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1.0 Purpose

This procedure describes the operation of the Thermo Scientific Sorvall Legend XFR Refrigerated Centrifuge.

2.0 Scope

This procedure applies to personnel who will be using the Thermo Scientific Sorvall Legend XFR Centrifuge in cGMP production.



3.0 Authority and Responsibility

- 3.1 The Director of Technical Operations, Biopharmaceutical Development Program (BDP), has the authority to define this procedure.
- 3.2 Manufacturing is responsible for the implementation of this procedure.
- 3.3 Manufacturing personnel are responsible for performing operations in compliance with this SOP.
- 3.4 Biopharmaceutical Quality Assurance (BQA) is responsible for quality oversight of this operation.




4.0 Procedure

4.1 Preparation


- 4.1.1 Turn on the power by pressing the switch to (I) located on the back panel of the unit.
- 4.1.2 The centrifuge will perform a software self-check. Once the self-check is complete the user can then proceed to open the centrifuge lid.
- 4.1.3 Press **OPEN** button and lift the centrifuge lid. The centrifuge screen will display **LID OPEN**.

- 4.1.4 Check that the appropriate rotor for the application is installed. Only use approved rotors listed in Attachment 1. Follow steps 4.1.4.1 to 4.1.4.6 if the rotor must be changed. Proceed to step 4.2 if the proper rotor is in place.
- 4.1.4.1 The centrifuge is equipped with an autolocking system. This system does not require a bolt to be removed to change the installed rotor.
- 4.1.4.2 Remove an already installed rotor by lifting on the rotor handle and depressing the green autolocking key. Gentle pull straight upwards as the autolocking key disengages from the centrifuge spindle.
- 4.1.4.2.1 The centrifuge has an available aerosol-tight rotor. When using this rotor, the lid of the centrifuge must be closed to disengage the rotor from the spindle.
- 4.1.4.2.2 The provided autolocking lid for aerosol-tight rotors should be used as directed by the rotor specific instructions.
- 4.1.4.3 Inspect the rotor autolocking system o-ring. If damage is visible, the system must be serviced before operations are to continue.
- 4.1.4.4 Slide the desired rotor straight down over the centrifuge spindle. Gently push down on the rotor handle until an audible click is heard.
- 4.1.4.5 After the autolocking key has engaged, gently pull up on the rotor handle to ensure the autolocking mechanism is engaged. If the rotor slides free, try reseating the rotor on the spindle. If the autolocking key will not engage, the centrifuge **must be** serviced before use.
- 4.1.4.6 Capture any rotor specific identification number and log the rotor change in the equipment log. The rotor specific number is also needed when programming which bucket/rotor is installed (step 4.2.2.)
- 4.2 Entering Run Parameters
- 4.2.1 Enter run parameters specified by the BPR or area supervisor. Parameter values from the previous centrifuge run will be displayed.
- 4.2.2 To select/verify the bucket/rotor in the centrifuge, press the **BUCKET**,  key. This will display the current bucket code selected. This should match the installed bucket/rotor from step 4.1.4. Press ENTER, , to accept the selection
- 4.2.2.1 If the bucket code does not match, press the **BUCKET**, key repeatedly until the displayed bucket code matches the bucket from step 4.1.4.
- 4.2.2.2 If bucket adaptors are used, a bucket radius will need to be entered in after selecting the bucket code. Refer to the user's manual to identify correct corresponding bucket radius, as it pertains to the installed adaptors, for the selected bucket/rotor.

4.2.2.3 If a standard bucket/rotor is used, the bucket radius field should be left at the default value.


4.2.3 To set the required centrifuge speed, press the **SPEED**, , key and enter the desired value. Press the **ENTER**, , key to accept the value. The **TOGGLE**, , key can be depressed to change between **RPM** and **RCF** as the application dictates. The **RPM** or **RCF** entered will be displayed during the cycle.


Note: The minimum centrifuge speed is 300 RPM and will auto correct to this value if one is entered below this value.


4.2.4 To set the required cycle time, press the **TIME**, , key to enter a centrifugation duration. The display will show a set time field and the user can enter a cycle time of HH.MM (hours and minutes) via the numeric keys.



4.2.4.1 Pressing the **TIME** key repeatedly will also switch the unit between HH.MM and hold timing.


4.2.4.2 Pressing and holding the TIME key will allow the cursor to switch between the minutes and seconds fields.



4.2.4.3 During a hold or continuous timed cycle, the centrifuge will continue to operate until the user presses the **STOP**, , key.



4.2.4.4 During a cycle the centrifuge can display the total run time and the run time after reaching the speed setpoint. Pressing the **TOGGLE**, , key will switch the display between these two displays.

4.2.5 To set the required cycle temperature, press the **TEMP**, , key and the cursor key to set the desired run temperature. The temperature can be set between -10 to 40°C.

4.2.5.1 Pressing the **TOGGLE**, , key switches the display from the sample temperature to the chamber temperature. Once the desired temperature location is selected, the user may enter the specified temperature setpoint. Press the **ENTER**, , key to save the desired value. The centrifuge will then use as the cycle's operational setpoint from the specified location.

4.2.5.2 Pressing the **TEMP**, key for three seconds will allow the user to select and set a PreTemp setpoint. The PreTemp setpoint specifies what temperature the centrifuge will attempt to achieve at idle and with the lid shut. Pressing the **START**, , key will initiate the PreTemp cycle.

4.2.6 The bucket/rotor acceleration rate can be set by pressing the **ACC DEC**, , key. Select the desired acceleration rate; 0 is the slowest and 9 is the fastest rate. Confirm your entry by pressing the ENTER, , key.

