



# Opal V2C<sup>®</sup> System Precision Motion

Reinvent endpoint measurement in clinical trials with wearable sensors for objective digital endpoints of mobility

CLARIO.

# Why does mobility matter?

Mobility is the ability to safely and independently move to accomplish tasks of daily living

- Poor mobility results in inactivity, loss of independence, poor quality of life and early mortality.
- Patients rate independent mobility very high among important health concerns.
- Mobility disability, due to impaired gait and balance, leads to falls and fall injuries.<sup>1,2</sup>

## Most neurological and musculoskeletal disorders impair gait and balance.

- Gait and balance are complex sensorimotor skills that are critical for independent living.
- Neural and musculoskeletal control of gait, turning and balance is complex as it involves many parts of the nervous system, including sensory, motor and higher level cognitive systems as well as coordination among many muscles.
- Changes in health of the nervous system, or of the peripheral sensory and motor systems, are reflected in measurable changes of quality of gait and balance.

## Precision measures of gait and balance quality provide sensitive outcomes of change.<sup>3-7</sup>

- Clinical scales of severity of nervous system disorders are limited by poor sensitivity, poor inter-rater reliability and coarse, step-wise outcomes.
- These limitations prevent successful clinical trials for rare diseases. In contrast, digital gait and balance outcomes precisely reflect meaningful measures of disease severity.
- Studies have shown that gait and balance are more sensitive than clinical scales to prodromal disease.



Opal V2C<sup>®</sup> System  
FDA Class II Medical Device  
CE Class I Medical Device



## Opal Knowledge Base:

Opal sensors have captured objective measures of human movement in

750+

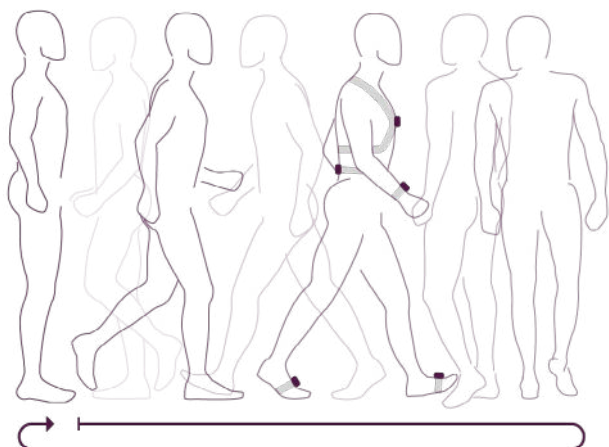
peer-reviewed scientific publications in

30+

therapeutic indications

To learn more, visit  
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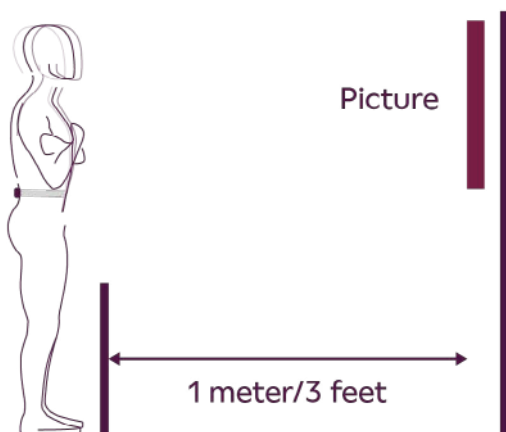
# Clario offers Opal-instrumented movement tests across 3 core domains



## 01 Gait

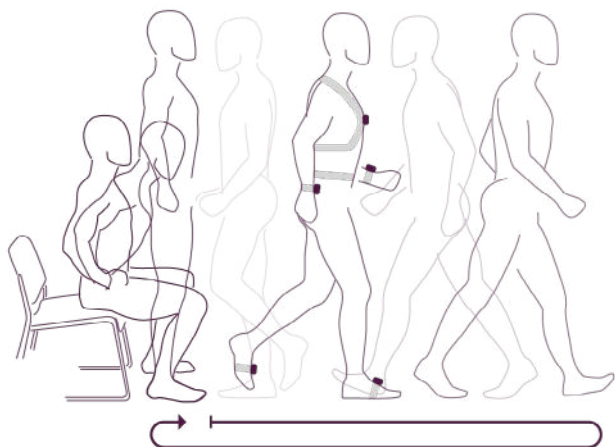
- 2-minute walk
- 6-minute walk
- Open-ended walk

Gait Initiation and Turns are included in the 2MWT and Open-Ended Walk, Turns are included in the 6MWT



