OPULUS Catalog

Valid to: 2024-12-31

Opulus introduced the PyroButton System (PBS) – *Temperature & Temperature/Humidity data-loggers, software, high-capacity docking stations, calibrators and accessories* - to the market 15+ years ago. We have provided best-in-class solutions for the medical device, sterilization and pharmaceutical industries; the users agree, as proven by the testimonials (see testimonials). Our aggressive & innovative R&D efforts reached a new milestone with the advanced PyroButton-X/System (PBX/S) sustainable and environmentally friendly high-performance family of PBX data-logger products. PBX/S represents a new paradigm for advanced process monitoring, regulatory compliance, economics, and optimum decision making.

- PBX is the smallest – 17mm diameter x 7.5mm height – sustainable, high-performance data-logger on the market
  - Battery and sensors are factory replaceable, optimized by Opulus exchange policy. *Warning: Do not take apart or try to take apart the PBX data-loggers! It is VERBOTEN! You will cause change in the specification of the device!*
- Improved stainless steel housing and advanced seal technology protects the electronics from corrosive environment,
- Increased _memory_ capacity by more than _30-fold_ provides higher data-load and improved data management, such as unique quality marker signature for each data-logger,
- Smart mission management supports smart data acquisition for measurement optimization,
- New high performance/high-throughput programmer/reader enhanced with intelligence for functional operation and positional recognition of the PyroButtons,
- Advanced application software – PyroButton-SQL v.4 – includes haptic type graphic user interface, MS SQL 16 database engine, _multiple sensors_ – temperature, humidity, pressure, Ethylene Oxide, VOC, etc. – support and new query models,
- Compare against the competition.

Products:

- PyroButton-X self-powered data-loggers
- *i*PBX programmer/reader adapters
- PyroButton software
- PyroButton calibration/verification Systems

Warranty periods:

- Calibrated data-loggers: 1 year warranty (Opulus condition in Manual) from date of delivery
- Calibration/Verification systems: 2 years warranty (Opulus condition in Manual) from date of delivery
- *i*PBX docking stations: 3 years warranty (Opulus condition in Manual) from date of delivery
- Software: Lifetime warranty (Opulus condition in Manual); upgrades & updates are not included.

Product Code	Description	List Price ($) 2024 March – 2024 Dec.
	*PyroButton data-logger packages*	
100-PKX-005-100	**Sterilization Process Management - Steam Package.** **A 21 CFR Part 11 compliant System with eManual & eTutorial.** **Includes:** (**1) 4 x PyroButton-X/PE** - Calibrated, self-powered temperature device. Temperature range 0 to 150°C; Temperature resolution ±0.015°C; Calibrated Temperature accuracy (uncertainty) ±0.1°C. Pressure range 1 to 700 kPa; Pressure resolution 120Pa. Memory capacity: 59800 recorded data points. Calibrated at 5-points relative to NIST reference or equivalent International Reference. Measurements are corrected relative to the calibration data. Data integrity protection inclusion for 21 CFR Part 11 requirement. **(2) iPBX-N28** Intelligent USB high speed Docking Station with automatic recognition of PBX positions. **Suitable for parallel programming /data-download for 28 PyroButtons and PyroButtons-X family.** **(3) PyroButton-SQL v.4** software with 21 CFR Part 11 compliance. *Windows 10 compatible.* Includes 2016 MS SQL Express with SPC (includes: Sterilization, Applications, Basic, Clean Room, Equipment, Facility, Meteorological, Process, Stability chamber, Transportation, Container/Closures modules; provides heat & moisture distribution map, loading effects, container/closure evaluation, PQ, and much more. Built-in automatic correction of measurement based on the calibration data. Signal processing program module for optimization of signal smoothing for the reduction of inherent noise of applicable sensors' measurements, which improves the reliability of results. Built-in uncertainty of measurement calculation). **(4) IQ-OQ-PQ & 21 CFR Part 11** Verification Protocols. **1 workstation license**	**13,587** /package
100-PKE-006-100	**Sterilization Process Management - ETO Package.** **A 21 CFR Part 11 compliant System with eManual & eTutorial.** **Includes:** **(1) 4 x PyroButton-Xi/TH** - Calibrated, self-powered Intrinsically Safe & IP68 compliant temperature/humidity data-logger*. Temperature range -20 to +85°C; Temperature resolution ±0.025°C; Calibrated temperature accuracy (uncertainty) ±0.1°C. Humidity range 0 – 100% RH; Calibrated humidity resolution ± 0.04% RH; Calibrated humidity accuracy (uncertainty) ±1.5% RH. Memory capacity: 59800 recorded data points. Calibrated at 5-temperature points relative to NIST reference and 5-humidity points. Measurements are corrected relative to the calibration data. Data integrity protection inclusion for 21 CFR Part 11 requirement. **(2) iPBX-N28** Intelligent USB high speed Docking Station with automatic recognition of PBX positions. **Suitable for parallel programming /data-download for 28 PyroButtons and PyroButtons-X family.** **(3) PyroButton-SQL v.4** software with 21 CFR Part 11 compliance. *Windows 10 compatible.* Includes 2016 MS SQL Express with SPC (includes: Sterilization, Applications, Basic, Clean Room, Equipment, Facility, Meteorological, Process, Stability chamber, Transportation, Container/Closures modules; provides heat & moisture distribution map, loading effects,	**15,170** /package

