

PRODUCT UPDATES

Liberator Plumbing Consolidation Retrofit Kit Instructions

There is a new Flow Control Valve (FCV) for Liberator units. Bulletin 21494713 guides technicians through removing the FCV with the Secondary Relief Valve (SRV) and install the replacement FCV and new economizer regulator, along with your current Primary Relief Valve (PRV) and a replacement SRV. These kits are required when there is a need to replace either the economizer regulator or the FCV, as the FCV's will no longer have an SRV port in them.

WARNING: Do not use the new FCV that does not have the SRV port on units manufactured prior to this design change without installing the entire kit.

PART NO. KIT DESCRIPTION FCV P/N SRV P/N **ECONOMIZER REGULATOR P/N** 21494709 30 PSI Lib 21341644 21449808 21215214 Plumbing Service Kit 21494710 65 PSI Lib 21449806 21215227 21341648 **Plumbing Service** Kit 21494711 30 PSI Lib 21449808 21215214 21341652 Plumbing Service Kit Japan 30 PSI Lib 21494787 21494712 21215214 21341644 Plumbing Service Kit – 2 LPM

Table 1. Available Kit Options

Please refer to Service Bulletin PN 21494713.

Freestyle® Comfort™ Battery Capacity Test

The below procedure should be used to test the full capacity of the Freestyle® Comfort™ power cartridge:

1. Fully recharge the battery using either a Freestyle Comfort connected to AC power or a desktop charger.



- 2. Install the fully-charged power cartridge into a Freestyle Comfort and remove any external power cords.
- 3. Turn the Freestyle Comfort on and enter on O2 Test Mode.
 - a. To enter test mode press +, +, -, -, +, on the keypad. The entire sequence needs to be entered within 5 seconds. If a mistake is made while entering this sequence, the user must wait 5 seconds before attempting again.
- 4. Once in test mode, the flow can be increased or decreased as usual.
- 5. While in test mode the unit will pulse at a pre-programmed frequency of 20 breaths per minute.
- 6. Using a stopwatch or timer, record the time it takes for the Freestyle Comfort to completely shut down.
- 7. Take the recorded time recorded and compare it to the full capacity operating time of a new power cartridge in the table below. If this time is less than 50% of the full capacity of a new power cartridge, it is recommended that the battery be taken out of service. See table below:

	Battery Pack Duration Freestyle® Comfort™						
Setting	New Single (8-cell) Minimum Duration New Double (16- Minimum Duration Battery Duration Time (50% of New Single Battery) Duration Double Battery)						
1	Up to 8 hours	4 hours (4:00)	16 hours	8 hours (8:00)			
2	Up to 4 hours	2 hours (2:00)	8 hours	4 hours (4:00)			
3	Up to 3 hours	1.5 hours (1:30)	6 hours	3 hours (3:00)			
4	Up to 2.25 hours	1.12 hours (1:07)	4.5 hours	2.25 hours (2:15)			
5	Up to 2 hours	1 hours (1:00)	4 hours	2 hours (2:00)			

Table 2. Battery Pack Duration

NOTE: There are many factors that influence battery run time on Freestyle Comfort:

- Ambient temperature
- Ambient pressure
- Compressor hours
- Battery age
- Test configuration
- 8. To exit test mode, turn the device off or enter the test mode sequence a second time. Be sure to exit test mode before returning the unit to patient use.

The Freestyle Comfort batteries are designed to last 300 charge/discharge cycles.

Please refer to Service Bulletin PN 21494318.

LOX Label Service Kits

CAIRE has created new symbolic labels for all LOX reservoirs and portable units. Prior to this change, CAIRE maintained a large variety of LOX labels in stock due to the number of different languages throughout our markets. The use of symbolic labels on LOX reservoirs and portables will greatly reduce the number of labels that are currently required.



In Europe, when replacing labelling on any CAIRE medical device, it is a regulatory requirement that the number of the notified body who authorized the medical device at the time of manufacture not be modified. In order to assist our European customers, CAIRE Inc. has created service kits for each unit type. The service kits are specific to the appropriate CE markings that are required for each unit. The CE requirements are based on the model and the age of the device. The European kits will include a symbolic warning label, a reference guide for the symbols, and a replacement CE label. U.S. customers are not required to maintain CE labeling on LOX reservoirs and portables. Because of this, CAIRE has created separate U.S. label service kits that only include the symbolic warning label and a reference guide for the symbols.

