



COPLEY

Critical Flow Controller TPK 200iX

Bringing Method Control to Critical Flow Control



The TPK 200iX is Copley's next-generation Critical Flow Controller for inhaler testing, developed to support both standalone operation and connected workflows through Inhalytix®+.

Building on the established TPK 100i, the TPK 200iX combines trusted critical flow control with enhanced, patent-pending flow control capability. It also adds secure user access, controlled methods, stored reports, audit trail functionality and advanced Inhalytix+ connectivity.

With extended run time, P1 rise-time logging and stronger digital workflow visibility, it helps laboratories support broader inhaler testing requirements while reducing manual set-up steps and strengthening traceability.



Critical flow control expertise

Builds on Copley's trusted TPK functionality for reliable inhaler testing.



Controlled methods and records

Supports management of users, equipment configurations, methods, audit trails and stored reports directly on the TPK 200iX, helping laboratories meet GMP and 21 CFR Part 11 requirements.



Guided test set-up

An intuitive, step-by-step user interface guides analysts through critical flow control set-up, with secure user access, method control and clear on-screen feedback.



Broader testing capability

Extended run time, lower flow rate capability and enhanced workflow visibility.

Designed for
Inhalytix®+

Critical flow control, connected through Inhalytix®+

The TPK 200iX has been designed to work as part of the wider Inhalytix+ workflow. Defined methods and authorised users can be managed centrally in Inhalytix+ and made available on the instrument, while comprehensive reports and supported operating information can be returned to the wider digital test record.

This helps reduce repeated set-up steps and strengthen consistency and traceability across the workflow. The TPK 200iX can also be used independently of Inhalytix+.

TPK 200iX: Key Features



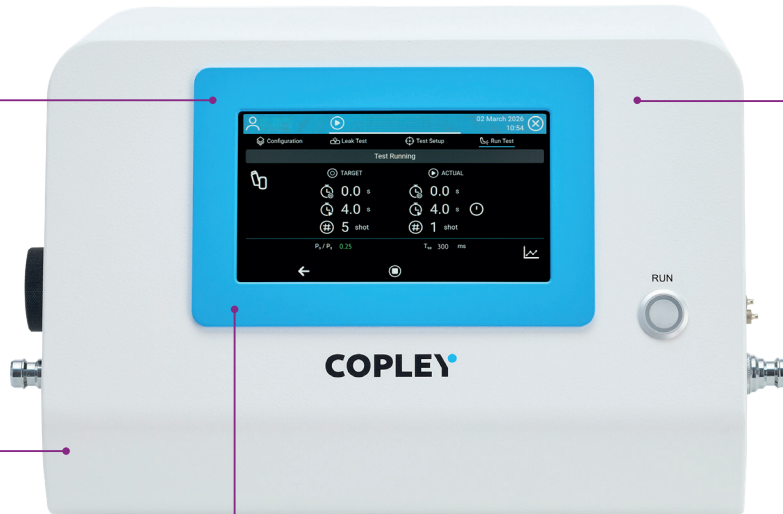
Critical Flow Status Alerts

User warnings alert operators when critical flow conditions are not met, helping ensure correct test set-up.



Compact benchtop footprint

Designed to support efficient use of laboratory bench space while maintaining access to key connections and controls.



Large touchscreen interface

Improved screen visibility helps analysts view settings, prompts and test information clearly during set-up and operation.



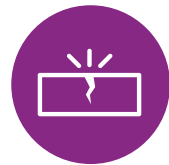
Flow measurement compatibility

Interfaces with compatible flow measurement devices, including the FRS and DFM 2000, to support in-line flow measurement as part of the test set-up.



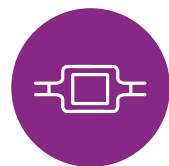
Pharmacopoeial compliance

Supports critical flow control requirements for relevant Ph. Eur. and USP inhaler testing methods, as well as other global pharmacopoeial requirements.



Automated in situ leak testing

Enables automated leak testing of the impactor set-up, helping confirm system integrity before testing.



In-line flow measurement

Accommodates in-line flow measurement to support accurate set-up and verification of test flow conditions.



