

# Caleva bench-top screen Extruder 20

## General Description

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

You can work with a wide range of batch sizes using a single apparatus. Includes option of “reduced height” screens for use with smaller batch sizes or screens with very small holes to reduce the cost.

Screens are interchangeable with production extruders minimising scale-up issues.



<b>Use:</b>	Laboratory & Development: <input checked="" type="checkbox"/>	Pilot plant: <input type="checkbox"/>	Production: <input type="checkbox"/>
<b>Operating capacity:</b>	Up to 15 kg per hour		
<b>Minimum batch size:</b>	50g or less with reduced height screens		
<b>Maximum capacity:</b>	About 10 to 15 Kg per hour depending on the product		

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## Extruder 20

### The Basic Machine

<b>Production capacity:</b>	<p>The Extruder 20 is designed for product development use on the laboratory bench-top. Throughput rates equivalent to approximately 15 kg per hour (with full height screen) have been achieved but the Extruder 20 is not designed for continuous production. This is product-dependent and may be exceeded or not reached.</p> <p>The Extruder 20 is designed for small batch product development on the bench-top and is not designed for intensive production. A comfortable working rate could be up to 10 kg/hour making the Extruder 20 ideal for development work.</p>
<b>Minimum batch:</b>	<p>With full height screens approximately 20 – 25 g of material is “lost” in the dead space within the apparatus for each operating batch. The minimum batch size would be the amount of extrudate required plus about 25 g. (If the reduced height screen options are taken then the size of the required sample size can be significantly reduced). Very small quantities (from about 20 gram can be extruded during development work) with reduced height screens.</p> <p>The most convenient working batch size will depend on the characteristics and availability of the product being extruded.</p>
<b>Cleaning and maintenance</b>	<p>Easy to dismantle and clean, the Extruder 20 uses a limited amount of bench space whilst being a powerful work horse for product development. Minimum maintenance is required</p>
<b>Companion Spheronizer</b>	<p>The working capacity is suited to the Caleva bench-top MBS Spheronizer with a 250 mm or 120 mm diameter bowl.</p>
<b>Scaling up:</b>	<p>The Caleva Screen Extruder 20 is designed to replicate Caleva production screen extruders (screens are interchangeable between laboratory and production extruders) and scale up to production can be made to very cost-effective production machines.</p>
<b>Restrictions:</b>	<p>The Extruder 20 should not be considered as a production machine and continuous production is not recommended.</p>
<b>Documentation package:</b>	<p>Full pharmaceutical industry qualification documentation packages are available if required.</p>
<b>Materials certificates:</b>	<p>Certified copies of original mill certificates for all product contact parts are available as an option if required.</p>
<b>Availability/ Delivery time</b>	<p>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.</p> <p>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 4 and 8 weeks.</p> <p>Please contact us for an exact delivery date when the required specifications are known.</p>



## Main Uses

- The Extruder 20 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 250 mm or 120 mm diameter bowl.
- The Extruder 20 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. Very small quantities (from about 20 gram can be extruded during development work) with reduced height screens.
- A comfortable working rate could be up to 10 kg/hour making the Extruder 20 ideal for development work.
- Easy to dismantle and clean, the Extruder 20 uses a limited amount of bench space whilst being a powerful work horse for product development.

## Extruder 20

### Standard Design Configuration

<b>Size</b>	Approximately 40x25x50 cm.
<b>Weight</b>	Approximately 25 kg.
<b>Material</b>	Cabinet is 304 stainless steel.
<b>Contact parts</b>	316 and/or 316L stainless steel and acrylic.
<b>Standard extrusion screen</b>	150 mm diameter with holes 1 mm diameter x deep. May be exchanged for other sizes if required. A wide range of screen hole sizes are available. Please contact us for details.
<b>Product feed</b>	Manual, with feed tray positioned above the inlet.

#### Safety

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.

