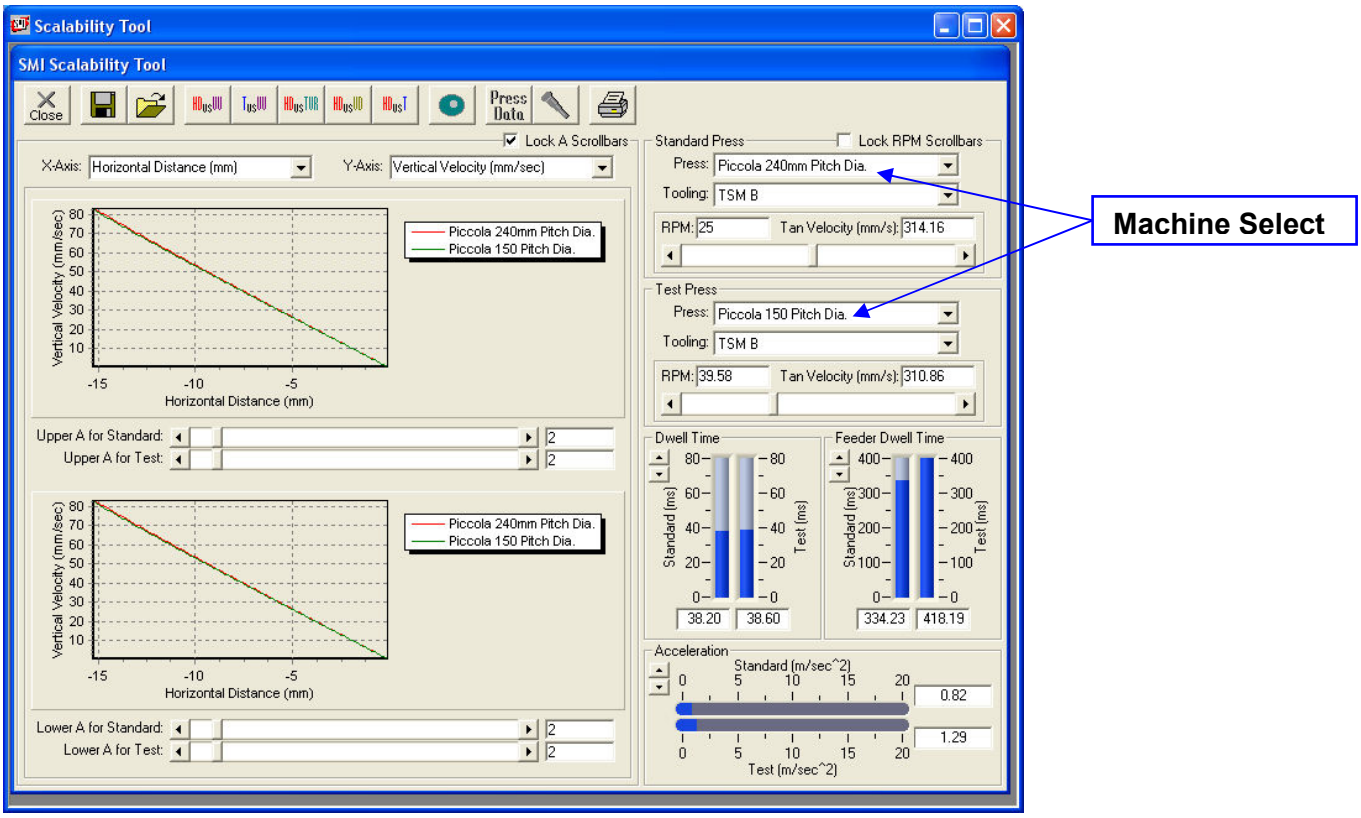
Development • Delivery • Dependability

The Director Software V4 and the Scalability Tool

Small bench top tablet presses can be used to successfully transfer a product into larger production machines provided that the proper tooling and speeds are selected. **"*The Director Software V4 Scalability Program*"** can successfully predict the operating parameters for any machine to match the loading rates of another.