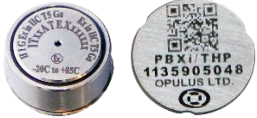|		
	container/closure evaluation, PQ, and much more. Built-in automatic correction of measurement based on the calibration data. Signal processing program module for optimization of signal smoothing for the reduction of inherent noise of applicable sensors' measurements, which improves the reliability of results. Built-in uncertainty of measurement calculation). **(4) IQ-OQ-PQ & 21 CFR Part 11** Verification Protocols 1 workstation license	
100-PKX-007-100	**Packaging Validation Process Management Pro Package.** **A 21 CFR Part 11 compliant System with eManual & eTutorial.** **Includes:** **(1) 4 x PyroButton-X/THP** - Calibrated, self-powered temperature/humidity/pressure data-logger. Temperature range -40 to +85°C; Temperature resolution ±0.005°C; Calibrated temperature accuracy (uncertainty) ±0.1°C. Humidity range 0 – 100% RH; Calibrated humidity resolution ± 0.08% RH; Calibrated humidity accuracy (uncertainty) ±1.5% RH. Pressure dynamic range: 30 (1) to 110 kPa Pressure resolution: 0.18 Pa Memory capacity: 29900 recorded data points. Calibrated at 5-temperature points relative to NIST reference and 5-humidity points. Measurements are corrected relative to the calibration data. Data integrity protection inclusion for 21 CFR Part 11 requirement. **(2) *i*PBX-N28** Intelligent USB high speed Docking Station with automatic recognition of PBX positions. **Suitable for parallel programming /data-download for** 28 PyroButtons and PyroButtons-X family. **(3) PyroButton-SQL v.4** software with 21 CFR Part 11 compliance. ***Windows 10 compatible.*** Includes 2016 MS SQL Express with SPC (includes: Applications, Basic, Clean Room, Equipment, Facility, Meteorological, Process, Stability chamber, Sterilization, Transportation, Container/Closures modules; provides heat & moisture distribution map, loading effects, container/closure evaluation, PQ, and much more. Built-in automatic correction of measurement based on the calibration data. Signal processing program module for optimization of signal smoothing for the reduction of inherent noise of applicable sensors' measurements, which improves the reliability of results. Built-in uncertainty of measurement calculation). **(4) IQ-OQ-PQ & 21 CFR Part 11** Verification Protocols 1 workstation license	**16,688** /package
100-PKX-010-100	**Transportation Temperature Management-Advanced System for Pharmaceutical, Biotech, & Medical Device.** **A 21 CFR Part 11 compliant product with eManual & eTutorial.** **Includes:** **(1) 4 x PyroButton-X/L** - Calibrated, self-powered IP68 compliant temperature data-logger. Temperature range -40 to +85°C; Temperature resolution 0.0078°C, Calibrated temperature accuracy ±0.1°C. Memory capacity: 119700 recorded data points. Calibrated at 5-points relative to NIST or International reference. Measurements are corrected relative to the calibration data. Data integrity protection inclusion for 21 CFR Part 11 requirement. **(2) *i*PBX-N28** Intelligent USB high speed Docking Station with automatic recognition of PBX positions. **Suitable for parallel programming /data-download for** 28 PyroButtons and	**13,276**/package