## 02 Balance

- Eyes open/closed
- Feet apart/together
- Firm/foam surface
- Tandem/single leg

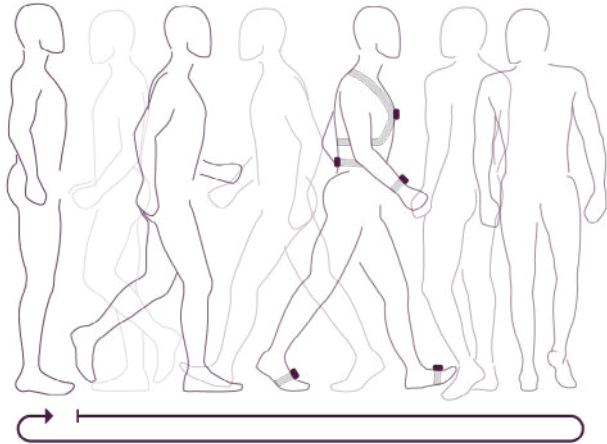


## 03 Additional mobility

- Timed up and go
- Sit to stand
- 360 degree turn
- Stand and walk

# Gait

## Opal-instrumented tests



### 2-Minute Walk Test

Clario's most comprehensive test to capture precise and objective spatiotemporal characteristics of participants' natural-paced gait. The  $\geq 7$  meters walkway, with  $180^\circ$  turns on either end, provides the minimum number of strides to accurately quantify full-body gait, gait variability, gait asymmetry and turning quality. Anticipatory postural adjustments (step initiation measures) are also captured during the stand to walk transition.<sup>8-13</sup>

### 6-minute Walk Test

Clario now also provides an instrumented version of the classic 6-Minute Walk Test in accordance with American Thoracic Society standards.<sup>14</sup> Participants are asked to walk as far as possible over a 30-meter walkway. Distanced walked is the primary endpoint calculated, however all of Clario's instrumented walk endpoints are additionally captured enabling deeper insights on gait performance and fatigue.<sup>15</sup>

### Walk Test Options

- Dual Task
  - Serial Subtraction
  - Category
- Walk Pace
  - Fast
  - Slow
- Walk Distance
  - 25-foot Walk
  - 400 meter
- Walk Duration

## Gait digital endpoints

Anticipatory postural adjustments (step initiation)	Gait turns	
APA duration (sec)	Average angle per step (degrees)	Angle (degrees)
First step duration (sec)	Average duration per Step (sec)	Duration (sec)
First step range of motion (degrees)	Average velocity per step (degrees/sec)	Turns (no.)
Forward APA peak (m/sec <sup>2</sup> )	Peak angle per step (degrees)	Average velocity (degrees/sec)
Lateral APA peak (m/sec <sup>2</sup> )	Peak duration per step (sec)	Peak velocity (degrees/sec)
	Peak velocity per step (degrees/sec)	Direction
	Steps in turn (no.)	

Lower body gait		Upper body gait
Cadence (steps/min)	Walk Distance (m)	Lumbar - Coronal Range of Motion (degrees)
Double Support (% Gait Cycle Time - GCT)	Toe Off Angle (degrees)	Lumbar - Sagittal Range of Motion (degrees)
Elevation at Midswing (cm)	Single Limb Support (%GCT)	Lumbar - Transverse Range of Motion (degrees)
Gait Cycle Duration (sec)	Stance (%GCT)	Trunk - Coronal Range of Motion (degrees)
Gait Speed (m/sec)	Step Duration (sec)	Trunk - Sagittal Range of Motion (degrees)
Lateral Step Variability (cm)	Stride Length (m)	Trunk - Transverse Range of Motion (degrees)
Circumduction (cm)	Swing (%GCT)	Upper Limb - Arm Swing Velocity (degrees/sec)
Valid Gate Cycles (no.)	Terminal Double Support (%GCT)	Upper Limb - Arm Range of Motion (degrees)
Foot Strike Angle (degrees)	Toe Out Angle (degrees)	

Endpoints are provided as means, standard deviations and measures of asymmetry if bilateral.

