

OPULUS Ltd.

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PyroButton Catalog

Valid to: 2018-12-31

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 (\$)
<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. 3.18 software with 21 CFR Part 11 compliance. Windows 7, Windows 8 and Windows 10 (32/64bits) compatible. 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>	9,275 /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. 3.18 software with 21 CFR Part 11 compliance. Windows 7, Windows 8 and Windows 10 (32/64bits) compatible. 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) IO-OQ-PQ & 21 CFR Part 11 Verification Protocols 1 workstation license</p>	10,356 /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. 3.18 software with 21 CFR Part 11 compliance. Windows 7, Windows 8 and Windows 10 (32/64bits) compatible. 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. (4) IO-OQ-PQ & 21 CFR Part 11 Verification Protocols 1 workstation license</p>	10,356 /package
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 ±0.5°C, Temperature accuracy ±0.5°C Calibrated at 5-points relative to NIST or International reference. Each measurement is corrected relative to</p>	5,500 /package

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	<p>the calibration curve. (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). (3) PyroButton SQL/T-Basic v.3.18 software with 21 CFR Part 11 compliance. <i>Windows 7, Windows 8 and Windows 10 (32/64bits) compatible.</i> 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 (4) Option: IQ-OQ-PQ & 21 CFR Part 11 Verification protocols</p>	
100-PKE-010-100	<p>Transportation Temperature Management-Advanced System for Pharmaceutical, Biotech, & Medical Device. A 21 CFR Part 11 compliant product Includes: (1) 4 x PyroButton-L - Self-powered temperature device (-40 to +85°C), Temperature resolution 0.0625°C, Temperature accuracy ±0.25°C Calibrated at 5-points relative to NIST or International reference. Each measurement is corrected relative to the calibration curve. (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). (3) PyroButton SQL/TA v. 3.18 software with 21 CFR Part 11 compliance. <i>Windows 7, Windows 8 and Windows 10 (32/64bits) compatible.</i> 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. (4) IQ-OQ-PQ & 21 CFR Part 11 Verification Protocols 1 workstation license</p>	9,063 /package

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Product Code	Description	Non-VAT Price (\$)
PyroButton Self-powered temperature & humidity data-loggers		
100-IBE-001-100	PyroButton-G – 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.	154 /each
100-IBE-003-100	PyroButton-L - Intrinsically Safe. 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.	217 /each
100-IBE-004-100	PyroButton-T - Intrinsically Safe. 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.	292 /each
100-IBE-006-100	PyroButton-E - Intrinsically Safe. 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.	398 /each
100-IBE-005-100	PyroButton-TH - Intrinsically Safe. 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.	398 /each

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Product Code	Description	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	795 /each
100-IAE-009-100	SPB-N16C smart docking station with USB Adapter. Suitable for parallel programming /data-download for 16 PyroButtons	1,431 /each
100-IAE-005-100	SPB-N50C smart docking station with USB Adapter. Suitable for parallel programming /data-download for 50 PyroButtons	3,578 /each

Product Code	Description	Non-VAT Price (\$)
<i>PyroButton software for Self-powered temperature & humidity monitoring system</i>		
100-PBE-007-020E	PyroButton SQL/Basics v.3.18 software with 21 CFR Part 11 compliance. Windows 7, Windows 8 and Windows 10 (32/64bits) compatible. Includes 2005 MS SQL Express & 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	4,500 /license
100-PBE-007-016	IQ-OQ-PQ verification protocol for PyroButton-SQL/Basic software	1,500 /each
100-PBE-007-017	21 CFR Part 11 verification protocol for PyroButton-SQL/Basic software	1,500 /each
100-PBE-007-021E	PyroButton SQL/PRO v. 3.18 software with 21 CFR Part 11 compliance. Windows 7, Windows 8 and Windows 10 (32/64bits) compatible. 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.	8,454 /license

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Product Code	Description	Non-VAT Price (\$)
Calibrators & Calibration Services		
100-ICE-021-100	<p>PyroButton TQM with PBC- TH18. A 21 CFR Part 11 ISO 17025 compliant system. <i>Windows 7, Windows 8 and Windows 10 (32/64bits) compatible.</i> Includes: (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>	16,785 /license
100-ICE-023-100	<p>PyroCheck-H18 – Humidity Verification system for 18 x PyroButton-TH in parallel. Certificate of Verification is generated automatically; integrated Excel compatibility <i>Windows 7 compatible</i></p>	6,890 /each
100-ICE-031-100	PBC-TH18 calibration service	1,585 /service
100-ICE-034-100	PyroPlate re-calibration service	1,600 /service
100-ICE-001-100A	<p>PyroButton data-logger temperature re-calibration with verification <i>NOTE: If the number of data-loggers are 10 or less add \$150 set-up fee</i></p>	50 /point
100-ICE-001-100B	<p>PyroButton data-logger temperature re-calibration <i>NOTE: If the number of data-loggers are 10 or less add \$150 set-up fee</i></p>	40 /point
100-ICE-001-100C	<p>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></p>	60 /point
100-ICE-003-100A	<p>PyroButton data-logger humidity re-calibration <i>NOTE: If the number of data-loggers are 10 or less add \$150 set-up fee</i></p>	45 /point