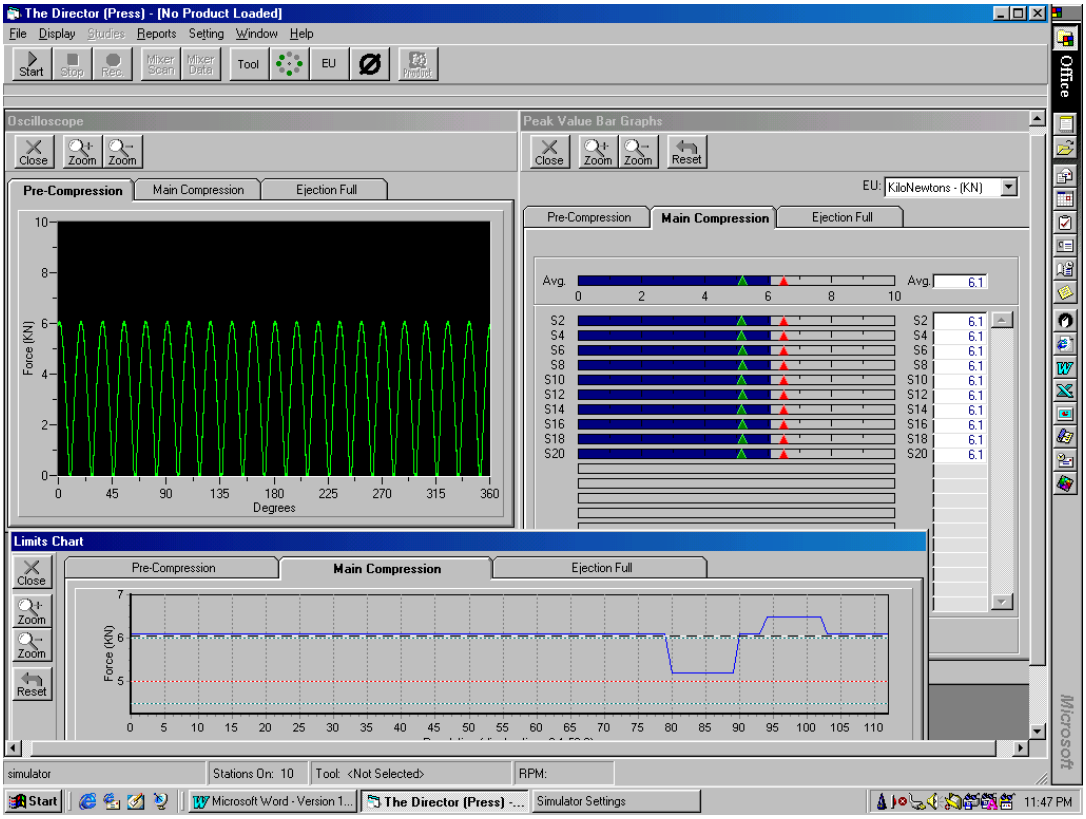


A mathematical relationship was developed taking into consideration factors such as turret pitch circle diameter, turret speed, and compression roll diameters, feeder residence time and punch head geometry. These parameters were programmed into the "*Director Software V4*" that would calculate the rate of force application, duration of the peak force, and time under the feeder for die fill for a specific tablet machine. The program permits visual displays for direct comparison between two selected machines. The user can vary the machine speeds (rpm) in an attempt to achieve similar loading profiles.

"The Director" Data Acquisition and Analysis System for Research, to Scale Up, through Production

"The Director" is a complete instrumentation package for tablet presses, granulators, roller compactors, and more. ***"The Director"*** is designed to integrate hardware and software into a comprehensive data acquisition and analysis system. All the components are engineered as a complete system, which includes:

Transducers **Electronics** **Original Software**



"The Director" is a complete data acquisition and analysis system designed to simplify the tableting process. ***"The Director"*** will guide you from research to scale up, through production.

Oscilloscopes **Control Charts** **Histograms** **Peak Value Bar Charts** **Limit Charts**

"The Director" will set up studies and experiments to guide you through the tableting process. The purpose of the program is to collect, analyze and display large amounts of data. Report generation is automatic from preliminary to detailed. Data can also be exported directly into Excel.

