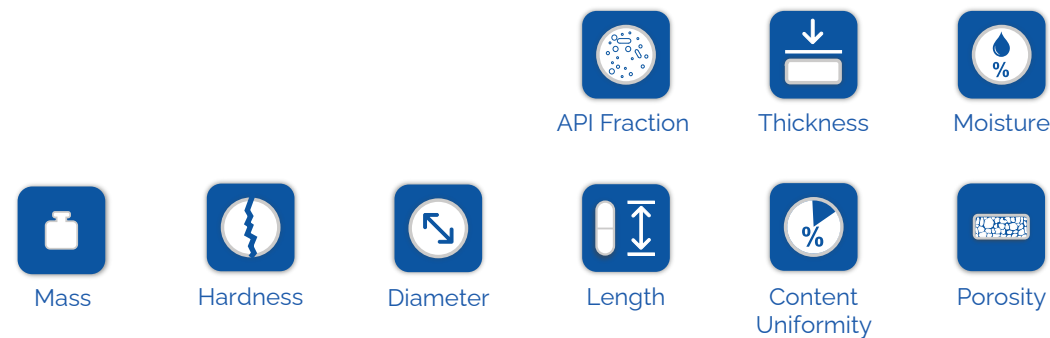


# CUB-X

A unique & versatile tool for OSD development and commercial production

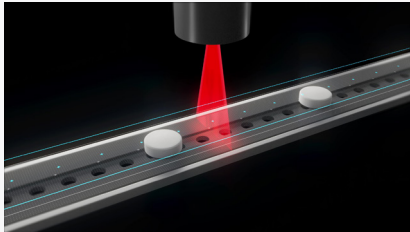


The CUB-X is an innovative and versatile tablet inspection system, which can be used for OSD product & process development, as well as for IPC sample analysis and full batch inspection & sorting.

It is equipped with novel spectroscopy and laser technologies allowing for high-speed highly accurate non-destructive measurement of tablet thickness, API's mass fraction and moisture content.

Additionally, the embedded 4P tablet tester allows for mass, hardness and diameter/length measurement, ultimately allowing for real-time monitoring of Tablet Content Uniformity and Porosity.

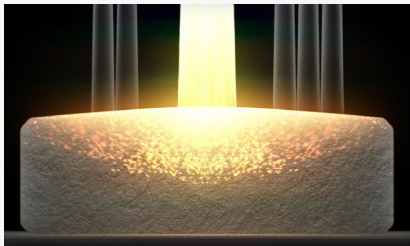
## EMBEDDED TECHNOLOGIES



### High-precision Tablet Laser Profiler

A laser line-scanning sensor profiles each tablet, while passing under the sensor, measuring its thickness with a precision of 50 µm.

The tablet laser profiler verifies also the correct position and orientation of the tablet on the conveyor belt before it passes under the NIR-SRS sensor.



### NIR-SRS spectroscopy

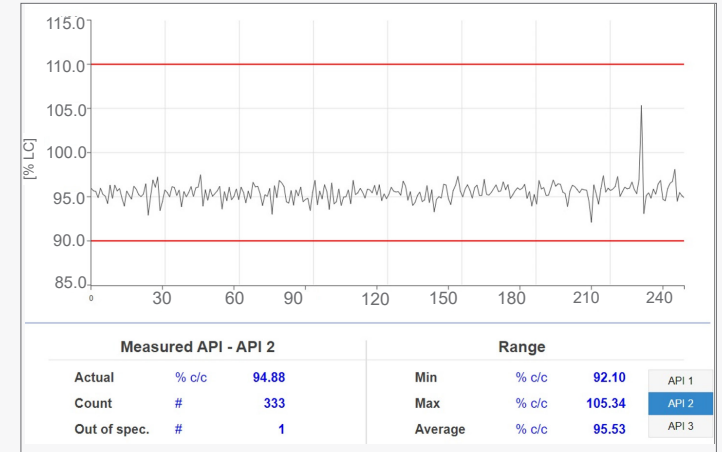
Each tablet is inspected by the multipoint NIR-SRS (Near-Infra-Red Spatially Resolved Spectroscopy) probe at a high frame rate, allowing multiple spectral acquisitions per tablet. An accurate prediction of one or multiple ingredients' mass fraction – including water - is then done by chemometric modelling.

