Thermaquil System Design Specification

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# Purpose

## Introduction and Scope

This document provides top-level design specifications for Welkins’ Thermal Regulating System developed and manufactured for Thermaquil—the THQ System—including performance requirements and design specifications.

This document applies only to the THQ System mechanics, electronics, and software. It defines the major system components, software functionality, and electrical interface requirements.

## Overview

The THQ System is a thermoregulatory device for increase and reduction of patient temperature. The system delivers temperature-controlled coolant ranging between -5°C (23°F) and 50°C (122°F) to a patient-contacting liquid circulating pad, resulting in heat exchange between the coolant and the patient. The major components of the THQ system are a conditioning unit, cooling pad and umbilical.

The conditioning unit features a touchscreen with graphical user interface (GUI), physical ON-OFF switch, DC power port, quick-release umbilical connector, and carry handle. Inside the conditioning unit are a thermoelectric liquid cooling module (LCM), a liquid heating module, two liquid pumps, two coolant reservoirs, controller board, sensors and various hydraulic components (solenoid valves, tubing, etc.). Sensors inside the conditioning unit provide temperature feedback to the control algorithm, which automatically modulates circulating coolant to achieve a target temperature determined by the clinician.

The liquid circulating pad is a patient-contacting heat exchanger that facilitates conductive heat transfer between patient and circulating coolant.

The umbilical is an insulated tube connecting, and enabling circulation of coolant between, the conditioning unit and patient-contacting cooling pad.

## Indications for Use

The THQ System is a thermal regulating system, indicated for temperature increase and reduction in patients where clinically indicated.

## Intended User

The system is intended for use by clinicians, surgeons, nurses, pharmacists and other hospital staff, in both civilian and military settings.

## Ratings

THQ SYSTEM shall be compliant with IEC 60601-1, IEC 60601-1-2 and IEC 60601-1-6, and designed for clearance through FDA (510k), CE and UL processes.

# Acronyms, Definitions & References

## Acronyms

* ANSI – American National Standards Institute
* CSA – Canadian Standards Organization
* dB – Decibel
* GB – Gigabyte
* Hz – Hertz or cycles per second
* IEC – International Electrotechnical Commission
* mA – Milliamp
* mL – Milliliter
* Oz – Ounce
* PSI – Pound per square inch
* SDS – Software Design Specification
* SRS – Software Requirements Specification
* VAC – Voltage Alternating Current.
* VDC – Voltage Direct Current
* UL – Underwriter’s Laboratory
* USB – Universal Serial Bus

## Definitions

* Alarm – Audible and visual signal which indicates that an error has occurred with the equipment and will stop the processing.
* Warning – Audible and visual signal which indicates that the processing has been paused and requires user intervention to continue.

## Reference Documents

* IEC 60601-1, Medical Electrical Equipment, General Requirements for Safety
* IEC 60601-1-2, Medical Electrical Equipment, Electromagnetic Compatibility
* IEC 60601-1-4, Medical Electrical Equipment, General Requirements for Programmable Electrical Medical Systems

## Supporting Schematics & Specifications

* + THQ Software Design Specification (SDS)
  + THQ Software Requirements Specification (SRS)
  + THQ Hydraulic Schematic
  + 87-1022 THQ Electronic Block Diagram

# System Elements

## Conditioning Unit

Diagram

Description automatically generated

The schematic above outlines the key hydraulic, refrigeration and mechanical components comprising the THQ system conditioning unit, which are described below:

### External housings– molded thermoplastic

### Master ON/OFF (C1300ALBB-602AW-B or equivalent) – physical power switch

### Power entry module (Molex P/N 39-28-1103 or equivalent) – inlet for external power supply plug

### TFT display – touchscreen for GUI, not in use for P1 systems

### Controller board – microcontroller for integration, control, and monitoring of system and components

### Liquid chiller module, “LCM” (Aspen P/N FP00116 or equivalent) – 24VDC thermoelectric refrigeration system

### Liquid heating module, powered by TGHDX1R00JE resistive heaters

### Coolant reservoirs – 10oz plastic bottle in HDPE or equivalent FDA-approved thermoplastic

### Level sensor (Optomax LLC200D3SH-LLPK1 or equivalent) – liquid level sensor for coolant level monitoring and alerts – not in the P1 systems

### Liquid pump –liquid pump for coolant circulation

### Bypass valves (RSC-A2-24VDC or equivalent) – normally-closed valve (solenoid pinch or ball type valve) for flow control of hot and cold loops during operation

### 3-way solenoid valves – electronically controlled valve selects between hot and cold flow during operation

### Liquid flow switch (GEMS FS-380P 216446 or equivalent) – sensor for monitoring coolant flow – not in use for P1 systems