Easy to Service **Minimal Hardware Components** **Simple to Validate**

Hardware Components of The Director:

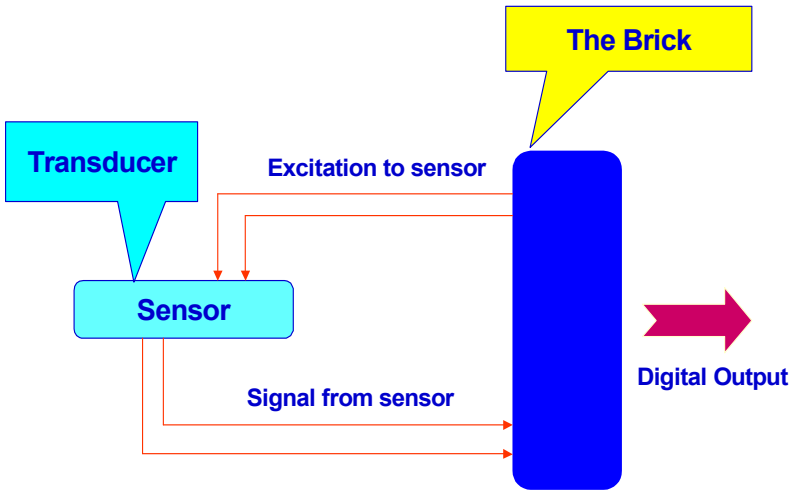
The **BRICK** is an electronic device designed by SMI. The Brick contains the:

- Power supplies
- Anti-alaising filters
- Programmable gain amplifiers
- Analog to digital converters

THE BRICK WILL BE INSTALLED ON EACH TABLET PRESS

Each press to be instrumented requires a Brick that is mounted to the press in a Nema 4X watertight enclosure. The Brick provides the interface between the transducers and the computerized data acquisition system.

The Brick is capable of obtaining data from eight (8) different sensors. The Brick automatically identifies the machine it is connected to, no operator selections are required, and this eliminates potential operator errors.

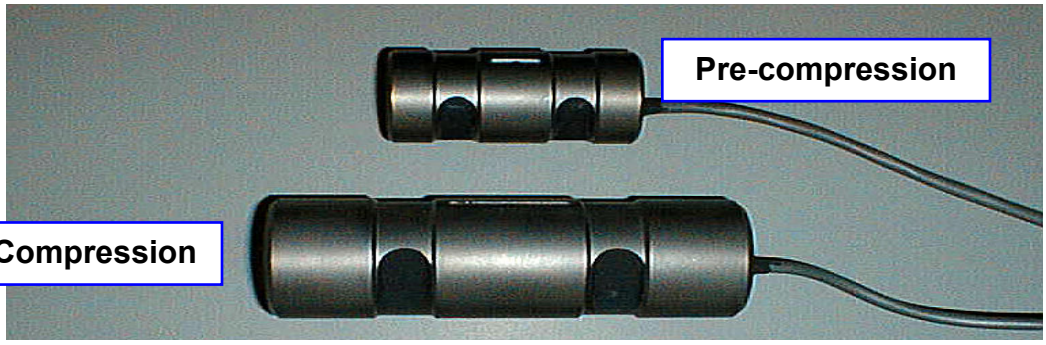


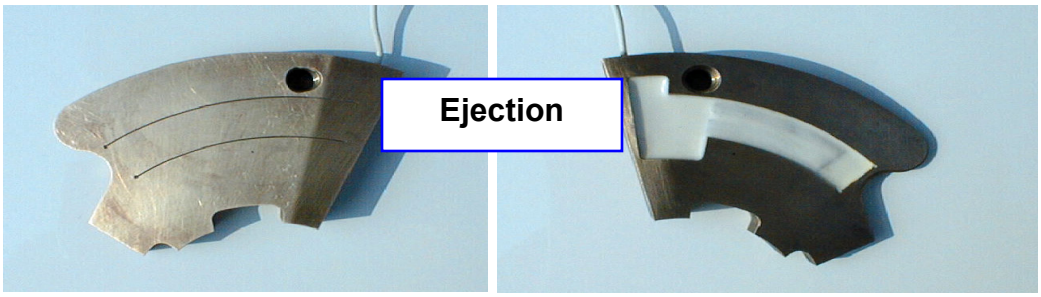
The **DSP,** a digital signal processor is installed in one of the PCI slots within computer. The DSP is used to convert the voltages into engineering units, perform the tarring function and perform software filtering. The DSP greatly alleviates the computational burden from the main CPU in the computer allowing The Director to collect an unlimited quantity of data while still offering real time displays.