The SRS technology allows to cover a larger tablet surface and a deeper measurement penetration compared to single-point NIR reflection techniques, resulting in more accurate prediction of the CQA's.



### Embedded high-speed 4P tablet testing

Samples can be sent to an embedded 4-parameter tablet tester at a rate of up to 400 tablets/h, measuring tablet mass, thickness, diameter/length and hardness. The high sampling rate is achieved thanks to a purpose-designed sampling gate, which feeds tablets one by one directly to the measurement instruments.



The CUB-X can measure tablet **mass fraction for multiple ingredients** - including **moisture** - at speeds up to 20.000 tablets/h using NIR-SRS spectroscopy, while tablets can be sampled at speeds up to 400 tablets/h for measurement of mass, thickness, diameter/length and hardness. This allows sampled tablets to be analyzed for **porosity, dosage** and **content uniformity**, while all tablets are analyzed for API mass fraction.



Mass



Hardness



Thickness



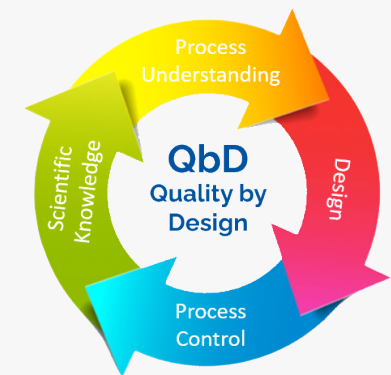
Diameter

## APPLICATIONS

R&D	At-line IPC & QC	Inspection & Sorting
<p>Applications <b>PRODUCT &amp; PROCESS DEVELOPMENT</b></p> <ul style="list-style-type: none"> <li>• Immediate CQA feedback</li> <li>• RTD modelling</li> <li>• Reject and QC strategy</li> <li>• Automated DoE &amp; APD (<i>Automated Process Development</i>)</li> <li>• APC (<i>Advanced Process Control</i>)</li> <li>• CPV (<i>Contin. Process Verification</i>)</li> </ul>	<p>Applications <b>COMMERCIAL PRODUCTION BATCH &amp; CONTINUOUS</b></p> <ul style="list-style-type: none"> <li>• At-line IPC</li> <li>• Automated (partial) QC</li> <li>• Support RTR testing</li> </ul>	<p>Applications <b>IN-LINE AND OFF-LINE FULL BATCH INSPECTION &amp; SORTING</b></p> <ul style="list-style-type: none"> <li>• Clinical trial batches</li> <li>• Reject analysis &amp; recovery</li> <li>• Batch saving</li> </ul>
<p>Benefits</p> <ul style="list-style-type: none"> <li>• Multiple individual tablet CQA measurements</li> <li>• Real-time feedback</li> </ul>	<p>Benefits</p> <ul style="list-style-type: none"> <li>• Higher sampling rate (up to 400 tablets/h)</li> <li>• More CQA's compared to 4P tester: <b>CU &amp; Porosity</b></li> </ul>	<p>Benefits</p> <ul style="list-style-type: none"> <li>• High speed/capacity (up to 20.000 tablets/h)</li> <li>• Consistent quality</li> <li>• Multiple non-destructive CQA's: <b>API fraction, thickness, moisture</b></li> </ul>

The CUB-X is an extremely versatile tablet analyzing tool, which can be used in R&D for **product and process development**, while in commercial production for **IPC testing and QC**. Additionally, the system can be used for **full batch inspection and sorting** of out-of-spec tablets.

As such the CUB-X can be used **off-line** as a stand-alone machine, or connected to a tablet compression machine for **at-, on- or in-line** tablet inspection with or without feedback to the tablet press control system.



