

# Caleva – Variable Density Extruder® (VDE)

## General Description

A bench-top screw type extruder designed for R&D process development and small batch production work in the laboratory.

Unique variable hole depth dies and screens available for both axial and radial extrusion.

Extrudate density can be varied according to the requirement of the formulation.



<b>Use:</b>	Laboratory & Development: <input checked="" type="checkbox"/>	Pilot plant: <input type="checkbox"/>	Production: <input type="checkbox"/>
<b>Minimum batch size:</b>	Dependant on configuration. Trials have shown that about 75g of material remained in the extruder after extrusion of 1 kilo batches. The minimum load can be about 300g for radial extrusion and less for axial extrusion.		
<b>Maximum capacity:</b>	Up to a 1 kg batch in two minutes depending on the product properties and extruder configuration (based on a 3 kg sample).		

## Contents

General Description .....	1	Training and Validation Options .....	10
The Basic Machine.....	2	Upgrade and Accessory Options.....	13
Main Uses .....	4	Extrusion screens/Extrusion dies .....	12
Standard Design Configuration .....	5	Companion Equipment.....	14
General Arrangement Diagram .....	8	Recommendations .....	15
Options Overview.....	9		

## Variable Density Extruder®

### The Basic Machine

- Extrusion types:**
- Radial and axial extrusion in a single bench-top unit.
  - Cone or dome extruder function in order to increase capacity is not required due to the inherent efficiency of the machine.
  - Flexibility according to the requirements of the formulation.
- Extrudate quality**
- Comparative trials have shown that useable pellet yield can be increased significantly compared to other screw type extruders without the “variable density function”.
  - Trials using a standard placebo formulation with similar competitive equipment gave an average 69% usable yield compared to 96% with the Caleva VDE at a higher density configuration.
- Production capacity:** The VDE is designed for flexible product development use on the laboratory bench-top. Combinations of hole diameters and depths provide the ability to vary the density of the extrudate produced.
- Capacity:
- Radial Screen:**  
Up to a 1kg batch in 2 minutes on 1mm deep x1mm diameter hole on an radial screen extrusion (based on a 3.0kg sample of a standard material containing 32% MCC + 32% Lactose + 38% Water), up to 1kg in approximately 2.4 minutes on 2mm deep x1mm diameter hole (based on a 0.5kg sample standard material).
- Axial die plate:**  
Up to 1kg in approximately 2.4 minutes on 4mm deep x1mm diameter hole on an axial screen extrusion (based on a 1.0kg sample of a standard material containing 32% MCC + 32% Lactose + 38% Water).
- Dome or cone extrusion:**  
Due to the high efficiency and even consistency of material produced by the axial and radial extrusion types, dome or cone extrusion is not necessary or recommended.
- Production capacity is product-dependent and may be exceeded or not reached.
- The VDE extruder is designed for small batch product development on the bench-top and is not designed for intensive production. A comfortable working level will depend on the characteristics of the product. The VDE is an extruder ideal for development work.
- Minimum batch:** Dependant on configuration. Trials have shown that about 75g of material remained in the extruder after extrusion of 1 kilo batches. The minimum load can be about 300g for radial extrusion and less for axial extrusion
- Tool-less cleaning and maintenance** Designed to be easy to clean and dismantle without tools, the VDE uses a limited amount of bench space whilst being a powerful work horse for product development. Minimum maintenance is required
- Companion Spheronizer** The working capacity is suited to the Caleva bench-top MBS Spheronizer with a 250mm drum.
- Scaling up:** An equivalent production machine designed for efficient and problem free scale up is currently in development. The ability of the VDE to mimic all types of extrusion (with variable density configuration) indicates that the VDE can be used for development of a wider variety formulations than other laboratory extruders.

## Variable Density Extruder®

<b>Restrictions:</b>	The VDE should not be considered as a production machine and continuous production is not recommended.
<b>Documentation package:</b>	Full pharmaceutical industry qualification documentation packages are available if required.
<b>Materials certificates:</b>	All product contact components are manufactured in 316 stainless steel, FDA approved PTFE and polypropylene. Certified copies of original mill certificates for all product contact parts are available as an option if required.
<b>Availability/ Delivery time</b>	It is our intention to keep one or more machines in stock at all times. However, stock machines may be sold or may not be the specifications that you require. The actual delivery date will depend on the level of work that we have at the time of order. In general if we do not have a suitable machine in stock then delivery will be between 8 and 10 weeks. Please contact us for an exact delivery date when the required specifications are known.
<b>Safety</b>	Fully safety interlocked.

