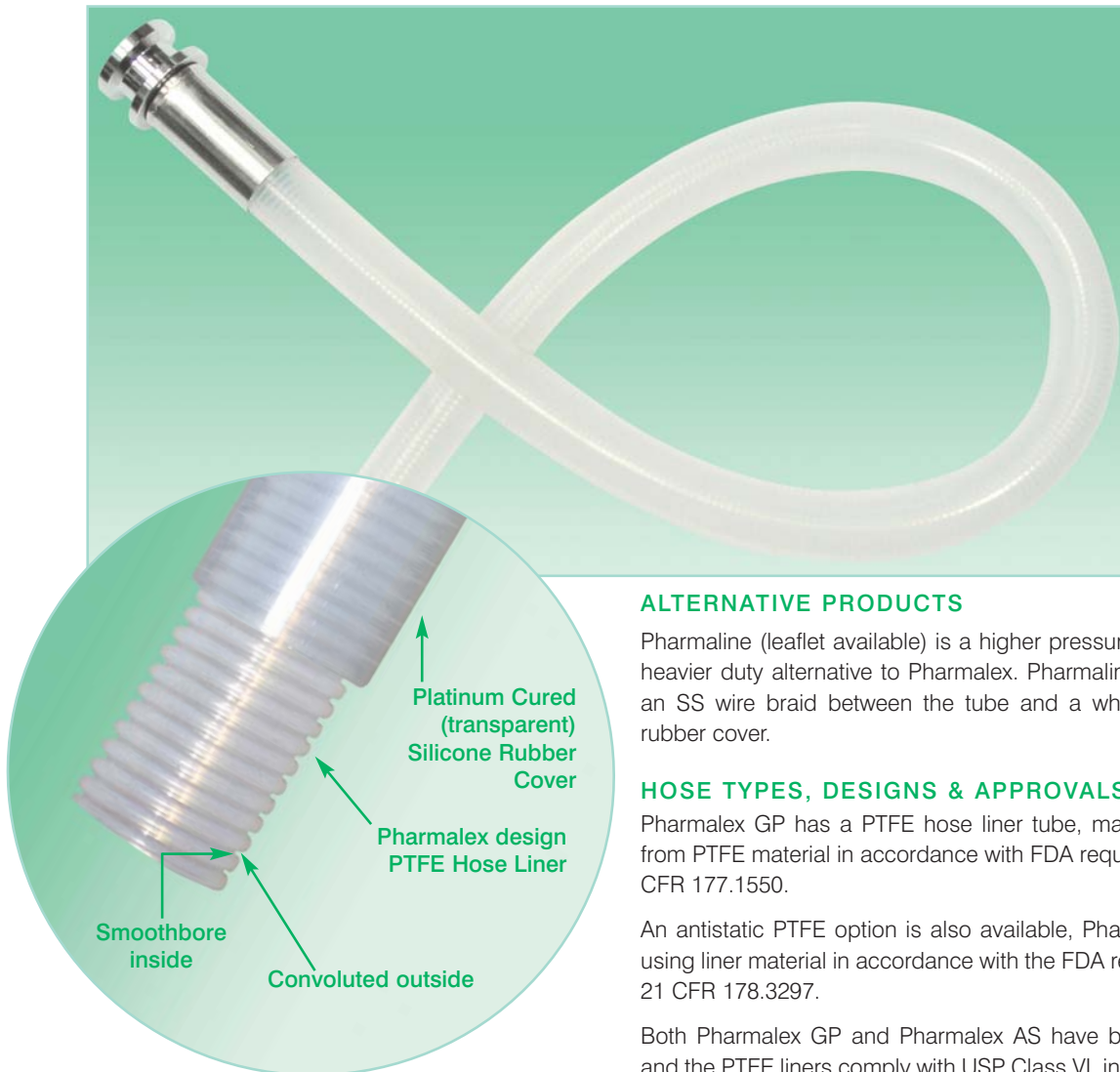


PHARMALEX



INTRODUCTION

Pharmalex is a very flexible, patented smoothbore PTFE lined hose product with a clear silicone rubber cover. It is designed to replace conventional all-silicone rubber hoses in applications where the inner silicone rubber liner may be subject to chemical reaction with fluids passing through, which may either contaminate the fluid, or degrade the rubber liner.