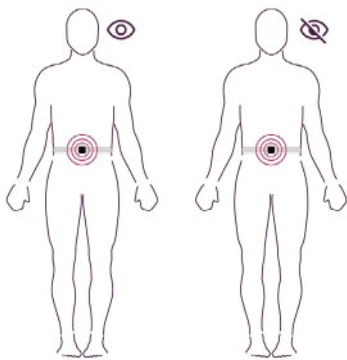
# Balance

## Opal-instrumented tests

### Static Balance Overview

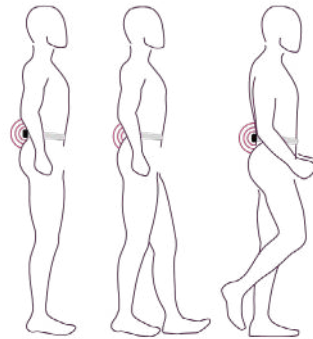
Postural sway tasks reflect the ability of the central nervous system to control the body's center of mass so that it remains within safe boundaries within the base of support. Standing still is a very active process, in which visual, somatosensory and vestibular systems must work together. When sensory input is distorted or removed, e.g., when vision is not available or the subject is standing on a foam surface, sway will increase. Impairments in sensory, motor or

central nervous function, caused by the natural aging process or pathology, will be reflected in changes in maintaining stability during postural sway. Clinicians often assess postural sway with stopwatches to time how many seconds a person can hold a particular stance. However, digital characteristics of postural sway measured with the Opal is a precise way to assess severity of a balance disorder even when patients can successfully hold a particular stance.<sup>16</sup>



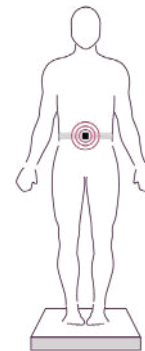
#### Altered Visual Input

- Eyes Open
- Eyes Closed



#### Altered Stance Position

- Feet Apart
- Feet Together
- Tandem
- One Foot



#### Altered Proprioception

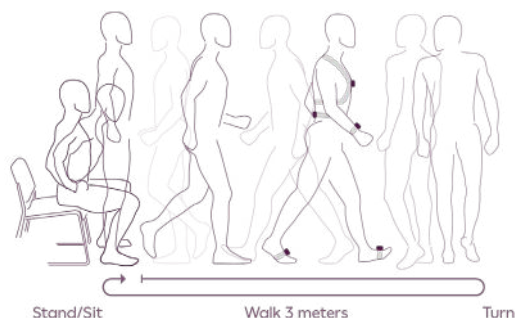
- Firm Surface
- Foam Surface

Balance digital endpoints		
Postural Sway - Acceleration		Postural Sway - Angles
Range (m/sec <sup>2</sup> )	Jerk (Coronal) (m <sup>2</sup> /sec <sup>5</sup> )	Sway Area (degrees <sup>2</sup> )
Range (Coronal) (m/sec <sup>2</sup> )	Jerk (Sagittal) (m <sup>2</sup> /sec <sup>5</sup> )	RMS Sway (degrees)
Range (Sagittal) (m/sec <sup>2</sup> )	Mean Velocity (m/sec)	RMS Sway (Coronal) (degrees)
Sway Area (m <sup>2</sup> /sec <sup>4</sup> )	Mean Velocity (Coronal) (m/sec)	RMS Sway (Sagittal) (degrees)
Centroidal Frequency (Hz)	Mean Velocity (Sagittal) (m/sec)	
Centroidal Frequency (Coronal) (Hz)	Path Length (m/sec <sup>2</sup> )	
Centroidal Frequency (Sagittal) (Hz)	Path Length (Coronal) (m/sec <sup>2</sup> )	
Frequency Dispersion (n/a)	Path Length (Sagittal) (m/sec <sup>2</sup> )	
Frequency Dispersion (Coronal) (n/a)	RMS Sway (m/sec <sup>2</sup> )	
Frequency Dispersion (Sagittal) (n/a)	RMS Sway (Coronal) (m/sec <sup>2</sup> )	
Jerk (m <sup>2</sup> /sec <sup>5</sup> )	RMS Sway (Sagittal) (m/sec <sup>2</sup> )	

Endpoints are provided as means, standard deviations and measures of asymmetry if bilateral.

# Additional Mobility Tests

## Opal-instrumented tests



### Timed Up & Go

Clario's instrumented version of the Timed Up & Go (TUG), is a commonly utilized assessment of overall mobility.<sup>17</sup> Participants are asked to stand from a chair, walk 3 meters, turn 180 degrees, walk back and sit down. The total TUG duration is often used as an indicator of frailty and fall risk.<sup>18</sup> Additional digital endpoints provide deeper insight by quantifying each phase of the TUG, including sit to stand, stand to sit and turning.



