# PMCF – Registry

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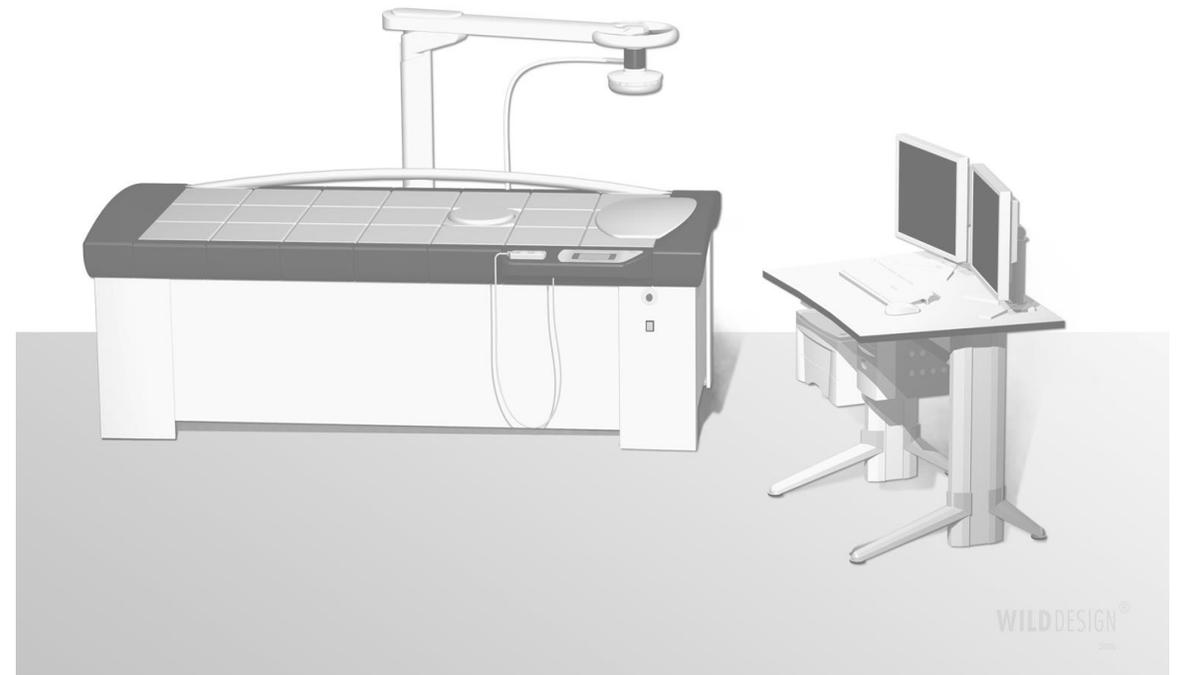
# Celsius42 TCS Hyperthermia System - Vigilance Registry
# Post Market Clinical Follow-Up (PMCF)

## Aim of the registry ?

For quality assurance purposes the user is obliged to document any incidents and malfunctions of a medical device, not just notifiable events.

In Germany, this is a demand of the Regulation on Collection, Evaluation, and Ward off Risks of Medical Devices (Medical Devices - Security Plan Regulation - MPSV)

The register offers a tool to perform the documentation according to a common standard for the Celsius42 TCS hyperthermia system.

## What more does the registry offer ?

Minor incidents are also recorded in this registry to give the user the possibility to enhance his / her quality of treatment and to optimize economical aspects of therapy.

Therefore notifiable incidents and not-notifiable events (e.g. minor burning of the skin) are captured as well as all disruptions of treatment (e.g. subjective sense of overheating).

Furthermore, the register enables to compare own rates of events with rates of all other participating centres (Benchmarking)

## Which data are generated / transferred ?

On one hand, the registry uses an excerpt of treatment data accumulated in the device; on the other hand, the user reports the events which occurred locally via an encrypted Web application.

The registry is hold and administered by a neutral, external Institute. Details will be agreed in a data usage contract between the centre and the Institute.

The company Celsius42 and other registry participants have only access to provided summary results, but not to individual data.

## When will the registry start ?

Participation in this registry is possible now.

The signing of the study plan and the data usage agreement is necessary for participation.

## What is the expenditure of time ?

The effort is limited to enter events in the Web application. The individual data entry takes at maximum 5 minutes.

In addition, a GCP-training for the PMCF-registry is conducted on a per -centre basis.