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<b>Created by</b>	<b>Created with the participation of</b>
Elmar Fischbach	QFS Team, Matt Heilbronn,

<b>Updates :</b>			
<b>Version</b>	<b>Date</b>	<b>Updated by :</b>	<b>Updates summary</b>
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1.6	23.5.2013	Elmar Fischbach	Final version agreed with supplier


<b>Cancelled and replaced documents</b>	<b>Reference specifications</b>

<b>Technical validation:</b>		
<b>Name:</b>	<b>Function:</b>	<b>Date &amp; Hour:</b>

<b>Approved by:</b>		
<b>Name:</b>	<b>Function:</b>	<b>Date &amp; Hour:</b>

<b>Responsibilities</b>	<b>Owner(s)</b>
Writing and up-dating this specification	Elmar Fischbach
Applying this specification	All DBN supply points using Can lines
Ensuring the conformity between this specification and other external or internal standards	


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## PURPOSE

Delivery of an standard X - Ray machine from **to Danone XXX.**

The machine will be used to analyse metal cans filled with Milk Powders, milk and plain cereals in a 3 shift mode; 7 days per week and 48 weeks/a. ( 8064 working hours/year)

The purpose of the X-ray machine is to prevent product that leaves the factory destined for the customer to have large contaminants. The **minimal size of contaminant** that is detected must be measured at **100% detection probability**. Contaminants are introduced by: several (packaging machines), the process equipment and via supplied raw materials.

The X-ray machine must be able to detect Ferro, Non-Ferro, dense rubber, glass and dense plastic. The range of bulk densities lies between 0.55 – 0.65 kg/l. for the Danone products.

## SCOPE OF APPLICATION

Line will be used to produce the following packs:

## PRODUCT CONTENT & NAME PLATE CAPACITY & PERFORMANCE

### Name Plate Capacity

- 1) Up to 200 cans/Min

### Line performance:

The following data refer to the maximum set output:

Technical availability:	99, 9 % mechanical, electrical
Machine related losses:	none
False Rejection Rate:	Max. 0.05 %
Technical Efficiency	99.9 %


The set performance is subject to the following factors:

1. Products produced according to Danone spec.
2. Proper operation and maintenance of the packaging plant
3. Physical environment (max. 25 C; 60 % r.H.)

## CRITERIONS OF NON CONFORMITIES OF THE FINISHED PRODUCTS: SEE ANNEX 2

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- a) Products not get damaged or dirty when passing the machine
- b) No Contaminants according above list passing the machine undetected.

### PACK CHARACTERISTICS:



a. Can

- a) Can dia 99 mm; height 123,5 mm; product weight: 400 g.
- b) Can dia 127 mm; height 162.5 mm; product weight: 900 g.

### DETECTION LIMITS:

see full report DBN-MT 0007 Can KPI Detection Matrix




DBN-MT 0007 Can  
KPI Detection Matrix.

400g Can – 99mm diameter

Zone	Volume	0.8mm SS	1.0m m SS	1.2m m SS	2.5mm M-type Glass	3.0mm M-type Glass	3.5mm M-type Glass	2.5mm Aluminium	3.0mm Aluminium	3.5mm Aluminium
Top	2%	70%	100%	100%	76%	99%	100%	76%	99%	100%
Middle	96%	70%	100%	100%	76%	99%	100%	76%	99%	100%
Base	2%	62%	100%	100%	64%	97%	100%	64%	97%	100%
Overall I P.O.D	100%	69.84%	100%	100%	75.68%	98.96%	100%	75.68%	98.96%	100%

\* if you check for glass make sure that you use M Type test sample.



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800g Can – 127mm diameter

Zone	Volume	0.8mm m SS	1.0mm SS	1.2m m SS	3.0mm M- type Glass	3.5mm M- type Glass	4.0mm M- type Glass	3.0mm Aluminium	3.5mm Aluminium	4.0mm Aluminium
Top	2%	68%	100%	100%	94%	100%	100%	94%	100%	100%
Middle	96%	68%	100%	100%	94%	100%	100%	94%	100%	100%
Base	2%	38%	78%	100%	58%	72%	100%	58%	72%	100%
Overall I P.O.D	100%	67.4%	99.56 %	100%	93.28 %	99.44 %	100%	93.28%	99.44%	100%

\* if you check for glass make sure that you use M Type test sample.


**FRR = 0,05 % or max 5 out of 10.000 packs.**

**PACKAGING MATERIAL CHARACTERISTICS:**

For details see [Annex 3](#)

Detailed specifications can be given on request.

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**UTILITIES & MACHINE CONSUMPTIONS:**

UTILITIES		CONSUMPTIONS
<b>Compressed air</b>	<ul style="list-style-type: none"> <li>• 6 bars oil free</li> </ul>	<p style="color: red;">Peak flow: XXX Nm<sup>3</sup>/h Average flow: XXX Nm<sup>3</sup>/h</p> <ul style="list-style-type: none"> <li>○ <b>Compressed air:</b> Dry and without oil (Class 2 ISO8573). Supplier to install pressure regulator with water &amp; oil filters. For HC application, air line should be equipped with sterile air filter as well.</li> </ul>
<b>Electricity</b>	<ul style="list-style-type: none"> <li>• 230 V single phase → installed power: XXX KW</li> </ul>	<p style="color: red;">Peak : XX KW – XX A Average while running: XX KW – XX A</p>
	<ul style="list-style-type: none"> <li>•</li> </ul>	


Supplier must ensure that all measurements are taken into the equipment to minimize the use of energy, as well electrical energy as well the use of compressed air.