Operating parameters are manual and directly controlled by the user.



## Variable Density Extruder®

### Main Uses

- The VDE is designed for product development use on the laboratory bench-top.
- The working capacity is suited to the Caleva bench-top MBS Spheronizer with a 250mm diameter bowl.
- The VDE is designed for small batch product development on the bench-top and is not designed for intensive production.
- The most convenient working batch size will depend on the characteristics and availability of the product being extruded
- The ability to produce extrudate with different densities makes the VDE an ideal and practical tool for development work.
- Easy to dismantle and clean (tool-less dismantling), the VDE uses a limited amount of bench space whilst being a powerful work horse for product development.

## Standard Design Configuration

<b>Size</b>	Approximately 72w x 43d x 37h cm.
<b>Weight</b>	Approximately 55kg
<b>Material</b>	Cabinet is 304 stainless steel.
<b>Contact parts</b>	316 and/or 316L stainless steel and approved FDA plastics
<b>Standard extrusion screen/die</b>	<p>The standard configurations are:-</p> <ol style="list-style-type: none"> <li>1. An extruder fitted with a 1mm diameter x 1 mm deep hole on an axial configuration or,</li> <li>2. An extruder set up with 1mm diameter x 1mm deep hole on radial configuration.</li> <li>3. An extruder set up to have both configurations available.</li> </ol> <p><b><u>Whichever configuration is chosen at the initial purchase the equipment can be upgraded at a later stage according to need.</u></b></p> <p>Please contact us for advice regarding the optimum configuration for your project.</p>
<b>Product feed</b>	Manual, with feed tray positioned above the inlet.

<b>Safety</b>	All Caleva equipment is designed to the high safety standards. A safety cover is fitted as standard and the machine cannot be operated if the safety cover is not in place. We would recommend any purchaser not to take the responsibility to purchase any extruder without safety cover and cut out switches.
<b>Technical data</b>	750W AC motor. Motor speed infinitely variable (within a fixed range of about 10 to 90 rpm).
<b>Utility requirements Electrical supply</b>	<p>Single-phase voltage according to customer requirement (we are able to offer the voltage that you specify). If voltage is not specified at time of order, then 220/240V equipment will be supplied.</p> <p>The speed is controlled by means of an inverter. Inverters are fitted with an RFI filter that may create an earth leakage of up to 30 mA. If the extruder is to be plugged into a standard mains socket then the socket will have to be fitted with circuit breakers that can accept up to this level of earth leakage. If this is not possible, or if you have any doubts, then please contact us for advice. It is possible to overcome this issue if necessary for an additional cost of about £130 by the use of an isolating transformer. Generally this is not required but in a very few cases it has been necessary to supply this modification.</p>
<b>Operation and controls</b>	Extruder auger rotation speed controlled by an external potentiometer. Digital speed readout in rpm. "Start" button." Stop" button. "Emergency stop" button. "Power on" indicator. "Motor on" indicator.

## Variable Density Extruder®

### Standard documentation supplied

- Installation and operation Manual.
- Parts list.
- Manufacturer's specifications for tachometer (when supplied), safety switches, breakers and inverter.
- Completed quality control check sheet.

