# SOLE SOURCE JUSTIFICATION

## PURCHASE AND SUPPLY OF THE PULSOID

### OVERVIEW

Izon Science Limited is the sole manufacturer of the Pulsoid (product code PUL-V1), a nanoparticle measurement instrument based on Nanopore Pulse Sensing (NPS). The Pulsoid instrument, its proprietary fluid cell, its solid-state nanopore chips and its dedicated software (Pulsoid Control Suite and Izon Data Suite 2) are exclusive to Izon Science Limited and are not available from any other supplier. The Pulsoid can be purchased directly from Izon Science Limited or through its authorised distributors. It is designed and manufactured in Christchurch, New Zealand, under a Quality Management System certified to ISO 13485:2016.

NPS builds on Izon Science's proprietary Tunable Resistive Pulse Sensing (TRPS) technology. The measurement principles of NPS are entirely different from light-based technologies. The Pulsoid fluid cell consists of two transparent chambers holding a solid-state silicon nanopore chip manufactured with high precision and consistency. Applied pressure and voltage drive particles through the nanopore one at a time. As a particle passes through, it causes a brief pulse in the ionic current: pulse height gives particle volume and size, pulse duration gives zeta potential, and pulse frequency gives concentration.

This allows the Pulsoid to measure four physical properties of nanoparticles in solution at the single-particle level: diameter, concentration, zeta potential and volume. Across its two nanopore chips (P4T and P5T), the Pulsoid measures particles from 30 nm to 210 nm, covering lipid nanoparticles (LNPs), liposomes, extracellular vesicles (EVs), bacteriophage and other nanoscale particles used in biological and therapeutic research. Because volume is measured directly from pulse height, no assumption about particle shape is required.

Every measurement is related back to a traceable calibration with Izon calibration particles of certified size and concentration, which serves as a built-in validation step. On NIST-traceable polystyrene standards (CPN70 and CPN80), Pulsoid size measurements were 101.4% and 99.7% of the TEM-certified reference size. Concentration is measured by directly counting individual particles and responds linearly to dilution ($R^2$ = 0.998 across a CPN80 dilution series), so a change in reported concentration reflects a change in the sample.

Ensemble techniques such as dynamic and electrophoretic light scattering report sample-wide averages of size or surface charge, and optical particle-tracking methods depend on how strongly each particle scatters light. The Pulsoid combines size, concentration, zeta potential and volume, measured particle by particle with traceable calibration, through a system supplied only by Izon Science: its proprietary two-chamber fluid cell, fixed-geometry solid-state nanopore chips, certified calibration particles and dedicated software (PCS and IDS2) are designed to work together and are not available from any other source. The fixed-geometry chips make measurements consistent and repeatable, with minimal set-up and maintenance.

The Pulsoid operates only with consumables supplied by Izon Science Limited: compatible nanopore chips, calibration particles and reagents are not available from any other source. Instrument service, repair, and software and firmware updates are likewise available only from Izon Science Limited.

In summary, the Pulsoid provides a unique combination of accurate particle size measurement, direct concentration measurement by particle counting, zeta potential and volume measurement at the single-particle level, enabled by its proprietary fluid cell and nanopore chips. This combination is not available from any alternative supplier.

## SPECIFICATIONS

### Measurement Capabilities

- Diameter, concentration, zeta potential and volume, measured at the single-particle level using Nanopore Pulse Sensing (NPS).

### Particle Size

- Measurable size range: 30 nm to 210 nm across the P4T and P5T nanopore chips.
- Size accuracy: 100% ± 2%, demonstrated using NIST-traceable particle standards within the validated measurement range. Accuracy varies across the measurable size range.
- Measurements are related back to a traceable calibration standard.
- Particle types: lipid nanoparticles, liposomes, extracellular vesicles, bacteriophage and other synthetic and biological nanoparticles.

