

OPULUS Ltd.

Address: 1420 Locust St., 18N Philadelphia, PA 19102, USA

Phone: 215-310-0455

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Email: sales@pyrobutton.comWeb: www.pyrobutton.com

PyroButton Catalog

Valid to: 2012-12-31

Minimal configuration of PyroButton self-powered data-logger system:

- PyroButton self-powered data-logger,
- PyroButton adapter,
- PyroButton software.

Warranty period: Calibrated data-loggers - 1 year warranty (Opulus Licensee is required)

Product Code	Description	Non-VAT Price (\$)	Non-VAT Price (€)
<i>PyroButton data-logger packages</i>			
100-PKE-005-100	<p>Sterilization Process Management - Steam/Basic Package. A 21 CFR Part 11 compliant System</p> <p>Includes:</p> <p>(1) 4 x PyroButton-T - Self-powered temperature device (0 to 125°C; see, option for PyroButton-E of 15 to 140°C), Temperature resolution ±0.0625°C, Temperature accuracy ±0.2°C Calibrated at 5-points relative to NIST reference or equivalent International Reference. Each measurement is corrected relative to the calibration curve.</p> <p>(2) SPB-N16C Smart Docking Station with USB adapter for the parallel programming & data-download of 16 PyroButtons (see, option for SPB-N50C docking station for 50 PyroButtons).</p> <p>(3) PyroButton-SQL/S v. 3.16 software with 21 CFR Part 11 compliance. Includes 2005 MS SQL Express with SPC (includes: Sterilization, Clean Room, Process, Facilities, & Container/Closure application modules; provides heat distribution map, heat penetration evaluation, loading effects, container/closure evaluation, PQ, and much more);</p> <p>(4) IQ-OQ-PQ & 21 CFR Part 11 Verification Protocols.</p> <p>1 workstation license</p>	8,520 /package	6,311 /package

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100-PKE-006-100	<p>Sterilization Process Management - ETO/Basic Package. A 21 CFR Part 11 compliant System</p> <p>Includes: (1) 4 x PyroButton-TH - Self-powered temperature/humidity data-logger Temperature (-20 to +85°C), ±0.0625°C resolution, ±0.3°C accuracy Humidity (3.4 – 97.3% RH), resolution ± 0.04% RH, ±2% RH accuracy Calibrated at 5-temperature points relative to NIST reference and 5-humidity points. Each measurement is corrected relative to the calibration curve.</p> <p>(2) SPB-N16C Smart Docking Station with USB adapter for the parallel programming & data-download of 16 PyroButtons (see, option for SPB-N50C docking station for 50 PyroButtons).</p> <p>(3) PyroButton-SQL/S v. 3.16 software with 21 CFR Part 11 compliance. Includes 2005 MS SQL Express with SPC (includes: Sterilization, Clean Room, Process, Facilities, & Container/Closure application 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 curve. Signal processing program module for optimization of signal smoothing for the reduction of inherent noise of humidity measurements, which improve accuracy, and reproducibility. Built-in uncertainty of measurement calculation.</p> <p>(4) IQ-OQ-PQ & 21 CFR Part 11 Verification Protocols 1 workstation license</p> <p>(5) Option: See, PyroPalm hand held computer with integrated software, including PyroButton-SQL 3.16 compatibility for start/stop, data-download, and data export.</p>	9,720 /package	7,200 /package
100-PKE-007-100	<p>Packaging Validation Process Management -Basic Package. A 21 CFR Part 11 compliant System</p> <p>Includes: (1) 4 x PyroButton-TH - Self-powered temperature/humidity data-logger Temperature (-20 to +85°C), ±0.0625°C resolution, ±0.3°C accuracy Humidity (3.4 – 97.3% RH), resolution ± 0.04% RH, ±2% RH accuracy Calibrated at 5-temperature points relative to NIST or International reference and 5-humidity points. Each measurement is corrected relative to the calibration curve.</p> <p>(2) SPB-N16C Smart Docking Station with USB adapter for the parallel programming & data-download of 16 PyroButtons (see, option for SPB-N50C docking station for 50 PyroButtons).</p> <p>(3) PyroButton-SQL/PV v. 3.16 software with 21 CFR Part 11 compliance. Includes 2005 MS SQL Express with SPC (includes: Sterilization, Clean Room, Process, Facilities, & Container/Closure application 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 curve. Signal processing program module for optimization of signal smoothing for the reduction of inherent noise of humidity measurements, which improve accuracy, and reproducibility. Built-in uncertainty of measurement calculation.</p> <p>(4) IQ-OQ-PQ & 21 CFR Part 11 Verification Protocols 1 workstation license IQ-</p> <p>(5) Option: See, PyroPalm hand held computer with integrated software, including PyroButton-SQL 3.16 compatibility for start/stop, data-download, and data export.</p>	9,720 /package	7,200 /package