Please refer to Service Bulletin PN 21174579.

Companion 5™ Software V 1.11 Update

CAIRE is releasing a software update to all Companion 5 models sold in China (except for model 21139079). Version 1.11 firmware changes the way some alarms appear. Upon startup, the O2 warning light will illuminate and the display screen will read "O2 UP". This means that the concentrator is warming up. Once the concentrator reaches an acceptable purity, the display screen will change to the number of hours and the O2 warning light will turn off. All alarms for the Companion 5 will now be an intermittent audible beep. There are no changes to the overall function or usage of the concentrator.

Note: Devices in the field do not require a mandatory firmware update.

Please refer to Service Bulletin PN 21494871.

Helpful Hints & FAQs

Aluminum Outlet Barb for the Spirit

As of October 2018, the OCD Assembly will have an aluminum barb. The change is to meet an IEC 60601 3rd edition requirement. It also will stop a cannula fire at this fitting, to avoid progression to the Spirit. Aluminum barb Part number: 21328868 FITTING BARB, SPIRIT O2 OUTLET.



Figure 1. Spirit POC Plastic Barb



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Please consult the applicable product instructions for use for product indications, contraindications, warnings, precautions, and detailed safety information.



SERVICE BULLETIN

PN: 21174579

RELEASE DATE: July 3, 2017

REVISION DATE(S): September 29, 2017 (Rev B), March 15, 2019 (Rev C), March 01, 2020 (Rev D)

MODEL: All LOX Portables and Reservoirs

ISSUE: LOX label service kits

NOTES: CAIRE has created new symbolic labels for all LOX reservoirs and

portable units. Prior to this change, CAIRE maintained a large variety of LOX labels in stock due to the number of different languages throughout our markets. The use of symbolic labels on LOX reservoirs and portables will greatly reduce the number of labels that are currently required. In Europe, when replacing labelling on any CAIRE medical device, it is a regulatory requirement that the number of the notified body who authorized the medical device at the time of manufacture not be modified. In order to assist our European customers, CAIRE Inc. has created service

kits for each unit type. The service kits are specific to the appropriate CE markings that are required for each unit.

The CE requirements are based on the model and the age of the device. The European kits will include a symbolic warning label, a reference guide for the symbols, and a replacement CE label. U.S. customers are not required to maintain CE labeling on LOX reservoirs and portables. Because of this, CAIRE has created separate U.S. label service kits that only include the symbolic warning label and a reference guide for the

symbols.

The tables below detail the applicable service kits for reservoirs and portable units. European customers can determine the age of manufacture by referencing each unit's serial number. Diagrams are also provided below that show the location where each label in the kit should be applied.

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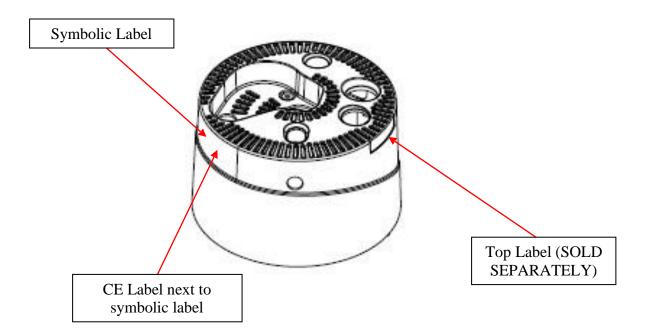
Non-CE Mark Kits (for the U.S.A and any country which does not require CE marked products)

Model	Label Service Kit Part Number
Liberator	21194752
Stroller, Sprint, Spirit	21194754
H300 / Plus	21194757
HELiOS Standard Reservoirs	21194755
HELiOS Universal Reservoirs	21194758
H850 / Marathon	21194759
C1000/C1000T	21194760

European Kits:

