



951201 JUN 15 7:44

June 12, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, Maryland 20852

RE: Public Docket #95D-0349
Docket to be revised: SUPAC Equipment Guidance Docket-Unit Dosage Task Force

To whom it may concern;

Stokes is a U.S. Manufacturer of Tablet Presses. We are requesting a revision to have Stokes Tablet Presses added to the SUPAC Addenda for the equipment listing for Sub-Group – Unit Dosing.

The Stokes equipment, (see information attached) to be included in both categories for 1.1.1. Tablet Presses, are as follows: Stokes model 328, 754, 570P, 571S and 757. The equipment classifications for each described Stokes Model Tablet Press should be listed in the 2.1.1.1 Gravity Feed Classification and added to the 2.1.1.2 Force Feed Classification. Each tablet press is designed to accommodate either application.

Enclosed are 2 sets of literature of each Stokes Model requiring the changes listed above. For further information, please contact:

David M. Weir
Manager Application /Service
Phone (215) 788-3500 ext 2141
Fax (215) 781-1122
Email dweir@stokesdti.com

Sincerely,

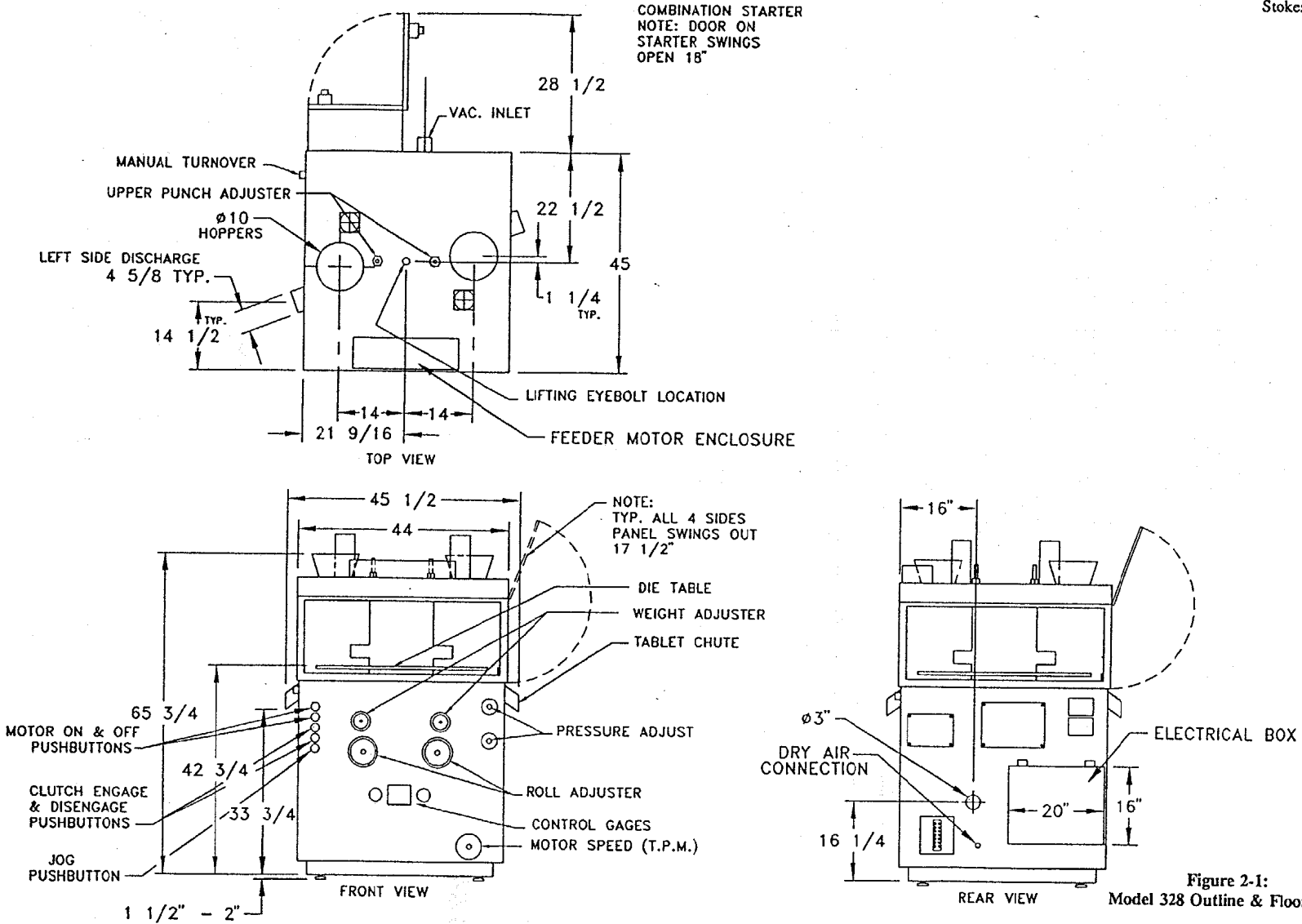
David M Weir

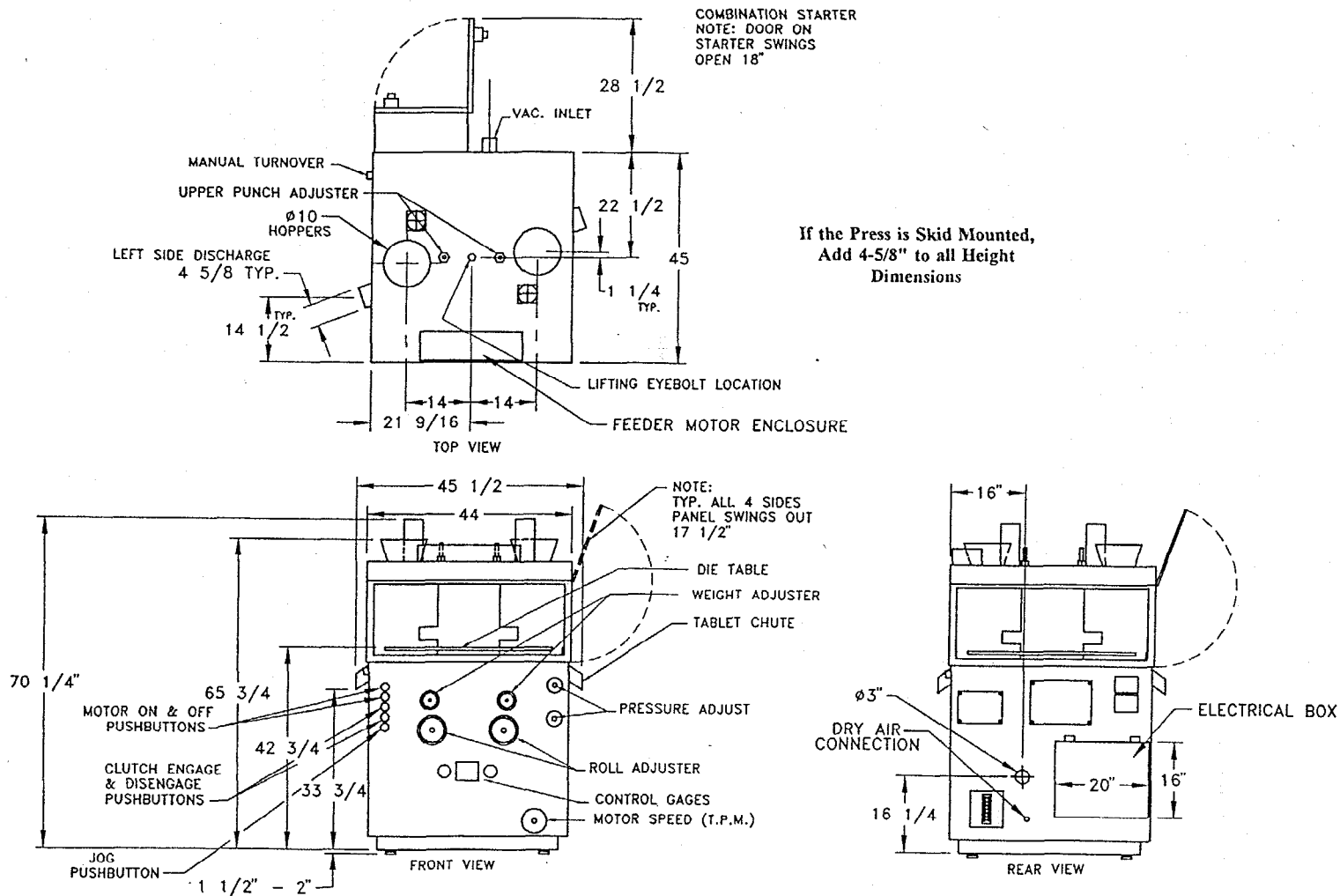
David M. Weir

DW/bmc

95D-0349

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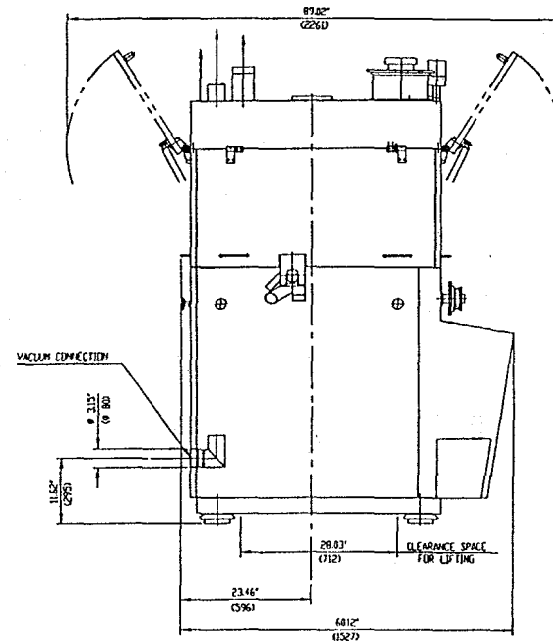
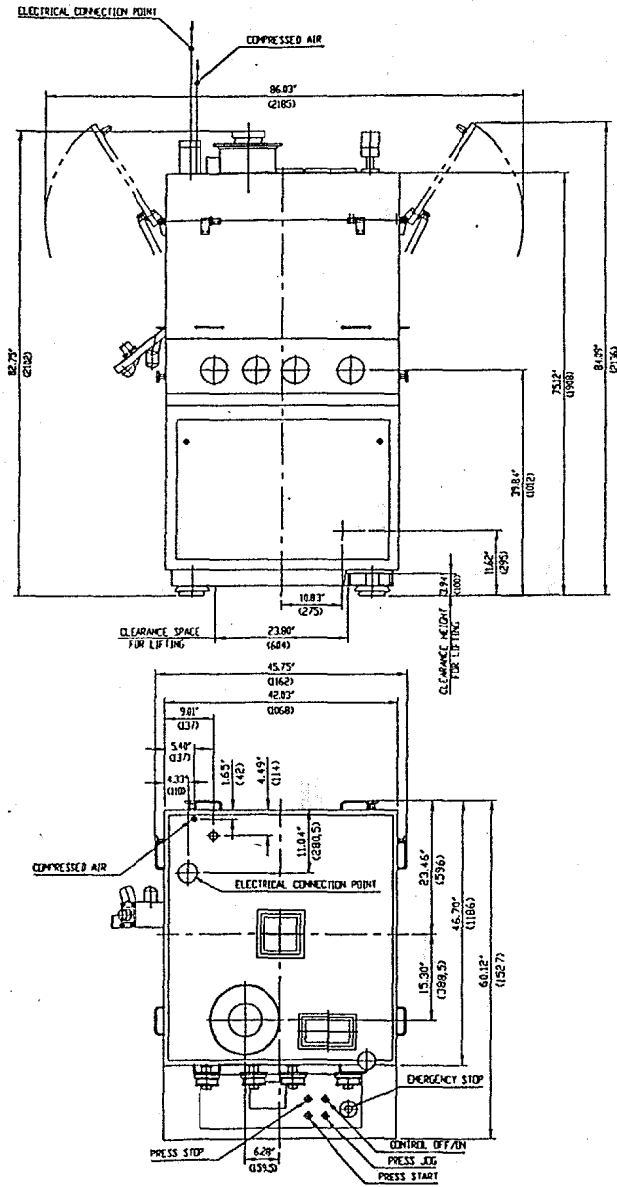




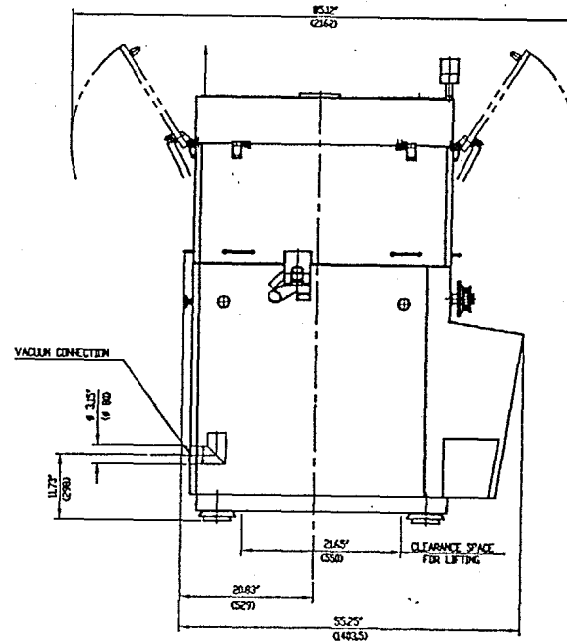
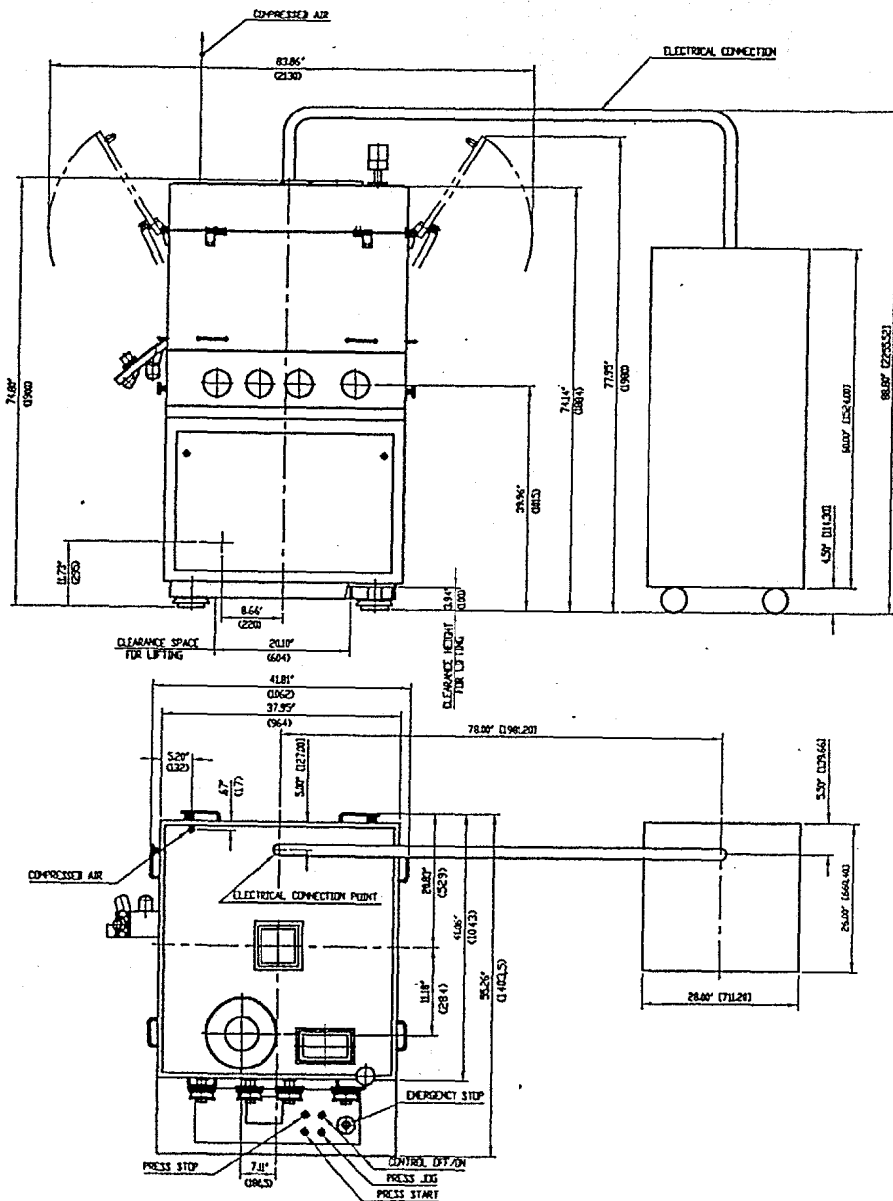
If the Press is Skid Mounted,
Add 4-5/8" to all Height
Dimensions

