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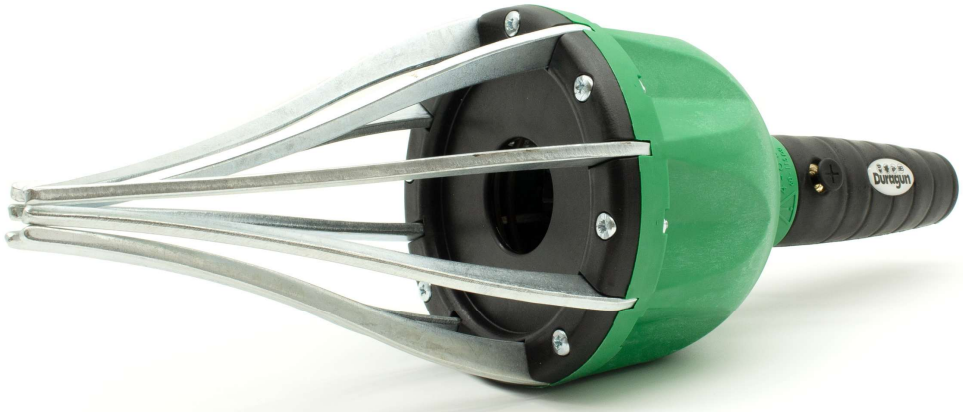
CE Data File

Type:	CV boot applicator
Product Name:	Duragun
Model:	Series 3
Sample Ref/Serial Number:	Specimen 01
Assessor:	David Hartley
Date:	07-07-2025

EN ISO 4414:2010 | **EN ISO 12100:2010** | **Risk Assessment** | **EHSR Report** | **Pneumatic Inpesction**



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Machinery Directive

Assessment of pneumatic fluid power systems to the requirements of

EN ISO 4414:2010

Type:	CV boot applicator
Product Name:	Duragun
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Document Ref:	14D0765

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1	**Scope**	
This checklist specifies general rules and safety requirements for pneumatic fluid power systems and components used on machinery as defined by ISO 12100:2010, 3.1.		
It deals with all significant hazards associated with pneumatic fluid power systems and specifies principles to apply in order to avoid those hazards when the systems are put to their intended use.		
NOTE 1: See Clause 4 and Annex A.		
The significant hazard noise is incompletely dealt with in this checklist.		
NOTE 2: Noise emission depends especially on the installation of pneumatic components or systems into machinery.		
This checklist applies to the design, construction and modification of systems and their components, also taking into account the following aspects: assembly;		
a) installation;		
b) adjustment;		
c) uninterrupted system operation;		
d) ease and economy of maintenance and cleaning;		
e) reliable operation in all intended uses;		
f) energy efficiency; and		
g) environment.		
This checklist does not apply to air compressors and the systems associated with air distribution as typically installed in a factory, including gas bottles and receivers.		
2	**Normative references**	
Refer to standard		Pass
3	**Terms and definitions**	
Refer to standard		Pass
4	**List of significant hazards**	
Refer to standard		Pass
5	**General rules and safety requirements**	
5.1	**General**	
5.1.1		
When designing pneumatic systems for machinery, all intended operations and use of systems shall be considered.		Pass
Risk assessment shall be carried out to determine the foreseeable risks associated with systems when they are used as intended.		Pass
Reasonably foreseeable misuse shall not cause hazards.		Pass
The risks identified shall be eliminated by design and, where this is not practicable, safeguards (first preference) or warnings (second preference) against such risks shall be incorporated, in accordance with the hierarchy established in ISO 12100.		Pass
NOTE: This checklist provides requirements for components of fluid power systems; some of these requirements are dependent on the hazards associated with the machine in which the system is installed. Therefore, the final specification and construction of the pneumatic system could need to be based on risk assessment and agreement between purchaser and supplier.		

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5.1.2		
The control systems shall be designed in accordance with the risk assessment.		Pass
This requirement is met when ISO 13849-1 is used.		N/A
5.1.3		
The prevention of damage to the machine, systems and the environment shall be considered.		Pass
5.1.4		
Deviations from this International Standard shall be agreed to in writing between the purchaser and supplier.		N/A
Attention should be drawn by the purchaser and/or the supplier to applicable national and local codes or laws.		N/A
5.2	**Basic requirements for the design and specification of pneumatic systems**	
5.2.1	**Component selection**	
5.2.1.1		
All components and piping in the system shall be selected or specified to provide for safety in use, and they shall operate within their rated limits when the system is put to its intended use.		Pass
Components and piping shall be selected or specified so as to ensure that they can operate reliably under all intended uses of the system.		Pass
Particular attention shall be paid to the reliability of components and piping that can create a hazard in the event of their failure or malfunction.		Pass
5.2.1.2		
Components and piping shall be selected, applied and installed in accordance with the manufacturer's recommendations.		Pass
5.2.1.3		
It is recommended that wherever practicable, components and piping made in accordance with recognized International Standards should be used.		Pass
5.2.2	**Unintended pressures**	
5.2.2.1		
All related parts of the system shall be designed or otherwise protected against foreseeable pressures exceeding the maximum working pressure of the system or the rated pressure of any part of the system if the excessive pressure can cause a hazard.		Pass
5.2.2.2		
The preferred means of protection against excessive pressure is one or more pressure-relief valves located to limit the pressure in all related parts of the system.		N/A
Other means, such as pressure regulators, may be used, provided these means satisfy the application requirements. *Comment: Advised*		Pass
5.2.2.3		
Systems shall be designed, constructed and adjusted to minimize pressure surges and fluctuations.		N/A
Pressure surges and fluctuations shall not cause hazards.		N/A
5.2.2.4		
Loss of pressure or pressure drop shall not expose persons to a hazard and should not damage the machinery.		Pass

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5.2.2.5		
All pneumatic components shall vent into a non-hazardous area with a connection to the atmosphere. *Comment: The Exhaust switch located on the underside of the handle, releases pressure from the vessel. This air is dispersed in a hazardous area but isn't harmful*		Pass
5.2.2.6		
Means shall be provided to prevent unacceptable pressure build-up where high external loads are reflected on actuators.		N/A
5.2.3	**Mechanical movements**	
Mechanical movements, whether intended or unintended (e.g. effects from acceleration, deceleration or lifting/holding of masses), shall not result in a situation hazardous to persons.		Pass
5.2.4	**Noise**	
In the design of pneumatic systems, the expected noise shall be taken into account. Depending on the application, measures shall be taken to minimize the risks caused by noise.		N/A
Airborne noise and structure- borne noise shall be considered.		N/A
NOTE: For the design of low-noise machinery and systems, see ISO/TR 11688-1.		
5.2.5	**Leakage**	
Leakage (internal or external) shall not cause hazards.		Pass
5.2.6	**Operational and functional requirements for pneumatic systems**	
The following specifications for operation and function shall be defined:		Pass
a)	working pressure range;	Pass
b)	working temperature range;	Pass
c)	type of gas to be used (e.g., air, nitrogen or other neutral gas);	Pass
d)	cycle rates;	N/A
e)	duty cycle;	N/A
f)	service life of components;	N/A
g)	sequence of events;	N/A
h)	filtration and lubrication, including identification of components not to be lubricated;	N/A
i)	lifting provisions;	N/A
j)	emergency, safety and energy isolation requirements;	N/A
k)	painting or protective coating;	N/A
l)	lubricant compatibility with components.	N/A
Annex B provides forms and checklists to facilitate the gathering and recording of this information.		N/A
These forms and checklists can also be useful to record those specifications that apply to pneumatic systems used in mobile machinery.		N/A
The individual forms in Annex B are also available in a separate revisable electronic format.		N/A
5.2.7	**Control or energy supply**	

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Whatever the type of control or energy supply used (e.g. electrical, pneumatic), the following actions or occurrences (whether unexpected or intentional) shall not create a hazard:		Pass
a) switching the supply on or off;		Pass
b) reducing the supply;		Pass
c) cutting off the supply;		Pass
d) restoring the supply (unexpectedly or intentionally).		Pass
5.2.8	**Positive isolation from energy sources**	
The system shall be designed to facilitate positive isolation from energy sources (see ISO 12100:2010, 6.3.5.4). *Comment: Isolation at source*		N/A
In pneumatic systems, this can be done, for example, by		N/A
- isolating the supply with a suitable shut-off device, which should be lockable, and shall be accessible without causing a hazard, or isolating and dissipating pressure from the system with a suitable shut-off device(s) having a pressure-release feature, which can need to be lockable;		N/A
- releasing or supporting mechanical loads when the system is depressurized;		N/A
- isolating the electrical supply (see IEC 60204-1:2009, 5.3).		N/A
The system shall facilitate dissipation of the fluid pressure.		N/A
Precautions should be taken when the supply is reinstated after isolation or depressurization.		N/A
5.2.9	**Location of components and controls**	
The system shall be designed and constructed so that components and controls are located where they are easily accessible for use, adjustment and maintenance without causing hazard.		Pass
5.2.10	**Unexpected start-up**	
In order to prevent unexpected start-up, precautions shall be taken in accordance with ISO 14118.		N/A
5.2.11	**Uncontrolled actuator movement**	
If rapid opening of the shut-off valve can produce uncontrolled movement of actuators, a soft-start/slow-start valve shall be incorporated.		N/A
5.2.12	**Airborne hazardous substances**	
Systems shall be so designed, constructed and/or equipped that airborne hazardous substances are minimized.		N/A
5.3	**Additional requirements**	
5.3.1	**Site conditions and operating environment**	
Site conditions and operating environment shall be defined.		N/A
Annex B provides forms and checklists to facilitate the gathering and recording of this information, which may include:		N/A
a) ambient temperature range of the installation;		N/A
b) ambient humidity range of the installation;		N/A
c) atmospheric pressure;		N/A
d) specification of pneumatic supply available, such as pressure, flow capability, pressure dew point, nominal filtration rating, and oil carry-over;		N/A

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e)	available utilities, e.g. electricity, water, waste;	N/A
f)	electrical network details, e.g. voltage and its tolerance, frequency, available power (if limited);	N/A
g)	protection for electrical circuits and devices;	N/A
h)	sources of contamination;	N/A
i)	sources of vibration;	N/A
j)	possible severity of a fire, explosion or other hazard and availability of related emergency resources;	N/A
k)	unusual environmental or geographical conditions, e.g. altitude, ultraviolet radiation;	N/A
l)	requirements for safeguarding;	N/A
m)	space required for access, use and maintenance as well as the location and mounting of components and systems to ensure their stability and security in use;	N/A
n)	legal and other environmental limiting factors (e.g. noise emission level);	N/A
o)	other safety and special requirements.	N/A
5.3.2	**Installation, use and maintenance of components, piping and assemblies**	
5.3.2.1	**Replacement**	
Components, piping and assemblies should be installed so that they can be easily replaced without dismantling other parts of the machine. *Comment: No inner maintenance required, send back to manufacturer for repair.*		N/A
5.3.2.2	**Lifting provisions**	
All components, assemblies or piping having a mass greater than 15 kg should have provision(s) for lifting (see ISO 12100:2010, 6.3.5.5).		N/A
5.3.3	**Cleaning and painting**	
5.3.3.1		
During external cleaning and painting of machinery, sensitive materials shall be protected from incompatible liquids. *Comment: Dry wipe clean after use.*		Pass
5.3.3.2		
During painting, areas that should not be painted (e.g. piston rods, indicator lights) shall be covered and the coverings removed afterwards.		N/A
After painting, all warnings and safety related markings shall be visible and legible.		N/A
5.3.4	**Preparation for transportation**	
5.3.4.1	**Identification of piping**	
Whenever it is necessary to dismantle pneumatic systems for transportation, the piping and corresponding connections shall be clearly identified.		N/A
The identification shall correspond to, and not conflict with, the data on any appropriate drawings.		N/A
5.3.4.2	**Packaging**	
All parts of the pneumatic system shall be packaged for transportation in a manner that preserves their identification and protects them from damage, distortion, contamination and corrosion.		Pass

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5.3.4.3	**Protection of openings**	
Exposed openings in pneumatic systems and components, in particular tubes and hoses, shall be protected during transportation either by being sealed or by being stored in an appropriately clean and closed container.		Pass
Male threads shall be protected.		Pass
Any protective device used shall be of the type that prevents reassembly until it is removed.		Pass
5.4	**Specific requirements for components and controls**	
5.4.1	**Air motors and semi-rotary actuators**	
5.4.1.1	**Protection**	
Air motors and semi-rotary actuators shall be mounted where they are protected from predictable damage, or be suitably guarded.		N/A
Rotating shafts and couplings shall be guarded to prevent hazard to personnel.		N/A
5.4.1.2	**Mounting**	
The mounting of air motors and semi-rotary actuators on, or related to, their drive assemblies shall be sufficiently rigid to ensure adequate alignment at all times and to accommodate the applied torque.		N/A
Protection against inadvertent damage from end and side forces should be considered.		N/A
5.4.1.3	**Load and speed considerations**	
The starting and stall torques, the effect of load variations, and the kinetic energy of the moving load shall be considered in the application of air motors and semi-rotary actuators.		N/A
5.4.2	**Cylinders**	
NOTE: Many cylinder designs are intended for a specific type of industry or application. These include rotary, rotating, rodless, cable, welded, foundry, air bag, etc.		N/A
5.4.2.1	**Resistance to buckling**	
Attention shall be given to stroke length, loading and cylinder mountings in order to avoid bending or buckling of the cylinder piston rod in any position.		N/A
5.4.2.2	**Loading and overrunning**	
Adequate structural and/or pressure-sustaining strength shall be provided for applications where overrunning or sustained and/or impact loads are encountered.		N/A
Cushioning is recommended to avoid impact when using the cylinder ends as a positive stop.		N/A
5.4.2.3	**Mounting ratings**	
Mounting attachments shall be selected for the required load.		Pass
Mountings and their supporting structures shall be designed for the maximum expected loads at any position within the stroke.		Pass
5.4.2.4	**Resistance to shock and vibration**	
Any attachment mounted on or connected to a cylinder shall be assembled in such a way that resists loosening caused by shock, vibration, etc. in use.		Pass
5.4.2.5	**Mounting fasteners**	
Mounting fasteners for cylinders and accessories shall be designed and installed to accommodate all predictable forces.		Pass
The mounting fasteners shall be adequate to absorb turning moments.		N/A
5.4.2.6	**Alignment**	

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Mounting surfaces shall be designed to prevent distortion of cylinders when installed.		N/A
Cylinders shall be mounted in such a way that avoids unintended side loads during operation.		N/A
5.4.2.7	**Adjustable stroke end stops**	
If stroke length is determined by external stroke end stops, means shall be provided for locking adjustable stroke end stops.		N/A
5.4.2.8	**Piston rod material, finish and protection**	
Piston rod material and finish should be selected to minimize wear, corrosion and foreseeable impact damage.		Pass
Piston rods should be protected against foreseeable damage from dents, scratches, corrosion, etc.		Pass
Protective covers may also be used.		Pass
5.4.2.9	**Air vent**	
Single-acting piston-type cylinders shall have air vent ports designed and/or positioned to avoid hazards to persons when displaced air is exhausted.		Pass
5.4.3	**Valves**	
5.4.3.1	**Selection**	
Valve type and method of mounting shall be selected to ensure correct function, adequate leak tightness and resistance against foreseeable mechanical and environmental influences.		N/A
5.4.3.2	**Mounting**	
When mounting valves, the following shall be considered:		N/A
a)	independent support from their associated piping or connector and ability to remove the valve with a minimum of disturbance to piping;	N/A
b)	means of avoiding incorrect mounting on the valve base, e.g. mounting-bolt pattern, port identification or other identification;	N/A
c)	effects of gravity, impact and vibration on the main elements of the valve, to minimize the probability of an inadvertent shift or destruction of parts of the valve;	N/A
d)	avoidance of the influence of back pressure, which can affect functioning and safe use when stacked or manifold valves or common exhaust lines are used;	N/A
e)	sufficient clearance for wrench and/or bolt access for removal, repair or adjustment of the valve and any related electrical connections.	N/A
5.4.3.3	**Manifolds**	
5.4.3.3.1	**Surface flatness and finish**	
Manifold surface flatness and finish shall be in accordance with valve supplier's recommendations.		N/A
5.4.3.3.2	**Distortion**	
Manifolds shall not malfunction due to distortion when operated within the intended range of operating pressures and temperatures.		N/A
5.4.3.3.3	**Mounting**	
Manifolds shall be rigidly and securely mounted.		N/A
5.4.3.3.4	**Internal passages**	
Internal passages, including cored and drilled holes, shall be free from detrimental foreign matter, such as scale, burrs, swarf, etc., that can restrict flow or that can be dislodged and cause malfunction of and/or damage to any component, including seals and packings.		N/A
5.4.3.4	**Valve control mechanisms and related operating devices**	

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5.4.3.4.1	**Mechanically and manually operated valves**	
Mechanically and manually operated valves shall be installed so that they cannot be damaged by foreseeable operating forces.		N/A
5.4.3.4.2	**Electrically operated valves**	
5.4.3.4.2.1	**Electrical connections**	
Electrical connections to a supply shall be in accordance with appropriate standards, e.g., IEC 60204-1.		N/A
For hazardous operating conditions, the appropriate degree of protection (e.g., explosion-proofing, water-proofing) shall be employed.		N/A
5.4.3.4.2.2	**Terminal block housing**	
Where terminal blocks and housings are specified on the valves, the terminal block housings shall be constructed with the following:		N/A
a)	appropriate degree of protection, in accordance with IEC 60529;	N/A
b)	adequate space for permanently located terminals and the terminal cable, including an additional length of cable;	N/A
c)	captive fasteners for the electrical access cover to prevent loss, e.g., screws with retaining washers;	N/A
d)	suitable securing device for the electrical access cover, e.g., a chain;	N/A
e)	cable connections with strain relief.	N/A
5.4.3.4.2.3	**Solenoids**	
Solenoids shall be selected (e.g., cyclic rate, temperature rating) so that they are capable of operating the valves reliably at minimum and maximum voltage, including the appropriate degree of protection in accordance with IEC 60529.		N/A
The temperature rise on the surface of the solenoid shall be considered.		N/A
Measures, by location or guarding, shall be taken to protect persons from surfaces when temperatures exceed touchable limits.		N/A
If this is not possible, warning labels shall be used; see ISO 13732-1.		N/A
5.4.3.4.2.4	**Manual override**	
If it is necessary to operate an electrically operated valve for safety or other reasons when electrical control is not available, then it should be fitted with manual override facilities.		N/A
These shall be designed or selected so that they cannot be operated inadvertently, and they shall reset when manual control is removed unless otherwise specified.		N/A
5.4.3.5	**Pressure-relief valves**	
Pressure relief valves shall be located near a component or piping whenever pressures in excess of the rated pressure of that component or piping are possible.		N/A
5.4.3.6	**Quick-exhaust valves**	
Quick-exhaust valves shall be installed such that exhausting air does not cause a hazard to personnel.		N/A
5.4.3.7	**Flow-control valves**	
Flow-control valves should be located on or near the cylinder ports.		N/A
5.4.3.8	**Three-position valves**	
Systems that use three-position valves, particularly those with a closed centre position, should be analyzed to determine if leakage from the system and/or leakage through a valve can result in undesired effects, such as unexpected cylinder movement.		N/A