PyroButtons-X family. **(3) PyroButton-SQL v.4** software with 21 CFR Part 11 compliance. ***Windows 10 compatible.*** Includes 2016 MS SQL Express with SPC (includes: Applications, Basic, Clean Room, Equipment, Facility, Meteorological, Process, Stability chamber, Sterilization, Transportation, Container/Closures modules; provides heat & moisture distribution map, loading effects, container/closure evaluation, PQ, and much more. Built-in automatic correction of measurement based on the calibration data. Signal processing program module for optimization of signal smoothing for the reduction of inherent noise of applicable sensors' measurements, which improves the reliability of results. Built-in uncertainty of measurement calculation). **(4) IQ-OQ-PQ & 21 CFR Part 11** Verification Protocols 1 workstation license	

Product Code	Description	List Price ($) 2024 March – 2024 Dec.
PyroButton Self-powered temperature & humidity data-loggers		
100-PBX-000-100	**PyroButton-XL (PBX/L) Calibrated Low Temperature data-logger** Minimum quantity purchase is 10. Dimensions: 17mm diameter x 7.5 mm height *Sensor and electronics are housed in a 304 ss food grade housing (i.e., FDA approved for use in food processing.) It is the smallest advanced self-powered temperature data-logger on the market.* **Advancements***: Improved laser engraving for enhanced visibility of identifiers including QR code. Battery & sensor are factory replaceable to ensure sustainable and environmentally friendly operation.* ***Warning****: Do not take apart or try to take apart the PBX data-loggers! It is VERBOTEN! You will cause change in the specification of the device!* Electronics integrity*: The electronics are sealed and protected up to IP68 and 700 kPa (7 Bar) load from corrosive environments.* Weight: 6.01 g Volume: 1.56 cm^3 Ingress Protection rating: IP68 Dynamic range: -40 to 85°C Temperature resolution: ±0.0078 °C Memory capacity at 0.0078 °C resolution: 119700 readings Enhanced Regulatory Compliance: Calibrated at 5-points relative to NIST or International reference. Measurements are corrected relative to the calibration data. In addition to the calibration results and critical meta data (PB), the verification results and complete meta data are stored in PBX. Calibrated Temperature accuracy (uncertainty): ±0.1°C Data acquisition rate: 1s ....24 hrs Measurements are corrected relative to the calibration data. Data integrity protection inclusion for 21 CFR Part 11 requirement.	**312** /each
100-PBX-001-100	**PyroButton-X*i*L (PBX*i*/L) Calibrated Low Temperature data-logger** Intrinsically Safe Minimum quantity purchase is 10. Dimensions: 17mm diameter x 7.5 mm height	**355** /each