Figure 2-1:
Model 754 Outline & Floor Plan

571S



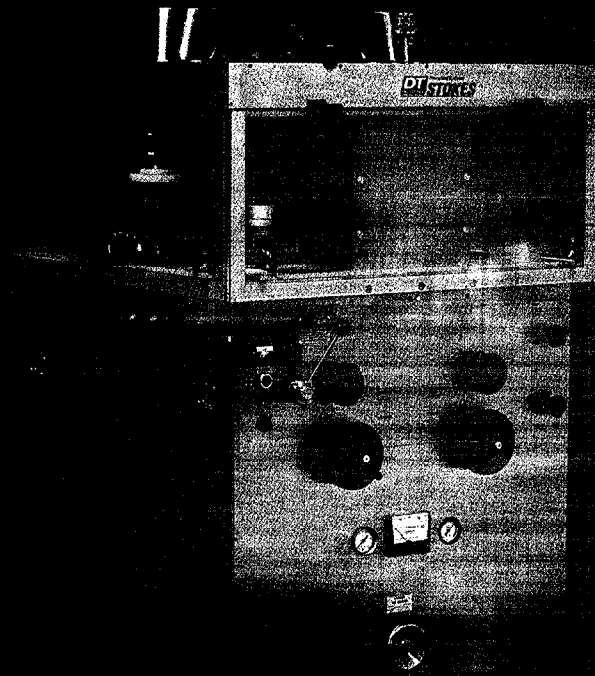
Gem Supreme
Layout and Dimensions



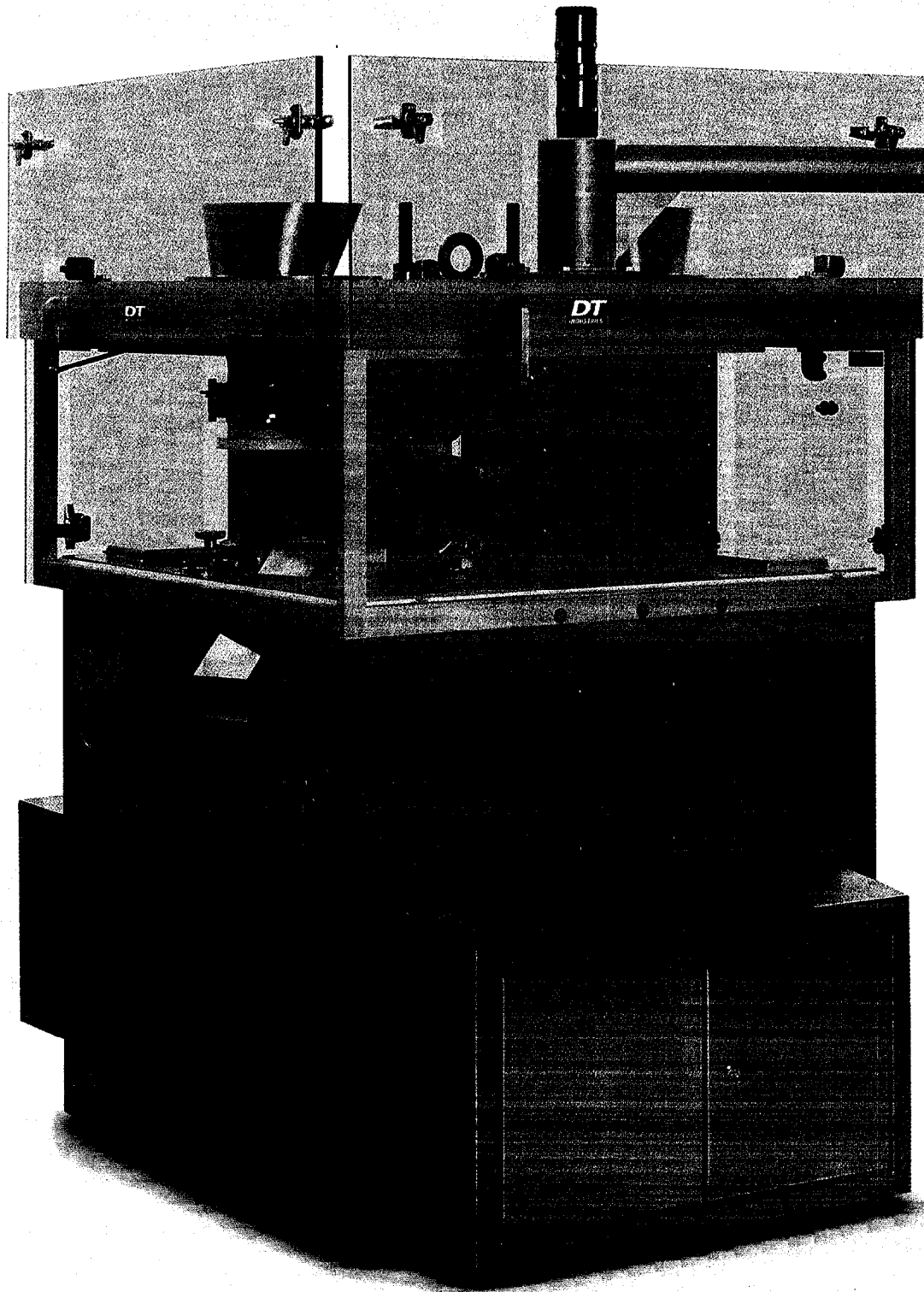
Gem Premier
Layout and Dimensions

model 328

rotary compacting press



model 328



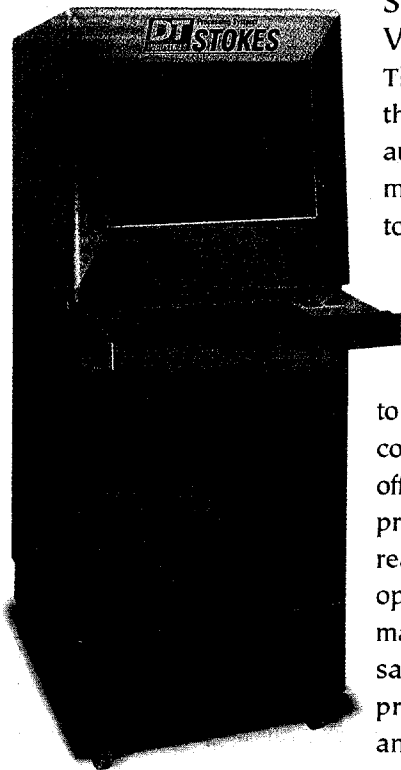
The Model 328 is the leading heavy-duty, high-speed compacting press. It produces large quality compacts and tablets in various shapes from a variety of materials. The Stokes Model 328 has a reputation for dependable, long term operation with very low maintenance costs. The Model 328 is available with manual, semi-automatic or fully automated control systems.

EXAMINE THE FEATURES - CONSIDER THE BENEFITS:

- **Neckless punches**
Extended dwell time, greater tooling strength
- **Heavy-duty design**
Less maintenance, longer machine life
- **Sealed pressure rolls**
Equipped with sealed roller bearings and races eliminating need for lubrication
- **Choice of gravity-type or mechanical feeder**
Choose best system for optimum weight control
- **Confined compacting section**
Confines dust, provides for operator safety and easier cleaning
- **Clean operation**
Complete accessibility to machine for thorough cleaning and changeover
- **Automatic Lubrication**
Longer life for moving parts
- **Can be arranged for two-layer compacts (optional)**
Affords greater versatility
- **Automatic set-up operation (optional)**
Quickly adjusts press to desired settings
- **Core rod tooling (optional)**
Can produce compacts with full or partial hole

CONTROL SYSTEMS

Stokes offers a vast selection of machine and weight control systems to meet your requirements- from manual to highly advanced, electronic control systems.



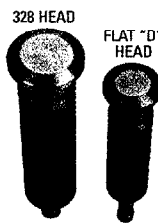
SERIES 3000 VALI-TAB®