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5.4.4	**Air-preparation components**	
5.4.4.1	**General**	
To ensure required air quality, an air-preparation unit shall be installed at the entry point of the pneumatic system.		N/A
Additional air-preparation units may be installed in sub-systems as necessary.		N/A
Air preparation units should be located as close as practicable to the device being protected and shall be readily accessible for maintenance.		N/A
NOTE: The selection of air-preparation units depends on flow and pressure requirements at the point of use.		
5.4.4.2	**Filtration**	
5.4.4.2.1	**General**	
Means shall be provided to remove detrimental solid, liquid and gaseous materials from the system.		N/A
5.4.4.2.2	**Nominal filtration rating**	
The degree of filtration shall be consistent with the requirements for the components and environmental conditions.		N/A
5.4.4.2.3	**Deterioration of filter performance**	
If deterioration of filter performance, which is sometimes indicated by increasing pressure drop across a filter, can lead to a hazardous situation, clear indication of such deterioration shall be given.		N/A
5.4.4.2.4	**Provisions for maintenance**	
Filters and separators shall be capable of being cleaned and drained or replaced without disturbing the piping.		N/A
Filters with removable or replacement elements shall be provided, where applicable.		N/A
The filter element rating shall be identifiable if more than one rating is available.		N/A
5.4.4.2.5	**Drains**	
Water drains should be used to drain air-line filters and separators, preferably of the automatic type.		N/A
Where required, drains shall be protected from damage caused by freezing.		N/A
Environmental and safety issues shall be considered when collecting and disposing waste fluids.		N/A
5.4.4.3	**Lubrication**	
5.4.4.3.1	**Application**	
Lubricants shall not be supplied to any component that does not require additional lubrication.		N/A
5.4.4.3.2	**Compatibility of lubricating fluids**	
Where necessary, appropriate lubricating fluids shall be specified for use in systems.		N/A
Such fluids shall be compatible with all components, elastomers, plastic tubing and flexible hoses in the system.		N/A
5.4.4.3.3	**Lubricators**	
When lubrication is required, a lubricator(s) should be located close to and above the device being lubricated.		N/A
Where it is not practicable to locate the lubricator above the device being lubricated, recirculating or injection type lubricators should be used.		N/A
Lubricators shall be located to allow easy access for filling.		N/A

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When necessary, lubricators shall have drains to remove water that has collected in the bottom of the lubricator bowl.		N/A
5.4.4.4	**Air drying**	
5.4.4.4.1		
Where a reduction of water-vapour content is required, an air dryer shall be used.		N/A
The type of air dryer used depends on the environment and system requirements.		N/A
5.4.4.4.2		
The air dryer shall be sized to deliver the required air flow rates at the specified pressure dew point.		N/A
5.4.4.5	**Shielding of air preparation components**	
5.4.4.5.1		
To protect personnel from the hazard of non-metallic bowl failures on filters, separators, filter-regulators and lubricators when the product of the rated pressure and the volume of the empty bowl is greater than 100 kPa.l (1 bar.l), the bowl should be capable of being shielded.		N/A
5.4.4.5.2		
To avoid the possible failure of plastic bowls in certain environments, or where shielding is not being used, metal bowls shall be used.		N/A
5.4.5	**Piping and fluid passages**	
5.4.5.1	**General requirements**	
5.4.5.1.1		
The design and selection of piping materials shall take into account site conditions.		N/A
5.4.5.1.2		
The flow rate through piping should not create hazards due to temperature change or pressure drop.		N/A
5.4.5.1.3		
Variations in the flow rate should be minimized by avoiding sudden changes in internal diameters of piping.		N/A
5.4.5.1.4		
In order to optimize response time, the length of the piping between actuators and their directional control valves should be kept to a minimum.		N/A
5.4.5.1.5		
To minimize energy losses, the number of connections should be kept to a minimum.		N/A
5.4.5.2	**Piping layout**	
5.4.5.2.1		
Piping should be designed to discourage its use as a step or ladder.		N/A
External loads should not be imposed upon the piping.		N/A
5.4.5.2.2		
Piping shall not be used to support components where they can impose undue loads on the piping.		N/A

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Undue loads can arise from component mass, shock, vibration and pressure surges.		N/A
5.4.5.3	**Piping identification, location and mounting**	
5.4.5.3.1		
Piping should be mounted to minimize installation stresses, should be located to protect against foreseeable damage, and should not restrict access for adjustment, repairs or replacement of components.		N/A
5.4.5.3.2		
Piping should be identified or located in such a manner that it is not possible to make an incorrect connection that can cause a hazard or malfunction.		N/A
5.4.5.4	**Foreign matter**	
Conductors, connectors, and fluid passages, including cored and drilled holes, shall be free from detrimental foreign matter, such as scale, burrs, swarf, etc., that can restrict flow or can be dislodged and cause malfunction of and/or damage to any component, including seals and packing.		N/A
5.4.5.5	**Support of tubes**	
5.4.5.5.1		
Tubes shall be securely supported.		N/A
5.4.5.5.2		
Supports shall not damage the tubes or reduce the flow.		N/A
5.4.5.5.3		
The table below gives recommendations for the maximum distance between tube supports.		N/A
Nominal tube outside diameter (mm)	**Recommended maximum distance between tube supports**	
≤ 10	1m	
> 10 and ≤ 25	1.5m	
> 25 and ≤ 50	2m	
> 50	3m	
5.4.5.6	**Piping between assemblies**	
Where the machine is constructed of separated assemblies, a rigidly mounted bulkhead-type terminal device or terminal manifold should be used to support the piping and provide connection for each end of the piping lengths between assemblies.		N/A
5.4.5.7	**Piping across access ways**	
Piping runs across access ways shall not interfere with the normal use of the access way.		N/A
They should be located either below or well above the floor level, and in accordance with site conditions.		N/A
These piping runs shall be readily accessible, rigidly supported, and where necessary, protected from external damage.		N/A
5.4.5.8	**Quick-action couplings**	
Quick-action (quick-release) couplings shall be selected and installed so that when they are being coupled or uncoupled,		N/A
a) the coupling shall not couple or uncouple in a hazardous manner;		N/A
b) compressed air or particles shall not be expelled in a hazardous manner;		N/A

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c) a controlled pressure-release system shall be provided where a hazard may exist.	N/A
5.4.5.9	**Hose assemblies**
5.4.5.9.1	**General requirements**
Hose assemblies shall	N/A
a) be constructed from hoses that have not been previously used in operation as part of another hose assembly;	N/A
b) be provided with a recommendation on the maximum storage time and storage conditions supplied by the hose manufacturer;	N/A
c) be used within the hose manufacturer's recommended pressure ratings;	N/A
d) be selected for its electrical conductivity or non-conductivity in applications where this characteristic can lead to a hazard.	N/A
5.4.5.9.2	**Installation**
Installation of hose assemblies shall:	N/A
a) have the minimum length necessary to avoid sharp flexing and straining of the hose during the component operation; hoses should not be bent with a radius smaller than the specified minimum bending radius;	N/A
b) minimize torsional deflection of the hose during installation and use, e.g., as the result of a rotating connector jamming;	N/A
c) be located or protected to minimize abrasive rubbing of the hose cover;	N/A
d) be supported, if the weight of the hose assembly can cause undue strain.	N/A
5.4.5.10	**Removal of piping**
Piping should be removable without disturbing components that are mounted separately from the piping and without using special tools.	N/A
5.4.5.11	**Failure of hose assemblies and plastic piping**
5.4.5.11.1	
When failure of a hose assembly or plastic piping constitutes a whiplash hazard, it shall be restrained or shielded by suitable means.	N/A
In addition, an air fuse for compressed air should be mounted.	N/A
5.4.5.11.2	
When the failure of a hose assembly or plastic piping constitutes a fluid ejection hazard, it shall be shielded by suitable means.	N/A
5.4.6	**Control systems**
5.4.6.1	**Unintended movement**
In all phases of operation, control systems shall be designed to prevent unintended hazardous movement and improper sequencing of actuators, particularly vertical and inclined motions.	Pass
5.4.6.2	**Pressure regulation**
5.4.6.2.1	
Control shall be provided to maintain the system pressure within safe limits, e.g., where pressure regulators are used in pneumatic circuits for safety, they should be of the self-relieving type; see 5.2.2.2 and 5.2.2.4.	Pass
5.4.6.2.2	

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A relieving-type pressure regulator that is not designed to be a safety component shall not be the sole device to prevent excess pressure where its relief capability is inadequate.	Pass
5.4.6.2.3	
The required accuracy of pressure regulation and flow rate characteristics for the application determines the type of regulator used (see ISO 6953-1).	Pass
5.4.6.3	**Adjustable control mechanisms**
5.4.6.3.1	
Pressure and flow control valves shall be constructed to permit adjustment within their ratings.	N/A
Adjustment beyond these ratings can be possible; the ratings are not maximum adjustable limits.	N/A
5.4.6.3.2	
Adjustable control mechanisms shall hold their settings within specified limits until reset.	N/A
5.4.6.3.3	
The required accuracy of pressure regulation and flow rate characteristics for the application determines the type of regulator used; see ISO 6953-1.	N/A
5.4.6.4	**Stability**
Pressure and flow control valves shall be selected so that changes in actual pressure, actual temperature or load do not cause a malfunction or a hazard.	N/A
5.4.6.5	**Tamper resistance**
Pressure and flow control valves or their enclosures shall be fitted with tamper-resistant devices (e.g. key lock on a pressure regulator) where an unauthorized alteration to pressure or flow can cause a hazard or malfunction.	N/A
5.4.6.6	**Manual control levers**
The direction of movement of manually operated levers shall not be confusing; for example, moving a lever up should not lower the controlled device; see IEC 61310-3.	N/A
5.4.6.7	**Manual set-up controls**
If manual control is provided for setting up, this control shall be safely designed and have priority over automatic controls in the set-up mode.	N/A
5.4.6.8	**Two-hand controls**
If two-hand controls are provided, they shall be designed and applied in accordance with ISO 13851.	N/A
5.4.6.9	**Safe position**
Any actuator required to maintain its position or to adopt a specific position for safety in the event of a control system failure shall be controlled by a valve that is held in or switched back to the safe position (e.g. by spring tension or comparable physical principle).	Pass
NOTE: To leave the safe position, pressure or force is necessary; see ISO 13849-2:2003, Table B.2.	
5.4.6.10	**Control systems with servo or proportional valves**
5.4.6.10.1	**Override systems**
Where actuators are controlled by servo or proportional valves and malfunction of the control system can result in the actuators causing a hazard, means shall be provided to maintain or recover control, or stop the motion, of these actuators.	N/A
5.4.6.10.2	**Additional devices**
Actuators whose speed is controlled by servo or proportional valves shall have means to hold or move the actuator to a safe position if unintended movement may cause a hazard.	N/A

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5.4.6.11	**Monitoring of system parameters**	
Where changes in the system operating parameters can constitute a hazard, clear indication of the system operating parameters, e.g. temperature, pressure, shall be provided.		N/A
5.4.6.12	**Control of multiple devices**	
Where there is more than one interrelated automatically and/or manually controlled device on the machine, and where failure of any of these devices can cause a hazard, protective interlocks or other safety means shall be provided.		N/A
Where practicable, these interlocks should interrupt all operations, provided that such interruption does not of itself cause a hazard.		N/A
5.4.6.13	**Control of sequencing by position sensing**	
Sequencing by position sensing shall be used wherever practicable and shall always be used when a sequencing malfunction of a pressure or a time-lapse control, on its own, can cause a hazard or damage.		N/A
5.4.6.14	**Location of controls**	
5.4.6.14.1	**Manual controls**	
The location and mounting of manual controls shall:		Pass
a)	place the control within reach of the operator's normal working position;	Pass
b)	not require the operator to reach past rotating or moving devices to operate the control;	Pass
c)	not interfere with the operator's required working movements;	Pass
d)	be designed, selected and located so that an operator is not exposed to hazards.	Pass
5.4.6.14.2	**Enclosures and compartments**	
The size of enclosures, compartments, doors and covers and the arrangement of the control devices within shall provide adequate room for maintenance and ventilation.		N/A
5.4.6.15	**Emergency controls**	
The system shall incorporate an emergency stop in accordance with ISO 13850, or emergency control.		N/A
5.4.7	**Diagnostics and monitoring**	
5.4.7.1	**Pressure measurement**	
5.4.7.1.1		
Pressure-measuring instruments should be selected with a pressure-measuring range such that the maximum working pressure of the system does not exceed 75 % of the maximum scale value for steady- state pressure or 65 % of the maximum scale value for cyclic pressure.		N/A
5.4.7.1.2		
Where pressure-measuring instruments are included as permanent items in a system, they shall be protected from rapidly fluctuating pressure.		N/A
5.4.7.2	**Electrical supply indicators**	
Electrical devices should be incorporated to indicate the state of the electrical signal to individual components.		N/A
5.4.8	**Pneumatic silencers**	
Pneumatic silencers shall be used where the sound pressure level caused by exhausting air is above that permitted by applicable codes and standards.		N/A
The use of exhaust-port silencers in themselves shall not create a hazard.		N/A

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Silencers should not create detrimental back pressure.		N/A
5.4.9	**Seals and sealing devices**	
Seals and sealing devices:		N/A
a)	shall not be adversely affected by air, moisture, temperature, fluids or lubricants used;	N/A
b)	shall be compatible with adjacent contact materials;	N/A
c)	shall be stored in accordance with the supplier's recommendations;	N/A
d)	shall be used within the limits of their shelf life;	N/A
e)	should be tested under conditions as close as possible to those of the actual application prior to being specified for production use.	N/A
5.4.10	**Receivers and surge tanks**	
When receivers and surge tanks are incorporated in a system (apart from the plant supply system), the following requirements shall be taken into consideration:		N/A
a)	sufficient capacity to provide the pressure stability required;	N/A
b)	design, construction and labelling in accordance with applicable regulations;	N/A
c)	provision of correct pressure measurement, if necessary;	N/A
d)	provision for a drain and protection from freezing when the location allows collection of condensates;	N/A
e)	venting or pneumatic pressure isolation when air supply is shut off.	N/A
If pressure is isolated, a lockable manual shut-off valve shall be provided to maintain pressure in the surge tank.		N/A
If venting of the receiver or surge tank is necessary, a manual vent shall be provided, and an appropriate service warning label shall be permanently installed on the component.		N/A
6	**Verification of safety requirements and acceptance testing**	
The pneumatic system shall be subjected to a combination of inspection and testing to verify that:		Pass
a)	the identification of systems and components conforms to the system's specifications;	Pass
b)	the connection of components in the system complies to the circuit diagram;	Pass
c)	the system, including all safety components, functions correctly;	Pass
d)	there is no audible leakage, with the exception of functional air consumption, after the system is subjected to the maximum pressure that can be sustained under all conditions of intended use; leakage in a pneumatic system should be overcome by the observance of proper installation procedures.	Pass
NOTE: Because a pneumatic system might not be a complete machine, many verification procedures cannot be carried out until the pneumatic system is incorporated into the machine.		
The results of verification by inspection and testing shall be documented.		Pass
7	**Information for use**	
7.1	**General requirements**	
Information for use shall be in accordance with ISO 12100:2010, 6.4, as far as applicable.		Pass
7.2	**Final information**	
The following documents, conforming to the system as finally accepted, shall be provided:		Pass
a)	final circuit diagrams in accordance with ISO 1219-2;	Pass

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NOTE: ISO 1219-2 provides a method for creating unique identification codes; see 7.4.2.1.		
b) parts list;		Pass
c) general arrangement drawing;		Pass
d) maintenance and operating instructions data and manuals; see 7.3;		Pass
e) certificates, if required;		Pass
f) assembly instructions;		N/A
g) lubrication fluid or grease material safety data sheets, if supplied with the system.		N/A
7.3	**Maintenance and operating data**	
7.3.1		
An instruction handbook describing system operation and maintenance, including the required maintenance and operating data in accordance with ISO 12100:2010, 6.4, for all pneumatic equipment, including piping shall be provided.		Pass
NOTE: It is generally expected that these requirements are dealt with by the system provider.		
These data shall clearly		Pass
a) describe start-up and shut-down procedures;		Pass
b) give any required depressurizing instructions and identify those parts of a system that are not depressurized by the normal venting device(s);		N/A
c) describe adjustment procedures;		N/A
d) indicate external lubrication points, the type of lubricant required and intervals to observe, and whether or not the lubricator(s) can be filled under pressure;		N/A
e) locate drains, filters, test points, etc., that require regularly scheduled maintenance;		N/A
f) state maintenance procedures for unique assemblies;		N/A
g) list recommended spare parts;		N/A
h) provide a recommendation on hose-assembly maintenance requirements.		N/A
7.3.2		
For service or replacement of components in safety-related parts of control systems, information shall be provided relating to service life and mission time.		N/A
NOTE: When ISO 13849-1 is applied, this information can be necessary to maintain the designed performance level.		
7.4	**Marking and identification**	
7.4.1	**Components**	
7.4.1.1		
The following particulars shall be provided and be shown, if practicable, in a permanent and readily visible form on all components:		Pass
a) manufacturer's or supplier's name and/or brand mark;		Pass
b) manufacturer's or supplier's product identification;		Pass
c) rated pressure;		Pass
d) symbols in accordance with ISO 1219-1, with all ports correctly identified in accordance with ISO 11727; these symbols should be oriented to correspond to the physical assembly.		N/A