	Sensor and electronics are housed in a 304 ss food grade housing (i.e., FDA approved for use in food processing.) It is the smallest advanced self-powered temperature data-logger on the market. **Advancements***: Improved laser engraving for enhanced visibility of identifiers including QR code. Battery & sensor are factory replaceable to ensure sustainable and environmentally friendly operation. **Warning**: Do not take apart or try to take apart the PBX data-loggers! It is VERBOTEN! You will cause change in the specification of the device!* Electronics integrity*: The electronics are sealed and protected up to IP68 and 700 kPa (7 Bar) load from corrosive environments, such as Ethylene Oxide (EO). Suitable for EO sterilization.* Weight: 6.01 g Volume: 1.56 cm³ Ingress Protection rating: IP68 Dynamic range: -40 to 85°C Temperature resolution: ±0.0078 °C Memory capacity at 0.0078 °C resolution: 119700 readings Enhanced Regulatory Compliance: Calibrated at 5-points relative to NIST or International reference. Measurements are corrected relative to the calibration data. In addition to the calibration results and critical meta data (PB), the verification results and complete meta data are stored in PBX. Calibrated Temperature accuracy (uncertainty): ±0.1°C Data acquisition rate: 1s ....24 hrs Measurements are corrected relative to the calibration data. Data integrity protection inclusion for 21 CFR Part 11 requirement.	
100-PBX-002-100	# PyroButton-XE (PBX/E) Calibrated High Temperature data-logger PBX/E 1352840925 pyrobutton.com ## Minimum quantity purchase is 10. Dimensions: 17mm diameter x 7.5 mm height *Sensor and electronics are housed in a 304 ss food grade housing (i.e., FDA approved for use in food processing). It is the smallest advanced self-powered temperature data-logger on the market.* **Advancements***: Improved laser engraving for enhanced visibility of identifiers including QR code. Battery & sensor are factory replaceable to ensure sustainable and environmentally friendly operation. **Warning**: Do not take apart or try to take apart the PBX data-loggers! It is VERBOTEN! You will cause change in the specification of the device!* Electronics integrity*: The electronics are sealed and protected up to IP68 and 700 kPa (7 Bar) load from corrosive environments.* Weight: 6.01 g Volume: 1.56 cm³ Ingress Protection rating: IP68 Dynamic range: 0 to 150°C Temperature resolution: ±0.0078°C Memory capacity at 0.0078 resolution: 119700 readings Enhanced Regulatory Compliance: Calibrated at 5-points relative to NIST or International reference. Measurements are corrected relative to the calibration data. In addition to the calibration results and critical meta data (PB), the verification results and complete meta data are stored in PBX. Calibrated Temperature accuracy (uncertainty): ±0.1°C Data acquisition rate: 1s ....24 hrs Measurements are corrected relative to the calibration data. Data integrity protection inclusion for 21 CFR Part 11	**520** /each
100-PBX-003-100	**PyroButton-XTH –(PBX/TH) Calibrated Temperature & Humidity data-logger**	**556**/each