APPLICATIONS

Generally, Pharmalex is designed for light duty applications, with low internal fluid or gas pressures.

Pharmalex is designed for use in high purity Pharmaceutical, Biotech, Chemical and Foodstuffs application areas, where ease of cleaning the hose is required, both internal and external.

It is also very suitable for use in other general industrial applications, particularly those where hot or corrosive fluids are being passed.

ALTERNATIVE PRODUCTS

Pharmaline (leaflet available) is a higher pressure capable, heavier duty alternative to Pharmalex. Pharmaline includes an SS wire braid between the tube and a white silicone rubber cover.

HOSE TYPES, DESIGNS & APPROVALS

Pharmalex GP has a PTFE hose liner tube, manufactured from PTFE material in accordance with FDA requirement 21 CFR 177.1550.

An antistatic PTFE option is also available, Pharmalex AS, using liner material in accordance with the FDA requirement 21 CFR 178.3297.

Both Pharmalex GP and Pharmalex AS have been tested and the PTFE liners comply with USP Class VI, including the Elution (Cytotoxicity) test.

Both include a Platinum Cured clear (transparent) silicone rubber cover (Post-cured 4 hours at 200 °C in accordance with requirements for USP Class VI). The Silicone Rubber material is in accordance with FDA requirement CFR-177-2600.

ATEX - Attestations of Conformity and Labelling Available for the Pharmalex range of hose and hose assemblies and include the following designation:



II 2 G D c

CERT. NO: SIRA 06ATEX6064U - for components intended for use in Gas: Zones 1 & 2 and Dust: Zones 21 & 22 Potentially Explosive Atmospheres - Directive 94/9/EC.

Alternative colours of the silicone rubber cover are also available, to special order.

The World's Leading Manufacturer of PTFE Flexible Hose.

Spring Bank Industrial Estate, Watson Mill Lane, Sowerby Bridge, Halifax HX6 3BW

Telephone: (01422) 317200 Fax: (01422) 836000

Website: www.aflex-hose.com



SPECIFICATIONS FOR PHARMALEX GP AND AS

Hose Size		Hose Actual I/D		O/D over Silicone Cover		Minimum Bend Radius		Maximum Working Pressure		Burst Pressure		Weight per Unit Length	
in	mm	in	mm	in	mm	in	mm	Psi	Bar	Psi	Bar	lb/ft	kg/mtr
1/4	6.4	0.270	6.8	0.456	11.6	1 1/4	30	109	7.5	435	30	0.06	0.09
3/8	9.5	0.375	9.5	0.610	15.5	1 1/2	38	87	6.0	348	24	0.09	0.14
1/2	12.7	0.500	12.7	0.767	19.5	2 1/2	63	84	5.8	334	23	0.14	0.21
3/4	19.0	0.750	19.0	1.074	27.3	4	100	62	4.3	247	17	0.21	0.32
1	25.4	1.000	25.4	1.370	34.8	6	150	52	3.5	203	14	0.33	0.49

ADVANTAGES OVER CONVENTIONAL HOSE DESIGNS

- Pharmalex can be used to replace silicone rubber hoses and tubing, particularly where the much better chemical resistance, and ease of cleaning of the PTFE hose liner is an advantage.
- Unlike silicone rubber lined hoses and tubing, Pharmalex can be steam sterilised any number of times, without degradation of the liner.
- Pharmalex can be used to replace conventional smoothbore PTFE tubing in applications where the much better flexibility of Pharmalex is an advantage.
- Pharmalex can be used in low pressure, light duty applications in place of more expensive reinforced PTFE and Silicone hose designs.

PROPERTIES

- Temperature Range: -60°C (-80°F) to +200°C (+400°F).
- Pressure vs Temperature - Pressure ratings are as listed up to 130°C (266°F), then reducing at 1% per 1°C (1.8°F) up to +200°C (400°F).
- Vacuum - All sizes are fully vacuum resistant up to 100°C.

FURTHER TECHNICAL INFORMATION

Further technical information related to PTFE material, Antistatic specifications, usage requirements and limitations, testing and flow rates etc. is available in the Bioflex and Corroflon Product Information pages on the Aflex Hose website.