#### Technical data

250 W AC motor. Motor speed infinitely variable (within a fixed range of about 16 to 35 rpm).

#### Utility requirements Electrical supply

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 220/240 V equipment will be supplied.

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.

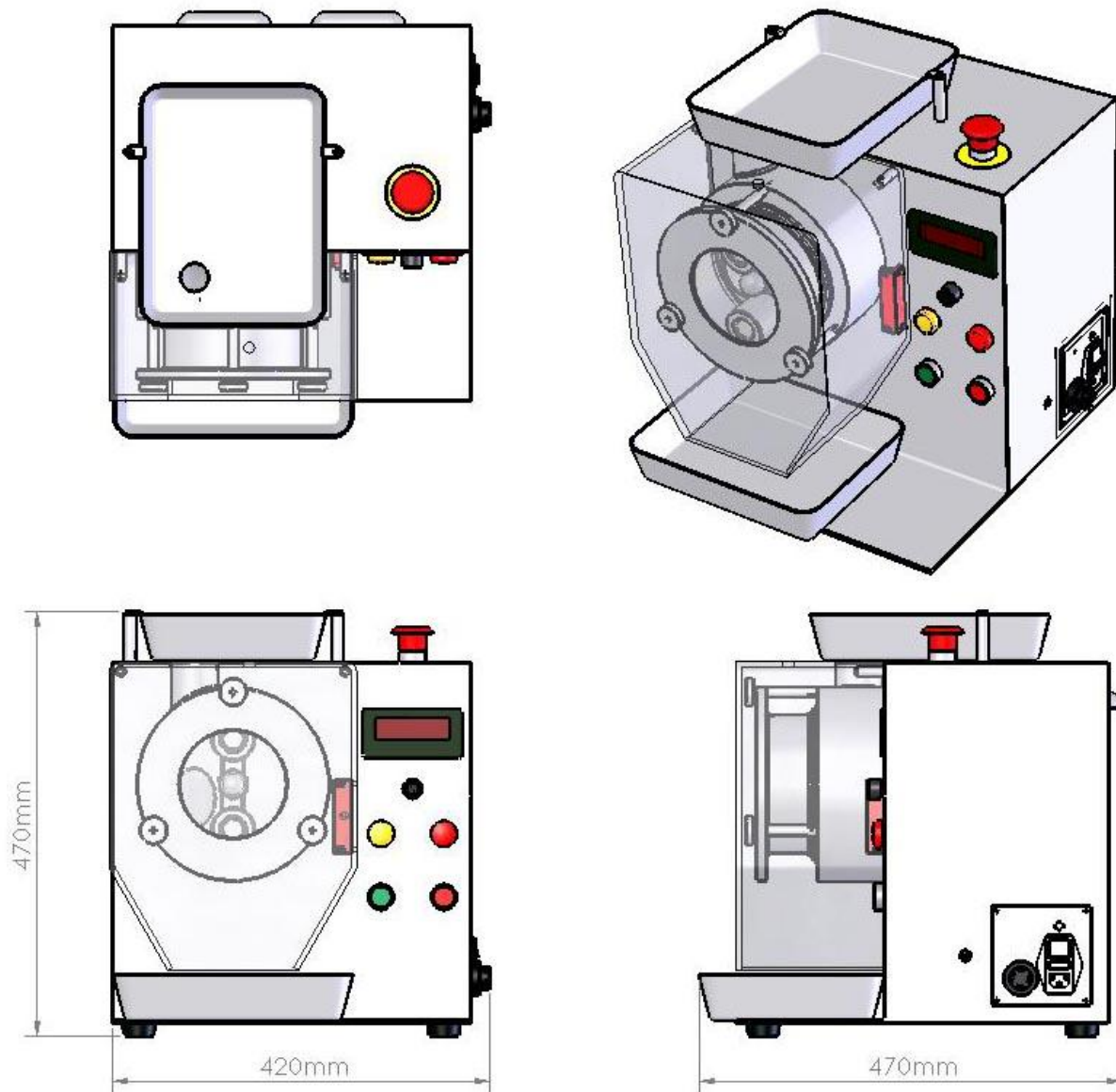
#### Operation and controls

Extruder wheel 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.