	Minimum quantity purchase is 10 Dimensions: 17mm diameter x 7.5 mm height Sensor and electronics are housed in a 304 ss food grade housing (i.e., FDA approved for use in food processing). It is the smallest advanced self-powered temperature & humidity data-logger on the market. **Advancements**: *Improved laser engraving for enhanced visibility of identifiers including QR code. Battery & sensor are factory replaceable to ensure sustainable and environmentally friendly operation. **Warning**: Do not take apart or try to take apart the PBX data-loggers! It is VERBOTEN! You will cause change in the specification of the device!* Electronics integrity: *The electronics are sealed and protected up to IP68 and 700 kPa (7 Bar) from corrosive environments.* Weight: 5.64 g Volume: 1.56 cm³ Ingress Protection rating: IP68 Dynamic Temperature range: -40 to 85°C Temperature resolution: ±0.025°C Memory capacity at 0.025 resolution: 59800 readings Enhanced Regulatory Compliance: Calibrated at 5-points relative to NIST or International reference. Measurements are corrected relative to the calibration data. In addition to the calibration results and critical meta data (PB), the verification results and complete meta data are stored in PBX. Calibrated Temperature accuracy (uncertainty): ±0.1°C Dynamic Humidity range at 25°C: 0 to 100 %RH Humidity resolution: ±0.04 %RH Memory capacity at 0.04 resolution: 59800 readings Calibrated Humidity accuracy (uncertainty): ± 1.5 %RH Measurements are corrected relative to the calibration data. Data integrity protection inclusion for 21 CFR Part 11 requirement.	
100-PBX-103-100	**PyroButton-X*i*TH –(PBX*i*/TH) Calibrated Temperature & Humidity data-logger** Intrinsically Safe Minimum quantity purchase is 10 Dimensions: 17mm diameter x 7.5 mm height Sensor and electronics are housed in a 304 ss food grade housing (i.e., FDA approved for use in food processing). It is the smallest advanced self-powered temperature & humidity data-logger on the market. **Advancements**: Improved laser engraving for enhanced visibility of identifiers including QR code. *Battery & sensor are factory replaceable to ensure sustainable and environmentally friendly operation. **Warning**: Do not take apart or try to take apart the PBX data-loggers! It is VERBOTEN! You will cause change in the specification of the device!* Electronics integrity: The electronics are sealed and protected up to 700 kPa (7 Bar) from corrosive environments, such as Ethylene Oxide (EO). Suitable for EO sterilization Weight: 5.64 g Volume: 1.56 cm³ Ingress Protection rating: IP68 Dynamic Temperature range: -20 to 85°C Temperature resolution: ±0.025°C Memory capacity at 0.025 resolution: 59800 readings Enhanced Regulatory Compliance: Calibrated at 5-points relative to NIST or International	**650**/each

	reference. In addition to the calibration results and critical meta data (PB), the verification results and complete meta data are stored in PBX. Calibrated Temperature accuracy (uncertainty): ±0.1°C Dynamic Humidity range at 25°C: 0 to 100 %RH Humidity resolution: ±0.04 %RH Memory capacity at 0.04 resolution: 59800 readings Calibrated Humidity accuracy (uncertainty): ± 1.5 %RH Measurements are corrected relative to the calibration data. Data integrity protection inclusion for 21 CFR Part 11 requirement.	
100-PBX-004-100	**PyroButton-XPE (PBX/PE) Calibrated High-Temperature and High-Pressure data-logger** Minimum quantity purchase is 10. Dimensions: 17mm diameter x 10.2 mm height *Sensor and electronics are housed in a 304 ss food grade housing (i.e., FDA approved for use in food processing.) It is the smallest advanced self-powered temperature and pressure data-logger on the market.* **Advancements**: *Improved laser engraving for enhanced visibility of identifiers including QR code. Battery & sensor are factory replaceable to ensure sustainable and environmentally friendly operation.* **Warning**: *Do not take apart or try to take apart the PBX data-loggers! It is VERBOTEN! You will cause change in the specification of the device!* Electronics integrity: *The electronics are sealed and protected up to 700 kPa (7 Bar) from corrosive environments. Suitable for Steam and Heat sterilization.* Weight: 6.56 g Volume: 2.12 cm³ Temperature Dynamic range: 0 to 150°C Temperature resolution: ±0.015 °C Memory capacity at high resolution: 59800 readings Enhanced Regulatory Compliance: Calibrated at 5-points relative to NIST reference or equivalent International Reference. In addition to the calibration results and critical meta data (PB), the verification results and extended meta data are stored in PBX. Calibrated Temperature accuracy (uncertainty): ±0.1°C Pressure dynamic range: 1 to 700 kPa Pressure resolution: 120 Pa Calibrated accuracy (uncertainty): TBA (to be announced) Data acquisition rate: 1s ….24 hrs Measurements are corrected relative to the calibration data. Data integrity protection inclusion for 21 CFR Part 11 requirement.	**952** /each
100-PBX-005-100	**PyroButton-XTHP (PBX/THP) Calibrated Temperature, Humidity and High-Precision Pressure data-logger** Minimum quantity purchase is 10. Dimensions: 17mm diameter x 7.5 mm height *Sensor and electronics are housed in a 304 ss food grade housing (i.e., FDA approved for use in food processing). It is the smallest advanced self-powered temperature, humidity and high sensitivity pressure data-logger on the market.* **Advancements**: Visual identification: *Improved laser engraving for enhanced visibility of identifiers including QR code. Battery & sensor are factory replaceable to ensure sustainable and environmentally*	**1037** /each

