6244 Lemay Ferry Rd. • St. Louis, MO 63129 Corporate: 636-600-4030 • F 636-600-4035 Toll Free: 866-333-4030 • F 866-333-4035

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The High Pressure Oxygen Experts

October 1, 2021

URGENT SAFETY ALERT

MEDICAL OXYGEN CYLINDERS USING SHERWOOD OR TEKNO VALVES

Dear Valued Customer:

This communication is to notify you of an important safety alert for a number of Tekno Valve and Sherwood branded oxygen cylinder valves. The aforementioned companies implemented a manufacturing process change in early 2021 and now lack a chamfer that is commonly used in the marketplace. The current valve corners now interfere with the aluminum regulator yoke radius. As a result, the majority of oxygen regulator brands sold in the U.S. market no longer mate properly to these valves and may not complete a positive seal. Patients and technicians may believe the regulator is installed properly, as the T-handle will fully tighten. However, the washer may not compress completely, resulting in the lack of a positive, gas-tight seal and presenting a safety risk. Both manufacturers acknowledge the industry-wide fit issue resulting from the manufacturing change.

Affected Brands/Models and Shipped Dates: Reference Page 2 for valve identification and regulator fit illustration Sherwood: Date codes 21-22 to 21-39, reference published Sherwood Safety Alert, included Tekno Valves – reference published Tekno Valve Safety Alert, included

Why are you being contacted?

According to our records, you supply high pressure oxygen equipment to the home care industry.

What is the problem?

The Tekno Valve and Sherwood branded oxygen cylinder valves are now manufactured with a rounded edge instead of the radius/chamfered edge that has historically been the industry standard design. The removal of this chamfer affects the proper seating and positive seal when used with the vast majority of oxygen regulators in the U.S. market. The <u>lack of a positive</u>, gas-tight seal is a **serious safety hazard**, as it may result in a leak due to the partial sealing on the regulator washers.

What actions are recommended?

- Conduct an inventory audit, inclusive of cylinders in patient homes, to identify and quarantine all cylinders with affected valves
- 2) Immediately discontinue patient use and remove the cylinders from the service
- 3) Post this notice in all cylinder storage and filling areas
- 4) Contact your cylinder supplier where you purchased the cylinders for resolution

If you have any questions concerning these instructions, please email Responsive Respiratory at sales@respondo2.com. For urgent assistance, please contact Responsive Respiratory at 1-866-333-4030.

Regards,

Thomas Bannon

President, Responsive Respiratory



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Valve Comparison:

Traditional Design

Chamfered Valve Corners

Sherwood



Slight Round Corner

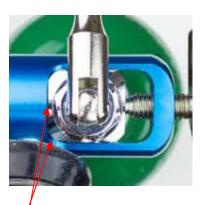
Tekno Valve



Slight Round Corner

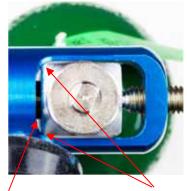
Regulator Fit:

Traditional Design



Proper washer seal and fit. Regulator yoke is flush to valve

Sherwood



Incomplete washer seal

Valve corners interfere with regulator yoke, hindering proper fit

Tekno Valve



Incomplete washer seal

Valve corners interfere with regulator yoke, hindering proper fit



October 1, 2021

Safety Alert #Sher1021 Use of Pin Index Valves with Non-Conforming Yoke Style Regulators

It has come to the attention of Sherwood Valve that various yoke style regulators in the market do not conform with the Compressed Gas Association V-1:2021 CGA 870 connection standard (referred to hereafter as "CGA V-1 870") and may not properly connect to certain oxygen valves made by Sherwood and other manufacturers, whose valves do conform with the CGA V-1 870 standard, resulting in a potential leak at the valve-regulator connection. Sherwood has made CGA aware of the non-conformity of the various yoke style regulators, and CGA is expected to issue further guidance regarding the subject. In the meantime, as described below, Sherwood recommends that you please take action to confirm that regulator yokes used with Sherwood valves conform to the CGA V-1 870 standard and that you share this important information with your distributors, customers, and end users of oxygen cylinders.

CGA V-1 870 specifies the required interface dimensions to manufacture the regulator yoke-to-valve connection. Manufacturers that sell and label their products with the CGA 870 designation must ensure that the features of their products conform to the CGA V-1 870 standard. Sherwood has two styles of valves that fully conform to the standard – one with chamfer corners and one with radius corners.

The CGA 870 dimensions allow for clearances sufficient to provide a gas tight seal with an approved gasket between the yoke and valve. As shown in Figures 1 & 2, when a conforming regulator is used, it is possible to fully close and seal the valve-regulator connection with a valve having chamfer corners (Figure 1) or radius corners (Figure 2).

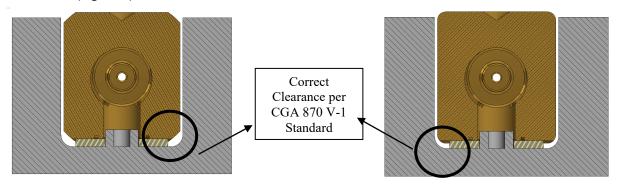


Figure 1 Figure 2



Such a seal, however, may not be achieved when a non-conforming regulator is used with a valve with radius corners. Figures 3 and 4 show one of the areas of non-compliance in the yoke where the blend radius of the connection is manufactured over two times the allowable requirement. The large radius may not allow the valve to seat properly in the yoke connection to sufficiently compress the gasket to form a gas tight seal. This condition could allow gas to leak by the gasket seal.