A water jacket is included as standard



Radial Extrusion through 1mm wide and 2mm deep holes







Variable Density Extruder®

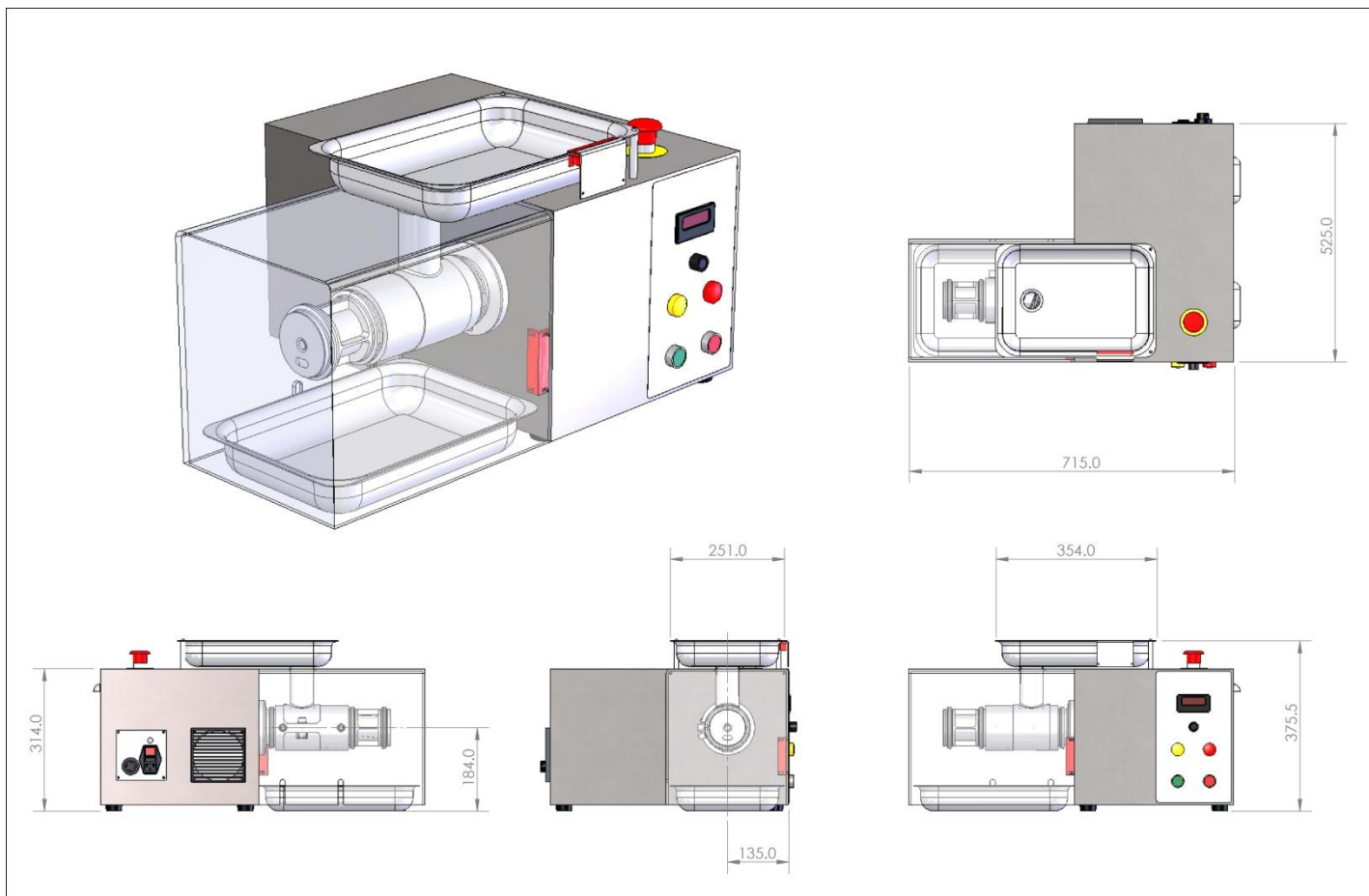


Axial Extrusion through 1mm wide and 4mm deep extrusion holes



Variable Density Extruder®

General Arrangement Diagram





## Options Overview

- There are no required options. The VDE extruder is fully functional as supplied.
- The standard configuration is either:-
  - An extruder fitted with a 1mm diameter x 1 mm deep hole on an axial extruder or,
  - An extruder set up with 1mm diameter x 1mm deep hole on radial configuration.
  - An extruder set up for both Axial and Radial extrusion
- Addition and custom made screens
  - Extrusion hole diameters can range from 0.2mm to 2.0mm and hole depths can range from 0.5mm deep to 4mm deep on radial extrusion and up to 8mm on axial extrusion. **Not all combinations of hole diameters and depths are available on all configurations.** Discuss your requirement with us.
  - This unique ability to offer all combinations allows the production of extrudates with controllable and variable density to be produced and tested quickly and easily in the laboratory for all your formulations. There is nothing else available that gives this possibility in single piece of equipment.
- A "Datastor™" package to monitor and record operating parameters such as temperature of the product as it is extruded, power consumption, rpm etc. during product processing.



## Variable Density Extruder®

## Training and Validation Options

## Installation/commissioning/training at the customer site

**Training within the UK.**

Including one day installation and training and two days travelling. All travel and subsistence cost are included in this price at Caleva expense

**Training in any other European country.**

Including one day installation and training and two days travelling. All travel and subsistence cost are included in this price at Caleva expense.

