MabTec® System

Installation, Operation & Maintenance Instructions

Parker

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Precautions

READ this manual BEFORE operating or servicing this equipment.
FOLLOW these instructions carefully.
SAVE this manual for future reference.
DO NOT allow untrained personnel to operate, clean, inspect, service or tamper with this equipment.
ALWAYS DISCONNECT this equipment from the power source before cleaning or performing maintenance.

	**WARNING** DISCONNECT ALL POWER TO THIS UNIT BEFORE INSTALLING, SERVICING, CLEANING OR REMOVING THE FUSE. FAILURE TO DO SO COULD RESULT IN BODILY HARM AND/OR PROPERTY DAMAGE.
	**CAUTION** OBSERVE PRECAUTIONS FOR HANDLING ELECTROSTATIC SENSITIVE DEVICES.
	**WARNING** ONLY PERMIT QUALIFIED PERSONNEL TO SERVICE THIS EQUIPMENT. EXERCISE CARE WHEN MAKING CHECKS, TEST AND ADJUSTMENTS THAT MUST BE MADE WITH POWER ON. FAILING TO OBSERVE THESE PRECAUTIONS CAN RESULT IN BODILY HARM.
	**WARNING** FOR CONTINUED PROTECTION AGAINST SHOCK HAZARD, CONNECT TO PROPERLY GROUNDED OUTLET ONLY. DO NOT REMOVE THE GROUND PRONG.

IF the power cord is lost or damaged, contact Customer Service to obtain a new one. Do not replace it on your own

Précautions

LISEZ ce manual AVANT de faire fonctionner ou d'entretenir cet équipment.
SUIVEZ attentivement ces instructions.
CONSERVEZ ce manuel pour future référence.
NE LAISSEZ PAS du personnel non qualifié utiliser, nettoyer, inspecter, entretenir, réparer ou manipuler cet équipement.
DÉBRANCHEZ TOUJOURS cet équipement de la source de courant avant de nettoyer ou d'exécuter l'entretien.
APPELEZ PARKER pour pièces détachées, renseignements et entretien.

	**⚠ ATTENTION** DÉBRANCHEZ TOUT COURANT DE CETTE UNITÉ AVANT DE FAIRE L'INSTALLATION, D'EFFECTUER L'ENTRETIEN, LE NETTOYAGE OU AVANT DE RETIRER LE FUSIBLE. NE PAS OBSERVER CES PRÉCAUTIONS RISQUERAIT DE CAUSER DES BLESSURES CORPORELLES OU/ET D'ENDOMMAGER L'ÉQUIPEMENT.
	**⚠ PRUDENCE** SOYEZ PRUDENT LORSQUE VOUS MANIPULEZ DES APPAREILS SENSIBLES À L'ÉLECTROSTATIQUE.
	**⚠ ATTENTION** AUTORISEZ SEULEMENT LE PERSONNEL QUALIFIÉ À ENTRETENIR CET ÉQUIPEMENT. SOYEZ PRUDENT LROSQUE DES VÉRIFICATIONS, TESTS ET AJUSTEMENTS DOIVENT ÊTRE EFFECTUÉS SOUS TENSIONS. NE PAS OBSERVER CES PRÉCAUTIONS RISQUERAIT DE CAUSER DES BLESSURES CORPORELLES.
	**⚠ ATTENTION** POUR ASSURER UNE PROTECTION CONTINUE CONTRE UNE DÉCHARGE ÉLECTRIQUE, BRANCHEZ UNIQUEMENT SUR UNE PRISE CORRECTEMENT RELIÉE Á LA TERRE. NE RETIREZ PAS LA FICHE DE TERRE.

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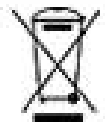
Standards:




- EN 61326-1:2006, Class B
- EN 6100-3-2:2006
- EN 6100-3-3:1995 +A1:2001 +A2:2006
- EN 61010-1 Issued: 2001/03/01
- Conforms to UL STD 61010-1:2012 Ed.3+R:29Apr2016
- Certified to: CAN/CSA-C22.2 No 61010-1-12:2012 Ed.3+U1:U2

Installation & Start-Up:

Installation of the MabTec™ System must be carried out only by trained personnel in accordance with the relevant regulations and this operations manual.

Make sure that the technical specifications and input ratings of the MabTec™ are observed. See “MabTec™ Specifications”.

The protection provided by this equipment may be impaired if the MabTec™ is used in a manner inconsistent with this manual or for purposes not specified by the manufacturer.

Maintenance & Cleaning:

The MabTec™ is practically maintenance free. The SciPres™ disposable sensors used with the system come pre-calibrated from the factory and require no maintenance. The Tandem™ peristaltic pump head should periodically have tubing debris cleaned from it, but requires no lubrication.

To remove dust, dirt and stains, the outer surfaces of the MabTec™ may be wiped using a soft, non-fluffing cloth moistened with water. If required, you may also use a mild detergent or 2-propanol.

The SciPres™ disposable sensors may be sanitized with 0.1 Molar NaOH, or 2-propanol. They may be autoclaved up to twice, and newer units with the grey rings around the cable connector may be gamma irradiated.

Please read the following instructions carefully!

Inspections: Remove the products carefully from the shipping container. Check the contents against the purchase order to verify that all parts are included and undamaged.

Please do the inspection now, even if the products are not used immediately. Many carriers must receive damage claims within seven days of delivery. Please retain all packing material so unit may be shipped safely, if necessary.

Customer Service: Parker customer service: If assistance is required, please contact us at:

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Bioscience Division – EMEA
Durham Road
Birtley, Co. Durham
DH3 2SF, England
phone +44 (0)191 4105121
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Parker Hannifin Corporation
Bioscience Division – N.A
2340 Eastman Avenue
Oxnard, California, USA 93030
toll free: 877 784 2234
phone: +1 805 604 3400
fax: +1 805 604 3401
email: bioscience.na@parker.com
www.parker.com/bioprocessing

Parker customer service personnel will be able to serve you more efficiently if you have the following information:

- Serial number and model name of the equipment
- Installation procedure being used
- Concise list of symptoms
- List of operating procedures and conditions in use when problem arose

Warranty

Country specific information can be found at: www.parker.com/termsandconditions

MabTec Maintenance

Factory based preventative maintenance is recommended on an annual basis.

Contact your Territory Manager or Parker Technical support to obtain a TSP Number and pricing on this procedure.

Introduction:

The MabTec provides control, measurement and documentation of the Feed, Harvest or TFF recirculation portion of the Perfusion process. Up to four pumps can be used for this with as many scales.

The MabTec handles the Harvest (Perfusion) portion of the process in a programmable mode. This provides a mass flow control either in ml/min or bioreactor exchanges/day. This allows changes over time as the process matures with programming in days: hours: minutes. A balance or scale is required.

The MabTec handles the Feed portion of the process in a gravimetric manner to maintain a constant bioreactor weight, monitoring the perfusion rate, and comparing the amount added and that perfused. As fluid is removed, fresh media is added. For full control, two scales are required, one for the feed vessel, and the other for the perfusion vessel. It also has inputs for a third scale, so that the reactor weight can be monitored. (An analog input for the Wave® Bioreactor is available if used.) There are two other modes available for the Feed process that require one or two scales, and use monitoring of the bioreactor weight as the control value.

The MabTec also handles the Recirculation of the bioreactor contents through a TFF hollow fiber filter (typical) or flat sheet membrane. Reverse flow through the filter is common and provided as a feature of this mode. All three pressures and the calculated TMP are measured, and related alarms are available.

The MabTec has an additional mode, Seed Induction, for periodic addition of seed material or anti-foaming agent to the reactor by weight at preset routine intervals.

By using a MabTec for each process, each portion of it can be easily controlled, measured, and documented over the entire life of the process.

Features and Benefits:

Perfusion Mode:

- Highly accurate mass flow-based perfusion control provides constant, long term perfusion rate and reproducible perfused media collection by weight. Requires (includes) an appropriately configured and sized electronic perfusion scale for hook-up to the MabTec.
- User friendly programmable perfusion rate and perfused media collection based on desired biomass weight exchanges per day. Easy implementation of existing perfusion protocols.
- Time programmable sequencing of perfusion rate and perfused media collection provides automated, user-defined changes (increasing/decreasing) in perfusion rate over time. Easy scheduling of perfusion profiles in terms of days, hours and minutes. The systems can Ramp Up, Ramp Down, or Exponential change, whatever is necessary to match the cells growth cycle.
- Automated data display of daily batch harvest as well as display of accumulated harvest weight of perfused media from start of cell culture; allows continual assessment of cell culture productivity.

- Automated alert when perfusion reservoir needs to be emptied or exchanged. Avoids overfilling of reservoir and potential loss of product.
- Monitoring of perfusion line pressure. Requires SciPres pressure sensor. User- definable low pressure limit alarm indicates plug-up of perfusion filter. Alarm indicates need for filter back flush or replacement – before membrane damage occurs. This is important because it gives flexibility in terms of cell line and total length of production.
- Automated alert when desired mass flow perfusion rate cannot be maintained. Alarm would indicate low perfusion rate limit showing need for filter back flush or filter replacement. Alarm is also used to indicate peristaltic pump (or tubing) degradation.
- Standalone Perfusion system gains added functionality when paired with Feed System, automated alarms on Feed System will ensure Perfusion system does not continue unchecked.

Exact Feed Mode:

- Highly accurate mass flow feed rate into bioreactor is based on data output received from perfusion and feed media scales. The amount of perfused media removed from the bioreactor is replaced by an equal amount of feed solution. Allows long term maintenance of a constant bioreactor weight/volume without operator intervention. Result: improved efficiency over manual operations.
- Automated tracking of collection rate and weight of perfused media. Both perfusion rate and weight data are used to match feed rate into bioreactor. Allows biomass to be maintained within +/- 2 grams
- An auditory alarm is activated when feed solution reservoir needs to be re-filled or replaced. Prevents unproductive bioreactor feed and unintentional starving of cell culture.
- Automated alarm is activated when required feed rate cannot be maintained. The MabTec feed pump will provide an alarm contact closure to pause the MabTec perfusion pump. Prevents unintentional removal of media from bioreactor when feed solution is unavailable.
- Real time display of rate and weight data for feed solution and perfused media. Alarm is activated when parameters move outside user definable limits.
- Optional hook-up of electronic bioreactor (third) scale for monitoring excessive under filling or overfilling of bioreactor vessel. Recommended for single-use bioreactors, e.g. Wave Bioreactor System 20/50 EHT and others. Added safety feature for monitoring system performance and prevent loss of product.

Re-Circulation Mode:

- Continuous, low-shear circulation of cell suspension. Low shear pump action maintains high cell viability condition and low dead cell count.
- Time programmable reversal of re-circulating flow. Reduces aggregation and build-up of cells in the perfusion filtration device.
- Automated, continually repeated pattern of flow reversals. Cell compaction and build-up inside the filtration device is significantly reduced.
- Real time monitoring of pressure differentials across filtration device utilizing Parker in-line pressure sensors (SciPres). Excessive filter back pressure activates a maintenance alarm indicating the need for filter back flush or replacement.
- Recirculation Mode eliminates the possibility of dead space or pockets of inconsistent media in the bioreactor and assures homogeneity in culture.

MabTec System Specifications:

Mechanical:

- **Dimensions:** Width: 5.75 in (14.6cm); Height: 8.5 in (212.6); Depth: 11in (27.9)
- **Weight:** 14 lbs (6.4kg)
- **Enclosure:** Aluminum / Steel; Corrosion Resistant, Recessed Handle.
- **Pump Head / Motor Options:**
    1. **Tandem 1081 peristaltic pump head with 8-RPM motor**, thin-walled (0.060") pump tubing: #13, 14, 16, 25, 17, and #18. Flow Range: 0.03 to 24.3 ml/min. **Recommended for**
    2. **Tandem 1081 peristaltic pump head with 160-RPM motor,** thin-walled (0.060") pump tubing: #13, 14, 16, 25, 17, and #18. Flow Range: 0.5 to 554 ml/min. **Recommended for**
    3. **Tandem 1082 peristaltic pump head with 600-RPM motor,** thick-walled (0.090") pump tubing: #15, 24 and #35. Flow Range: 59 to 2,258 ml/min. **Recommended for**
- **Pressure Sensors:** Accommodates up to three (3) SciPres™ disposable sensors: P1 = Feed Line Pressure. P2 = Retentate Line Pressure, P3 = Permeate Line Pressure. MabTec calculates and displays Trans-membrane Pressure (TM), TM = (P1 + P2) / 2 - P3.
- **Pressure Displayed** with a resolution of 0.1 psi; choice of bar, psi, kpa.
- **Pressure Range: 0-60psi.** This can be re-calibrated using an external pressure reference source.

Electrical:

- **Power:** 90 - 264 V~, 47-63 Hz, 150 VA, listed Class 2 switching power supply. Double fused: 1A-T, 250V (CE: IR35A 250V~).
- **Battery:** CR1220, used to support the internal clock only, not user serviceable
- **Motor:** Choice of three (3) motors: 8, 160 and 600 RPM at 24V ⎓, 3.8 Amperes, Variable Pump Speed optically encoded servo-controlled motors.
- **Encoder:** 100 lines per / rev. for 600-RPM motor. 120 lines per / rev. for 8 and 160 RPM motors.
- **I/O Ports:**
- **"Printer",** Female DB9 connector for data collection with Printer or PC.
- **"S1",** Male DB9 connector for RS-232 connection to an electronic scale.
- **"S2",** Male DB9 connector for RS-232 connection to an electronic scale.
- **"S3",** Male DB9 connector for RS-232 connection to an electronic scale.
- **"External I/O",** Female DB37 connector used for remote On/Off control of MabTec via footswitch, or for Analog interface with 4-20 ma sources, A1, A2, A3.
- **"V",** Female DB15 connector, not utilized on MabTec.
- **"Temperature",** 2 pin Conxall connector for SciTemp™ disposable Temperature Sensor.
- **"P1, P2, P3",** RJ11 connectors used for SciPres disposable Pressure Sensors.
- **"USB",** USB-A connector, used for RS-232 data collection with a PC.
- "**Ethernet",** RJ-45 connector, used for Modbus TCP/IP connection with system. (when available)
- **Display:** Two line LCD, 20 characters each, back-lit.
- **Data Entry:** Membrane keyboard with auditory feedback.

Environmental:

- Temperature range: 4 to 40° C.
- Altitude: up to 2000 Meters
- Indoor, dry environments only, clean-up is wipe down only (IP 20)
- Relative humidity: 0-95%
- Voltage fluctuations +/- 10%
- Pollution degree: 2

MabTec Balances

- The MabTec can communicate with up to three balances/scales depending on the Operational Mode in use.
- An analog interface is available for communication with the balance that is built into the Wave® Bio Reactor.
- Several models of Mettler Toledo scales are available for use with the system. Sizes range from 3000 gm. x .01 gm. to 150 kg x 2 gm. In some modes, the need for two RS-232 outputs from the same scale is required.
- The Parker WeighStation, used for holding media bags, is also available for use with the MabTec system.

MabTec Software

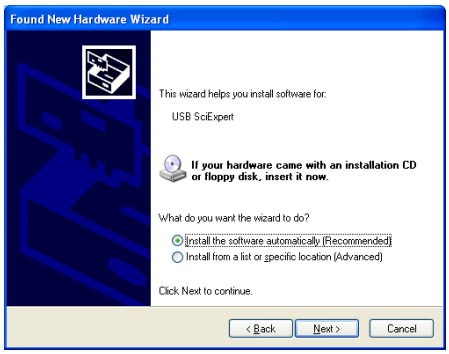
- **Main menu with four operational modes:**
  - **Exact Feed: 2 Scales Mode:** Feeds the Bioreactor maintaining a constant weight, controlled by feedback from a pair of scales, one under the feed vessel, and the other under the perfusion harvest vessel. Does not require a scale under the Bioreactor. (This may be attached to another MabTec controlling the perfusion).
  - **Perfusion: One Scale Mode:** Harvests fluid from the Bioreactor at a programmable mass flow rate expressed in ml. / gm. or exchanges / day using feedback from a scale. This scale also can provide data for Exact Feed: 2 Scales Mode above.
  - **Re-Circulation: Vol. Mode:** Provides programmable flow and time both forward and reverse through a filtration device to facilitate the harvest or removal of byproducts of the Bioreactor. Monitors up to three pressures and one temperature.
  - **Feed: One Scale Mode:** Feeds the Bioreactor to maintain a constant weight by monitoring the actual weight of the Bioreactor with a scale and adding fluid as the weight drops.
  - **Feed: Two Scale Mode:** Feeds the Bioreactor as One Scale above, adding a second scale under the feed vessel to provide an alarm if the vessel nears empty.
  - **Seed Induction Mode:** Add defined amounts by weight to the Bioreactor at repeatable user defined intervals in Days: Hours: Minutes.
  - **Setup Mode:** Selection of user preferences and interface options.
  - **Manual Mode:** Manual motor control as % of motor speed, no alarms.
  - **Analog Interface:** Up to three devices with 4-20ma output can be directly connected for monitoring, including an interface for the balance output from a Wave® Bioreactor.
  - **Optimizes and Documents all or part of the Perfusion Process:** Feed, Perfusion Harvest, and Recirculation.

Documentation Software for PC

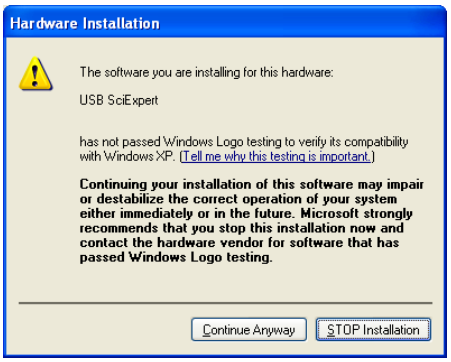
- SciDoc Excel spreadsheet with custom macros for data compilation. Uses Winwedge Standard as the COM Port interface. Sent to you ready to use.
- Complete process analysis with graphing of data
- Real-time verification and documentation of process parameters

Installation of the USB Driver:

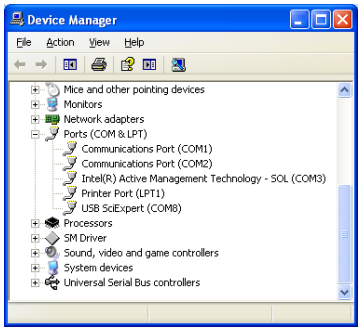
- Upon connecting the MabTec to the PC via a USB cable, the “New Hardware Wizard” window appears. Select ‘No, not at this time” and click “Next”. The second screen appears:



- Insert the CD containing the MabTec Operating Manual into the PC, choose “Install the software automatically” and click “Next”. The following screen appears:

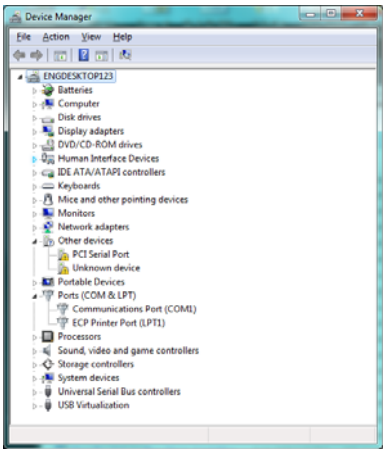


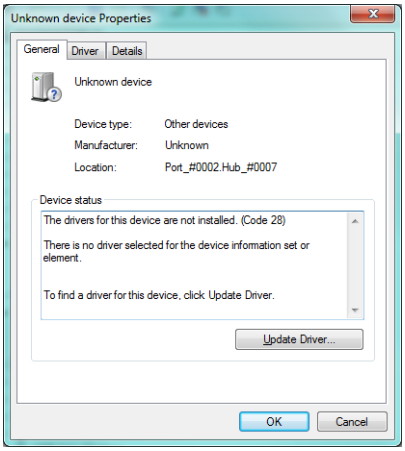
- Choose “Continue Anyway”, and the driver will finish loading, allowing you to communicate to the MabTec via the assigned Com Port.
- By opening Windows Device Manager and clicking on the + for Ports, you can determine the Com Port assigned to the MabTec. It will be listed as “USB SciExpert”. (COM8 as shown)



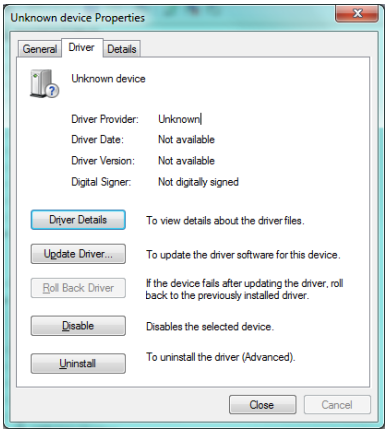
Windows 7 users often will not have the “New Hardware Wizard” run properly, and the driver will not be installed. When this occurs:

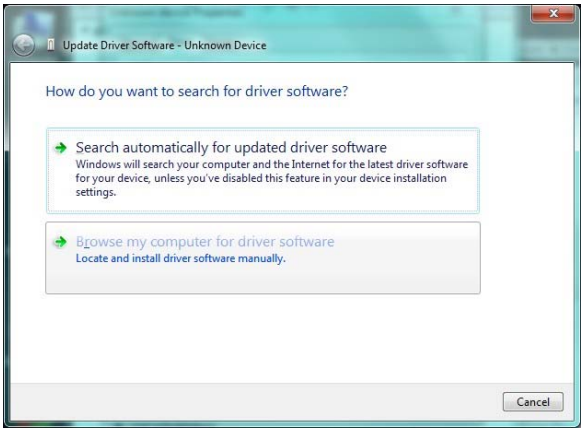
1. Open Device Manager and look under Other Devices for “Unknown Device” or similar and double-click on that device.



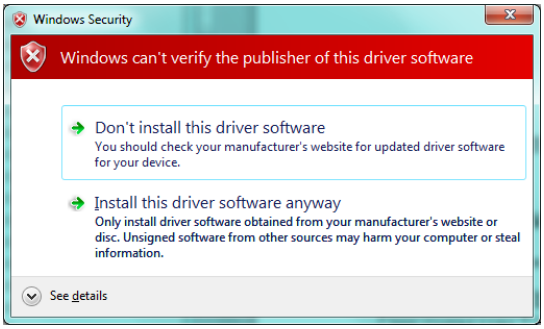


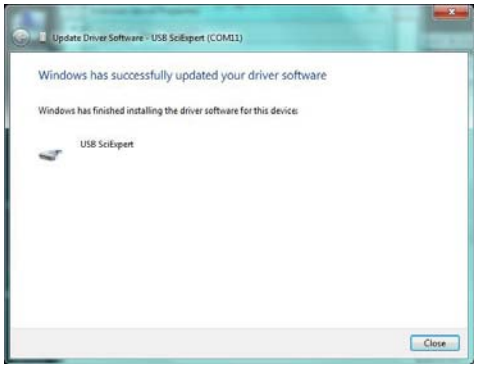
2. Click on “Update Driver” on that screen or on the Driver Tab. Click on “Browse my computer” on the next screen and browse to the CD drive that contains the MabTec Manual and click on OK.





3. As mentioned earlier you will get a security warning about windows verification for the driver. Click on Install anyway and the installation will finish properly.





- Please review Device Manager at completion of this process to confirm the COM port assigned to the MabTec, now listed under Ports as “USB SciExpert”.

Part A: MabTec™ Hardware:

Overview:

The MabTec is a laboratory-scale Perfusion Control system that enables you to control, optimize and document Bioreactors performing long time duration perfusion processes.

The MabTec is designed to handle as many as four different roles in the process.

- It can be used as the Perfusion pump, removing fluid from the permeate line at a programmable mass flow rate over many days.
- It can be used as the Re-Circulation pump, monitoring all four pressures, feed, retentate, permeate and TMP, and perform this in a time based reversible manner. This also is set to run for many days.
- It can be used in three different ways to be the long-term Feed pump for the system, utilizing one, two, or even three scale inputs for control and alarms.
- It can be used as a Seed Induction pump, adding measured amounts of seed material or anti-foaming agent on a periodic basis over many days for as many repeats as needed.

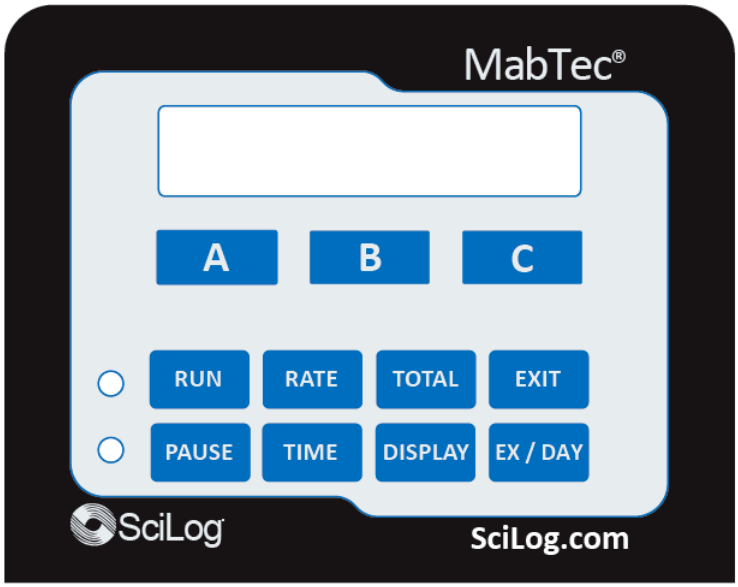
The MabTec system provides ease of use and operational safety: Several user definable alarm conditions can be continuously monitored and displayed.

The user programmable alarms include:

- **High Pressure Alarm** to monitor the inlet of the filter,
- **Low Pressure Alarm** to monitor the permeate pressure,
- **Permeate Hi Alarm** to monitor when it's time to change the permeate container.
- **Feed Lo Alarm** to alert the operator of a nearly empty feed vessel,
- **Run Time Alarm** that stops the pump action when a user defined process time has elapsed.
- **Bio Weight Bandwidth Alarm** to assure the weight of the Bioreactor does not get too high or too low.
- **Flow Rate Alarm** to alert the operator if the pump is unable to maintain the programmed mass flow rate.

All alarms provide an auditory signal; the pump stops when user defined alarm limits are exceeded. Alternatively, any alarm can be selectively disabled. All system processes, as well as alarm parameters can be printed out at user defined time intervals with a Parker serial printer. Alternatively, all of the collected data can be sent to a supervisory computer for data archiving.

2.0 Front Panel: Data Entry & Display:



The front panel consists of a user interface, which includes an alphanumeric display and a membrane keypad to select operational modes and alarm settings. The display is a two line, 20 character each, liquid crystal display (LCD). The display is backlit to allow easy viewing over a wide range of lighting conditions.

The lower line on the LCD is used to signify the function of the “soft keys” marked “A”, “B” and “C”. The “soft key” current labels are displayed in the lower line of the LCD. If you press these keys, then the function displayed above it will be performed.

RUN	Executes the selected operational mode and starts / re-starts the pump.
PAUSE	Interrupts current operational mode and stops the pump.
RATE	Sets the pump Rate.
TIME	Used to enter a TIME statement in Perfusion Mass Mode, Edit.
TOTAL	Sets motor direction, counter clockwise or clockwise in Manual Mode.
DISPLAY	Changes between alternate displays in all modes.
EXIT	Exits current operational mode or menu level, stops pump.
EX / DAY	Used for entering Exchanges/Day statements, and during Re-calibration.

Two LED’s are also on the front panel, just to the left of the main keypad. These indicate the current pump status. A green light indicated the pump is in motion; the red light indicated that the pump has stopped.

3.1 Back Panel: Interface Options

The MabTec back panel provides interfacing ports for:

- **Parker Printer (P/N: 080-095) or PC RS-232 connection:** Female DB9, labeled “Printer”.
- **Electronic Balances:** Male DB9, labeled “S1, S2, S3”.
- **Foot Switch (P/N: 080-059) or Analog Input:** Male DB37, Labeled “External I/O”.
- **SciPres Disposable Pressure Sensors:** 3 RJ11 telephone jacks, one for each pressure sensor. Labeled “P1, P2, P3”.
- **SciTemp Disposable Temperature Sensor:** Conxall 2 pin connector. Labeled “Temperature”.

3.2 **PRINTER PORT:** The MabTec can be connected to a PC for data collection or to a Parker Printer via the female DB9 RS-232 port labeled “Printer”. You need a Parker RS-232 cable (P/N 080-073) to connect to a PC for data archival. Alternatively, a USB cable (090-158) may be used. A printer cable (080-096) is required to make the connection between the Parker serial printer and the MabTec. As both are available, one may gather data in both methods simultaneously.

3.3 **SCALE PORTS:** The male DB9 ports labeled “S1”, “S2” and “S3” are RS-232 ports for electronic scales. This allows you to interface with several different Mettler-Toledo and Ohaus top-loading scales. It is highly recommended that these scales be purchased through Parker for proper configuration. They will ship as a tested system.

The following scale cables may be required:

- **Mettler:** PGS, PM, Viper, BBA422 Models: P/N: 080-067PGS
- **Ohaus:** Adventurer Pro Series: P/N: 080-067PGS

In the MabTec **Setup: Scale** mode, select the scale manufacturer; the MabTec will automatically implement the correct communications parameters. **Check that the proper communications parameters are also implemented in the scale being used.**

3.4 **PRESSURE SENSOR PORTS:** RJ11 Telephone jacks for the SciPres disposable Pressure Sensors, labeled “P1”, “P2”, and “P3”. The disposable pressure sensors plug into these jacks using the included cables.

3.5 **TEMPERATURE PROBE PORT:** The SciTemp disposable Temperature Senor connects to this port with a twist-lock connector cable. Temperature is measured in degrees Celsius.

3.6 **VALVE V PORT:** Not used in conjunction with the MabTec.

3.7 **USB PORT:** Used for connection to a PC, providing a Com Port. Can be used for data collection as an alternative to the Printer port. The driver is included on the CD that contains this manual.

3.8 **ETHERNET PORT:** Used for connection to the MabTec via a LAN. IP Address, Subnet Mask, and Gateway are configured in the Setup menu. The communication protocol is Modbus TCP/IP, and a list of registers is in the appendix of this manual. (When available.)

3.9 EXTERNAL I/O CONNECTOR: DB37 connector used to interface with various devices, allowing up to three 4-20 ma Analog inputs (A1, A2 & A3) for recording data or alarming based upon that data. It also allows an interface with Parker foot switch (P/N: 080-059) and allows remote Start / Stop control of the MabTec.