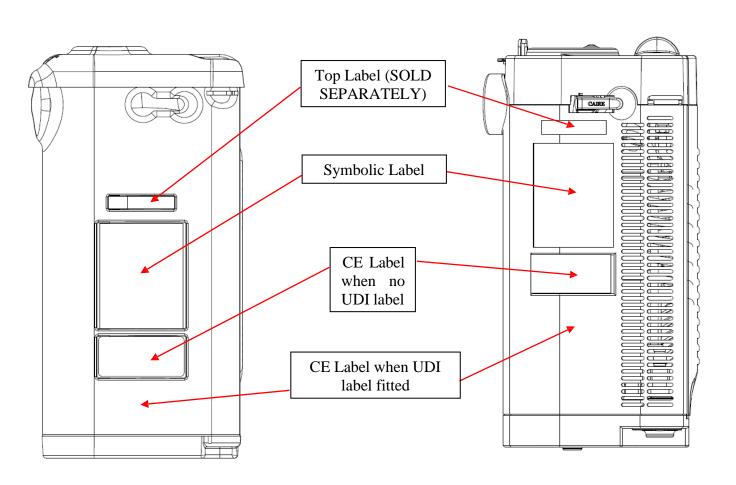
Liberator	Date Range	SN format	Range
	Prior 2006	For Liberators manufactured before 2006, the serial number was nine or ten numerical digits.	All numerical only serial numbers.
CE0029 Label Kit Ref: 21152753	2006 - May 7, 2016	CB B30 10 29 0964 Designates Designates Designates Designates Designates Manufacturing Reservoir Product Code The Year Week of Unit Produced that Week	CBB3006XXXXXX- CBB301618XXXX X=any value
CE0459 Label Kit Ref: 21150538	May 9, 2016 - Present	CB B30 10 29 0964 Designates Designates Designates Designates Designates Manufacturing Reservoir Product Code The Year Designates D	CBB301619XXXX- Present X=any value

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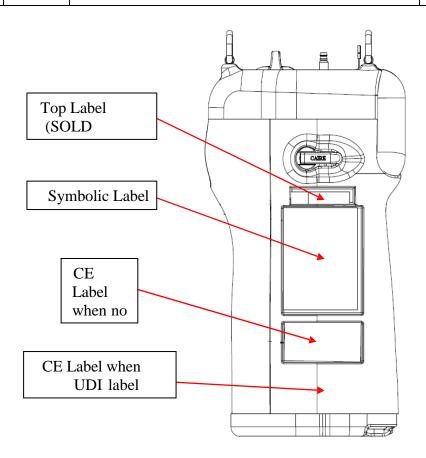
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Stroller / Sprint / Hi- Flow	Date Range	SN format	Range
	Prior 2006	For Strollers and Sprints manufactured before 2006, the serial number was nine or ten numerical digits.	All numerical only serial numbers.
CE0029 Label Kit Ref: 21152754	2006 - May 7, 2016	CB B31 10 29 0964 Designates Designates Designates Designates Designates Manufacturing Reservoir Product Code The Year Week of Unit Produced that Week	CBB3106XXXXXX- CBB311618XXXX X=any value
CE0459 Label Kit Ref: 21150537	May 9, 2016 - Present	CB B31 10 29 0964 Designates Designates Designates Designates Designates Manufacturing Reservoir Product Code The Year Week of Unit Produced that Week	CBB311619XXXX- Present X=any value



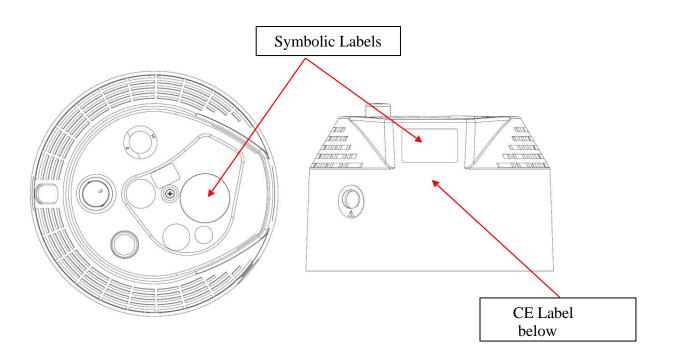
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Spirit	Date Range	SN format	Range
	Prior 2006	For Spirits manufactured before 2006, the serial number was nine or ten numerical digits.	All numerical only serial numbers.
CE0029 Label Kit Ref: 21152754	2006 - May 7, 2016	CB B37 10 29 0964 Designates Designates Designates Designates Designates Manufacturing Reservoir Year Week of Number Location Product the Year of Specific Unit Produced that Week	CBB3706XXXXXX- CBB371618XXXX X=any value
CE0459 Label Kit Ref: 21150537	May 9, 2016 - Present	Designates Designates Designates Designates Designates Manufacturing Reservoir Year Week of Number the Year of Specific Unit Produced that Week	CBB371619XXXX- Present X=any value