**MACHINE LOCATION:**

<b>Machine dimensions</b>	<ul style="list-style-type: none"> <li>• Ground surface for total machine: XXX sqm</li> <li>• Length: XXX meters</li> <li>• Maximum height: XXX meters</li> <li>• Machine weight: XXX kg</li> </ul>
<b>Machine environment</b>	<ul style="list-style-type: none"> <li>• Temperature range: 20-35°C</li> <li>• Altitude (air pressure range): XXXX meters → Pay attention with sales/production altitude</li> </ul>
<b>Load limits for floor and ceiling</b>	<ul style="list-style-type: none"> <li>• Floor: XXX Kg/cm<sup>2</sup></li> <li>• Ceiling: XXX Kg/linear meter (for support fixing)</li> </ul>
<b>Delivery / handling constraints (to deliver the machine in the plant)</b>	<ul style="list-style-type: none"> <li>• The machine must have a suspension tool or suitable framework for unloading and handling.</li> <li>• Mind the slope of the floor in the production area. ( if any )</li> </ul>

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### INTERFACES:

<b>Process limit (input):</b>	<ul style="list-style-type: none"> <li>• Y/N information exchange with line before.</li> <li>• For details see Annex 7</li> </ul>
<b>Packaging supply:</b>	<ul style="list-style-type: none"> <li>• All handling equipment required for installation should be provided by the machine supplier.</li> </ul>
<b>End of line (output):</b>	<ul style="list-style-type: none"> <li>• Y/N information exchange with end of line</li> <li>• Regulation of output has to be integrated by the supplier</li> </ul>
<b>Production control system:</b>	<ul style="list-style-type: none"> <li>• PLC is equipped with an Ethernet coupling unit.( Modem ) - as option</li> <li>• Data transfer to external PC is possible.</li> </ul>

for details see [Annex 7](#) Exchange of signals


### CHANGEOVER TIME:

- All parts/ positions of the X - Ray that have to be changed for a size change must be designed according to SMED, this means using keys, jigs, spaces, quick release and fastening etc;
- All parts used for changeover must be easily identified e.g. id mark on item (e.g. guiding tools etc.)
- Parts should be removed without any major tools.
- All changeable parts should only be able to be positioned in one (correct) way. No fitting or fine tuning must be necessary; no tools should be used and change over should be carried out by ONE operator.

All changeovers are defined to start when the machine slows down with the old product, changeover ends when the machine is running on speed again.

- Product change ( SKU change ): max 1 minutes
- Size change: max 5 minutes

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## **ACCEPTANCE AND MINIMUM PERFORMANCES REQUIRED:**

The minimum performances required, which allow the provisional and definitive acceptance, are described in Annex 8.

### **LIMITS of RESPONSABILITIES:**

#### 1) WORKS/SERVICES TO SUPPLIER CHARGE:

- The month after the order: the detailed schedule, the equipments lay out, the needs in energy supply (air, electricity ...) and the needs in samples (quantity, delivery time).
- Functional analysis of the X - Ray
- Drawings (lay-out )
- Technical documentation useful to the knowledge of the equipments
- Setting of the whole of line in workshop
- Setting, starting-up of the whole and staff training for equipment using.
- The whole of equipment is in conformity with the CE and UL norms, and Danone specifications (on request, for USA: FDA, UL and for Russia: GHOST).

#### 2) WORKS/SERVICES TO DANONE CHARGE:


- Delivery of the pack material necessary to test in workshop (quantity, delivery time)
- Functional analysis validation
- Drawings validation
- Reception for equipments in workshop by Danone before their delivery.
- Power connection, process gas and air necessary to all the equipments.
- Unloading, moving and put in place in charge of Danone under supplier responsibility.

## **TECHNICAL DOCUMENTATION:**

- A provisional document will be delivered to the plant before the delivery of the machine and will be updated all along the setting-up.
- Definitive technical documentation must be written in language of the user (e.g. German, Spanish, French, English) of the equipment (or other if written in quotation) and must be send to Danone in 2 copies within one on reproducible support (CD-ROM). Their last up-dated will be done after the starting-up to take into account the ultimate modifications eventually made on the machine.
- Documents will be regarded as a complete set only with handing-over plans and detailed diagrams that are in conformity with realisation on site.
- Documents must include: technical file for maintenance and production as well as all certificates of used materials, especially for those coming in direct food contact.
- Files with technical drawings (electrical, pneumatic, mechanical, machine layout) must be delivered on CD-ROM in system CAD. Provided files must be directly exploitable by AutoCAD. They should have an extension DWG, DXF, DXB, IGES. Mechanical drawings are in PDF version.

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- The overview of the filler with its environment is required in 2D and 3D.
- The content of required technical documentation and its delivery time is shown in [Annex 4](#).

### **TRAINING:**

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- The content of required training is shown in [Annex 5](#).

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**GENERAL CONSTRUCTION:**

FUNCTION	SUBFUNCTION	FUNCTIONALITY & REQUIREMENTS	TECHNICAL REQUEST
Mechanical Conception		<ul style="list-style-type: none"> <li>Facilitate floor and machine cleaning</li> <li>Facilitate machine operating</li> </ul>	<ul style="list-style-type: none"> <li>There must be minimum 125 mm distance between machine and ground, and under electrical enclosure in order to facilitate floor cleaning.</li> <li>Materials that are used must be compatible with the environment. Operator should be able to operate machine without changing the level and circumventing obstacles.</li> <li>Arrangement of operator's stand must support a global vision of the machine.</li> </ul>