	friendly operation. **Warning**: *Do not take apart or try to take apart the PBX data-loggers! It is VERBOTEN! You will cause change in the specification of the device!* Electronics integrity: *The electronics are sealed and protected up to 700 kPa (7 Bar) from corrosive environments.* Three-in-One/Triple-sensor: *In addition to temperature and humidity highly sensitive/high resolution pressure sensor provide small pressure changes* Weight: 5.89 g Volume: 1.56 cm³ Temperature dynamic range: -40 to 85°C Temperature resolution: ±0.005°C Memory capacity: 29900 readings Enhanced Regulatory Compliance: Calibrated at 5-temperature points relative to NIST reference and 5-humidity points. In addition to the calibration results and critical meta data (PB), the verification results and extended meta data are stored in PBX. Calibrated Temperature accuracy (uncertainty): ±0.1°C Dynamic Humidity range at 25°C: 0 to 100%RH Humidity resolution: ±0.008 %RH Calibrated Humidity accuracy (uncertainty): ±1.5 %RH Pressure dynamic range: 30 (1) to 110 kPa Pressure resolution: 0.18 Pa Data acquisition rate: 1s ….24 hrs Measurements are corrected relative to the calibration data. Data integrity protection inclusion for 21 CFR Part 11	
100-PBX-105-100	**PyroButton-X*i*THP (PBX*i*/THP) Calibrated High Precision Pressure, Humidity and Temperature data-logger** Intrinsically Safe Minimum quantity purchase is 10. Dimensions: 17mm diameter x 7.5 mm height *Sensor and electronics are housed in a 304 ss food grade housing (i.e., FDA approved for use in food processing). It is the smallest advanced self-powered temperature, humidity and high sensitivity pressure data-logger on the market.* Advancements: Visual identification: *Improved laser engraving for enhanced visibility of identifiers including QR code. Battery & sensor are factory replaceable to ensure sustainable and environmentally friendly operation.* **Warning**: *Do not take apart or try to take apart the PBX data-loggers! It is VERBOTEN! You will cause change in the specification of the device!* Electronics integrity: *The electronics are sealed and protected up to 700 kPa (7 Bar) from corrosive environments, such as Ethylene Oxide (EO). Suitable for EO sterilization.* Three-in-One/Triple-sensor: *In addition to temperature and humidity highly sensitive/high resolution pressure sensor determines small pressure changes* Weight: 5.89 g Volume: 1.56 cm³ Temperature dynamic range: -20 to 85°C Temperature resolution: ±0.005°C Memory capacity: 29900 readings Enhanced Regulatory Compliance: Calibrated at 5-temperature points relative to NIST reference and 5-humidity points. In addition to the calibration results and critical meta data (PB), the verification results and extended meta data are stored in PBX. Calibrated Temperature accuracy (uncertainty): ±0.1°C Dynamic Humidity range at 25°C: 0 to 100%RH Humidity resolution: ±0.008 %RH Calibrated Humidity accuracy (uncertainty): ±1.5 %RH Pressure dynamic range: 30 (1) to 110 kPa	1,140 /each

Pressure resolution: 0.18 Pa Data acquisition rate: 1s ....24 hrs Measurements are corrected relative to the calibration data. Data integrity protection inclusion for 21 CFR Part 11	