END FITTINGS

- Sanitary and Mini Sanitary Triclamp (Triclover) Fittings in 316 SS, with bores polished to <math><0.375\mu\text{m}</math> (<math><15\mu\text{in}</math>).



- I-Line Fittings.
- Compression Fittings.
- BSPT and NPT Fixed Male Pipe Fittings.
- Flanges, Camlocks, DIN11851, RJT, SMS, RJP and others to special order.

HOSE ASSEMBLIES

Pharmalex can be assembled using the same end fittings and ferrules as used for Pharmaline.

IDENTIFICATION OPTIONS

- Silicone encapsulated colour coding, and/or text information to suit customer's requirements.
- 'Flotag' RFID Chip, programmed to suit customer requirements.
- Unique Serial Numbers and other information for each hose, stamped on Ferrules or SS tags, to give total traceability.

Hose Configurations & Length Calculations

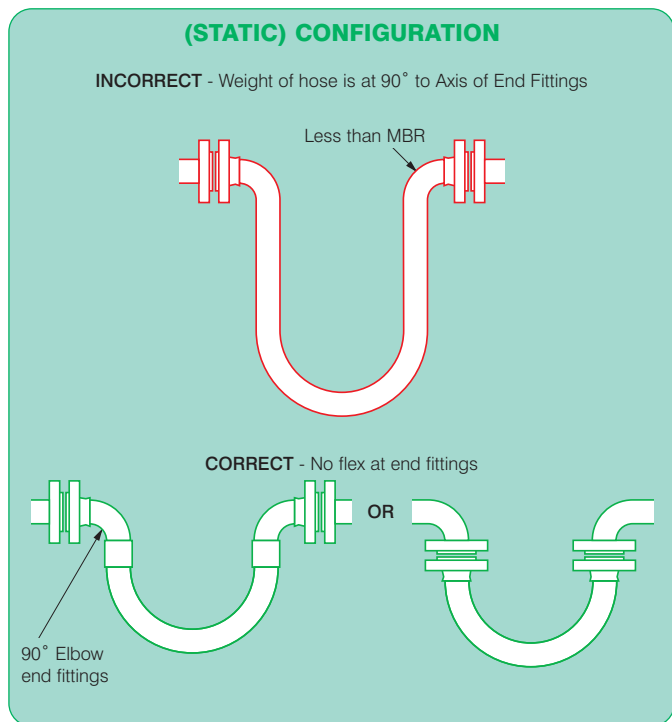
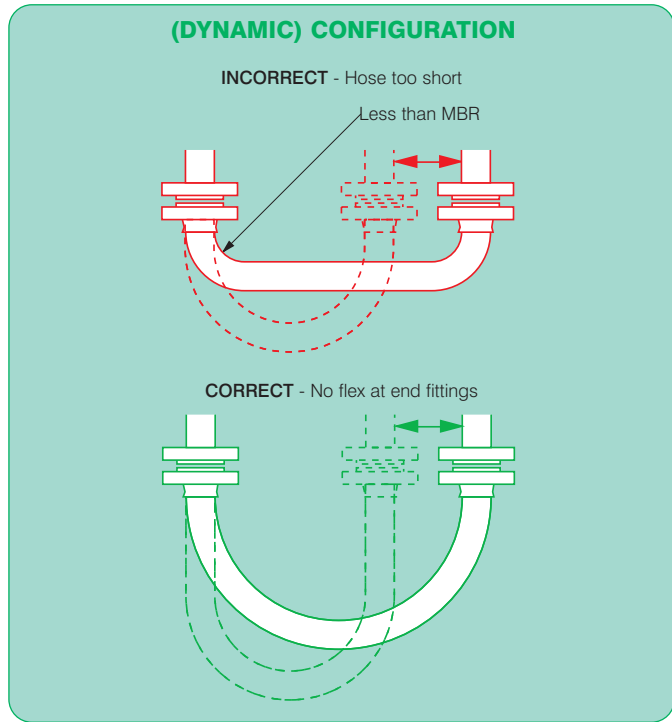
HOSE CONFIGURATION REQUIREMENTS

Hose Assemblies are usually connected at both ends in service. They may then either remain in a fixed, or static configuration or in a flexing, or dynamic configuration.

Whether static or dynamic, the First Rule concerning the configuration of the hose is that the bend radius of the hose must never be less than the Minimum Bend Radius (MBR) for the hose as listed in the relevant hose brochure.