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100-PKE-009-100	<p>Transportation Temperature Management-Basic Package. A 21 CFR Part 11 compliant System</p> <p>Includes: (1) 4 x PyroButton-G - Self-powered temperature device (-40 to +85°C), Temperature resolution $\pm 0.5^\circ\text{C}$, Temperature accuracy $\pm 0.5^\circ\text{C}$ Calibrated at 5-points relative to NIST or International reference. Each measurement is corrected relative to the calibration curve.</p> <p>(2) SPB-N80 Smart Docking Station with USB adapter for the parallel programming & data-download of 8 PyroButtons (see, options for SPB-N16C for 16 or SPB-N50C docking station for 50 PyroButtons).</p> <p>(3) PyroButton-SQL/T-Basic v.3.16 software with 21 CFR Part 11 compliance. Includes 2005 MS SQL Express. Built-in automatic correction of measurement based on the calibration curve. Signal processing program module for optimization of signal smoothing for the reduction of inherent noise of humidity measurements, which improve accuracy, and reproducibility. Built-in uncertainty of measurement calculation. 1 workstation license</p> <p>(4) Option: IQ-OQ-PQ & 21 CFR Part 11 Verification protocols.</p> <p>(5) Option: See, PyroPalm hand held computer with integrated software, including PyroButton-SQL 3.16 compatibility for start/stop, data-download, and data export.</p>	4,750 /package	3,520 /package
100-PKE-010-100	<p>Transportation Temperature Management-Advanced System for Pharmaceutical, Biotech, & Medical Device. A 21 CFR Part 11 compliant product</p> <p>Includes:</p> <p>(1) 4 x PyroButton-L - Self-powered temperature device (-40 to +85°C), Temperature resolution 0.0625°C, Temperature accuracy $\pm 0.25^\circ\text{C}$ Calibrated at 5-points relative to NIST or International reference. Each measurement is corrected relative to the calibration curve.</p> <p>(2) SPB-N16C Smart Docking Station with USB adapter for the parallel programming & data-download of 16 PyroButtons (see, option for SPB-N50C docking station for 50 PyroButtons).</p> <p>(3) PyroButton-SQL/TA v. 3.16 software with 21 CFR Part 11 compliance. Includes 2005 MS SQL Express with SPC (includes: Sterilization, Clean Room, Process, Facilities, & Container/Closure application 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 curve. Signal processing program module for optimization of signal smoothing for the reduction of inherent noise of humidity measurements, which improve accuracy, and reproducibility. Built-in uncertainty of measurement calculation.</p> <p>(4) IQ-OQ-PQ & 21 CFR Part 11 Verification Protocols 1 workstation license</p> <p>(5) Option: See, PyroPalm hand held computer with integrated software, including PyroButton-SQL 3.16 compatibility for start/stop, data-download, and data export.</p>	8,350 /package	6,185 /package

