

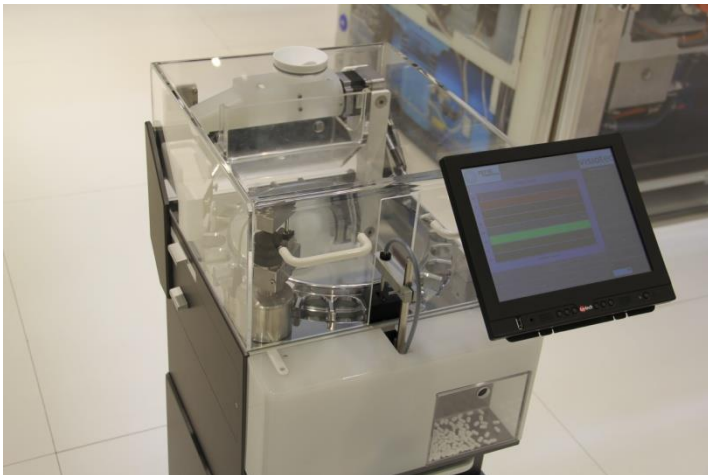
### Product Information

#### Background

Nowadays, batches easily reach sizes > 1,000,000 tablets. However, only 30 tablets are used for content uniformity (CU) release testing. This same „assay of samples“ is typically checked for other parameters such as weight, hardness, height and diameter.

An innovative and dedicated product test system such as Kraemer's new UTS-Extended with integrated NIR technology can check for these physical-chemical characteristics. As opposed to the required 30 samples, the UTS-Extended can significantly increase the sampling size.

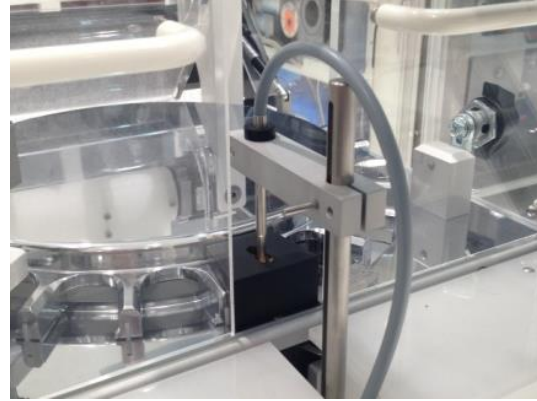
The new UTS-Extended is the latest addition to the successful Kraemer UTS Series (Universal Test System). Visiotec's VisionNIR LS system is fully integrated into the UTS hardware and software platform. The system can be run in at-line configuration for automated tablet feeding from a connected tablet press or off-line.



*UTS-Extended: HMI shows acquired NIR spectra classification ranges*

#### VisionNIR LS System

The VisionNIR LS is a high speed Near Infrared spectrometer for the in-line and at-line use of Content Uniformity (CU) inspection. The system can be run in the described at-line configuration either in reflection or transmission mode. This guarantees best results for all tablet sizes and shapes. The reliable trend monitoring visualizes the CU prediction value of each sampled tablet. Outliers can be safely identified. The resulting spectra are evaluated by the multivariate data analysis software "The Unscrambler".



*Close-up of UTS-Extended tablet transport system with NIR head*

VisionNIR LS is the result of continuous development from customer requirements, process understanding and experience in the pharmaceutical production. As a result of the flexible hardware and intuitive operating software, VisionNIR LS is easy to retrofit and meets the pharmaceutical requirements.

#### Flexibility

VisionNIR LS can be implemented directly into the host machine. The system can run in reflection and transmission mode. As a result of using diode array technology, the system is robust towards outside influences such as vibration.