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FUNCTION	SUBFUNCTION	FUNCTIONALITY & REQUIREMENTS	TECHNICAL REQUEST
Pneumatic conception		<ul style="list-style-type: none"> <li>All pneumatic devices (materials) must be in conformity with standards equipments</li> <li>No leakage of air or exhausts inside the line.</li> <li>Air has to be water free.</li> <li>In case that lubricated air is required this is not available in the factory. The main air supply connection has to be outside of the machine.</li> <li>All devices to adjust pressure should be outside of the machine.</li> </ul>	<ul style="list-style-type: none"> <li>ISO norm for all pneumatic devices.</li> <li>One distributor per connector is required.</li> <li>It should be possible to operate manually all distributors and electro-distributors (in front access).</li> <li>Each level of pressure must be obtained by means of gas pressure regulator including obligatory:                             <ul style="list-style-type: none"> <li>pressure reducer</li> <li>gauge indicating the pressure</li> </ul> </li> <li>Green and red indicators (marks) are required on manometers to facilitate their reading (target value and limit value).</li> <li>A cut off valve is installed at the beginning of installation supplying compressed air or vacuum to the machine.</li> <li>Any pneumatic supply must be lockable with a padlock. , preferred valve Type: Fesio HE LO – lockable and parallel pressure release.</li> </ul>  <ul style="list-style-type: none"> <li>Screw stainless steel connectors are required in the filling area.</li> <li>All exhausts should be collected outside the machine and equipped with silencer.</li> <li>All installation, connections and collars should resist +20% of the nominal overpressure.</li> </ul>

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FUNCTION	SUBFUNCTION	FUNCTIONALITY & REQUIREMENTS	TECHNICAL REQUEST
Power supply and element of power		<ul style="list-style-type: none"> <li>Compliance with national regulation.</li> <li>One lockable main breaker outside of the machine.</li> </ul>	<ul style="list-style-type: none"> <li>Power supply must be stabilized with protection against short circuits.</li> <li>Power circuits separated from networks and other appliances are expected.</li> <li>Connection of engines or machinery must be done with flexible hose (with exception in case of high powers)</li> <li>All cables for frequency controlled drives must be in copper shielding.</li> </ul>
Electrical enclosure		<ul style="list-style-type: none"> <li>Easy access to the electrical components</li> <li>Its conception must avoid any stagnation</li> </ul>	<ul style="list-style-type: none"> <li>Each electrical enclosure must be equipped with main circuit breaker (lockable with padlock) - if mounted on front doors it must be possible to open the door without switching off the power supply.</li> <li>Any electrical cabinet are in stainless steel and on its bottom part there must be mounted a dismountable plate with drilled holes for passage of cables (all holes should be sealed by stoppers).</li> <li>Conceived to avoid stagnant water penetration while of door opening.</li> <li>If put on the ground it must be equipped with adjustable feet (anti-vibrating pad and stainless steel plate)</li> <li>Under it there should be mounted a special basket for holding entering cables.</li> <li>The conception of any enclosure (&gt; 350 mm) must not allow any foreign body retention (water, oil...), but must facilitate their cleaning (10° to 30° sloping).</li> <li>Must be equipped with front door (max width should not exceed 1.300mm and any door &gt; 800 mm must be strengthened).</li> <li>Enclosure's door must be equipped with internal stainless hinges, closings by lock wrist and internal "pocket" in order to put all documentation.</li> </ul>

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FUNCTION	SUBFUNCTION	FUNCTIONALITY & REQUIREMENTS	TECHNICAL REQUEST
Ventilation		<ul style="list-style-type: none"> <li>• Ventilation must guarantee a temperature below 30°C in the higher part of the enclosure.</li> <li>• Good accessibility for maintenance is required.( not on top of the machine )</li> </ul>	<ul style="list-style-type: none"> <li>• The electrical cabinets are fitted with an air conditioning unit if applicable.</li> <li>• The ventilation device:               <ul style="list-style-type: none"> <li>- works in suction (sucks the outside air)</li> <li>- is located in lower part of the enclosure</li> <li>- is equipped with a filter (easily accessible and removable)</li> <li>- is secured with stainless steel water deflector</li> <li>- Air extraction grid (equipped with a white filter) is located on the upper part of the enclosure to allow a good air flow.</li> </ul> </li> </ul>
Internal Structure			<ul style="list-style-type: none"> <li>• Spare space in enclosure should not be less than 30% .</li> <li>• Fixing of units and terminals: snapped onto top hat rails.</li> <li>• Arrangements of elements and terminal strip:               <ul style="list-style-type: none"> <li>- motor circuit breaker: horizontal</li> <li>- contactors: horizontal</li> <li>- terminal strip: vertical and horizontal</li> </ul> </li> <li>• Earth wire connection: to earth bus bar or terminal strip.</li> <li>• Neutral wire connection: to neutral bus bar or terminal strip.</li> <li>• Terminals for potential free contacts: on separate terminal strip.</li> <li>• Parts under voltage: protected by covers.</li> <li>• Terminal arrangement: separated according to power and control units.</li> <li>• Localization of terminals must be done with respect to their functions and cards.</li> <li>• Electromagnetic relays with LED indicating their states (on, off) are expected.</li> </ul>




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FUNCTION	SUBFUNCTION	FUNCTIONALITY & REQUIREMENTS	TECHNICAL REQUEST
		<ul style="list-style-type: none"> <li>Compliance with national regulation.</li> </ul>	<ul style="list-style-type: none"> <li>Electric components must have a degree of protection adapted to the environment of the food industry:               <ul style="list-style-type: none"> <li>- displays of defects, terminals: IP 65</li> <li>- boxes area for electrical equipment: IP 65 (stainless steel) for the most exposed zones. IP 54 for the enclosures with ventilators.</li> <li>- Engines: IP 55 with housing.</li> </ul> </li> <li>No electric cable laid on the ground.</li> <li>Engines must be protected from over currents and overloads.</li> <li>All pneumatic and electric actuators should be separated "geographically".</li> </ul>
	Internal wiring	<ul style="list-style-type: none"> <li>Colours and diameters of wires must respect the standards in force</li> <li>All wires must fulfil the regulations on low voltage for calculation of their section</li> </ul>	<ul style="list-style-type: none"> <li>"Screw" type connectors or "WAGO" spring terminal are expected.</li> <li>In case of using screw-type connector, wire ends must be equipped with "wire end ferrules" and plastic collars.</li> <li>Entrance of wires must be done from the bottom, rear or side of the enclosure without any chutes (necks).</li> <li>No rigid wires</li> <li>Wires individual fixed on trays</li> </ul> 