**Training outside Europe.**

Including one day installation and training and four days travelling. All travel and subsistence costs are included in this price at Caleva expense.

Includes installation, commissioning and training at customer site of up to one day, but does not include IQ/OQ which is separately chargeable. The customer will provide local transport for the Caleva technician if required. The customer will supply all consumable products required according to further discussion. Trained electricians will be provided by the customer if required (generally not required). Installation does not include any alteration to the customer site and does not include installation of any electrical services.

The customer will be responsible for the unpacking and location of the machines at the use site. This is not included in the quotation.

If more than one item is purchased then training can be done together for other equipment with considerable savings in cost. Contact us for details.

## Factory acceptance test at Caleva UK site

We make our own quality check before the extruder is shipped (a copy is supplied to the customer) and thus a separate FAT is not normally necessary but can be completed with the customer if required.

The customer will be responsible for all his or her expenses incurred in getting to and from the Caleva site.

## Customer training at the Caleva site (overseas customers)

Training is recommended if extrusion and spheronization is a relatively new technique to the company or if new staff would benefit from it. Contact us for details.

Customers from outside the UK will be collected at any London main airport and transferred to Bournemouth, accommodation and all meals for one trainee whilst in Bournemouth, UK. Transport to and from the Caleva site is included. Any extras (such as phone calls etc.) at hotel are for guest's account. One night bed & breakfast in London hotel before return flight to home country can be included if requested. Up to two days training (as required) at the Caleva site on customer's own equipment prior to shipment.

Transport to and from the customer's own country to London Main airport is not included and is for the customer's account.

If more than one item is purchased then training can be done together with considerable savings in cost. Contact us for details.

Variable Density Extruder®

**Validation and IQ/OQ documentation package**

Recommended if required for regulatory purposes.

**At Caleva site:**

The IQ/OQ package completed at the Caleva site by us. The customer can attend if he or she wished to do so at their own cost. An additional set of blank documents will be provided to allow the customer to re-do the IQ/OQ in their own facility if required.

**At customer site:**

IQ/OQ and installation completed at the customer site as part of the training (training will be charged separately). The cost shown is an additional cost for the IQ/OQ in addition to the costs for installation and training.

**Note:** there may be additional country-specific charges depending on location. Contact us for details.

**Material certificates (included in IQ/OQ package)**

If the IQ/OQ package is not required. Certified copies of mill certificates for product contact parts

If the IQ/OQ package is not required. Certificate from Caleva confirming that copies of the mill certificates are held by Caleva.



## Variable Density Extruder®

## Extrusion screens/Extrusion dies

**Extrusion types:**

Screens and dies for the bench-top VDE extruder are available in different configurations.

<b>Radial screens</b>	Radial screens offer more holes available for extrusion and therefore can generally offer greater capacity. It is more difficult to produce deeper holes in radial screens and they can be more costly to produce. Radial screens may not have the same flexibility as axial screens.
<b>Axial dies</b>	Axial dies are the most flexible and is the axial die is the extrusion method of choice if sufficient capacity can be reached. In general, a wider range of options are available for combinations of hole sizes and diameters with axial dies. Capacity can be at rates of about 1kg of extrudate in 2.4 minutes (1mm holes with 4mm deep holes) and this is normally more than sufficient for an R&D development.
<b>Hole diameters and depths</b>	<p>Note that Caleva only offers drilled holes. Screens from other suppliers can be laser cut or punched. Both these other options lead to inferior and variable hole shapes and can lead to less consistent extrudate which can affect usable yield.</p> <p>Hole diameters can range from 0.2mm to 2.0mm in diameter</p> <p>Extrusion hole depths can be variable between 0.5mm and 8mm.</p> <p><b><i>Note that all configurations of hole depths and diameters are not available on all type of extrusion configurations. Contact us for advice.</i></b></p>

**Standard configurations**

Custom made screens can be offered if required

## Upgrade and Accessory Options

### Datator-2™



Computer screen shot of the Datator-2™

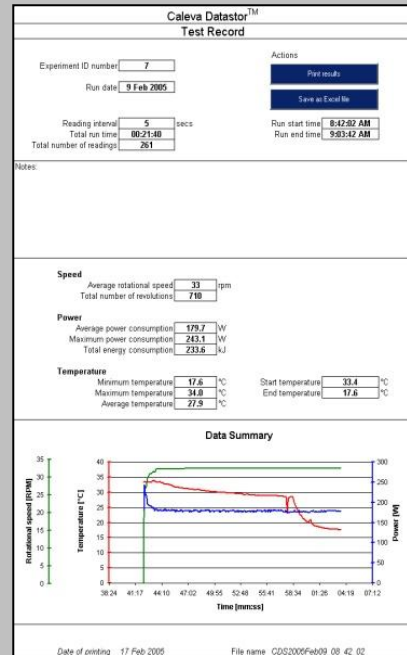
With this option the extruder can be connected to any available USB port your own bench top or laptop computer.