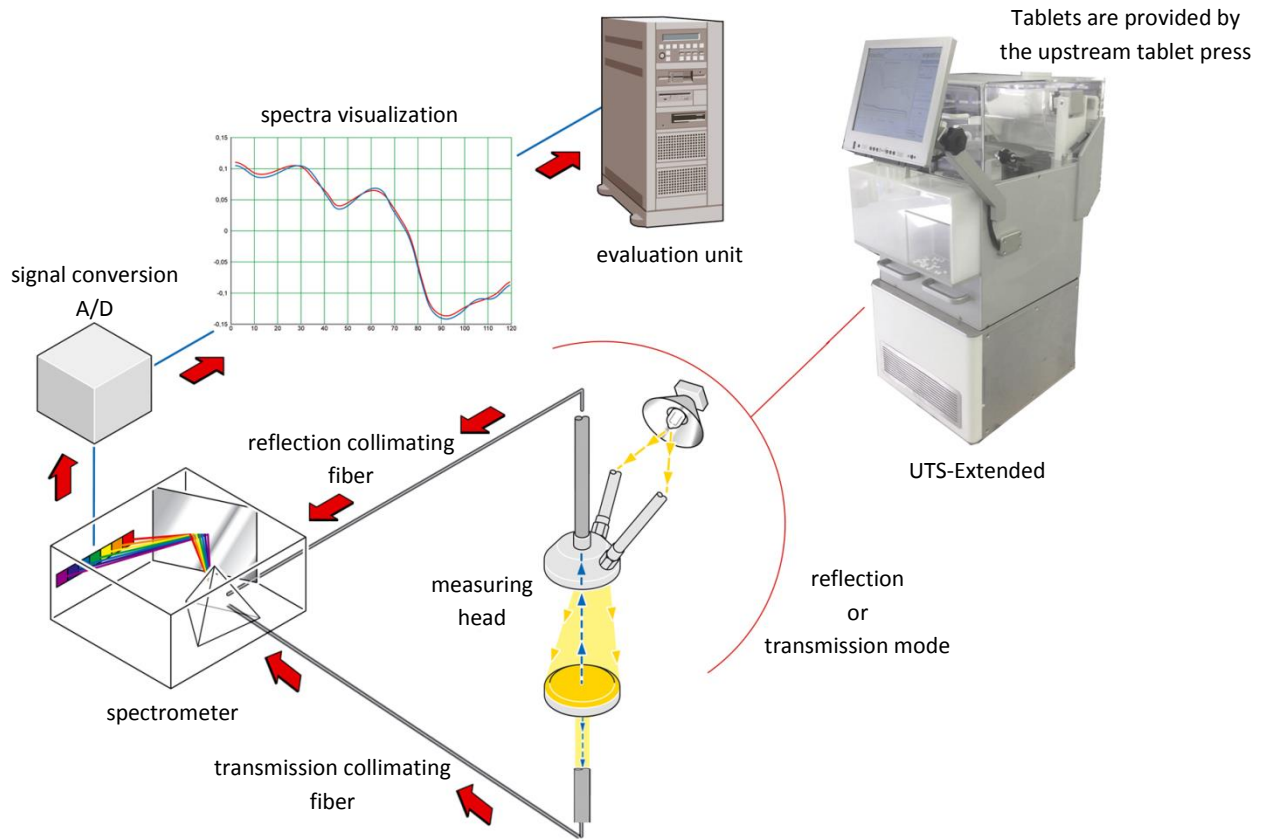
#### Knowledge and Competence

Visiotec has an excellent team of NIR experts to support you with your application. Our long term experience in method calibration helps to find the best correlation between your process data and your critical quality attributes (CQA). We provide consultancy for the design of experiments (DOE), design space calculation and process calibration & validation.



*Top view showing the different stations of the UTS-Extended system*

### Functional Principle



### Highlights

The tungsten halogen illumination source provides NIR radiation from 700 – 2500 nm and the illumination fibers for reflection and transmission mode transport the radiation to the tablet. The reflected or transmitted NIR radiation with spectral information is collected by the collimation fiber and transported to the diode array NIR spectrometer and the transmission grid splits the polychromatic NIR radiation into its single wavelengths. The single diodes are counting the number of photons regarding their wavelength range and the AD converter visualizes the NIR spectrum. The spectra will be evaluated in terms of CU or hardness in the evaluation PC with multivariate statistics. The results can be visualized on the trend monitoring screen.

- Sophisticated at-line technique
- Increasing sampling size due to rapid spectra acquisition
- Rapid and robust diode array technology
- Integrated solution
- Compact design
- Fiber optics technology
- Multivariate evaluation
- Reflection and transmission measurement modes
- CU inspection