Product Code	Description	List Price ($) 2024 March – 2024 Dec.
PyroButton adapters- programming/data-download		
100-IAE-009-100	**SPB-N16C** smart docking station with USB Adapter. **Suitable for pseudo-parallel programming /data-download for** 16 PyroButtons. To be discontinued by the end of 2022!	**1,923** /each
100-IAE-005-100	**SPB-N50C** smart docking station with USB Adapter. **Suitable for pseudo-parallel programming /data-download for** 50 PyroButtons. To be discontinued by the end of 2022!	**4,750** /each
100-XAE-004-100	**iPBX-N4** intelligent USB high speed docking station with automatic recognition of PBX positions. **Suitable for parallel programming /data-download for** 4 PyroButtons-X.	**436** /each
100-XAE-028-100	**iPBX-N28** intelligent USB high speed docking station with automatic recognition of PBX positions. **Suitable for parallel programming /data-download for** 28 PyroButtons and PyroButtons-X family.	**2,259** /each
100-XAE-060-100	**iPBX-N60** intelligent USB high speed docking station with automatic recognition of PBX positions. **Suitable for parallel programming /data-download for** 60 PyroButtons and PyroButtons-X family.	**5,189** /each

Product Code	List Price ($)	List Price ($) 2024 March – 2024 Dec.
PyroButton software for Self-powered temperature & humidity monitoring system		
100-PBX-007-020E	**PyroButton-X Simple** software for PyroButton-X data-loggers. *Windows 10 compatible* PBX Simple is an effective solution for self-powered PyroButton-X (PBX) data-logger temperature, humidity, and pressure measurements, including validation, mapping, monitoring, sterilization, and stability studies. This is a file version software, which means there is no database behind the software.	**436**/license

100-PBX-007-023E	**PyroButton-SQL v.4** software with 21 CFR Part 11 compliance. *Windows 10 compatible (network version available) with 2016 MS SQL Engine and SPC.* <u>**New – expanded sensor capabilities**</u>: *Supports Temperature, Humidity, Pressure, Ethylene Oxide, VOC and others, as added.* Includes 2016 MS SQL Express with SPC (includes: Applications, Basic, Clean Room, Equipment, Facility, Meteorological, Process, Stability chamber, Sterilization, Transportation, Container/Closures modules; provides heat & moisture distribution map, loading effects, container/closure evaluation, PQ, and much more. Built-in automatic correction of measurement based on the calibration data. Signal processing program module for optimization of signal smoothing for the reduction of inherent noise of applicable sensors' measurements, which improves the reliability of results. Built-in uncertainty of measurement calculation). 21 CFR Part 11 compliant 1 workstation license. <u>Includes</u>: eManual, eTutorial IQ-OQ-PQ & 21 CFR Part 11 verification protocols.	**15,840** /license

Product Code	Description	List Price ($) 2024 March – 2024 Dec.
Calibrators & Calibration Services		
100-ICE-221-100	**PyroButton-TQM v.4 with PBC-TH28** **A 21 CFR Part 11 ISO 17025 compliant system Windows 10 (32/64bits) compatible.** *Suitable for the temperature & humidity calibrations of PyroButton (legacy) and PyroButton-X (new advanced) data-loggers.* **Specification:** 1. Capacity: 28 x PyroButtons or PyroButton-Xs 2. Temperature Dynamic Range: -30 °C to +150 °C with Low Temperature Circulator (see, Opulus Water Chiller) 3. Temperature accuracy (uncertainty): u ≤0.1°C (-30°C .. 150°C), 4. Humidity via salt slush dynamic range at 25 °C: 3.7 %RH to 93.6 %RH 5. Humidity via salt slush accuracy: u ≤1.3%RH at 25°C (with Salt Slush as humidity reference) 6. Humidity via OpHumGen dynamic range at 25°C: 10 %RH to 90 %RH 7. Humidity via OpHumGen accuracy: u ≤1%RH at 25°C (with OpSens-RH as humidity reference) **Includes:** ✓ Calibration Operating System with Total Quality Management ✓ SQL 2016 Data Base Engine (network version available) ✓ PyroButton Calibration & Verification Life Cycle Management ✓ PBC-H28 calibrator's Calibration & Life Cycle Management ✓ Automatic generation of Calibration Certificates ✓ Integration of multiple Opulus calibrators & calibrator types ✓ CAPA & OOS Management ✓ Integrated Compliance Management ✓ Integrated Material Management ✓ High performance digital Humidity Sensor ✓ Optional Humidity Generator Can be integrated with PyroButton softwares for fully automatic correction.	**31,314** /license