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NOTE: It is generally expected that these requirements are dealt with by the system provider.		
7.4.1.2		
Where lack of available space would result in lettering too small to be legible, information may be provided on supplementary literature such as instruction/maintenance sheets, catalogue sheets or accessory tags.		Pass
7.4.1.3		
For air motors, the direction of rotation shall be indicated.		N/A
For filters, lubricators and regulators, the direction of flow shall be indicated.		N/A
7.4.1.4		
Optional information that can be given either on the component or in supplementary literature as described in Table 2 in the standard.		Pass
7.4.2	**Components within a system**	
7.4.2.1		
Each component and hose assembly in the pneumatic system shall be given a unique identification code; see 7.2 a).		N/A
This identification code shall be used to identify the components and hose assemblies on all parts lists, general arrangement drawings and/or circuit diagrams.		N/A
It should be clearly and permanently marked on the installation adjacent to, but not on, the component or hose assembly.		N/A
7.4.2.2		
The order and orientation of stack valves should be clearly indicated adjacent to, but not on, the stacked valve assembly; see Figure 1 in the standard.		N/A
7.4.3	**Ports and conductors**	
7.4.3.1		
All ports shall be clearly and distinctly identified.		N/A
All identifiers shall match those on the circuit diagram.		N/A
7.4.3.2		
If mismatching is not avoided by any other means, the conductors that connect the pneumatic system to other systems shall be clearly and distinctly identified and correspond to the data in related documentation.		N/A
One of the following possibilities for the identification of conductors, based on the data of the circuit diagram may be used:		N/A
a) marking by use of the identification number of the conductors;		N/A
b) marking of conductor ends by use of component and port identification, either		N/A
- local-end connection marking, or		N/A
- both-end connection marking;		N/A
c) marking of all conductors and their ends by a combination of a) and b).		N/A
7.4.3.3		

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The following particulars shall be provided on the hose and be shown in a permanent and readily visible form:	N/A
a) manufacturer's or supplier's name and/or brand mark;	N/A
b) date of manufacture (year/quarter);	N/A
c) rated pressure;	N/A
d) nominal inside diameter (optional).	N/A
NOTE: It is generally expected that these requirements are dealt with by the hose manufacturer.	
7.4.3.4	
The following particulars shall be provided on the plastic tube and be shown in a permanent and readily visible form:	N/A
a) manufacturer's or supplier's name and/or brand mark;	N/A
b) date of manufacture (year/quarter);	N/A
c) nominal outside diameter (optional).	N/A
NOTE: It is generally expected that these requirements are dealt with by the plastic tube manufacturer.	
7.4.4	**Valve control mechanisms**
7.4.4.1	
Valve control mechanisms and their functions shall be clearly and permanently identified with the same identification used on the circuit diagram.	N/A
7.4.4.2	
When the same electrical valve control mechanism (e.g., a solenoid and its attaching plugs or cables) is shown on a pneumatic and related electrical circuit diagram, it shall be identified in the same way on both circuit diagrams.	N/A
7.4.5	**Internal devices**
Valves and other functional devices [e.g., orifice plugs, passages, shuttle valves, non-return (check) valves, etc.] located within a manifold, mounting plate, pad or connector shall be identified adjacent to their access openings.	N/A
Where access openings are located under a component or components, identification shall, if practicable, be provided adjacent to the concealed component and marked “CONCEALED”.	N/A
Where this is not possible, the identification shall be provided by other means.	N/A
7.4.6	**Function plate**
A function plate should be provided for each control station and located where it can be easily read.	N/A
It shall be clearly understood and provide positive identification of each system function controlled.	N/A
Where this is not possible, the identification shall be provided by other means.	N/A
8	**Identification statement**
It is strongly recommended to manufacturers who have chosen to conform to the standard that the following statement be used in test reports, catalogues and sales literature: “Pneumatic systems and their components are in accordance with ISO 4414.”	Pass

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Normative references

Standard	Year	Amend.	Title
BS EN ISO 4414	2010		Pneumatic fluid power — General rules and safety requirements for systems and their components

Issue	Date	Reference	Comments
1	12/05/2014	14D0763	First draft
2	14/01/2022	14D0764	Second draft
3	07/07/2025	14D0765	Third draft

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Machinery Directive

Assessment of general principles for machinery design to the requirements of

EN ISO/DIS 12100:2024

Type:	CV boot applicator
Product Name:	Duragun
Model:	Series 3
Sample Ref/Serial Number:	Specimen 01
Assessor:	David Hartley
Date:	07-07-2025
Document Ref:	14D1732

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Machinery Directive - Assessment of general principles for machinery design to the requirements of EN ISO/DIS 12100:2024

1	Scope
This document specifies basic terminology, principles and a methodology for achieving safety in the design of machinery.	
It specifies principles of risk assessment and risk reduction to help designers in achieving this objective.	
These principles are based on knowledge and experience of the design, use, incidents, accidents and risks associated with machinery.	
Procedures are described for identifying hazards and estimating and evaluating risks during relevant phases of the machine life cycle, and for the elimination of hazards or the provision of adequate risk reduction.	
Guidance is given on the documentation and verification of the risk assessment and risk reduction process.	
This standard covers principal implications on machinery safety in case of implementation of artificial intelligence/machine learning, and vulnerability against cybersecurity attacks / corruption regarding their impact on safety. It specifies generic measures to address both aspects.	
Safety of machinery includes hygiene aspects.	
This document is also intended to be used as a basis for the preparation of type-B or type-C safety standards.	
It does not cover risk and/or damage to domestic animals, property or the environment.	
NOTE 1: While this document refers to risks of harm to persons, the risk assessment process set out in this document can be equally effective in assessing other types of risks such as damage to domestic animals, property or the environment	
NOTE 2: Annex B gives, in separate tables, examples of hazards, hazardous situations and hazardous events, in order to clarify these concepts and assist the designer in the process of hazard identification.	
NOTE 3: The practical use of a number of methods for each stage of risk assessment is described in ISO/TR 14121-2.	
NOTE 4: As used in this document the designer of a machine can include the manufacturer, integrator, supplier; or the user in case of safety-relevant modifications.	
2	**Normative references**
Refer to standard	
3	**Terms and definitions**
Refer to standard	
4	**Strategy for risk assessment and risk reduction**
To implement risk assessment and risk reduction, the following actions shall be taken, in the order given (see Figure 1 and Figure 2 in the standard):	
Determine the limits of the machinery, which include the intended use and any reasonably foreseeable misuse thereof	
a) identify the hazards and associated hazardous situations;	
b) estimate the risk for each identified hazard and hazardous situation;	
c) evaluate the risk and make decisions about the need for risk reduction;	
d) eliminate the hazard or reduce the risk associated with the hazard by means of risk reduction measures until the risk is adequately reduced to achieve tolerable risk.	
NOTE 1: Any misuse of a machine which is illegal or not readily predictable human behaviour is outside the scope of a risk assessment. However, cybersecurity attacks with potential impacts to safety should be considered.	
Figure 1 in the standard shows the overall approach to the risk assessment/risk reduction process.	
Two important aspects of the overall process in Figure 1 are	

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- identifying hazards, hazardous situations and hazardous events, and	
- reducing risks.	
Resources and efforts should be focused on these two key elements. Nevertheless, other aspects of the process shown in Figure 1 in the standard are necessary and important.	
Risk assessment is a series of logical steps to enable, in a systematic way, the analysis and evaluation of the risks associated with machinery.	
Risk assessment is followed, whenever necessary, by risk reduction. Iteration of this process can be necessary to eliminate hazards as far as practicable and to adequately reduce risks by the implementation of risk reduction measures.	
NOTE 2: It is generally accepted that the residual risk is equal or lower than the tolerable risk.	
The method to implement the process of Figure 1 in the standard is shown in Figure 2 in the standard. Figure 2 in the standard intentionally mirrors Figure 1 in the standard, but provides additional details on the aspects of the three steps of risk reduction to be taken by the machine designer to achieve tolerable risk. Whereas Figure 1 in the standard highlights the “what” of the risk assessment process, Figure 2 in the standard demonstrates “how” the intended risk reduction is achieved.	
NOTE 3: This document deals only with the application of risk reduction measures by the designer.	
Risk reduction measures are the combination of the measures implemented by the designer and the user in accordance with Figure 3 in the standard. Measures which can be incorporated at the design stage are preferable to those implemented by the user and usually prove more effective.	
Further details on the impact of risk reduction measures taken by both the machine designer and machine user are shown in Figure 3 in the standard. The impacts shown illustrate the effectiveness of the three-step method shown in Figure 2 in the standard and the information flow between the designer and user in order to achieve and maintain an overall outcome of tolerable risk.	
The objective to be met is the greatest practicable risk reduction, taking into account the four factors below. The strategy defined in this Clause is represented by the flowcharts in Figure 1 in the standard and Figure 2 in the standard. The process itself is iterative and several successive applications can be necessary to reduce the risk, making the best use of available technology. In carrying out this process, it is necessary to take into account these four factors, in the following order of preference:	
- the safety of the machine during all the phases of its life cycle;	
- the ability of the machine to perform its function;	
- the usability of the machine;	
- the manufacturing, operational and dismantling costs of the machine.	
NOTE 4: The ideal application of these principles requires knowledge of the function and use of the machine, the accident history and health records, available risk reduction techniques, and the legal framework in which the machine is to be used.	
NOTE 5: A machine design which is acceptable at a particular time could be no longer justifiable when technological development allows the design of an equivalent machine with lower risk.	
As result of this process it shall be assumed that the particular machine will result in a design that can be used with tolerable risk achieved by adequate risk reduction (see Figure 1 in the standard).	
Annex C provides guidance as to how the system of existing type-A, type-B and type-C standards on machinery safety should be applied in order to design a machine to achieve a level of tolerable risk by adequate risk reduction. It explains how this type-A standard should be used for practical cases in conjunction with type-B and type-C standards on machinery safety.	
All products and systems include hazards and, therefore, some level of residual risk. However, the risk associated with those hazards shall be reduced to a tolerable level.	
5	**Risk assessment**
5.1	**General**
Risk assessment comprises (see Figure 2 in the standard):	Pass
- risk analysis, comprising:	Pass
- determination of the limits of the machinery (see 5.3),	Pass

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- hazard identification (5.4 and Annex B), and	Pass
- risk estimation (see 5.5), and	Pass
- risk evaluation (see 5.6).	Pass
Risk analysis provides information required for the risk evaluation, which in turn allows judgments to be made about whether or not risk reduction is required.	Pass
These judgments shall be supported by a qualitative or, where appropriate, quantitative estimate of the risk associated with the hazards present on the machinery.	Pass
Note: A quantitative approach can be appropriate when useful data is available. However, a quantitative approach is restricted by the useful data that are available and/or the limited resources of those conducting the risk assessment. Therefore, in many applications only qualitative risk estimation will be possible.	
The risk assessment shall be documented according to Clause 7.	Pass
5.2 Information for risk assessment	
5.2.1 The information for risk assessment should include the following.	
a) Related to machinery description:	Pass
1) user specifications;	Pass
2) anticipated machinery specifications, including	Pass
i) a description of the various phases of the whole life cycle of the machinery,	Pass
ii) design drawings or other means of establishing the nature of the machinery, and	Pass
iii) required energy sources and how they are supplied;	Pass
3) documentation on previous designs of similar machinery, if relevant;	N/A
4) information for use of the machinery, as available.	Pass
b) Related to regulations, standards and other applicable documents:	Pass
1) applicable regulations;	Pass
2) relevant standards;	Pass
3) relevant technical specifications;	Pass
4) relevant safety data sheets.	Pass
c) Related to experience of use:	N/A
1) any accident, incident or malfunction history of the actual or similar machinery;	N/A
2) the history of damage to health resulting, for example, from emissions (noise, vibration, dust, fumes, etc.), chemicals used or materials processed by the machinery;	N/A
3) the experience of users of similar machines and, whenever practicable, an exchange of information with the potential users.	N/A
Note: An incident that has occurred and resulted in harm can be referred to as an “accident”, whereas an incident that has occurred and that did not result in harm can be referred to as a “near miss” or “dangerous occurrence”.	
d) Related to human factors and ergonomics aspects, e.g.:	N/A
1) required variability for different operators; e.g. size, weight, maneuverability	N/A

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2) required work postures or movements and manual force exertions;	N/A
3) required space for movements of the parts of the operator's body;	N/A
4) required human-machine interactions;	N/A
5) machine work rate.	N/A
5.2.2	**The information shall be updated as the design develops or when modifications to the machine are required.**
Comparisons between similar hazardous situations associated with different types of machinery are often possible, provided that sufficient information about hazards and accident circumstances in those situations is available.	N/A
Note: The absence of an accident history, a small number of accidents or low severity of accidents ought not to be taken as a presumption of a low risk.	
For quantitative analysis, data from databases, handbooks, laboratories or manufacturers' specifications may be used, provided that there is confidence in the suitability of the data.	Pass
Uncertainty associated with these data shall be indicated in the documentation (see Clause 7).	N/A
5.3	**Determination of limits of machinery**
5.3.1	**General**
Risk assessment begins with the determination of the limits of the machinery, taking into account all the phases of the machinery life.	Pass
This means that the characteristics and performances of the machine or a series of machines in an integrated process, and the related people, environment and products, should be identified in terms of the limits of machinery as given in 5.3.2 to 5.3.5.	Pass
5.3.2	**Use limits**
Use limits include the intended use and the reasonably foreseeable misuse. Aspects to be taken into account include the following:	Pass
a) the machine operating modes and intervention procedures for the users, including interventions required by malfunctions of the machine;	N/A
b) the use of the machinery (for example, industrial, non-industrial and domestic) by persons identified by sex, age, dominant hand usage, or limiting physical abilities (visual or hearing impairment, size, strength, etc.);	N/A
c) the anticipated levels of training, experience or ability of users including	Pass
1. operators,	Pass
2. maintenance personnel or technicians,	N/A
3. trainees and apprentices, and	N/A
4. the general public;	N/A
d) exposure of other persons to the hazards associated with the machinery where it can be reasonably foreseen:	Pass
1. persons likely to have a good awareness of the specific hazards, such as operators of adjacent machinery;	Pass
2. persons with little awareness of the specific hazards but likely to have a good awareness of site safety procedures, authorized routes, etc., such as administration staff;	N/A
3. persons likely to have very little awareness of the machine hazards or the site safety procedures, such as visitors or members of the general public, including children.	N/A
If specific information is not available in relation to b), above, the manufacturer should take into account general information on the intended user population (for example, appropriate anthropometric data).	N/A
e) specific limitations of cybersecurity attributes for a machine	N/A

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f) limitations for the use of artificial intelligence (e.g. machine learning), such as the type of data used to train artificial intelligence system	N/A
5.3.3 Space limits	
Aspects of space limits to be taken into account include	Pass
a) the range of movement,	Pass
b) space requirements for persons interacting with the machine, such as during operation and maintenance,	Pass
c) human interaction such as the operator–machine interface, and	Pass
d) the machine–power supply interface.	Pass
5.3.4 Time limits	
Aspects of time limits to be taken into account include	N/A
a) the life limit of the machinery and/or of some of its components (tooling, parts that can wear, electromechanical components, etc.), taking into account its intended use and reasonably foreseeable misuse, and	N/A
b) recommended service intervals.	N/A
5.3.5 Other limits	
Examples of other limits include	N/A
a) properties of the material(s) to be processed,	N/A
b) housekeeping — the level of cleanliness required, and	N/A
c) environmental — the recommended minimum and maximum temperatures, whether the machine can be operated indoors or outdoors, in dry or wet weather, in direct sunlight, tolerance to dust and wet, etc.	N/A
5.4 Hazard identification	
After determination of the limits of the machinery, the essential step in any risk assessment of the machinery is the systematic identification of reasonably foreseeable hazards (permanent hazards and those which can appear unexpectedly), hazardous situations and/or hazardous events during all phases of the machine life cycle, i.e.:	Pass
- transport, assembly and installation;	N/A
- commissioning;	N/A
- use;	Pass
- dismantling, disabling and scrapping.	N/A
Only when hazards have been identified can steps be taken to eliminate them or to reduce risks. To accomplish this hazard identification, it is necessary to identify the operations to be performed by the machinery and the tasks to be performed by persons who interact with it, taking into account the different parts, mechanisms or functions of the machine, the materials to be processed, if any, and the environment in which the machine can be used.	
The designer shall identify hazards taking into account the following.	
a) Human interaction during the whole life cycle of the machine	Pass
Task identification shall be performed for all modes of operation and all tasks associated with every phase of the machine life cycle as given above.	Pass
Task identification should also take into account, but not be limited to, the following tasks:	Pass

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- setting;	N/A
- testing;	Pass
- teaching/programming;	Pass
- process/tool changeover;	N/A
- starting the machine;	N/A
- feeding the machine;	N/A
- removal of product from machine;	Pass
- stopping the machine;	N/A
- stopping the machine in case of emergency;	N/A
- recovery of operation from jam or blockage;	N/A
- restart after unscheduled stop;	N/A
- fault-finding/trouble-shooting (operator intervention);	N/A
- cleaning and housekeeping;	Pass
- preventive maintenance;	N/A
- corrective maintenance	N/A
All reasonably foreseeable hazards, hazardous situations or hazardous events associated with the various tasks shall then be identified.	Pass
Annex B gives examples of hazards, hazardous situations and hazardous events to assist in this process. Several methods are available for the systematic identification of hazards. See also ISO/TR 14121-2	
In addition, reasonably foreseeable hazards, hazardous situations or hazardous events not directly related to tasks shall be identified.	
Example: Seismic events, lightning, excessive snow loads, noise, break-up of machinery, hydraulic hose burst.	
b) Possible states of the machine	Pass
These are as follows:	Pass
- the machine performs the intended function (the machine operates normally);	Pass
- the machine does not perform the intended function (i.e. it malfunctions) due to a variety of reasons, including	N/A
- variation of a property or of a dimension of the processed material or of the workpiece,	N/A
- failure of one or more of its component parts or services,	N/A
- external disturbances (for example, shocks, vibration, electromagnetic interference),	N/A
- design error or deficiency (for example, software errors),	N/A
- disturbance of its power supply, and	N/A
- surrounding conditions (for example, damaged floor surfaces).	N/A
- unintended self evolving behaviour of applied artificial intelligence (see ISO/TR 22100-5)	N/A

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- cybersecurity breach	N/A
NOTE 1 At the design stage, the machine manufacturer should observe basic principles/measures to minimize the cybersecurity risks of safety-related parts of the entire machine (see 6.3.5.7.3).	
NOTE 2 A cybersecurity breach does not introduce new hazards however it should be seen as a source for initiating hazardous events e.g., cyber is an additional consideration. See also ISO/TR 22100-4.	
c) Unintended behaviour of the operator or reasonably foreseeable misuse of the machine	N/A
Examples include	N/A
- loss of control of the machine by the operator (especially for hand-held or mobile machines),	N/A
- reflex behaviour of a person in case of malfunction, incident or failure during the use of the machine,	N/A
- behaviour resulting from lack of concentration or carelessness,	N/A
- behaviour resulting from taking the “line of least resistance” in carrying out a task,	N/A
- behaviour resulting from pressures to keep the machine running in all circumstances, and	N/A
- behaviour of certain persons (for example, children, disabled persons).	N/A
Note: Examination of the available design documentation can be a useful means of identifying hazards related to the machinery, particularly those associated with moving elements such as motors or hydraulic cylinders.	
5.5 Risk estimation	
5.5.1 General	
After hazard identification, risk estimation shall be carried out for each hazardous situation by determining the elements of risk given in 5.5.2. When determining these elements, it is necessary to take into account the aspects given in 5.5.3.	
5.5.2 Elements of risk	
5.5.2.1 General	
The risk associated with a particular hazardous situation depends on the following elements:	Pass
a) the severity of harm;	Pass
b) the probability of occurrence of that harm, which is a function of	Pass
1) the exposure of person(s) to the hazard,	Pass
2) the occurrence of a hazardous event, and	Pass
3) the technical and human possibilities to avoid or limit the harm.	Pass
The elements of risk are shown in Figure 4 in the standard. Additional details are given in 5.5.2.2, 5.5.2.3 and 5.5.3.	
5.5.2.2 Severity of harm	
The severity can be estimated by taking into account the following:	Pass
a) the severity of injuries or damage to health, for example,	Pass
- slight,	Pass
- serious,	Pass