For pin configuration, consult the drawing on this page. The DB37 port at the back panel provides three analog input channels:

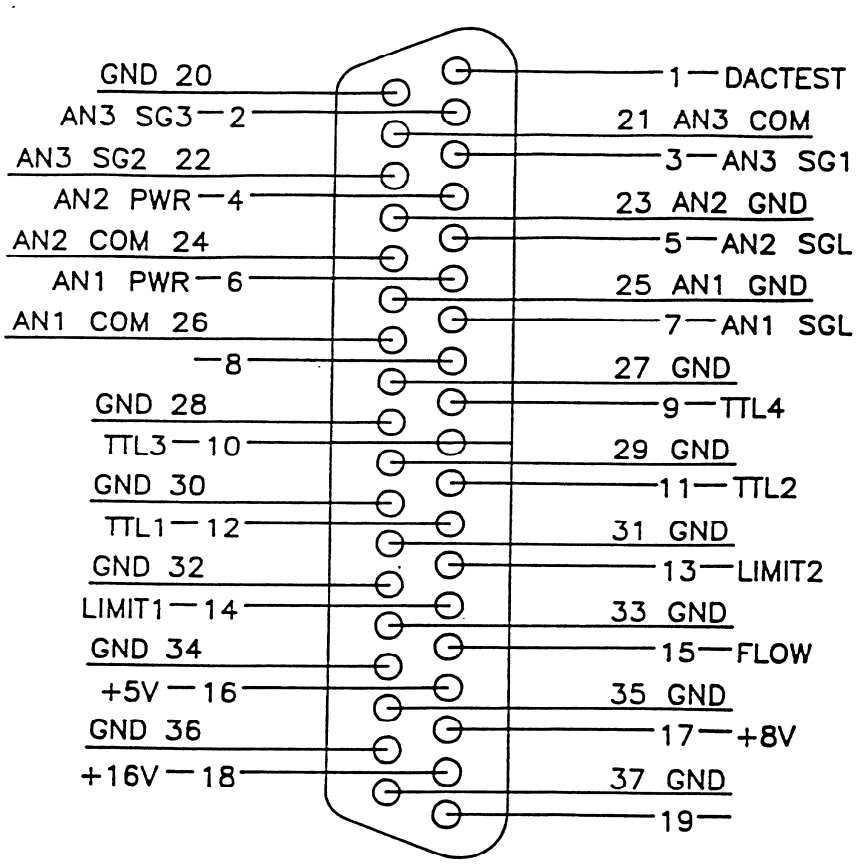
Analog channel 1 (pin 7 signal, pin 25 ground)

Analog channel 2 (pin 5 signal, pin 23 ground)

Analog channel 3 (pin 2 signal SG3, pin 21 common)

When a Footswitch or External Run / Stop Cable is desired, Pins 19 and 37 are used.

Pin out of DB37 External I/O Connector on Rear Panel:



4.1 TANDEM™ Dual Channel Pump Head:

The TANDEM peristaltic pump head is specifically designed for use with the MabTec system. The Parker TANDEM pump head will provide you with rugged reliability as long as common sense maintenance and good quality pump tubing are used. For filtration applications, you should be using either Platinum-Cured Silicone or PharMed pump tubing in the correct sizes.

The TANDEM pump head is driven by an 8, 160, or 600-RPM, high-torque motor. The pump motor is optically encoded and servo-controlled, thus the TANDEM pump head will maintain a constant output over a wide range of filtration conditions.

However, when the pump head requires excessive torque because of pump tube failure or "freezing" of the pump head, then the MabTec control software will recognize this condition and go into a stand-by mode, the pump motor is turned off and the following message is displayed:

CHECK PUMP HEAD
Press Any Key

Before continuing with your pumping application, remove the defective pump head / tubing and either clean or replace with a functional pump head. This feature (PumpSense™) has been implemented by Parker to protect your pump motor and electronics. **NOTE: There is nothing wrong with the MabTec controller when you see this display. The problem lies with the pump head and /or pump tubing you are using.**

When you "Press Any Key" to leave the stand-by mode, you will enter the Main Menu. After you check and replaced your pump head / tubing, you may re-initialize your application.

4.2 Pump Tubing / Rate Selection:

The approximate flow rate ranges associated with various pump tube sizes and motor speeds are shown in the table below:

Tubing Size	13	14	16	25	17	18	15	24	35
Silicone Part #	400-113	400-114	400-116	400-125	400-117	400-118	400-115	400-124	400-135
PharMed Part #	400-313	400-314	400-316	400-325	400-317	400-318	400-315	400-324	400-335
Pump Rate Range*	ml/min	ml/min	ml/min	ml/min	ml/min	ml/min	ml/min	ml/min	ml/min
CP-8 8RPM	0.03 - 0.45	0.1 -1.6	0.4-6.4	0.9 - 12.6	1.1 -18.3	1.7 - 24.3	0.4 – 13	0.6 – 20	0.8 - 32
CP-120 160RPM	0.5 - 10	1.7 - 35.2	6.3 - 129	12.5 - 283	18.5 - 405	24.7 - 554	9 – 260	13 – 435	16 – 650
CP-200 600RPM	2 - 34	8.6- 132	29 - 533	49 -974	70 - 1048	103 - 1515	59-993	85-1348	111- 2258
* Nominal Values									
Pump Head Model:	**TANDEM 1081**						**TANDEM 1082**		

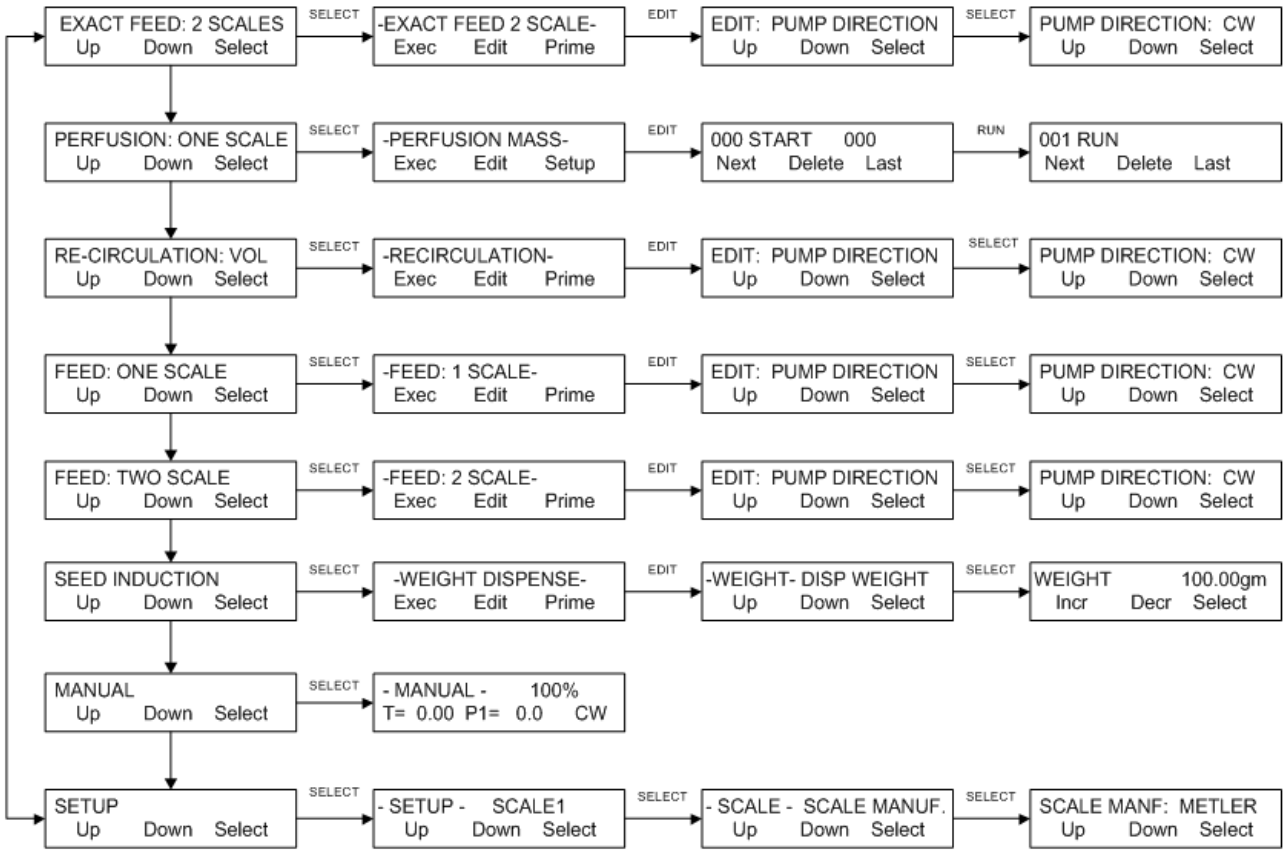
For perfusion applications, the selected MabTec pump rate should not fall below the minimum feed rate for your system. First select the appropriate pump tubing size from the table above. The minimum feed rate of your system should fall into the midrange for the selected pump tube size. For example, if your Minimum flow rate is 60 ml/min., then the appropriate pump tubing is #16 when using a 160-rpm motor. In general, avoid using pump tube sizes that force you to work at either the low or high pump rate extremes whenever possible.

The MabTec software contains permanent, factory installed calibration tables for each of the nine (9) pump tube sizes listed above. The calibration table relates the pump motor RPM to the pump output in terms of ml / minute. However, the MabTec can be recalibrated by utilizing the front panel star (*) key of the MabTec. These are used in Recirculation Mode, the scale inputs are used in both Feed Control and Perfusion Mass Flow Mode.

NOTE: The MabTec usually is configured with a 160-rpm motor, and the built-in calibration curves for that motor. If your flow rate needs require, the MabTec is also available with either a 600-rpm or 8-rpm motor. By accessing SETUP:PUMP:Motor RPM, from the front panel, you can select the RPM of the installed motor. The MabTec will then implement the factory installed calibration curves for that motor. This will have been done for you at the factory prior to testing and shipping.

Differences in pump tube formulation/manufacture, as well as pump tube wear over time may cause the MabTec pump output to change slightly. Thus for very high pump rate accuracy you may want to recalibrate the MabTec with your particular pump tubing in place. Recalibration of the MabTec is very easy and straightforward; please refer to the page on Re-calibration.

1.0 MAIN MENU


EXACT FEED: 2 SCALES
Up Down Select
SELECT
-EXACT FEED 2 SCALE-
Exec Edit Prime
EDIT
EDIT: PUMP DIRECTION
Up Down Select
SELECT
PUMP DIRECTION: CW
Up Down Select
PERFUSION: ONE SCALE
Up Down Select
SELECT
-PERFUSION MASS-
Exec Edit Setup
EDIT
000 START 000
Next Delete Last
RUN
001 RUN
Next Delete Last
RE-CIRCULATION: VOL
Up Down Select
SELECT
-RECIRCULATION-
Exec Edit Prime
EDIT
EDIT: PUMP DIRECTION
Up Down Select
SELECT
PUMP DIRECTION: CW
Up Down Select
FEED: ONE SCALE
Up Down Select
SELECT
-FEED: 1 SCALE-
Exec Edit Prime
EDIT
EDIT: PUMP DIRECTION
Up Down Select
SELECT
PUMP DIRECTION: CW
Up Down Select
FEED: TWO SCALE
Up Down Select
SELECT
-FEED: 2 SCALE-
Exec Edit Prime
EDIT
EDIT: PUMP DIRECTION
Up Down Select
SELECT
PUMP DIRECTION: CW
Up Down Select
SEED INDUCTION
Up Down Select
SELECT
-WEIGHT DISPENSE-
Exec Edit Prime
EDIT
-WEIGHT- DISP WEIGHT
Up Down Select
SELECT
WEIGHT 100.00gm
Incr Decr Select
MANUAL
Up Down Select
SELECT
- MANUAL - 100%
T= 0.00 P1= 0.0 CW
SETUP
Up Down Select
SELECT
- SETUP - SCALE1
Up Down Select
SELECT
- SCALE - SCALE MANUF.
Up Down Select
SELECT
SCALE MANF: METLER
Up Down Select

Part B MabTec Software:

1.1 Software Overview: Main Menu

The MabTec main menu consists of eight operational modes as shown on the previous page. Use "**Up**" and "**Down**" to scroll through the main menu. Press the "**Select**" to enter a chosen operational mode, i.e. Feed: One Scale. Pressing "Select" enters the 1st submenu level, which provides access to the "**Exec**", "**Edit**", and "**Prime**" or "**Setup**" functions. Press "Edit" to select the parameters for the process. Press "Exec" and the parameters chosen under "Edit" are executed. "Prime" runs the pump at full speed while the button is held down to 'prime' the system and remove the air bubbles when needed. Press "**Pause**" to stop the system and "**Exit**" to return to the previous menu.

Exact Feed: Two Scales:

Maintains bioreactor weight via addition of fresh media, accepts feedback from two balances (one under fresh media container, one under perfused media container) this feedback loop regulates flow from feed system to match the increase in weight in the perfused media container; the weight increase in the perfused media container is generated from any connected perfusion system extracting mass from a bioreactor. Feed 2 Scale system will alarm from weight limits; measured on scales. An optional scale under the bioreactor may be added to generate a bioreactor weight variance limit. Requires user input of:

- Lower weight limit for fresh media container scale.
- Upper weight limit for perfused media container scale.
- Optional Bioreactor balance requires input of bioreactor δW (+/- weight differential)
- Optional Run Time Alarm

This mode provides automatic feeding of a bioreactor. The main scale is located under the harvest vessel to monitor the perfused weight and its collection rate. The second scale is located under the feed vessel to monitor the fed media. The system uses this data to maintain a constant weight in the bioreactor. Additionally, if desired, a scale input for the bioreactor may be used in conjunction with a bandwidth setting provide additional control. Appropriate alarms and limits are provided.

Perfusion: One Scale:

Perfusion system automates waste and spent media removal through filter or membrane. The integrated scale perfusion unit can pause both itself and a connected feed system at a preset weight limit on perfused media scale. The programmed perfusion strategy can mimic the optimized exchange required to optimize ultra-high density cell concentration.

Requires input of:

- Approximate Mass of bioreactor.
- Upper weight limit for perfused media scale.
- Stepwise programming logic containing incubation periods, gravimetric pump rate and or a number of exchanges/day, and an amount of time for the system to remain on the current step.
- High /Low Pressure Alarms

This mode provides time programmable control of the perfusion or harvest rate via mass flow. A scale is placed under the collection vessel, and a program is implemented controlling the rate in gm./min. or exchanges/day. Rates are changeable in a stepwise manner for times programmed in days: hours: minutes. Output from this scale is often shared with the Feed Control system. Appropriate alarms and limits are provided.

Re-Circulation: Vol:

Recirculation system is designed for generation of tangential flow and continuous recirculation of media to ensure consistent mixing and provides a stream of media to be perfused using any attached perfusion system. An automated flow reversal strategy prevents membrane fouling and provides a driver for gentle low shear flow.

Requires user input of:

- Recirculation volumetric pump rate
- Desired frequency of flow reversal
- Duration of flow reversal
- Volumetric reversal recirculation rate
- P1 High Pressure Alarm
- P3 Low Pressure alarm

This mode provides bi-directional flow control of the TFF process through the filter (hollow fiber is typical) while monitoring all three pressures and the trans-membrane pressure. Time for forward and reverse flow control is set and automatically repeated. Appropriate alarms and limits are provided.

Feed: One Scale:

Feed system with one balance under bioreactor to maintain weight in bioreactor. Accurately measures ΔW in bioreactor and refills lost mass. Feed system maintains bioreactor within a tolerance and alarms if system variance becomes too great.

Required User Input:

- Dead band for Bioreactor ΔW alarm.
- Feed Volume alarm.

The Feed: One Scale mode uses the MabTec as the feed pump for the Bioreactor. The Bioreactor is placed on the scale, and feedback from the scale is provided to the pump. As the weight of the Bioreactor reduces, additional media is added to maintain the weight. If this weight change is reasonably constant, the MabTec will match the flow rate. Appropriate alarms and limits are provided.

Feed: Two Scale:

Feed system with one balance under bioreactor to maintain weight in bioreactor and one balance under the feed container to monitor available feed media. Accurately measures ΔW (change in weight) in the bioreactor and refills lost mass. Feed system maintains bioreactor within a tolerance and alarms if system variance becomes too great.

Required user input:

- Dead band for Bioreactor ΔW alarm.
- Feed Volume alarm.
- Lower Feed Weight limit for fresh media container scale.

The Feed: Two Scale mode uses the MabTec as the feed pump for the Bioreactor. The Bioreactor is placed on one scale, and feedback from the scale is provided to the pump. As the weight of the Bioreactor reduces, additional media is added to maintain the weight. If this weight change is reasonably constant, the MabTec will match the flow rate. The Feed vessel is placed on a second scale. This provides a Feed Weight Low alarm that alerts the operator and pauses the process when the weight of the feed vessel is low. Appropriate alarms and limits are provided.

Seed Induction:

Seed/Induction system is designed for time delayed, precise, and repeatable dispensing of cells/organisms, media, nutrients, or chemicals by weight.

Required inputs:

- Mass to dispense
- Time Delay
- Number of repeats
- Low Weight on Feed Scale

The Seed Induction mode allows the MabTec to add a set weight of solution to the Bioreactor at repeatable user defined intervals. A scale is required for this mode. The intervals may be hours or even days apart, and provision is made for “bolus” additions in between the set time intervals. Appropriate alarms and limits are provided.

Setup: This operational mode allows selection of various user preferences and interface options.

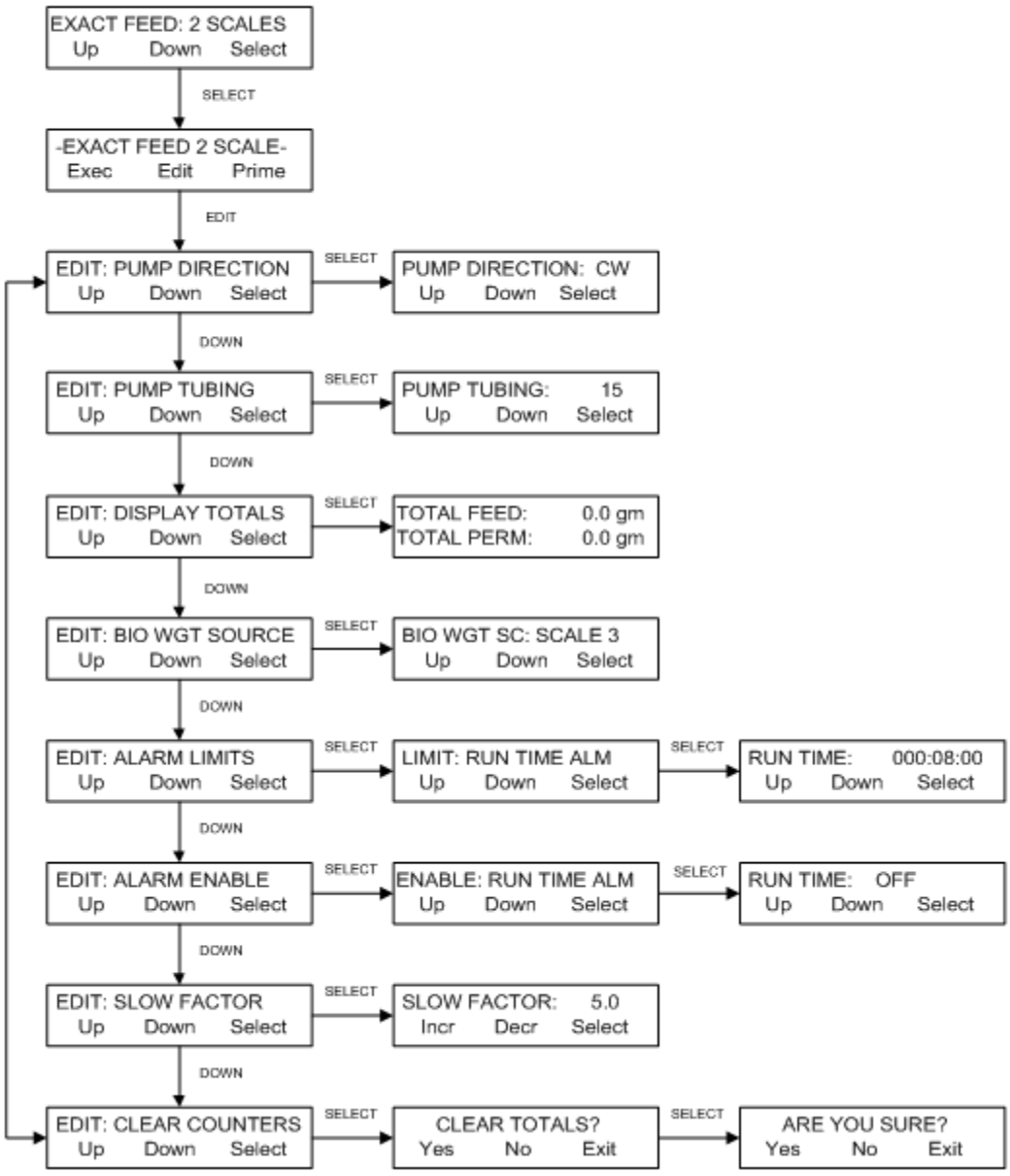
- **Scale** sub menu provides electronic balance options. Balances that can interface with the MabTec must have bi-directional serial communication, and NOT have internal calibration or be “delta-range” models that change readability on the fly. Many Mettler and Ohaus scales are available.
- **Clock** sub menu allows setting of the time and date used in the display.
- **System Test** sub menu allows checkout of MabTec outputs and inputs and requires purchase of a special test fixture.

  Test Mode allows testing of these same inputs and outputs independently.
- **Printer sub** menu is used for setting up the printer / pc communications parameters as well as print time interval and the print delay.
- **Analog** is used to set the upper and lower ranges for the analog inputs.
- **Temperature Offset** is used to offset the temperature measured by the available in-line probe.
- **Pressure Sensor** is used to zero the three pressure sensors, set the units (psi, bar, kpa), and choose the source for control and the main display.
- **Pump** allows you to set various pump user preferences, most importantly the Motor RPM.
- **Modes Visible** allows all modes except Manual and Setup to be hidden. This provides additional safety by avoiding use of the improper mode for a specific process.

Manual: Allows manual control of pump speed and direction. Alarms and data output are not functional in the Manual mode.

2.0 EXACT FEED: 2 SCALES

Edit Menu



2.1 Exact Feed: 2 Scales Mode:

SUMMARY: Exact Feed: 2 Scales: This mode provides automatic feeding of a bioreactor to maintain a constant weight in the bioreactor. The system utilizes two scales. The main scale is located under the harvest vessel to monitor the perfused weight and its collection rate (S1). The second scale is located under the feed vessel to monitor the weight of fed media (S2). The system uses this data to maintain a constant weight in the bioreactor. Additionally, if available, a scale input for the bioreactor may be used in conjunction with a bandwidth setting to alarm and stop the process when the bandwidth is exceeded. Appropriate alarms and limits are provided.

When executed, operator may press “Pause” to change the Permeate Vessel, and then “Run” to continue. Press “Pause” and “Exit” to leave the mode entirely.

NOTE: Use “**Up**” and “**Down**” keys to make a selection, then press “**Select**” to implement that selection.

The Permeate Scale must be connected to S1, and the Feed Scale to S2. The Manuf. setting must be selected properly in Setup: Scale 1 and Scale 2.

Edit Sub Menu:

PUMP DIRECTION: Select CW, Clockwise, or CCW, Counterclockwise.

DISPLAY TOTALS: Displays the current Total Feed and Total Permeate values. This allows confirmation of the “Clear Counters” action.

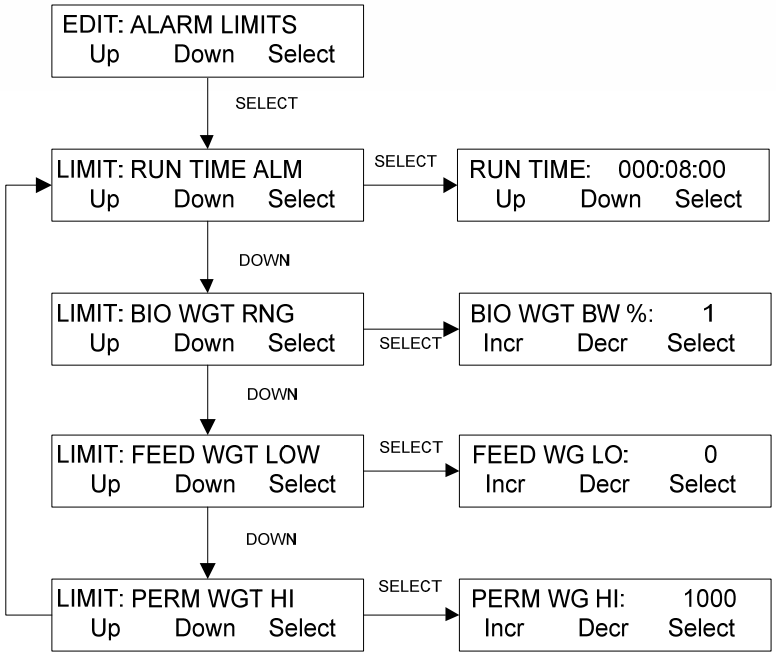
BIO WGT SOUCRE: Enter the source of the Bioreactor Weight. Choose Scale 3 or Analog 1. Scale 3 communication must be RS-232 with appropriate Scale Manuf. Setting in Setup: Scale 3. Analog 1 is available for a 4-20 ma scale output of a Wave Bioreactor if available.

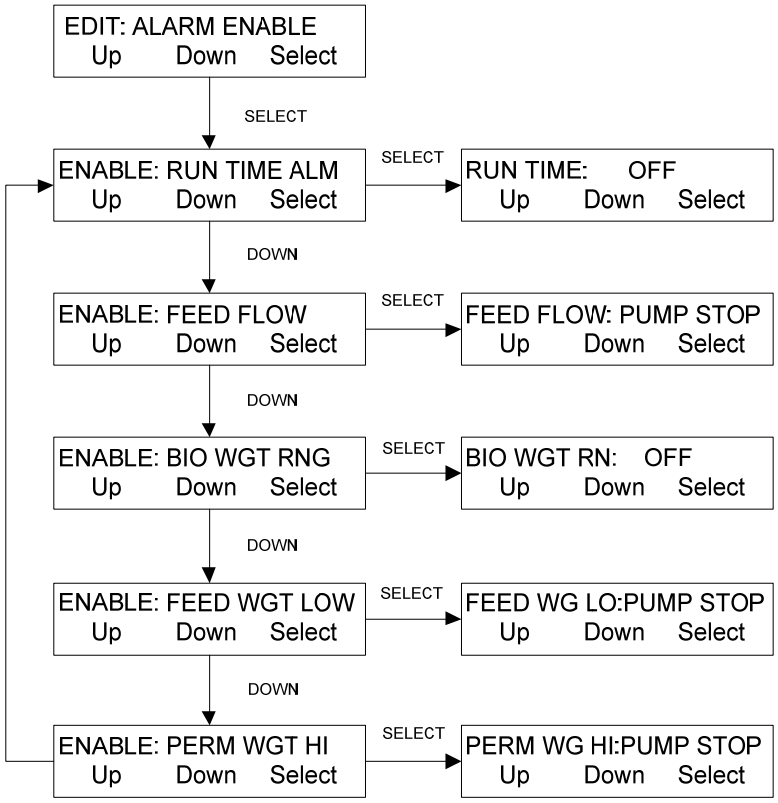
ALARM LIMITS: Limits related to Alarms, see the next section.

ALARM ENABLE: See Alarm Menu in the next section. This allows selection of alarm options. Three options are available: 1. Disable the Alarm (Off); 2. Enable an auditory alarm (Alarm Only); or 3. Stop the pump and provide an auditory alarm (Pump Stop). The alarms are triggered when user defined alarm limits are exceeded.

SLOW FACTOR: Controls the response to change of flow rate when the Permeate weight changes.

CLEAR COUNTERS: Clears all cumulative values. Select Yes or No when prompted.


EDIT: ALARM LIMITS
Up Down Select
SELECT
LIMIT: RUN TIME ALM
Up Down Select
SELECT
RUN TIME: 000:08:00
Up Down Select
DOWN
LIMIT: BIO WGT RNG
Up Down Select
SELECT
BIO WGT BW %: 1
Incr Decr Select
DOWN
LIMIT: FEED WGT LOW
Up Down Select
SELECT
FEED WG LO: 0
Incr Decr Select
DOWN
LIMIT: PERM WGT HI
Up Down Select
SELECT
PERM WG HI: 1000
Incr Decr Select


EDIT: ALARM ENABLE
Up Down Select
SELECT
ENABLE: RUN TIME ALM
Up Down Select
SELECT
RUN TIME: OFF
Up Down Select
DOWN
ENABLE: FEED FLOW
Up Down Select
SELECT
FEED FLOW: PUMP STOP
Up Down Select
DOWN
ENABLE: BIO WGT RNG
Up Down Select
SELECT
BIO WGT RN: OFF
Up Down Select
DOWN
ENABLE: FEED WGT LOW
Up Down Select
SELECT
FEED WG LO:PUMP STOP
Up Down Select
DOWN
ENABLE: PERM WGT HI
Up Down Select
SELECT
PERM WG HI:PUMP STOP
Up Down Select

2.1 Exact Feed: 2 Scales Mode: Alarm Limits / Alarm Enable

SUMMARY: This section allows the assignment of limiting values for several alarm conditions: **Run Time** in Days: Hours: Minutes; **Bio Wgt RNG** (Bioreactor Weight Range or Bandwidth) in %; **Feed Wgt Low** (Feed Weight Low) in grams; **Perm Wgt Hi** (Permeate Weight High) in grams.

NOTE: The alarm condition is triggered when the alarm limit is exceeded. Alarms are not mutually exclusive. Any combination of alarms may be selected. For critical alarms the MabTec should stop (**Pump Stop**), for less critical alarm conditions choose an auditory alarm (**Alarm Only**). Each alarm may be disabled (**Off**) if not required.

NOTE: Use "Up" and "Down" keys to make a selection, then press "Select" to implement that selection.

Limits:

Run Time: This alarm setting allows the setting of a timer for the process. For example, if the Run Time Alarm is set to 20:01:30, then the MabTec will provide an auditory alarm and / or stop the pump after twenty (20) days, one (1) hour and thirty (30) minutes have passed. This allows control of the processing time.

Bio Wgt RNG: This setting represents the % range, bandwidth or "dead band" around the captured bioreactor weight. Values outside the bandwidth can cause the process to stop based upon the Bio Wgt Rng Enable setting, see below.

Feed Wgt Low: This setting is set to Stop or Alert that the Feed Scale is nearly out of solution. Upon occurrence, change the vessel and press "RUN" to continue. This is usually a critical alarm and should be set to Pump Stop.

Perm Wgt Hi: This setting is set to Stop or Alert that the Permeate Scale is nearing the capacity of the vessel. Upon occurrence, change the vessel and press "RUN" to continue. This is a critical alarm. Pump Stop is recommended.

Alarms:

Run Time Alarm: Set to Off, Alarm Only or Pump Stop, See Run Time Limit above.

Feed Flow Alarm: Triggered when system is unable to maintain the flow rate needed to maintain the Bioreactor weight. (Pump can't go fast enough) Set to Off, Alarm Only or Pump Stop.