This system combines the convenience of fully automatic recipe management, the simplicity of a touch screen panel and the precision of servo controlled setup. The Vali-Tab® continuously monitors force relative to the weight of each tablet compacted and rejects any off-spec tablets. The system provides the operator with real-time graphics of press operation in a dynamic machine interface. Provides sampling, color graphic printouts, event logging, and extensive product recipe management.

EXTENDED VACUUM

The vacuum manifold extends 360° around the lower section of the head keeping the press clean resulting in longer running time between cleanups.

LARGE PUNCH HEAD FLAT



A unique neckless punch design featuring a large punch head flat results in a 40% increase in compression dwell. This design enables the press to handle a wide variety of materials without precompression.

RIGID PRESS DESIGN

The press is designed to operate at full rated tonnage with low frame deflection and vibration. Upper and lower frames are machined from high tensile strength castings to provide rigidity for high tonnage pressure.

AIR CLUTCH AND BRAKE

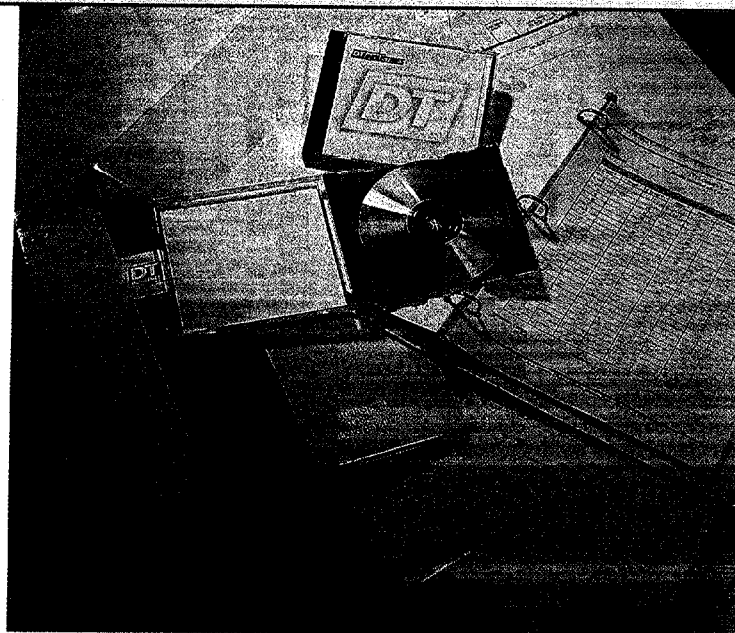
Allows for positive stopping of press. The system does not require adjustment, and minimal maintenance is necessary.

MECHANICAL FEEDERS

An optional twin mechanical feed system features a dual agitator, which moves material directly into the die cavity for superior weight control at higher speeds.

SPECIFICATIONS

Number of tool sets	45	33
Type of tooling	328	328
Maximum tablet diameter		
inches	.750	1.187
mm	18.75	29.7
Turret speed range (rpm)	18-50	18-50
Output of tablet (per min.)	1600-4500	1200-3300
Fill Depth (std)		
inches	.6875	
mm	17	
Fill Depth (max)		
inches	1.375	
mm	34	
Max compression force (tons)	10	
Power (H.P.)	7-1/2	
Floor space		
inches	52x46	
mm	1300x1150	
Overall height		
inches	67	
mm	1650	
Net weight		
pounds	5000	
kg	2500	



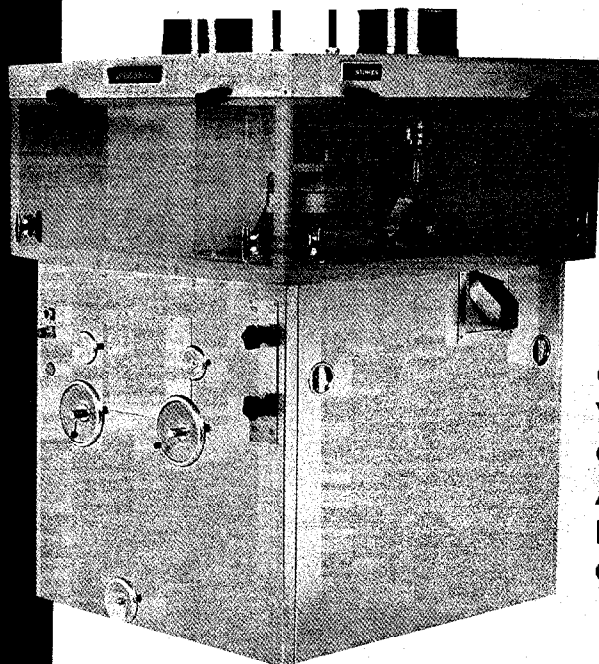
Complete IQ/OQ validation documentation and assistance is available for each press (optional).

