

# VitaloJAK

Validated system for objective measurement of cough



The VitaloJAK® Cough Monitor provides the only fully validated system for objective measurement of cough. Ambulatory cough recordings of up to 24 hours undergo centralized, semi-automated analysis to provide quantified data.

Data generated by the system is proven to have median sensitivity >99% and excellent integrity. The system has been used for research since 2005 and in phase 2 and 3 studies globally since 2014.

This is a validated, 510k cleared and CE marked medical device system.

## Features

Using analysis software and processes developed in partnership with internationally renowned cough researchers working at Manchester University NHS Foundation Trust, the VitaloJAK system comprises 3 distinct components, all essential to ensure high quality data:

- VitaloJAK high fidelity cough monitoring device and test kits
- Vitalograph Web Portal to collect and manage analysis of cough data
- Cough Analysis including event markers for awake and sleep periods

VitaloJAK system QA processes have been independently validated and found to support exceptionally high data accuracy<sup>1</sup>.

- eLearning modules for cough studies are available via Vitalograph Web Portal



Cough Monitoring



Vitalograph Web Portal



Cough Analysis

<sup>1</sup> Mines et al. Assessment of Inter- and Intra- Rater Reliability of Objective Cough Frequency in Patients with Chronic Cough. European Respiratory Journal 2019; 54: Suppl. 63, PA4342

The VitaloJAK Cough Monitor has proven suitable for quantifying 24 hour cough sessions in large Phase 2 and 3 studies where other methods of cough data collection and analysis are too costly, time consuming or inconsistent. Study endpoint is typically “average hourly cough count”. It has been fully validated by the specialist cough research unit at the Manchester University NHS Foundation Trust through multiple phase 1 and academic research studies.

*“measures of both intra- and inter-rater reliability for both filtered and full-length 24-hour recordings were found to be excellent, exceeding a reliability of 0.99” Mines et al, 2019.*

## Technical Specification

<b>Product:</b>	VitaloJAK Cough Monitor
<b>Model</b>	7100
<b>Essential Performance</b>	Recording audio inputs from the Cough Sensor and Microphone
<b>Size</b>	78mm x 108mm x 32mm (device)
<b>Weight</b>	240g – device with battery pack
<b>QA/GMP Standards</b>	EN ISO 13485, SOR/98-282 & FDA 21 CFR 820
<b>Power Supply</b>	1 x Battery Pack containing 3 x AA Alkaline Batteries. USB powered during configuration/download 5V/500mA (custom cable).
<b>Memory</b>	Internal Memory: 32GB sufficient for 10 days of 24 hour recordings. SD Card, Size: min 4GB sufficient for 24 hour recording. Additional recording periods can be configured.
<b>Communications</b>	USB 2.0/3.0 for data download and device configuration (custom cable). SD Card (Optional)
<b>Sampling Rate</b>	8kHz Write speed: 20 MB/sec
<b>User Interface</b>	LCD – 1.77” 4 button keypad for configuration and event marking On/off key switch