subject Eligibility Criteria Checklist

All subjects enrolled must meet eligibility criteria based on the inclusion/exclusion criteria detailed in the application and approved by the IRB.

I. Study Information

Protocol Title:	iThermonitor study	Protocol Number:	14-485
Principal Investigator:	Stephen Agboola, MD, MPH		

II. Subject Information:

Subject Name/ID:
Gender: ☐ Male ☐ Female

III. Inclusion/Exclusion Criteria

Inclusion Criteria (From IRB approved protocol)	**Yes**	**No**	**Supporting Documentation***
1. Dyad consists of a pediatric patient aged 2-17 years undergoing myelosuppressive therapies for acute leukemia and other childhood cancers.	☐	☐	
2. Dyad also includes a caregiver, ≥ 18 years of age that is willing to participate in the study.	☐	☐	
3. Ability of caregiver and or patient (if old enough) to read and speak English.	☐	☐	
4. If applicable, willingness of the patient to shave axillary (armpit) hair.			
5. Caregiver (parent or legal guardian) must give informed consent for dyad participation.	☐	☐	
Exclusion Criteria (From IRB approved protocol)			
1. Patient has a history of allergy to hydrogel dressing or ongoing skin diseases	☐	☐	
2. Patients with ongoing febrile illness or documented infectious disease.	☐	☐	

*All subject files must include supporting documentation to confirm subject eligibility. The method of confirmation can include, but is not limited to, laboratory test results, radiology test results, subject self-report, and medical record review.

IV. Statement of Eligibility

This subject is **[** ☐ **eligible** / ☐ **ineligible**] for participation in the study.

Signature:	Date:
Printed Name:	

Subject ID: _____ **Date of Enrollment:** _____

iThermonitor Daily Event Monitoring Log

Please indicate **Yes** or **No** for each column everyday during the study.

Day	The iThermonitor stayed on the body for most of the day		I was able to view the temperature data on the iPad mini	
	Yes	No	Yes	No
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				

Caregiver Signature_____ **Date**_____

iThermonitor Study

Is your child (age 2 – 17 yrs) undergoing chemotherapy?

Do you need to monitor your child's temperature as part of your follow up care?

If you are **over the age of 18**, you and your child may be eligible to participate in a study to test a new, small continuous temperature-monitoring device.

- You will be asked to use the new device in your home along with your standard treatment for 2 weeks in an effort to see how it works in a home setting.

- Compensation is provided in recognition of your time and willingness to participate.

Ask your doctor for more information and to see if you qualify!

Contact - Amanda Centi at acenti@partners.org for more details

This study is being conducted by Partners HealthCare, Connected Health Innovation in conjunction with the MGH and DFCI Pediatric Oncology Groups.

A Pilot study to evaluate the use feasibility of a continuous temperature monitoring device for pediatric patients on myelosuppressive therapies for childhood cancers.

Is your child (age 2 - 17 yrs) undergoing chemotherapy? Do you need to monitor your child's temperature as part of your follow up care?

We are enrolling pediatric patients (ages 2-17) undergoing myelosuppressive therapies for childhood cancers. You and your child may be eligible to participant in a study to test a new, small continuous temperature-monitoring device. You will be asked to use the new device in your home along with your standard treatment for 2 weeks in an effort to see how it works in a home setting. There will be up to be two study visits: study enrollment and study closeout.

Compensation of $100 will be provided upon completion of the study.

Please contact 617-726-6831 or email iThermoStudy@partners.org and ask about the iThermonitor study!