Stokes is a member of DT Industries Packaging Group. DT Industries is a leading global designer, manufacturer, and integrator of automated production equipment and systems used to manufacture and package industrial and consumer products.



1500 Grundy's Lane • Bristol, PA 19007
 215-788-3500 • 1-800-635-0036 • Fax 215-781-1122
 email: info@stokesdti.com • www.stokesdti.com

Model 754 - High Speed 10 Ton Double Rotary Tablet Press



**For
Pharmaceutical,
Chemical,
Vitamin,
Confectionary,
Agricultural and
Industrial
Compacting**

■ SPECIFICATIONS & DIMENSIONS

Model 754-1 / Model 754-2

Number of tool sets	33 / 45	53/65
Maximum production rate (TPM)	3300/4500	6500/ 8000
Maximum tablet diameter (in.)	1 ³ / ₁₆ / 1 ³ / ₄	5 ⁵ / ₈ / 7 ⁷ / ₁₆
Fill depth, adjustable range (in.)		
Standard		0 - 1 ¹¹ / ₁₆
Optional		0 - 7 ¹ / ₁₆
Optional Deep Fill		0 - 1 ³ / ₈
Maximum operating pressure (tons)		10
Pressure release adjustment (in.)		0 - 10
Upper punch entrance adjustment (in.)		3 ¹ / ₁₆ - 7 ⁷ / ₁₆

DRIVE

Electrical service (volts, cycles, phase)	230/60/3	460/60/3
Motor:		
HP		7 ¹ / ₂
RPM		1800

DIMENSIONS & WEIGHTS

Overall height (in.)	66 ¹ / ₄
Floor to bottom of discharge chute (in.)	33 ³ / ₄
Width (in.)	45 ³ / ₄
Depth (in.)	52
Net weight (lb.)	5000
Shipping weight, approx. (lb.)	5500
Boxed for export (cu. ft.)	120

■ OUTSTANDING FEATURES & BENEFITS

- **Automatic Setup**
From product library
- **Designed for Safe Operation**
Interlocked panels to prevent access during operation
- **Compartmentalized**
Dust is contained in working zone
- **Automatic Lubrication**
Oil and grease are supplied to all critical parts.
- **Mechanical Feed System**
With Flow Control Gears
- **Centralized Control and Message Display Panel**
Pushbutton control for fill, thickness, hardness and speed. Direct reading of punch function and safety features.
- **Neckless Punch Design**
Provides longer dwell time and greater tooling strength
- **Stainless Steel Panels**
With sound absorbing inserts
- **Lower Punch Support System**
For accurate weight control
- **Versatility**
Press can be arranged for pre-compression and two layer compacts.

STOKES-MERRILL CORPORATION

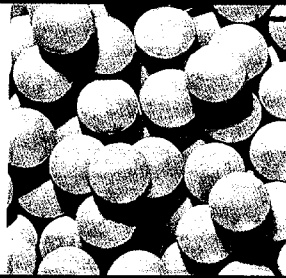
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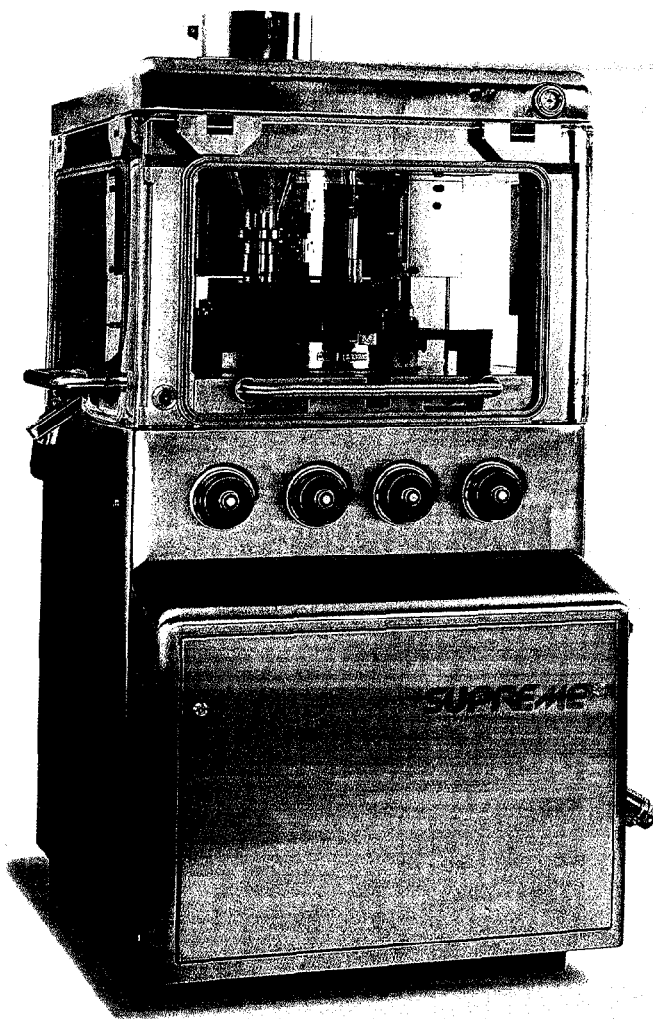
STOKES-MERRILL

Gem



DT *Processing Systems*
INDUSTRIES STOKES





GEM SUPREME

F E A

- ◆ Single Sided with Pre Compression
- ◆ Isolated Compression Zone
- ◆ 360 Degree Vacuum System
- ◆ Upper and Lower Punch Seals
- ◆ Tight Punch Sensors

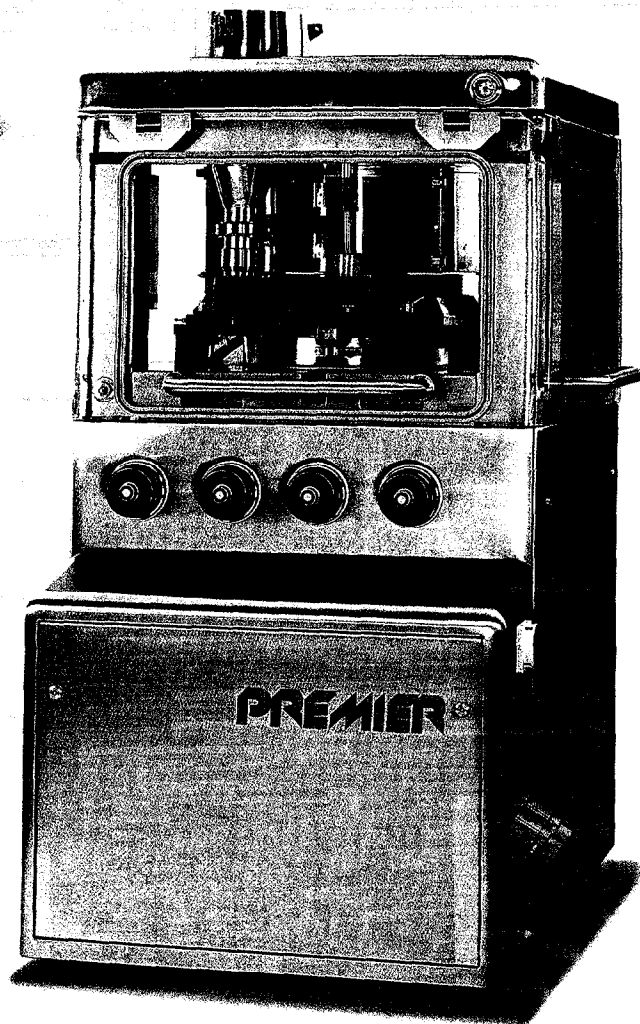
SPECIFICATIONS

Type of Tooling	IPT B	IPT B	IPT D
Maximum Tablet Dia. (mm)	13	18	25
Diameter of Die (mm)	24	30.16	38.1
Turret Speed Range (rpm)	5-100	5-100	5-100
Tablet Output (per hour)	15,000 - 300,000	12,600 - 252,000	10,200 - 204,000
Maximum Fill Depth (mm)		18	
Maximum Compression Force (kN)		80	
Maximum Pre-Compression Force (kN)		20	
Power (kW)		5.5	
Floor Space (mm)		1160 x 1527	
Machine Height with Hopper (mm)		2102	
Net Weight (kg)		2800	