### Reservoir temperature sensors (TDK B57020M2 or equivalent) – thermistors to monitor the hot and cold reservoir temperatures

### In-line temperature sensors–thermistors to monitor the outlet and inlet temperature for system control and safety

### Umbilical connector – valved, quick-release plugs for connection to umbilical

## Umbilical

### The umbilical is an insulated dual-line tube that connects and enables coolant circulation between conditioning unit and patient-contacting cooling pad

### The umbilical connects to the system via valved, quick-release sockets

## Liquid Circulating pad

### The liquid circulating pad is a patient-contacting heat exchanger that facilitates conductive heat transfer between patient and circulating coolant

### The cooling pad may be available in multiple configurations, including, without limitation: skull cap, front and rear of head, limb wraps

## Power Supply

### The THQ system is powered by an external 300W medical grade, class II power supply with 24VDC output (TDK Lambda P/N DTM300PW-240D2 or equivalent)

### The THQ system may also run off an internal or external rechargeable battery

# Specifications

## Physical Dimensions & Material

### The conditioning unit shall be lightweight (<20 lbs.) and housed in a durable enclosure with a footprint of approximately one square foot (1 sq. ft.).

### The conditioning unit enclosure shall be constructed of medical-grade thermoplastics with high heat and impact ratings.

### A built-in handle on top of the conditioning unit facilitates system mobility.

## Environmental

### Operating ambient temperatures and humidity: 0°C (32°F) to 50°C (122°F), 5 to 90% relative humidity.

### Transport and storage temperature and humidity: -5°C (23°F) to 50°C (122°F), 5 to 90% relative humidity.

### Altitude: The device shall function normally at altitudes of -100 to +3,048 meters (10,000 feet).

### Contaminants, spill/splash and drip resistance: conditioning unit enclosure and umbilical shall be easily cleaned with standard hospital, clinic, or household cleaners.

### Shipping: system and packaging shall withstand typical freight shipment.

## Power Supply

### The system shall have a universal external power supply (medical grade, class II) with the following specifications:

#### Input: 115/230 VAC, 50/60 Hz

#### Output voltage: 24 VDC

#### Current: max surge 12.5A, operating <10A

#### Power: 300 W

### The system shall operate normally with 24 VDC input from an external medical grade power supply, which can handle 115-230VAC at 50-60 Hz with the appropriate country specific power cord. In addition, the power supply shall accommodate different variations within the target regions consisting of North America, EU, Japan, and Russia.

#### The system shall also be capable of running with 24 VDC supply from an internal or external rechargeable battery

### The system shall draw less than 300 Watts of power.

### Removal of external power, whether deliberate or accidental, shall not create a safety hazard.

### The device shall have an external switch to power the unit ON or OFF.

## Temperature Control

### The THQ system shall regulate patient temperature by controlling coolant temperature to the patient-contacting pad through cycles of cooling and heating:

#### During operation, the system will continuously monitor and modulate coolant temperature to maintain target output.

#### At termination of treatment, once the user-set duration has elapsed or a user has manually ended treatment, the system will stop delivering coolant to the patient-contacting pad.

### The system shall control coolant temperature in a range of -5°C (23°F) to 50°C (122°F) in increments of 1.0°F.

### The system shall use multiple thermistor probes to continuously monitor (for control and safety functions) and display (via GUI) coolant temperature in increments of 0.1°C or 0.1°F.

## Data System

### System Maintenance Data

#### The system shall record time-stamped operational data in a log that can be viewed after treatment.

#### System maintenance data (principally ‘System Runtime’) shall be used to provide notifications of regularly scheduled maintenance to the operator (e.g. at “2,000 hours, operator is instructed during POST to contact Welkins for regularly schedule maintenance”)

* + - * 1. Maintenance intervals shall be determined during pre-market bench testing and routinely reviewed/updated thereafter.

## Labeling

### External labeling of the device shall comply with governing standards (21 CFR 807.87(e), etc.) for durability, legibility and content.

## Quality Control

### Throughout the development cycle special attention shall be placed on manufacturability with assembly procedures and processes in mind to minimize the labor content to reduce the total cost of the system. Welkins shall emphasize reliability, safety, repeatability, high manufacturing standards and quality control consistent with FDA good manufacturing practices.

## General

### Connectors shall be keyed so that misconnection of system and/or components devices is prevented.

### Connectors shall be of a type for use in a continuously moving device and able to perform well under high shock / vibration conditions.

### Umbilical connectors shall be of a breakaway type that quick-release at approximately 8 lbs. pressure to avoid a tripping hazard.

### Umbilical connectors shall be valved so that they automatically close upon disconnection to prevent leakage.