4.2.7 The bucket/rotor deceleration rate can be set by pressing the **ACC DEC**, , key twice. Select the desired deceleration rate; 0 is the slowest and 10 is the fastest rate. Confirm your entry by pressing the ENTER, , key.

4.3 Operation of the Centrifuge

4.3.1 Before daily use, or between manufacturing lots, clean per **SOP 19102 - Routine Use and Disinfection of Biological Safety Cabinets, Incubators, Shakers, and Centrifuges**.


4.3.2 Load the rotor with samples, assuring that the rotor is balanced. Use a blank (tube or bag, filled with WFI to balance the centrifuge), if necessary.


4.3.2.1 If using inserts/carriers within the buckets, those inserts must be loaded symmetrically to ensure stability.


4.3.3 Tighten the lid onto the buckets, if equipped, and close the centrifuge door by pressing firmly down on the center of the door front until a clicking sound is heard.

4.3.4 Verify that all parameters are set, using step 4.2, as directed by the BPR or area supervisor.

4.3.5 Ensure that the gap between the lid and the top of the centrifuge housing is free from blockage. The gap is reduced in size once the cycle starts as the lid safety latch is engaged.


4.3.6 Press **START**, , key. If the centrifuge was just turned on or has not been used for more than two hours, the display will illuminate "Check Castor Brakes." Upon checking the wheel brakes and ensuring they are engaged, press the **START** key again.

4.3.7 A timed run will end when the **TIME** display counts down to zero. To end a run in progress, press the **STOP**, , key to set the centrifuge for deceleration.

4.3.7.1 Alternatively, a non-timed cycle maybe performed by pressing and holding the **PULSE**, , key to run the bucket/rotor for a brief period of time. If a

PULSE run is initiated, any predefined time, acceleration, deceleration, and speed setpoints will be ignored.

Caution: Performing a PULSE cycle should only be performed if the installed bucket/rotor will be operated within its normal specifications. The centrifuge will allow a PULSE cycle to start even if the PULSE period exceeds the bucket/rotor's limits.

- 4.3.8 When the display shows a message "END", the lid can be opened by pressing the **OPEN**, , key.
- 4.3.9 Remove the contents. Inspect for leakage, if leakage is detected, clean per **SOP 19102 - Routine Use and Disinfection of Biological Safety Cabinets, Incubators, Shakers, and Centrifuges**.
- 4.3.10 At the completion of daily operations, clean the unit per **SOP 19102 - Routine Use and Disinfection of Biological Safety Cabinets, Incubators, Shakers, and Centrifuges**.
- 4.3.10.1 If disinfected, allow all parts to air dry before running additional cycles.
- 4.3.10.2 Avoid using bleach-based disinfectants on the bucket/rotor and accessories.
- 4.4 Rotor Autoclaving
- 4.4.1 Place the rotor and associated accessories on a flat surface within an available sterilizing autoclave shelf.
- 4.4.2 Rotors, listed on Attachment 1, and their associated accessories can be autoclaved at 121°C for a maximum duration of 20 minutes.
- 4.4.3 Upon completion of the autoclave cycle, inspect the rotor for signs of wear. If excessive wear or corrosion is observed, notify the area supervisor immediately. The rotor **must be** replaced.
- 4.5 Troubleshooting
- 4.5.1 For troubleshooting, refer to the user's manual for recommended actions. Notify your supervisor if any problems persist that can't be resolved with the user's manual.
- 4.6 Maintenance
- 4.6.1 Wipe condensation out of the chamber bowl between runs to prevent the chamber from icing.
- 4.6.2 Lubricate all aluminum surfaces with an approved lubricant (such as Thermo Fisher Cat# 70009824) at least once a month during periods of use.
- 4.6.3 The swing arms of the rotors should be treated with lubricant once a month during periods of use. Use approved lubricant Thermo Fisher Cat# 75003786.



5.0 Documentation

- 5.1 Document usage for every centrifuge run, cleaning, autoclaving, and maintenance on Form 19102-03 in the equipment logbook per **SOP 21531 - Equipment Logs**, and on the product-specific batch record where requested.

6.0 References and Related Documents

Instruction Manual; Thermo Scientific Sorvall Legend XF/XFR

SOP 19102 *Routine Use and Disinfection of Biological Safety Cabinets, Incubators, Shakers, and Centrifuges*

SOP 21531 *Equipment Logs*

7.0 Attachments

- 7.1 **Attachment 1** Rotor Selection



Attachment 1

Rotor Selection

Rotor Selection

The Sorvall Legend XF / XFR is supplied without a rotor.

Various rotors are available to choose from.

TX-750	7500 3607
with round buckets	7500 3608
with rectangular buckets	7500 3614
incl. Microtiter carrier	7500 3617
incl. ABI-bucket	7500 3618
BIOSHIELD™ 1000A	7500 3603
BIOLiner™	7500 3667
HIGHPlate™ 6000	7500 3606
FIBERLite™ H3LV	7500 3665
FIBERLite™ F14S-6 x 250 LE	7500 3662
FIBERLite™ F15-6 x 100	7500 3698
FIBERLite™ F13S-14 x 50c	7500 3661
FIBERLite™ F15-8 x 50c	7500 3663
FIBERLite™ F21-48 x 2	7500 3664
Microliter 48 x 2	7500 3602
HIGHConic™ 6 x 100	7500 3620
M-20	7500 3624

The technical data of the rotors and the corresponding adapters and reduction sleeves for various commercially available containers can be found in the corresponding rotor operating manuals.