PREMIER

U R E S

- ◆ Dual Level Mechanical Feeder
- ◆ Automatic Lubrication
- ◆ Adjustable Pressing Position in Die
- ◆ Free Service Policy
- ◆ Accepts IPT/TSM B and D Tooling

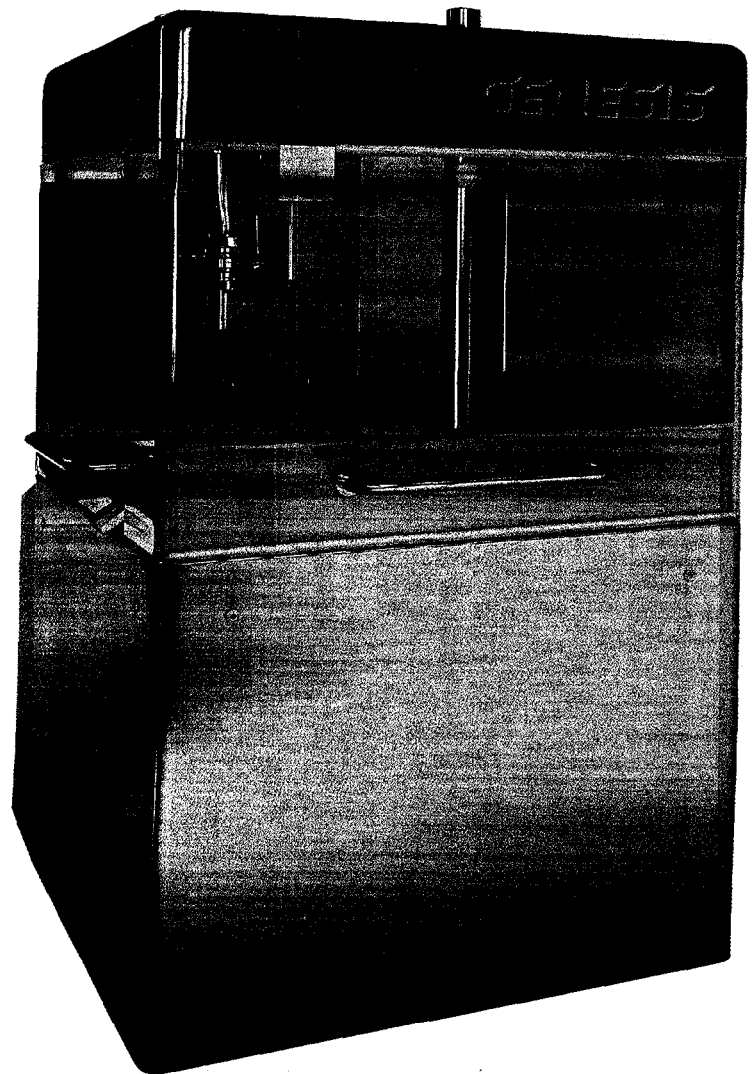


SPECIFICATIONS

Type of Tooling	IPT B	IPT B	IPT D
Maximum Tablet Dia. (mm)	13	18	25
Diameter of Die (mm)	24	30.16	38.1
Turret Speed Range (rpm)	5-100	5-100	5-100
Tablet Output (per hour)	10,800 - 216,000	9,000 - 180,000	7,500 - 150,000
Maximum Fill Depth (mm)		18	
Maximum Compression Force (kN)		80	
Maximum Pre-Compression Force (kN)		20	
Power (kW)		5.5	
Floor Space (mm)		1160 x 1400	
Machine Height with Hopper (mm)		2080	
Net Weight (kg)		1800	

YOUR COMPETITIVE EDGE IN TABLET MANUFACTURING

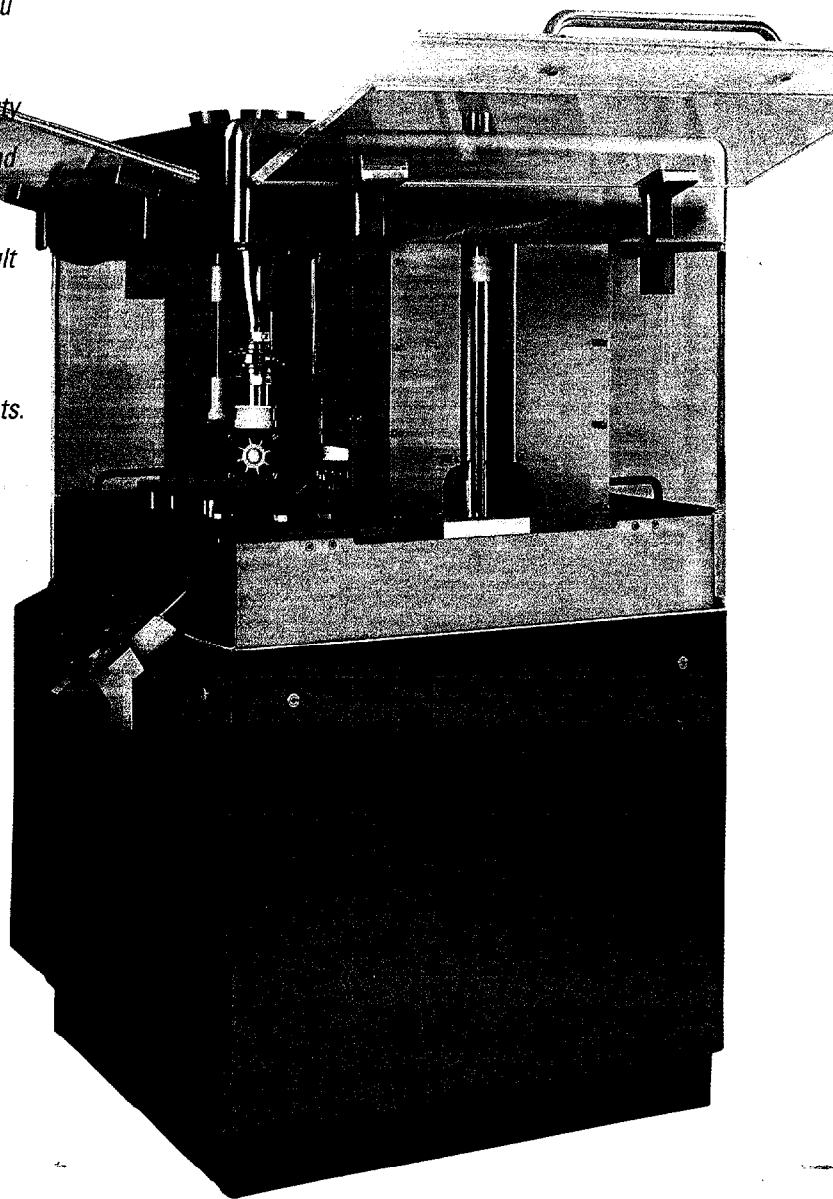
DT Processing Systems
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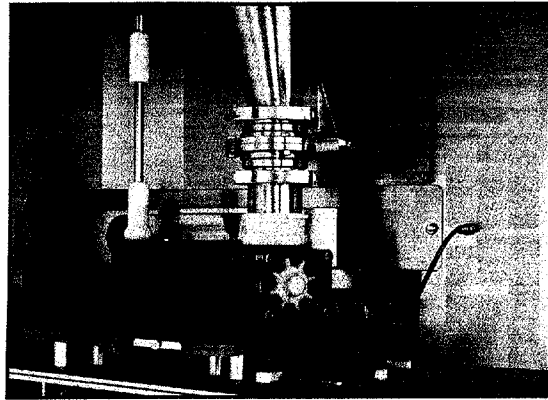
STOKES ~~GENESIS~~ ROTARY COMPACTING PRESS