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Product Code	Description	Non-VAT Price (\$)	Non-VAT Price (€)
<i>PyroButton Self-powered temperature & humidity data-loggers</i>			
100-IBE-001-100	<u>PyroButton-G</u> – Sensor and electronics are housed in a 305 ss food grade housing (i.e., FDA approved for use in food processing) of 17 mm diameter and 6 mm height. It is the smallest data-logger on the market. Self-powered temperature device (-40 to +85°C), Temperature resolution ±0.5°C, Temperature accuracy ±0.5°C Calibrated at 5-points relative to NIST or International reference. Each measurement is corrected relative to the calibration curve. Data integrity protection for 21 CFR Part 11 requirement.	135 /each	100 /each
100-IBE-003-100	<u>PyroButton-L - Intrinsicly Safe</u> . Sensor and electronics are housed in a 305 ss food grade housing (i.e., FDA approved for use in food processing) of 17 mm diameter and 6 mm height. It is the smallest data-logger on the market. Self-powered temperature device (-40 to +85°C); Temperature resolution ±0.0625°C, Temperature accuracy ±0.2°C Calibrated at 5-points relative to NIST reference. Each measurement is corrected relative to the calibration curve. Data integrity protection for 21 CFR Part 11 requirement.	185 /each	137 /each
100-IBE-004-100	<u>PyroButton-T - Intrinsicly Safe</u> . Sensor and electronics are housed in a 305 ss food grade housing (i.e., FDA approved for use in food processing) of 17 mm diameter and 6 mm height. It is the smallest data-logger on the market. Self-powered temperature device (0 to 125°C), Temperature resolution ±0.0625°C, Temperature accuracy ±0.2°C Calibrated at 5-points relative to NIST reference. Each measurement is corrected relative to the calibration curve. Data integrity protection for 21 CFR Part 11 requirement.	255 /each	189 /each
100-IBE-006-100	<u>PyroButton-E - Intrinsicly Safe</u> . Sensor and electronics are housed in a 305 ss food grade housing (i.e., FDA approved for use in food processing) of 17 mm diameter and 6 mm height. It is the smallest data-logger on the market. Self-powered temperature device (15 to 140°C), Temperature resolution ±0.0625°C, Temperature accuracy ±0.2°C Calibrated at 5-points relative to NIST reference. Each measurement is corrected relative to the calibration curve. Data integrity protection for 21 CFR Part 11 requirement.	357 /each	265 /each
100-IBE-005-100	<u>PyroButton-TH - Intrinsicly Safe</u> . Sensor and electronics are housed in a 305 ss food grade housing (i.e., FDA approved for use in food processing) of 17 mm diameter and 6 mm height. It is the smallest data-logger on the market. Self-powered temperature/humidity data-logger Temperature (-20 to +85°C), ±0.0625°C resolution, ±0.3°C accuracy Humidity (3.4 – 97.3% RH), resolution ± 0.04% RH, ±2% RH accuracy Calibrated at 5-temperature points relative to NIST reference and 5-humidity points. Each measurement is corrected relative to the calibration curve. Data integrity protection for 21 CFR Part 11 requirement.	357 /each	265 /each

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Product Code	Description	Non-VAT Price (\$)	Non-VAT Price (€)
<i>PyroButton adapters- programming/data-download</i>			
100-IAE-007-100	SPB-N80 smart docking station with USB Adapter. Suitable for parallel programming /data-download for 8 PyroButtons	550 /each	407 /each
100-IAE-009-100	SPB-N16C smart docking station with USB Adapter. Suitable for parallel programming /data-download for 16 PyroButtons	975 /each	722 /each
100-IAE-005-100	SPB-N50C smart docking station with USB Adapter. Suitable for parallel programming /data-download for 50 PyroButtons	2,850 /each	2,111 /each

Product Code	Description	Non-VAT Price (\$)	Non-VAT Price (€)
<i>PyroButton software for Self-powered temperature & humidity monitoring system</i>			
100-PBE-007-002E	PyroButton-Standard 2.0 software - Capable of both temperature & humidity measurements; compatible with all PyroButtons. Built-in automatic correction of measurement based on 5-point calibration curve. Signal processing program module for optimization of signal smoothing for the reduction of inherent noise of humidity measurements, improves accuracy, and reproducibility. Built-in uncertainty of measurement calculation. 21 CFR Part 11 compliant, if used in a closed document environment. 1 workstation license	780 /license	578 /license
100-PBE-007-006	IQ-OQ-PQ verification protocol for PyroButton-Standard software	850 /each	630 /each
100-PBE-007-007	21 CFR Part 11 verification protocol for PyroButton-Standard software	850 /each	630 /each
100-PBE-007-020E	PyroButton-SQL-/Basics v.3.8 software with 21 CFR Part 11 compliance. Includes MSDE & SPC. Built-in automatic correction of measurement based on the calibration curve. Signal processing program module for optimization of signal smoothing for the reduction of inherent noise of humidity measurements, which improve accuracy, and reproducibility. Built-in uncertainty of measurement calculation. Optional: IQ-OQ-PQ & 21 CFR Part 11 Verification Protocols 1 workstation license	3,670 /license	2 936 /license
100-PBE-007-016	IQ-OQ-PQ verification protocol for PyroButton-SQL/Basic software	1,250 /each	926 /each
100-PBE-007-017	21 CFR Part 11 verification protocol for PyroButton-SQL/Basic software	1,250 /each	926 /each