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- death.	Pass
b) the extent of harm, for example, to	Pass
- one person,	Pass
- several persons due to a single hazardous event.	Pass
When carrying out a risk assessment, the risk from the most severe harm that can realistically occur from each identified hazard, even if the probability of such an occurrence is not high, shall be considered. See ISO/TR 14121-2.	
5.5.2.3 Probability of occurrence of harm	
5.5.2.3.1 Exposure of persons to the hazard	
The exposure of a person to the hazard influences the probability of the occurrence of harm.	
Factors to be taken into account when estimating the exposure are, among others,	N/A
a) the need for access to the hazard zone (e.g. during use, correction of malfunction, maintenance or repair),	Pass
b) the nature of access (e.g., manual feeding of materials),	Pass
c) the time spent in the hazard zone,	Pass
d) the number of persons requiring access, and	Pass
e) the frequency of access.	Pass
5.5.2.3.2 Occurrence of a hazardous event	
The occurrence of a hazardous event influences the probability of occurrence of harm.	
Factors to be taken into account when estimating the occurrence of a hazardous event are, among others,	Pass
a) reliability and other statistical data,	Pass
b) accident history,	Pass
c) history of damage to health, and	Pass
d) comparison of risks (see 5.6.3).	Pass
Note: The occurrence of a hazardous event can be of a technical or human origin.	
5.5.2.4 Possibility of avoiding or limiting harm	
The possibility of avoiding or limiting harm influences the probability of occurrence of harm.	
Factors to be taken into account when estimating the possibility of avoiding or limiting harm are, among others, the following:	Pass
a) different persons who can be exposed to the hazard(s), for example,	Pass
- skilled,	Pass
- unskilled;	Pass
b) how quickly the hazardous situation could lead to harm, for example,	Pass

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- suddenly,	Pass
- quickly,	Pass
- slowly;	Pass
c) any awareness of risk, for example,	Pass
- by general information, in particular, information for use,	Pass
- by direct observation,	Pass
- through warning signs and indicating devices, in particular, on the machinery;	Pass
d) the human ability to avoid or limit harm (for example, reflex, agility, possibility of escape);	Pass
e) practical experience and knowledge, for example,	Pass
- of the machinery,	Pass
- of similar machinery,	Pass
- no experience.	Pass
5.5.3 Aspects to be considered during risk estimation	
5.5.3.1 Persons exposed	
Risk estimation shall take into account all persons (operators and others) for whom exposure to the hazard is reasonably foreseeable.	Pass
5.5.3.2 Type, frequency and duration of exposure	
The estimation of the exposure to the hazard under consideration (including long-term damage to health) requires analysis of, and shall account for, all modes of operation of the machinery and methods of working.	Pass
In particular, the analysis shall account for the needs for access during loading/unloading, setting, teaching, process changeover or correction, cleaning, fault-finding and maintenance.	Pass
The risk estimation shall also take into account tasks, for which it is necessary to suspend risk reduction measures.	Pass
5.5.3.3 Relationship between exposure and effects	
The relationship between an exposure to a hazard and its effects shall be taken into account for each hazardous situation considered.	Pass
The effects of accumulated exposure and combinations of hazards shall also be considered.	Pass
When considering these effects, risk estimation shall, as far as practicable, be based on appropriate recognized data.	Pass
Note 1: Accident data can assist in establishing the probability and severity of injury associated with the use of a particular type of machinery with a particular type of risk reduction measure.	
Note 2: Zero accident data is, however, no guarantee of the low probability and severity of an injury.	
5.5.3.4 Human factors and ergonomics	
Human factors can affect risk and shall be taken into account in the risk estimation, including, for example,	Pass
a) the interaction of person(s) with the machinery, including correction of malfunction,	Pass
b) interaction between persons,	Pass

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c) stress-related aspects,	Pass
d) ergonomic aspects,	Pass
e) the capacity of persons to be aware of risks in a given situation depending on their training, experience and ability,	Pass
f) fatigue aspects, and	Pass
g) aspects of limited abilities (due to disability, age, etc.).	Pass
Training, experience and ability can affect risk; nevertheless, none of these factors shall be used as a substitute for hazard elimination, risk reduction by inherently safe design or safeguarding, wherever these risk reduction measures can be practicably implemented.	
5.5.3.5 Suitability of risk reduction measures	
Risk estimation shall take into account the suitability of risk reduction measures and shall	Pass
a) identify the circumstances which can result in harm,	Pass
b) whenever appropriate, be carried out using quantitative methods to compare alternative risk reduction measures (see ISO/TR 14121-2), and	Pass
c) provide information that can assist with the selection of appropriate risk reduction measures.	Pass
When estimating risk, those components and systems identified as immediately increasing the risk in case of failure need special attention.	Pass
When risk reduction measures include user organization measures, competency requirements or correct behaviour, attention, use of personal protective equipment (PPE), skill or training, the relatively low reliability of such risk reduction measures compared with proven technical risk reduction measures shall be taken into account by the designer in the risk estimation.	Pass
5.5.3.6 Possibility of defeating or circumventing risk reduction measures	
For the continued safe operation of a machine, it is important that the risk reduction measures allow its easy use and do not hinder its intended use. Otherwise, there is a possibility that risk reduction measures might be bypassed in order for maximum utility of the machine to be achieved.	
Risk estimation shall take account of the possibility of defeating or circumventing risk reduction measures.	Pass
It shall also take account of the incentive to defeat or circumvent protective measures when, for example,	Pass
a) the risk reduction measure slows down production or interferes with another activity or preference of the user,	N/A
b) the risk reduction measure is difficult to use,	N/A
c) persons other than the operator are involved, or	N/A
d) the risk reduction measure is not recognized by the user or not accepted as being suitable for its function.	Pass
e) the risk reduction measure prevents a task or operation from being performed.	N/A
Whether or not a risk reduction measure can be defeated depends on both the type of risk reduction measure, such as an adjustable guard or programmable trip device, and its design details.	N/A
Risk reduction measures that use programmable electronic systems introduce additional possibilities of defeat or circumvention if access to safety-related software is not appropriately restricted by design and monitoring methods.	N/A
Risk estimation shall identify where safety-related functions are not separated from other machine functions and shall determine the extent to which access is possible.	Pass
This is particularly important when remote access for diagnostic or process correction purposes is required.	N/A
5.5.3.7 Ability to maintain protective measures	
Risk estimation shall consider whether the risk reduction measures can be maintained in the condition necessary to provide the required level of protection.	Pass

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Note: If the risk reduction measure cannot easily be maintained in correct working order, this can encourage the defeat or circumvention of the protective measure in order to allow continued use of the machinery.		
5.6	**Risk evaluation**	
5.6.1	**General**	
After risk estimation has been completed, risk evaluation shall be carried out to determine if risk reduction is required.		Pass
If risk reduction is required, then appropriate risk reduction measures shall be selected and applied (see Clause 6).		Pass
As shown in Figure 2 in the standard, the adequacy of the risk reduction shall be determined after applying each of the three steps of risk reduction described in Clause 6.		Pass
As part of this iterative process, the designer shall also check whether additional hazards are introduced or other risks increased when new risk reduction measures are applied.		Pass
If additional hazards do occur, they shall be added to the list of identified hazards and appropriate risk reduction measures will be required to address them.		Pass
5.6.2	**Adequate risk reduction**	
Application of the three-step method described in 6.1 is essential in achieving adequate risk reduction. As a result of this process, it shall be assumed that the design will result in a machine that can be used with tolerable risk achieved by adequate risk reduction (see Figures 1 and 2 in the standard).		
Following the application of the three-step method, adequate risk reduction is achieved when		Pass
- all operating conditions and all intervention procedures have been considered,		Pass
- the hazards have been eliminated or risks reduced to a tolerable level,		Pass
- any new hazards introduced by the risk reduction measures have been properly addressed,		Pass
- users are sufficiently informed and warned about the residual risks (see 6.1, step 3),		Pass
- risk reduction measures are compatible with one another,		Pass
- sufficient consideration has been given to the consequences that can arise from the use in a non-professional/non-industrial context of a machine designed for professional/ industrial use, and		Pass
- the risk reduction measures do not adversely affect the operator's working conditions or the usability of the machine.		Pass
5.6.3	**Comparison of risks**	
As part of the process of risk evaluation, the risks associated with the machinery or parts of machinery can be compared with those of similar machinery or parts of machinery, provided the following criteria apply:		Pass
- the similar machinery is in accordance with the relevant type-C standard(s);		Pass
- the intended use, reasonably foreseeable misuse and the way both machines are designed and constructed are comparable;		Pass
- the hazards and the elements of risk are comparable;		Pass
- the technical specifications are comparable;		Pass
- the conditions for use are comparable.		Pass
The use of this comparison method does not eliminate the need to follow the risk assessment process as described in this document for the specific conditions of use. For example, when a band saw used for cutting meat is compared with a band saw used for cutting wood, the risks associated with the different material shall be assessed.		
6	**Risk reduction**	
6.1	**General**	

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The objective of risk reduction can be achieved by the elimination of hazards, or by separately or simultaneously reducing each of the two elements that determine the associated risk:	Pass
- severity of harm from the hazard under consideration;	Pass
- probability of occurrence of that harm.	Pass
All risk reduction measures intended for reaching this objective shall be applied in the following sequence, referred to as the three-step method (see also Figure 2 in the standard).	
Step 1: Inherently safe design	Pass
Inherently safe design eliminates hazards or reduces the associated risks by a suitable choice of design features of the machine itself and/or interaction between the exposed persons and the machine. See 6.2.	Pass
Note: This stage is the only one at which hazards can be eliminated, thus avoiding the need for additional risk reduction measures such as safeguarding or complementary risk reduction measures.	
Step 2: Safeguarding and/or complementary protective measures	Pass
Taking into account the intended use and the reasonably foreseeable misuse, appropriately selected safeguarding and complementary risk reduction measures can be used to reduce risk when it is not practicable to eliminate a hazard, or reduce its associated risk sufficiently, using inherently safe design. See 6.3.	Pass
Step 3: Information for use	Pass
Where risks remain despite inherently safe design, safeguarding and complementary risk reduction measures, the residual risks shall be described in the information for use.	Pass
The information for use shall include, but not be limited to, the following:	Pass
- operating procedures for the use of the machinery consistent with the expected ability of personnel who use the machinery or other persons who can be exposed to the hazards associated with the machinery;	Pass
- recommended safe working practices and related training requirements for the use of the machinery;	Pass
- sufficient information with warnings of residual risks related to the different phases of the life cycle of the machinery;	Pass
- the description of any recommended personal protective equipment, including detail as to its need as well as to training needed for its use.	Pass
Information for use shall not be a substitute for the correct application of inherently safe design, safeguarding or complementary risk reduction measures.	
6.2 **Inherently safe design**	
6.2.1 **General**	
Inherently safe design measures are the first and most important step in the risk reduction process.	
This is because risk reduction measures inherent to the characteristics of the machine are likely to remain effective, whereas experience has shown that even well-designed safeguarding can fail or be defeated and information for use may not be followed.	
Inherently safe design is achieved by avoiding hazards or reducing risks by a suitable choice of design features for the machine itself and/or interaction between the exposed persons and the machine.	
Note: See 6.3 for safeguarding and complementary measures that can be used to achieve the risk reduction objectives in the case where inherently safe design measures are not sufficient (see 6.1 for the three-step method).	
6.2.2 **Consideration of geometrical factors and physical aspects**	
6.2.2.1 **Geometrical factors**	
Such factors include the following.	Pass
a) The form of machinery is designed to maximize direct visibility of the working areas and hazard zones from the operating position — reducing blind spots, for example — so as to take into account the characteristics of human vision, particularly when safe operation requires permanent direct control by the operator, for example:	Pass

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- the travelling and working area of mobile machines;	Pass
- the zone of movement of lifted loads or of the carrier of machinery for lifting persons;	Pass
- the area of contact of the tool of a hand-held or hand-guided machine with the material being worked.	Pass
The design of the machine shall be such that, from the main control position, the operator is able to confirm that there are no exposed persons in the danger zones.	Pass
b) The form and the relative location of the mechanical component's parts: for instance, crushing and shearing hazards are avoided by increasing the minimum gap between the moving parts, such that the part of the body under consideration can enter the gap safely, or by reducing the gap so that no part of the body can enter it (see ISO 13854 and ISO 13857).	Pass
c) Avoiding sharp edges and corners, protruding parts: in so far as their purpose allows, accessible parts of the machinery shall have no sharp edges, no sharp angles, no rough surfaces, no protruding parts likely to cause injury, and no openings which can "trap" parts of the body or clothing. In particular, sheet metal edges shall be deburred, flanged or trimmed, and open ends of tubes which can cause a "trap" shall be capped.	Pass
d) The form of the machine is designed so as to achieve an ergonomic operating position and provide accessible manual controls (actuators).	Pass
6.2.2.2 Physical aspects	
Such aspects include the following:	Pass
a) limiting the actuating force to a sufficiently low value so that the actuated part does not generate a mechanical hazard;	Pass
b) limiting the mass and/or velocity of the movable elements, and hence their kinetic energy;	Pass
c) limiting the emissions by acting on the characteristics of the source using measures for reducing	Pass
1) noise emission at source (see ISO/TR 11688-1),	Pass
2) the emission of vibration at source, such as redistribution or addition of mass and changes of process parameters [for example, frequency and/or amplitude of movements (for hand-held and hand-guided machinery, see CR 1030-1)],	Pass
3) the emission of hazardous substances, including the use of less hazardous substances or dust-reducing processes (granules instead of powders, milling instead of grinding), and	N/A
4) radiation emissions, including, for example,	N/A
I. avoiding the use of hazardous radiation sources,	N/A
II. limiting the power of radiation to the lowest level sufficient for the proper functioning of the machine,	N/A
III. designing the source so that the beam is concentrated on the target, increasing the distance between the source and the operator or providing for remote operation of the machine	N/A
NOTE: Measures for reducing emission of non-ionizing radiation are given in 6.3.4 (see also EN12198-1 and EN 12198-3).	
6.2.3 Taking into account general technical knowledge of machine design	
This general technical knowledge can be derived from technical specifications for design (standards, design codes, calculation rules, etc.), which should be used to cover	Pass
a) mechanical stresses such as	Pass
- stress limitation by implementation of correct calculation, construction and fastening methods as regards, for example, bolted assemblies and welded assemblies,	Pass
- stress limitation by overload prevention (bursting disk, pressure-limiting valves, breakage points, torque-limiting devices, etc.),	Pass
- avoiding fatigue in elements under variable stresses (notably cyclic stresses), and	Pass
- static and dynamic balancing of rotating elements,	N/A
b) materials and their properties such as	Pass

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- resistance to corrosion, ageing, abrasion and wear,	Pass
- hardness, ductility, brittleness,	Pass
- homogeneity,	Pass
- toxicity, and	Pass
- flammability, and	Pass
c) emission values for	Pass
- noise,	Pass
- vibration,	Pass
- hazardous substances, and	Pass
- radiation.	Pass
When the reliability of particular components or assemblies is critical for safety (for example, ropes, chains, lifting accessories for lifting loads or persons), stress limits shall be multiplied by appropriate working coefficients.	Pass
6.2.4 Choice of appropriate technology	
One or more hazards can be eliminated or risks reduced by the choice of the technology to be used in certain applications such as the following:	N/A
a) on machines intended for use in explosive atmospheres, using	N/A
- appropriately selected pneumatic or hydraulic control system and machine actuators,	N/A
- intrinsically safe electrical equipment (see IEC 60079-11);	N/A
b) for particular products to be processed (for example, by a solvent), by using equipment that ensures the temperature will remain far below the flash point;	N/A
c) the use of alternative equipment to avoid high noise levels, such as	N/A
- electrical instead of pneumatic equipment,	N/A
- in certain conditions, water-cutting instead of mechanical equipment.	N/A
6.2.5 Applying principle of positive mechanical action	
Positive mechanical action is achieved when a moving mechanical component inevitably moves another component along with it, either by direct contact or via rigid elements.	Pass
An example of this is positive opening operation of switching devices in an electrical circuit (see IEC 60947-5-1 and ISO 14119).	
NOTE: Where a mechanical component moves and thus allows a second component to move freely (for example, by gravity or spring force), there is no positive mechanical action of the first component on the second.	
6.2.6 Provisions for stability	
Machines shall be designed so that they have sufficient stability to allow them to be used safely in their specified conditions of use.	Pass
Factors to be taken into account include	Pass
- the geometry of the base,	Pass
- the weight distribution, including loading,	Pass

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- the dynamic forces due to movements of parts of the machine, of the machine itself or of elements held by the machine which can result in an overturning moment,	Pass
- vibration,	Pass
- oscillations of the centre of gravity,	Pass
- characteristics of the supporting surface in case of travelling or installation on different sites (ground conditions, slope, etc.), and	Pass
- external forces, such as wind pressure and manual forces.	Pass
Stability shall be considered in all phases of the life cycle of the machine, including handling, travelling, installation, use, dismantling, disabling and scrapping.	Pass
Other risk reduction measures for stability relevant to safeguarding are given in 6.3.	
6.2.7 Provisions for maintainability	
When designing a machine, the following maintainability factors shall be taken into account to enable maintenance of the machine:	N/A
- accessibility, taking into account the environment and the human body measurements, including the dimensions of the working clothes and tools used;	N/A
- ease of handling, taking into account human capabilities;	N/A
- limitation of the number of special tools and equipment.	N/A
6.2.8 Observing ergonomic principles	
Ergonomic principles shall be taken into account in designing machinery so as to reduce the mental or physical stress of, and strain on, the operator.	Pass
These principles shall be considered when allocating functions to operator and machine (degree of automation) in the basic design.	Pass
NOTE 1: Also improved are the performance and reliability of operation and hence the reduction in the probability of errors at all stages of machine use.	
NOTE 2: See ISO/TR 22100-3 for guidance on ergonomics.	
Account shall be taken of body sizes likely to be found in the intended user population, strengths and postures, movement amplitudes, frequency of cyclic actions (see ISO 10075-1 and ISO 10075-2).	Pass
All elements of the operator–machine interface, such as controls, signalling or data display elements, shall be designed to be easily understood so that clear and unambiguous interaction between the operator and the machine is possible. See EN/A 614-1, EN/A 13861 and IEC 61310-1.	Pass
The designer's attention is particularly drawn to following ergonomic aspects of machine design.	Pass
a) Avoid the necessity for stressful postures and movements during the use of the machine (for example, providing facilities to adjust the machine to suit the various operators).	Pass
b) Design machines, especially hand-held and mobile machines, so as to enable them to be operated easily, taking into account human effort, actuation of controls and hand, arm and leg anatomy.	Pass
c) Limit as far as possible noise, vibration and thermal effects such as extreme temperatures.	Pass
d) Avoid linking the operator's working rhythm to an automatic succession of cycles.	N/A
e) Provide local lighting on or in the machine for the illumination of the working area and of adjusting, setting-up and frequent maintenance zones when the design features of the machine and/or its guards render the ambient lighting inadequate.	N/A
Flicker, dazzling, shadows and stroboscopic effects shall be avoided if they can cause a risk.	N/A
If the position or the lighting source has to be adjusted, its location shall be such that it does not cause any risk to persons making the adjustment.	N/A
f) Select, locate and identify manual controls (actuators) so that	Pass