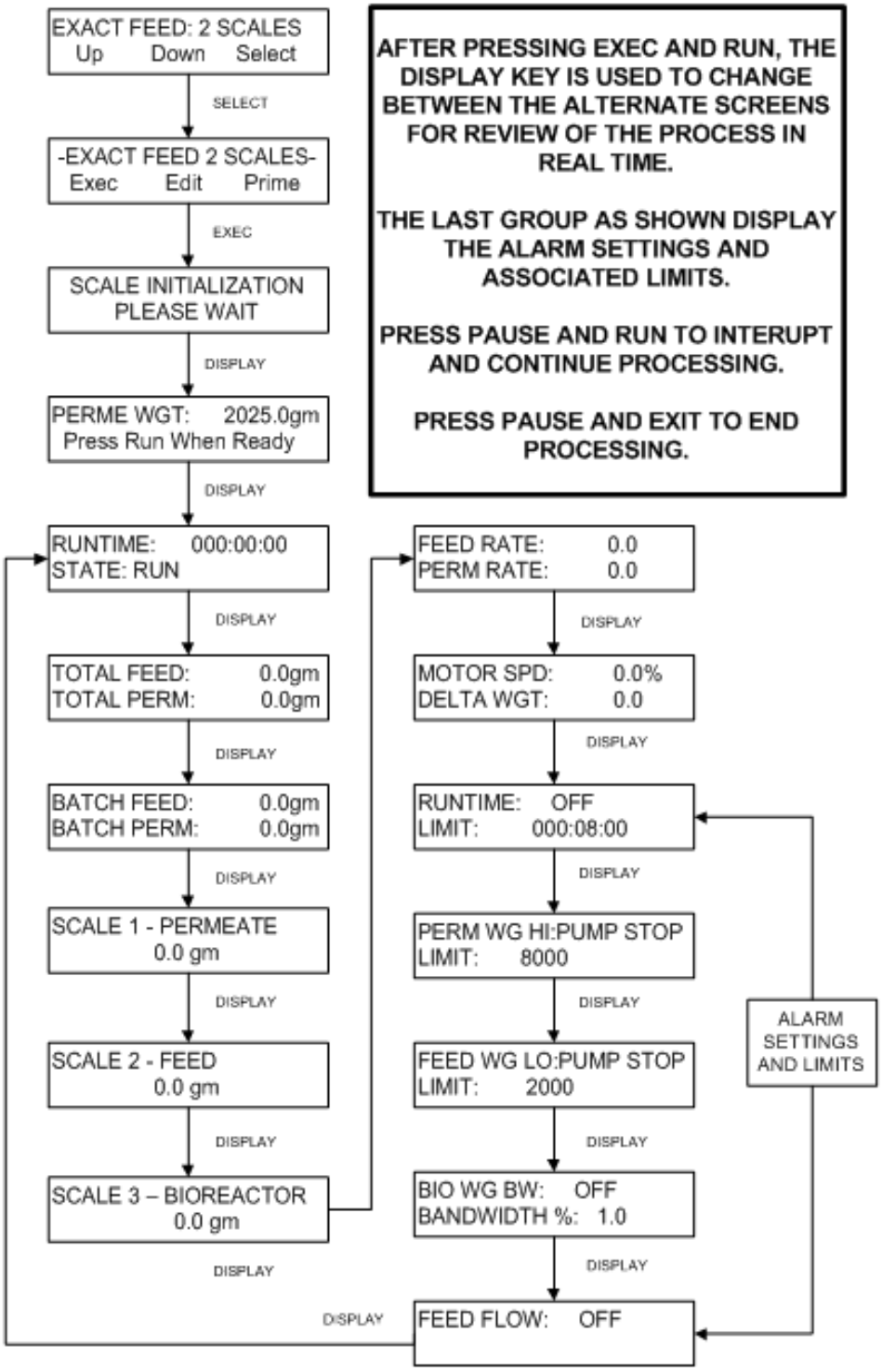
Bio Wgt Rng: (Bioreactor Weight Range) When enabled, the bioreactor weight captured at start up and the bandwidth are used to Alarm or Stop the pump if the Bandwidth set is exceeded.

Feed Wgt Low: Set to Off, Alarm Only or Pump Stop, See related Limit above.

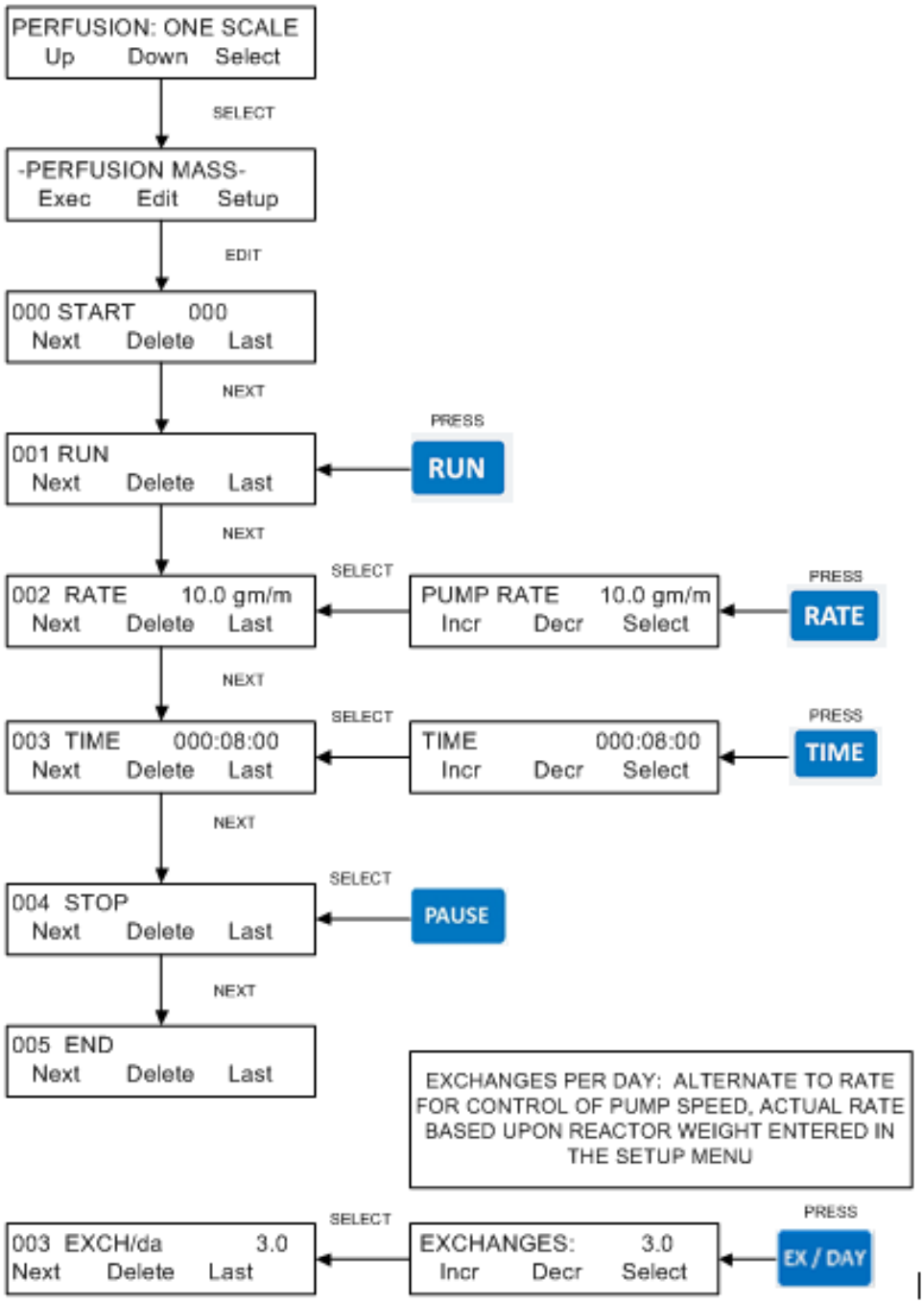
Perm Wgt Hi: Set to Off, Alarm Only or Pump Stop, See related Limit above.

2.2 EXACT FEED: 2 SCALES

Execute Menu



3.0 Perfusion: One Scale: EDIT



3.0 Perfusion: One Scale: How to generate a program.

SUMMARY: In the Perfusion: One Scale Mode, the MabTec meters solution from the output of the Bioreactor TFF loop gravimetrically, i.e. by weight. The permeate reservoir is positioned on an electronic scale (S1). By continually monitoring the scale output, the MabTec adjusts the pump speed to maintain a desired mass flow rate. If the selected mass flow rate cannot be maintained during a 60 second interval, e.g. the bioreactor has run empty, the MabTec will alert the user with an auditory signal and stop the pump, provided the Perfusion Flo Alarm is enabled. (See Setup in next section)

The flow rate may be changed in a stepwise manner by entering another RATE or EXCH/DA and TIME statement.

At any time during the process the PAUSE key may be pressed to change vessels on the permeate scale. Press RUN to continue from the point the process was paused.

When executing the Perfusion Mass Mode, the MabTec will display "**SCALE INITIALIZATION // Please Wait**". If balance communication fails, the ChemTec will display "**SCALE ERROR // Hit any key**". Check the cable connection as well as the communications parameters in the scale. Also make sure the correct manufacturer in the Setup: Scale submenu has been selected.

When generating or editing a Perfusion Mass program, all program statements that are to be implemented during a specific timing block or interval **must precede the TIME statement for that program block**. For example, on the opposite page, the statement: 001 RUN, 002 RATE, are all implemented at the beginning of the first timing block defined by statement 003 TIME: 000:08:00 (eight hours).

RUN: This statement is implemented by pressing the key labeled "RUN", it instructs the MabTec to turn on the pump motor.

RATE, Pump Rate: Press "RATE" key then select the desired mass flow rate, make sure that the selected mass flow rate does not exceed the capacity of the installed pump head /motor combination.

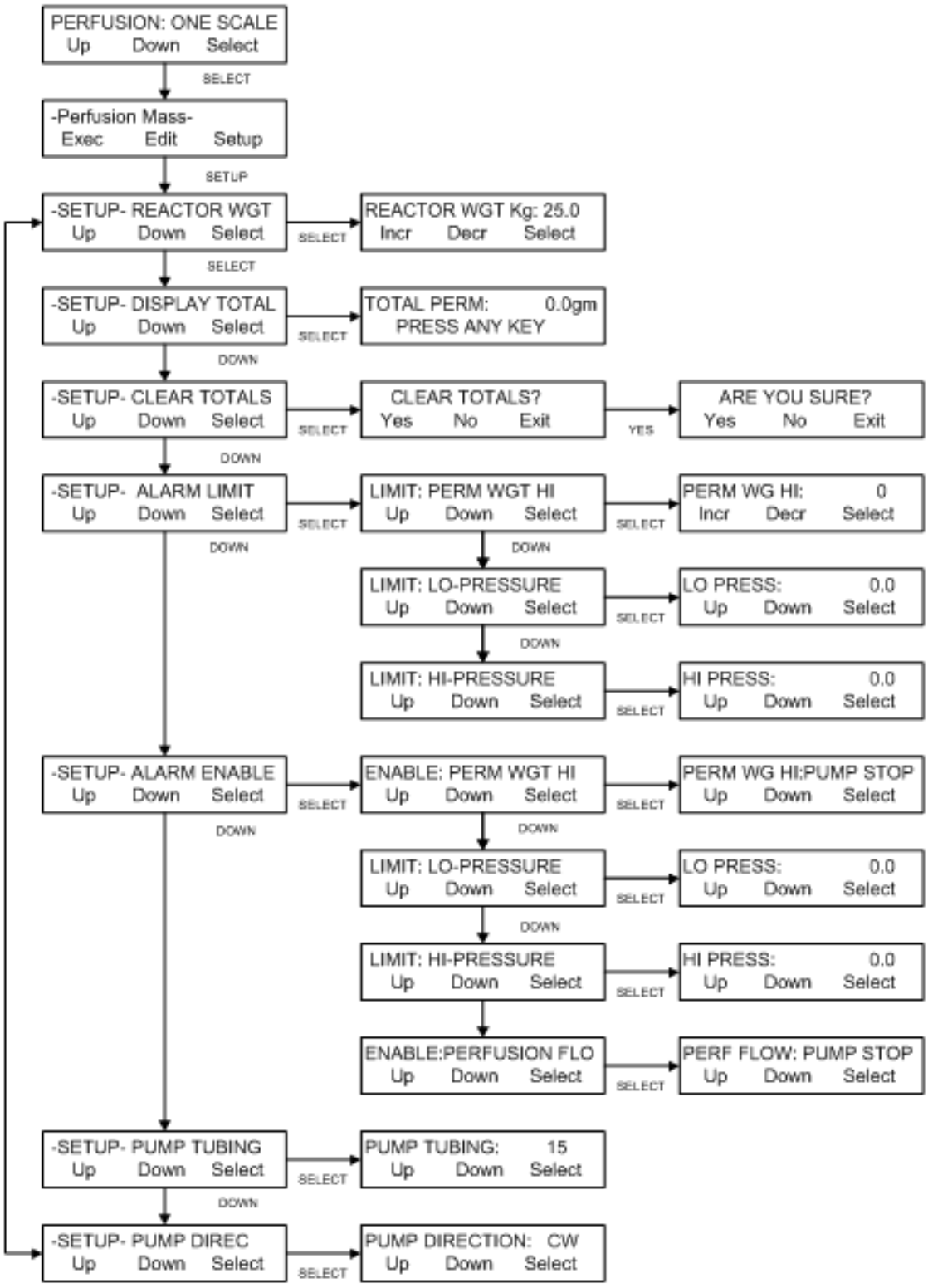
TIME, Timing Interval: Press "TIME" key, then select the desired time interval in Days: Hours: Minutes. All preceding program statements are implemented at the beginning of this TIME statement. Max Time is 365 Days: 59 hours: 59 minutes.

STOP: This statement is implemented by pressing the "PAUSE" key. It tells the MabTec to stop the pump motor

EXCH/da: As an alternate to the RATE statement, Exchanges / Day may be used. Actual flow rate used is based upon Reactor Weight value entered in the Setup sub Menu. Press the "DISPLAY" key to implement this statement.

3.1 Perfusion: One Scale

Setup Menu



3.1 Perfusion: One Scale: Setup Menu

SUMMARY: This menu allows setting limiting values for several different alarm conditions: **Permeate Weight Hi** in grams, Hi Pressure and Lo Pressure in psi, and **Perfusion Flow Rate**.

NOTE: The alarm condition is triggered when the alarm limit is exceeded. Alarms are not mutually exclusive. Any combination of alarms may be selected. For critical alarms set the pump to stop (**Pump Stop**), for less critical alarm conditions an auditory alarm (**Alarm Only**) can be chosen.

Setup also provides for setting of the starting Reactor Weight, the Tubing used, and the Direction of the pump.

REACTOR WEIGHT: Enter the starting Reactor Weight in kilograms. This value is used for the Exchanges/Day calculations. Default = 25.0, Max = 50.0 kg.

CLEAR TOTALS: Use to clear all cumulative values, Run Time, Permeate Weight, etc. Press Select and answer the “Are you sure?” question.

PERMEATE WEIGHT HI: This setting allows the setting of a high limit for the Permeate weight, so that the capacity of the scale is not exceeded. Set this value below the capacity of the scale, and set the Enable to “Pump Stop”. This will pause the process and allow changing of the container for an empty one to continue the process. Press “Run” on the pump to continue the process. It will continue from the point at which it paused.

LO-PRESSURE: This alarm is triggered when the pressure measured at P1 drops below the limit after first exceeding it. This will keep the process from damaging the filter if the sensor is on the permeate output of the filter.

HI-PRESSURE: This alarm is triggered when the pressure measured at P1 exceeds the limit.

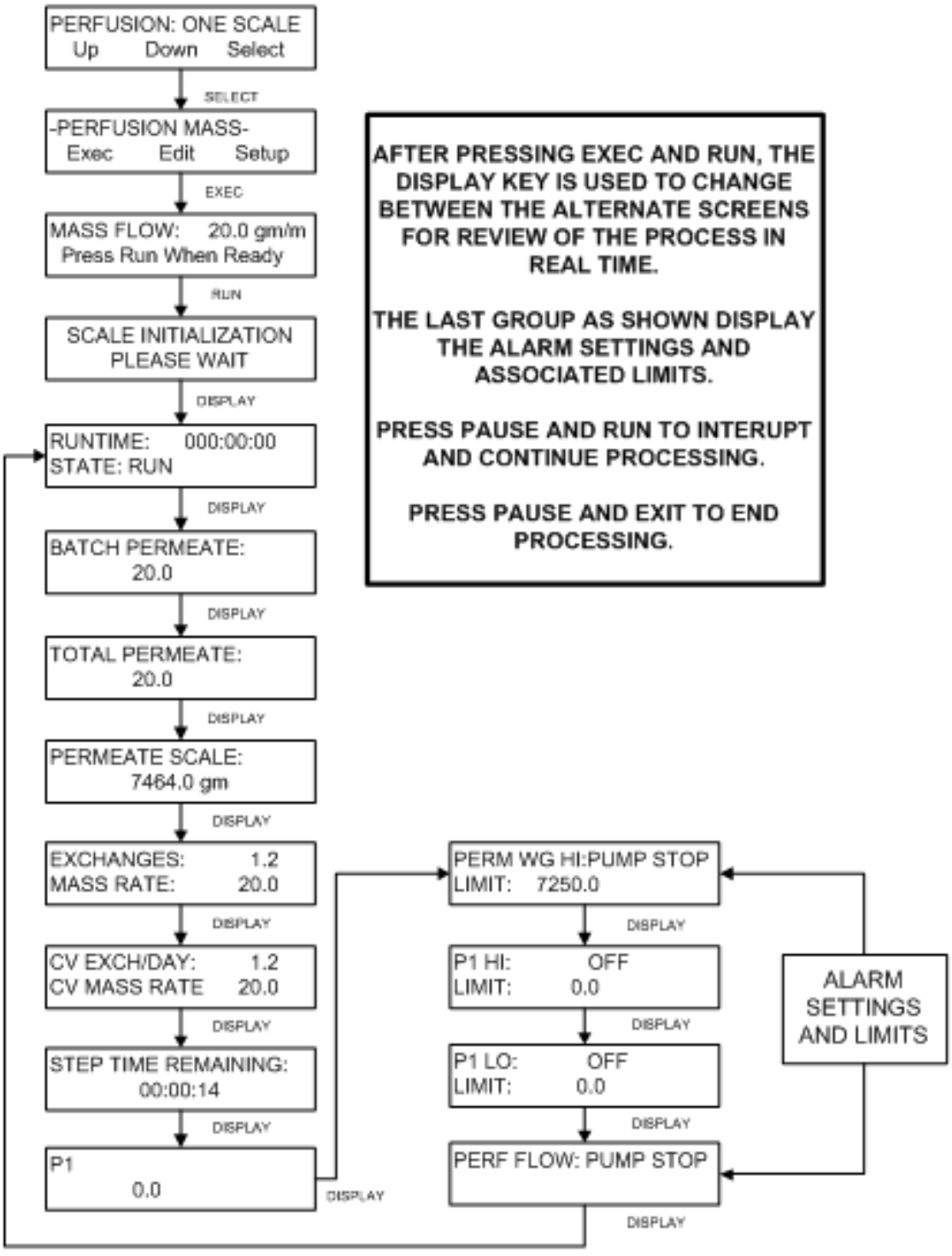
PERFUSION FLOW RATE: This alarm has no related limit. It is triggered by the pump ramping to 100% and being unable to maintain the programmed rate based upon scale feedback. This may occur if the Bioreactor has run dry, the tubing/motor combination is too small, or the tubing has sprung a leak. This is a critical alarm and should be set to “Pump Stop”.

PUMP TUBING: Set this to the Masterflex size of the tubing in use. Sizes available are 13, 14, 16, 25, 17, 18 for thin walled tubing, and 15, 24, and 35 for thick walled tubing.

PUMP DIRECTION: This is used to set the direction of the pump head for this mode. Select between CW (clockwise) and CCW (counter-clockwise). It cannot be changed on the fly or in the program.

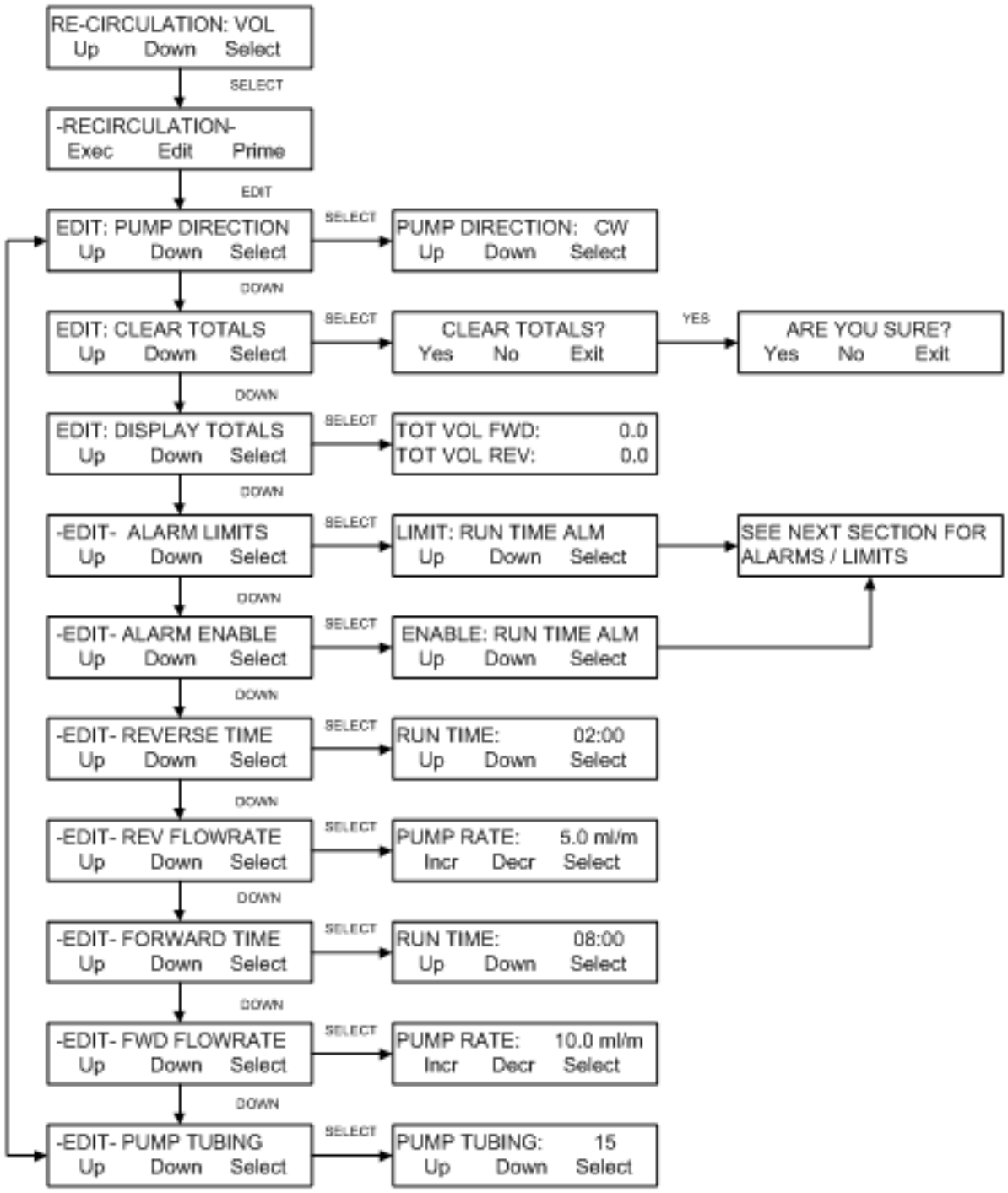
3.2 PERFUSION: ONE SCALE

Execute Menu



4.0 RE-CIRCULATION: VOL

Edit Menu



4.0 Re-Circulation: Vol: Edit Menu

SUMMARY: The Re-Circulation: Vol mode uses the MabTec as the TFF Re- Circulation pump for the Bioreactor. Hollow fiber filters are the most common for this application, and many processes require the flow to be reversed periodically. The settings in this mode allow for a Forward direction to be chosen, along with a flow rate and time. A Reverse flow rate and time is also available, and the unit will automatically reverse at the time intervals chosen. The reverse flow rate is typically much slower than the forward flow rate, and both must lie in the available range based upon the installed motor rpm and tubing size in use. Appropriate alarms are provided, and process sensor data displayed. SciPres Sensors are utilized to monitor Feed (P1), Retentate (P2) and Permeate (P3) pressures at the filter.

Use “Up” and “Down” keys to make a selection, then press “Select” to implement that selection.

PUMP DIRECTION: This is used to set the forward direction of the pump head for this mode. Select between CW (clockwise) and CCW (counter-clockwise).

CLEAR TOTALS: Select and choose YES to clear all cumulative values.

DISPLAY TOTALS: Select to display the total volume recirculated in both directions. This is based upon the built-in calibration curves.

ALARM LIMITS: A short list of Alarm Limits is available. See the menu in the next section.

ALARM ENABLE: A short list of Alarms is available and listed in the next section. Enable settings are: OFF (Disabled), Alarm Only (MabTec beeps and keeps going), or Pump Stop (Beep and the MabTec stops).

REVERSE TIME: Set the amount of time (hh:mm) the MabTec should run in Reverse before going forward again. The MabTec will always start in the assigned Forward direction.

REVERSE FLOW RATE: Set the Reverse Flow Rate in ml/min. The flow rate range is dependent upon the Motor RPM setting and the Pump Tubing chosen.

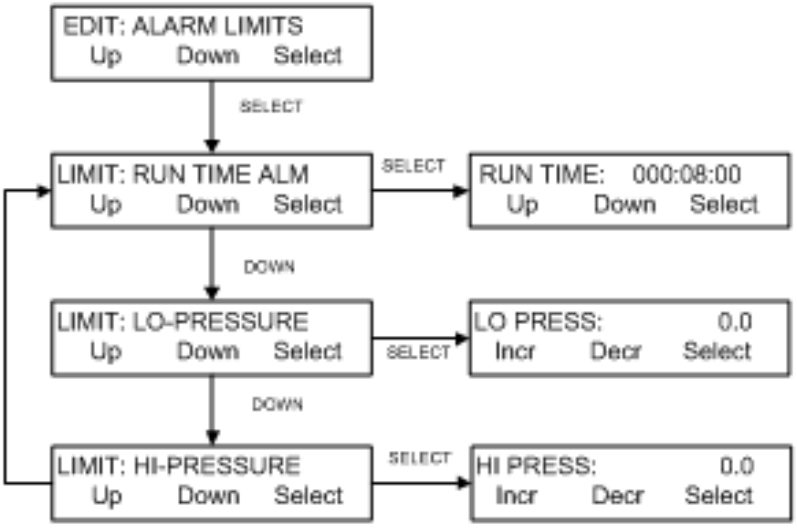
FORWARD TIME: Set the amount of time (hh:mm) the MabTec should run Forward before going in Reverse again. The MabTec will always start in the assigned Forward direction.

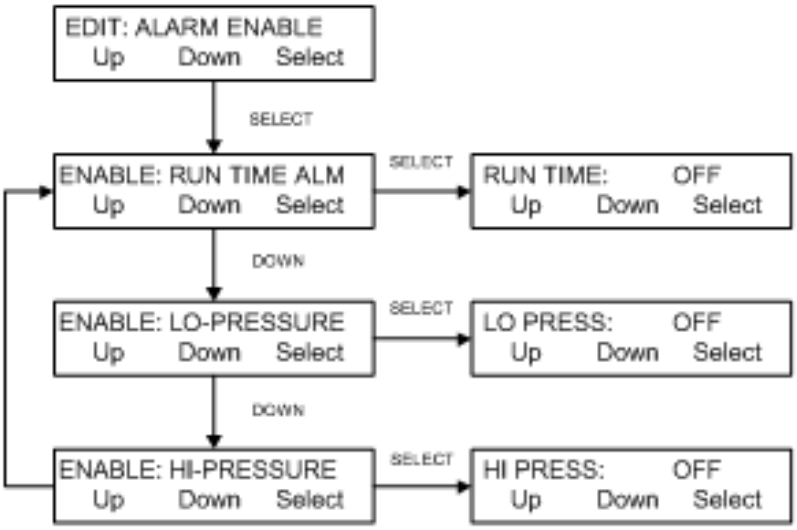
FORWARD FLOW RATE: Set the Forward Flow Rate in ml/min. The flow rate range is dependent upon the Motor RPM setting and the Pump Tubing chosen.

PUMP TUBING: Set this to the Masterflex size of the tubing in use. Sizes available are 13, 14, 16, 25, 17, 18 for thin walled tubing, and 15, 24, and 35 for thick walled tubing.

4.1 Re-Circulation: Vol

Alarm Limits / Alarm Enable Menus:





4.1 Re-Circulation: Vol Mode: Alarm Limit / Alarm Enable Menu:

SUMMARY: This section allows the assignment of limiting values for several alarm conditions: **Run Time** in Days: Hours: Minutes; **Low Pressure** in psi. and **High Pressure** in psi.

NOTE: The alarm condition is triggered when the alarm limit is exceeded except for Low Pressure. The Low Pressure limit must first be exceeded and trips as the pressure drops past the limit.

Alarms are not mutually exclusive. Any combination of alarms may be selected. For critical alarms the MabTec should stop (**Pump Stop**), for less critical alarm conditions choose an auditory alarm (**Alarm Only**). Each alarm may be disabled (**Off**) if not required.

NOTE: Use "**Up**" and "**Down**" keys to make a selection, then press "**Select**" to implement that selection.

Limits:

Run Time: This alarm setting allows the setting of a timer for the process. For example, if the Run Time Alarm is set to 20:01:30, then the MabTec will provide an auditory alarm and / or stop the pump after twenty (20) days, one (1) hour and thirty (30) minutes have passed. This allows control of the processing time.

