



DR. SCHLEUNIGER®
PHARMATRON

10X

10X – Fully automatic tablet testing system

Exact measurement in the production environment

IP65 – Uniquely protected against dust and water

Can be used as a separate unit or in combination with a tablet press

Rapid, simple cleaning when the product is changed



The machine for the production environment

The fully automatic tablet testing system sets a new standard for the measurement of weight, thickness, diameter and hardness. In contrast to other test equipment, the 10X was designed specifically to meet the requirements of monitoring tablet quality during the production process. Its unique concept and design is impressive. Precise design and manufacture results in a machine that is protected against dust and water (IP65), allowing decontamination with water or recommended solvents. Doubts about the use of automatic testing equipment for monitoring purposes during production are thus completely dispelled. The 10X also performs well in the most severe production conditions and is ideally suited for installation in an isolator.



Flexible

The Model 10X includes a unique separation unit and patented computer controlled tablet-transport positioning paddle. Product specific alignment and orientation is therefore possible for practically all tablet shapes. The test and transport parameters specific to a particular product can be entered and stored in the product catalog for future recall via an external PC (TabStatPro software) or via the user interface of the tablet press.

Water and dust-proof to IP65 standard

The mechanical construction of the 10X is simple, allowing rapid and efficient cleaning. The component modules fitted on the machine can be dismantled easily. This facilitates thorough cleaning, for example when the product is changed or should the machine have to be decontaminated. Reassembly is easy and uncomplicated.

Top quality

Dr. Schleuniger Pharmatron products are very reliable, durable and achieve the highest standard of quality. Those parts of the 10X which come into contact with the product are made exclusively from V4A stainless steel.



Method of operation

Upon starting the test, a group of tablets is delivered either manually or automatically to the machine. The separating device ensures that the tablets are fed to the balance individually. After the weight has been measured, the tablet is moved on and automatically orientated correctly for the thickness measurement. The tablet is then transported by a freely programmable paddle to the diameter and hardness measurement station. After the sample is broken, the resulting fragments are automatically removed and the pressing jaws cleaned.

Can be upgraded with NIR technology

The 10X-T model can also be retrofitted with a Bruker NIR analyzer (Tandem). This provides a means of measuring the % API in the tablet and determining content uniformity of the batch. Control of the system is entirely via TabStatPro software.



A secure investment

High production throughput and flexible programming with the optional TabStatPro software (complies with 21 CFR part 11) guarantee high cost-effectiveness and thus rapid payback of the investment.

Calibration/Verification

Calibration and verification of the 10X is very simple and can be undertaken by users themselves. On request, a technician can be sent to carry out the work on-site.

Validation/Support/Training

On request, we carry out installation of the equipment at the customer's premises. This includes performance of the IQ/OQ, including the relevant documentation and certification. We offer customer training courses at any time, either in our facility or on-site.



Specifications

Weight-measurement range	0,1mg – 121 g *) ₁
Thickness-measurement range	1 – 15 mm
Diameter-measurement range	1 – 25 mm
Hardness-measurement range	0 – 400N (500N Load Cell)
Electrical power supply	85-264 V AC 47-63 Hz
Weight	62 kg
IP classification	IP65 in «Wash down position» IP54 in operation



*)₁ Including scale-pan. The actual accuracy depends on environmental effects at the installation site.
The user of the system is responsible for operating the 10X in a suitable environment.

Parts which come into contact with the product

Waste flap	DIN: V4A-1.4404 (X ^o CrNiMO 17132) ASTM: 316 L
Waste chute	Polyacetal nature (POM-C) FDA: 21CFR177.2470
Tablet funnel	DIN: V4A-1.4404 (X ^o CrNiMO 17132) ASTM: 316 L
1/2/3 linear transport unit	DIN: V4A-1.4404 (X ^o CrNiMO 17132) ASTM: 316 L
Thickness-measurer measuring foot	DIN: V4A-1.4404 (X ^o CrNiMO 17132) ASTM: 316 L
Y-axis with paddle	DIN: V4A-1.4404 (X ^o CrNiMO 17132) ASTM: 316 L
Scale-pan	Aluminum coated with Topinox



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