The most common situation when this is likely to occur is when the hose is flexed at the end fitting, with stress being applied to the hose at an angle to the axis of the end fitting. Typically, this happens either because the length of the hose is too short, or because the weight of the hose plus contents creates a stress at an angle to the end fitting.

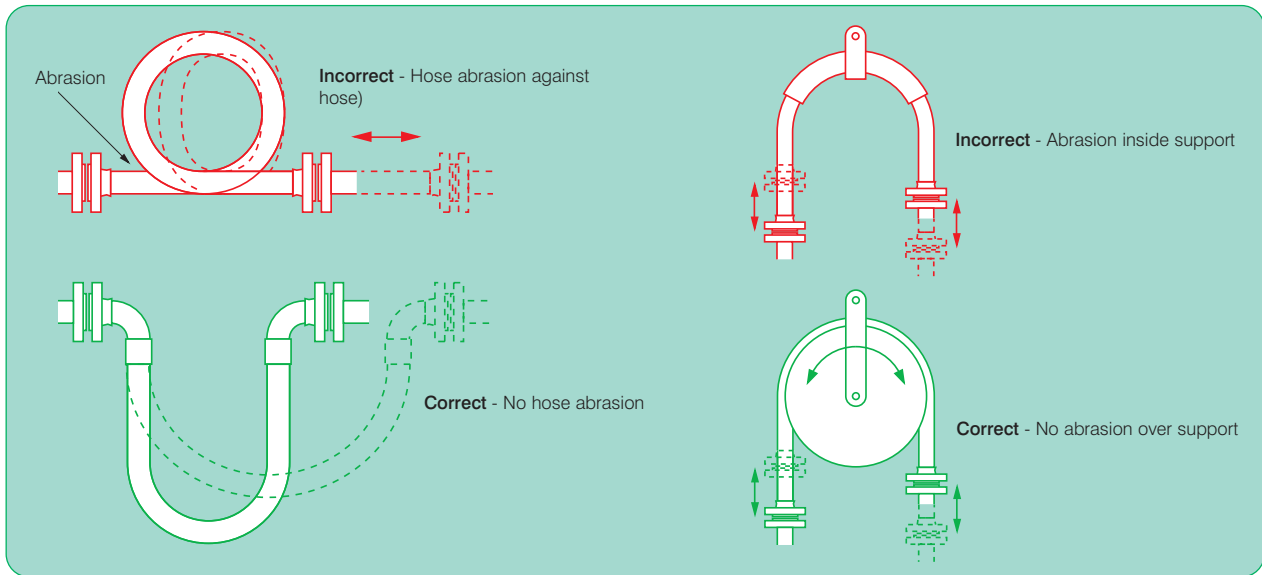
The Second Rule, therefore, if possible, is to design the configuration to ensure that any flexing in the hose takes place away from the end fittings.



Hose Configurations & Length Calculations

The Third Rule is that **the hose configuration should always be designed, and supported where necessary, to avoid any possibility of external abrasion.**

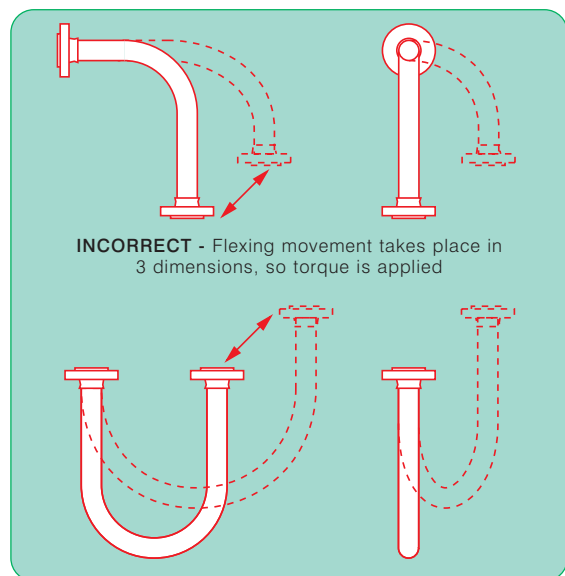
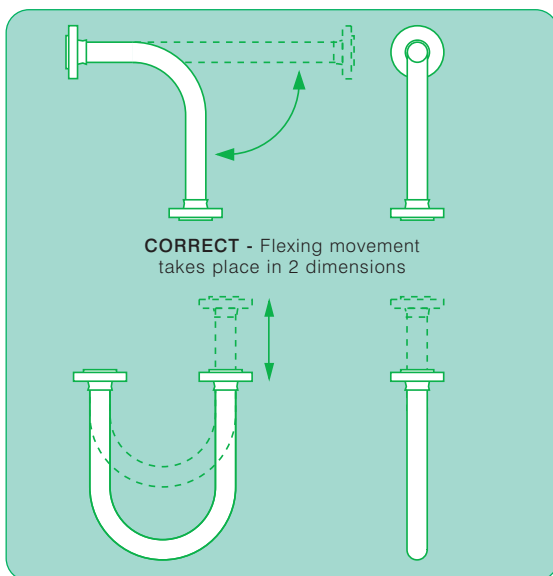
In some cases, the length, configuration and angle of the hose can be designed to avoid abrasion. In others, static or moving support frames or support wheels are required.