Lo-Pressure: This setting is used to monitor Permeate pressure (P3) in the system alerting the operator to potential damage to the filter. Default = 0.0, Min = -5.0, Max = 60.0

High-Pressure: This setting is set to trigger on based upon excessive Feed pressure as measured by P1. Default = 0.0, Normal range = 20-30, Max = 60.0

Alarms:

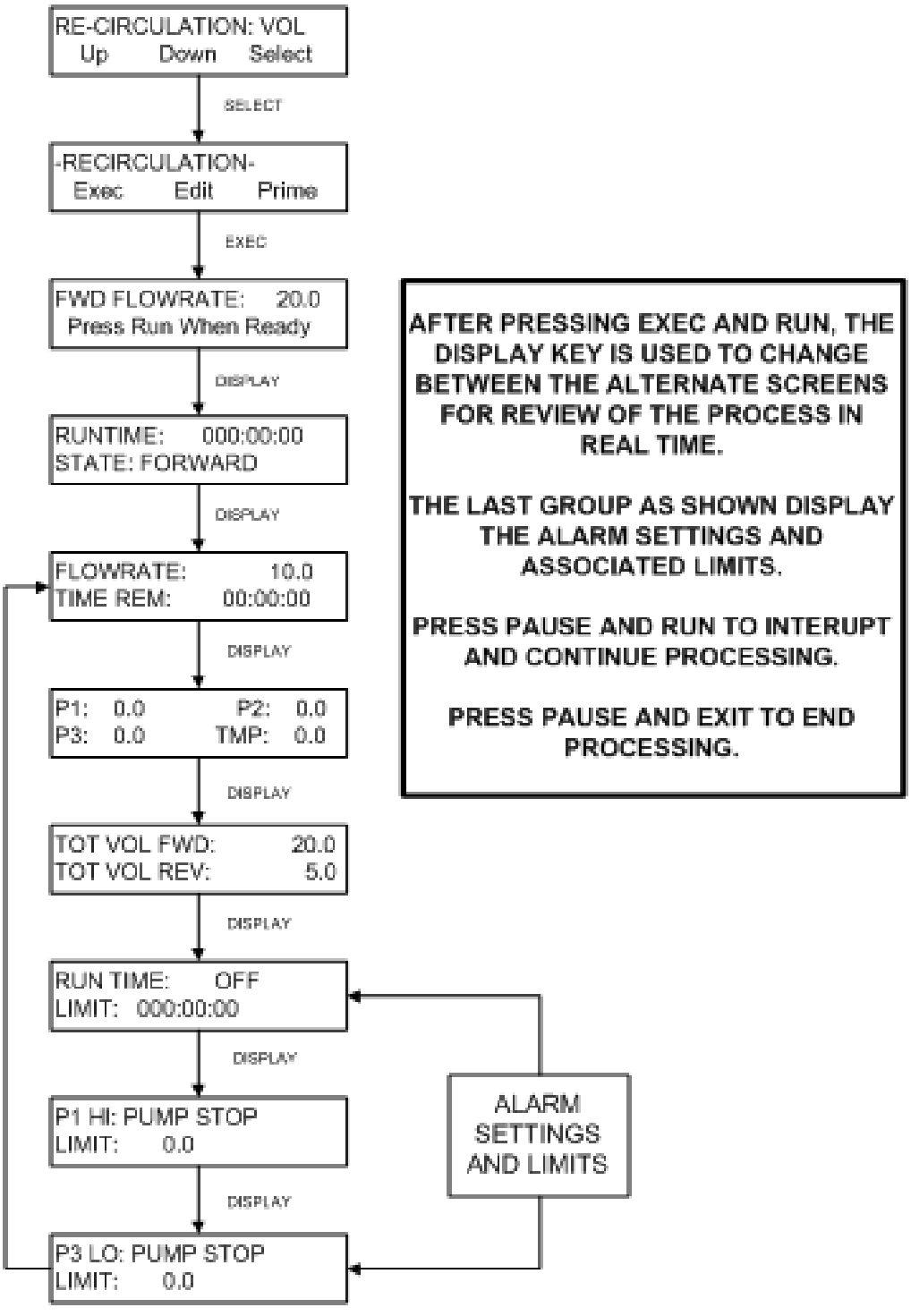
Run Time Alarm: Set to Off, Alarm Only or Pump Stop, See Run Time Limit above. Default = Off.

Lo-Pressure Alarm: Set to Off, Alarm Only or Pump Stop, See related Limit above. Default = Off.

Hi-Pressure Alarm: Set to Off, Alarm Only or Pump Stop, See related Limit above. Default = Off.

4.2 RE-CIRCULATION: VOL

Execute Menu



4.3 Pump Volumetric Re-calibration:

The MabTec software contains a permanent calibration table for each of the nine (9) tubing sizes: 13, 14, 16, 25, 17, 18, 15, 24 & 35. For a given pump tube size, the calibration table relates the pump motor RPM with the pump output in terms of ml / minute. However, the user can update the MabTec pump calibration very easily.

NOTE: The MabTec usually is configured with a 160-rpm motor, and the built-in calibration curves for that motor. If your flow rate needs require, the MabTec is also available with either a 600-rpm or 8-rpm motor. In order for the MabTec to properly display the correct flow rates and cumulative volume when using these motors, access SETUP: PUMP: Motor RPM and select the appropriate RPM for the installed motor. The MabTec will then implement the factory installed calibration curves for that particular motor. (This will have been done at the factory prior to testing and shipping, and should only need to be changed if a different motor subassembly is purchased and installed by the end user.)

To use this recalibration feature, first select (in **EDIT**) the pump tube size you are using, e.g. size #15, then select the desired Forward Rate, e.g. 50ml/min. Next, set the Forward Time to 15 minutes, and the Reverse Time to 00:00:00. Press the **EXIT** key and then the **EXEC** key. MabTec will now show the following display:

FWD FLOW RATE: 50.0 Press RUN when Ready

The system is now ready to recalibrate the #15 tubing. For calibration purposes, pump water into a container, e.g. 1000grams, placed onto a top-loading balance. Alternatively use a 1000ml volumetric flask.

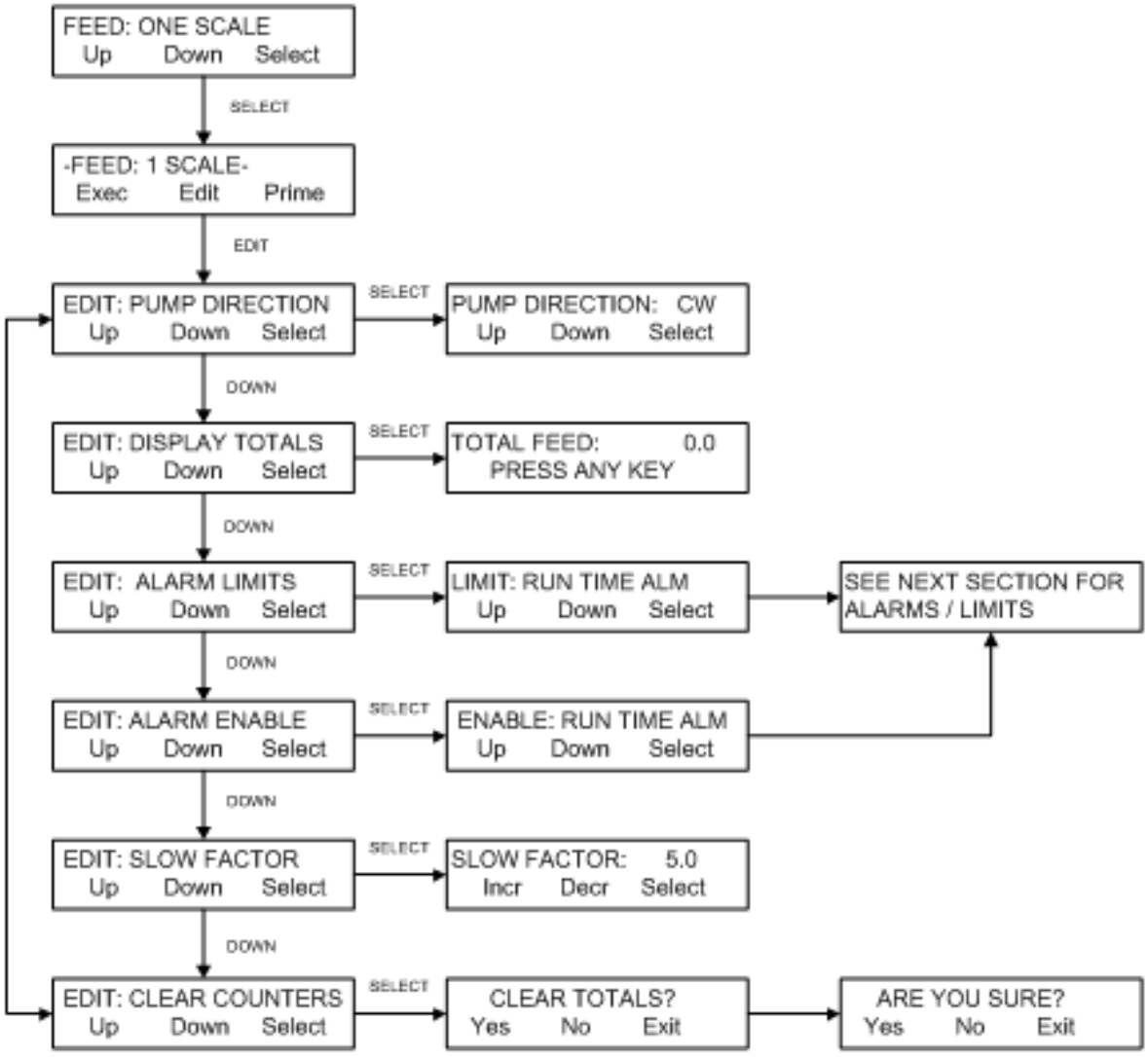
Press the **RUN** key and begin dispensing. Press the **PAUSE** key (not EXIT) to stop pumping when 1000 grams have been dispensed. Press the **EX/DAY** key and the following display will be shown:

DV:1000		AV:1000
Incr.	Decr.	Select

Adjust (increase or decrease) the AV (Average Volume) parameter to 1000, or whatever the actual dispensed weight is and press Select. The calibration table for #15 tubing will now been updated.

Important: The selected calibration volume or weight should be 2-4 times the selected pump rate. For example, if your selected pump rate is 500 ml/min. the minimum calibration volume / weight should be between 1000 - 2000 mls or grams. There is no need to perform this for the Reverse Flow Rate.

5.0 Feed: One Scale
Edit Menu



5.1 Feed: One Scale: Edit Menu

SUMMARY: The Feed: One Scale mode uses the MabTec as the feed pump for the Bioreactor. The Bioreactor is placed on the scale, and feedback from the scale is provided to the pump. As the weight of the Bioreactor reduces, additional media is added to maintain the weight. If this weight change is reasonably constant, the MabTec will match the flow rate.

Use “Up” and “Down” keys to make a selection, then press “Select” to implement that selection.

PUMP DIRECTION: This is used to set the forward direction of the pump head for this mode. Select between CW (clockwise) and CCW (counter-clockwise).

ALARM LIMITS: A short list of Alarm Limits is available. See the menu in the next section.

DISPLAY TOTALS: Select to display the Total Feed amount. Use to confirm that “Clear Counters” below has been accomplished.

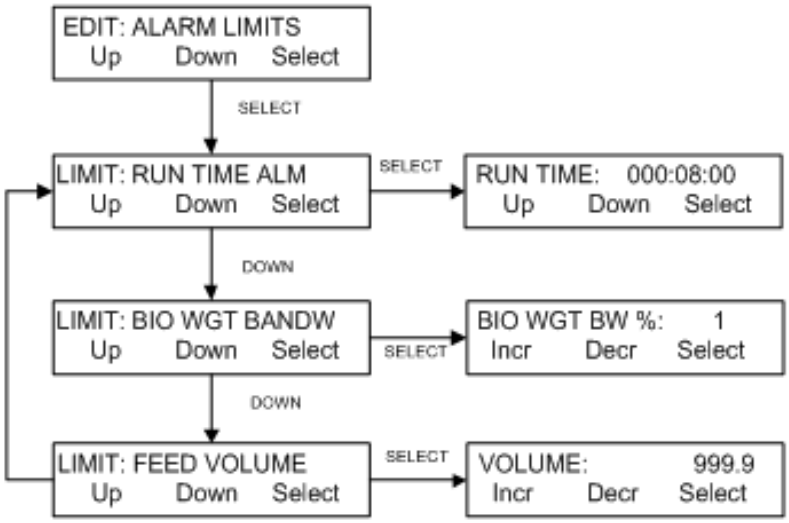
ALARM ENABLE: A short list of Alarms is available and listed in the next section. Enable settings are: OFF (Disabled), Alarm Only (MabTec beeps and keeps going), or Pump Stop (Beep and the MabTec stops).

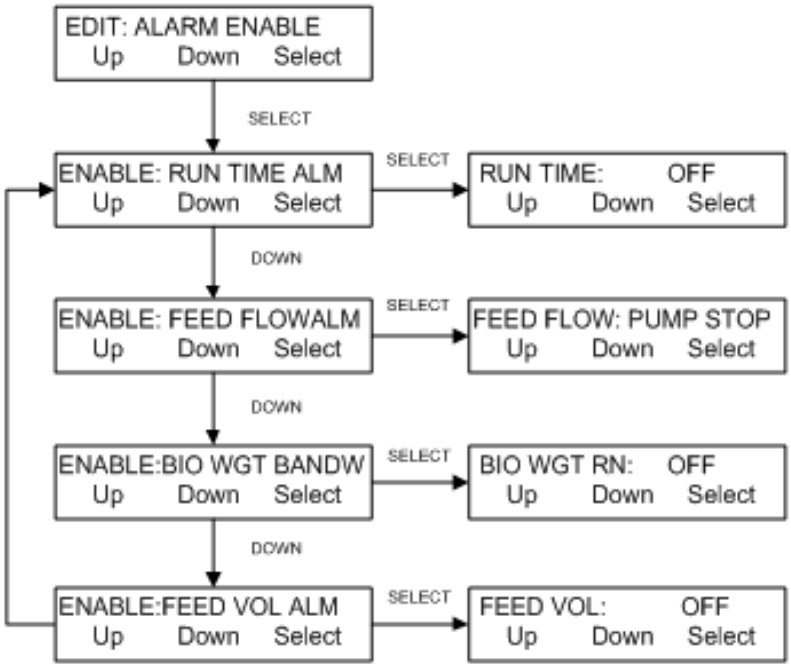
SLOW FACTOR: Sets the response speed of the MabTec to changes in the weight. Increase the value to speed up the response. Default = 5.0.

CLEAR COUNTERS: Use to clear the cumulative values: Run Time, Feed Volume, etc. Press Select and then answer the “Are You Sure?” question.

5.1 Feed: One Scale

Alarm Limits / Alarm Enable Menus:





5.1 Feed: One Scale: Alarm Limit / Alarm Enable Menu:

SUMMARY: This section allows the assignment of limiting values for several alarm conditions: Run Time in Days: Hours: Minutes; **Bio Weight Bandwidth** in %; and Feed Volume in ml.

NOTE: The alarm condition is triggered when the alarm limit is exceeded.

Alarms are not mutually exclusive. Any combination of alarms may be selected. For critical alarms the MabTec should stop (**Pump Stop**), for less critical alarm conditions choose an auditory alarm (**Alarm Only**). Each alarm may be disabled (**Off**) if not required.

NOTE: Use **"Up"** and **"Down"** keys to make a selection, then press **"Select"** to implement that selection.

Limits:

Run Time: This alarm setting allows the setting of a timer for the process. For example, if the **Run Time Alarm** is set to 20:01:30, then the MabTec will provide an auditory alarm and / or stop the pump after twenty (20) days, one (1) hour and thirty (30) minutes have passed. This allows control of the processing time.

Bio Weight Bandwidth: This setting is used to monitor the weight of the Bioreactor, and establishes a range around the initial captured weight. Alarm is triggered when the weight exceeds the established range plus or minus. Default = 1%.

Feed Volume: This setting is set to trigger when the set Feed Volume is exceeded. This is calculated based upon the motor rpm and tubing settings. This will pause the process and allow additional feed media to be connected to the system. Pressing RUN again will resume the process.

Alarms:

Run Time Alarm: Set to Off, Alarm Only or Pump Stop, See Run Time Limit above. Default = Off.

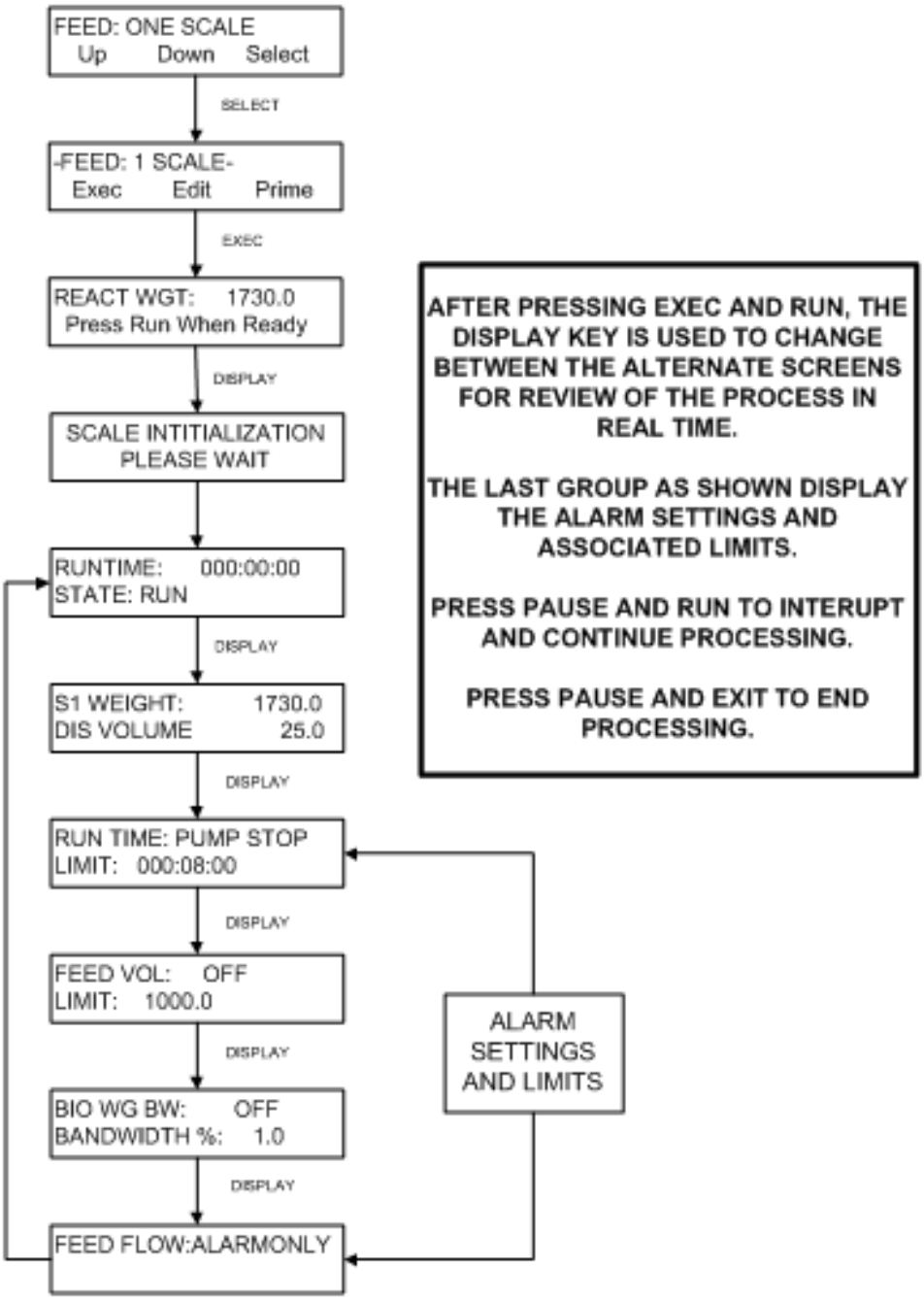
Bio Wgt Bandw: Set to Off, Alarm Only or Pump Stop, See related Limit above. Default = Off.

Feed Volume: Set to Off, Alarm Only or Pump Stop, See related Limit above. Default = Off.

Feed Flow Alarm: This alarm has no limit. It is triggered by the pump ramping to 100% and being unable to maintain the target weight based upon scale feedback. This will occur if the feed vessel has run dry, the tubing/motor combination is too small, or the tubing has sprung a leak. This is a critical alarm and should be set to "Pump Stop".

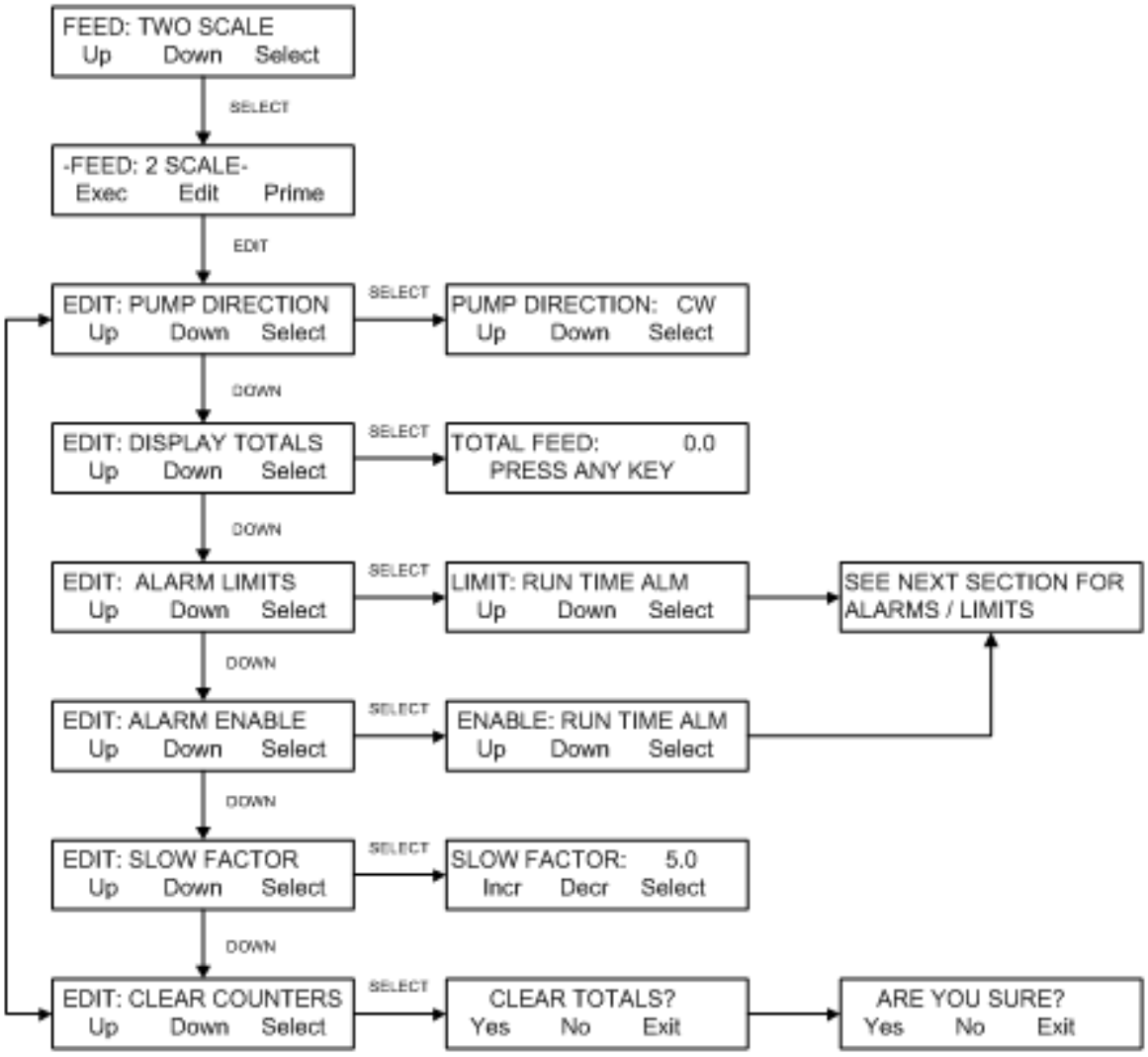
5.2 FEED: ONE SCALE

Execute Menu



6.0 Feed: Two Scale

Edit Menu



6.1 Feed: Two Scale: Edit Menu

SUMMARY: The Feed: Two Scale mode uses the MabTec as the feed pump for the Bioreactor. The Bioreactor is placed on one scale, and feedback from the scale is provided to the pump. As the weight of the Bioreactor reduces, additional media is added to maintain the weight. If this weight change is reasonably constant, the MabTec will match the flow rate. The Feed vessel is placed on a second scale. A Feed Weight Low alarm that alerts the operator and stops the process when the weight of the feed vessel is low replaces the Feed Volume alarm in the Feed: One Scale mode.

Use “Up” and “Down” keys to make a selection, then press “Select” to implement that selection.

Pump Direction: This is used to set the forward direction of the pump head for this mode. Select between CW (clockwise) and CCW (counter-clockwise).

Display Totals: Select to display the Total Feed amount. Use to confirm that “Clear Counters” below has been accomplished.

Alarm Limits: A short list of Alarm Limits is available. See the menu in the next section.

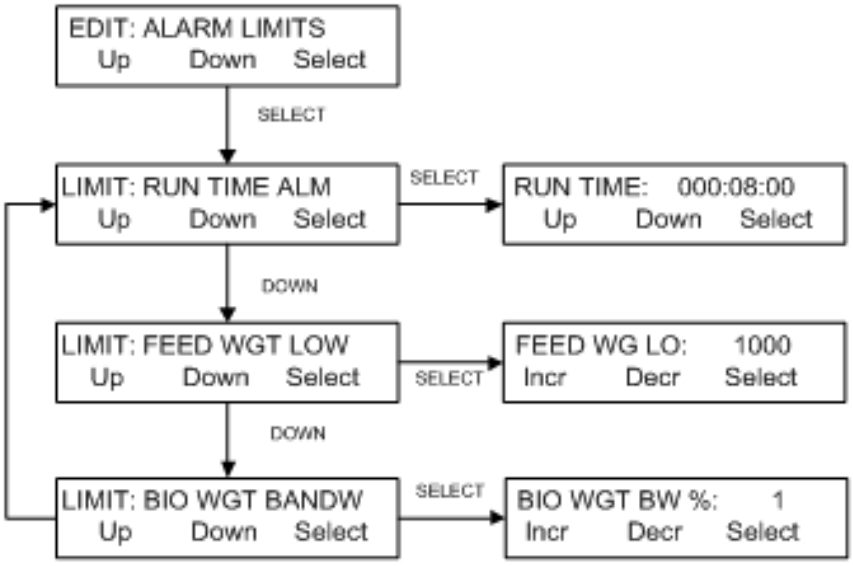
Alarm Enable: A short list of Alarms is available and listed in the next section. Enable settings are: OFF (Disabled), Alarm Only (MabTec beeps and keeps going), or Pump Stop (Beep and the MabTec stops).

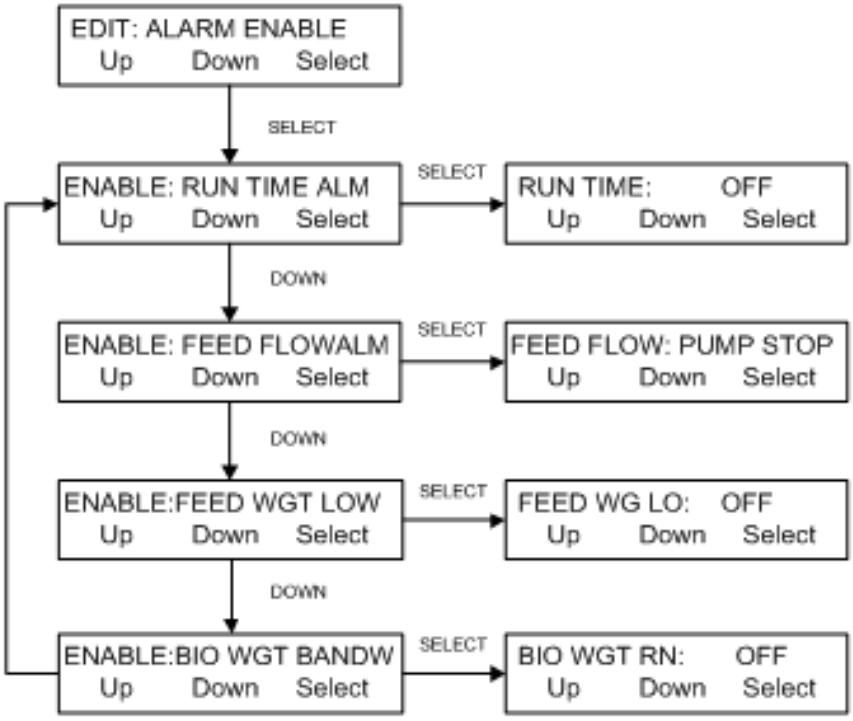
Slow Factor: Sets the response speed of the MabTec to changes in the weight. Increase the value to speed up the response. Default = 5.0.

Clear Counters: Use to clear the cumulative values: Run Time, Feed Volume, etc. Press Select and then answer the “Are You Sure?” question.

6.1 Feed: Two Scale

Alarm Limits / Alarm Enable Menus:





6.1 Feed: Two Scale: Alarm Limit / Alarm Enable Menu:

SUMMARY: This section allows the assignment of limiting values for several alarm conditions: Run Time in Days: Hours: Minutes; Bio Weight Bandwidth in %; and Feed Weight Low in gm.

NOTE: The alarm condition is triggered when the alarm limit is exceeded.

Alarms are not mutually exclusive. Any combination of alarms may be selected. For critical alarms the MabTec should stop (Pump Stop), for less critical alarm conditions choose an auditory alarm (Alarm Only). Each alarm may be disabled (Off) if not required.

NOTE: Use “Up” and “Down” keys to make a selection, then press “Select” to implement that selection.

Limits:

Run Time: This alarm setting allows the setting of a timer for the process. For example, if the Run Time Alarm is set to 20:01:30, then the MabTec will provide an auditory alarm and stop the pump after twenty (20) days, one (1) hour and thirty (30) minutes have passed. This allows control of the processing time.

Feed Weight Low: This setting is set to trigger when the weight of the Feed vessel is low and should be changed. This will pause the process and allow additional feed media to be connected to the system. Pressing RUN again will resume the process.

Bio Weight Bandwidth: This setting is used to monitor the weight of the Bioreactor, and establishes a range around the initial captured weight. Alarm is triggered when the weight exceeds the established range plus or minus. Default = 1%.

Alarms:

Run Time Alarm: Set to Off, Alarm Only or Pump Stop, See Run Time Limit above. Default = Off.

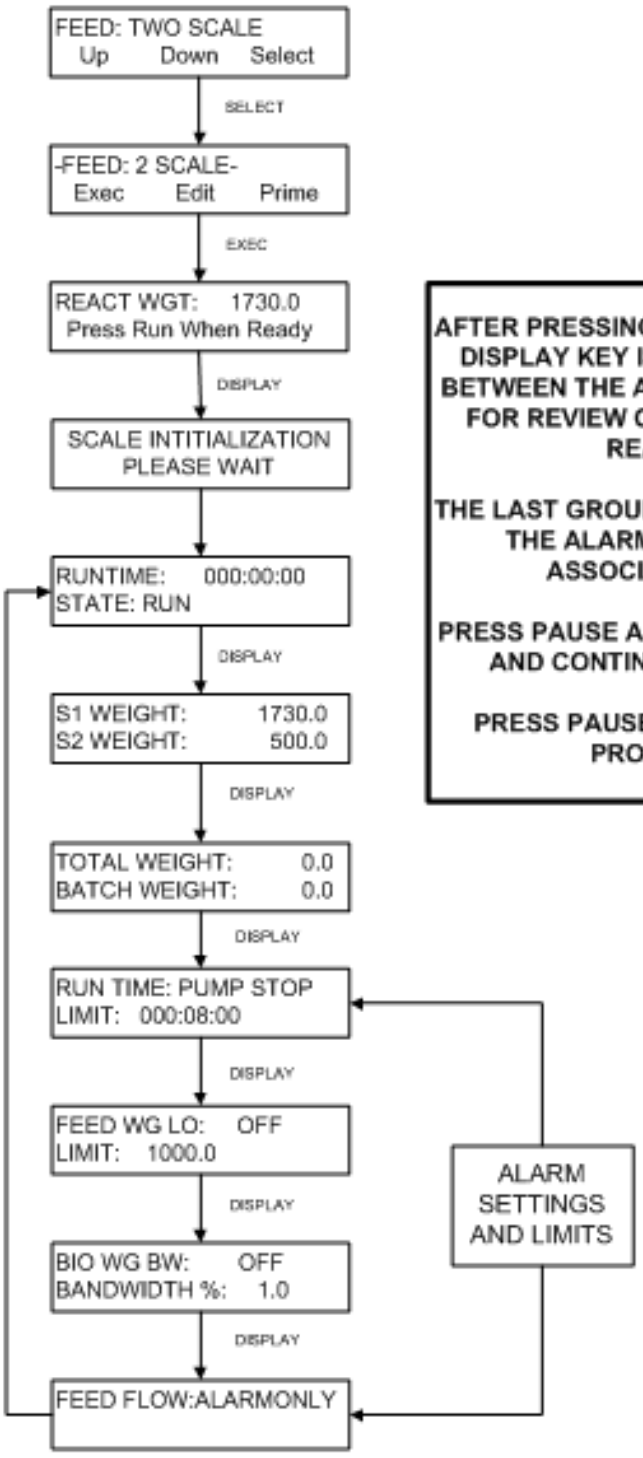
Feed Wgt Lo: Set to Off, Alarm Only or Pump Stop, See related Limit above. Default = Pump Stop.