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Companion Reservoirs	Date Range	SN format	Range
CE0050 Label Kit Ref: 21150541	Prior March 2010	For Companion Reservoir units manufactured before March 2010, the serial number was five or eight numerical digits.	All numerical only serial numbers.
CE0029 Label Kit Ref: 21152758	March 2010 - May 7, 2016	Designates Designates Designates Designates Designates Manufacturing Reservoir Year Week of Number Location Product the Year of Specific Unit Produced that Week	CBB3010XXXXXX- CBB301618XXXX X=any value
CE0459 Label Kit Ref: 21152849	May 9, 2016 - Present	CB B30 10 29 0964 Designates Designates Designates Designates Designates Manufacturing Reservoir Year Week of Number the Year of Specific Code Unit Produced that Week	CBB301619XXXX- Present X=any value



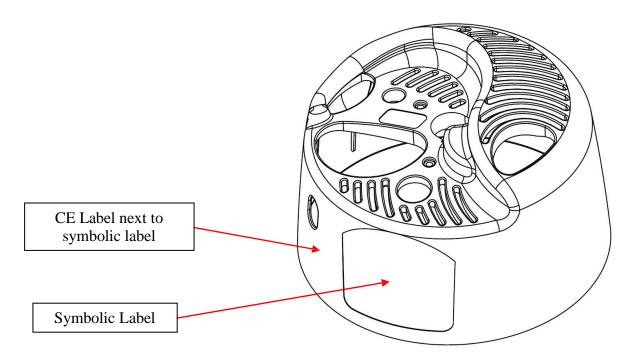
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Helios Standard Reservoirs (H36/H46)	Date Range	SN format	Range
CE0050 Label Kit Ref: 21150539	Prior March 2010	For Helios Standard Reservoir units manufactured before March 2010, the serial number was five or eight numerical digits.	All numerical only serial numbers.
CE0029 Label Kit Ref: 21152759	March 2010 - May 7, 2016	CB B30 10 29 0964 Designates Designates Designates Designates Designates Manufacturing Reservoir Year Week of Number the Year of Specific Unit Produced that Week	CBB3007XXXXXX- CBB301618XXXX X=any value
CE0459 Label Kit Ref: 21152755	May 9, 2016 - Present	CB B30 10 29 0964 Designates Des	CBB301619XXXX- Present X=any value

Helios Universal Reservoirs (U36/U46)	Date Range	SN format	Range
CE0050 Label Kit Ref: 2115300 4	Prior March 2010	For Helios Universal Reservoir units manufactured before March 2010, the serial number was five or eight numerical digits.	All numerical only serial numbers.
CE0029 Label Kit Ref: 2115300 6	March 2010 - May 7, 2016	Designates Designates Designates Designates Designates Manufacturing Reservoir Product Code Designates Designa	CBB3010XXXXXX- CBB301618XXXX X=any value

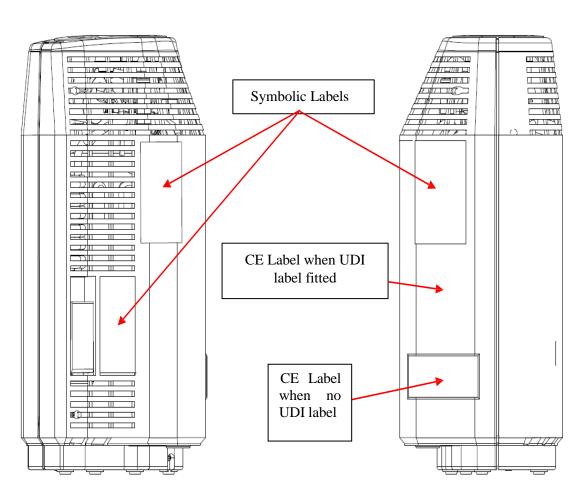
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CBB301619XXXX-<u>CB B30 10 29 0964</u> Present CE0459 X=any value Designates May 9, Designates Designates Designates Week of Number Manufacturing Reservoir Year Label Kit 2016 -Location Product the Year of Specific Ref: Present Unit 2115300 Code Produced 5 that Week