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- they are clearly visible and identifiable, and appropriately marked where necessary (see 6.4.4),	Pass
- they can be safely operated without hesitation or loss of time and without ambiguity (for example, a standard layout of controls reduces the possibility of error when an operator changes from a machine to another one of similar type having the same pattern of operation),	Pass
- their location (for push-buttons) and their movement (for levers and hand wheels) are consistent with their effect (see IEC 61310-3), and	Pass
- their operation cannot cause additional risk. See also ISO 9355-3.	Pass
Where a control is designed and constructed to perform several different actions - namely, where there is no one-to-one correspondence (for example, keyboards) - the action to be performed shall be clearly displayed and subject to confirmation where necessary.	N/A
Controls shall be so arranged that their layout, travel and resistance to operation are compatible with the action to be performed, taking account of ergonomic principles.	Pass
Constraints due to the necessary or foreseeable use of personal protective equipment (such as footwear, gloves) shall be taken into account.	Pass
g) Select, design and locate indicators, dials and visual display units so that	Pass
- they fit within the parameters and characteristics of human perception,	N/A
- information displayed can be detected, identified and interpreted conveniently, i.e., long-lasting, distinct, unambiguous and understandable with respect to the operator's requirements and the intended use, and	Pass
- the operator is able to perceive them from the operating position.	Pass
6.2.9 Electrical hazards	
For the design of the electrical equipment of machines, IEC 60204-1 gives general provisions about disconnection and switching of electrical circuits and for protection against electric shock.	N/A
6.2.10 Pneumatic and hydraulic hazards	
Pneumatic and hydraulic equipment of machinery shall be designed so that	Pass
- the maximum rated pressure cannot be exceeded in the circuits (using, for example, pressure-limiting devices),	Pass
- no hazard results from pressure fluctuations or increases, or from loss of pressure or vacuum,	Pass
- no hazardous fluid jet or sudden hazardous movement of the hose (whiplash) results from leakage or component failures,	Pass
- air receivers, air reservoirs or similar vessels (such as in gas-loaded accumulators) comply with the applicable design standard codes or regulations for these elements,	Pass
- all elements of the equipment, especially pipes and hoses, are protected against harmful external effects,	Pass
- as far as possible, reservoirs and similar vessels (for example, gas-loaded accumulators) are automatically depressurized when isolating the machine from its power supply (see 6.3.5.4) and, if not possible, means are provided for their isolation, local depressurizing and pressure indication (see also ISO 14118:2017, Clause 5), and	Pass
- all elements which remain under pressure after isolation of the machine from its power supply are provided with clearly identified exhaust devices, and there is a warning label drawing attention to the necessity of depressurizing those elements before any setting or maintenance activity on the machine.	Pass
NOTE: See also ISO 4413 and ISO 4414.	
6.2.11 Limiting exposure to hazards through reliability of equipment	
Increased reliability of all component parts of machinery reduces the frequency of incidents requiring intervention, thereby reducing exposure to hazards.	Pass
This applies to power control elements (operative part, see Annex A in the standard) as well as to control systems, and to safety functions as well as to other functions of machinery.	Pass
Safety-related components (for example, certain sensors) of known reliability shall be used.	Pass

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The elements of guards and of protective devices shall be especially reliable, as their failure can expose persons to hazards, and also because poor reliability would encourage attempts to defeat them.		Pass
6.2.12	**Limiting exposure to hazards through mechanization or automation of loading (feeding) / unloading (removal) operations**	
Mechanization and automation of machine loading/unloading operations and, more generally, of handling operations — of workpieces, materials or substances — limits the risk generated by these operations by reducing the exposure of persons to hazards at the operating points.		N/A
Automation can be achieved by, for example, robots, handling devices, transfer mechanisms and pneumatic equipment. Mechanization can be achieved by, for example, feeding slides, push-rods and hand-operated indexing tables.		N/A
While automatic feeding and removal devices have much to offer in preventing accidents to machine operators, they can create danger when any faults are being corrected. Care shall be taken to ensure that the use of these devices does not introduce further hazards, such as trapping or crushing, between the devices and parts of the machine or workpieces/materials being processed. Suitable safeguards (see 6.3) shall be provided if this cannot be ensured.		N/A
Automatic feeding and removal devices with their own control systems and the control system of the associated machine shall be interconnected after thorough study of how all safety functions are performed in all the control and operation modes of the entire equipment.		N/A
6.2.13	**Limiting exposure to hazards through location of setting and maintenance points outside danger zones**	
The need for access to danger zones shall be minimized by locating maintenance, lubrication and setting points outside these zones.		N/A
6.2.14	**Hygiene aspects**	
Machines and equipment used in applications with hygiene and cleanability requirements (e.g., food and pharmaceuticals) shall be designed to allow cleaning and where necessary disinfection.		N/A
NOTE: Guidance for the hygienic design of machinery can be found in ISO 14159, ISO 21469 and EN/A 1672-2.		
6.3	**Safeguarding and complementary risk reduction measures**	
6.3.1	**General**	
Guards and protective devices shall be used to protect persons whenever an inherently safe design does not reasonably make it possible either to remove hazards or to sufficiently reduce risks.		N/A
Complementary risk reduction measures involving additional equipment (for example, emergency stop equipment) may have to be implemented.		N/A
NOTE: The different kinds of guards and protective devices are defined in 3.27 and 3.28.		
Certain safeguards may be used to avoid exposure to more than one hazard.		
Example: A fixed guard preventing access to a zone where a mechanical hazard is present used to reduce noise levels and collect toxic emissions.		
6.3.2	**Selection and implementation of guards and protective devices**	
This subclause gives guidelines for the selection and the implementation of guards and protective devices (see Figure 5 in the standard) the primary purpose of which is to protect persons against different types of hazards according to the nature of those hazards and to the need for access to the danger zone(s).		N/A
The exact choice of a safeguard for a particular machine shall be made on the basis of the risk assessment for that machine.		N/A
For the selection of adequate safeguarding and complementary risk reduction measures the following aspect should be considered:		N/A
- Possibility of defeating or circumventing risk reduction measures (see 5.5.3.6)		N/A
- Ability to maintain risk reduction measures (see 5.5.3.7)		N/A
In selecting an appropriate safeguard for a particular type of machinery or hazard zone, it shall be borne in mind that a fixed guard is simple and shall be used where the access of an operator into a danger zone is not required during the intended operation of the machinery.		N/A
As the need for frequency of access increases, this inevitably leads to the fixed guard not being replaced. This requires the use of an alternative protective measure (movable interlocking guard, sensitive protective equipment).		N/A

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A combination of safeguards can sometimes be required. For example, where, in conjunction with a fixed guard or impeding device, a mechanical loading (feeding) device is used to feed a workpiece into a machine, thereby removing the need for access to the primary hazard zone, a trip device can be required to protect against the secondary drawing-in or shearing hazard between the mechanical loading (feeding) device, when reachable, and the fixed guard.		
Consideration shall be given to the enclosure of operating positions or intervention zones to provide combined protection against several hazards including		N/A
a)	hazards from falling or ejected objects, using, for example, protection in the form of a falling object protection structure (FOPS),	N/A
b)	emission hazards (protection against noise, vibration, radiation, substances hazardous to health, etc.),	N/A
c)	hazards due to the environment (protection against heat, cold, foul weather, etc.),	N/A
d)	hazards due to tipping over or rolling over of machinery, using, for example, protection in the form of roll-over or tip-over protection structures (ROPS and TOPS).	N/A
The design of enclosed operating positions, such as cabs and cabins, shall take into account ergonomics principles concerning visibility, lighting, atmospheric conditions, access, posture.		N/A
Additional requirements may apply. See ISO 14120:2015, 6.4.		
6.3.3	**Requirements for design of guards and protective devices**	
6.3.3.1	**General requirements**	
Guards and protective devices shall be designed to be suitable for the intended use, taking into account mechanical and other hazards involved.		N/A
Guards and protective devices shall be compatible with the working environment of the machine and designed so that they cannot be easily defeated.		N/A
They shall provide the minimum possible interference with activities during operation and other phases of machine life, in order to reduce any incentive to defeat them.		N/A
NOTE: For additional information, see ISO 14120, ISO 13849-1, ISO 13851, ISO 14119, ISO 13856, IEC 61496 and IEC 62061.		
Guards and protective devices shall		N/A
a)	be of robust construction,	N/A
b)	not give rise to any additional hazard,	N/A
c)	not be easy to bypass or render non-operational,	N/A
d)	be located at an adequate distance from the danger zone (see ISO 13855 and ISO 13857),	N/A
e)	cause minimum obstruction to the view of the production process, and	N/A
f)	enable essential work to be carried out for the installation and/or replacement of tools and for maintenance by allowing access only to the area where the work has to be carried out — if possible, without the guard having to be removed or protective device having to be disabled.	N/A
For openings in the guards, see ISO 13857.		
6.3.3.2	**Requirements for guards**	
6.3.3.2.1	**Functions of guards**	
The functions that guards can achieve are		N/A
-	prevention of access to the space enclosed by the guard, and/or	N/A
-	containment/capture of materials, workpieces, chips, liquids which can be ejected or dropped by the machine, and reduction of emissions (noise, radiation, hazardous substances such as dust, fumes, gases) that can be generated by the machine.	N/A

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Additionally, they could need to have particular properties relating to electricity, temperature, fire, explosion, vibration, visibility (see ISO 14120) and operator position ergonomics (for example, usability, operator's movements, postures, repetitive movements).	N/A
6.3.3.2.2 Fixed guards	
Fixed guards shall be securely held in place either	N/A
- permanently (for example by welding), or	N/A
- by means of fasteners (screws, nuts) making removal/opening impossible without using tools; they should not remain closed without their fasteners (see ISO 14120).	N/A
NOTE: A fixed guard can be hinged to assist in its opening.	
6.3.3.2.3 Movable guards	
Movable guards shall be designed and associated with the machine control system so that	N/A
- moving parts cannot start up while they are within the operator's reach and the operator cannot reach moving parts once they have started up, with this able to be achieved by interlocking guards, with guard locking when necessary,	N/A
- they can be adjusted only by an intentional action, such as the use of a tool or a key, and	N/A
- he absence or failure of one of their components either prevents starting of the moving parts or stops them, with this able to be achieved by automatic monitoring (see 6.3.5.13).	N/A
Movable guards protecting persons from hazards generated by moving transmission parts shall	N/A
- as far as possible when open remain fixed to the machinery or other structure (generally by means of hinges or guides), and	N/A
- be interlocking (with guard locking when necessary).	N/A
See Figure 5 in the standard and ISO 14119.	
6.3.3.2.4 Adjustable guards	
Adjustable guards may only be used where the hazard zone cannot for operational reasons be completely enclosed.	N/A
Manually adjustable guards shall be	N/A
- designed so that the adjustment remains fixed during a given operation, and	N/A
- readily adjustable without the use of tools.	N/A
Automatically adjustable guards shall be	N/A
- designed and constructed so that the gap between the guard and the material is always limited to the minimum that is necessary for the work, and	N/A
- as far as practicable designed to prevent the automatic adjustment being defeated.	N/A
6.3.3.2.5 Requirements for interlocking guards with a start function (control guards)	
An interlocking guard with a start function may only be used provided that	N/A
a) all requirements for interlocking guards are satisfied (see ISO 14119),	N/A
b) the cycle time of the machine is short,	N/A
c) the maximum opening time of the guard is preset to a low value (for example, equal to the cycle time) and, when this time is exceeded, the hazardous function(s) cannot be initiated by the closing of the interlocking guard with a start function and resetting is necessary before restarting the machine,	N/A

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d)	the dimensions or shape of the machine do not allow a person, or part of a person, to stay in the hazard zone or between the hazard zone and the guard while the guard is closed (see ISO 14120),	N/A
e)	all other guards, whether fixed (removable type) or movable, are interlocking guards,	N/A
f)	the interlocking device associated with the interlocking guard with a start function is designed such that — for example, by duplication of position detectors and use of automatic monitoring (see 6.3.5.13) — its failure cannot lead to an unintended/unexpected start-up, and	N/A
g)	the guard is securely held open (for example, by a spring or counterweight) such that it cannot initiate a start while falling by its own weight.	N/A
6.3.3.2.6	**Hazards from guards**	
Care shall be taken to prevent hazards which could be generated by		N/A
-	the guard construction (sharp edges or corners, material, noise emission, etc.),	N/A
-	the movements of the guards (shearing or crushing zones generated by power-operated guards and by heavy guards which are liable to fall).	N/A
6.3.3.3	**Technical characteristics of protective devices**	
Protective devices shall be selected or designed and connected to the control system such that correct implementation of their safety function(s) is ensured.		N/A
Protective devices shall be selected on the basis of their having met the appropriate product standard (for example, IEC 61496-2 for active optoelectronic protective devices)		N/A
Protective devices shall be installed and connected to the control system so that they cannot be easily defeated.		N/A
6.3.3.4	**Provisions for alternative types of safeguards**	
Provisions should be made to facilitate the fitting of alternative types of safeguards on machinery where it is known that it will be necessary to change the safeguards because of the range of work to be carried out.		N/A
6.3.4	**Safeguarding to reduce emissions**	
If the measures for the reduction of emissions at source specified in 6.2.2.2 are not adequate, the machine shall be provided with additional risk reduction measures.		Pass
NOTE: Emission values for existing machinery or prototypes can be used to determine emission values of similar machines.		
This makes it possible for the designer to		Pass
-	estimate the risk associated with the emissions,	Pass
-	evaluate the effectiveness of the risk reduction measures implemented at the design stage,	Pass
-	provide potential buyers with quantitative information on emissions in the technical documentation, and	Pass
-	provide users with quantitative information on emissions in the information for use.	Pass
Hazards other than emissions that are described by measurable parameters can be dealt with in a similar manner. For noise comparison see ISO 11689.		
6.3.5	**Design of control systems**	
6.3.5.1	**General**	
The correct design of machine control systems should avoid unforeseen and potentially hazardous machine behaviour.		
Typical causes of hazardous machine behaviour are		Pass
-	an unsuitable design or modification (accidental or deliberate) of the control system logic,	Pass

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- a temporary or permanent defect or failure of one or several components of the control system,	Pass
- a variation or a failure in the power supply of the control system, and	Pass
- inappropriate selection, design and location of the control devices.	Pass
- systematic dangerous failures in software.	N/A
- signal or data insertion, deletion, repetition, or resequencing at interfaces.	N/A
- signal or data corruption.	N/A
- loss of automatic monitoring/diagnostics.	N/A
- unintended self-evolving behaviour of AI (e.g., false negative, false positive and erratic correlations).	N/A
- unintended behaviour of AI.	N/A
- systematic failures at the AI/human interface.	N/A
Typical examples of hazardous machine behaviour are	N/A
- unexpected start-up (see ISO 14118),	N/A
- uncontrolled speed change,	N/A
- failure to stop moving parts,	N/A
- dropping or ejection of part of the machine or of a workpiece clamped by the machine, and	N/A
- machine action resulting from inhibition (defeating or failure) of protective devices.	N/A
Typical examples of hazardous events	N/A
- movement beyond limits/restrictions/domain.	N/A
- inhibition of protective devices/functions.	N/A
- Inhibition of or missing protective measures	N/A
The design measures of the control system for safety functions shall be chosen so that their safety-related performance provides a sufficient amount of risk reduction. For corresponding design methodologies see ISO 13849-1 and IEC 62061.	N/A
NOTE: See also Annex D for how this document and ISO 13849-1 can be applied.	
Control systems shall be designed to enable the operator to interact with the machine safely and easily.	Pass
This requires one or several of the following solutions:	N/A
- systematic analysis of start and stop conditions;	N/A
- provision for specific operating modes (for example, start-up after normal stop, restart after cycle interruption or after emergency stop, removal of the workpieces contained in the machine, operation of a part of the machine in case of a failure of a machine element);	N/A
- clear display of the faults;	N/A
- measures to prevent accidental generation of unexpected start commands (for example, shrouded start device) likely to cause dangerous machine behaviour (see ISO 14118:2017, Figure 1);	N/A
- maintained stop commands (for example, interlock) to prevent restarting that could result in dangerous machine behaviour (see ISO 14118:2017, Figure 1).	N/A