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FUNCTION	SUBFUNCTION	FUNCTIONALITY & REQUIREMENTS	TECHNICAL REQUEST
	Marking of elements		<ul style="list-style-type: none"> <li>• All the electric and pneumatic components, inside and outside of the enclosure, must be permanently marked (connector blocks, terminals, relays, jacks, distributors, cells, etc.).</li> <li>• Text of labelling (marking) must be the same as text written on electrical or pneumatic drawings.</li> <li>• All elements should carry a maker badge (plate) with their design features and must hold in the time (even in a humid atmosphere).</li> <li>• Should be readable from the left to the right or down to up.</li> <li>• All closures of ducts must be marked (letter, number, colour point, ...)</li> </ul>
	Ducts for wires	<ul style="list-style-type: none"> <li>• Not allowed</li> </ul>	
	Trays for wires		<ul style="list-style-type: none"> <li>• Wires must be attached in opened grid electrical paths (trays type: cablofil), except:               <ul style="list-style-type: none"> <li>- the two channels in upper part on both sides of the machine</li> <li>- both between the main electrical cabinet.</li> </ul> </li> <li>• Distance between tray's supports assures no deformation of the mounted tray.</li> <li>• Trays must be mounted vertically to avoid dust accumulation.</li> <li>• In case of changing the levels or directions trays should be in form of soft curves to facilitate the housing of the cables and to optimize to maximum its capacity.</li> <li>• Provide 20% of spare space for future wires</li> </ul>





**DANONE**  
BABY NUTRITION

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FUNCTION	SUBFUNCTION	FUNCTIONALITY & REQUIREMENTS	TECHNICAL REQUEST
Performance needs	Fulfil capacity needs	<ul style="list-style-type: none"> <li>Record trace of main production parameters (specified by the plant)</li> <li>(see Annex 8 . Acceptance procedure)</li> </ul>	<ul style="list-style-type: none"> <li>Use decentralised network architecture with field BUS and integrated connexions to reduce connexion problems</li> <li>Machine parameter program selection for the different product/formats</li> <li>Provide communication interface (Ethernet / SAP) to access production planning and dialog with process.</li> </ul>
Safety	<ul style="list-style-type: none"> <li>Ensure operators safety</li> </ul>	<ul style="list-style-type: none"> <li>Respect Danone WISE- and the local safety regulations.</li> <li>Safety design will be checked by an independent expert and complaints have to be fixed by supplier without extra charge.</li> <li>Protection of all hazard areas</li> <li>All operating and maintenance points must be easily accessible and secured.</li> <li>All special tools necessary to make interventions must be delivered with the machine.</li> <li>Special protection of all areas permitted to maintenance only.</li> <li>Operating Noise should be &lt; 75 db in 1 m from the machine</li> </ul>	<ul style="list-style-type: none"> <li>Visible red emergency stop buttons in all hazard area.</li> <li>Safety loop on doors / openings / protections forbidding access to any hazard area while machine is running: Alarm + Emergency stop if safety loop is opened.</li> <li>A simple Alarm + Stop should not put any person in danger situation: lights, air supplies, handling equipments should not be disabled.</li> <li>Any electrical supply and pneumatic supply must be lockable with padlock</li> <li>Key protection on electric cupboards doors.</li> <li>Code or key protection on machine parameter set-up</li> <li>All external parts of machine should be washable (ex. by water jet) without attempting the security of operators.</li> </ul>

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FUNCTION	SUBFUNCTION	FUNCTIONALITY & REQUIREMENTS	TECHNICAL REQUEST
Ergonomics	<ul style="list-style-type: none"> <li>Optimise problem identification and solving</li> <li>Provide best machine accessibility / ergonomics for maintenance and cleaning purpose</li> <li>See Annex 6 Lean and Ergonomics Guideline</li> </ul>	<ul style="list-style-type: none"> <li>Identification of all electric connexions, coherent with documentation</li> <li>Identification of all machine malfunctioning causes</li> <li>Display of machine parameters</li> <li>Display of alarms</li> <li>Access to all operating functions</li> <li>Easy access to parts requiring operator's intervention (cleaning for example).</li> <li>See documentation and training</li> </ul>	<ul style="list-style-type: none"> <li>Graphical display screen.</li> <li>Alarm code + explicit text description on operating display screen for all machines malfunctioning causes.</li> <li>Machine reset function with re-synchronisation of all stations (after a problem)</li> <li>Provide automatic display of alarm cause (at least with a text)</li> <li>Provide automatic status of preventive maintenance (technical documentation).</li> <li>System is equipped with an Ethernet coupling unit</li> <li>Machine designed with easily interchangeable subsets in order to avoid any risk of prolonged stop of the machine.</li> <li>The production operator must not make efforts requiring a pushing or traction superior to 10 kg.</li> <li>The operator must have the necessary commands to do an operation in manual means close to the place of its realization.</li> <li>All elements handled by the operator must be positioned to ergonomic height.</li> <li>The lubrication of the system (addition of oil, verification of level, etc...) must be accessible without stopping the machine.</li> <li>No false mounting possibilities for preventive maintenance spare parts or for format parts. Clear marks in colour or no. system?</li> </ul>