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100-PBE-007-021E	PyroButton-SQL/PRO v. 3.16 software with 21 CFR Part 11 compliance. Includes 2005 MS SQL Express with SPC (includes: Sterilization, Clean Room, Process, Facilities, & Container/Closure application 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 curve. Signal processing program module for optimization of signal smoothing for the reduction of inherent noise of humidity measurements, which improve accuracy, and reproducibility. Built-in uncertainty of measurement calculation. 21 CFR Part 11 compliant 1 workstation license IQ-OQ-PQ verification protocol 21 CFR Part 11 verification protocol are included.	7,975 /license	5,910 /license
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Product Code	Description	Non-VAT Price (\$)	Non-VAT Price (€)
Calibrators & Calibration Services			
100-ICE-020-100	<p>PyroButton-TQM with PBC- T48. A 21 CFR Part 11 ISO 17025 compliant system. Includes:</p> <p>(1) Calibration Operating System with Total Quality Management (2) MS SQL 2005 Express (i.e., network version available) (3) PyroButton Calibration & Verification Life Cycle Management (4) PBC-T48 calibrator's Calibration & Life Cycle Management (5) Automatic generation of Calibration Certificates (6) Integration of multiple Opulus calibrators & calibrator types (7) CAPA & OOS Management (8) Integrated Compliance Management (9) Integrated Material Management</p> <p>Temperature Calibrator System for simultaneous calibration of 48 PyroButtons (-35°C ... +140°C). Can be integrated with PyroButton softwares for fully automatic correction.</p>	28,720 /license	21,274 /license
100-ICE-021-100	<p>PyroButton-TQM with PBC- TH18. A 21 CFR Part 11 ISO 17025 compliant system. Includes:</p> <p>(1) Calibration Operating System with Total Quality Management (2) MS SQL 2005 Express (i.e., network version available) (3) PyroButton Calibration & Verification Life Cycle Management (4) PBC-H18 calibrator's Calibration & Life Cycle Management (5) Automatic generation of Calibration Certificates (6) Integration of multiple Opulus calibrators & calibrator types (7) CAPA & OOS Management (8) Integrated Compliance Management (9) Integrated Material Management</p> <p>Combined Temperature/Humidity Calibrator System for simultaneous calibration of 18 PyroButtons (3.4 %RH ... 97.3 %RH & 10 °C to 70 °C). Can be integrated to PyroButton softwares for fully automatic correction.</p>	15,835 /license	11,730 /license
100-ICE-023-100	PyroCheck-H18 - Humidity Verification system for 18 x PyroButton-TH in parallel. Certificate of Verification is generated automatically; integrated Excel compatibility	4,500 /each	3,335 /each
090-PPE-015-000	PyroPlate - 21 CFR Part 11 compliant product with MS SQL database & SPC. It is a Self-powered 5-sensor temperature verification system for incubators of microplate readers with sophisticated graphics capabilities, statistics, SQL Models & Excel compatibility. Includes: IQ-OQ-PQ & 21 CFR Part 11 Verification protocols	3,475 /each	2,574 /each
100-ICE-031-100	PBC-TH18 calibration service	1,495 /service	1,107 /service
100-ICE-032-100	PBC-T48 re calibration service	1,495 /service	1,107 /service
100-ICE-034-100	PyroPlate re-calibration service	685 /service	507 /service
100-ICE-001-100A	PyroButton data-logger temperature re-calibration with verification NOTE: If the number of data-loggers are 10 or less add \$150 set-up fee	45 /point	33 /point

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100-ICE-001-100B	PyroButton data-logger temperature re-calibration <i>NOTE: If the number of data-loggers are 10 or less add \$150 set-up fee</i>	25 /point	19 /point
100-ICE-001-100C	PyroButton data-logger humidity re-calibration with verification <i>NOTE: If the number of data-loggers are 10 or less add \$150 set-up fee</i>	60 /point	44 /point
100-ICE-003-100A	PyroButton data-logger humidity re-calibration <i>NOTE: If the number of data-loggers are 10 or less add \$150 set-up fee</i>	35 /point	26 /point