The minimum computer requirement is a 400 m-Hertz Pentium II processor with 128 MB of ram. The monitor resolution must be at least equivalent to XGA.

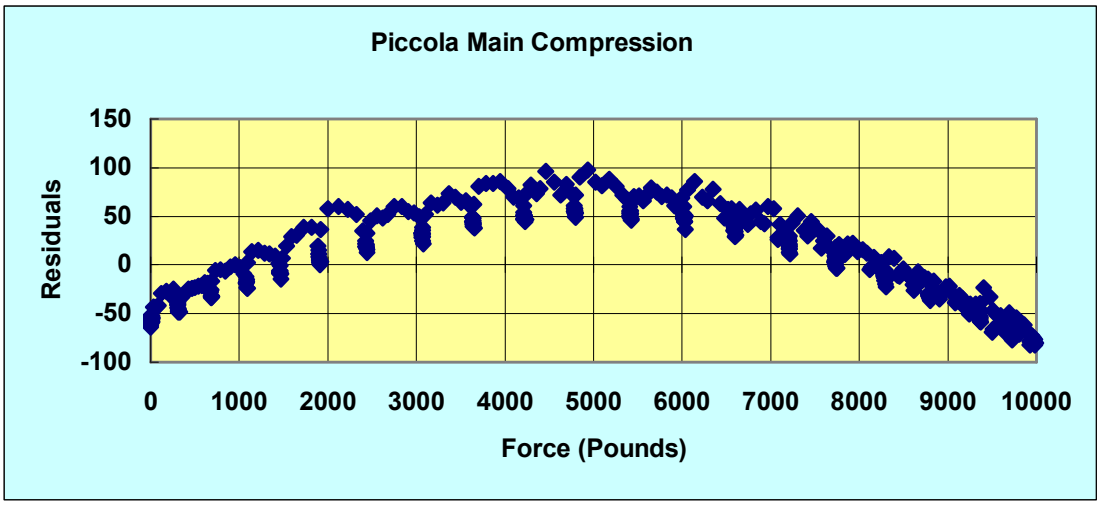
Development • Delivery • Dependability

Representative Transducers





A unique form of a differential bending beam, one at each end



The Director Software Platform

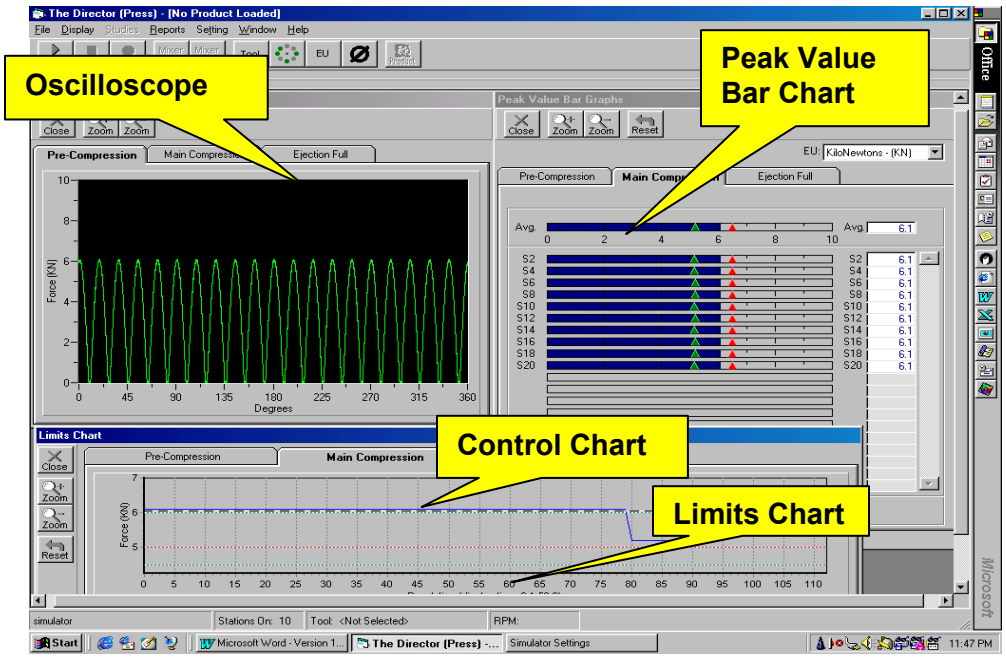
The core data acquisition program for The Director software is written in C. The user interface is written in Visual Basic 6. Third party controls for the graphics were purchased to supplement the Visual Basic library.