The Fourth Rule is that **the hose must not be subjected to torque, either during connection, or as a result of the flexing cycle.**

Torque (twist) in the hose can be applied during connection if the hose is accidentally twisted, or if the second end being connected is a screwed connection, and the hose is subjected to torque during final tightening.

In a flexing application, if any flexing cycle of the hose occurs in 3 dimensions instead of 2, then torque will also occur:



Both Corroflon and Bioflex hose have good resistance to a small level of torque, much better resistance than rubber or SS hose types, but it is still the best practice to take whatever steps are necessary to eliminate torque. If in doubt, consult Aflex Hose.

Hose Configurations & Length Calculations Continued

CALCULATING THE HOSE LENGTH

The formula for calculating the bent section of the hose length around a radius is derived from the basic formula that the circumference of a circle = $2\pi R$, where R = the radius of the circle, and π = a constant, = 3.142.

So, if the hose goes around a 90° bend, which is $1/4$ of a full circumference, and the radius of the bend is R , then the length of the hose around the bend is = $1/4 \times 2\pi R$. Or half way round, in a U-shape, = $1/2 \times 2\pi R$.

Note :

In calculating the length of a hose assembly, the (non-flexible) length of the end fittings must be added in, also the length of any straight sections of hose, as in the following example:

Example :

To calculate the length for a 2" bore size hose with flange end fittings, to be fitted in a 90° configuration with one leg 400mm long, the other 600mm long.

$$\begin{aligned} \text{Length of Bent Section (yellow)} &= 1/4 \times 2\pi R \text{ (334)} \\ &= 1/4 \times 2 \times 3.142 \times 334 = \mathbf{525\text{mm}} \end{aligned}$$

$$\begin{aligned} \text{Length of top, Straight Section, including the top end fitting length} &= 600 - 334 = \mathbf{266\text{mm}} \end{aligned}$$