### Sit to Stand

The instrumented Sit to Stand test is an assessment of functional lower body strength.<sup>19</sup> Participants are asked to stand and sit from a seated position for a total of 5 times or for a duration of 30 seconds. The total Sit to Stand duration or the number of repetitions, respectively, are also commonly used to assess fall risk.<sup>20</sup> Additional digital endpoints, such as lean angle, may provide further understanding of movement ability.



### 360 Degree Turn

The instrumented 360 Degree Turn test is a measure of dynamic balance. Participants are asked to turn a full 360 degrees to the left and to the right. This test is often used in the elderly and movement disorders to assess fall risk. New research indicates the 360 Degree Turn test may also provide an advantage in freezing of gait studies.<sup>21-23</sup>

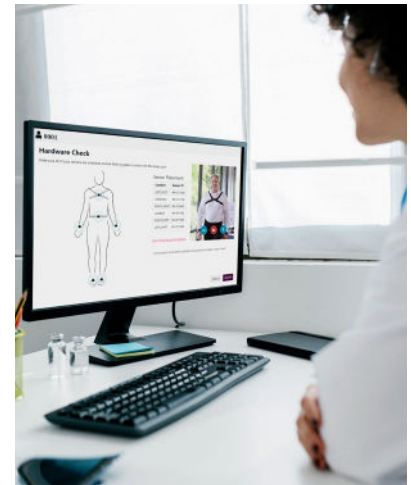
## Additional Mobility digital endpoints

Timed up and go	Sit to stand	360 degree turn
Trial Duration (sec)	Trial Duration (sec)	Turns - Angle (degrees)
Sit to Stand - Duration (sec)	Sit to Stand - Duration (sec)	Turns - Duration (sec)
Sit to Stand -Lean Angle (degrees)	Sit to Stand - Lean Angle (degrees)	Turns - Turns (no.)
Sit to Stand - Sit to Stand Events (No.)	Sit to Stand - Sit to Stand Events (#)	Turns - Peak Velocity (degrees/sec)
Stand to Sit - Duration (sec)	Stand to Sit - Duration (sec)	
Stand to Sit -Lean Angle (degrees)	Stand to Sit - Lean Angle (degrees)	
Stand to Sit - Stand to Sit Events (no.)	Stand to Sit - Stand to Sit Events (no.)	
TUG - Duration (sec)		

Endpoints are provided as means, standard deviations and measures of asymmetry if bilateral.

# Opal product solutions

In-clinic, remote or hybrid



## In-clinic active assessments

In-clinic laptop

Mobility Lab software

- Instrumented Tests & Endpoints

Opal hardware

- Opal sensors
- Access Point
- Docking Station

## Remote active assessments

In-clinic laptop

Mobility web app

- Instrumented tests and endpoints

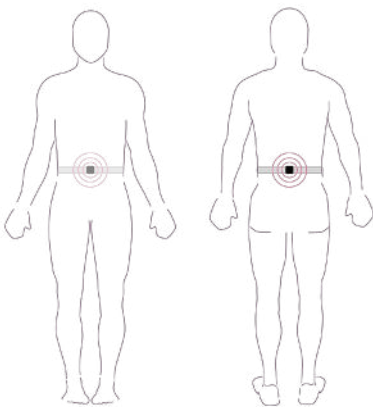
Virtual visits platform

- To instruct and observe patient

Subject kit

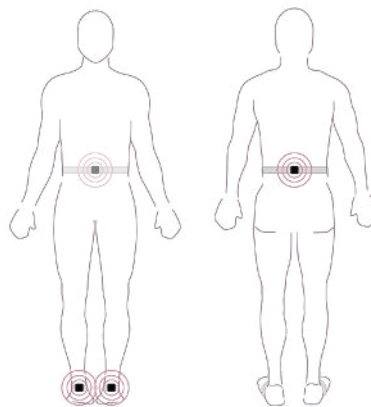
- Opal sensors
- Opal DataHub
- Mobile device and stand

## Sensor configuration options



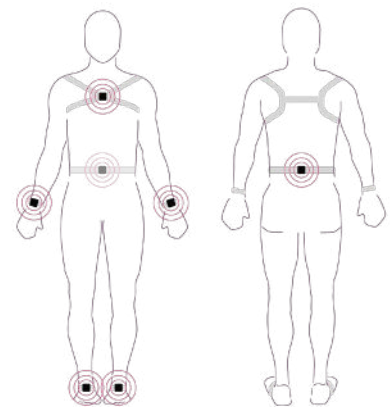
### 1 Opal

For balance only



### 3 Opals

For balance and lower body measures of gait and additional mobility tests



### 6 Opals

For balance and full body measures of gait and additional mobility tests



# Scientific consulting services

Need help selecting the optimal Opal-instrumented test sequence, digital endpoints or product solution for your study? Clario's Scientific Consulting Service team provides expert guidance on generating the richest clinical evidence by capturing precise and meaningful aspects of mobility in clinical trials.