### Nanopore Chips

- P4T (formerly SC80): measurable range 30 nm to 140 nm. Recommended for small, clean particles, such as small LNPs. Supplied in packs of five (P4T-5).
- P5T: measurable range 45 nm to 210 nm. Recommended for LNPs, EVs and bacteriophage; the default chip for most samples. Supplied in packs of five (P5T-5).
- Nanopore chips are available only from Izon Science Limited.

### Particle Volume

- Particle volume is measured directly from pulse height, with no assumption about particle shape, so non-spherical particles are reported as they are.

## Sample Concentration (particles/mL)

- Concentration is determined by directly counting individual particles.
- Concentration is reported over a defined particle size range, allowing accurate data comparison.
- Concentration range: $1 \times 10^{9}$ to $1 \times 10^{12}$ particles/mL, with a linear response to dilution. Note: this is dependent on nanopore chip.

## Zeta Potential

- Zeta potential distribution of nanoparticles in solution, measured particle by particle.
- Can be measured alongside particle size, revealing charge distributions and subpopulations that ensemble methods average together.

## Calibration

- Measurements are calibrated with Izon calibration particles of certified size and concentration, available only from Izon Science Limited. CPN80 particles are recommended for calibrating size and concentration measurements, and CPC100 particles for calibrating size and zeta potential measurements.

## Sample Volume

- 65 µL of diluted sample is loaded into the sample side of the fluid cell for each measurement. Samples are diluted in Measurement Electrolyte to a target concentration of $2.5 \times 10^{9}$ to $2.5 \times 10^{11}$ particles/mL.

## Testing Speed

- Typically 2 to 5 minutes per sample when measuring multiple samples within a single session.
- Measurement time varies based on sample characteristics.

## Electrolyte

- Measurement Electrolyte is prepared from the NPS Reagent Kit supplied by Izon Science Limited. Zeta potential measurements require Izon's Measurement Electrolyte.
- The same electrolyte must be used for all sample and calibration recordings that will be analysed together.

## Instrument Dimensions

- The Pulsoid is portable and compact: 33 × 21.5 × 13 cm (L × W × H), weighing 5.75 kg unboxed.

## Computer System

- Pulsoid Control Suite (PCS) is required to operate the instrument, and Izon Data Suite 2 (IDS2) is required for data review and analysis. The 30 nm lower limit requires PCS 1.4.0 and IDS2 2.5.0 or later. Both are available exclusively from Izon's online support portal, and software licences and updates are included.
- A computer with PCS and IDS2 installed is supplied with the instrument. If a different computer is used, it must meet these minimum requirements:
  - 16 GB RAM
  - i7 processor
  - 256 GB SSD
  - Dedicated graphics processor (GPU) with at least 1 GB graphics memory
  - Windows 10 Pro or above

## Power Supply

- Normal wall-socket power, on universal AC 100 to 240 V, 47 to 63 Hz electrical supply. Converts to 24 V DC.
- Power consumption: 12.75 W.

## SUPPORT AND SUPPLY

### What's Included

- Pulsoid instrument (PUL-V1); reference cell; two fluid cells; 24 V power supply and power lead; USB-A to USB-C 3.0 cable; computer with PCS and IDS2 installed; NPS Training Kit, which contains the NPS Reagent Kit; pressure syringe kit and pressure application device (PAD); starter nanopore chips.

### Training and Support

- Izon Science Support Centre: online support resources.
- Remote video support available.
- Onsite training and support can be provided at additional cost.
- NPS Training Kit supplied with the instrument for initial training and familiarisation.

### Service and Repair

- Service, repair, and software and firmware updates for the Pulsoid are provided only by Izon Science Limited. The Pulsoid has no user-serviceable parts, and repairs must be carried out by an Izon-approved technician.

### User Manuals and Supporting Documentation

- The Pulsoid User Manual and instructions for operation are provided as PDFs on Izon's online support portal at support.izon.com.
- The NPS Reagent Kit Specifications and Preparations Guide is available at support.izon.com/nps-kit-documents.

### Warranty

- A 24-month warranty is provided by the manufacturer.

### Shipment

- Packaged weight: 8.6 kg
- Box dimensions: 26 × 33 × 46 cm (L × W × H)