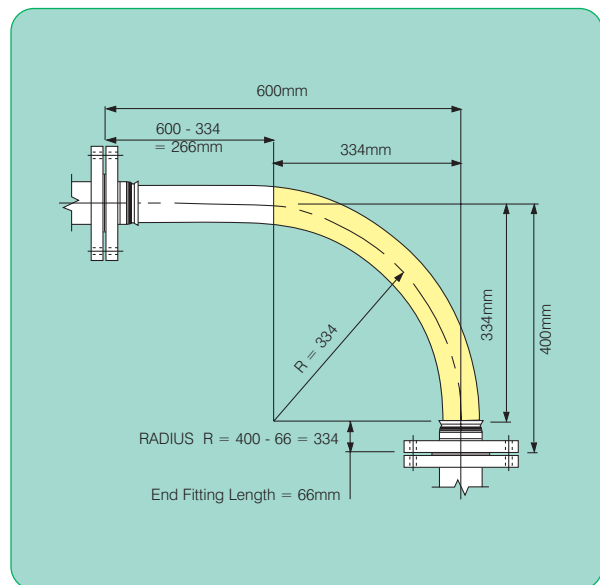
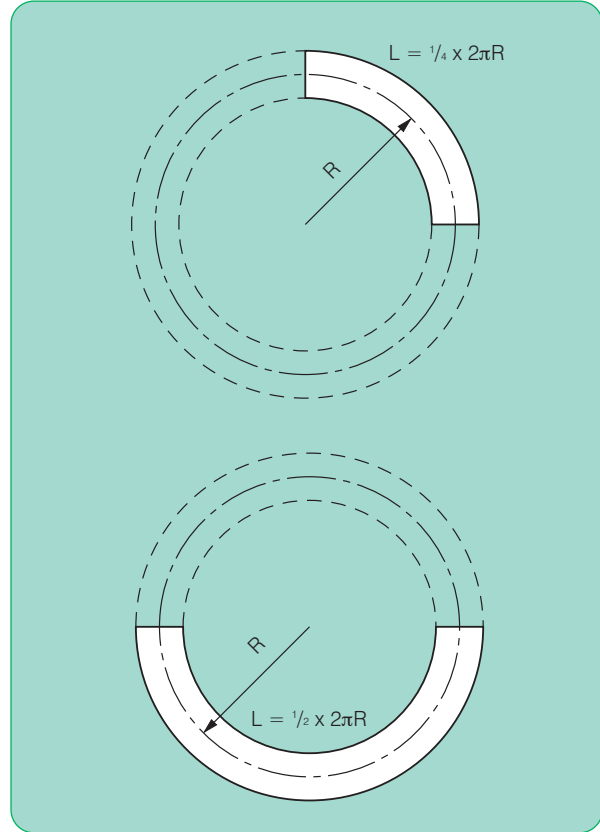
$$\text{Length of bottom end fitting} = \mathbf{66\text{mm}}$$

$$\text{Total length of Hose Assembly} = 525 + 266 + 66 = \mathbf{857\text{mm}}$$

Things to consider

- A hose will normally take the longest radius available to it to go around a corner, not the MBR! Also - always remember to include the **non-flexible** end fitting lengths.
- In dynamic applications, remember to always calculate the lengths for the most extended configuration during the flexing cycle, not the least extended.
- If the configuration is simply too complex for calculation, then obtain a length of flexible tubing of some kind, mark on paper, or a wall, or floor, or both where the connection points will be relative to each other, scaled down if necessary, then manually run the flexible tubing between them with full radii round bends. Measure the extended length, then scale up if necessary to determine the approximate length of the hose.

If in doubt, consult Aflex Hose.



General

Aflex PTFE hose products have not been designed or tested to be suitable for use in Aerospace or Medical Implantation applications, and such use is therefore strictly prohibited unless written approval from Aflex Hose Ltd has been given.

Similarly, PTFE hose should not be used in any radio active environment as radiation has a detrimental effect on the mechanical and electrical properties of PTFE.

Aflex Hose Ltd will not accept liability for any failures of the Aflex Hose Products which are caused by customers failing to perform their Responsibilities as specified in these Conditions of Sale.

It is the customer's strict Responsibility to review all of the usage limitations given for the hose which he intends to use in an application, to ensure that the application conditions are in compliance with those usage limitations. The usage limitations are specified both on this page, and throughout the relevant sections under "Products and Information" on the Aflex Hose website. Customers must always consult the latest, up to date information, which is available and downloadable from the Aflex website, or request from Aflex Hose Ltd.

It must be accepted, however, that the usage limitations specified elsewhere in the Hose Product Information and on this page are intended as a guide only, since every possible factor in every type of application cannot possibly be covered. It is therefore the Customer's Responsibility to ensure the design suitability and safety of the products in their intended applications, giving particular consideration to the chemical and electrostatic compatibility of the fluids or gases passing through, the possibility of diffusion of fluid or gases through the PTFE hose lining, the possibility of external corrosive conditions, the types and likelihood of excessive mechanical abuse, such as abrasion (internal or external), crushing, excessive flexing or vibrations etc, and any excessive temperature and/or pressure "pulsing" conditions, all of which may cause premature hose failure. It is also the Customer's Responsibility to consider, and take account of the degree of risk involved in any hose failure, including the provision of adequate protection in the event of any risk to employees or the general public. In applications where any type of hose failure would lead to financial losses if the hose is not replaced immediately, it is the Customer's Responsibility to order and hold in stock spare hose(s) accordingly. It is also the Customer's Responsibility to advise Aflex Hose in writing if there are any special requirements for the hose, including cleaning, or drying, or extra testing requirements which are in addition to normal industrial standards.