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**PROCESS**

FUNCTION	SUBFUNCTION	FUNCTIONALITY & REQUIREMENTS	TECHNICAL SOLUTIONS
X - Ray		<ul style="list-style-type: none"> <li>The X-ray must run empty after a controlled stop; no packs are allowed to remain in the machine.</li> <li>The height of the conveyor is in between +900 and +1100 mm from floor level (+0 mm). Together with the conveyor supplier will be determined the exact final height;</li> <li>The way the packs are run through the machine is standing upright for Cans and Eazy Pack.</li> <li>The X-ray must be able to operate at 100% speed immediately after a stop;</li> <li>Supplier has to specify the minimal detection size possible for a contaminant at 100% detection probability, indicating 0% false rejects.</li> </ul>	
	<ul style="list-style-type: none"> <li><b>NECESSARY MATERIALS TO BE DETECTED ARE:</b></li> <li>Ferro (especially Iron, Stainless Steel);</li> <li>Non-Ferro (especially Aluminium);</li> <li>Glass;</li> <li>Dense Plastic</li> <li>Dense Rubber and Bones.</li> </ul>		<p>Scoop detection should not harm the detection limits of the other contaminants.</p>





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FUNCTION	SUBFUNCTION	FUNCTIONALITY & REQUIREMENTS	TECHNICAL SOLUTIONS
	<ul style="list-style-type: none"> <li>DETECTION LIMITS X – RAY.</li> </ul>	<ul style="list-style-type: none"> <li>Detection Limits see table on page 4</li> </ul>	<ul style="list-style-type: none"> <li>Contaminant samples of minimum detection limits have to be supplied together with the machine.</li> </ul>



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FUNCTION	SUBFUNCTION	FUNCTIONALITY & REQUIREMENTS	TECHNICAL SOLUTIONS
		<ul style="list-style-type: none"> <li>• There must not be a difference in detection accuracy between Large and Small packs;</li> <li>• No parts/ positions of the X-ray must be manually changed for a size change. If a certain part does have to be changed, this must be done automatically;</li> <li>• The supplier must specify the maximal conveyor speed running through the machine and the required minimal gap between cans;</li> <li>• If inside a pack a contaminant is detected, the pack has to be pushed out and adequate warning signals must be provided.</li> <li>• After 3 contaminated packs in a row the line has to be stopped and adequate warning signal must be provided.</li> <li>• For validation a procedure must be made by the supplier to check the correct working. The supplier must deliver sample packs who are clearly visible as sample pack and contain the validated contamination. (for all sizes and types)</li> <li>• The supplier must deliver a suitable cabinet near the machine to store the sample packs.</li> <li>• The system must be able to store a fault history and be able to communicate with the line control system.</li> </ul>	

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FUNCTION	SUBFUNCTION	FUNCTIONALITY & REQUIREMENTS	TECHNICAL SOLUTIONS
		<ul style="list-style-type: none"> <li>• Where the machine is supplied as a standalone unit it may not exert levels of radiation above legal limits.</li> <li>• The machine must be delivered fully complying with Local / European law and must have a CE certificate.</li> <li>• The machine may not exert levels of radiation above legal limits.</li> <li>• The rejection pusher must reject a contaminated pack on separate rejection conveyor or a lockable box or container. On this conveyor space for at least 8 packs should be available. When this conveyor is full, the line should stop.</li> </ul>	
	<p><b>ACCESSIBILITY &amp; HANDLING</b></p>	<p>Every part of the machine can be</p> <ul style="list-style-type: none"> <li>• reached in ergonomics way by a person</li> <li>• with a height between 100 - 150 cm.</li> <li>• Good accessibility for cleaning and maintenance.</li> </ul>	

WA

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FUNCTION	SUBFUNCTION	FUNCTIONALITY & REQUIREMENTS	TECHNICAL SOLUTIONS
Performance needs	<b>FULLFILL CAPACITY NEEDS</b> <ul style="list-style-type: none"> <li>Machine parts designed for intensive use: 24h a day, 7 days a week, 52 weeks</li> <li>Annex 8 ( Acceptance procedure)</li> </ul>		<ul style="list-style-type: none"> <li>Use decentralised network architecture with field BUS and</li> <li>Integrated connexions to reduce connexion problems.</li> <li>Machine parameter program selection for the different product/formats</li> <li>Provide communication interface (Ethernet / SAP) to</li> <li>Access production planning and dialog with process.</li> </ul>
Data Records	<b>STORING OF FAULTY IMAGES</b> <ul style="list-style-type: none"> <li>Each faulty image is stored</li> <li>Image analysis possible</li> <li>Shape detection possible</li> <li>Link with other control machines e.g. optical; infrared or systems e.g. ERP is possible</li> </ul>		Image Library Purge can transfer images to a windows desktop PC. Simulators can be run off-line for Image Analysis. Digital IO for a range of functions. ProdX over Ethernet. OPC over Ethernet. Barcode Scanner over RS232 or USB.
	<b>FULLFILL MAINTENANCE AND PRODUCTION OPERATORS NEEDS</b>	<ul style="list-style-type: none"> <li>Compliance with national regulation.</li> <li>For operation only supervision is required.</li> <li>Compliance with factory standards</li> <li>See Annex 9 Component list and</li> <li>Annex 10 Factory Component Standards</li> </ul>	



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<b>FUNCTION</b>	<b>SUBFUNCTION</b>	<b>FUNCTIONALITY &amp; REQUIREMENTS</b>	<b>TECHNICAL SOLUTIONS</b>
Belts	PRODUCT TRANSPORT	• Advice on belt design via supplier	

**DEVICE LIST & INSTRUMENTATION:**

see Annex 9 – Component list

**PARTS LIST FACTORY:**


See ANNEX 10 ( not always available )

**BIBLIOGRAPHY/REFERENCES:**

CODE	VERSION NUMBER	DATE OF ISSUE	TITLE
• DBN-GU-LEA-001_LEAN			▪ DBN-GU-LEA-001_LEAN Engineering_V5
• DBN –GU LOT 001			▪ LOTO Engineering Guideline
• Construction Safety guidelines			
• Local Contractor Safety Program			