Bio Wgt Bandw: Set to Off, Alarm Only or Pump Stop, See related Limit above. Default = Off.

Feed Flow Alarm: This alarm has no limit. It is triggered by the pump ramping to 100% and being unable to maintain the target weight based upon scale feedback. This should only occur if the feed vessel has run dry, the tubing/motor combination is too small, or the tubing has sprung a leak. This is a critical alarm and should be set to “Pump Stop”.

6.2 FEED: TWO SCALE

Execute Menu



AFTER PRESSING EXEC AND RUN, THE DISPLAY KEY IS USED TO CHANGE BETWEEN THE ALTERNATE SCREENS FOR REVIEW OF THE PROCESS IN REAL TIME.

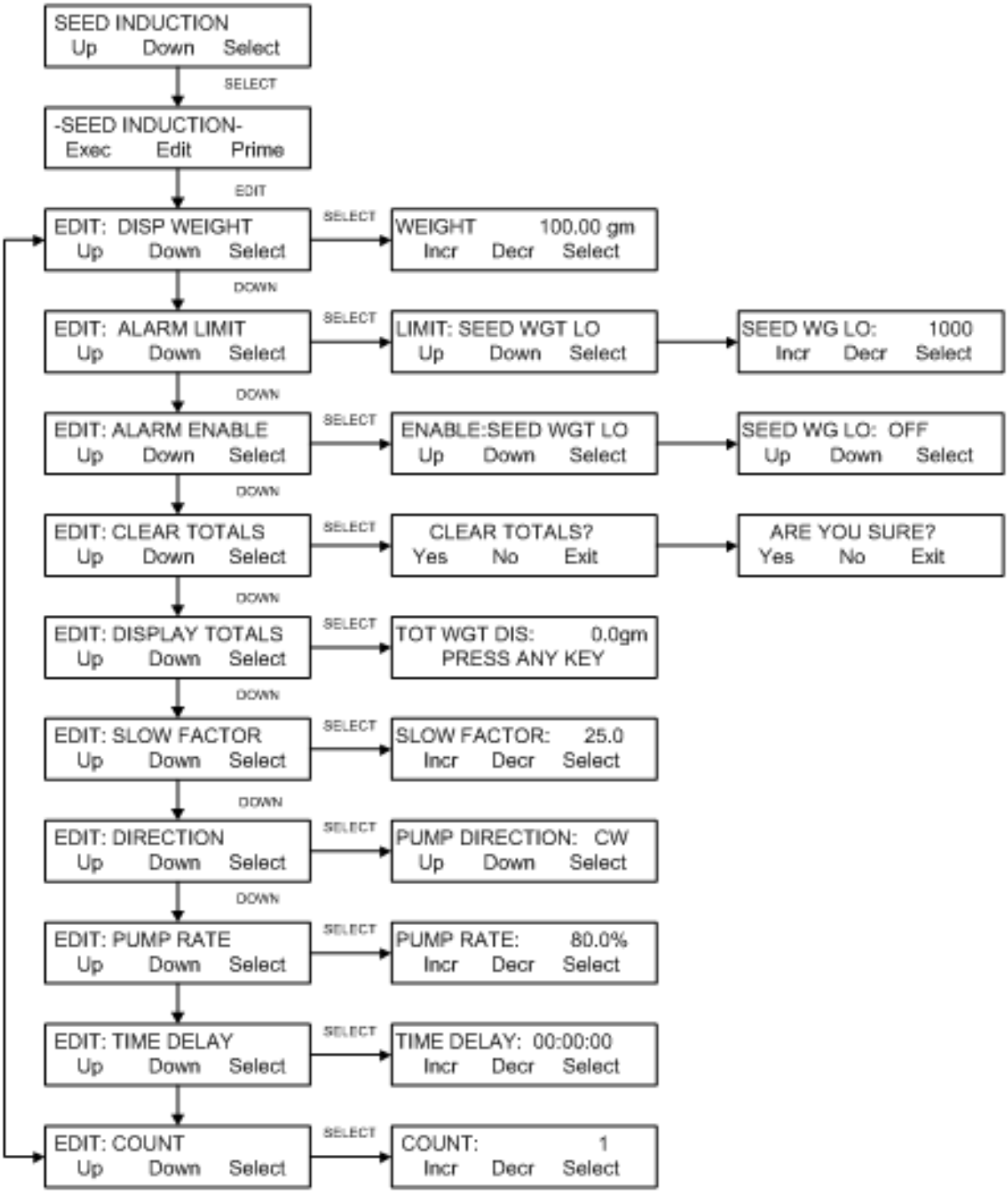
THE LAST GROUP AS SHOWN DISPLAY THE ALARM SETTINGS AND ASSOCIATED LIMITS.

PRESS PAUSE AND RUN TO INTERUPT AND CONTINUE PROCESSING.

PRESS PAUSE AND EXIT TO END PROCESSING.

7.0 SEED INDUCTION

Edit Menu



7.0 Seed Induction: Edit Menu

SUMMARY: The Seed Induction mode allows the MabTec to add a set weight of solution to the Bioreactor at repeatable user defined intervals. A scale (S1)is required for this mode. The intervals may be hours or even days apart, and provision is made for “bolus” additions in between the set time intervals by pressing the “RUN” key.

Use “Up” and “Down” keys to make a selection, then press “Select” to implement that selection.

DISPENSE WEIGHT: Enter the desired dispense weight in grams.

ALARM LIMITS: Seed Weight Low: Set a value that alerts the operator that the Seed Vessel is low. This is a low limit based upon the scale input. Note that the scale is not tared during this process, so this limit should include the empty container weight.

ALARM ENABLE: Seed Weight Low: Enable settings are: OFF (Disabled), Alarm Only (MabTec beeps and keeps going), or Pump Stop (Beep and the MabTec stops). If this is a critical alarm, set to Pump Stop. Upon triggering of the alarm, the MabTec will stop. Change the Seed vessel for a new one and press RUN to continue the process.

CLEAR TOTALS: Use to clear the cumulative values: Dispensed Weight, Run Time, etc. Press Select and then answer the “Are You Sure?” question.

DISPLAY TOTALS: Press Select to display the Total Weight Dispensed. (TOT WGT DIS) This also provided confirmation of the “Clear Totals” action above.

SLOW FACTOR: Sets the point at which the pump slows down to improve the dispense accuracy. 25.0 gm. is the default, and works well for dispenses of 100 gm. or larger and #24 tubing. It should be lowered if the dispense weight is smaller. Default = 25.0.

DIRECTION: This is used to set the forward direction of the pump head for this mode. Select between CW (clockwise) and CCW (counter-clockwise).

PUMP RATE: Set the speed of the motor in %. Default = 80%. An optimized combination of the pump rate and slow factor will provide precise results. (80% and a slow factor of 25.0 is optimized for dispenses of 100 gm. or larger. If higher speeds are needed, larger tubing or a faster motor are options.)

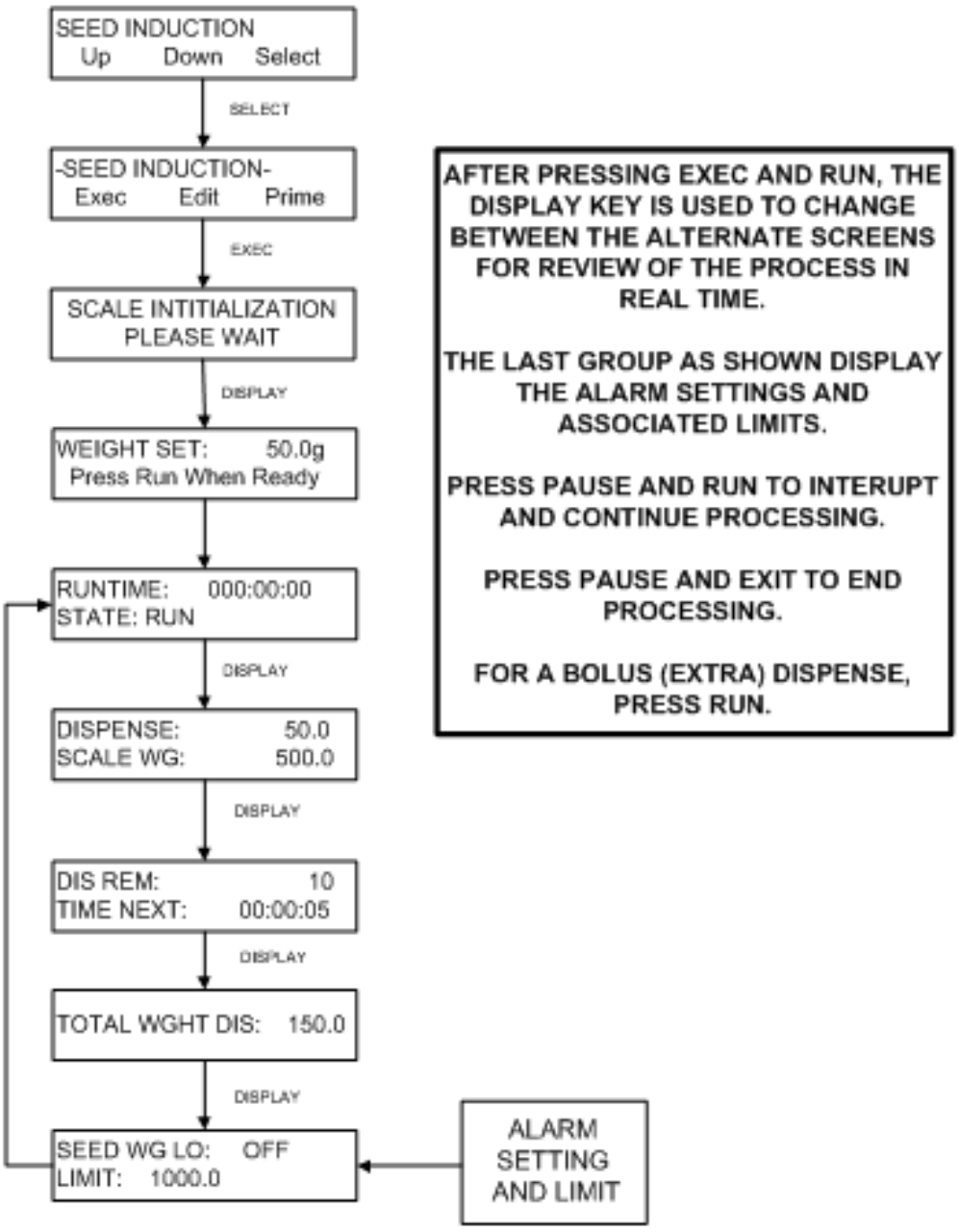
TIME DELAY: Set the time to occur between dispenses in Days: Minutes: Hours. This works in direct conjunction with the Count parameter below. Default = 00:00:00

COUNT: Set the number of dispenses to repeat. A Count of 1 will provide one dispense for each pressing of the RUN key. A Count of 2 or larger will cause multiple dispenses to occur with a pause equivalent to the Time Delay set above. A Count of 999 (the max) will cause endless repeats. Default = 1

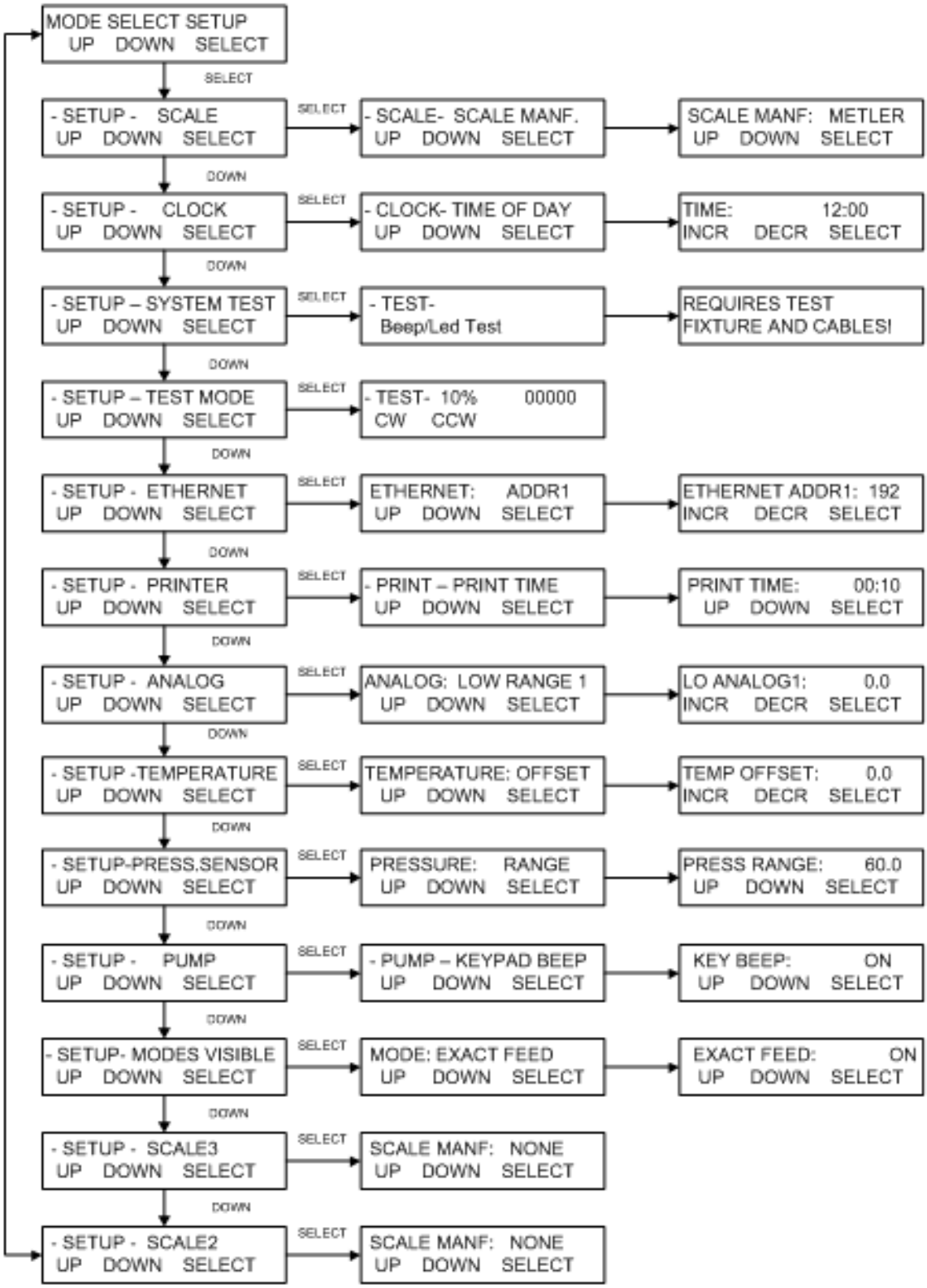
BOLUS ADDITIONS: To add another dispense in-between scheduled dispenses, press the RUN key, and answer the “Are You Sure?” question that follows. This does not reset the time delay.

7.1 SEED INDUCTION

Execute Menu



8.0 SETUP


MODE SELECT SETUP
UP DOWN SELECT
SELECT
- SETUP - SCALE
UP DOWN SELECT
SELECT
- SCALE- SCALE MANF.
UP DOWN SELECT
SCALE MANF: METLER
UP DOWN SELECT
DOWN
- SETUP - CLOCK
UP DOWN SELECT
SELECT
- CLOCK- TIME OF DAY
UP DOWN SELECT
TIME: 12:00
INCR DECR SELECT
DOWN
- SETUP – SYSTEM TEST
UP DOWN SELECT
SELECT
- TEST-
Beep/Led Test
REQUIRES TEST
FIXTURE AND CABLES!
DOWN
- SETUP – TEST MODE
UP DOWN SELECT
SELECT
- TEST- 10% 00000
CW CCW
DOWN
- SETUP - ETHERNET
UP DOWN SELECT
SELECT
ETHERNET: ADDR1
UP DOWN SELECT
ETHERNET ADDR1: 192
INCR DECR SELECT
DOWN
- SETUP - PRINTER
UP DOWN SELECT
SELECT
- PRINT – PRINT TIME
UP DOWN SELECT
PRINT TIME: 00:10
UP DOWN SELECT
DOWN
- SETUP - ANALOG
UP DOWN SELECT
SELECT
ANALOG: LOW RANGE 1
UP DOWN SELECT
LO ANALOG1: 0.0
INCR DECR SELECT
DOWN
- SETUP -TEMPERATURE
UP DOWN SELECT
SELECT
TEMPERATURE: OFFSET
UP DOWN SELECT
TEMP OFFSET: 0.0
INCR DECR SELECT
DOWN
- SETUP-PRESS.SENSOR
UP DOWN SELECT
SELECT
PRESSURE: RANGE
UP DOWN SELECT
PRESS RANGE: 60.0
UP DOWN SELECT
DOWN
- SETUP - PUMP
UP DOWN SELECT
SELECT
- PUMP – KEYPAD BEEP
UP DOWN SELECT
KEY BEEP: ON
UP DOWN SELECT
DOWN
- SETUP- MODES VISIBLE
UP DOWN SELECT
SELECT
MODE: EXACT FEED
UP DOWN SELECT
EXACT FEED: ON
UP DOWN SELECT
DOWN
- SETUP - SCALE3
UP DOWN SELECT
SELECT
SCALE MANF: NONE
UP DOWN SELECT
DOWN
- SETUP - SCALE2
UP DOWN SELECT
SELECT
SCALE MANF: NONE
UP DOWN SELECT

8.0 Setup

SUMMARY: The Setup Menu consists of the following items; the following sections provide further explanation:

SCALE: The following electronic scale is recommended for the MabTec and will ship with most systems: **Mettler BBA442 (Viper).** Proper communications are set by selecting Mettler as the Scale Manuf. Other scales, Mettler, Ohaus or Sartorius may be used. Submenu allows setting of Scale Manuf., Units, Alarm, and Tare. Default = "Mettler".

CLOCK: Set the time of day (military), **day, month**, and **year**. **Print Enable** allows choice of Time of Day, or Relative (Run) Time for printout and display. In most cases the clock will be set at the factory for the destination time zone. Default = Relative Time.

SYSTEM TEST: Allows testing of the I/O's of the MabTec, requires purchase of IQ/OQ Document. Use Test Mode if needed for trouble shooting.

TEST MODE: Allows independent testing of the MabTec I/O's. Motor, Keypad, Scale, Pressure, Temperature, Valves, Analog, TTL switches.

ETHERNET: Allows setting of the IP Address, Subnet Mask and Gateway values for Modbus TCP/IP communication via the Ethernet Port. (not functional at this time.)

PRINTER: Select communications parameters for Parker printer (P/N 080-095) or PC. Default settings are **Print Time** (Default = 30 sec.), **Type** (Seiko), **Baud Rate** (9600), **Stop Bits** (2), **Parity** (None), **Word Length** (8), **Print Delay** (0 sec).

ANALOG: Allows setting of Hi and Lo Range, as well zeroing of all three available 4-20 ma analog inputs.

TEMPERATURE: Select an Offset for the SciTemp Temperature sensor if needed.

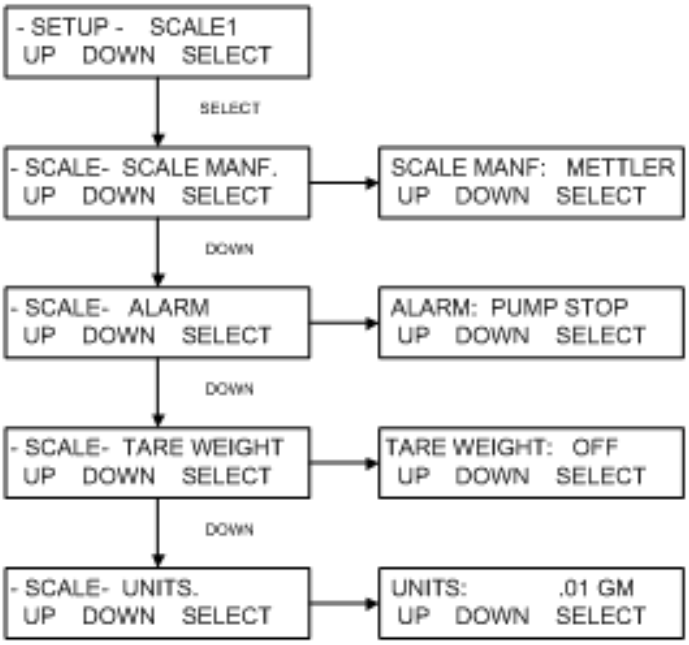
PRESS. SENSOR: Allows user to **Zero** all three SciPres pressure sensors. (**Span** is used for factory calibration.) Source is used to select the desired sensor for related alarms and control in all modes. **Units:** Choose from Psi (default), Bar, or Kpa. **Range:** Default is 60, can be set lower, will require re-calibration of the input. DO NOT change the Range when Units are changed! Units other than psi are a conversion from psi. Contact Parker Customer Service for assistance.

PUMP: Select the following user preferences: **Keypad Beep:** (On/Off), **Switch Configuration:** (Level / Pulse), **Switch Polarity:** (Normal/Inverted), TTL1:On-Off: (Yes/No), **Motor Start:** (Hard / Soft-Ramp), **Motor RPM:** (3400, 600, 160, 8), **Pump Head:** (Peristaltic, RH1, RH0, RH00, Mag 040, Mag 120, Mag 122, Mag 201), **Pump Tubing:** (13/14/16/25/17/18/15/24/35), Power Up: (Mode/Menu/Run), **External Run-Stop:** (Pulse/Level), ASCII Feedback (On / Off), **Factory Reset:** (Resets all variable parameters to their original factory defaults).

MODES VISIBLE: Allows all modes except Manual and Setup to be rendered "Invisible" (Turned ON or OFF) This can prevent improper modes being used for a given process.

SCALE2 AND SCALE3: Set to appropriate Scale Manufacturer values. (See Scale above). Default = None.

8.1 Setup: Scale1



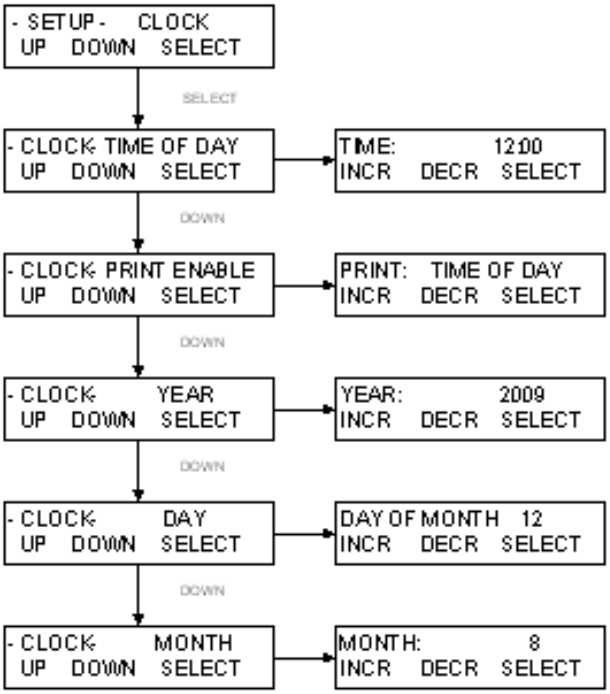
Scale Manuf: Select the appropriate value for the scale in use. Options: Ohaus, Ohaus2, Ohaus3, Mettler, Metler2, Sartor, Sartor2. Default = Mettler. Proper configuration of the scale's parameters is required, as well as correct interface cable.

- Ohaus3: Adventurer Pro.
- Ohaus2: Adventurer, Explorer, Explorer Pro.
- Mettler: Viper, Series 4, IND560, IND331.
- Metler2: Speedweigh, Panther.
- Sartor2: Current default Sartorius setting, all series.

- **ALARM:** Triggered if communication with the scale is lost. Options: Pump Stop, Alarm Only or Off. Default = Pump Stop.
- **TARE WEIGHT:** Determines if the system tares the scale upon pressing Execute and Run in the main operational modes. This is counterintuitive. Options: On, Off. Default = OFF, which causes the system to tare the scale. ON will cause the tare to not occur.

  NOTE: The Tare Weight setting is ignored by the MabTec. The MabTec will not tare any of the connected scales.
- **UNITS:** Select from: .001 gm, .01 gm, 0.1 gm, Kg, T, Lbs, OzT, Oz, C, Dwt. Default =.01 gm.

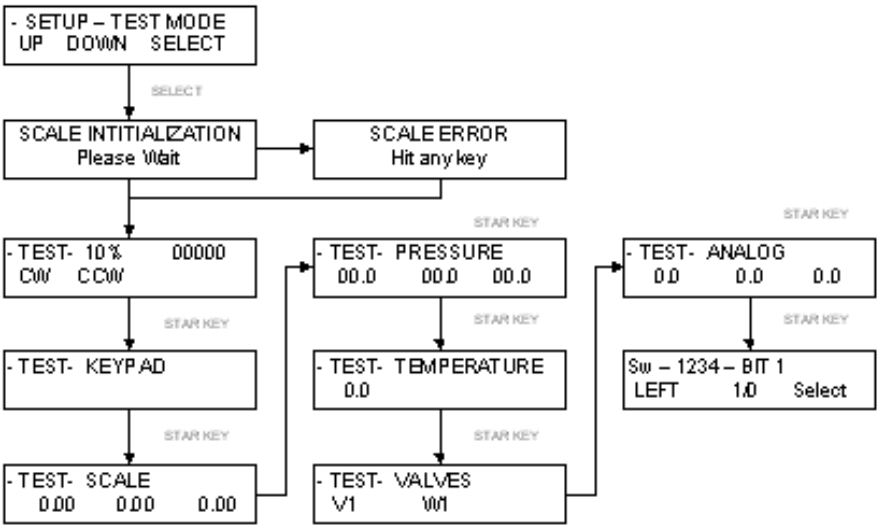
8.2 Setup: Clock



Clock is used to set the Date and Time in the MabTec real time clock, and control the displayed and output time format.

- **TIME OF DAY:** Press Select and use the Incr. and Decr. buttons to set the current time in 24 hour format. This should be preset by the factory prior to shipping.
- **PRINT ENABLE:** Controls displayed and output time. Choose between Time of Day and Relative Time. Time of Day yields current time, and Relative Time starts at 00:00:00 at the beginning of a processing run. Default = Relative Time.
- **YEAR:** Press Select and use Incr. and Decr. to set the current year.
- **DAY OF MONTH:** Press Select and use Incr. and Decr. to set the current day of the month.
- **MONTH:** Press Select and use Incr. and Decr. to set the current month.

8.3 Setup: Test Mode:



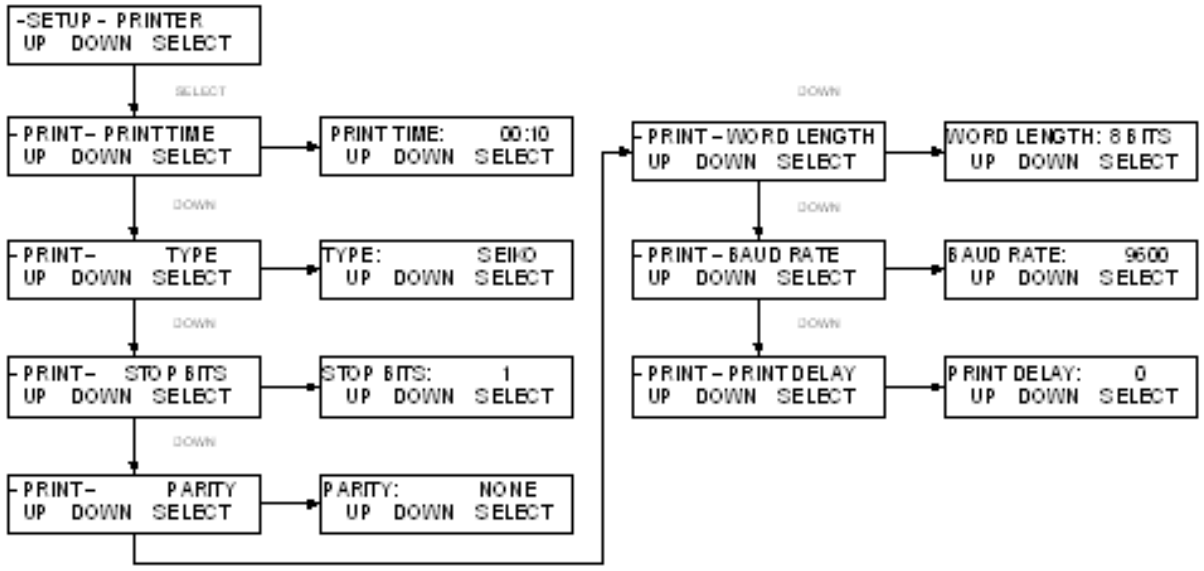
Test Mode provides the ability to test the inputs and outputs (I/O's) of the MabTec outside of the normal operational modes. Upon pressing Select, the MabTec will attempt Scale Initialization. If it passes, the next Test appears. If it fails, press any key and the next Test appears. Use the Star (*) button to move between tests.

- **MOTOR:** This tests the motor. Use the Rate/Pressure button to change the motor speed. Use the Run / Stop buttons, and the CW / CCW keys to exercise the motor. The encoder pulses/second is displayed.
- **KEYPAD:** This tests the keypad. Press the buttons in any order, and an appropriate number is displayed. Left to right, top to bottom, they are numbered 1 through 0, the Star key passes if it moves to the next test.
- **SCALE:** If a scale is connected and is communicating properly, the value here will match that of the scale. (There are three shown, due to the three interfaces, but only one is used with the FilterTec.)
- **PRESSURE:** If SciPres Disposable Pressure Sensors are connected, they will display the measured pressure, P1, P2, P3. By pressing the A, B, or C keys, the sensors may be zeroed. If there is no sensor connected, --.- will be displayed.
- **TEMPERATURE:** If a SciTemp Disposable Pressure Sensor is connected, the measured temperature in □C will be displayed. If no sensor is connected, 0.0 is displayed.
- **VALVES:** If Valve V or W is connected, press the A or B button to test them.
- **ANALOG:** Displays the analog value for Channels 1, 2 and 3 based upon input and Hi/Lo range settings.
- **TTL SWITCHES:** By using Left and 1/0 to change the BIT setting, the TTL outputs may be tested. You must have a DMM connected to measure the voltage, it will be 0.0 if Switch is set to 0, and 5.0 Vdc if set to 1. (The display is 1234 if all are high, 0000 if all are low)

8.4 Setup: Ethernet

This feature is disabled.