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Companion Portable (C1000/C1000T)	Date Range	SN format	Range
CE0050 Label Kit Ref: 21150701	Prior March 2010	For Companion Portable units manufactured before March 2010, the serial number was five or eight numerical digits.	All numerical only serial numbers.
CE0029 Label Kit Ref: 21131485	March 2010 - May 7, 2016	CB B31 10 29 0964 Designates Designates Designates Designates Designates Manufacturing Reservoir Product Code Tunit Produced that Week	CBB3110XXXXXX- CBB311618XXXX X=any value
CE0459 Label Kit Ref: 21152747	May 9, 2016 - Present	CB B31 10 29 0964 Designates Designates Designates Designates Designates Manufacturing Reservoir Product Code Designates Designate	CBB311619XXXX- Present X=any value

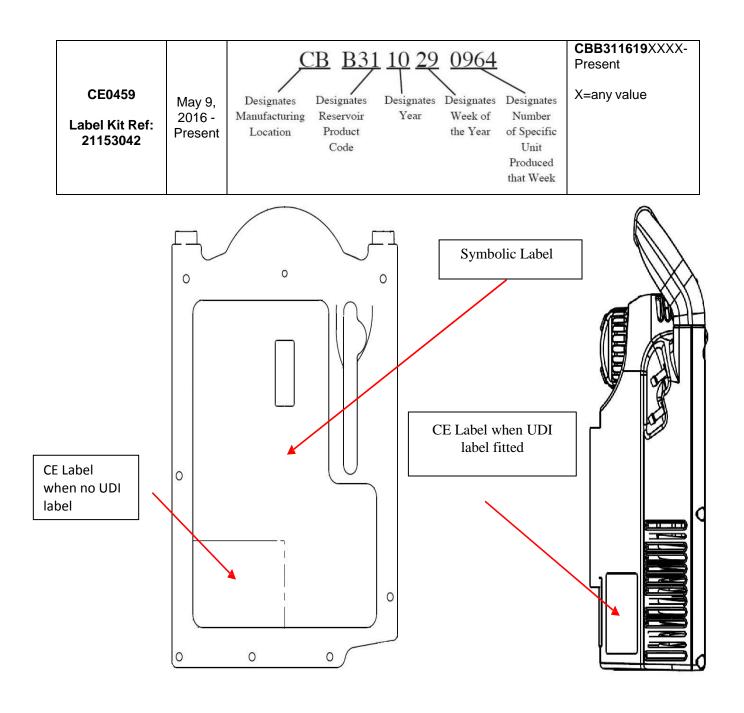


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Helios H300/Plus Portable	Date Range	SN format	Range
CE0050 Label Kit Ref: 21150540	Prior March 2010	For Helios H300/Plus Portable units manufactured before March 2010, the serial number was five or eight numerical digits.	All numerical only serial numbers.
CE0029 Label Kit Ref: 21152761	March 2010 - May 7, 2016	Designates Designates Designates Designates Designates Manufacturing Reservoir Year Week of Number Location Product Code Unit Produced that Week	CBB3110XXXXXX- CBB311618XXXX X=any value
CE0459 Label Kit Ref: 21152760	May 9, 2016 - Present	Designates Designates Designates Designates Designates Manufacturing Reservoir Product Code Designates Designa	CBB311619XXXX- Present X=any value

Helios H850/Marathon Portable	Date Range		Range			
CE0050 Label Kit Ref: 21153040	Prior March 2010	For Helios H850/Marathon Portable units manufactured before March 2010, the serial number was five or eight numerical digits.				All numerical only serial numbers.
CE0029 Label Kit Ref: 21153041	March 2010 - May 7, 2016	Designates Designates Manufacturing Location Production Code	oir Year et	Designates Week of the Year	Designates Number of Specific Unit Produced that Week	CBB3110XXXXXX- CBB311618XXXX X=any value

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Should you have any issues with identifying the correct notified body number for your device, please contact Customer or Technical Service with the serial number of the device.