## Protocol development

- Protocol synopsis preparation
- Protocol review and commentary
- Hourly KOL consulting



## Statistical and data analysis

- Statistical analysis plan preparation
- Statistical analysis package
- Hourly data analysis
- Data interpretation



## Customization

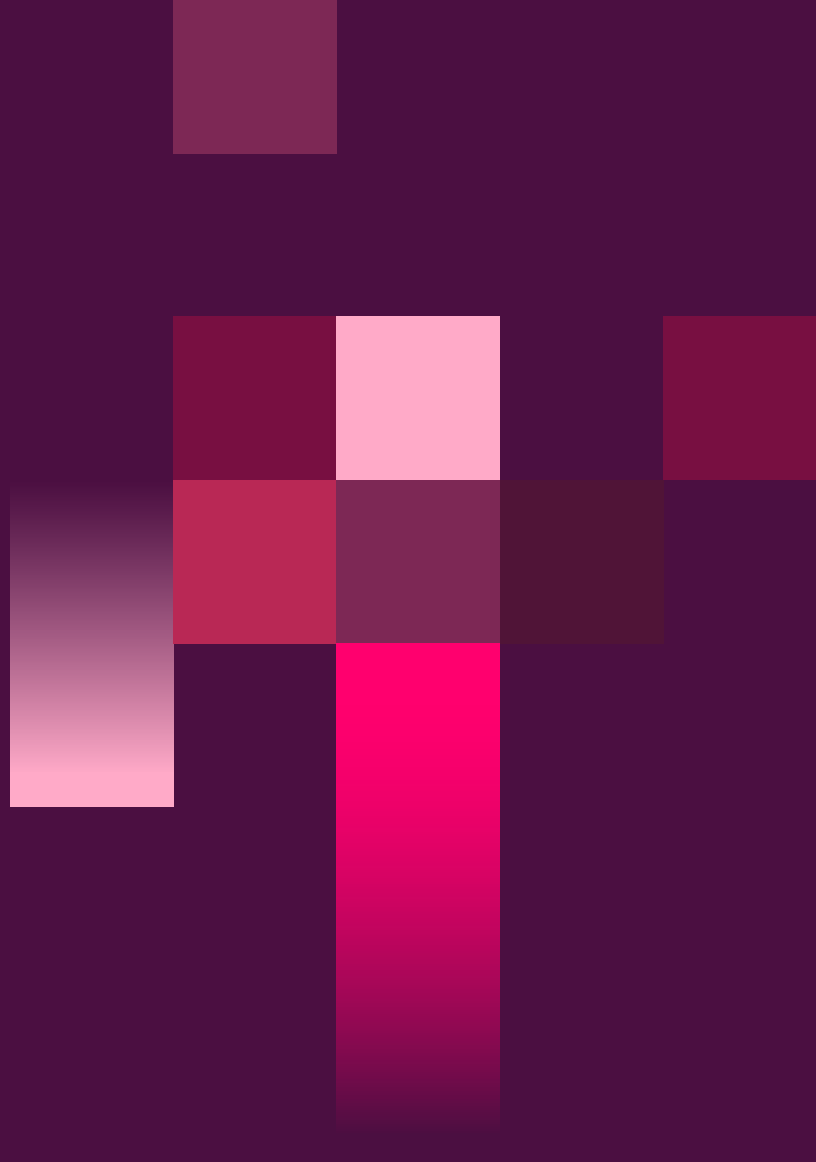
- Novel instrumented tests
- Standard instrumented test instruction customization

Learn more about [Precision Motion Consulting Services](#)

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## About Clario

Clario is a leading healthcare research and technology company that generates the richest clinical evidence in the industry for our pharmaceutical, biotech and medical device partners. Across decentralized, hybrid and site-based trials, our deep scientific expertise, global scale and the broadest endpoint technology platform in the industry allows our partners to transform lives. Clario has the only technology platform that combines eCOA, cardiac safety, medical imaging, precision motion, and respiratory endpoints. Clario's global team of science, technology and operational experts have helped deliver over 24,000 trials and contributed to over 500 FDA and EMEA new drug approvals involving more than five million patients in 120 countries. Our innovation has been transforming clinical trials for 50 years.