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An assembly of machines may be divided into several zones for emergency stopping, for stopping as a result of protective devices and/or for isolation and energy dissipation.	N/A
The different zones shall be clearly defined and it shall be obvious which parts of the machine belong to which zone.	N/A
Likewise, it shall be obvious which control devices (for example, emergency stop devices, supply disconnecting devices) and/or protective devices belong to which zone.	N/A
The interfaces between zones shall be designed such that no function in one zone creates hazards in another zone which has been stopped for an intervention (see ISO 11161).	N/A
Control systems shall be designed to limit the movements of parts of the machinery, the machine itself, or workpieces and/or loads held by the machinery, and to the safe design parameters (for example, range, speed, acceleration, deceleration, load capacity). Allowance shall be made for dynamic effects (swinging of loads, etc.).	N/A
For example:	N/A
- the travelling speed of mobile pedestrian-controlled machinery other than remote-controlled shall be compatible with walking speed;	N/A
- the range, speed, acceleration and deceleration of movements of the person-carrier and carrying vehicle for lifting persons shall be limited to non-hazardous values, taking into account the total reaction time of the operator and the machine;	N/A
- the range of movements of parts of machinery for lifting loads shall be kept within specified limits.	N/A
When the machinery contains various elements that can be operated independently, the control system shall be designed to prevent risks arising out of a lack of coordination (for example, collision prevention system).	N/A
6.3.5.2 Starting of an internal power source or switching on an external power supply	
The starting of an internal power source or switching-on of an external power supply shall not result in a hazardous situation.	Pass
For example:	N/A
- starting the internal combustion engine shall not lead to movement of a mobile machine;	N/A
- connection to mains electricity supply shall not result in the starting of working parts of a machine. See IEC 60204-1:2021, 7.5 (see also Annexes A and B in the standard). *Comment: Power souce = connection to airline*	Pass
6.3.5.3 Starting or stopping of a mechanism	
The primary action for starting or accelerating the movement of a mechanism should be performed by the application or an increase of voltage or fluid pressure, or — if binary logic elements are considered — by passage from state 0 to state 1 (where state 1 represents the highest energy state).	Pass
The primary action for stopping or slowing down should be performed by removal or reduction of voltage or fluid pressure, or — if binary logic elements are considered — by passage from state 1 to state 0 (where state 1 represents the highest energy state).	Pass
In certain applications, where this principle cannot be followed, other measures should be applied to achieve the same level of confidence for the stopping or slowing down.	N/A
6.3.5.4 Restart after power interruption	
If a hazard could be generated, the spontaneous restart of a machine when it is re-energized after power interruption shall be prevented (for example, by use of a self-maintained relay, contactor or valve).	Pass
6.3.5.5 Interruption of power supply	
Machinery shall be designed to prevent hazardous situations resulting from interruption or excessive fluctuation of the power supply.	Pass
At least the following requirements shall be met:	Pass
- the stopping function of the machinery shall remain;	Pass
- all devices whose permanent operation is required for safety shall operate in an effective way to maintain safety (for example, locking, clamping devices, cooling or heating devices, power-assisted steering of self-propelled mobile machinery);	N/A

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-	parts of machinery or workpieces and/or loads held by machinery which are liable to move as a result of potential energy shall be restrained or allowed to be safely lowered.	Pass
6.3.5.6	**Failure of the power supply or communication network connection**	
The interruption, the re-establishment after an interruption or the fluctuation in whatever manner of the power supply or communication network connection to the machinery shall not lead to hazardous situations.		Pass
6.3.5.7	**Safety functions implemented by programmable electronic control systems**	
6.3.5.7.1	**General**	
Where a programmable electronic control system is used to implement safety functions at machinery, it is necessary to consider its performance requirements in relation to the requirements for the safety functions.		N/A
The design of the programmable electronic control system shall be such that the probability of random hardware failures and the likelihood of systematic failures that can adversely affect the performance of the safety-related control function(s) is sufficiently low.		N/A
Where a programmable electronic control system performs a monitoring function, the system behaviour on detection of a fault shall be considered.		N/A
NOTE: Both, ISO 13849-1 and IEC 62061, specific to machinery safety, provide guidance applicable to programmable electronic control systems.		
The programmable electronic control system shall be designed and verified to ensure that the specified performance [for example, performance level (PL) in ISO 13849-1 or safety integrity level (SIL) in IEC 62061] for each safety function has been achieved.		N/A
The programmable electronic control system shall be validated. Validation shows that all parts interact correctly to perform the safety function and that unintended functions do not occur.		N/A
6.3.5.7.2	**Hardware aspects**	
The hardware (including, for example, sensors, actuators and logic solvers) shall be selected, and/or designed and installed, to meet both the functional and performance requirements of the safety function(s) to be performed, in particular, by means of		N/A
-	architectural constraints (the configuration of the system, its ability to tolerate faults, its behaviour on detection of a fault, cybersecurity, etc.),	N/A
-	selection, and/or design, of equipment and devices with an appropriate low probability of dangerous random hardware failure, and	N/A
-	the incorporation of measures and techniques within the hardware so as to avoid systematic failures and control systematic faults.	N/A
6.3.5.7.3	**Software aspects**	
The safety-related software, including embedded software and application software, shall be designed to satisfy the performance specification for the safety functions (see also ISO 13849-1, IEC 62061 and IEC 61508-3).		N/A
The following software aspects shall be considered:		N/A
a)	whether application software should not be reprogrammable by the user;	N/A
b)	whether protection against unauthorized safety-related software changes should be focused on possible impact on the integrity of safety function(s), e.g. due to	N/A
-	changes of safety-related parameters	N/A
-	or any corruption of data or information of a network, control system, and information system.	N/A
Measures to protect against unauthorized software changes shall be implemented according to ISO 13849-1, IEC 62061 or IEC 61508-3.		N/A
6.3.5.8	**Minimizing probability of failure of safety functions**	
6.3.5.8.1	**General**	
Safety of machinery is not only dependent on the reliability of the control systems but also on the reliability of all parts of the machine.		Pass

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The continued operation of the safety functions is essential for the safe use of the machine. This can be achieved by the measures given in 6.3.5.8.2 to 6.3.5.8.4.		Pass
6.3.5.8.2	**Use of reliable components**	
"Reliable components" means components which are capable of withstanding all disturbances and stresses associated with the usage of the equipment in the conditions of intended use (including the environmental conditions), for the period of time or the number of operations fixed for the use, with a low probability of failures generating a hazardous malfunctioning of the machine. Components shall be selected taking into account all factors mentioned above (see also 6.2.11).		Pass
NOTE 1: "Reliable components" is not a synonym for "well-tried components" (see ISO 13849-1:2023, 6.1.11).		
NOTE 2: Environmental conditions for consideration include impact, vibration, cold, heat, moisture, dust, corrosive and/or abrasive substances, static electricity and magnetic and electric fields. Disturbances which can be generated by those conditions include insulation failures and temporary or permanent failures in the function of control system components.		
6.3.5.8.3	**Use of "oriented failure mode" components**	
"Oriented failure mode" components or systems are those in which the predominant failure mode is known in advance and which can be used so that the effect of such a failure on the machine function can be predicted.		Pass
NOTE: In some cases, it will be necessary to take additional measures to limit the negative effects of such a failure.		
The use of such components should always be considered, particularly in cases where redundancy (see 6.3.5.8.4) is not employed.		Pass
6.3.5.8.4	**Duplication (or redundancy) of components or subsystems**	
In the design of safety-related parts of the machine, duplication (or redundancy) of components may be used so that, if one component fails, another component or components continue to perform the respective function(s), thereby ensuring that the safety function remains available.		N/A
In order to allow the proper action to be initiated, component failure shall be detected by automatic monitoring (see 6.3.5.13) or in some circumstances by regular inspection, provided that the inspection interval is shorter than the expected lifetime of the components.		N/A
Diversity of design and/or technology can be used to avoid common cause failures (for example, from electromagnetic disturbance) or common mode failures.		N/A
6.3.5.9	**Selection of control and operating modes**	
If machinery has been designed and built to allow for its use in several control or operating modes requiring different risk reduction measures and/or work procedures (for example, to allow for adjustment, setting, maintenance, inspection), it shall be fitted with a mode selector which can be locked in each position.		N/A
Each position of the selector shall be clearly identifiable and shall exclusively allow one control or operating mode.		N/A
The selector may be replaced by another selection means which restricts the use of certain functions of the machinery to certain categories of operators (for example, access codes for certain numerically controlled functions).		N/A
NOTE: Adequate risk reduction measures associated with each of the operating modes and intervention procedures reduce the possibility of operators being induced to use hazardous intervention techniques in case of technical difficulties.		N/A
6.3.5.10	**Principles relating to manual control**	
These are as follows.		Pass
a)	Manual control devices shall be designed and located according to the relevant ergonomics principles given in 6.2.8, item f).	Pass
b)	A stop control device shall be placed near each start control device. Where the start/stop function is performed by means of a hold-to-run control, a separate stop control device shall be provided when a risk can result from the hold-to-run control device failing to deliver a stop command when released.	Pass
c)	Manual controls shall be located out of reach of the danger zones (see IEC 61310-3), except for certain controls where, of necessity, they are located within a danger zone, such as emergency stop or teach pendant.	Pass
d)	Whenever possible, control devices and operating positions shall be located so that the operator is able to observe the working area or hazard zone.	Pass

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1) The driver of a ride-on mobile machine shall be able to actuate all control devices required to operate the machine from the driving position, except for functions which can be controlled more safely from other positions.	N/A
2) On machinery intended for lifting persons, controls for lifting and lowering and, if appropriate, for moving the carrier shall generally be located in the carrier. If safe operation requires controls to be situated outside the carrier, the operator in the carrier shall be provided with the means of preventing hazardous movements.	N/A
e) If it is possible to start the same hazardous machine parts by means of several controls, the control circuit shall be so arranged that only one control is effective at a given time. This applies especially to machines which can be manually controlled by means of, among others, a portable control unit (such as a teach pendant), with which the operator can enter danger zones.	N/A
f) Control actuators shall be designed or guarded so that their effect, where a risk is involved, cannot occur without intentional operation (see ISO 9355-1, ISO 9355-3 and ISO 447).	Pass
g) For machine functions whose safe operation depends on permanent, direct control by the operator, measures shall be implemented to ensure the presence of the operator at the operating position (for example, by the design and location of control devices).	Pass
h) For cableless control, an automatic stop shall be performed when correct control signals are not received, including loss of communication (see IEC 60204-1).	N/A
6.3.5.11 Control mode for setting, teaching, process changeover, fault-finding, cleaning or maintenance	
Where, for setting, teaching, process changeover, fault-finding, cleaning or maintenance of machinery, a guard has to be displaced or removed, and/or a protective device has to be disabled, and where it is necessary for the purpose of these operations for the machinery or part of the machinery to be put into operation, the safety of the operator shall be achieved using a specific control mode which simultaneously	N/A
a) disables all other control modes,	N/A
b) permits operation of the hazardous machine parts only by continuous actuation of a control device (e.g., enabling device, two-hand control device, hold-to-run control device),	N/A
c) permits operation of the hazardous machine parts only in reduced risk conditions (for example, reduced speed, reduced power/force, step-by-step with a limited movement control device), portable control unit (remote controller or teach pendant) and/or	N/A
d) prevents any operation of hazardous functions by voluntary or involuntary action on the machine's sensors.	N/A
NOTE: For some special machinery other risk reduction measures can be appropriate.	
This control mode shall be associated with one or more of the following measures:	N/A
- restriction of access to the danger zone as far as possible;	N/A
- emergency stop control within immediate reach of the operator;	N/A
- portable control unit (teach pendant) and/or local controls (allowing sight of the controlled machine parts). See IEC 60204-1.	N/A
6.3.5.12 Applying measures to achieve electromagnetic compatibility (EMC)	
For guidance on electromagnetic compatibility, see IEC 60204-1 and IEC 61000-6.	N/A
6.3.5.13 Use of automatic monitoring	
Automatic monitoring is intended to ensure that a safety function or functions implemented by a risk reduction measure do not fail to be performed if the ability of a component or an element to perform its function is diminished, or if the process conditions are changed such that hazards are generated.	N/A
Automatic monitoring either detects a fault immediately or carries out periodic checks so that a fault is detected before the next demand upon the safety function. In either case, the safety function can be initiated immediately or delayed until a specific event occurs (for example, the beginning of the machine cycle).	N/A
The safety function may be, for example,	N/A
- the stopping of the hazardous process,	N/A
- preventing the restart of this process after the first stop following the failure, or	N/A
- the triggering of an alarm.	N/A

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6.3.5.14	**Provision of diagnostic systems to aid fault-finding**	
Diagnostic systems to aid fault-finding should be included in the control system so that there is no need to disable any risk reduction measure.		N/A
NOTE: Such systems not only improve availability and maintainability of machinery, they also reduce the exposure of maintenance staff to hazards.		
6.3.5.15	**Cybersecurity and protection against corruption**	
Risk reduction measures to support cybersecurity and protection against corruption shall be implemented.		N/A
Measures shall be applied as layers of protection e.g.,		N/A
-	means to prevent unauthorized access to hardware, software, application software and related configuration data,	N/A
-	preventing accidental or unintended changes,	N/A
-	air gapping,	N/A
-	locking access to ports,	N/A
-	control of remote access.	N/A
NOTE: For information and requirements about cybersecurity see prEN 50742		N/A
6.3.6	**Complementary risk reduction measures**	
6.3.6.1	**General**	
Risk reduction measures which are neither inherently safe design, nor safeguarding (implementation of guards and/or protective devices), nor information for use, could have to be implemented as required by the intended use and the reasonably foreseeable misuse of the machine. Such measures include, but are not limited to, those dealt with in 6.3.5.2 to 6.3.5.6.		
6.3.6.2	**Components and elements to achieve emergency stop function**	
If, following a risk assessment, a machine needs to be fitted with components and elements to achieve an emergency stop function for enabling actual or impending emergency situations to be averted, the following requirements apply:		N/A
-	the actuators shall be clearly identifiable, clearly visible and readily accessible;	N/A
-	the hazardous process shall be stopped as quickly as possible without creating additional hazards, but if this is not possible or the risk cannot be reduced, it should be questioned whether implementation of an emergency stop function is the best solution;	N/A
-	the emergency stop control shall trigger or permit the triggering of certain safeguard movements where necessary.	N/A
NOTE: For more detailed provisions see ISO 13850.		
Once active operation of the emergency stop device that has initiated an emergency stop command has ceased this command shall be sustained until it is reset. This reset shall be possible only at the location where the emergency stop command has been initiated. The reset of the device shall not restart the machinery, but shall only permit restarting.		N/A
6.3.6.3	**Measures for the escape and rescue of trapped persons**	
Measures for the escape and rescue of trapped persons may consist, among others, of		N/A
-	sufficiently dimensioned escape and rescue routes and shelters in installations generating operator trapping hazards,	N/A
-	arrangements for moving some elements by hand, after an emergency stop,	N/A
-	arrangements for reversing the movement of some elements,	N/A
-	anchorage points for descender devices,	N/A

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- means of communication to enable trapped operators to call for help.	N/A
6.3.6.4 Measures for isolation and energy dissipation	
Machines shall be equipped with the technical means to achieve isolation from power supply(ies) and dissipation of stored energy by means of the following actions:	Pass
a) isolating (disconnecting, separating) the machine (or defined parts of the machine) from all power supplies;	Pass
b) locking (or otherwise securing) all the isolating units in the isolating position;	N/A
c) dissipating or, if this is not possible or practicable, restraining (containing) any stored energy which can give rise to a hazard;	N/A
d) confirming, by means of safe working procedures, that the actions taken according to a), b) and c) above have produced the desired effect.	N/A
See ISO 14118:2017, Clause 5, and IEC 60204-1:2021, 5.5 and 5.6.	
6.3.6.5 Provisions for easy and safe handling of machines and their heavy component parts	
Machines and their component parts which cannot be moved or transported by hand shall be provided or be capable of being provided with suitable attachment devices for transport by means of lifting gear.	N/A
These attachments may be, among others,	N/A
- standardized lifting appliances with slings, hooks, eyebolts, or tapped holes for appliance fixing,	N/A
- appliances for automatic grabbing with a lifting hook when attachment is not possible from the ground,	N/A
- fork locating devices for machines to be transported by a lift truck,	N/A
- lifting and stowing gear and appliances integrated into the machine.	N/A
Parts of machinery which can be removed manually in operation shall be provided with means for their safe removal and replacement.	N/A
See also 6.4.4 c), item 3).	
6.3.6.6 Measures for safe access to machinery	
Machinery shall be so designed as to enable operation and all routine tasks relating to setting and/or maintenance to be carried out as far as possible by a person remaining at ground level.	Pass
Where this is not possible, machines shall have built-in platforms, stairs or other facilities to provide safe access for those tasks; however, care should be taken to ensure that such platforms or stairs do not give access to danger zones of machinery.	N/A
The walking areas shall be made from materials which remain as slip resistant as practicable under working conditions and, depending on the height from the ground, shall be provided with suitable guard-rails (see ISO 14122-3).	N/A
In large automated installations, particular attention shall be given to safe means of access, such as walkways, conveyor bridges or crossover points.	N/A
Means of access to parts of machinery located at height shall be provided with collective means of protection against falls (for example, guard-rails for stairways, stepladders and platforms and/or safety cages for ladders). As necessary, anchorage points for personal protective equipment against falls from height shall also be provided (for example, in carriers of machinery for lifting persons or with elevating control stations).	N/A
Openings shall, whenever possible, open towards a safe position. They shall be designed to prevent hazards due to unintended opening.	N/A
The necessary aids for access shall be provided (steps, handholds, etc.). Control devices shall be designed and located to prevent their being used as aids for access.	N/A
When machinery for lifting goods and/or persons includes landings at fixed levels, these shall be equipped with interlocking guards for preventing falls when the platform is not present at a level. Movement of the lifting platform shall be prevented while the guards are open.	N/A
For detailed provisions see the ISO 14122 series.	