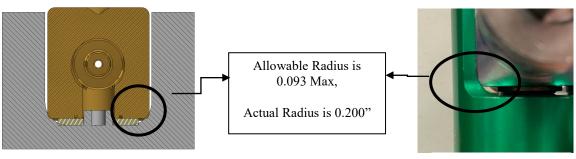


Figure 3 Figure 4

Users should check for this condition before opening the valve. If such condition is encountered, users should disconnect the regulator yoke from the valve, and that regulator should never be used with such valve.

Again, the Sherwood valve with radius corners fully conforms with CGA V-1 870 and can be safely used with yoke style regulators that conform with CGA V-1 870. A potential issue only arises when a valve with radius corners is used with a non-conforming regulator.

A valve with radius corners can be identified by visually observing the shape of the valve and also by the valve's date code. Sherwood has manufactured valves with radius corners from June to September in 2021. Sherwood's date code consists of four digits indicating year and week of manufacture (see below drawing), and is found at the backside of the valve, at the lower portion just before the threaded section (see below photo). The Sherwood valves with radius corners have date codes ranging from **21-22** to **21-39**.







The condition described above is not the result of any problem with, or defect in, a Sherwood valve. Rather, the condition is the result of the non-conformity of various yoke style regulators that do not meet the dimensional requirements of CGA V-1 870. We recommend that you contact your regulator manufacturer or distributor to confirm that their regulators fully conform with the CGA V-1 870 standard and for further guidance.

For any questions regarding Sherwood's valves, please contact Tim Madden, VP of Sales & Marketing, at tmadden@sherwoodvalve.com and 1-216-264-5061.



Safety Alert

SA No. – 01/21-22 REV-00, Date – 29th July 2021

Use of Pin Index Valves (MYC-10C) as per CGA V-1 with Non-standard Yoke Regulators

It has come to our attention that there could be an interference issue in pin index valves (Series - MYC-10C) with at least one brand of Yoke regulators manufactured in China that are not conforming to drawing No. 860 of CGA V-1:2021.

The CGA 860 drawing specifies a radius or chamfer value (YY) between 1.35-1.85 mm (0.052-0.072") on the valve body and yoke radius value (AK) 2.36 mm (0.96") MAX. The CGA design provides adequate clearance allowing a gas-tight seal at the outlet even if the chamfer is on the lower side of tolerance and the yoke radius is maximum specified. Refer below Figure-1 and Table-1 created to show no interference between the valve body and yoke, even at the extreme end of specified tolerances that influence the sealing on the outlet.

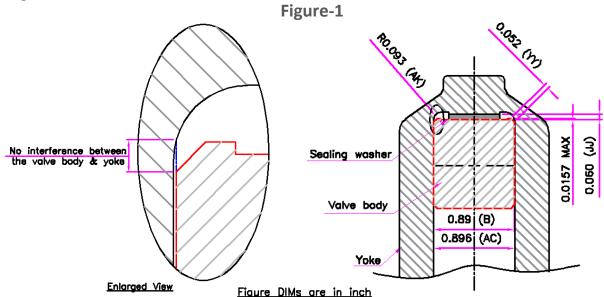


Table-1

Dimensions influencing fitment of yoke with valve body affecting outlet sealing				
Legend	Description	CGA 860 specification, mm (in)	Worst case DIM	Comments
B	Width of valve body	21.80-22.60 (0.86-0.89)	22.60 (0.89) MAX	Smaller width will facilitate sealing
AC	Inside width of Yoke	23.01 ±0.25 (0.906 ±0.01)	22.76 (0.896) MIN	Larger width will facilitate sealing
AK	Yoke Radius	2.36 (0.093) MAX	2.36 (0.093) MAX	Lower radius will facilitate sealing
ŊĴ	Thickness of washer	1.52-2.29 (0.060-0.115)	1.52 (0.060) MIN	Higher thickness will facilitate sealing
**	Radius or Chamfer of valve body	1.35-1.85 (0.052-0.072)	1.35 (0.052) MIN	Higher radius or chamfer will facilitate sealing
-	Spotface	-	0.40 (0.0157)	Lawer depth of spotface will facilitate sealing



Safety Alert

SA No. – 01/21-22 REV-00, Date – 29th July 2021

We have observed the radius (AK) on some yokes to be as high as 5 mm (0.196"), which could lead to interference with the valve body even if the valve body chamfer is within the CGA requirement.

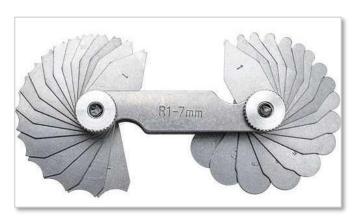


Yoke with 5.0 mm radius



Valve body with 1.50 mm chamfer

We would urge users to ensure the Yoke dimensions, especially the radius AK, meet the CGA 860 value of 2.36 mm (0.0929") MAX. The radius can be checked using a radius gauge (See picture below).



Radius Gauge

References:

CGA V-1:2021 (15th edition) — Standard for compressed gas cylinder valve outlet and inlet connections

Product catalogue of MYC-10C design:

https://www.teknovalves.com/Product/ProductDetail/60

Email: post@teknovalves.com
Website: www.teknovalves.com