#### 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.

# General Arrangement Diagram



## Extruder 20

### Options Overview

- All machines are supplied with a 150 mm diameter extrusion screen. Additional screens are available as extras. Amongst the options available are:
- There are no required options. The Extruder 20 is fully functional as supplied.
- Screens with apertures from 0.5mm to 2.0 mm can be supplied as standard.
- Customer specific apertures in 0.1 mm increments can be supplied as required.
- Although we can make screens with very small apertures or apertures larger than 2.0 mm diameter, we do not currently recommend aperture sizes below 0.5mm or above 2.0 mm in diameter.
- Replacement screens of different designs at full height or reduced height can be supplied as needed.
- Additional stainless steel collection bins can be supplied to collect product as it is discharged from the machine.
- 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.





## 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 costs 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.

## Extruder 20

### 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.





## Upgrade and Accessory Options

### Datator-2™



Computer screen shot of the Datator-2™

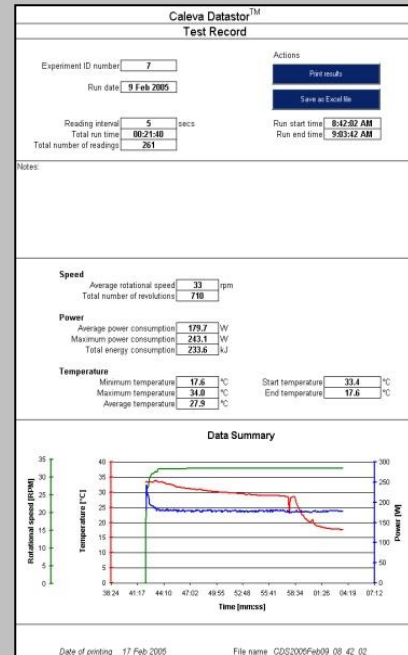
With this option the extruder can be connected to any available USB port your own bench top or laptop computer.

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.



### Knurled extrusions rollers

Some users prefer to have knurled surfaces to the extrusion rollers. These can be offered if requested as a non-standard option. The cost is an additional cost if knurled rollers are requested in place of the standard smooth rollers.

### Additional roller assembly unit with knurled rollers

Additional roller assembly unit complete with knurled rollers





## Extruder 20

## Consumables (Extrusion screens)

**Screen types:**

Screens for the bench-top Extruder 20 and production/pilot scale Extruder 35 are interchangeable. Screens are available in different configurations.

<b>Screen height</b>	Screens can be supplied at full height or reduced height. Full height screens are the standard and reduced height screens are offered either to reduce cost or to be able to efficiently extruded smaller amounts of material. Full height screens are 63 mm high in total and the extrusion area is 45.5 mm high. Reduced height screens are 35 mm high in total and the extrusion area is 17.5 mm high.
<b>Full height screens</b>	<p>Full height screens with very small hole sizes (0.5mm—0.7mm etc) can contain more than 19,000 holes that are individually drilled four times. Caleva drill rather than punch or laser cut holes as the quality of the individual hole is improved. The quality and consistency of the holes is important to ensure a regular extrudate to obtain the best possible consistency and highest usable in pellet production. The manufacturing cost of screens can be lowered if reduced height screens are used for development work. Caleva can supply reduced height screens for R&amp;D work that would allow a cost saving. It would be necessary to purchase the appropriate rollers and spindles for non-standard height screens. If screens with very small holes are required then we would recommend that reduced height screens are purchased in the first instance. Irrespective of the screens initially purchased as standard the Extruder 20 can subsequently use either full height or reduced height screens.</p> 
<b>Reduced height screens</b>	<p>Reduced height screens and roller assemblies are available when product availability is low or very costly and are recommended when the spheronizer to be used is the Caleva MBS with a 120 mm bowl option. Contact us for further details. Standard screens can be substituted for reduced height screens on the standard machine without any additional cost if required. Both full and reduced height screens.</p> 
<b>Hole diameter</b>	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.
<b>Different hole pitch (% open area)</b>	Screens are offered as standard capacity. Some holes sizes are offered as high capacity screens (greater open area). High capacity screen have more holes per unit area and thus are able to increase the hourly throughput. However high-capacity screens are not as physically robust as standard screens.