Automatic test duration calculation

Calculates test duration from defined volume and flow rate, helping reduce manual calculation steps during method set-up.

Connected equipment records

The **QR Code Scanner**, connected to the TPK 200iX, allows compatible QR-coded Copley equipment to be recorded during the workflow. Identifiers, such as model and serial number, can be captured without manual entry and stored on the TPK 200iX against the relevant method and test record.

When the TPK 200iX is connected with **Inhalytix⁺**, equipment information can be transferred into the wider digital test record, helping laboratories build a more complete and traceable record of the inhaler testing set-up.

QR-coded Copley equipment can be scanned and linked to the relevant method and test record.



Bringing Method Control to Critical Flow Control with



The TPK 200iX can operate as a standalone critical flow controller, with users, methods, audit trails and stored reports managed directly on the instrument. When connected with **Inhalytix+**, this method control can be extended across the wider inhaler testing data workflow.

Inhalytix+ provides the central software hub for managing approved methods and authorised users across connected TPK 200iX units. These controlled settings can be made available at the instrument for use during testing, while supported reports and operating information can be returned to Inhalytix+ as part of the wider digital test record. This helps laboratories reduce repeated set-up, support consistent use of approved methods across instruments and strengthen traceability across the critical flow control workflow.



1. Configure and manage in Inhalytix+

Set-up approved methods, user access and controlled workflow settings centrally.



2. Make available on TPK 200iX

Make methods and user permissions available on the TPK 200iX for use at the instrument.



3. Run the test

Carry out critical flow control using the selected method and user access controls.



4. Record in Inhalytix+

Return supported reports and operating information to Inhalytix+ as part of the wider digital test record.

Benefits of connected critical flow control



Reduced manual set-up

Manage methods centrally in Inhalytix+ and make them available on the TPK 200iX, reducing repeated set-up steps at the instrument.



Consistent, controlled use

Apply approved methods and authorised user permissions consistently across users, instruments and sites.



Wider digital test record

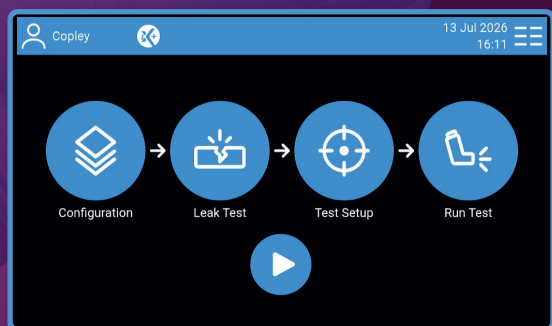
Return supported reports and operating information to Inhalytix+ to strengthen traceability and review.



Clearer workflow visibility

Help laboratories link method set-up, instrument operation and test records more clearly across the inhaler testing workflow.

TPK 200iX: User Interface



Guided test set-up process

Guides analysts through key set-up steps, helping support consistent method execution and reducing the risk of missed parameters.

A screenshot of the 'Create User' dialog box. It shows a list of users on the left: A Leyland, B Smith, C Jones, and D Taylor. The main area contains fields for 'Username' (Sarah_Connor), 'Role' (Manager), 'Password' (masked), and 'Confirm Password' (masked). There are 'Cancel' and 'Create' buttons at the bottom.

User management

Create and manage authorised users, helping control access and support traceability across critical flow control workflows.

A screenshot of the 'Equipment configurator' interface. It shows a list of components under 'Before Components' and 'After Components'. The 'Before Components' list includes Flow Meter, Induction Port, and Preseparator. The 'After Components' list includes Flow Controller, Vacuum Pump, and EnviroMate. An 'Impactor/Impinger' component is highlighted in the center.

Equipment configurator

Enables controlled equipment configurations to be defined and saved for each test method, helping standardise set-up and maintain traceability.