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SERVICE BULLETIN

PN: 21494318

RELEASE DATE: November 19, 2019

MODEL: FreeStyle® Comfort®

ISSUE: FreeStyle Comfort Battery Pack Duration Test

NOTES: The below procedure should be used to test the performance of the

FreeStyle Comfort battery pack. Be sure to only use a FreeStyle Comfort that is in good working condition for this test. If the device displays an alarm while in test mode, the unit will need service before being used to

perform the battery pack test.

- 1. Remove the FreeStyle Comfort from any carrying bags, backpacks, or other accessory carrying cases.
- 2. Fully recharge the battery using either a FreeStyle Comfort connected to AC power or a desktop charger.
- 3. Install the fully charged battery pack into a FreeStyle Comfort and remove any external power cords.
- 4. Turn the FreeStyle Comfort on and enter Test Mode pressing +, +, -, -, +, -, +, on the keypad. The entire sequence needs to be entered within 5 seconds. If a mistake is made while entering this sequence, the user must wait 5 seconds before attempting the sequence again. Patients should not breath off the device while it is in test mode.
- 5. Once in test mode the flow can be increased or decreased as usual. The battery duration test can be done at any flow setting.
- 6. While in test mode the unit will pulse at a pre-programmed frequency of 20 breaths per minute.
- 7. Using a stopwatch or timer, record the time it takes for the FreeStyle Comfort to completely shut down.
- 8. Take this time recorded and compare it to the full capacity operating time of a new battery pack in the table below. If this time is less than 50% of the full capacity of a new battery pack, it is recommended that the battery pack be taken out of service. See table below:

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	FreeStyle Comfort Battery Duration							
Setting	New Single (8-cell) Battery Duration	Minimum Duration Time (50% of New	New Double (16-cell) Battery Duration	Minimum Duration Time (50% of New				
		Single Battery)		Double Battery)				
1	Up to 8 hours	4 hours (4:00)	16 hours	8 hours (8:00)				
2	Up to 4 hours	2 hours (2:00)	8 hours	4 hours (4:00)				
3	Up to 3 hours	1.5 hours (1:30)	6 hours	3 hours (3:00)				
4	Up to 2.25 hours	1.12 hours (1:07)	4.5 hours	2.25 hours (2:15)				
5	Up to 2 hours	1 hours (1:00)	4 hours	2 hours (2:00)				

NOTE: There are many factors that influence battery run time on FreeStyle Comfort:

- Ambient temperature
- Ambient pressure
- Compressor hours
- Device condition
- Battery age
- 9. To exit test mode, turn the device off or enter the test mode sequence a second time. Be sure to exit test mode before returning the unit to patient use.

FreeStyle Comfort batteries are designed to last 300 charge/discharge cycles: however, battery packs may perform to specifications past 300 charge/discharge cycles.

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Please consult the applicable product instructions for use for product indications, contraindications, warnings, precautions, and detailed safety information.

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SERVICE BULLETIN

PN: 21494713

RELEASE DATE: March 18, 2020

MODEL: Liberator® Liquid Oxygen Reservoir

ISSUE: Liberator Plumbing Consolidation Retrofit Kit Instructions

NOTES: This instruction is to guide technicians on how to remove the Flow Control Valve

(FCV) w/ Secondary Relief Valve (SRV) and install the replacement FCV, new economizer regulator along with your current Primary Relief Valve (PRV) and a replacement SRV. These kits are required when there is a need to replace either the economizer regulator, or the FCV as the flow control valves will no longer have an

SRV port in them.

WARNING: Do not use the new FCV that does not have the SRV port on units manufactured prior to this design change without installing the entire kit.

Table 1. Available Kit Options

KIT PART NO.	KIT DESCRIPTION	FCV P/N	SRV P/N	ECONOMIZER REGULATOR P/N
	30 PSI Lib Plumbing			
21494709	Service Kit	21449808	21215214	21341644
	65 PSI Lib Plumbing			
21494710	Service Kit	21449806	21215227	21341648
	30 PSI Lib Plumbing			
21494711	Service Kit Japan	21449808	21215214	21341652
	30 PSI Lib Plumbing			
21494712	Service Kit – 2 LPM	21494787	21215214	21341644

Tools Required:

- 9/16" Open End Wrench
- Phillips Head #1
- Torque Wrench (inch lbs)
- 11/16" Open End Wrench