STOKES GENESIS ROTARY COMPACTING PRESS

Stokes Genesis Press provides you with the power and performance you have come to expect from a Stokes rotary press. The Genesis heavy-duty construction provides for reliable and trouble-free operation. It features pre-compression for handling difficult materials and its innovative feeding system results in close tolerance weight control and high quality tablets. Its modern, ergonomic design with its rounded corners and stainless steel casing personifies the modern technology embodied in the press design.



REVOLUTIONARY DESIGN FEATURES



Vacuum Assist Filling:

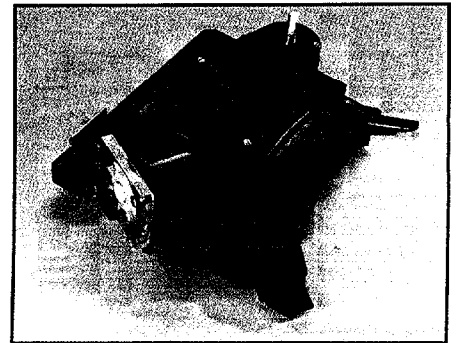
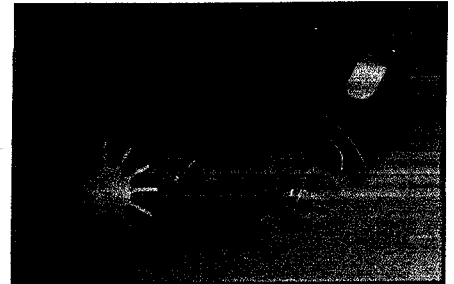
A negative pressure is drawn under the die during the filling cycle to assist in filling the material into the die.

Dual Chamber Mechanical Feeder:

Feeding chamber and hopper chamber are separated, reducing the time material is in the feed chamber. This minimizes material size reduction.

Metering Feed System:

Innovative feeding system utilizes a unique metering wheel. This metering system controls the volume of material which is fed to the feeding chambers, minimizing weight variations caused by fluctuations in overhead feed hoppers.



NEW LOWER CAM DESIGN

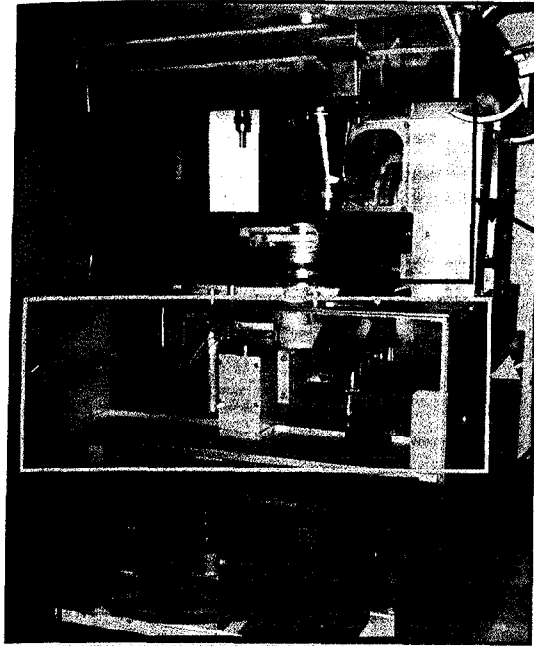


New Positive Settling Fill Cam

The new cam design consists of two stages.

The first stage is made up of a positive settling cam. This cam has been fitted with a series of actuating steps. As the punch passes over each step it settles the material in the die progressively, for an exact fill each time.

FAST CHANGE OVER, CLEANER OPERATION

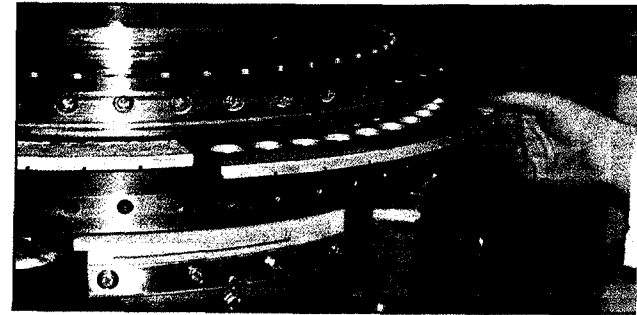


Three Seperate Zones For Cleaner Operation

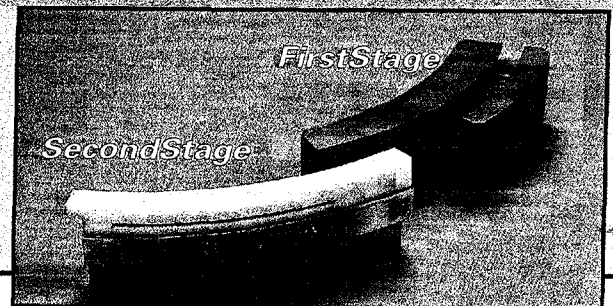
The press is divided into three zones, Upper Processing Zone, Compression Zone and the Lower Drive Zone. The zones are protected by sealed barriers to reduce the possibility of dust migrating to unwanted areas of the press during operation. Coupled with the 360 degree vacuum system, dust control is excellent, reducing your cleaning and changeover time.

Upper Processing Zone
Compression Zone
Lower Drive Zone

**Lower Punch Seal shelf
is quickly removed for
complete cleaning.**



The second stage is the "ZERO" Clearance Roof Cam. As each punch enters the cam segment, it is positioned precisely to the parameter as set by the servo controlled weight adjuster. This unbeatable two stage combination ensures the absolute best in weight control.