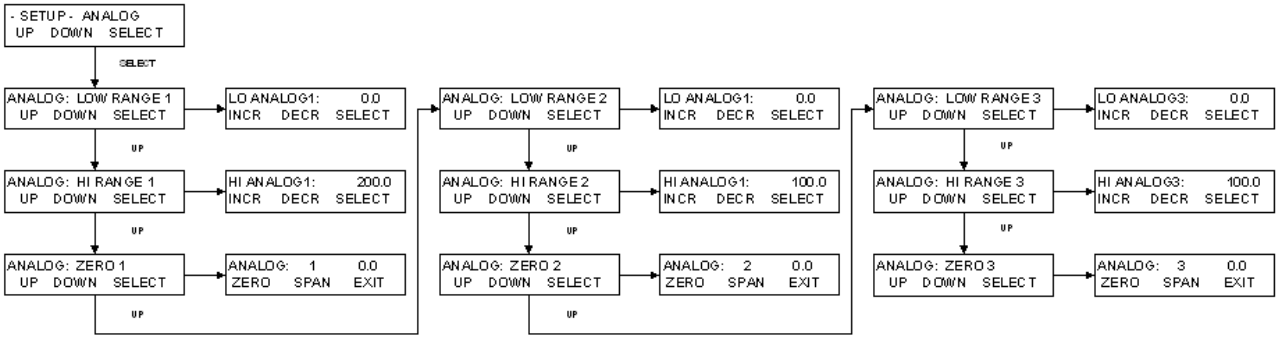
8.5 Setup: Printer



Printer allows the setting of RS-232 communication parameters needed for connection to a Parker serial printer or to a PC for data collection.

- **PRINT TIME:** Controls how fast the FilterTec sends data points in Minutes: Seconds. Max is 30:00 minutes; Min is 00:05 seconds. Default = 00:30 seconds.
- **TYPE:** Allows use of two styles of small serial printers, Seiko, a thermal unit, and Starr, a dot matrix. For all other printers, and PC communication, Seiko setting is used and is the default.
- **STOP BITS:** Select 1 or 2. Default = 1.
- **PARITY:** Select Even, Odd or None. Default = None.
- **WORD LENGTH:** Select 7 or 8 Bits. Default = 8 Bits.
- **BAUD RATE:** Select 300, 600, 1200, 2400, 4800, 9600, or 38.4. Default = 9600
- **PRINT DELAY:** Used to slow down the output for printers with small buffers. Select 0 – 5 seconds. Default = 0 seconds.

8.6 Setup: Analog

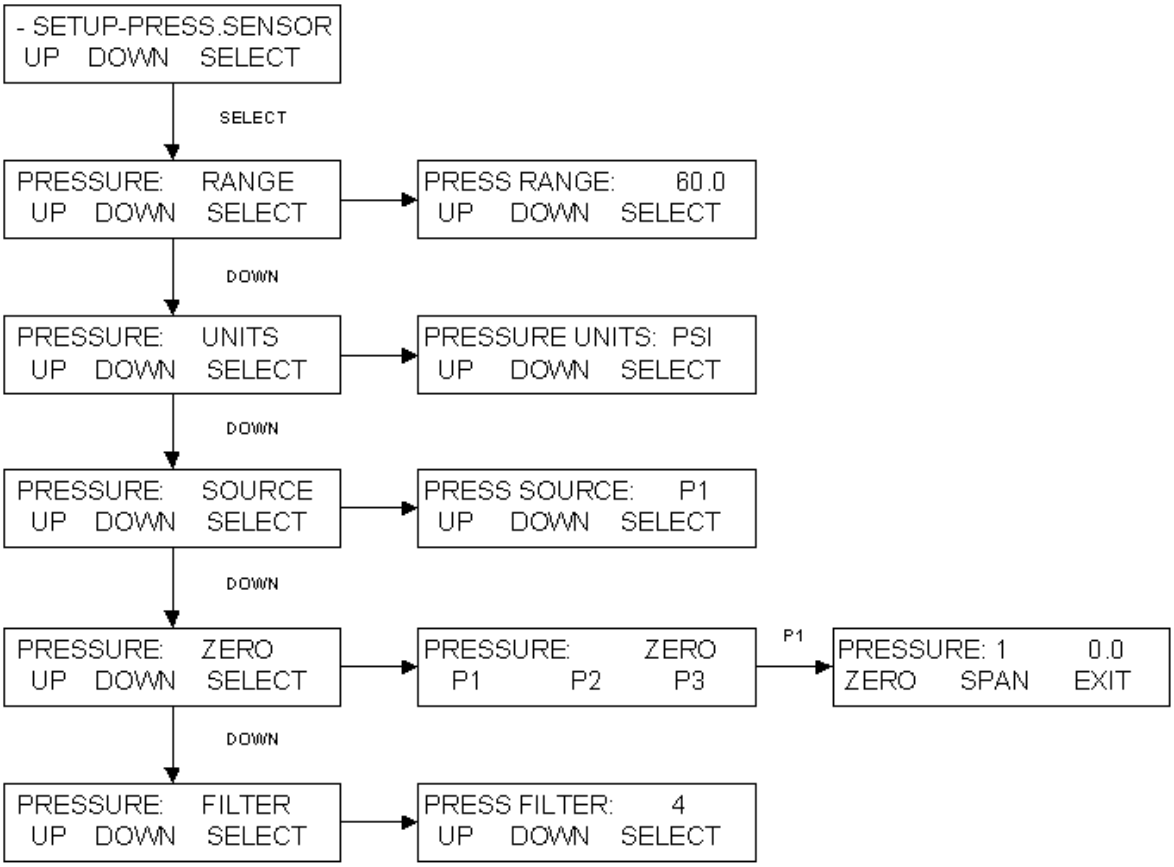


Analog provides for configuration of the three available 4-20 mA Analog inputs. The Hi/Lo Range values can be set, the signal can be calibrated via a Zero/Span function, and Hi/Lo Alarms and Limits can be set for any or all three of the inputs.

- **LO RANGE 1:** Set the value for the 4 mA input on Channel 1. Default = 0.0
- **HI RANGE 1:** Set the value for the 20 mA input on Channel 1. Default = 200.0
- **ZERO 1:** Provides for calibration of the Analog Channel 1 input. Provide a 4 mA signal and press “Zero”. Provide a 20 mA signal and press “Span”. Press Exit to finish. The device being interfaced or a source traceable to NIST should be used for this procedure.
- **LO RANGE 2:** Set the value for the 4 mA input on Channel 2. Default = 0.0
- **HI RANGE 2:** Set the value for the 20 mA input on Channel 2. Default = 100.0
- **ZERO 2:** Provides for calibration of the Analog Channel 2 input. Provide a 4 mA signal and press “Zero”. Provide a 20 mA signal and press “Span”. Press Exit to finish. The device being interfaced or a source traceable to NIST should be used for this procedure.
- **LO RANGE 3:** Set the value for the 4 mA input on Channel 3. Default = 0.0
- **HI RANGE 3:** Set the value for the 20 mA input on Channel 3. Default = 100.0
- **ZERO 3:** Provides for calibration of the Analog Channel 1 input. Provide a 4 mA signal and press “Zero”. Provide a 20 mA signal and press “Span”. Press Exit to finish. The device being interfaced or a source traceable to NIST should be used for this procedure.

  NOTE: Maximum range value for any channel is 9999.9.

8.7 Setup: Pressure Sensor



Pressure Sensor is used to configure settings related to the SciPres Disposable Pressure Sensors. The following can be configured; Range, Units, Source (control and alarms), Filter (signal noise) and Zero/Span.

- **RANGE:** Set the overall pressure range, the Default is 60.0 psi, and is the maximum. Changing this setting requires re-calibration of the sensor signals. **NOTE:** DO NOT change the range when changing the Units below. Units other than psi are a conversion from psi.
- **Units:** Select between Psi, Bar, and KPA. Default = Psi.
- **SOURCE:** Controls the source pressure sensor for control in Constant Pressure Mode, and for all pressure alarms. Select between P1, P2, P3, or TM. Default = P1
- **ZERO:** Used to "Zero" the sensors to establish the zero offset cause by the circuitry and any inherent hydraulic pressure in your tubing beyond the pump head. Connect the sensor, and remove any pressure from the system. Select the sensor, P1, P2 or P3 and press "Zero". You are prompted to confirm the action. "Span" should not be used on a routine basis, as it sets the max input value. **NOTE:** Do not Zero P1, P2 or P3 unless a sensor is connected. The display should read "--.-" with no sensor connected. If it reads 0.0 in this state, connect the sensor and re-zero it.
- **FILTER:** This feature filters out the pulsations in the pressure signal due to the peristaltic nature of the pump head. This provides better control and easier to read values, as well as improved graphed data. Select from 1 to 7, 1 = no signal filter, 7 = maximum filter. Default =

8.8 Setup: Pressure Sensor, Calibration

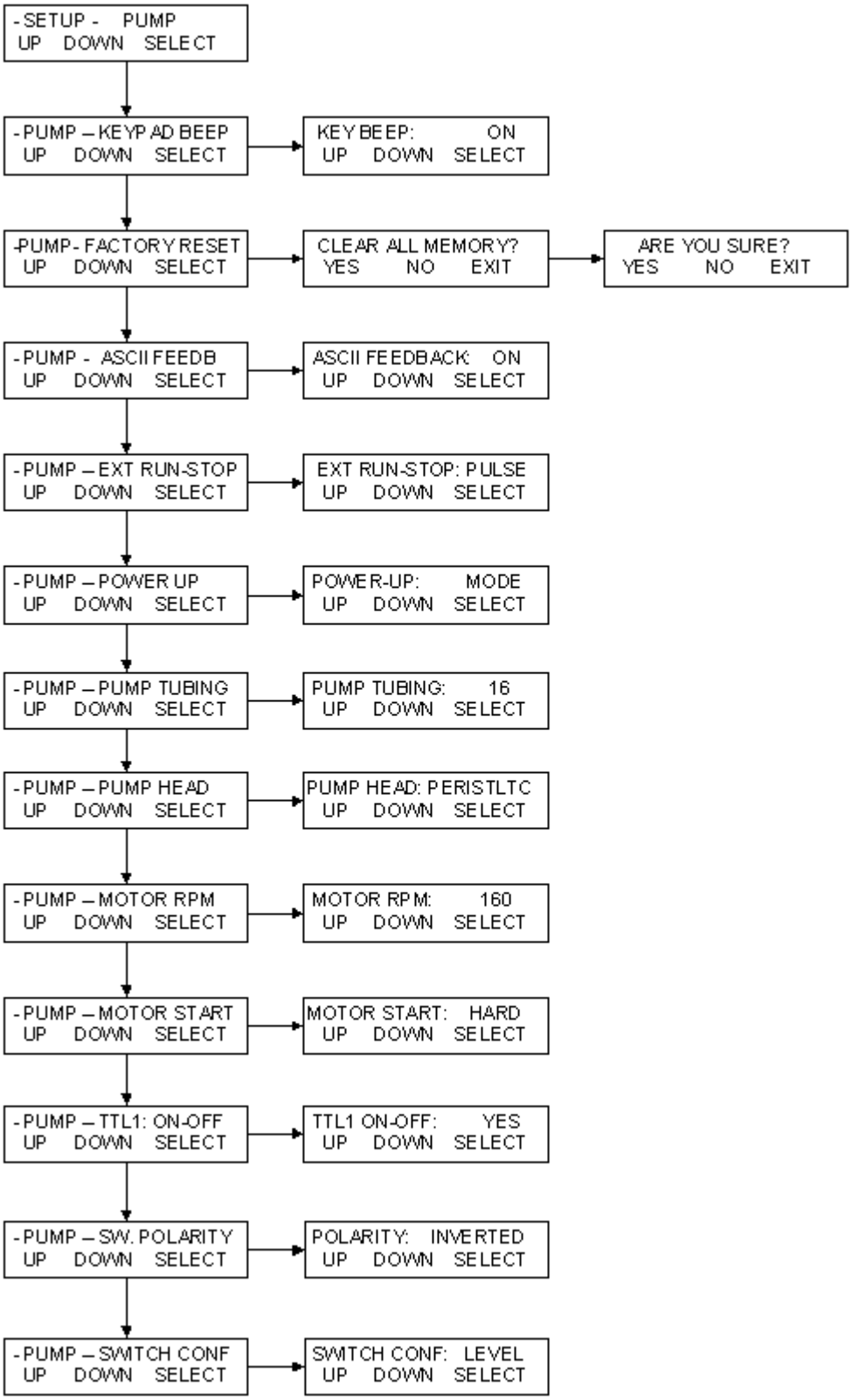
The MabTec has built in calibration curves for the SciPres disposable pressure sensors that are inherently very accurate for the installed default range of 0 – 60 psi, and there should be no need for you to change it. If your metrology department insists that they calibrate them periodically, the procedure follows.

To calibrate the MabTec / SciPres Disposable Sensors:

1. Obtain a NIST traceable regulated source of compressed gas (i.e. air, nitrogen) and pressure gauge.
2. Go to Mode Select; Setup; Pressure Sensor, then to Pressure: Range, and note the range specified, change if desired. (Default is 60 psi.)
3. Press Exit and scroll to Pressure: Zero.
4. Choose P1.
5. With no pressure on the sensor, press Zero (“A” button).
6. Connect regulated pressure source to P1, and carefully increase to match range noted in step 2.

   NOTE: Pressurizing the SciPres Sensors beyond 60 psi can damage the sensor.
7. Press Span (“B” button).
8. Turn off pressure source, Press exit.
9. Repeat steps 5 – 8, choosing P2 and then P3.
10. You have now recalibrated (spanned) all 3 SciPres sensors. It is still advisable to zero each sensor again with no pressure in the system, prior to running your tests via the Edit: Press. Sensor menu in the operating mode of choice.

8.9 Setup: Pump

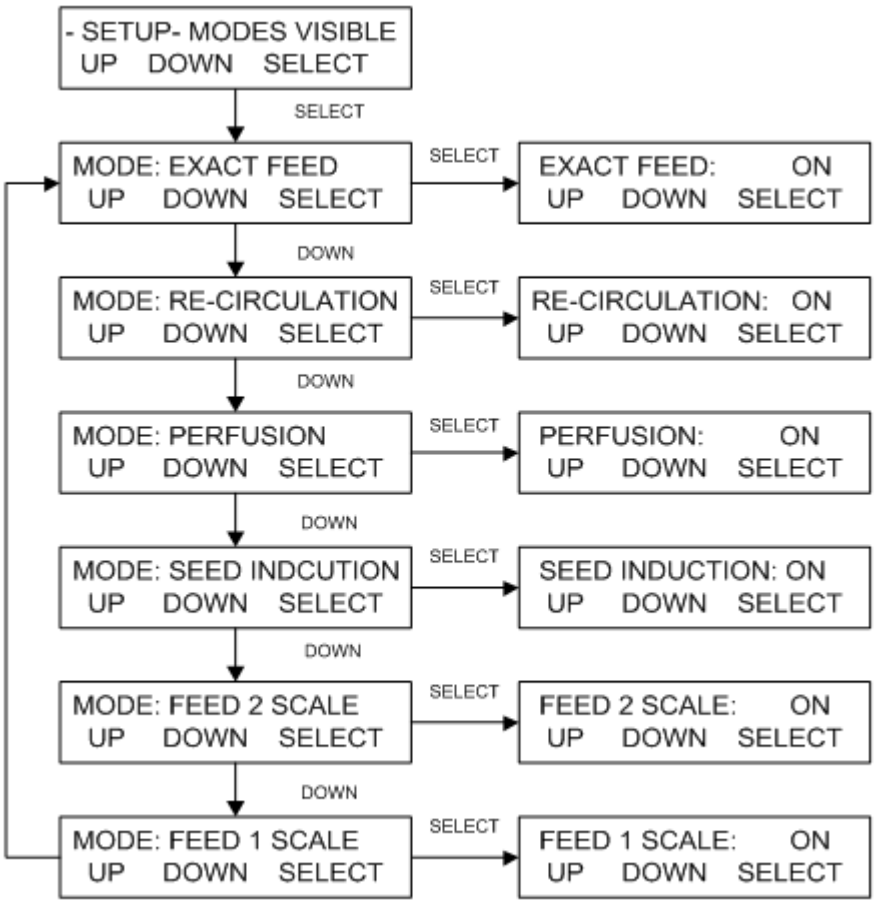


8.9 Setup: Pump:

Setup: Pump provides configuration of global settings related to the pump. Generally, the default values here do not need to be changed. Any changes required for a particular system will be made at the factory, and would only need to be modified if a “Factory Reset” is performed.

- **KEYPAD BEEP:** Determines if the buttons “beep” when pressed. Default = ON.
- **FACTORY RESET:** Resets the system to the factory default settings for all menus. Requires pressing “YES” to both the “Clear All Memory?” and “Are You Sure?” prompts.
- **ASCII FEEDBACK:** Controls responses sent to a PC upon receipt of a remote command. Default = ON.
- **EXTERNAL RUN-STOP:** Controls action of the Footswitch connection, which is part of the External I/O DB37 connector (pins 19 and 37). Choose Pulse for footswitch type control where the contacts are closed and then opened. Choose Level for contact closure control where closed = Run and open = Stop. Run key is disabled when this is set to Level except in Manual Mode. Default = Pulse.
- **POWER-UP:** Controls the action of the system upon power-up. Choose from Menu, Mode, or Run. Menu = the system returns to the top of the Menu. Mode = the system returns to the last Mode it was in. Run = the system returns to the last Mode it was in and starts the process.
- **PUMP TUBING:** If Pump Head is set to Peristaltic, all nine standard tubing sizes can be chosen. Used with Motor RPM setting to determine proper calibration curve. Default = 16.
- **PUMP HEAD:** Choose between Peristaltic, RH1, RH0, RH00, Mag 201, Mag 122, Mag 120, and Mag 040. Used to access the proper calibration curve. Default = Peristaltic.
- **MOTOR RPM:** Choose between 8, 160, 600 and 2400 rpm, matching the motor installed in the system. This will be set at the factory. It will need to be reset after a Factory Reset if other than the default. Default = 160.
- **MOTOR START:** Controls how fast the motor starts. Hard is fast, Soft is slow. Default = Hard.
- **TTL 1 ON-OFF:** Controls action of TTL Switch 1, used for Master/Slave control of another system or device with TTL input control. Set to Yes, TTL 1 changes states from High to Low when the system is told to run the motor. Set to No, it does not. Default = Yes.
- **SWITCH POLARITY:** Controls the polarity of the TTL switches. Inverted = High when not activated, Low when activated. Normal = Low when not activated, High when activated. Default = Inverted to allow for proper Master/Slave control.
- **SWITCH CONFIGURATION:** Sets the action of the TTL switches. Choose between Level and Pulse. Default = Level to allow for proper Master/Slave control.

8.10 Setup: Modes Visible:



Modes Visible is used to turn ON or OFF (render invisible) any or all modes in the MabTec except Manual and Setup. This allows the end user to dedicate the MabTec for a particular part of process, eliminating the possibility of choosing an incorrect operational mode.

9.0 Manual:

SUMMARY: In the Manual Mode the MabTec can be manually operated. The pump speed can be set by pressing the “Rate” key. The pump will also display the pressure indicated on SciPres Sensor P1 and the Temperature if a SciTemp Sensor is connected.

NOTE: The other mode parameters, including the alarms, cannot be accessed in the Manual Mode.

When in Manual mode, the pump speed and/or pressure can be adjusted in terms of % motor speed while the pump is running. Just press the “RATE” key, make the appropriate adjustment, and press “SELECT”.

10.0 Data Acquisition:

SUMMARY: Parker has available a software package called SciDoc that includes data collection software and a Custom Excel spreadsheet that is automatically populated when any of the modes are executed except Manual. It also has charts that are automatically populated as the data is generated.

Either the Printer Port or USB Port may be used for data collection. The instructions for installing the USB driver appear at the beginning of this manual. The MabTec Printer Port is required for use with a Parker serial printer, and both Thermal and Dot Matrix are available. By using both ports, the data can be simultaneously captured on a PC and a Printer.

When a PC is connected, all data generated in the operational modes, except Manual, can be sent to the PC for archiving. Please use the Parker SciDoc Data Collection Software described below. Alternatively, a PC running “HyperTerminal”, a program that used to come with Windows, or a similar terminal program, may be used to capture the data. The HyperTerminal settings are provided for you in section 6.2 entitled “PC HyperTerminal Settings.” When interfacing with a PC you will need a separate RS-232 cable (P/N: 080-073) or USB cable (P/N: 090-158).

NOTE: For a successful hook-up with your PC, the MabTec and the PC must use the same communications protocol. Make sure that the communication parameters in Setup: Printer are the same as those listed in for HyperTerminal below or the default values.

The MabTec is also equipped with a USB port that can be connected to your PC. You will find the driver for this connection on the CD this manual came on. You will need to look in Device Manager on your PC to determine the Com Port number assigned to the MabTec.

The MabTec is also equipped with an Ethernet Port. Settings for the Ethernet connection are described in an earlier section. This is for communication via Modbus TCP/IP, and when the register list is available, it will be added to the manual as an appendix.

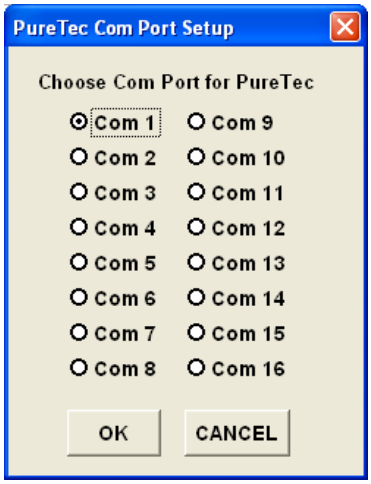
10.1 MabTec SciDoc Data Collection Software:

THIS SECTIN TO BE UPDATED AS SOON AS MABTEC SCIDOC IS AVAILABLE!

SciDoc is a software package that captures the data output of the MabTec and places it in an Excel spreadsheet. This spreadsheet also performs some basic calculations and populates several graphs to aid you in the analysis of your process. It consists of a copy of WinWedge32 from TalTech Inc. and a custom spreadsheet with built in macros. It requires the use of a Parker RS-232 cable, (P/N: 080-073) or USB cable, (P/N: 090-158) to connect your MabTec to an available Com Port on your PC.

Minimum system requirements for are Windows 98 and Excel 2000. WinWedge32 v3.4 is included in the package and is Vista compatible. Installation instructions are included with the package.

Once installed, click on the shortcut for the spreadsheet, and the following dialog box is presented:

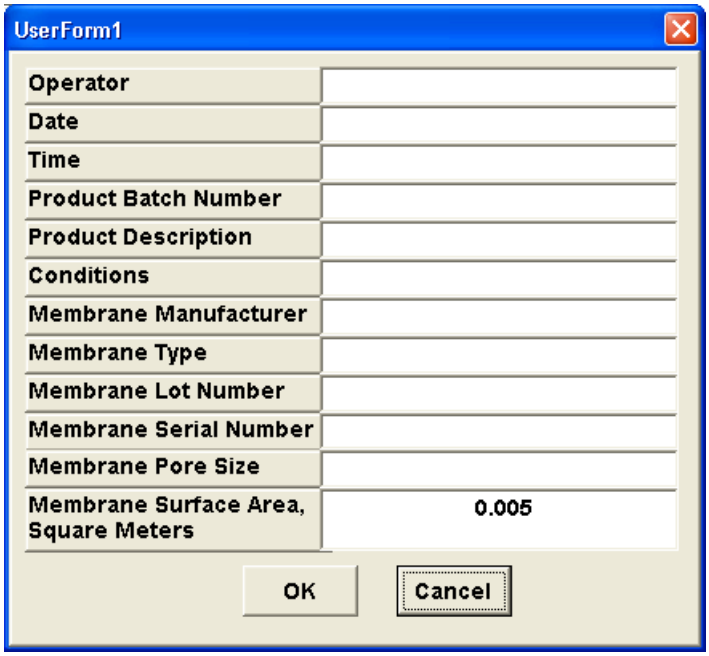


If you do not get this screen, you will need to change the Macro Security settings in Excel. If it does not prompt to enable macros or does not prompt for the COM port, the security level is too high.

1. If using a version of Office older than 2007, from the Excel menu bar, click on Tools, Macros, and Security. Set it to Medium, close the spreadsheet and re-launch it.
2. If using Office 2007, from the Excel window, click on the Office logo in the upper left corner. Then click on Excel Options in the lower left of this window. Highlight the Trust Center, and click on Trust Center Settings in the lower left.
    a. In this window you have two options:
        i. Click on Trusted Locations, then Add new location, browsing to the Winwedge folder where the spreadsheet is located and making it a trusted location.
        ii. Click on Macro Settings, and choose Enable all macros.

Choose the Com Port the MabTec is connected to. Click on the OK button and WinWedge32 will start, showing itself as an icon in your system tray.

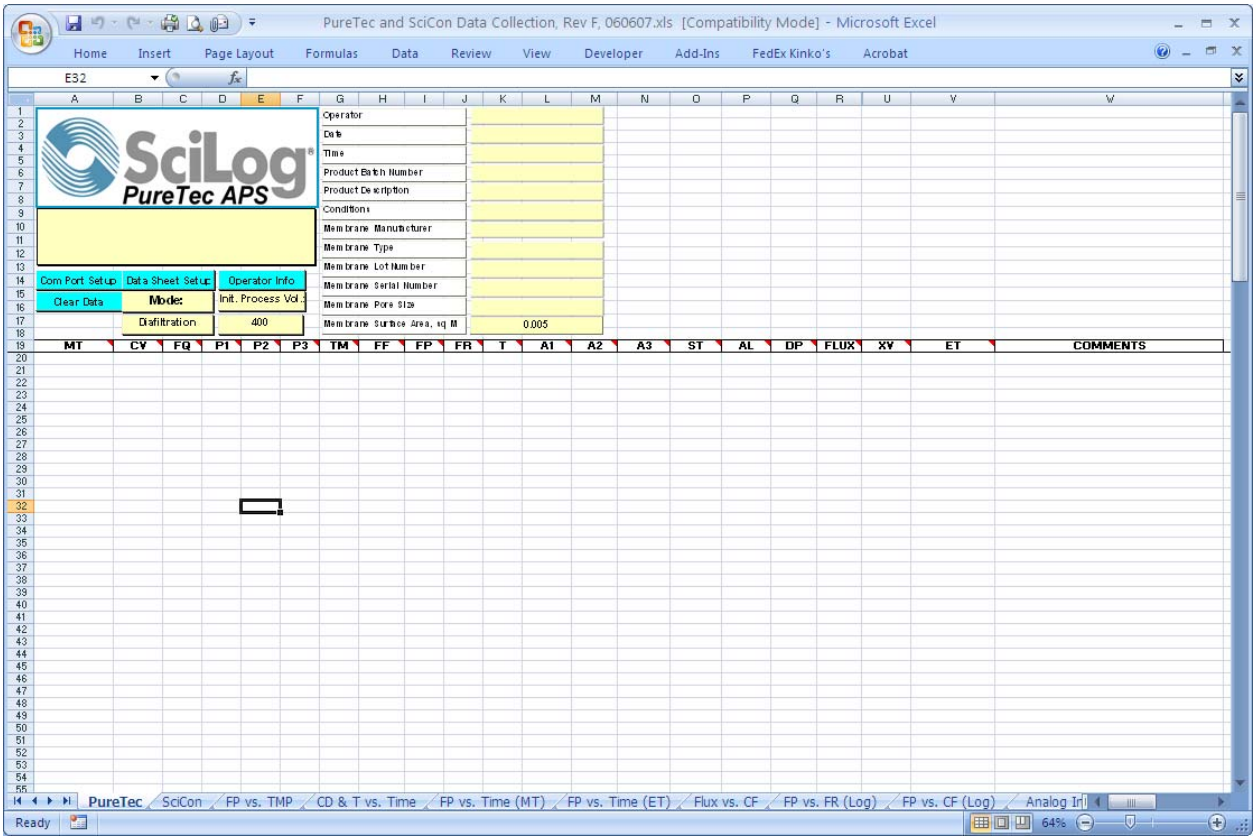
Once this is complete, you will have the next dialog box:



Enter the operator's information and that of the filter and sample being run and press "OK".

PLEASE NOTE: the "Clear Data" button does not affect the information in these fields. You may click on the "Operator Info" button and update these fields as needed.

Clicking on “OK” leaves you with this screen, ready to start collecting data from the MabTec.



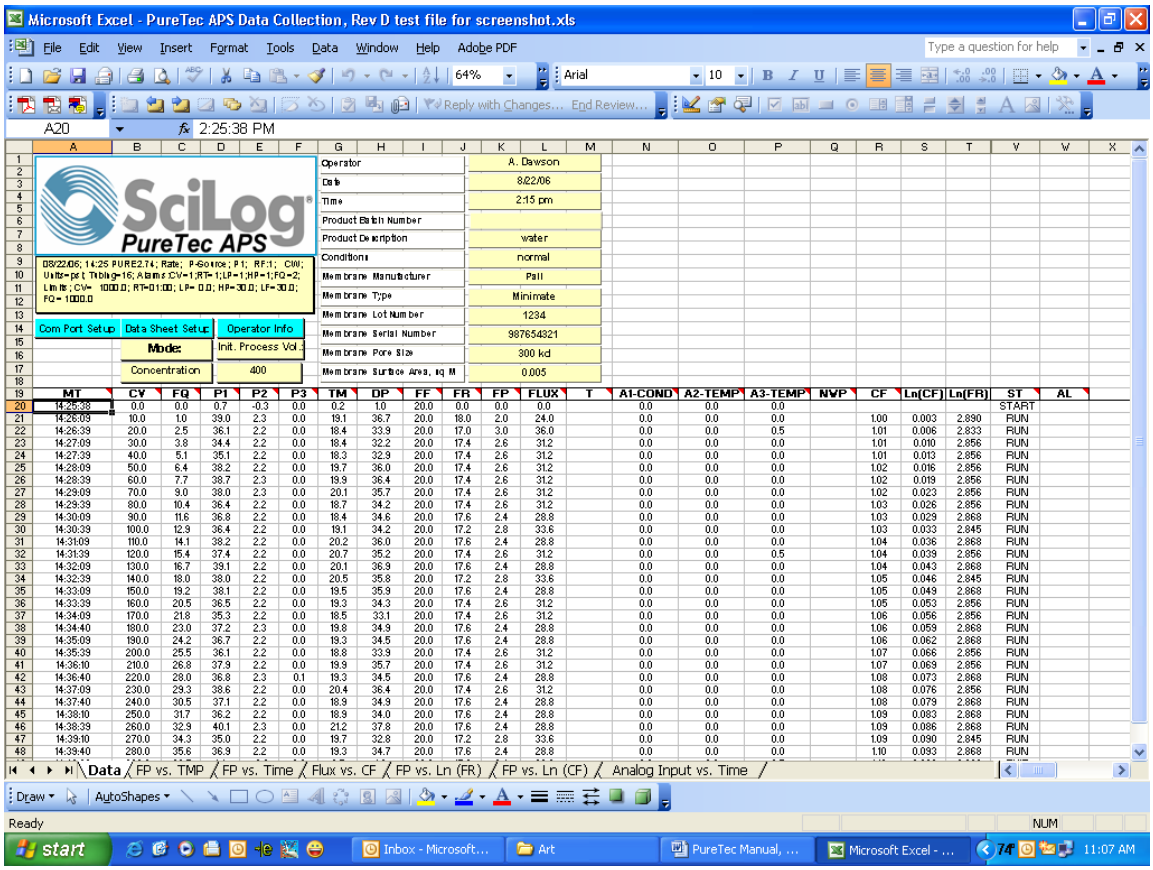
When ready, press Exec on the MabTec, and then RUN after the balance has initialized. If using a SciCon, press the On/Stby button to power it up at the same time. The data generated by one or both will automatically be placed in the cells of the spreadsheets, and the charts populated with the same data. The text box in the upper right of the spreadsheet contains the header information that is generated by the MabTec. This will list the Operational Mode, the date and time, all operating parameters, alarm settings and alarm limits. A similar text box exists on the SciCon tab, and its data appears on that tab as well.