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Table 2. Parts Included in 30 PSI Lib Plumbing Service Kit P/N 21494709

PART	-
NUMBER	DESCRIPTION
21449808	FCV 20PSI 0-15 LPM G4 BASE
21215214	RV 9/16-20UNF 30PSI TPED
21341644	REGULATOR 20PSI ECON
21494713	Liberator Service Bulletin / Instruction

Table 3. Parts Included in 65 PSI Lib Plumbing Service Kit P/N 21494710

PART	5	
NUMBER	DESCRIPTION	
21449806	FCV 50PSI 0-15 LPM G4 BASE	
21215227	RV 9/16-20UNF 65PSI TPED	
21341648	REG ECON 50PSI	
21494713	Liberator Service Bulletin / Instruction	

Table 4. Parts Included in 30 PSI Lib Plumbing Service Kit Japan P/N 21494711

PART	-
NUMBER	DESCRIPTION
21449808	FCV 20PSI 0-15 LPM G4 BASE
21215214	RV 9/16-20UNF 30PSI TPED
21341652	REGULATOR 20PSI ECON W/ PRV-SRV CODED
21494713	Liberator Service Bulletin / Instruction

Table 5. Parts Included in 30 PSI Lib Plumbing Service Kit – 2LPM P/N 21494712

PART	DESCRIPTION	
NUMBER	DESCRIPTION	
21494787	FCV 20PSI 0-2 LPM V2 BASE TPED	
21215214	RV 9/16-20UNF 30PSI TPED	
21341644	REGULATOR 20PSI ECON W/PRV-SRV PORT	
21494713	Liberator Service Bulletin / Instruction	

1. Retrofit Kit Procedure:

Caution: The unit must be empty, warm and vented before starting procedure.

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1.1. Remove Top Shroud using Phillips Head #1 Screwdriver.



Figure 1.1

1.2. Remove Flow Control Valve Knob, and remove Flow Control Valve warming coil connection using 9/16" Open End Wrench.

(Note: Retain Flow Control Valve Knob)





Figure 1.2

1.3. Remove (2x) screws from Locking Plate, then remove the Flow Control Valve. (Note: Retain Locking Plate, Flow Control Decal, and Screws. Discard Flow Control Valve/SRV)



Figure 1.3

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1.4. Install new Flow Control Valve, Flow Control Decal, and Locking Plate, using the (2x) Locking Plate Screws to hold the Flow Control Valve secure. Reconnect Flow Control Valve warming coil connection. Reinstall the Flow Control Knob. (Note: If changing from a 15 LPM FCV to a 2 LPM FCV or vice versa, the appropriate setting decal will need to ordered separately and installed along with the replacement FCV at this step)



Figure 1.4

1.5. Remove Economizer Valve assembly using 9/16" Open End Wrench to loosen the three coil connections. Remove Primary Relief Valve from Economizer. (Note: Retain Primary Relief Valve, discard Economizer Assembly)





Figure 1.5

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1.6. Install the new Secondary Relief Valve (using 11/16" Wrench) and the retained Primary Relief Valve (using 9/16" Wrench) onto the new Economizer.
SRV torque value = 180 +/- 18 inch pounds, PRV torque value = 80-90 inch pounds. Install Economizer Assembly, tightening the 3 coil connections.



Figure 1.6

- 1.7. Perform leak check.
- 1.8. Reinstall Top Shroud and screw.

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SERVICE BULLETIN

PN: 21494871

RELEASE DATE: March 20, 2020

MODEL: Companion 5TM

ISSUE: Companion 5TM Software V 1.11 Update

NOTES: CAIRE is releasing a software update to all Companion 5 models, with

the exception of model 21139079 sold in China. Version 1.11 firmware will change the way some alarms appear. Upon startup the O2 warning light will illuminate and the display screen will read "O2 UP". This means that the concentrator is warming up and once the concentrator reaches an acceptable purity the display screen will change to the number of hours and the O2 warning light will turn off. All alarms for the Companion 5 will now be an intermittent audible beep with the 1.11 version. There are no changes to the overall function or usage of the

concentrator.

Note: Devices in the field do not require a mandatory firmware update.

Previous software:

Country	Version
USA	2.0.1
Europe	1.9
China	1.9

Updated software:

Country	Version	
USA	1.11	
Europe	1.11	
China	1.9	

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