If the Customer has any doubts concerning these or any other usage limitation or safety parameters, it is the Customer's Responsibility to consult Aflex Hose Ltd, to request a written response to any queries.

It is the Responsibility of the Customer to ensure that if the product is sold on, or passed on, however many times, that all the necessary information including this page and the Aflex Hose website address are also passed on to the final user, together with a specific requirement that the final user must review the usage limitations in terms of his own application.

Hose Service Life

It is not possible to guarantee a minimum service life for any of the Aflex Hose products which can be applicable for every type of application.

(For example, PTFE lined hose has been used in one application where it was cycled with hot steam, then cold water, also flexed every 17 seconds 24 hours per day, and the customer was very satisfied with a service life of 3 weeks before failure. In other light duty applications carrying pharmaceutical products, however, many Corroflon hoses are still performing satisfactorily after 20 years in service).

Service life predictions or guarantees can only be given in cases where all the relevant information concerning the application is given in writing to Aflex Hose, and Aflex Hose subsequently replies in writing prior to the order being placed.

If such a written undertaking is not sought and given, then Aflex Hose cannot be held liable for any hose product failure which the customer considers to be premature, excepting failures which are due to faulty materials or manufacturing defects.

24 Month Warranty

Aflex Hose Ltd warrants its products to be free from faulty materials or manufacturing defects from the date of the initial sale, for 24 months.

Product Failure

In the event of a product failure, Aflex Hose requests that the product should not be cut up or tampered with, but should be de-contaminated and returned to Aflex Hose, plus a decontamination certificate, for examination and analysis of the fault. The customer should also provide full details in writing of the application conditions under which the hose failed, including Pressure, Vacuum, Temperature, Flexing and any cycling of any of these, also the fluid and gases passing through the hose, and the total time that the hose has been in service. The customer may send his own witness to the examination if required. Aflex Hose will provide a full Non Conformance Report for the customer.

If faulty materials or a manufacturing defect in the hose was responsible for the failure to perform then, the maximum liability to be accepted by Aflex Hose would include the invoice value of the failed hose itself, or the invoice value of the whole customer order if appropriate, also any reasonable costs for removal and replacement of the hose, and costs for packing and despatching the failed hose back to Aflex Hose. Aflex Hose Ltd will not accept liability for any other consequential or financial losses, including, but not limited to loss of profits, loss of products or downtime costs.

Untested Hose for Self Assembly by Customers

Aflex Hose sometimes supplies "loose" hose, without end fittings attached to Self Assembly Customers, who will then cut the hose to length and attach end fittings to make up Hose Assemblies.

Self Assembly Customers must then accept the responsibility to carry out pressure testing of 100% of such assemblies to 1 1/2 times the Maximum Working Pressure before supply for end use, to validate both the hose and the end fitting attachment.

Unless the customer requests, and Aflex Hose confirm that their loose hose is pressure tested before supply, such testing is not normally applied by Aflex Hose, because this testing requirement is satisfied by the Self Assembly Customer during his own testing of the finished Hose Assembly.

The Self Assembly Customer must also accept responsibility for determining and approving the Design Suitability of the hose assemblies for their intended use before supply.

This includes determining and requesting or applying any special tests which may be identified as necessary to ensure suitability for the intended use.

Aflex Hose will only accept liability for its hose products which are assembled by customers themselves if all the hose and fitting components were either supplied by Aflex Hose or manufactured in accordance with Aflex Hose drawings, and they were assembled and tested in accordance with Aflex Hose's current Manufacturing and Testing Instructions.

Untested Hose Assemblies

Aflex Hose is sometimes requested by customers to attach non-standard end fittings to hose assemblies which they supply, and in some cases it is not possible to connect these fittings to the pressure test system. In such cases a Concession not to test is obtained from the Customer, and a label is attached to the hose assembly, warning that it requires pressure testing before use.

Force Majeure

Aflex Hose Ltd shall not be liable for any delay or default in performing in accordance with any Customers' order if the delay or default is caused by conditions beyond its control, including, but not limited to wars, insurrections, strikes, natural disasters or performance failures by Carriers, sub-contractors or other third parties outside the control of Aflex Hose Ltd.

Legal System

These Conditions of Sale are subject to English Law.