## Additional screens

### Standard capacity full height screens (1 mm deep holes)

- Hole size 0.5 mm diameter, Open area % = 16.5
- Hole size 0.6 mm diameter, Open area % = 20
- Hole size 0.7 mm diameter, Open area % = 20
- Hole size 0.8 mm diameter, Open area % = 21
- Hole size 0.9 mm diameter, Open area % = 20
- Hole size 1.0 mm diameter, Open area % = 22.5. (This is the Caleva standard screen)
- Hole size 1.1 mm diameter, Open area % = 21
- Hole size 1.2 mm diameter, Open area % = 19
- Hole size 1.3 mm diameter, Open area % = 18
- Hole size 1.4 mm diameter, Open area % = 16.5
- Hole size 1.5 mm diameter, Open area % = 15
- Hole size 2.0 mm diameter, Open area % = 10

### Standard capacity full height screens (2 mm deep holes)

- Hole size 0.8 mm diameter, Open area % = 21
- Hole size 1.0 mm diameter, Open area % = 22.5

### High capacity full height screens (1 mm deep holes)

- Hole size 0.7 mm diameter, Open area % = 32
- Hole size 0.8 mm diameter, Open area % = 28.7
- Hole size 0.9 mm diameter, Open area % = 26

### Standard capacity reduced height screens (1 mm deep holes)

- Hole size 0.5 mm diameter, Open area % = 16.5
- Hole size 0.6 mm diameter, Open area % = 20
- Hole size 0.7 mm diameter, Open area % = 20
- Hole size 0.8 mm diameter, Open area % = 21
- Hole size 0.9 mm diameter, Open area % = 20
- Hole size 1.0 mm diameter, Open area % = 22.5
- Hole size 1.1 mm diameter, Open area % = 21
- Hole size 1.2 mm diameter, Open area % = 19
- Hole size 1.3 mm diameter, Open area % = 18
- Hole size 1.4 mm diameter, Open area % = 16.5
- Hole size 1.5 mm diameter, Open area % = 15
- Hole size 2.0 mm diameter, Open area % = 10

### Low capacity full height screen – for tough products (1 mm deep holes)

- Hole size 0.8 mm diameter, Open area % = 14

## Other consumable items

FDA approved polymer bushes for extruder rollers. Per set of 4

## Extruder 20

## Companion Equipment

### Multi Bowl bench-top Spheronizer

The Caleva Multi bowl bench-top spheronizer with its interchangeable 120 mm and 250 mm bowl is an ideal comparison spheronizer for the Extruder 20.

- 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 Extruder 20 is designed to work in conjunction with the Caleva MBS (Multi Bowl Spheronizer) with either **the 250 mm or the 120 mm diameter bowls. If the MBS with the 120 mm bowl option is foreseen as partner** equipment then we would recommend the use of reduced height screens with the Extruder 20. If the MBS with the 250 mm bowl option is foreseen as partner equipment then we would recommend the use of full height screens with the Extruder 20. 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

A range of screens are available with different hole sizes, heights and % open area. Initially we would recommend that in addition to the standard 1.0 mm hole, full height, 22.5% open area screen supplied that an additional two full height screens with hole sizes of 0.8 mm and 1.2 mm are purchased at the time of the initial machine purchase. Other screens can be purchased later if required. This option (two 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 required.

**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.