100-ICE-222-110	**Opulus Humidity Generator (OpHumGen)** OpHumGen maintains a given relative humidity for calibration of PyroButton data loggers with PBC-TH28 calibrator. All functions of the OpHumGen are controlled by the PBC-TH28 measurement program (part of Opulus PyroButton-TQM framework). Includes: (1) Opulus Air Compressor (OPAC) is included (2) Relative Humidity Range: (10-40°C) - 10-90%RH (3) Relative Humidity Range: (40-50°C) - 10-85%RH (4) Temperature Range: (10-50°C)	**19,228** /each
100-ICE-229-110	**Opulus Air Compressor (OPAC)** The OpHumGen and the OPAC work together with the PBC-TH28 Calibrator. All functions of the OPAC are controlled by the PBC-TH28 measurement program (part of Opulus PyroButton-TQM framework).	**3,144** /each
100-ICE-422-110	**Opulus Water Chiller (OWC)** OWC can be used for operating the PBC-TH28 calibrator below 0°C. All functions of the OWC are controlled by the PBC-TH28 measurement program (part of Opulus PyroButton-TQM framework).	**5,482** /each
100-ICE-322-110	**OpiCal suite** OpiCal suite is a sophisticated real-time temperature calibration system for the PBC-TH28 calibrator. Includes: (1) 32 pcs OpiCal Reference Sensors (2) 1 pc OpiCal Chamber Calibration Insert (CCI/28)	**13,010** /each
100-ICE-001-100A	**PyroButton/PyroButton-X data-logger temperature re-calibration with verification** *NOTE: If the number of data-loggers are 10 or less add $150 set-up fee*	**61** /point
100-ICE-001-100B	**PyroButton/PyroButton-X data-logger temperature re-calibration** *NOTE: If the number of data-loggers are 10 or less add $150 set-up fee*	**49** /point
100-ICE-001-100C	**PyroButton/PyroButton-X data-logger humidity re-calibration with verification** *NOTE: If the number of data-loggers are 10 or less add $150 set-up fee*	**74** /point
100-ICE-003-100A	**PyroButton/PyroButton-X data-logger humidity re-calibration** *NOTE: If the number of data-loggers are 10 or less add $150 set-up fee*	**56** /point
100-BRP-004-100S	**PyroButton-X data-logger battery replacement & 3-point calibration** *Performed by Opulus in Hungary via 3 options: (1) 2 business weeks (battery change + 3-point calibration at $278), (2) 2 business weeks (battery change + 5-point calibration at $300), (3) via USA or Hungary/2 business weeks exchange/replacement with 3-point calibration & 5-point verification at $305)* *Note: Add $49 + 1 business week, if sensor change is required.*	**$278**

Testimonials

"We have now been working with the PyroButton system for about 18 months. The previous system we were working with was significantly more expensive to purchase and to maintain but we used it for many years as we considered it to

be the best product on the for our application. However, I now think the PyroButton system is far superior than anything else currently available, it beats all other systems in every department especially in the ease of use, data analysis and the time spent to calibrate."

Sterigenics

"I would like to tell you that PyroButton system is really useful, semiautomatic and paperless; is a cutting edge system that changed completely the level of service of Metrology (my department) to Validations (final users)."

Head Metrology, Becton Dickinson, Mexico

"Your organization is a game changer around EO and for other processes as well"

Sterilization Technology Director, Zimmer Biomet