

## Field Safety Notice

To our Customers and users of the

AL-11100-000/5.V001	SEPTIFLOW CIRCUIT WITH INTEGRATED GSL
AL-11101-060/5.V001	SEPTIFLOW CIRCUIT WITH INTEGRATED GSL
AL-11101-060/5.V002	SEPTIFLOW CIRCUIT WITH INTEGRATED GSL
AL-11101-060/5.V003	SEPTIFLOW CIRCUIT WITH INTEGRATED GSL
AL-11101-060/5.V004	SEPTIFLOW CIRCUIT WITH INTEGRATED GSL
AL-11103-110/5.V001	SEPTIFLOW CIRCUIT
AL-11103-110/5.V002	SEPTIFLOW CIRCUIT
AL-11120-000/5.V001	SEPTIFLOW CIRCUIT W/WATERTRAP-GSL
AL-11120-000/5.V002	SEPTIFLOW CIRCUIT W/WATERTRAP-GSL
AL-11121-060/5.V001	SEPTIFLOW CIRCUIT W/WATERTRAP-GSL
AL-11121-110/5.V001	SEPTIFLOW CIRCUIT W/WATERTRAP
AL-11121-160/5.V001	SEPTIFLOW CIRCUIT W/WATERTRAP
AL-11121S-566/5.V002	SEPTIFLOW CIRCUIT W/WATERTRAP (STERILE EO)
AL-11123-060/5.V001	SEPTIFLOW CIRCUIT W/WATERTRAP-GSL

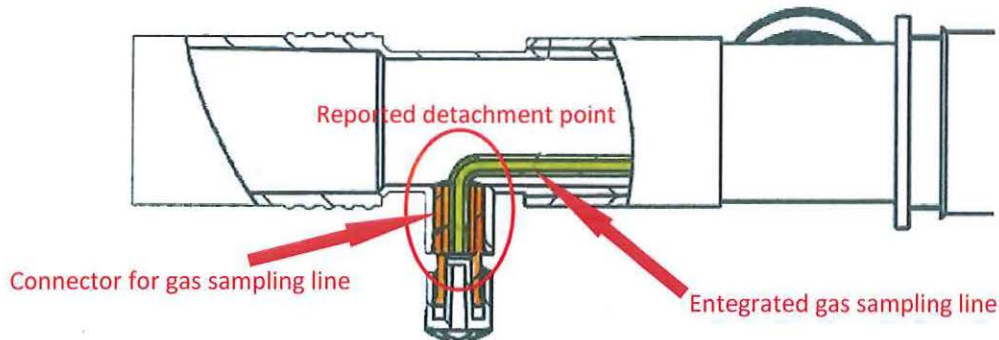
19 February 2019

Dear Sir or Madam,

The purpose of this letter is to advise users that Altera Tibbi Malzeme San. Ve Tic. A.Ş. is issuing a Field Safety Notice (FSN).

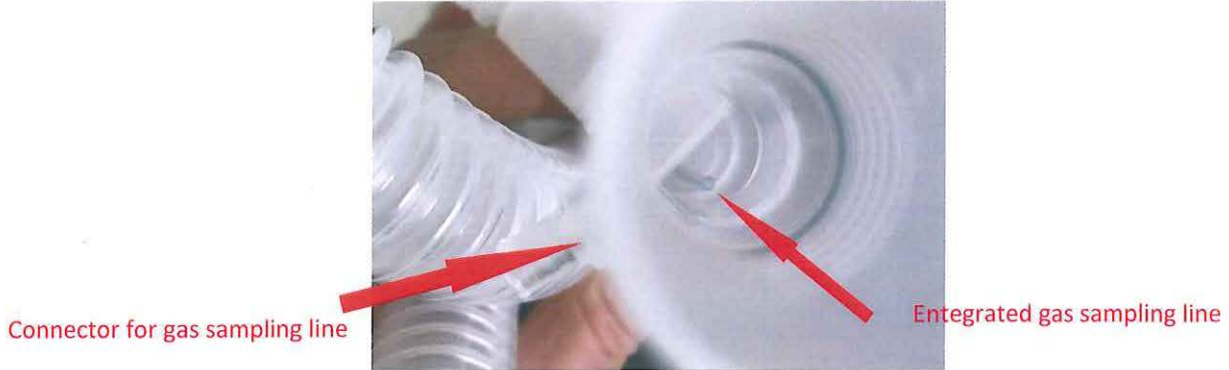
### Description of the problem:

During post market surveillance activities, we have been reported 2 cases regarding Septiflow circuits with integrated gas sampling lines. One of the reports does not include clear definition of the failure, however the second report clearly addresses disconnection of gas sampling line from the luer connector at the machine side of the circuit and stay lose within the inspirium line.



The problem was observed after the treatment started due to missing CO2 measurement values on monitor.

The defined failure can be visualized as shown in picture below.



### Results of manufacturer's final investigation:

Investigation shows that the gas sampling line and the connector is assembled within the breathing circuit production line just before connectors' permanent assembly on the circuit. The assembly steps of the circuit after affixing the gas sampling line to the connector might be weakening the connection as such steps are performed in seconds after the application of the solvent bonding on the gas sampling line.

Accordingly, Altera team resolved to assemble gas sampling line at a separate line dedicated for such microbore tube connections and assemble it into the circuit after the performance of release process confirming the strength of the connection.