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**ANNEXES:**

Annex 1: Drawing

Annex 2: Non Conformities


**NONE CONFORM PRODUCTS:**

- Product losses
  - Products not get damaged or dirty when passing the machine
  - No Contaminants according above list passing the machine undetected
- < 0,0 %

Annex 3: Material Specs/ Drawings

On request




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**Annex 4: Documents to be received**

FILE	CONTENT		DELIVERY TIME
MINTENANCE	General Information	<ul style="list-style-type: none"> <li>• general plans and peripheral establishment with the positioning of the various subsets of the machine, dimensions, openings and obstructions reserved for technical interventions</li> <li>• description of all functions of the system</li> </ul>	Full layout of equipment with utility requirements must be provided within four weeks from an order confirmation
	Mechanical	<ul style="list-style-type: none"> <li>• diagram showing the location of all parts mounted in the machine (with diagrams or cross-sections of all parts with its reference number)</li> <li>• complete specification of all (elements) parts used in installation (no. of elements, producer, etc.)</li> <li>• complete list of spare parts (for one year of operation of the machine – parts of which the replacement is considered, either because of a fair wear and tear, or because of accidental damage) with manufacturer name and price</li> <li>• Main drawings, lay-out, equipment, from 3 sides, details assembly drawings of main units</li> </ul>	Before provisional acceptance Final version of documentation – before definitive reception however not later than two months after provisional acceptance
	Electrical	<ul style="list-style-type: none"> <li>• electrical drawings (printed on paper and saved on CD in AutoCAD – DWG / DXF)</li> <li>• diagrams of power, control and indication.</li> <li>• diagrams of terminals and all connections *</li> <li>• diagrams of wiring inside each cupboard.</li> <li>• schematic diagram of the installation *</li> <li>• diagram with localization of all sensors, terminals and actuators (inside and outside of electrical enclosure) *</li> <li>• complete specification of all (elements) parts used in installation (no. of elements, producer, etc.)</li> <li>• complete list of spare parts (for one year of operation of the machine – parts of which the replacement is considered, either because of a fair wear and tear, or because of accidental damage) with manufacturer name and price</li> <li>• detailed description of all frequency converters, photo cells, detectors</li> </ul>	Before provisional acceptance Final version of documentation – before definitive reception however not later than two months after provisional acceptance
	Automation	<ul style="list-style-type: none"> <li>• Programme comments will be in English</li> <li>• Detailed explanation of the structure of the program.</li> <li>• list of the in/out signals with mnemonic *</li> <li>• tables of assignment of bits, meters and temporization</li> </ul>	Before provisional acceptance Final version of documentation – before definitive reception however not later than two months after provisional acceptance

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	<ul style="list-style-type: none"> <li>listing of the values of meters and temporization</li> <li>program of the machine, graphical terminals etc. saved on CD (spare program)</li> <li>list of the messages appearing on terminal display *</li> <li>PLC program listing and Panel view documentation,</li> <li>Complete specification of all (elements) parts used in installation (no. of elements, producer, etc.)</li> <li>complete list of spare parts (for one year of operation of the machine – parts of which the replacement is considered, either because of a fair wear and tear, or because of accidental damage) with manufacturer name and price</li> </ul>		
Pneumatic	<ul style="list-style-type: none"> <li>pneumatic and hydraulic diagrams (drawings) *</li> <li>diagram of the circuits of lubrication and points of greasing *</li> <li>Complete specification of all (elements) parts used in installation (no. of elements, producer, etc.)</li> <li>complete list of spare parts (for one year of operation of the machine – parts of which the replacement is considered, either because of a fair wear and tear, or because of accidental damage) with manufacturer name and price</li> </ul>		Before provisional acceptance (Final version of documentation – before definitive reception however not later than two months after provisional acceptance
Manual instruction for maintenance	<ul style="list-style-type: none"> <li>Checklists of the adjustment check operations, greasing with the procedures.</li> <li>summary table of the adjustments (all machines parameters)</li> <li>overall plans defining the position of the pneumatic and electric devices *</li> <li>list (procedures) of activities: preventive, predictive, curative with suggested time intervals</li> <li>written explanations how to facilitate the operations of assembly, disassembling and adjustments</li> <li>list of all additional tools needed for maintenance</li> <li>LOTO isolation sheet will be delivered and agreed with DBN during design phase</li> </ul>		With delivery of all the equipment Final version of documentation – before definitive reception however not later than two months after provisional acceptance
General information	<ul style="list-style-type: none"> <li>General establishment of the machine revealing the positioning of the various subsets and a simple description of their operation.</li> <li>Presentation of each subset: simplified functional diagrams.</li> <li>functional description of the control desk (pulpit)</li> <li>Description of the security systems and security instructions.</li> </ul>		Not later than one week since visit confirmation for SAT
Operational handbooks	<ul style="list-style-type: none"> <li>Detailed description of the operations of the machine (starting, control, stopping, cleaning etc..)</li> <li>checklist of controls, and small adjustments that can be made by machine operator,</li> <li>checklist of the malfunctions (incidental, breakdowns...) and detailed description of the methods for</li> </ul>		Not later than one week since visit confirmation for SAT







# SPECIFICATION

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solving these malfunctions.

VL

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### Annex 5: Training

#### Training animation:

The sessions have to be animated by a dedicated person.

The training must be in English language.

The training will be done at supplier and at Danone site.

The training program must to be adapted to the trained teams:

- Production operators
- Electro-mechanicals
- Maintenance people.

The training has to cover theoretical and practical aspects.

#### Training electrical and mechanical technician:


The objective is to train the maintenance team from Danone autonomous on the mechanical points, automation, instrumentation as well as the utility networks for the good working of the machine. A clear instruction on LOTO - isolation and - procedures is part of the training for production & maintenance people.