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6.4	**Information for use**	
6.4.1	**General requirements**	
6.4.1.1		
Drafting information for use is an integral part of the design of a machine (see Figure 2 in the standard).		
Information for use consists of communication links, such as texts, words, signs, signals, symbols or diagrams, used separately or in combination to convey information to the user.		Pass
Information for use is intended for professional and/or non-professional users.		Pass
When drafting user information, considerable care shall be taken to provide adequate information quality.		Pass
NOTE 1: See ISO 20607 for drafting safety relevant parts of an instruction handbook.		
NOTE 2: See also IEC/IEEE 82079-1 for structuring and presentation of information for use..		
6.4.1.2		
Information shall be provided to the user about the intended use of the machine, taking into account, notably, all its operating modes.		Pass
The information shall contain all directions required to ensure safe and correct use of the machine.		Pass
With this in view, it shall inform and warn the user about residual risk.		Pass
The information shall indicate, as appropriate,		Pass
-	the need for training,	Pass
-	the need for personal protective equipment, and	Pass
-	the possible need for additional guards or protective devices (see Figure 3, Footnote d in the standard).	N/A
It shall include uses of the machine that can reasonably be expected from its designation and description and shall also warn about the risk which would result from using the machine in other ways than the ones described in the information, especially considering its reasonably foreseeable misuse.		Pass
6.4.1.3		
Information for use shall cover, separately or in combination:		Pass
1.	transport,	N/A
2.	assembly and installation,	N/A
3.	commissioning,	N/A
4.	use of the machine:	Pass
-	setting,	N/A
-	teaching/programming or process changeover,	N/A
-	operation,	Pass
-	cleaning,	Pass
-	fault-finding and	N/A

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- maintenance *Comment: Wipe clean and visual inspection only.*	N/A
and, if necessary,	N/A
- dismantling,	N/A
- disabling and	N/A
- scrapping.	N/A
6.4.2 Location and nature of information for use	
Depending on the risk, the time when the information is needed by the user and the machine design, it shall be decided whether the information - or parts thereof - are to be given	Pass
a) in/on the machine itself (see 6.4.3 and 6.4.4),	Pass
b) in accompanying documents or electronic forms (in particular instruction handbook, see 6.4.5),	Pass
c) on the packaging,	Pass
d) by other means such as signals and warnings outside the machine.	Pass
Standardized phrases shall be considered where important messages such as warnings are given.	Pass
6.4.3 Signals and warning devices	
Visual signals, such as flashing lights and audible signals such as sirens may be used to warn of an impending hazardous event such as machine start-up or overspeed. Such signals may also be used to warn the operator before the triggering of automatic risk reduction measures.	N/A
It is essential that these signals	N/A
a) be emitted before the occurrence of the hazardous event,	N/A
b) be unambiguous,	N/A
c) be clearly perceived and differentiated from all other signals used, and	N/A
d) be clearly recognized by the operator and other persons.	N/A
The warning devices shall be designed and located such that checking is easy.	N/A
The information for use shall prescribe regular checking of warning devices.	N/A
The attention of designers is drawn to the possibility of “sensorial saturation”, which can result from too many visual and/or acoustic signals and which can also lead to defeating the warning devices.	N/A
NOTE: Consultation of the user on this subject is often necessary.	
6.4.4 Markings, signs (pictograms) and written warnings	
Machinery shall bear all markings which are necessary	Pass
a) for its unambiguous identification, including at least	Pass
1. the name and address of the manufacturer, *Comment: Manufacturer detailed in instruction manual*	N/A
2. the designation of series or type, and	Pass

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3. the serial number, if any,	Pass
b) in order to indicate its compliance with mandatory requirements, comprising	Pass
1) marking, and	Pass
2) written indications, such as	Pass
- the authorized representative of the manufacturer,	Pass
- designation of the machinery,	Pass
- year of construction, and	Pass
- intended use in potentially explosive atmospheres	N/A
c) for its safe use, for example,	N/A
1) maximum speed of rotating parts,	N/A
2) maximum diameter of tools,	N/A
3) mass (in kilograms) of the machine itself and/or of removable parts, *Comment: Included in instructions*	N/A
4) maximum working load,	Pass
5) necessity of wearing personal protective equipment, *Comment: Included in instructions*	N/A
6) guard adjustment data, and	N/A
7) frequency of inspection. *Comment: Included in instructions*	N/A
Information printed directly on the machine should be permanent and remain legible throughout the expected life of the machine.	Pass
Signs or written warnings indicating only “Danger” shall not be used.	N/A
Markings, signs and written warnings shall be readily understandable and unambiguous, especially as regards the part of the function(s) of the machine to which they are related.	Pass
Readily understandable signs (pictograms) should be used in preference to written warnings.	Pass
Written warnings shall be drawn up in the language(s) of the country in which the machine will be used for the first time and, on request, in the language(s) understood by operators.	Pass
NOTE: In some countries the use of specific language(s) is covered by legal requirements.	
Markings shall comply with recognized standards (for example, ISO 2972 or ISO 7000, for pictograms, symbols and colours in particular).	Pass
See IEC 60204-1 as regards marking of electrical equipment.	N/A
See ISO 4413 and ISO 4414 for hydraulic and pneumatic equipment. *Comment: ISO 4414*	Pass
6.4.5 Accompanying documents (in particular — instruction handbook)	
6.4.5.1 Contents	
The instruction handbook or other written instructions (for example, on the packaging) shall meet the requirements of ISO 20607, and shall contain, among others, the following:	Pass

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a)	information relating to transport, handling and storage of the machine, such as	Pass
1)	storage conditions for the machine,	Pass
2)	dimensions, mass value(s), position of the centre(s) of gravity, and	Pass
3)	indications for handling (for example, drawings indicating application points for lifting equipment);	Pass
b)	information relating to installation and commissioning of the machine, such as	Pass
1)	fixing/anchoring and dampening of noise and vibration requirements,	N/A
2)	assembly and mounting conditions,	N/A
3)	space needed for use and maintenance,	N/A
4)	permissible environmental conditions (for example, temperature, moisture, vibration, electromagnetic radiation),	Pass
5)	instructions for connecting the machine to power supply (particularly on protection against electrical overloading),	Pass
6)	advice on waste removal/disposal, and	N/A
7)	if necessary, recommendations related to risk reduction measures which have to be implemented by the user — for example, additional safeguards (see Figure 3, Footnote d of the standard), safety distances, safety signs and signals;	N/A
c)	information relating to the machine itself, such as	Pass
1)	detailed description of the machine, its fittings, guards and/or protective devices,	Pass
2)	the comprehensive range of applications for which the machine is intended, including prohibited usages, if any, taking into account variations of the original machine if appropriate,	Pass
3)	diagrams (especially schematic representation of safety functions),	Pass
4)	data on noise and vibration generated by the machine, and on radiation, gases, vapours and dust emitted by it, with reference to the measuring methods (including measurement uncertainties) used,	Pass
5)	technical documentation of electrical equipment (see IEC 60204-1), and	N/A
6)	documents attesting that the machine complies with mandatory requirements;	N/A
d)	information relating to the use of the machine, such as that related to or describing	Pass
1)	intended use,	Pass
2)	manual controls (actuators),	Pass
3)	setting and adjustment,	Pass
4)	modes and means for stopping (especially emergency stop),	Pass
5)	risks which could not be eliminated by the risk reduction measures implemented by the designer,	Pass
6)	particular risks which can be generated by certain applications, by the use of certain fittings, and about specific safeguards necessary for such applications,	N/A
7)	prohibited use resulting from reasonably foreseeable misuse ,	Pass
8)	fault identification and location, for repair and for restarting after an intervention, and	N/A
9)	personal protective equipment needed to be used and the training that is required; and	Pass

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10) meaning and purpose of signals and warning devices.	N/A
e) information for maintenance, such as	Pass
1) the nature and frequency of inspections for safety functions, *Comment: Inspected before each use.*	Pass
2) specification of the spare parts to be used when these can affect the health and safety of operators,	N/A
3) instructions relating to maintenance operations which require a definite technical knowledge or particular skills and hence need to be carried out exclusively by skilled persons (for example, maintenance staff, specialists),	N/A
4) instructions relating to maintenance actions (replacement of parts, etc.) which do not require specific skills and hence may be carried out by users (for example, operators), and	N/A
5) drawings and diagrams enabling maintenance personnel to carry out their task rationally (especially fault-finding tasks);	N/A
f) information relating to dismantling, disabling and scrapping;	N/A
g) information for emergency situations, such as	N/A
1) the operating method to be followed in the event of accident or breakdown,	N/A
2) the type of fire-fighting equipment to be used, and	N/A
3) a warning of possible emission or leakage of hazardous substance(s) and, if possible, an indication of means for fighting their effects;	N/A
h) maintenance instructions provided for skilled persons [item e) 3) above] and maintenance instructions provided for unskilled persons [item e) 4) above], that need to appear clearly separated from each other.	N/A
6.4.5.2 Production of instruction handbook	
The instruction handbook shall meet the requirements of ISO 20607, and in particular, the following requirements as applies to the production and presentation of the instruction handbook.	Pass
a) The type fount and size of print shall ensure the best possible legibility. Safety warnings and/or cautions should be emphasized by the use of colours, symbols and/or large print.	Pass
b) The information for use shall be given in a language(s) as determined by the country in which the machine will be used for the first time. If more than one language is to be used, each should be readily distinguished from another, and the translated text and relevant illustration should be kept together.	Pass
NOTE: In some countries the use of specific language(s) is covered by legal requirements.	
c) Whenever helpful to the understanding, text should be supported by illustrations.	Pass
- These illustrations should be supplemented with written details enabling, for example, manual controls (actuators) to be located and identified.	Pass
- They should not be separated from the accompanying text and should follow sequential operations.	Pass
d) Consideration should be given to presenting information in tabular form where this will aid understanding.	Pass
- Tables should be adjacent to the relevant text.	Pass
e) The use of colours should be considered, particularly in relation to components requiring quick identification.	N/A
f) When information for use is lengthy, a table of contents and/or an index should be provided.	N/A
g) Safety-relevant instructions which involve immediate action should be provided in a form readily available to the operator.	Pass
6.4.5.3 Drafting and editing information for use	
The following applies to the drafting and editing of information for use.	Pass

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a)	Relationship to model: the information shall clearly relate to the specific model of machine and, if necessary, other appropriate identification (for example, by serial number).	Pass
b)	Communication principles: when information for use is being prepared, the communication process "see–think–use" should be followed in order to achieve the maximum effect and should follow sequential operations.	Pass
	- The questions, "How?" and "Why?" should be anticipated and the answers provided.	Pass
c)	Information for use shall be as simple and as brief as possible, and should be expressed in consistent terms and units with a clear explanation of unusual technical terms.	Pass
d)	When it is foreseen that a machine will be put to non-professional use, the instructions should be written in a form that is readily understood by the non-professional user.	Pass
	- If personal protective equipment is required for the safe use of the machine, clear advice should be given, for example, on the packaging as well as on the machine, so that this information is prominently displayed at the point of sale.	Pass
e)	Durability and availability of physical documents: documents giving instructions for use should be produced in durable form (i.e. they should be able to survive frequent handling by the user).	Pass
	- It can be useful to mark them "keep for future reference".	Pass
Further details are specified in ISO 20607		
7	**Documentation of risk assessment and risk reduction**	
The documentation shall demonstrate the procedure that has been followed and the results that have been achieved. This includes, when relevant, documentation of		Pass
a)	the machinery for which the risk assessment has been made (for example, specifications, limits, intended use);	Pass
b)	any relevant assumptions that have been made (loads, strengths, safety factors, etc.);	N/A
c)	the hazards and hazardous situations identified and the hazardous events considered in the risk assessment;	Pass
d)	the information on which risk assessment was based (see 5.2):	Pass
1)	the data used and the sources (accident histories, experience gained from risk reduction applied to similar machinery, etc.);	Pass
2)	the uncertainty associated with the data used and its impact on the risk assessment;	Pass
e)	the risk reduction objectives to be achieved by risk reduction measures;	Pass
f)	the risk reduction measures implemented to eliminate identified hazards or to reduce risk;	Pass
g)	residual risks associated with the machinery;	Pass
h)	the result of the risk assessment (see Figure 2 in the standard);	Pass
i)	any forms completed during the risk assessment.	Pass
Standards or other specifications used to select risk reduction measures referred to in f) above should be referenced.		Pass
NOTE: No requirement is given in the standard to deliver the risk assessment documentation together with the machine. See ISO/TR 14121-2 for information on documentation.		

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Machinery Directive - Assessment of general principles for machinery design to the requirements of EN ISO 12100:2024

Normative references

Standard	Year	Amend.	Title
EN/A ISO 12100	2010		Safety of machinery — General principles for design — Risk assessment and risk reduction
ISO/DIS 12100	2024	Amend	Safety of machinery — General principles for design — Risk assessment and risk reduction

Issue	Date	Reference	Comments
1	30/09/2014	14D1730	First draft
2	14/01/2022	14D1731	Second draft
3	07/07/2025	14D1732	Third draft

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Risk Assessment

To the requirements of

EN ISO 4414:2010 - EN ISO 12100:2010

Type:	CV boot applicator
Product Name:	Duragun
Model:	Series 3
Sample Ref/Serial Number:	Specimen 01
Supply:	Air @ 130psi (Max recommended pressure)
Additional Notes:	This equipment is for stretching rubber boots that go over Constant Velocity Joints on drive shafts.
Assessor:	David Hartley
Date:	07-07-2025

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Key to Risk Assessment

Likelihood of Occurrence (LO)	
0.0	Impossible, Cannot Happen
0.1	Almost unlikely, Possible in extreme circumstances
0.5	Highly unlikely, though conceivable
1	Unlikely, but could occur
2	Possible but unusual
5	Even chance, could happen
8	Probable, not surprised
10	Likely, to be expected
15	Certain, no doubt

Frequency of Exposure (FE)	
0.1	Infrequently
0.2	Annually
1	Monthly
1.5	Weekly
2.5	Daily
4	Hourly
5	Constantly

Degree of Possible Harm (DPH)	
0.1	Scratch or Bruise
0.5	Laceration or mild ill health effect
1	Break of a minor bone or Minor illness (temporary)
2	Break of a major bone or Minor illness (permanent)
4	Loss of limb/eye/serious illness of a temporary nature
8	Loss of limb/eye/serious illness of a permanent nature
15	Fatality

Number of Persons at Risk (NP)	
1	1-2 persons
2	3-7 persons
4	8-15 persons
8	16-50 persons
12	50+ persons

Risk	Negligible	Very Low	Low	Significant	High	Very High	Extreme	Unacceptable
HRN	0-1	1-5	5-10	10-15	50-100	100-500	500-1000	1000+

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Risk Assessment No: 1

Hazard Description | Danger of injury because of the weight of the equipment which is approximately 2.2kg could cause work related upper limb disorder. (WRULD)

LO	FE	DPH	NP	HRN
2.0	5.0	1.0	1.0	10.0

Degree of Risk | Low

Control measure(s) | The weight of the finished tool should be such that it can easily be used by one person. When the finished tool is ready for production a manual handling assessment should be carried out to ensure the WRULD can be avoided.

LO	FE	DPH	NP	HRN
0.1	5.0	1.0	1.0	0.5

Implemented | 01/07/2025
Degree of Risk | Negligible

Additional Notes about hazard

The unit has been re-designed to reduce the weight and change the balance in the hand.

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Risk Assessment No: 2

Hazard Description | Danger of injury because the air pressure could exceed the maximum tool design levels as there is no regulator on the tool.

LO	FE	DPH	NP	HRN
0.1	5.0	1.0	1.0	0.25

Degree of Risk | Negligible

Control measure(s) | This risk is deemed negligible because there is a Relief Valve that is regularly batch tested and declared in compliance by the manufacturer (Bailcast Ltd). No action required.

LO	FE	DPH	NP	HRN
0.1	5.0	0.5	1.0	0.25

Implemented | 01/07/2025
Degree of Risk | Negligible

Additional Notes about hazard

The tool regularly undergoes Destructive testing. This test is to ensure that the components comply with the specifications and achieve 1.5x MAX working pressure. Components which don't achieve the requirement are rejected and are not used in production.

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Risk Assessment No: 3

Hazard Description | Danger of injury because there are trapping points on this tool between the operating arms and vehicle suspension components.

LO	FE	DPH	NP	HRN
1.0	5.0	1.0	1.0	5.0

Degree of Risk | Very Low

Control measure(s) | The instructions should give information on the correct use of the tool in respect to trapping of hands and fingers and any PPE required during the operation of the tool.

LO	FE	DPH	NP	HRN
0.1	5.0	1.0	1.0	0.5

Implemented | 01/07/2025
Degree of Risk | Negligible

Additional Notes about hazard

The operation instructions detail safe operation.

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Risk Assessment No: 4

Hazard Description | Danger of injury because there is a possibility of fingers being trapped between the operating arms and the driveshaft when releasing the air and the spring pressure returning the arms to the closed position.

LO	FE	DPH	NP	HRN
1.0	5.0	1.0	1.0	5.0

Degree of Risk | Very Low

Control measure(s) | The spring tension should be checked to ensure that it will not cause injury of the persons fingers where between operation arms and the driveshaft when the air pressure is released.

LO	FE	DPH	NP	HRN
0.1	5.0	0.1	1.0	0.05

Implemented | 01/07/2025
Degree of Risk | Negligible

Additional Notes about hazard

The operation instructions detail safe operation.

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Risk Assessment No: 5

Hazard Description | Danger of injury because the pressure housing may burst if the maximum pressure of 150 psi is exceeded.

LO	FE	DPH	NP	HRN
1.0	5.0	1.0	1.0	0.5

Degree of Risk | Negligible

Control measure(s) | This risk is deemed negligible because the calculations and specifications indicate that the pressure housing is capable of withstanding pressures above 30 bar. No action required.

LO	FE	DPH	NP	HRN
0.1	5.0	1.0	1.0	0.5

Implemented | 01/07/2025
Degree of Risk | Negligible

Additional Notes about hazard

The tool regularly undergoes Destructive testing. This test is to ensure that the components comply with the specifications and achieve 1.5x MAX working pressure. Components which don't achieve the requirement are rejected and are not used in production.

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Risk Assessment No: 6

Hazard Description | Danger of injury because the exhausting air will be above 2bar on initial exhaust, this could break the skin and cause an embolism.

LO	FE	DPH	NP	HRN
0.5	5.0	15.0	1.0	37.5

Degree of Risk | Significant

Control measure(s) | The design of the tool should be such that the exhausting air will not be above 2 bar and the location of the exhausted air is away from operators.

LO	FE	DPH	NP	HRN
0.1	5.0	0.1	1.0	0.05

Implemented | 01/07/2025
Degree of Risk | Negligible

Additional Notes about hazard

The controls have been re-designed and presents little possibility of injury.

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Risk Assessment No: 7

Hazard Description | Danger of injury because this equipment may not comply with the requirements of the PED.

LO	FE	DPH	NP	HRN
2.0	5.0	1.0	1.0	10.0

Degree of Risk | Low

Control measure(s) | The equipment uses air at 10 bar and a volume of 1.17 litres it is a vessel and comes under Safe Engineering Practices (SEP) using chart 2 “Vessels for Group 2 Gasses” of the PED.it should be ensured that the tool is safe and complies with the requirements for SEP.

LO	FE	DPH	NP	HRN
0.1	0.1	0.1	1.0	0.001

Implemented | 01/07/2025
Degree of Risk | Negligible

Additional Notes about hazard

No further action required.

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Risk Assessment No: 8

Hazard Description | Danger of damage to machinery, of which could cause improper use.

LO	FE	DPH	NP	HRN
0.1	0.1	0.1	1.0	0.001

Degree of Risk | Negligible

Control measure(s) | The risk is deemed negligible because of the use of a relief valve inside the tool. This will prevent any over pressurization which could cause injury.

LO	FE	DPH	NP	HRN
0.1	0.1	0.1	1.0	0.001

Implemented | 01/07/2025
Degree of Risk | Negligible

Additional Notes about hazard

The Relief Valve undergoes rigorous and regular testing to ensure it complies.