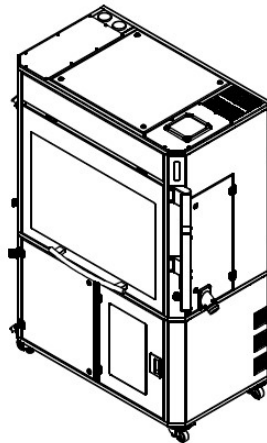
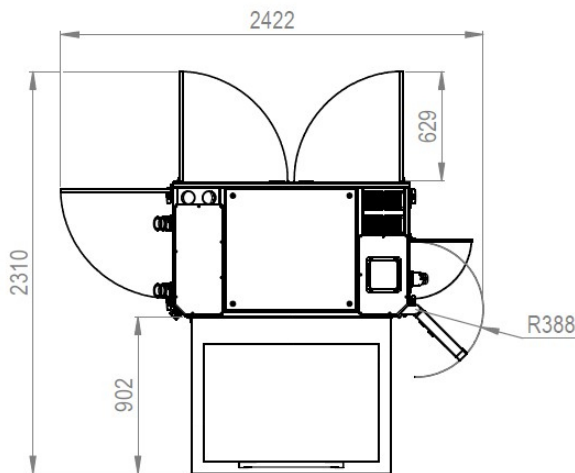
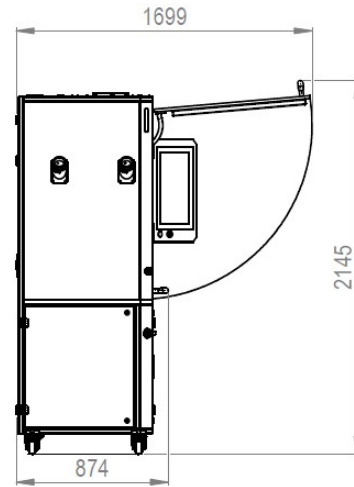
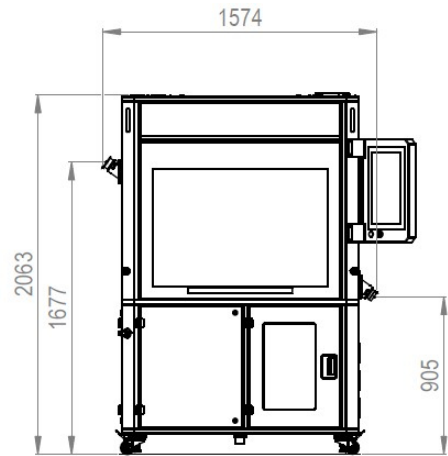
The **QbD (Quality by Design)** approach builds quality into the manufacturing process by establishing a science based QTPP (Quality Target Product Profile) and developing a robust production process. This requires in-depth process understanding over the entire **design space** of material attributes and process parameters. **PAT (Process Analytical Technologies)** assist developers in this extensive work.

Thanks to its capacity to measure multiple CQA's at high-speed, the CUB-X allows to scan a larger and more-dimensional design space in less time with less material.

Moreover, when the CUB-X is connected to a tablet press or a continuous manufacturing line, it allows for **automated DoE** and **Automated Process Development (APD)**.

Automated and fast **product & process development** - using few amount of expensive drug substance - results in robust manufacturing processes while **cost & time to market** is kept to a minimum.

## SPECIFICATIONS



Rue Graham Bell 8  
 B-1402 Thines (Nivelles) - Belgium  
 Phone : +32 (0)67 70 13 00  
 E-Mail : info@pharmatec.be

Technical data :	CUB-X
Maximum inspection speed	20.000 tablets/h
Maximum sampling rate	400 tablets/h
Minimum product width	4 mm
Maximum product width	24 mm
Minimum product height	3 mm
Maximum product height	10 mm
Thickness measurement accuracy	± 0.05 mm
Mass accuracy	± 1 mg in stable environment
Hardness measurement accuracy	± 2 N (4-400 N range)
Length measurement accuracy	± 0.1 mm
Air extraction	Integrated Hepa filter H13
Requested compressed air	Min 500 L/min - Min. 6 bar
Nosie level	≤70 dB (A)
Power supply	380 V 3ph + N + PE
Frequency	50 Hz / 60 Hz
Polymer contact parts	FDA approved

## KEY BENEFITS

- Simple and fast product format change-over.
- Process data is easily exported via OPC UA and/or batch reporting. Spectral data can be exported by file transfer.
- Data storage and processing software is GAMP and CFR21 compliant.
- Machine and documentation CE compliant
- Optional documentation: IQ/OQ, FDS/HDS/SDS, Process Risk Assessment
- Services: FAT, SAT, Training, Commissioning, Recipe Creation
- Special care has been taken to simplify the chemometric recipe preparation work. Pharma Technology experts can assist and teach you in the development of your chemometric models.