A screenshot of the 'Device resistance measurement' interface. It shows a table of test results:

Test Setup Completed			
P ₁	3.59 kPa	P ₂	85.6 kPa
P ₃ / P ₂	0.37	P ₃	31.3 kPa
Q	60.0 L/min	P _A	102.2 kPa
R	0.032 kPa ^{0.5} L/min ⁻¹	T	22.1 °C
		RH	53.8 % RH

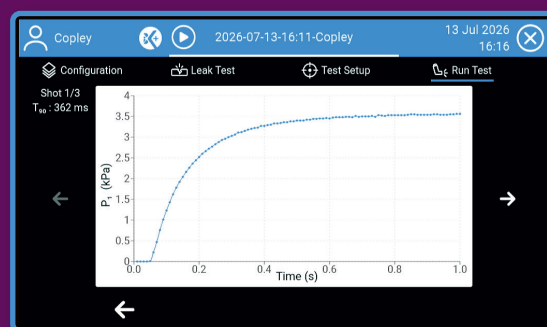
Device resistance measurement

Measures device resistance to support correct critical flow control set-up for the device under test.

A screenshot of the 'Run test' interface. It shows a 'Prepare to Collect Dose' screen with 'TARGET' and 'ACTUAL' values for time and shot count. The 'TARGET' values are 0.0 s, 4.0 s, and 3 shot. The 'ACTUAL' values are 0.0 s, 4.0 s, and 2 shot. There are also pressure and temperature readings: P₁ 3.57 kPa, P₃ / P₂ 0.37, and T_{ss} 361 ms.

Run test

Shows live test progress and key operating information during the run, helping analysts monitor the test in real-time.



P1 rise-time logging

Shows how quickly the test set-up reaches the required pressure at the start of a run, giving analysts a visual indication of pressure behaviour that may influence aerosol dispersion.

TPK 200iX: Technical Specifications

User interface	7" touchscreen
Flow setting	Manual and automated
Flow rate range	5 - 100 L/min
Temperature / relative humidity measurement capabilities	Yes (see Temperature and Relative Humidity Sensor)
Auto-trigger	MDI Actuation Sensor Footswitch
Vacuum pump control	Auto-triggering of 7-series pumps
Solenoid valve opening / closing time	<100 ms / <100 ms
Timer range	0.0 - 3,000.0s (resolution 0.1s)
Dimensions (w x d x h)	415 x 315 x 250 mm



TPK 200iX vs TPK 200iX-R

The TPK 200iX is available in standard and reversed configurations. The TPK 200iX-R provides the same functionality as the standard unit, with reversed pneumatic connections to support easier integration with different inhaler testing set-ups.

TPK 200iX: Accessories

Temperature and Relative Humidity Sensor

The Temperature and Relative Humidity Sensor is designed to provide analysts with accurate data about environmental conditions.





Footswitch

Enabling precise synchronisation of device actuation with the onset of flow, the Footswitch connects directly to the TPK 200iX.

Alternatively, an MDI Actuation Sensor can be used for synchronisation of MDI actuation and the onset of flow.

Label Printer

The Label Printer offers space-efficient printing for laboratories, with easy setup, intuitive operation, and high-quality report output. When used with supported Copley products, the Label Printer prints critical test parameters on to adhesive labels; ideal for affixing directly into laboratory notebooks.





Reporting

Extensive data output options are available as standard, including reporting to Inhalytix[®]+, a printer, or PC.

Available reports:

- Test Reports
- Audit Reports
- User Reports
- Method Reports
- Calibration Reports



Qualification & Maintenance

- Certificate of compliance to Ph. Eur./USP provided as standard.
- Comprehensive IQ/OQ documentation packages and toolkits available.
- Extended warranty available

Critical Flow Controller TPK 200iX

Cat. No.	Description
8980	Critical Flow Controller Model TPK 200iX
8980-R	Critical Flow Controller Model TPK 200iX-R
1086	TPK 200iX/R Extended Warranty – 1 year
1087	TPK 200iX/R Extended Warranty – 2 years

Accessories

8976	Temperature and Relative Humidity Sensor
8791	Footswitch
8797	MDI Actuation Sensor
9765	Label Printer
8988	TPK 200iX Re-calibration Certificate
1086	TPK 200iX/R Extended Warranty – 1 year
1087	TPK 200iX/R Extended Warranty – 2 years
8752	Flow Time Verification Kit
8753	Re-calibration of Flow Time Verification Kit
8269	QR Code Label for 10 Items
8981	QR Code Scanner, Wireless
8982	QR Code Scanner, Wired

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