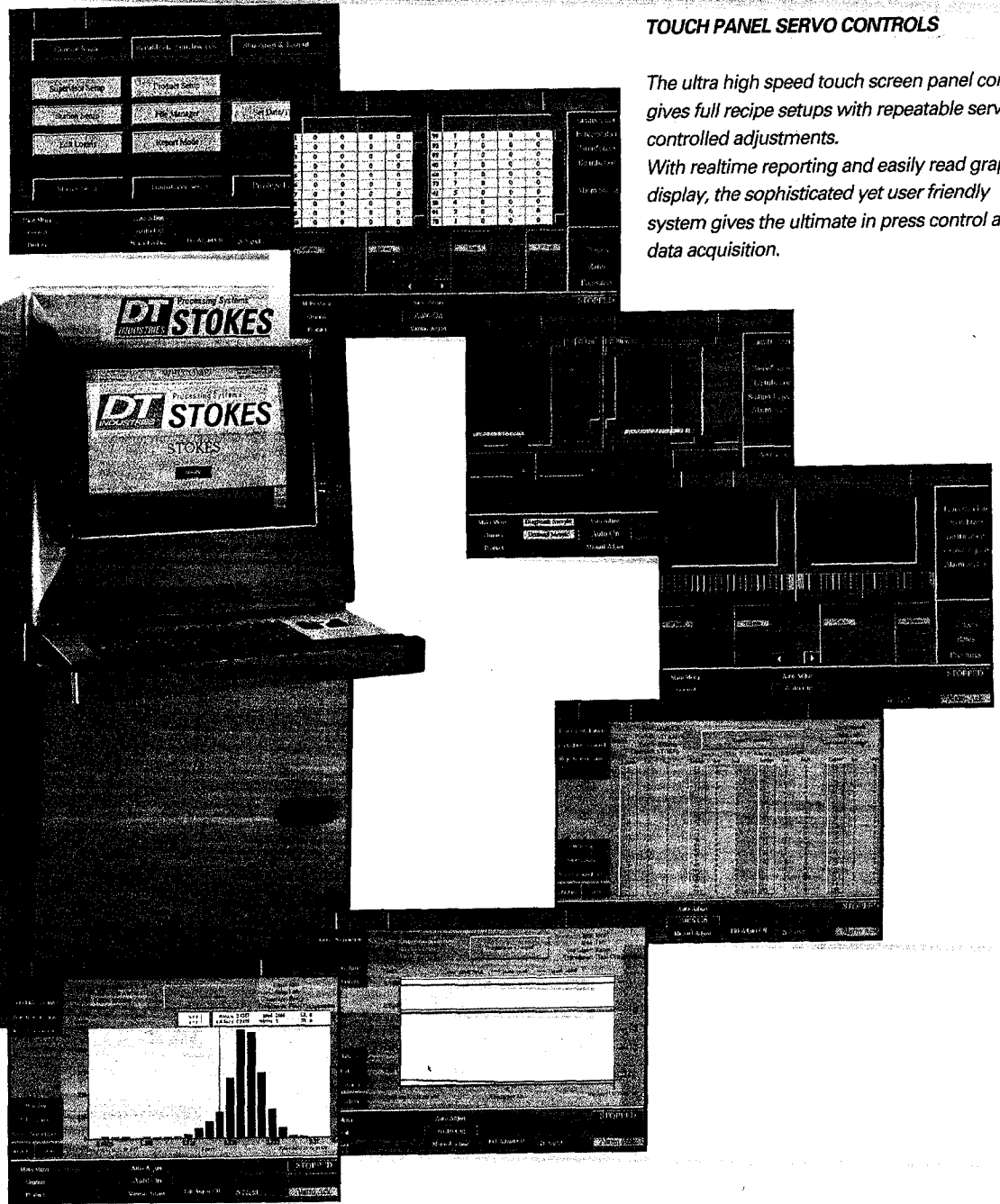
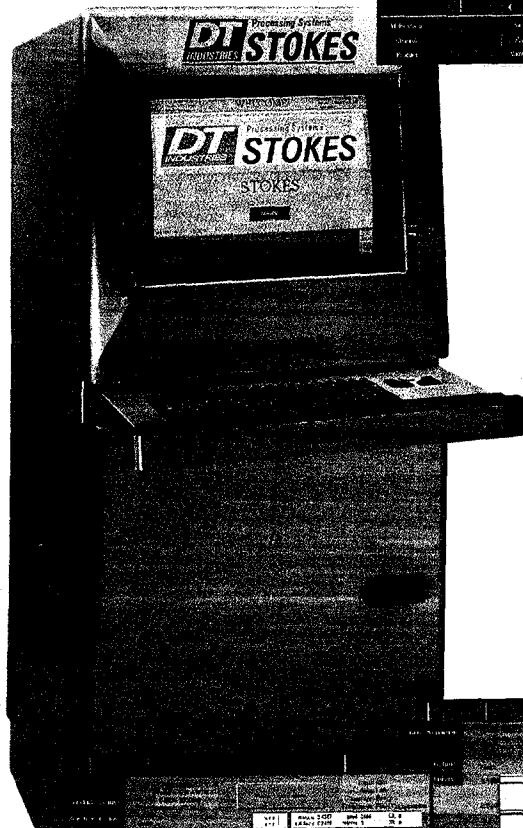


CONTROL SYSTEM

TOUCH PANEL SERVO CONTROLS

The ultra high speed touch screen panel control gives full recipe setups with repeatable servo controlled adjustments.

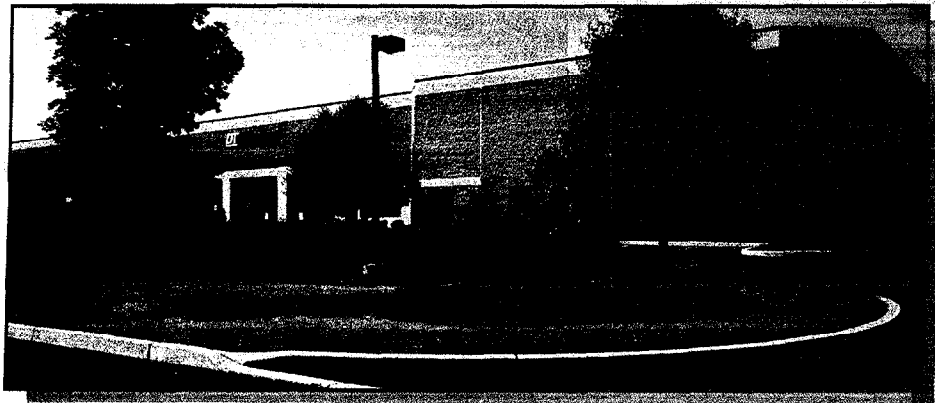
With realtime reporting and easily read graphic display, the sophisticated yet user friendly system gives the ultimate in press control and data acquisition.



SPECIFICATIONS

Number of Stations	63	51	39	39
Tooling Type	BB	BB	D	Neckless
Maximum Precompression Tonnage	2 Tons (20 Kn)			
Maximum Final compression Tonnage	10 Tons (100 Kn)			
Maximum Tablet Diameter	7/16" (11.1 mm)	5/8" (15.9 mm)	15/16" (23.8 mm)	1-1/16" (27.0 mm)
Depth of Fill - Maximum Standard Fill	5/8" (17.5 mm)			
Depth of Fill - Maximum Deep Fill Cams	3/4" (19.0 mm)			
Upper Punch Entrance	3/32" - 5/16" (2.4 mm - 7.9 mm)			
Maximum Turnable Speed	110 RPM			
Maximum Output (Tablet per Minute)	12,600	10,200	7,800	7,800
Drive Motor Horsepower	20			
Width	67 5/8" (171.8 cm)			
Depth	58 5/8" (148.9 cm)			
Height	80" (200.7 cm)			
Approximate Shipping Weight	8,000 Pounds (3636 kg)			

** Specifications subject to change and can be modified to meet individual customers specific requirements*



Stokes' manufacturing facility located in Bristol, Pennsylvania

DT Processing Systems
INDUSTRIES STOKES

STOKES DIVISION
DT Industries Packaging Group

1500 Grundy's Lane * Bristol, PA 19007 * 215-788-3500 * 800-635-0036 * FAX: 215-781-1122 * E-mail: PressPac@aol.com