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EHSR Report

To the requirements of

EN ISO 4414:2010 - EN ISO 12100:2010

Type:	CV boot applicator
Product Name:	Duragun
Model:	Series 3
Sample Ref/Serial Number:	Specimen 01
Supply:	Air @ 130psi (Max recommended pressure)
Additional Notes:	This equipment is for stretching rubber boots that go over Constant Velocity Joints on drive shafts.
Assessor:	David Hartley
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1.1.2 Principles of Safety Integration

Is machine 'fit for its function' and can it be operated and maintained without putting persons at risk?	Machine is 'fit for its function' and it can be operated and maintained without putting persons at risk.
For hazards, which cannot be designed out, have safeguards been designed in?	Not Applicable
Have risk assessments been carried out on the completed machine?	Risk Assessments have been carried out on the completed machine
If there are any residual risks have warnings been provided?	Warnings have been supplied for residual risks.
If there are any residual risks will training be available where required?	Not Applicable
Has the machine design taken into account ergonomic principles to minimise discomfort, fatigue, and psychological stress faced by the operator?	Ergonomic factors have been considered during design in order to minimise discomfort, fatigue and psychological stress faced by the operator.
Has the machine design taken into account operator constraints due to the use of Personal Protection Equipment (such as footwear, gloves, etc.)?	Operator constraints due to the use of personal protection equipment (such as footwear, gloves, etc.) have been taken into account during design.
Is essential equipment and accessories to allow use, adjustment and maintenance without risk, supplied?	Essential equipment and accessories to allow use, adjustment and maintenance without risk, has been supplied.

1.1.3 Materials and products

Is the machine constructed of non-hazardous materials?	The machine is constructed of non-hazardous materials.
Are exposed persons protected from any hazards due to materials or products used or created by machine?	Exposed persons are protected from any hazards caused by materials or products used or created by machine.

1.1.4 Lighting

Has local lighting been furnished if ambient lighting of normal intensity is not sufficient for safe operation or frequent inspection and normal maintenance?	Not Applicable

1.1.5 Design of machinery to facilitate its handling

Are lifting points clearly identified where necessary?	Not Applicable
Are parts, which are to be transported, separately clearly identified with their weight?	All transported parts are clearly identifiable, including their weight.
Are changeover tooling/parts that can be moved by hand easy to move and handle safely?	Changeover tooling/parts that can be moved by hand are easy to move and can be handled safely.
Has a lifting and handling procedure been included in the instruction manual?	A lifting and handling procedure has been included in the instruction manual.

1.2.1 Safety and reliability of control systems

Will controls withstand the rigors of normal use?	Controls will stand the rigors of normal use
In the event of any errors of logic will the machine stop safely?	The machine will stop safely in the event of logic errors
Are all controls Millennium Compliant?	All controls are millennium compliant.
Are safety circuits wired through an adequate safety relay?	Not Applicable

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1.2.2 Control devices

Are the control devices clearly visible and identified with their functions?	Control devices are clearly visible and have been identified with their functional purpose
Are the control devices located outside the danger zones?	All control devices are located outside the danger zone
Are the control devices designed to avoid unintentional operation?	Control devices have been designed to reduce unintentional operation
If visual or acoustic warning devices have been supplied, are they functional?	Not Applicable

1.2.3 Starting

Is the machine started from one point only by the voluntary actuation of a control provided for the purpose?	The machine can only be started from one position.

1.2.4 Stopping

Will the machine be able to come to a complete stop safely?	The machine can come to a safe stop
Is the machine fitted with emergency stops?	Not Applicable
Are E stops of correct type?	Not Applicable
Are emergency stop circuits independent of the PLC and wired through a safety relay?	Not Applicable
If the machine is part of a complex assembly has the machine been designed so that the Emergency Stop stops equipment up & down stream if its continued operation can cause a dangerous situation?	Not Applicable

1.2.5 Mode Selection

If mode selector affects safety circuits, is it implemented safely?	Not Applicable
Does the mode selector override all other control systems with the exception of the emergency stop?	Not Applicable
Can the mode selector be locked in each position if it is to perform in different control position (eg adjustment, maintenance and inspection)?	Not Applicable
If the mode selector is via software, is the access restricted by passwords etc.?	Not Applicable
If protection devices are neutralised by the mode selector is the automatic mode disabled, is the machine operated by hold to run controls, does the machine run at reduced speed, disable internal sensor devices?	Not Applicable

1.2.6 Failure of power supply

If the power fails will the machine stop safely?	Machine will stop safely in the event of a power failure.
If the power is reconnected does the machine have to be manually restarted by operation of the start control?	Machine can only be restarted by the use of the start function (if power is reconnected)

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If the power fails and is then reinstated will the safety devices be immediately functional?	Safety devices have immediate functionality upon re-initiation of power.
If the power fails will any part of the machine or product be prevented from failing or being ejected?	No part of the machine or product will fall or be ejected upon a power failure

1.2.7 Failure of the control circuits

If the control circuits fail will the machine stop safely and all safety devices remain active?	All safety devices remain active and the machine will come to a safe stop if the control circuits fail.
If the control circuits fail does the machine have to be manually restarted by operation of the start control?	The machine can only be restarted by the start option in the event of the control circuits failing.
If the control circuits fail will any part of the machine or product be prevented from falling or being ejected?	No part of the machine or product will fall or be ejected if the control circuits fail.

1.2.8 Software

Is interactive software between the operator and the control system user friendly?	Not Applicable

1.3.1 Stability

Is the machine designed and constructed so that it is stable enough, under foreseen operating conditions, for use without risk of overturning, falling or unexpected movement?	Not Applicable

1.3.2 Risk of break-up during operation

Is the machine strong enough to withstand normal operation stresses?	The machine is strong enough to withstand normal operational stresses
Do the instructions indicate the frequency and type of safety inspections required?	All instructions indicate the frequency and type of safety inspections required

1.3.3 Risks due to failing or effected objects

Have precautions been taken to prevent risks from falling or ejected objects.	Precautions been taken to prevent risks from falling or ejected objects

1.3.4 Risks due to surfaces, edges or angles

Have rough surfaces and sharp edges and angles likely to cause injury been removed?	Rough surfaces and sharp edges and angles likely to cause injury been removed

1.3.5 Risks related to combined machinery

Can each element of a complex installation be operated independently without creating a hazard?	Not Applicable

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1.3.6 Risks relating to variations in the rotational speed of tools

Is the machine designed in such a way that selection and adjustment to perform different operations can be carried out safely?	The machine has been designed in such a way that selection and adjustment to perform different operations can be carried out safely.

1.3.7 Prevention of risks related to moving parts

Have hazards been designed out where possible?	Hazards been designed out where possible
Have guards and/or protection devices been incorporated to eliminate any hazards, which have not been designed out?	Guards and/or protection devices been incorporated to eliminate any hazards, which have not been designed out.

1.3.8 Choice of protection against risks related to moving parts

Are fixed guards only used where access is infrequent?	Fixed guards only used where access is infrequent.
Are movable guards used where access is frequent?	Not Applicable

1.4.1 General Requirements

Are guards and protection devices adequate for their purpose and sufficiently strong enough to contain any ejected objects?	Guards and protection devices adequate for their purpose and sufficiently strong enough to contain any ejected objects
Are guards or protection devices designed to not lead to additional hazards?	Guards or protection devices designed to not lead to additional hazards
Is it difficult for guards or protection devices to be bypassed and rendered non-operational?	It is difficult for guards or protection devices to be bypassed and rendered non-operational
Are guards or protection devices located at an adequate distance from the danger zone?	Guards or protection devices located at an adequate distance from the danger zone.
Do guards and protection devices cause minimal obstruction to the view of the production process?	Guards and protection devices cause minimal obstruction to the view of the production process.

1.4.2 Special Requirements for guards.

Are fixed guards securely held in place with fixings, which require special tools for removal? N.B No single slot screws?	Fixed guards are securely held in place with fixings, which require tools for removal.
If possible, are fixed guards unable to remain in place without fasteners?	Fixed guards are unable to remain in place without fasteners (where applicable)
Are movable guards fixed to the machine when open?	Not Applicable
Are movable guards interlocked with fail safe devices?	Not Applicable
Are movable guards adjustable only with tools?	Not Applicable

1.4.3 Special requirements for protective devices

Are protective devices fail-safe?	Not Applicable
Are protective devices difficult to adjust unintentionally?	Not Applicable

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1.5.1 Electricity supply

Is machine electrically safe?	Not Applicable

1.5.2 Static Electricity

Is machine electrically safe?	Not Applicable

1.5.3 Energy supply other than electricity

If the machine uses hydraulic, pneumatic or thermal energy supplies, have the hazards associated with these been considered?	Hazards identified with the power source(s) have been designed out

1.5.4 Errors of fitting

Are all electrical, pneumatic and hydraulic connections clearly marked and are circuit diagrams available?	All connections are clearly marked and circuit diagrams provided

1.5.5 Extreme temperatures

Have steps been taken to eliminate any risk or injury caused by contact with or proximity to machinery parts or materials at high or very low temperatures?	Not Applicable
Have steps been taken to prevent the risk of very hot or very cold material been ejected?	Not Applicable

1.5.6 Fire

Have sources of ignition been eliminated?	Not Applicable

1.5.7 Explosion

Is the machine designed and constructed to avoid any risk of explosion posed by the machine itself or by gases, liquids, dusts, vapours or other substances produced or used by the machine?	Explosion is highly unlikely

1.5.8 Noise

If the noise level is less than 70 dBA has this been noted in the instruction manual?	Noise levels and any recommended actions to reduce noise has been noted in the instruction manual.
If the noise level is above 70 dBA has the actual reading been recorded in the instruction manual?	Not Applicable
Is the noise level above 85 dBA are ear protection warnings posted on the machine and in the instruction manual?	Not Applicable
Is there any noise insulation fitted to reduce the noise level to a minimum?	Not Applicable

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1.5.9 Vibration

If the machine produces excessive vibration are measures in place to reduce vibration to a minimum?	Not Applicable

1.5.10 Radiation

Is the machine EMC Compliant?	Not Applicable
Is the machine designed and constructed so that any emission of radiation is limited to the extent necessary for its operation and that the effects on exposed persons are non-existent or reduced to non-dangerous proportions?	Not Applicable

1.5.11 External Radiation

Is the machine designed and constructed that external radiation does not interfere with its operation?	Not Applicable

1.5.12 Laser equipment

Is the laser equipment designed and constructed to prevent any accidental radiation?	Not Applicable

1.5.13 Emissions of dust, gases, etc.

Is the machine designed, constructed and/or equipped so that risks due to gases, liquids, dust, vapours and other waste materials, which it produces can be avoided?	Not Applicable

1.5.14 Risk of being trapped in a machine

Is machine designed to prevent an exposed person from being enclosed within it or, if that is impossible, is there a means of summoning help?	Not Applicable

1.5.15 Risk of slipping, tripping or falling

Is the machine designed to prevent persons slipping, tripping or falling?	Not Applicable

1.6.1 Machinery maintenance

Can the machine be adjusted; lubricated and maintained outside the danger zones or whilst the machine is immobilised?	The machine can be adjusted; lubricated and maintained outside the danger zones or whilst the machine is immobilised.

1.6.2 Access to operating position/servicing points

Is there safe means of access to all areas used for production, maintenance and adjustment?	There is safe means of access to all areas used for production, maintenance and adjustment.

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1.6.3 Isolation of energy sources

Can all energy sources be isolated by clearly identifiable devices? Are these lockable? Can residual stored energy be stored after isolation and be safely dissipated?	All energy sources can be isolated by clearly identifiable devices.

1.6.4 Operator intervention

Has the machine been designed to minimise the need for operator intervention?	The machine has been designed to minimise the need for operator intervention.

1.6.5 cleaning of internal parts

Can the machine be cleaned without entering the danger zones or while the machine is immobilised?	The machine can be cleaned without entering the danger zones or whilst the machine is immobilised.

1.7 Indicators

Is information needed to control machine unambiguous and easily understood?	Information needed to control the machine is unambiguous and easily understood.

1.7.1 Warning devices

Are devices unambiguous?	Not Applicable
Are devices easily checked for operation?	Not Applicable
Are devices easily understood?	Not Applicable

1.7.2 Warning of residual risks

Are there warnings for all residual risks?	Warnings have been provided for all residual risks
Are warnings in the language of the normal machine operator?	Warnings are in the language of the intended (normal) machine operator.

1.7.3 Marking

Has the makers name & address been marked on machine?	The makers name & address been marked on machine.
Has year of manufacture been marked on the machine?	The year of manufacture is marked on the machine.
Has the serial number been marked on the machine?	The serial number is marked on the machine
Has the make & type been marked on the machine?	The make & type is marked on the machine
Has the maximum safe speed been marked on the machine?	Not Applicable
Has the CE Mark (UKCA Mark for British retail) been marked on the machine?	Both the CE and UKCA marks have been marked on the machine

1.7.4 Instructions

Does the manual include: foreseen use of the machine?	The manual includes foreseen use of the machine
Does the manual include: A Repeat of the information of which the machine is marked?	The manual includes repeated information of the machine's markings.

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Does the manual include: work stations likely to be occupied by operators?	The manual includes work stations likely to be occupied by the operator.
Does the manual include instruction for safe: lifting, handling and installation?	The manual includes instructions for safe lifting, handling and installation.
Does the manual include instruction for safe: use and cleaning?	The manual includes instructions for safe use and cleaning.
Does the manual include instruction for safe: adjustment & maintenance?	The manual includes information for safe adjustment and maintenance
Does the manual include instruction for safe: dismantling?	Not Applicable
Does the manual indicate: training needs for operators & maintenance staff?	The manual indicates training needs for operators and maintenance staff
Does the manual indicate: tools needed for safe maintenance?	Not Applicable
Does the manual indicate: ways in which the machine should not be used?	The manual indicates ways in which the machine should not be used.
Does the manual include: all relevant drawings?	The manual includes all relevant drawings.
Have the instructions been translated in the language of the user?	All instructions have been translated into the language of the intended end user.

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Pneumatic Inspection checklist

To the requirements of

EN ISO 4414:2010 - EN ISO 12100:2010

Type:	CV boot applicator
Product Name:	Duragun
Model:	Series 3
Sample Ref/Serial Number:	Specimen 01
Supply:	Air @ 130psi (Max recommended pressure)
Additional Notes:	This equipment is for stretching rubber boots that go over Constant Velocity Joints on drive shafts.
Assessor:	David Hartley
Date:	07-07-2025

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Question	
Are all components used fit for their purpose and within their design limits?	Yes
If any component fails, will it fail in a safe manner?	Yes
Is the system protected against pressures exceeding maximum working pressure?	Yes
In the event of low or loss of pressure, will a hazardous situation be avoided?	Yes
Are all components accessible, and can they be safely adjusted and serviced?	Yes
Is there positive lockable isolation of the pressure source?	Yes
Can the pressure be safely dissipated on isolation?	Yes
Are persons protected from mechanical movements whether intended or unintended, including effects from acceleration, deceleration or lifting/holding of masses?	Yes
Is the exhaust air safely controlled to minimise hazards due to hazardous substances in the exhausting air?	Yes
Have external influences been taken into consideration, such as vibration, noise, specification of pressure etc been taken into consideration?	Yes
For transportation, are pipes and connections identified as on the relevant drawing?	Yes
Can all systems or components be packaged safely for transportation?	Yes
Are any rotating shafts and/or couplings guarded?	N/A
Are cylinders mounted to prevent distortion when installed?	Yes
Are components mounted on or connected to cylinders attached in such a way as to resist loosening caused by shocks, vibration etc?	Yes
Is there means of locking adjustable end stops? (If applicable)	N/A
Are all mountings free of shear forces, or have systems to absorb such forces?	N/A
Is the air vented safely from single acting cylinders?	Yes
Are piston rods protected against foreseeable damage (dents, scratches, fluids)?	Yes
Are valves of correct type and mounted correctly to ensure safe function, leak tightness and resistance to external influences?	Yes
Can valves only be mounted in correct orientation?	Yes
Have back pressure effects been taken into consideration?	Yes
If actuators are required to hold their position, are valves spring biased or detent located to the safe position?	Yes
Are mechanically operated valves protected from damage by the operating device?	Yes
Are electrically operated valves connected in accordance with EN 60204-1?	N/A
Where terminal blocks and housings are fitted, is the terminal block housing constructed to an adequate degree of protection under EN60529 and is there adequate space for components and cabling?	N/A
Where terminal blocks and housings are fitted are captive fasteners used for electrical access cover used, with a suitable retaining device (i.e. chain), and do cable connections have strain relief?	N/A
Are solenoids sized to operate the valves reliably at the normal voltage +/- 10%?	N/A
If the electrically operated valve needs to be operated manually, can this be done safely and deliberately?	N/A
Is filtration fitted to be consistent with the expected working environment?	N/A
Is there a specification and COSHH sheet supplied for any lubricating fluids?	N/A
Is piping protected against being used as steps or ladders, and supported safely?	N/A

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Is piping identified and located correctly and safely?	N/A
Has all foreign matter been removed during assembly?	Yes
Are flexible hose assemblies constructed from hoses not previously used and do they fulfil all performance requirements?	N/A
is the service life of flexible hose assemblies specified, and are they installed to avoid sharp bends, strain and rubbing?	N/A
Are persons protected from the whiplash and/or fluid ejection hazards by failure of flexible hose assemblies, and are they supported adequately?	N/A
Are non-metallic fluid conditioning units protected where the pressure is greater than 1 bar/litre?	N/A
Is control provided to maintain system pressure within safe limits and of the self-relieving type?	N/A
Are pressure and flow controls able only to be adjusted within their ratings?	N/A
Where failure of any control device may lead to a hazard, are interlocks provided to interrupt all operations?	N/A
Is means of preventing unacceptable pressure build up from external loads on actuators?	Yes
Have pressure and flow control valves been selected so that changes in pressure, temperature and load do not influence the operation in a hazardous way?	Yes
Where changes in system operating parameters may lead to a hazard, is clear indication provided?	N/A
Is sequencing by position sensing used (Preferred method)?	N/A
If sequencing by position sensing not used, will malfunction not lead to a hazard?	N/A
If actuators are controlled by servo or proportional valves, is there means for holding or moving actuator to a safe position in the event of failure leading to a hazard?	N/A
Are silencers used that do not lead to a further hazard?	N/A
Have systems and components been inspected to verify compliance with the pneumatic diagram, and if so by who?	Yes
Have operational tests been carried out to prove correct operation of system and safety devices?	Yes
Has system been pressure tested at maximum working pressure?	Yes
Has a final circuit diagram been provided in accordance with ISO/DIS 1219-2?	Yes
Have details of any lubrication fluids been supplied i.e. COSHH sheet?	N/A
Has maintenance data been supplied clearly showing lubrication points, type of lubricant, location of components requiring regular maintenance, identification of any parts not depressurised by normal vent, and give depressurising instructions?	N/A
Do components have marking showing manufacturer identification, rated pressure, port identification, date of hose manufacture and the order of any stacking modules?	Yes
Is each pneumatic component identified with a letter or number, and is it identified on the drawings and on the installation close to the relevant component?	N/A
Are all ports clearly identified?	Yes
Are all valve control mechanisms clearly identified as the circuit diagram?	N/A
Are any concealed components identified close to their access openings as CONCEALED?	N/A
Has a qualified engineer helped to complete this checklist?	Yes