As containment action Altera suspended all sales of products with the integrated gas sampling lines and check the current inventory. Altera also decided to perform 100% inspection on existing inventory of our customers and their customer health care facilities to.

Therefore, it is decided to issue this Field Safety Notice.

### Actions to be taken by the end-users:

- All users are required to read and understand the content of this FSN.
- Please, stop use and sales of the products listed herein above and assure that hospitals cease use of the same
- Please check your inventory if you or any of your customers are in possession of either above listed product codes.
- Please fill in the attached "Customer Feedback Report" clearly indicating the product codes and quantities in your or your customers' possession and send it back to us by mail as stated on the form.

### Actions being taken by the manufacturer:

- Altera will send this Field Safety Notice for customers of the product involved in the incident in European Union.
- All products reported in "Customer Feedback Report" will be transferred back to Altera facility for 100% inspection. Only products in Turkish market will be 100% inspected at the healthcare facilities on site.

- Production line development will be performed and risk analysis will be updated in the manner that will permanently eliminate the detachment of gas sampling line tubing from the connector.

**Contact reference person:**

Ayşem Ferda Sevinçli

Quality Director

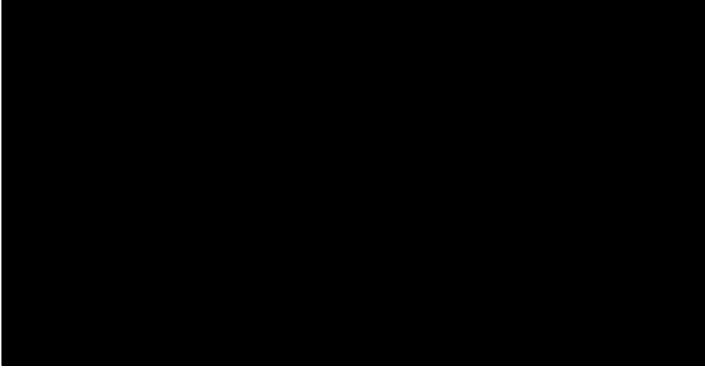
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## MÜŞTERİ GERİ BİLDİRİM RAPORU CUSTOMER FEEDBACK REPORT KUNDEN-RÜCKMELDUNG-BERICHT

Müşteri Adı /Customer Name / Kudennamée			
Müşteri Adresi /Customer Address / Kundenadresse			
İletişim Yetkilisi Contact person Gesprächspartner		e-posta e-mail Email	
Tel. No		Fax. No.	

Entegre gaz örnekleme hatlı devrelere ilişkin Altera'nın 19.02.2019 tarihli Saha Güvenlik Bildirimi Formunu aldık. Gerekli çalışanlarımız ile paylaştık.

- Şirketimiz ve müşterilerimiz stoklarında 19.02.2019 tarihli Saha Güvenlik Bildirimi Formunda listelenen ürünlerin herhangi biri bulunmamaktadır.
- Şirketimiz ve müşterilerimiz stoklarında 19.02.2019 tarihli Saha Güvenlik Bildirimi Formunda listelenen ürünlerden aşağıda belirtilen ürünler ve adetler bulunmaktadır.

Ürün Kodu	Ürün Adedi	Bulunduğu Yer
		<input type="checkbox"/> Kendi Stoğumuzda <input type="checkbox"/> Müşteri Adı _____
		<input type="checkbox"/> Kendi Stoğumuzda <input type="checkbox"/> Müşteri Adı _____
		<input type="checkbox"/> Kendi Stoğumuzda <input type="checkbox"/> Müşteri Adı _____

We received Altera's Field Safety Notice dated 19 February 2019 regrading circuits integrated gas sampling lines. We shared information with our personnel.

- The products listed in your Field Safety Notice dated 19 February 2019 do not exist in our nor our customers' stocks.
- Out of the products listed in your Field Safety Notice dated 19 February 2019, the below listed products and quantities exists in our and/or our customers' stocks.

Product Code	Product Quantity	Location of Product
		<input type="checkbox"/> In our inventory <input type="checkbox"/> At customer _____
		<input type="checkbox"/> In our inventory <input type="checkbox"/> At customer _____
		<input type="checkbox"/> In our inventory <input type="checkbox"/> At customer _____

Wir haben das vom 19.02.2019 datierte Feldsicherheitsmeldung Formular von Altera , in Bezug auf die integrierte Gasentnahmeleitung erhalten. Wir haben Informationen mit unseren Mitarbeitern geteilt.

- Die in Ihrer Sicherheitsmitteilung vom 19. Februar 2019 aufgeführten Produkte sind nicht in unseren Kundenbeständen vorhanden.
- Von den Produkten, die in Ihrer Sicherheitsinformation vom 19. Februar 2019 aufgeführt sind, sind die unten aufgeführten Produkte und Mengen in unseren und / oder unseren Kunden vorhanden.

Produktcode	Produktmenge	Standort des Produkts
		<input type="checkbox"/> In unserem Inventar <input type="checkbox"/> Beim Kunden _____
		<input type="checkbox"/> In unserem Inventar <input type="checkbox"/> Beim Kunden _____
		<input type="checkbox"/> In unserem Inventar <input type="checkbox"/> Beim Kunden _____

Unvan / Title	
İsim / Name	
İmza Signature Unterschrift	
Tarih / Date / Datum	