The following charts have been included for your use, and you may view them by clicking on the appropriate tab at the bottom of the worksheet:

- Permeate Flow Rate (FP) vs. Trans-Membrane Pressure (TMP)
- Permeate Flow Rate (FP) vs. Time
- Flux (FX) vs. Concentration Factor (CF)
- Permeate Flow Rate (FP) vs. Ln {Retentate Flow Rate (FR)}
- Permeate Flow Rate (FP) vs. Ln {Concentration Factor (CF)}
- Conductivity vs. Time (based upon the SciCon Data)

You may, of course, create your own charts or modify those included by adding trend lines, changing titles, etc.

When you are finished with a run, your screen will look similar to the one on the following page:



A couple items of Note: The columns that are visible on the spreadsheet will change based on the mode. When finished with a run, click on File-Save as: and choose an appropriate file name. For another run, simply press the “Clear Data” button, or close and re-open the file.

- The **STOP** and **RUN** keys on the MabTec may be used to interrupt the filtration process. This will only cause minor changes in the data and charts. They show up in the data set by displaying the word PAUSE or START in the ST (Status) column of the Data worksheet.
- Using the **EXIT** key however and then pressing Exec and RUN again in the same data collection run, will replace the header information in the text box at the top of the worksheet, while continuing to add data to the bottom of the sheet. <u>It is recommended that you eithersave the data as mentioned above, or dispose of it by clicking on the “Clear Data” button prior to pressing the Exec and RUN keys again to begin a new set of data.</u>
- The MabTec allows the Rate or Pressure to be changed on the fly by pressing the RATE/PRESSURE key on the front panel. This is a very useful tool in determining the optimum parameters for a process. When this key is pressed, the MabTec will stop sending data to the worksheet until approx 15 seconds after having pressed the “Select” button on the front panel to finalize the choice. As the process is continuing while this is done, the data will reflect the change.

Please contact Parker Technical Customer service at 805-604-3400 if you have any questions, comments or suggestions regarding the use of this data collection software.

10.2 PC HyperTerminal Settings:

MabTec to PC: For PC Connections via the Printer Port a Parker RS-232 Cable (P/N: 080-073) is needed. When not using the Parker printer, this allows process data to be "dumped" into a PC for archiving. The list of settings below must match those in Setup: Printer of the FilterTec, and Print Delay should be set to "0". Alternatively, the USB port may be used. The driver for the USB connection is on the CD this manual is on, and may be downloaded from www.Parker.com.

The following terminal setting procedure is intended for PCs with a **Window 98/XP** software installation: Press the **START** button in the lower left corner of your screen, select **"Programs"** then select and open **"Accessories",** select **"Hyper Terminal".**

If using **Vista**, HyperTerminal Personal Edition can be downloaded from the internet at: http://www.hilgraeve.com/hyperterminal.html

From the **"Connection Description"** screen, select an icon and enter a file name, i.e. FilterTec.

Press "Ok"

From the **"Connect To"** screen, select **"Direct to Com 1"** in the box labeled "Connect Using" or the Com Port assigned to the FilterTec and **Press "Ok".**

From the "**Com 1 Property**" screen, select the following parameters

Bits per Second:	9600
Data Bits:	8
Parity:	None
Stop Bits:	1
Flow Control:	None

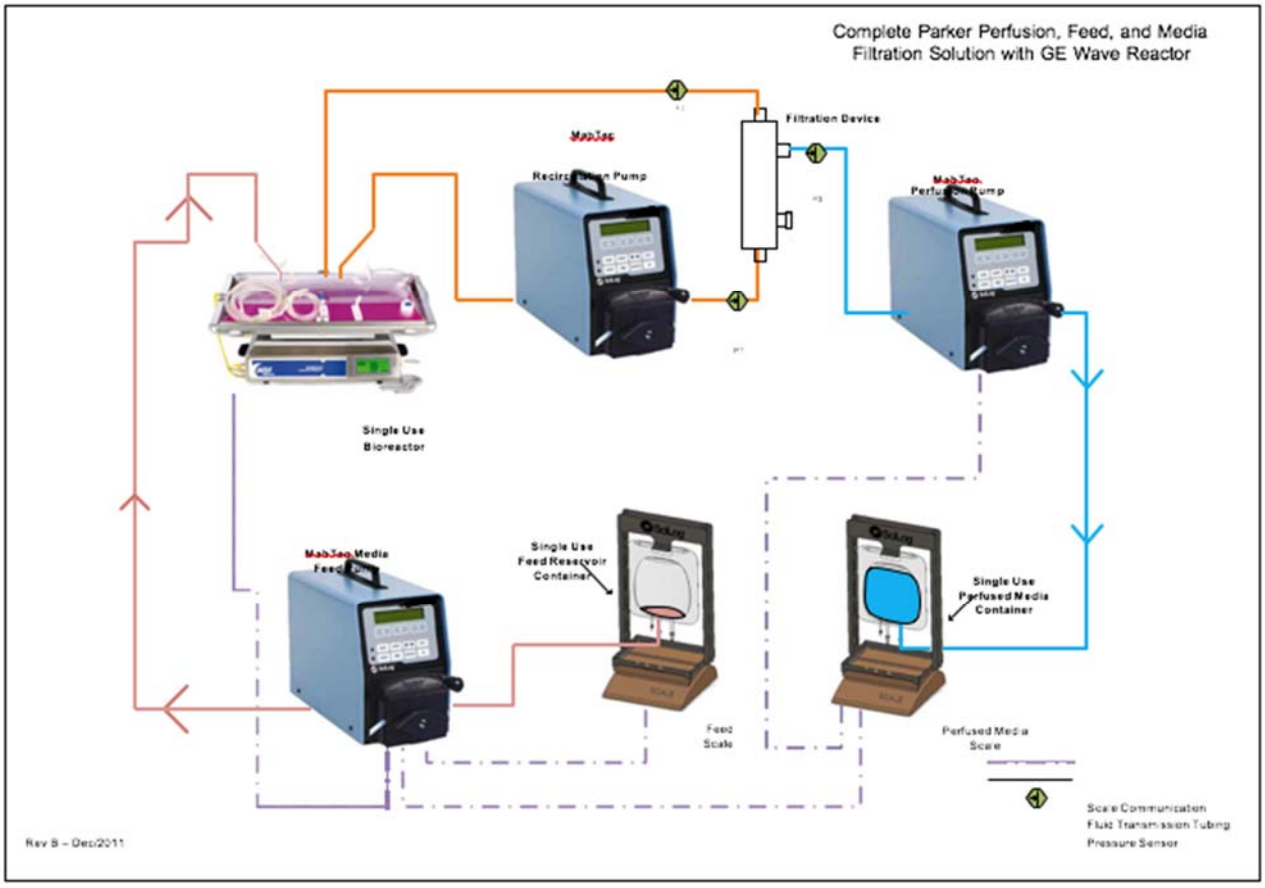
Press "Ok"

Press "Ok" at the bottom of the "FilterTec Setup" screen.

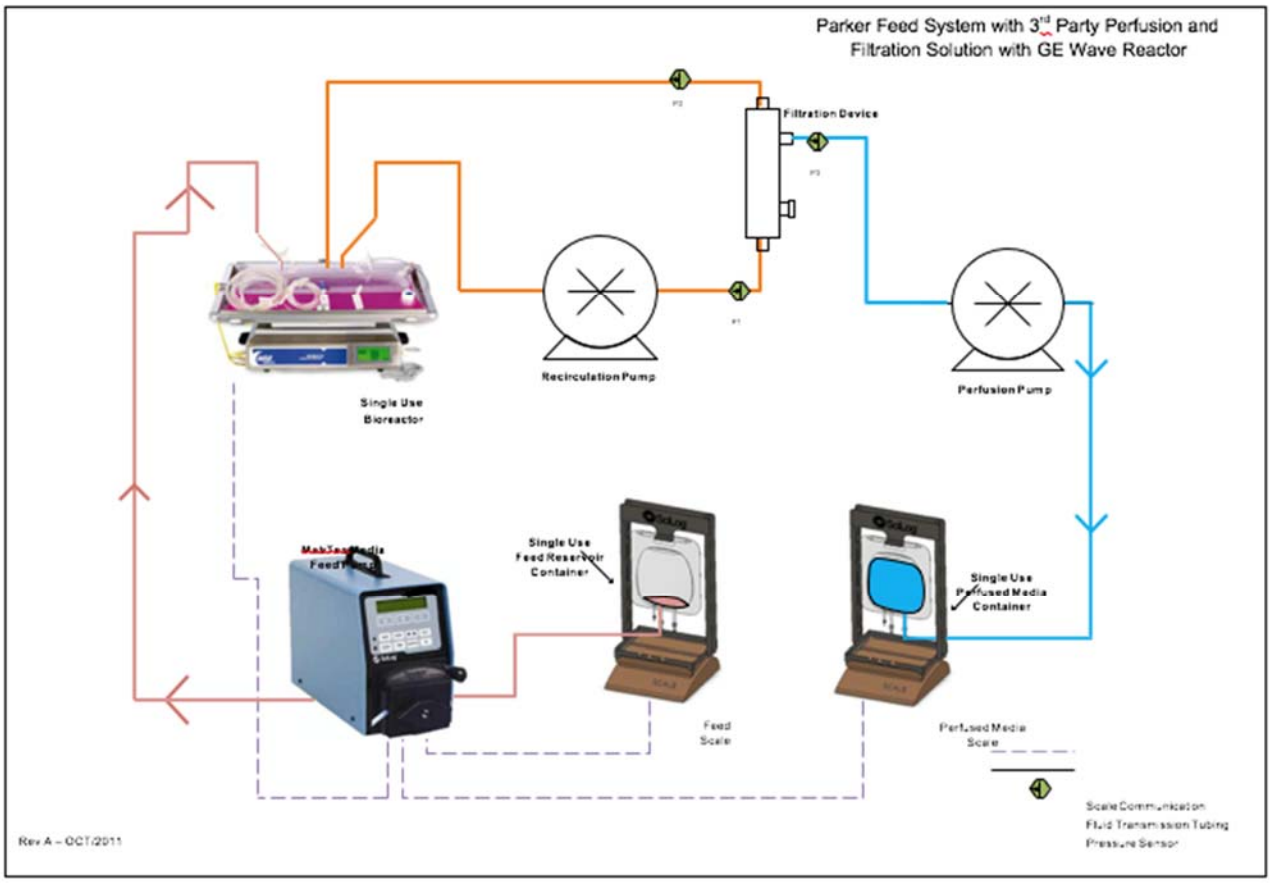
A window with a blinking cursor will be presented, and the data stream from the FilterTec will be displayed as it occurs.

Appendix A: Application Examples

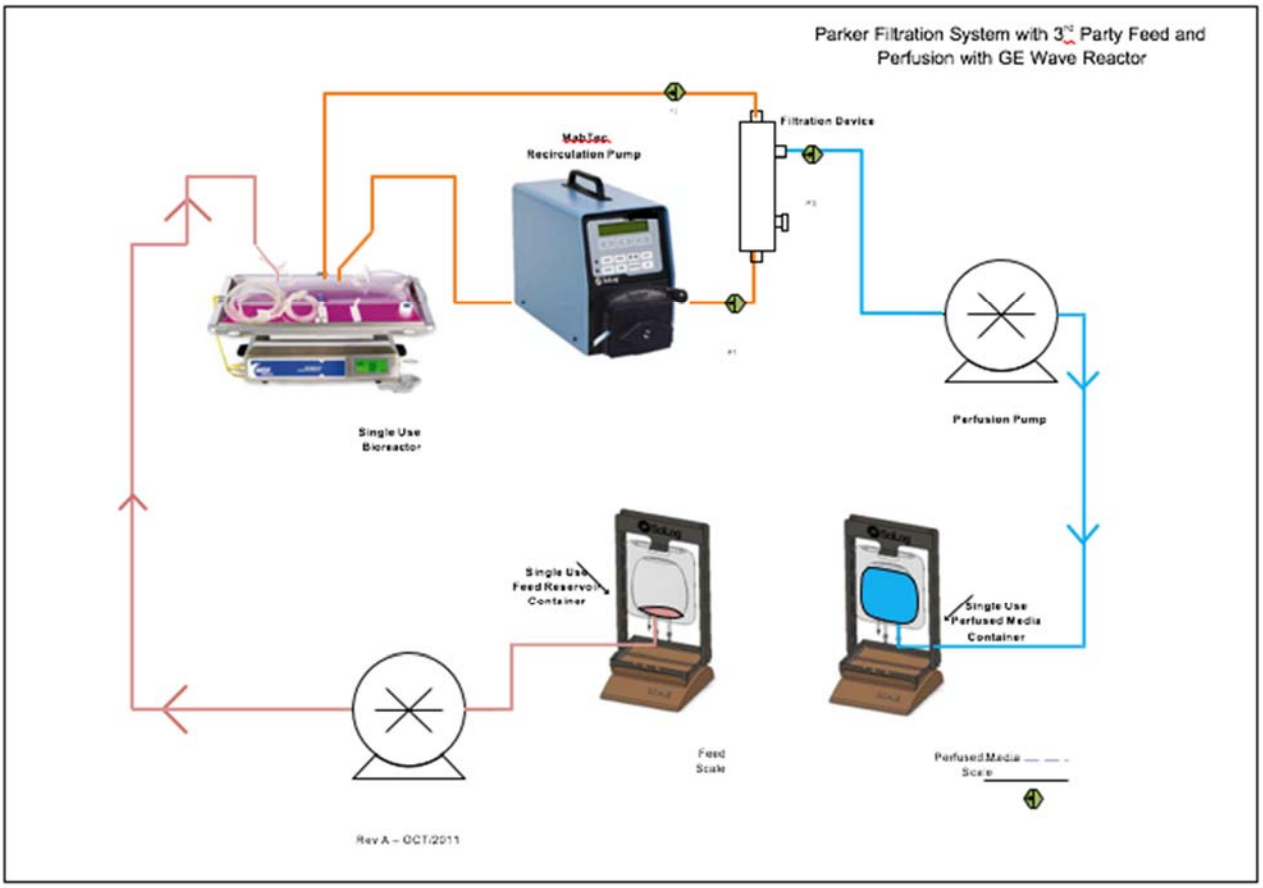
1. Complete Parker System, GE Wave Bioreactor:



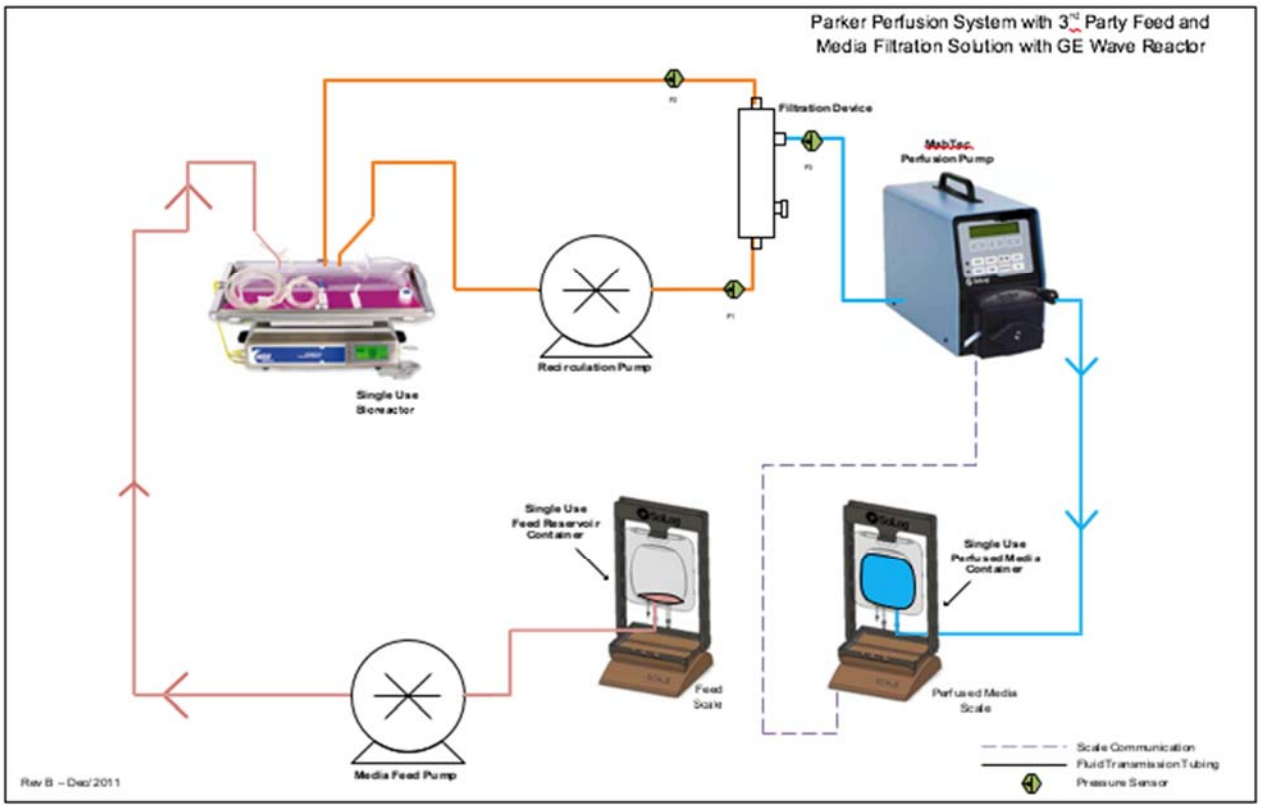
2. Parker Feed System



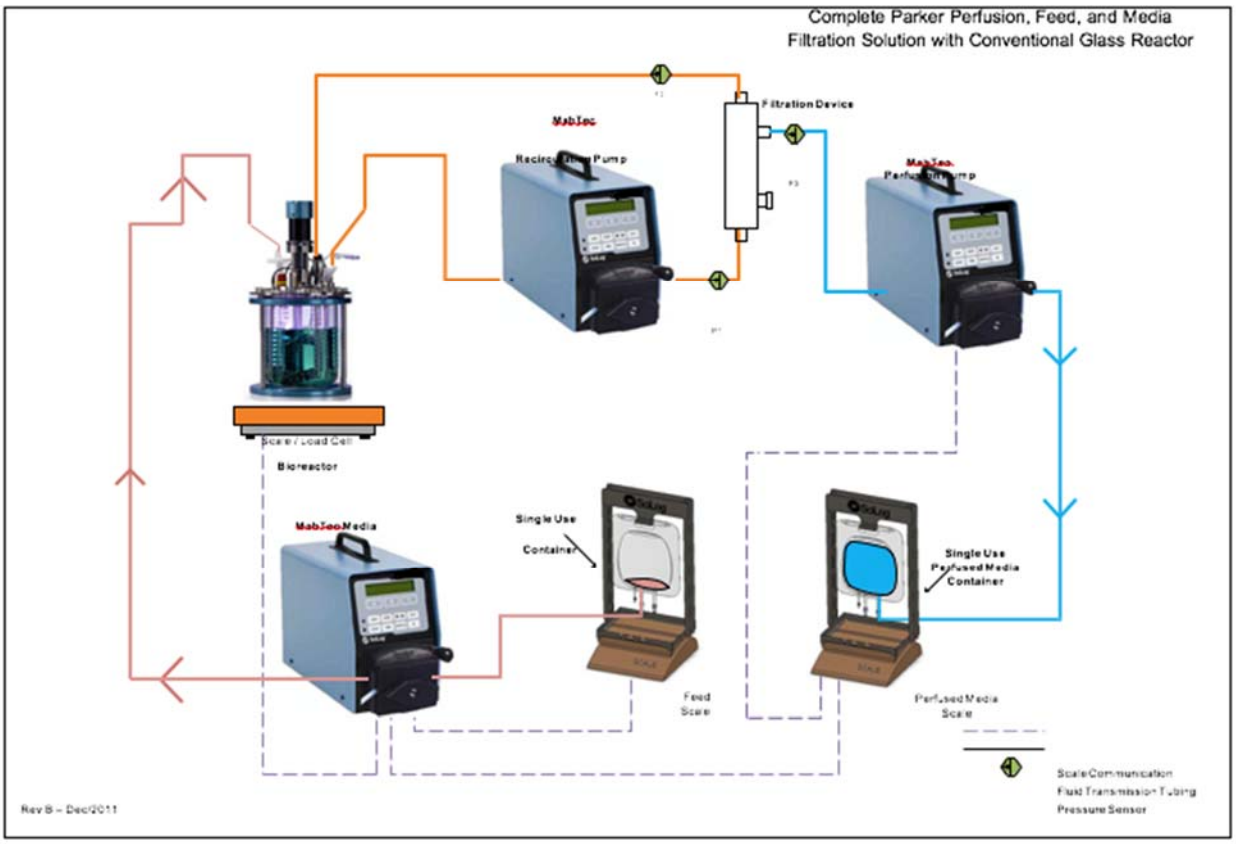
3. Parker Recirculation System:



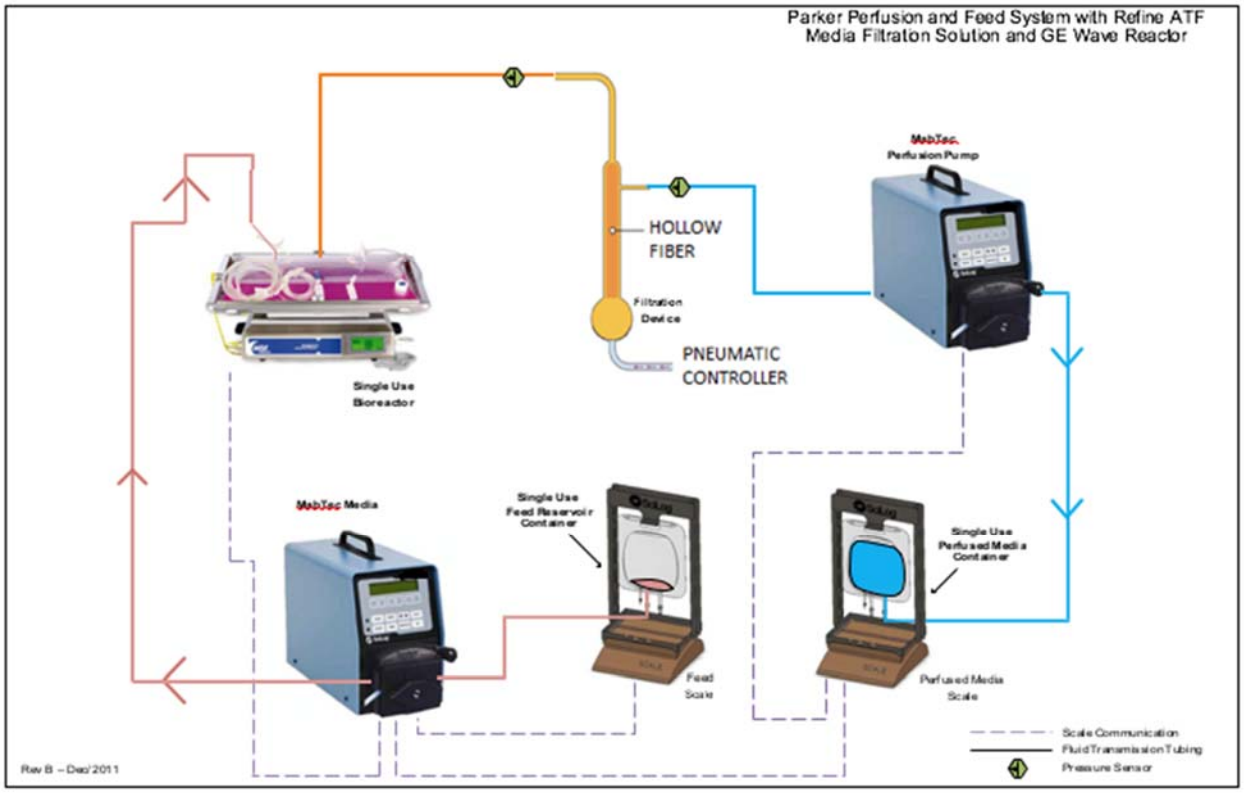
4. Parker Perfusion System:



5. Parker Complete System, Non-GE Bioreactor:



6. Parker Perfusion and Feed System with Refine ATF Filtration:



Appendix B: Troubleshooting

1. Peristaltic Pump Heads

When this occurs:	Check the following:	Possible Solution:
When “Check Pump Head” error occurs with your peristaltic head.	Does “Check Pump Head” occur with no tubing in the head? Confirm the tubing sizes you are using.	If it occurs with no tubing in the head, call Parker. You may need a new motor. If no, make sure you are using the correct size tubing. Thick walled tubing in a thin wall pump head will cause this, and may break the head
When peristaltic pump head turns, but no fluid flows.	Check the tubing size and pump head type, as you may be using the wrong size for that head. Tubing Size is ok	Tandem 1081 is for thin-walled tubing, and 1082 is for thick-walled tubing. Thin-walled tubing in a thick walled head won’t produce much flow. Use the correct size tubing. The pump head may be cracked from being forced closed with the tubing crosswise or the wrong size tubing. Contact Parker for repair or replacement parts.
When the pump head turns ok with no tubing installed, won’t turn when you put tubing in, and you don’t get a “Check Pump Head” error.	The coupler is loose or broken.	Contact Parker for tech support, or to arrange for service and an RGA#

When this occurs:	Check the following:	Possible Solution
When “Scale Error” “Hit any key” shows on your screen.	Is your scale turned on, and are the cables tight? Ok, the scale is on, cables are ok, and it still won’t work?	Press any key to clear the error, tighten the cables, turn on the scale, and try it again. Refer to Section 4, Setup: Scale of this manual, then go to Setup Mode of the pump, select Scale, then Scale Mfr, and confirm the selection is correct.
	Ok, the scale is chosen correctly, and it still doesn’t work. Now what?	Either refer to the same manual section mentioned above to check the scale settings, or call Parker tech support for help correcting them if you are not using the default scale.
When the pump is acting weird. The flows and pressures are all wrong; it gets data from the balance, but slows down way to early; etc.	Has someone messed with your MabTec?	If someone other than yourself or your supervisor has changed the settings without your knowledge, you can to return them to their original settings.
	Have you had electrical problems in the building lately?	Power spikes and brown outs can cause problems. Enter Setup; Pump, and then select Factory Reset. This step is a last resort. This will return the unit to the factory default values. You will need to return to Setup; Pump; Motor RPM, and verify its setting, as well as Setup, Pump; Pump Head to verify it as well. Call Parker tech support if needed.

2. Piston and Magnetic Gear Heads

When this occurs:	Check the following:	Possible Solution
When “Check Pump Head” error occurs with your piston or magnetic gear head.	When was the last time you had the head serviced?	If you believe the head is stuck due to being dried out, you can try wetting it by placing an appropriate solvent in the upper tubing overnight.
	Are you pumping a gritty solution, or one that can crystallize if allowed to dry out?	If it still won’t turn, contact Parker to arrange an RGA to send your pump in for service, or purchasing a service kit if you have a magnetic gear head.
When your piston pump head seems to turn and the motor runs, but no fluid flows.	Either the piston is broken, or the coupler is loose.	Contact Parker for tech support or to arrange for service for your pump and RGA#
When your magnetic pump head seems to turn and the motor runs, but no fluid flows.	Has the unit run dry?	Magnetic gear head pumps do not dry prime well after they have been broken in. You must keep the pump wet. Be sure you are using a check valve as your dispensing tip so the fluid doesn’t run back into the container.
	Is it a high viscosity fluid?	Magnetic gear heads do not perform well with viscous fluids, as they can de-couple. Either reduce the viscosity, provide head pressure, or choose a different style of head.

3. SciDoc Documentation Software

When this occurs:	Check the following:	Possible Solution
When you get a “Device Error, Com Port Not Available” error from your computer.	This is a computer related error, not one generated by the pump. The Com port you specified is in use or does not exist on your computer	Check Device Manager from the properties page of the My Computer Icon. Expand the + next to Ports, Com and LPT. What Com ports exist, and are they functioning properly? If all in Device Mgr is fine, then some other program is using the Com Port, consult your IT or MIS dept. for assistance. You may have to specify a different Com Port for use with the SciDoc spreadsheet. Known devices/programs that cause this error: • Installed but not used Serial Mouse. • RS-232 bar code reader installed on the same Com port. • Hot Sync or Synchronize program for your PDA. • An already open instance of SciDoc using that Com port.

When this occurs:	Check the following:	Possible Solution
You have SciDoc open, and the FilterTec running, but no data is being collected.	There is no communication between the spreadsheet and the FilterTec. Check that you are using the correct cable, and that it’s installed correctly.	The RS-232 cable for the PC can look nearly identical to that used for the balance. They should be labeled.
	WinWedge may not be running	Check the System Tray for the WinWedge Icon. If it’s not there, click on the Setup Button, and indicate which port you are using.
	WinWedge may not be able to access the Com Port.	You will find a button on the Taskbar indicating a “Device Error”, refer to the previous troubleshooting subject for help with Com Port errors.

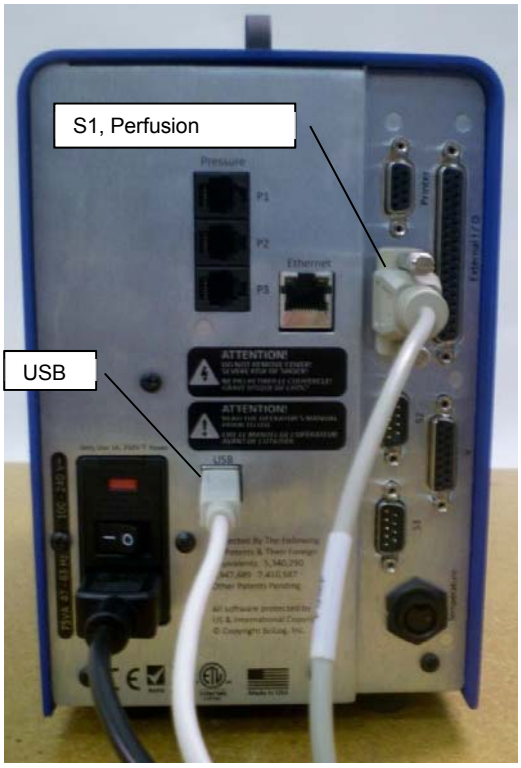
Appendix C: Quick Reference Setup Guide

This may be removed or print separately for use at the bench.

MabTec Setup Guide, Perfusion

It is common to use more than one MabTec for process control. One used as the Perfusion or Harvest unit, one for the Feed, and another for Re-Circulation. It is desirable for the Perfusion and Feed units to share data from the Perfusion scale.