If a bench-top extruder or spheronizer is connected to a USB port on the PC then, with minimal additional operator intervention, the following data is recorded:

- Power usage
- Operating speed in rpm
- Product temperature

The software can recognize and monitor up to two machines working independently at the same time. Results are stored and the software allows the printing of a one page summary of all relevant data that can be printed as a permanent record.

A PC is not supplied in this option as most users prefer to supply their own. We can supply a suitable PC with the Datator software preloaded if required please let us know if you wish us to quote.



## Variable Density Extruder®

### Companion Equipment

#### ■ Bench-top Multi Bowl Spheronizer (MBS)

The Caleva Multi bowl bench-top spheronizer with its interchangeable 120mm and 250 mm bowl is an ideal comparison spheronizer for the VDE extruder.

- Ideal for experimental formulation development and very small quantity batch production.
- Interchangeable bowls allow the batch size to range from 1 gram to 1000 gram.
- Operational data collection direct to your computer is available.
- A flexible spheronizer system for bench-top product development.



#### ■ Cost effective laboratory bench-top mixer

The first step in the development of pellets in the laboratory is the mixing of the dry powder materials with some form of liquid binder. For many development applications a cost-effective professional grade planetary mixer is adequate for this process. Caleva can offer to supply with any order for a Caleva Extruder or Spheronizer this durable professional mixer with a stainless Steel bowl.

##### Equipment characteristics:

- Large capacity mixer with safety cut-out and finger guard for your security
- Large capacity 6.7 litre stainless steel bowl
- Professional grade on/off buttons
- Automatic electronic speed control maintains speed and power regardless of load
- Unique planetary mixing action within the bowl for perfect results
- Metal body, metal gears and powerful 800 watt motor.



#### ■ Laboratory extrudate drying equipment

If the extrudate is not to be used for spheronization then it may be desirable to dry the extrudate to remove excessive moisture. The Caleva bench top laboratory extrudate and spheroid drying system is a cost-effective way to efficiently dry extrudate.

Laboratory pellet drying system drier

- Trays with approximately 7000 cm sq. of space
- Adjustable Thermostat: 30° - 60°C
- Built-in on/off switch
- Convenient Removable Door
- 26-hour Adjustable Timer





## Recommendations<sup>1</sup>

### Options

**There are no required options.** The basic equipment as offered is fully functional. If you require any advice regarding the options or wish us to make any recommendations based on your planned use then please contact us.

### Companion equipment - Spheronizer

The VDE extruder is designed to work in conjunction with the Caleva MBS (Multi Bowl Spheronizer) with the 250mm bowl. This spheronizer option is **strongly recommended**.

### Companion equipment -Tray drier

If your laboratory has no installed facility for the drying of extrudate of spheroids then the very cost-effective Tray Drier option is **strongly recommended**.

### Additional screens and dies

A range of screens and dies are available with different hole sizes. The best option would depend on the foreseen requirements according to your foreseen use. Discuss your plans with us and we can advise on your best options.. Other screens can be purchased later if required. This option (the consideration of additional screens) is **recommended**.

### IQ/OQ before shipment

Installation can be provided at customer site if required but is not considered necessary for this equipment. Installation charges are listed in Training and Validation Options on next page. This option is **recommended** if required for regulatory purposes.

### Training at Caleva site

Training in the use of the equipment at the customer site or at our site in the UK prior to shipment is available. This option is **suggested** if extrusion and spheronization is a new technique for the user.

<sup>1</sup> **Strongly recommended:** We consider that this option is a “must” for most cases unless you have specific reasons why this option is not needed.

**Highly recommended:** Most users would consider this option as something that they would want.

**Recommended:** We consider that it is sensible to purchase these options.

**Suggested:** We suggest that you consider these options according to circumstances. Please contact us for any advice.