The Director Software Overview

The Director Program is designed to acquire, display and analyze incoming data from transducers installed in tablet presses, mixers, granulators, roller compactors and other machines used within the pharmaceutical industry. It is capable of acquiring data at a rate of 10,000 samples per second per transducer while offering real time displays in engineering units of force or pressure in English, Metric or SI conversions. The program will guide an unfamiliar user through the necessary steps to achieve a desired goal and print summary reports of the results upon completion.

The tablet press module has built in sub-programs to acquire data in a manner appropriate for specific purposes, such as performing a compaction profile, detailed analysis of a single compaction event, or statistical analysis of a longer production run. For each sub-program there is a set of on screen instructions on exactly how to perform the task.

"The Director" will set up studies and experiments to guide you from research, to scale up, through production.



The purpose of this screen is to demonstrate that the user can customize the data acquisition screen to suit their individual preferences.

This figure represents three of the presentations available on one screen, all running simultaneously.

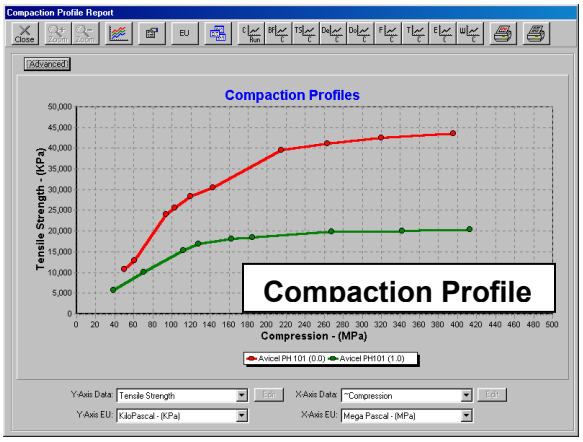
Each display can be opened numerous times to achieve the desired look. Each display has tabs at the top allowing the user to select the transducer to be observed. The user can toggle between the transducers during the running of the tablet press if desired.

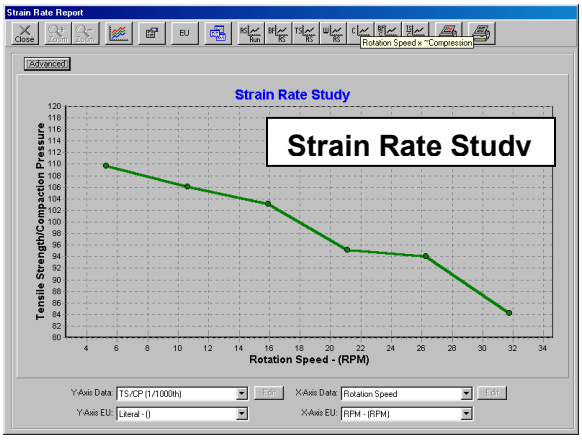
Development • Delivery • Dependability

A Rotary Tablet Press used in conjunction with The Director is the next logical progression in the development of a robust formulation beyond the Single Station Tablet Press.

This module has built in subprograms to perform these specific functions:

- **Compaction profiles**
- **Strain Rate studies**
- **Detailed analysis of a single compaction event**
- **Statistical analysis of a production run**





Data obtained with this system can be used to perform compaction profiles and strain rate studies for scalability as well as for lubrication and ejection studies. The Director can be used to normalize the results so that the effects of different tooling sizes can be accounted for.

Using this module formulation can easily be evaluated for robustness and scalability. This module can be used to develop a formulation that satisfies the requirements for tablet properties such as friability, dissolution, disintegration, weight and thickness.