- Supplier must provide a clear agenda of the training.
- Number of person per group of training will be maximum XX
- Number of person to be trained in production area : XX
- Number of person to be trained in maintenance area : XX

Following agenda have to be reviewed within the parties before PO.

- a) PRODUCTION: 1 training day to operate the machine accompanied
- Knowledge of the general characteristics of the machine

*W*

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- Knowledge of XXX
- Knowledge of XXX and first maintenance level
- Operating of the machine
- Breakdowns and security management

b) MAINTENANCE: 4 hours split in two parts

Mechanical part: 2 hours


- Knowledge of the general characteristics of the whole equipment
- Knowledge of XXXX
- Knowledge of XXX
- Assembling and dismantling of subsets
- Help to make a good diagnosis, to improve the repairs time

Electrical part: 2 hours

- Knowledge of the program
- Knowledge of XXX principle to allow its adjustment and its maintenance
- Maintenance of the equipment
- Explanations for the knowledge of electrical and automation parts (electric diagram, program,

KL



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- In terms of safety, all contractors must comply with The Danone Contractor Construction Safety Program. A copy of this program is available upon request. This policy must be strictly followed and will be enforced.
- All supplied equipment and service by The Supplier complies with European Community rules, or Local rules in the case Local rules are more restricted than European Community.
- The supplier must follow the safety guideline from FM Global. Approved components can be found on [www.approvalguide.com](http://www.approvalguide.com) (free access with E-mail and password)

a. Lean & Ergonomics Guideline ( see sep. Annex 6 A)



Lean Engineering  
Guidelines v6 2009. pr


b. LOTO Guideline ( see Example below and sep. Annex 6 B)



DBN-GU-LOT-003\_V3  
July 2012.pdf

- Supply a one page description ( with pictures ) describing LOTO procedure.  
See following Example:

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Loto Sheet.doc


**Annex 7: Signal List ( see sep. Annex if applicable )**

**Annex 8: Acceptance Procedure**

**Validation procedure for new processes/ systems**

For new systems, all steps of the so-called V-scheme (see Figure 1) should be followed. The different steps of the scheme are explained below.

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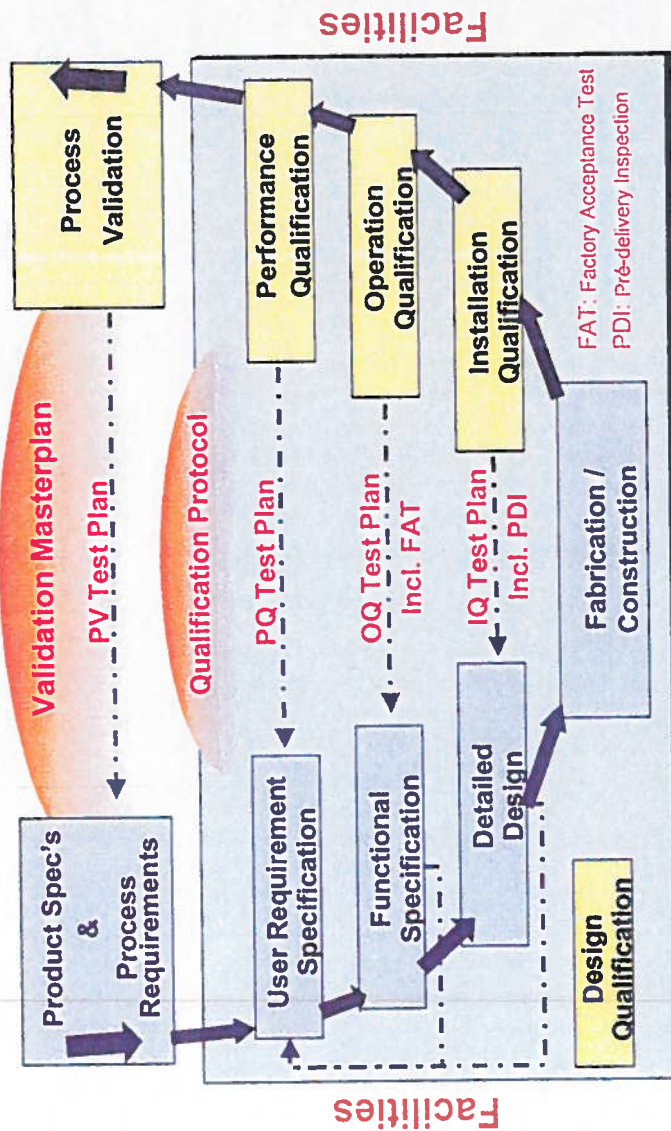



Figure 1- V-scheme of validation process- source: W. van Gerwen, 2006

In preparation for the purchase of new equipment or systems, **Product Specs and Process Requirements** are defined (e.g. viscosity range, batch size). Based on these inputs, the **Technical Specification** is composed, outlining what the new equipment or system is required to do e.g. capacity, process requirements, the environment in which the system must operate – equipment constraints, maintenance, testing and support. The Spec. will contain the acceptance criteria for the Performance Qualification. The Spec. must contain the critical process parameters and control parameters. After approval of the Spec, the **Final Functional Technical Spec** is written. The FTS defines which functions the new equipment or system should perform in order to meet the requirements of the URS.

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After approval of the FTS the **Detailed design** of the new equipment or system can be prepared. Documents like Process and Instrument Diagrams, Equipment sheets and Electrical Connection Schematics are created.

Documents generated in the design phase are continuously checked for compliance to requirements in the FTS and then approved. This process of checking and approving in the design phase is called **Design Qualification (DQ)**. When the DQ has been completed, the **fabrication or construction** phase starts.

Before the new equipment or system is delivered to the production facility, a final check of the equipment at the manufacturer takes place. Any observed deviations or defects could be fixed before it is delivered at the premises. This is also called a **pre delivery inspection**.