Perfusion: One Scale: Physical Setup



1. Position the Bioreactor, Perfusion MabTec and the Perfusion scale in close proximity to each other, keeping cabling, tubing, and replacement of the Perfusion vessel in mind.
2. Connect one cable from perfusion scale to the S1 port on rear of the Perfusion MabTec.
3. Connect the other perfusion scale cable, if available, to the S1 port on the rear of the Feed MabTec. (S2 on the Feed MabTec will come from the Feed Scale.)
4. Connect a USB cable to the USB port on the rear of the MabTec and the appropriate USB port of the data collection computer.
5. Zero the scale, and place the Perfusion (harvest) vessel on it.
6. Route the tubing from the permeate port of the filter through the pump head of the MabTec and into the vessel.
    a. Support the tubing to allow for ease of replacement of the vessel when full.

Perfusion: One Scale: Unit and Mode Setup

1. Power up the MabTec.
2. Scroll Main Menu options and select Setup.

- SETUP -	SCALE1 UP
DOWN	SELECT

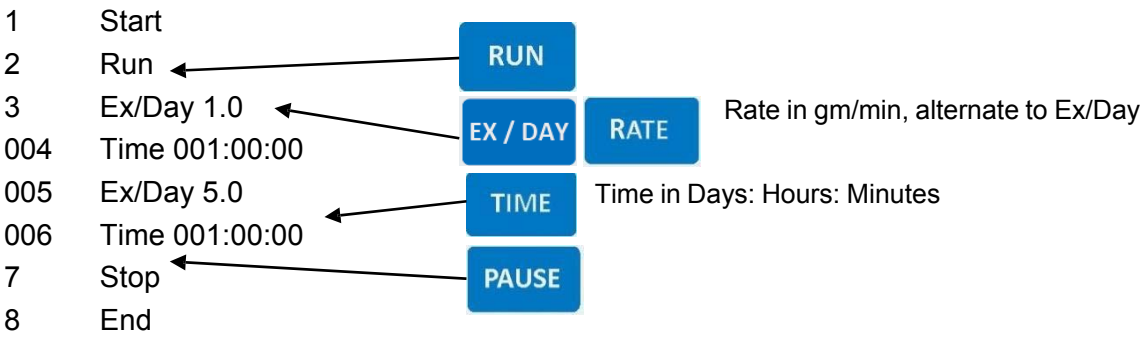
3. Scroll Setup options and select Scale1.
   a. Select Scale Manufacturer.
   b. Scroll through the list and make appropriate selection. Default = Mettler.
   c. Press Exit three times to return to the top of the main menu.
4. Scroll Main Menu options and select Perfusion: One Scale.

PERFUSION: ONE SCALE		
Up	Down	Select

5. Press Setup from Perfusion Mass window.
6. Reactor Weight is first. Press Select and enter the weight in Kg.
   a. This is the weight of the fluid inside the reactor. This value will be referenced in the exchanges per day calculations.
   b. (Ex. 20/50 Wave Reactor with 10L of solution. Program the bioreactor weight to 10.00 Kg.)
7. Press Up to Pump Direction and press Select.
   a. Choose CW (clockwise) or CCW (counterclockwise) and press Select to return to the Setup menu.
8. Press Up to Pump Tubing and press Select.
   a. Choose the pump tubing size and press Select to return to the Setup menu.
9. Press Up to Alarm Enable press Select.
   a. Scroll options and select Alarm to be enabled.
   b. Scroll options and select if you wish to disable alarm (Off), only audible (Alarm Only), or Pump Stop.
      *** At a minimum we recommend enabling Permeate Weight High and Perfusion Flow alarms with Pump Stop action.
   c. Repeat steps a and b until all desired alarms have been enabled or disabled
   d. Press Exit once to return to the Setup menu.
10. Press up to Alarm Limit and press Select.
    a. Scroll options and select Alarm Limit to be set.
    b. Set the limit value and press Select to return to the Alarm Limit submenu.
       *** At a minimum we recommend setting Permeate Weight High limit to a value that works with perfusion container.
    c. Repeat a and b until all Alarm Limits are set.
    d. Press Exit once to return to the Setup menu.
11. Press Up to Clear Totals and press Select.
    a. (If desired – note this will clear all mode totals).
    b. Confirm “Clear Totals?” and “Are You Sure?”
    c. This action will bring you back to the Setup section.
12. Press Up to Display Total and press Select.
    a. If totals exist, they will be displayed. Use this to confirm the action of “Clear Totals” above.
    b. Press any key to return to the Setup menu.
13. Press Exit once to return to the Perfusion Mass / Exec – Edit - Setup screen.

Perfusion: One Scale: Programming

1. Return to the Perfusion Mass / Exec – Edit - Setup screen.
2. Select Edit from Perfusion Mass window.
3. In Edit Screen, use the keypad to enter Rate's, Time's, and Exchanges / Day. Use the "Next" "Delete" and "Last" to insert and remove entries.
   a. Please note that the menu logic requires you to enter an action (Rate or Exchange) followed by a time period.
   b. Rates and Exchanges per day are calculated from the Reactor Weight setting in the Setup submenu (see the section above).
   c. Each logic step requires a time period.
4. Use the two examples below as guides.
   a. (LONG) Below is an example program that will do 1 reactor exchange per day for 1 day and at the end of 1 day it will switch to 5 reactor exchanges for 1 day.



   b. (Short) Below is an example program that will do 1 reactor exchange per day for 2 minutes and at the end of 2 minutes it will switch to 5 reactor exchanges for 2 minutes.

1 Start
2 Run
3 Ex/Day 1.0
004 Time 000:00:02
005 Ex/Day 5.0
006 Time 000:00:02
7 Stop
8 End

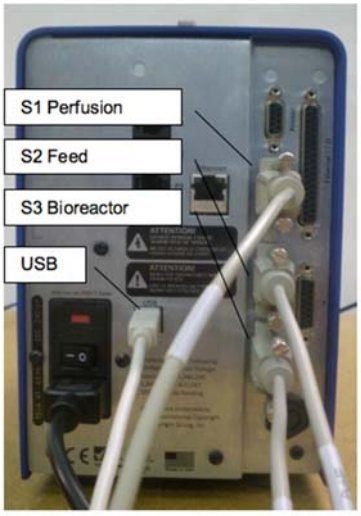
5. Press Exit once to return to the Perfusion Mass / Exec – Edit - Setup screen.

Perfusion: One Scale: Execution

1. Return to the Perfusion Mass / Exec – Edit - Setup screen.
2. Select Exec from Perfusion Mass window.
3. “Mass Flow x.x gm/min / Press Run When Ready” is displayed.
4. Press the Run key from keypad.
5. Scale initialization window will appear.
   a. In the event of an issue with the scale, a Scale Com Error will appear.
   b. If so, double-check the cable connections and the Scale Manufacturer setting in the main Setup menu and retry.
6. Upon successful initialization, the process will begin.
7. The Display key may be used to toggle between the various data and alarm setting display screens.
8. Press Pause to stop process temporarily for changing of the Perfusion vessel or any other reason.
   a. It is **not** necessary to tare or re-zero the scale when changing the vessel.
9. Press Run to resume.
10. To completely stop the process, Press Pause and then Exit.

MabTec Setup Guide, Exact Feed: 2 Scales

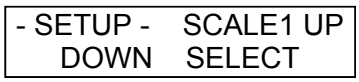
Exact Feed: 2 Scales: Physical Setup



1. Position the Bioreactor, Exact Feed MabTec and the Feed scale in close proximity to each other, keeping cabling, tubing, and replacement of the Feed vessel in mind.
2. Connect scale cable from Perfusion scale to S1 port on rear of Exact Feed MabTec.
3. Connect the cable from Feed scale to S2 port on rear of the MabTec.
4. If available, connect the cable from the Bioreactor Scale to the S3 port.
5. Connect a USB cable to the USB port on the rear of the MabTec and the appropriate USB port of the data collection computer.
6. Zero the Feed scale, and place the Feed vessel on it.
    a. Route the tubing from the Feed vessel through the pump head of the MabTec and into the Bioreactor.
7. Support the tubing above the Feed and Perfusion vessels to allow for ease of replacement of the vessels when full.

Exact Feed: 2 Scales: Unit Setup

1. Power up the MabTec.
2. Scroll Main Menu options and select Setup.
3. Scroll Setup options and select Scale1.
   a. Select Scale Manufacturer.
   b. Scroll through the list and make appropriate selection. Default = Mettler.
   c. **NOTE:** This setting is for the Perfusion scale.
   d. Press Exit once to return to the Setup menu.
4. Press Up to Scale2 and press Select. Select Scale Manufacturer.
   a. Scroll through the list and make appropriate selection. Default = Mettler.
   b. **NOTE:** this is setting for the Feed scale.
   c. Press Exit three times to return to the Main menu.
5. Repeat for Scale3 if a Bioreactor Scale is used.



Exact Feed: 2 Scales: Programming

1. Scroll Main Menu options and select Exact Feed: 2 Scales.
2. Select Edit from “Exact Feed 2 Scale / Exec – Edit – Prime” window.
3. Pump Direction is the first setting.
   a. Press Select and set the pump to run clock wise or counter clockwise.
   b. Press Select to return to the Edit menu.
4. Press Up and select Clear Counters. (If desired – note this will clear all mode totals)
   a. Confirm “Clear Totals?” and “Are You Sure?”
   b. This action will bring you back to the Edit menu.
5. Press Up again and select Slow Factor.
   a. This setting controls the response rate of the system to changes on the Perfusion scale. Default = 5.0 which is mid-range. Leave at this value, change later if needed.
   b. Press Select to return to the Edit menu.
6. Press Up and select Alarm Enable.
   a. Scroll options and select alarm to be enabled
   b. Scroll options and select if you wish to disable alarm (Off), only audible (Alarm Only), or Pump Stop, and press Select to return to the Alarm Enable submenu.

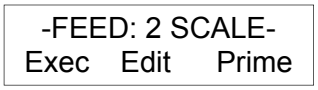
      *** At a minimum we recommend enabling Permeate Weight High alarm and Feed Weight Low alarm with pump stop action.
   c. Repeat steps a. and b. until all desired alarms have been enabled or disabled.
9. Press Exit once to return to the Edit menu.
10. Press Up once to Bio Wgt Source and press Select.

a. Choose between Scale3 and Analog1 depending upon the scale in use with the Bioreactor. If no scale is connected to the unit, leave this as Scale3.
b. (If Scale3 or Analog are used, the appropriate items in Setup: Scale3: Scale Manufacturer or Setup: Analog must be configured.)

11. Press Select to return to the Edit menu.
12. Press Up once to Pump Tubing and press Select.
    a. Set the pump tubing to the size in use.
    b. Press Select to return to the Edit menu.
13. Press up once to Display Totals and press Select.
    a. If totals exist, they will be displayed. Use this to confirm the action of "Clear Counters" above.
    b. Press any key to return to the Edit menu.
14. Press Exit once to return to the "Exact Feed 2 Scale / Exec – Edit – Prime" window.

Exact Feed: 2 Scales: Execution

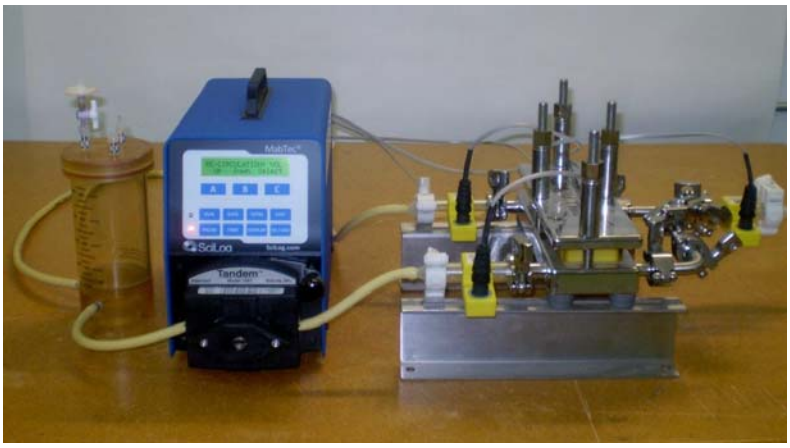
1. Return to the "Exact Feed 2 Scale / Exec – Edit – Prime" screen.
2. Press Exec.

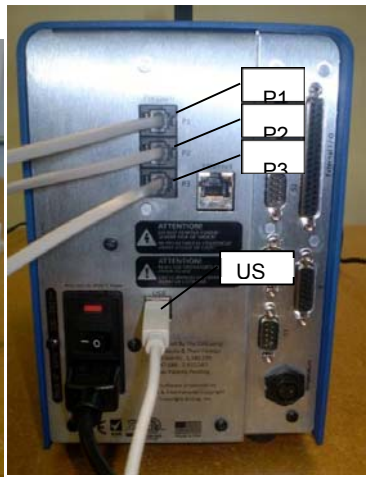


3. Scale initialization window will appear.
    a. In the event of an issue with the scale, a Scale Com Error (S1 or S2) will appear.
    b. If so, double-check the cable connections and the Scale Manufacturer settings in the main Setup menu and retry.
4. Upon successful initialization, the Press Run When Ready screen is displayed.
5. Press the Run key, and the process will begin.
6. The Display key may be used to toggle between the various data and alarm setting display screens.
7. Press Pause to stop process temporarily for changing of the either vessel or any other reason.
    a. It is not necessary to tare or re-zero the scale when changing the vessel.
8. Press Run to resume.
9. To completely stop the process, Press Pause and then Exit.

MabTec Setup Guide, Re-Circulation: Volume

Re-Circulation: Volume: Physical Setup





1. Position the Bioreactor, Re-Circulation MabTec and the Filter in close proximity to each other, keeping cabling, tubing, and placement of the SciPres Pressure Sensors in mind.
   a. The filter above is flat sheet, if using hollow fiber; keep the system within reach of the needed sensor locations.
2. Connect the Feed line SciPres Sensor to the P1 port on the rear of the MabTec.
3. Connect the Retentate Line SciPres Sensor to the P2 port.
4. Connect the Permeate Line SciPres Sensor to the P3 port.
5. Connect a USB cable to the USB port on the rear of the MabTec and the appropriate USB port of the data collection computer.
6. Route the output tubing from the Bioreactor through the pump head on the Re-Circulation MabTec and connect it to the Feed line SciPres on the Filter.
7. Connect tubing from the Retentate SciPres on the Filter and route it back to the connection on the Bioreactor.
8. Route tubing from the Permeate SciPres sensor on the Filter, through the head of the Perfusion MabTec (if used) and connect to the Perfusion Vessel.
9. As the Perfusion MabTec can also monitor the Permeate line pressure from the Filter, there may be a pair of SciPres Sensors to connect to each other.
   a. Low pressure on the Permeate line can indicate fouling of the Filter, or a Perfusion flow rate that is too high.

Re-Circulation: Vol: Mode Programming

RE-CIRCULATION: VOL		
Up	Down	Select

1. Power up the MabTec.
2. Scroll Main Menu options and select Re-Circulation: Vol.
3. Select Edit from “Recirculation / Exec – Edit – Prime” window.
4. Pump Direction is the first setting.
   a. Press Select and set the pump to run clockwise or counter clockwise.
5. Press Up once to Pump Tubing and press Select.
   a. Set the pump tubing to the appropriate size.
   b. Press Select to return to the Edit menu.
6. Press Up to FWD Flowrate and press Select.
   a. Use Incr and Decr to set the Forward Flow Rate in ml/min.
   b. Press Select to return to the Edit menu.
7. Press Up to Forward Time and press Select.
   a. Use Incr and Decr to set the Forward Time in Hours: Minutes.
   b. Press Select to return to the Edit menu.
8. Press Up again to REV Flowrate and press Select.
   a. Use Incr and Decr to set the Reverse Flow Rate in ml/min.
   b. Press select to return to the Edit menu.
9. Press up to Reverse Time and press Select.
   a. Set the Reverse Time in Hours: Minutes.
   b. Press Select to return to the Edit Menu.
10. Press up to Alarm Enable and press Select.
    a. Scroll options and select alarm to be enabled
    b. Scroll options and select if you wish to disable alarm (Off), only audible (Alarm Only), or Pump Stop, and press Select to return to the Alarm Enable submenu.
       *** At a minimum we recommend enabling Low Pressure (P3) Alarm with pump stop action.
    c. Repeat steps a. and b. until all desired alarms have been enabled or disabled.
11. Press Exit once to return to the Edit menu.
12. Press Up once and select Alarm Limit.
    a. Scroll options and select Alarm Limit to be set.
    b. Set value and press Select to return to the Alarm Limit submenu.
       *** At a minimum we recommend setting the Low Pressure (P3) limit to a value that would indicate excessive fouling of the Filter.
    c. Repeat steps a. and b. until all desired Limits have been set.
13. Press Exit once to return to the Edit menu.
14. Press Up to Display Total and press Select.
    a. If totals exist, they will be displayed. Use this to confirm the action of “Clear Totals” below.
    b. Press any key to return to the Setup menu.
15. Press Up to Clear Totals and press Select.
    a. (If desired – note this will clear all mode totals).
    b. Confirm “Clear Totals?” and “Are You Sure?”
    c. This action will bring you back to the Setup section.
16. Press Exit once to return to the “Recirculation / Exec – Edit – Prime” window.

Re-Circulation: Vol: Execution

-RECIRCULATION-
Exec Edit Prime

1. Return to the “Recirculation / Exec – Edit – Prime” screen.
2. Press Exec.
3. The Press Run When Ready screen is displayed.
4. Press the Run key, and the process will begin in the Forward Direction.
    a. The MabTec will run Forward at the programmed FWD Flow Rate for the programmed Forward Time, then run Reverse at the programmed REV Flow Rate for the programmed Reverse Time.
    b. This continues to repeat until the Run Time Alarm / Limit stops the process or the Pause and Exit keys are pressed.
5. The Display key may be used to toggle between the various data and alarm setting display screens.
6. Press Pause to stop process temporarily, and press Run to resume.
7. To completely stop the process, Press Pause and then Exit.
8. If the process is stopped by the Hi or Lo Pressure Alarms, press Pause to cancel the Alarm, clear the cause of the condition, and press Run to resume the process.

MabTec Setup Guide, Feed: One Scale

Feed: One Scale: Physical Setup

1. Position the Bioreactor, Bioreactor Scale, and the Feed: One Scale MabTec in close proximity to each other, keeping cabling, tubing, and access to the Feed vessel in mind.
2. Connect the cable from the Bioreactor Scale to the S1 connector on the rear of the Feed: One Scale MabTec.
3. Connect a USB cable to the USB port on the rear of the MabTec and the appropriate USB port of the data collection computer.
4. Route the tubing from the Feed Vessel through the pump head on the Feed: One Scale MabTec and connect it to the Bioreactor.
    a. Support the tubing coming from the Feed vessel such that changing the vessel can be easily accomplished.

Feed: One Scale: Unit Setup

1. Power up the MabTec.
2. Scroll Main Menu options and select Setup.
3. Scroll Setup options and select Scale1.

- SETUP -	SCALE1
UP DOWN	SELECT

    a. Select Scale Manufacturer.
    b. Scroll through the list and make appropriate selection. Default = Mettler.
    c. **NOTE:** This is the setting for the Bioreactor scale.
    d. Press Exit three times to return to the top of the main menu.

Feed: One Scale: Programming

1. Power up the MabTec.
2. Scroll Main Menu options and select Feed: One Scale.
3. Select Edit from “Feed: 1 Scale / Exec – Edit – Prime” window.
4. Pump Direction is the first setting.
    a. Press Select and set the pump to run clockwise or counter clockwise.
5. Press Up and select Clear Counters. (If desired – note this will clear all mode totals)
    a. Confirm “Clear Totals?” and “Are You Sure?”
    b. This action will bring you back to the Edit menu.
6. Press Up again and select Slow Factor.
    a. This setting controls the response rate of the system to changes on the Bioreactor scale. Default = 5.0 which is mid-range. Leave at this value, change later if needed.
    b. Press Select to return to the Edit menu.
7. Press up to Alarm Enable and press Select.
    a. Scroll options and select alarm to be enabled
    b. Scroll options and select if you wish to disable alarm (Off), only audible (Alarm Only), or Pump Stop, and press Select to return to the Alarm Enable submenu.

        *** At a minimum we recommend enabling Feed Volume with pump stop action.
    c. Repeat steps a. and b. until all desired alarms have been enabled or disabled.
8. Press Exit once to return to the Edit menu.
9. Press Up once and select Alarm Limit.
    a. Scroll options and select Alarm Limit to be set.
    b. Set value and press Select to return to the Alarm Limit submenu.

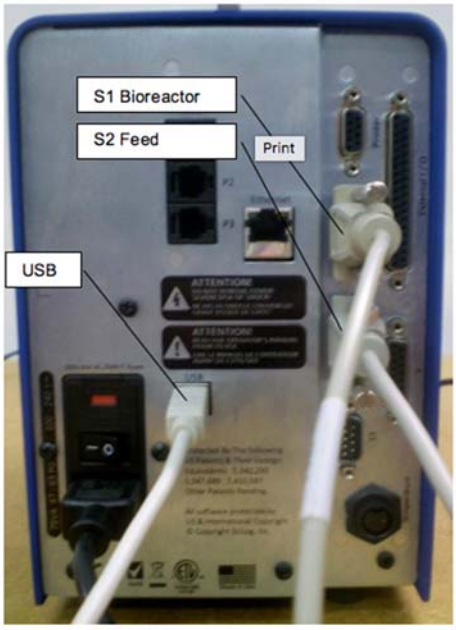
        *** At a minimum we recommend setting the Feed Volume limit to a value that is appropriate for the Feed vessel volume.
    c. Repeat steps a. and b. until all desired Limits have been set.
10. Press Exit once to return to the Edit menu.
11. Press Up to Display Total and press Select.
    a. If totals exist, they will be displayed. Use this to confirm the action of “Clear Counters” above.
    b. Press any key to return to the Setup menu.
12. Press Exit once to return to the “Feed: 1 Scale / Exec – Edit – Prime” window.

Feed: One Scale: Execution

1. Return to the “Feed: 1 Scale / Exec – Edit – Prime” screen.
2. Press Exec.
3. Scale initialization window will appear.
    a. In the event of an issue with the scale, a Scale Com Error (S1) will appear.
    b. If so, double-check the cable connections and the Scale Manufacturer settings in the main Setup menu and retry.
4. Upon successful initialization, the Press Run When Ready screen is displayed.
5. Press the Run key, and the process will begin.
6. The Display key may be used to toggle between the various data and alarm setting display screens.
7. Press Pause to stop process temporarily for changing of the Feed vessel or any other reason.
    a. It is **not** necessary to tare or re-zero the scale when changing the vessel.
8. Press Run to resume.
9. To completely stop the process, Press Pause and then Exit.

MabTec Setup Guide, Feed: Two Scale

Feed: Two Scale: Physical Setup



1. Position the Bioreactor, Bioreactor Scale, Feed Scale and the Feed: Two Scale MabTec in close proximity to each other, keeping cabling, tubing, and access to the Feed vessel in mind.
2. Connect the cable from the Bioreactor Scale to the S1 connector on the rear of the Feed: Two Scale MabTec.
3. Connect the cable from the Feed Scale to the S2 connector on the rear of the MabTec.
4. Connect a USB cable to the USB port on the rear of the MabTec and the appropriate USB port of the data collection computer.
5. Route the tubing from the Feed Vessel through the pump head on the Feed: Two Scale MabTec and connect it to the Bioreactor.
    a. Support the tubing coming from the Feed vessel such that changing the vessel can be easily accomplished.

Feed: Two Scale: Unit Setup

1. Power up the MabTec.
2. Scroll Main Menu options and select Setup.
3. Scroll Setup options and select Scale1.

- SETUP -		SCALE1
UP	DOWN	SELECT

   a. Select Scale Manufacturer.
   b. Scroll through the list and make appropriate selection. Default = Mettler.
   c. Note: this is the setting for the Bioreactor scale.
   d. Press Exit once to return to the Setup menu.
4. Press Up to Scale2 and press Select.
   a. Select Scale Manufacturer.
   b. Scroll through the list and make appropriate selection. Default = Mettler.
   c. **NOTE** this is setting for the Feed Scale
   d. Press Exit three times to return to the Main menu.

Feed: Two Scale: Programming

1. Power up the MabTec.
2. Scroll Main Menu options and select Feed: Two Scale.
3. Select Edit from “Feed: 2 Scale / Exec – Edit – Prime” window.
4. Pump Direction is the first setting.
   a. Press Select and set the pump to run clockwise or counter clockwise.
5. Press Up and select Clear Counters. (If desired – note this will clear all mode totals)
   a. Confirm “Clear Totals?” and “Are You Sure?”
   b. This action will bring you back to the Edit menu.
6. Press Up again and select Slow Factor.
   a. This setting controls the response rate of the system to changes on the Bioreactor scale. Default = 5.0 which is mid-range. Leave at this value, change later if needed.
   b. Press Select to return to the Edit menu.
7. Press up to Alarm Enable and press Select.
   a. Scroll options and select alarm to be enabled
   b. Scroll options and select if you wish to disable alarm (Off), only audible (Alarm Only), or Pump Stop, and press Select to return to the Alarm Enable submenu.

      *** At a minimum we recommend enabling Feed Wgt Low alarm with pump stop action.
   c. Repeat steps a. and b. until all desired alarms have been enabled or disabled.
8. Press Exit once to return to the Edit menu.
9. Press Up once and select Alarm Limit.
   a. Scroll options and select Alarm Limit to be set.
   b. Set value and press Select to return to the Alarm Limit submenu.

      *** At a minimum we recommend setting the Feed Weight Low limit to a value appropriate to the size of the Feed vessel.
   c. Repeat steps a. and b. until all desired Limits have been set.
10. Press Exit once to return to the Edit menu.
11. Press Up to Display Total and press Select.

a. If totals exist, they will be displayed. Use this to confirm the action of “Clear Counters” above.

b. Press any key to return to the Setup menu.

12. Press Exit once to return to the “Feed: 1 Scale / Exec – Edit – Prime” window.

Feed: Two Scale: Execution

1. Return to the “Feed: 2 Scale / Exec – Edit – Prime” screen.
2. Press Exec.
3. Scale initialization window will appear.
   a. In the event of an issue with the scale, a Scale Com Error (S1 or S2) will appear.
   b. If so, double-check the cable connections and the Scale Manufacturer settings in the main Setup menu and retry.
4. Upon successful initialization, the Press Run When Ready screen is displayed.
5. Press the Run key, and the process will begin.
6. The Display key may be used to toggle between the various data and alarm setting display screens.
7. Press Pause to stop process temporarily for changing of the Feed vessel or any other reason.
   a. It is not necessary to tare or re-zero the scale when changing the vessel.
8. Press Run to resume.
9. To completely stop the process, Press Pause and then Exit.

MabTec Setup Guide, Seed Induction

Seed Induction: Physical Setup

1. Position the Seed Scale, Seed vessel, Bioreactor, and the Seed Induction MabTec in close proximity to each other, keeping cabling, tubing, and access to the Seed vessel in mind.
2. Connect the cable from the Seed Scale to the S1 connector on the rear of the Seed Induction MabTec.
3. Connect a USB cable to the USB port on the rear of the MabTec and the appropriate USB port of the data collection computer.
4. Route the tubing from the Seed Vessel through the pump head on the Seed Induction MabTec and connect it to the Bioreactor.
    a. Support the tubing coming from the Seed vessel such that changing the vessel can be easily accomplished.

Seed Induction: Unit Setup

1. Power up the MabTec.
2. Scroll Main Menu options and select Setup.
3. Scroll Setup options and select Scale1.

- SETUP - SCALE1
UP DOWN SELECT

    a. Select Scale Manufacturer.
    b. Scroll through the list and make appropriate selection. Default = Mettler.
    c. **NOTE:** This is the setting for the Seed scale.
    d. Press Exit three times to return to the top of the main menu.

Seed Induction: Programming

1. Power up the MabTec.
2. Scroll Main Menu options and select Seed Induction.
3. Select Edit from “Seed Induction / Exec – Edit – Prime” window.
4. Dispense Weight is the first setting.
   a. Press Select and use Incr and Decr to set the weight of solution to be dispensed in grams. Press Select to return to the Edit Menu.
5. Press Up and select Count. (If desired – note this will clear all mode totals)
   a. Set the number of dispenses to be accomplished and press Select.
6. Press Up again and select Time Delay.
   a. This setting controls the time between dispenses in Days: Hours: Minutes.
   b. Press Select to return to the Edit menu.
7. Press Up to Pump Rate and press Select.
   a. Use Incr and Decr to set the desired Pump Rate in % of Motor Speed.
   b. The default is 80%. This may be higher or lower as needed.
   c. Press Select to return to the Edit menu
8. Press Up again to Pump Direction and press Select.
   a. Set the Direction of the pump head to Clockwise or Counter-clockwise.
9. Press Select to return to the Edit menu.
10. Press Up once and select Slow Factor.
    a. This controls the point (in grams) at which the system slows down at the end of the dispense. The default is 25. This works well for large tubing at fast flow rates. For smaller tubing and slower rates, values as low as 3-5 grams can be used.
    b. Set value and press Select to return to the Edit menu.
11. Press Up to Display Total and press Select.
    a. If totals exist, they will be displayed. Use this to confirm the action of “Clear Total” below.
    b. Press any key to return to the Edit menu.
12. Press Up to Clear Total and press Select.
    a. (If desired – note this will clear all mode totals).
    b. Confirm “Are You Sure?”, and the system returns to the Edit menu.
13. Press up to Alarm Enable and press Select.
    a. Seed Weight Lo is the only alarm, press Select again.
    b. Scroll options and select if you wish to disable alarm (Off), only audible (Alarm Only), or Pump Stop, and press Select to return to the Alarm Enable submenu.
       *** We recommend enabling Seed Wgt Low alarm with pump stop action.
14. Press Exit once to return to the Edit menu.
15. Press Up once and select Alarm Limit.
    a. Seed Weight Lo is the only Limit, press Select again.
    b. Set value and press Select to return to the Alarm Limit submenu.
       *** We recommend setting the Seed Weight Low limit to a value appropriate to the size of the Seed vessel.
16. Press Exit once to return to the Edit menu.
17. Press Exit once to return to the “Seed Induction / Exec – Edit – Prime” window.

Seed Induction: Execution

1. Return to the “Seed Induction / Exec – Edit – Prime” screen.
2. Press Exec.
3. Scale initialization window will appear.
    a. In the event of an issue with the scale, a Scale Com Error (S1) will appear.
    b. If so, double-check the cable connections and the Scale Manufacturer settings in the main Setup menu and retry.
4. Upon successful initialization, the Press Run When Ready screen is displayed, showing the size of the programmed dispense.
5. Press the Run key, and the first dispense will begin.
    a. The system will perform subsequent dispenses based upon the Time Delay setting.
    b. This setting includes the time needed to complete the dispense. (i.e. the time delay is between dispense start times, not end and start times.)
6. The Display key may be used to toggle between the various data and alarm setting display screens.
7. Press Pause to stop process temporarily for changing of the Feed vessel or any other reason.
    a. It is **not** necessary to tare or re-zero the scale when changing the vessel.
8. Press Run to resume.
9. To completely stop the process, Press Pause and then Exit.

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