During installation and commissioning at our premises, it is verified step-by-step whether the system and equipment comply with the detailed design, the FRS and the URS. All qualifications are done according to **Test Plans** and by using checklists.

First of all, **Installation Qualification (IQ)** takes place. It is verified that systems and equipment as installed, comply with the approved design; e.g. are valves correctly installed? Do pumps rotate in the right direction? Are utilities are connected correctly? Was the correct construction material used?

All observed deviations are documented and corrective actions are taken to correct them.

At this phase also operating instructions are collected / compiled and requirements as to maintenance and calibration should be determined in cooperation with supplier.

Before proceeding from IQ to OQ for example, one should assess whether all items required for a proper functioning of the system are correctly installed, all open issues should be documented and one must see to it that these issues are resolved.

When all items required to operate the system are correctly installed, separate functions of the system as described in the FTS are checked in the **Operation Qualification (OQ)**; e.g. Does the temperature increase when it should? Do alarms work?

This phase usually includes test runs with a simulant like water, related to foreseen processes (usual operation conditions) and "worst case scenario". The compilation of the corresponding operation-, cleaning-, calibration and maintenance instructions should be completed.

After approval of the OQ, it is verified if the systems, equipment and facilities, as connected together can perform effectively and reproducibly, based on the approved method and specification. During this **Performance Qualification (PQ)**, it is checked whether the critical requirements as defined in the FTS are met. During PQ trials are conducted applying the foreseen raw materials, packaging materials etc. The test runs cover routine operation conditions and as well defined worst case conditions (i.e. operation at upper and lower limits).


The final step is **Process Validation**. For this stage the steps outlined in Part 1 of this document should be followed.

The different steps of the validation process must be performed in the following order: DQ, IQ, OQ and / or in combination with PQ and finally Process validation.

However, experience shows that this is not always possible due to time constraints and **certain stages may need to be combined**

### **8-1. ACCEPTANCE PROCEDURE: to refer to the FAT – SAT documents**



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**8-1-1. FACTORY ACCEPTANCE TEST (FAT – Pre Delivery Inspection):**

- It will be done on supplier's workshop and carried out to check all compliances according to technical specification.
- There will be a written acceptance report, with possible reservations agreed by both parties, which must be completed before provisional acceptance.
- Forwarding of the machine to the factory of destination will not take place without agreement of Danone representatives.
- Supplier must inform Danone about the possible date of visit conformity at least 2 weeks earlier.
- Machine can not be shipped without signed FAT document from both sides.


**8-1-2. PROVISIONAL ACCEPTANCE TEST (SAT – Operation Qualification): (validation time during 4 hours)**

- Submitted to the request of Danone's project manager.
- The line is ready for industrial production.
- The line is in nominal capacity condition.
- The training defined in the line project is performed.
- If all the criterions required in the specifications are not fulfilled, a punch list will be written.
- If the provisional acceptance is not validated, the provider will make modification and advise to repeat tests.
- Minimal performances must be measured over a period of one eight-hour shift.
- Danone must provide all packing materials and products that are necessary to make test.
- On request, the machine can be led during tests by operator of the provider, under the normal conditions of operation.

**Provisional acceptance conditions:** during 1 shift continuous production of maximum 3 products

- Flawless working of the software (no manual actions required)
- No product losses due to installation failure (mechanical or software failure) in the new installation or in the installations affected.
- No repetitive failures
- Hygienic execution must be 100% done and installation must be leak free

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- No Production time losses. (OE breakdown mandatory)
- Punch list made based on specification, execution and performance and KPI's and signed by both parties.
- Punch list elements value must be lower than the pending payment (As element is understood the complete equipment where the problem is).
- Training to users (Operators & maintenance) done with the required documentation.
- Provisional documentation delivered.
- Microbiological results conformity (food safe production possible)
- The suppliers must provide as part of the offer an estimation (+/- 25% accurate) of the testing product that is needed to reach the approved provisional acceptance.

### **8.1.3. DEFINITIVE ACCEPTANCE TEST (SAT – Performance Qualification): (validation time during 8 hours)**

- Made maximum 4 weeks after the provisional acceptance and submitted to the request of Danone's project manager. Between the provisional acceptance test and the final acceptance test continuously start up support should be available. The exact amount and profession of people during the start have to be defined after the provisional acceptance, depending on the results.
- The technical reception will be done during a normal production cycle and the filling line should be in operation at least one hour before starting the validation time.
- The technical efficiency of the machine is at 99.5 % at nominal capacity. **The installation is completely finished.**
- If the definitive acceptance is not validated, the provider will make modification and advise to repeat the test.
- Final documentation and spare parts are delivered. All the criterions required in the specifications are fulfilled (lifting of all the written reservations).


#### Final acceptance conditions:

- Conditions of provisional acceptance are maintained
- No repetitive software errors.
- No product losses due to installation failure (mechanical or software failure) in the new installation or in the installations affected higher than
- Punch list is closed: no open points pending.
- Final documentation has been fully delivered.
- The Danone specifications and requested parameters are fully respected.

At the end of each step an Acceptance Document will be signed by both parties. With the Provisional Acceptance Test the official punch list will be agreed by both parties.





		SPECIFICATION		RESTRICTED CIRCULATION	
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The decision to proceed with the Test belongs to Danone project team when it is considered that it would be successful.

Cleaning validation: with specific focus on allergens where common installation/lines will be clarified later. Cleaning validation will be performed by means of bacteriological tests, carried out by Danone.

**8-2 Acceptable limit for losses:** to be validated by trials inside Danone's factory

- There should be no product losses caused by X Ray machine..

Annex 9: Component List ( see sep. Annex if applicable )

Annex 10: Parts List Factory ( see sep. Annex if applicable )

Annex 11: Others

