

Data logging and data extractions

Contribute to maintenance of DS/EN ISO 13485:2016

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Basic data	Incl	Uniformity data	Incl	Safety data	Incl
No. of units produced for every batch	✓	Time for each function doing a full cycle: <ul style="list-style-type: none">• Contact airtime• Forming airtime• Vacuum time• Total Forming time• Sealing time	✓	Unique login on the machine: <ul style="list-style-type: none">• Supervisor login: create users and control access level• Manager login: change parameters on the machine (time, pressure, temperature, amount etc.)• Operator login: to run the machine (cannot change any parameters)	✓
Operator credential	✓	Pressure for each function doing a full cycle: <ul style="list-style-type: none">• Max & min pressure doing the forming process• Max & min pressure doing the sealing process	✓	Quality control for produced material <ul style="list-style-type: none">• Reject blisters which are parametrically out of range	✓
Batch number for the following: <ul style="list-style-type: none">• Product• Material• Tooling	✓	Temperature for each function doing a full cycle: <ul style="list-style-type: none">• Max & min temp. doing the forming process• Max & min temp. doing the sealing process	✓	Secure correct tooling for machine set-up: <ul style="list-style-type: none">• Scan labels, product and material for batch number control• Optional. <i>Can be included at additional cost</i> Data extraction: <ul style="list-style-type: none">• Simple data extraction by USB or similar means• Service Module: Data extraction and transfer through Laan access point set-up for your online access. Option also available for TN login for service, assistance, and software update by telecommunication/control of the machine• Optional. <i>Can be included at additional cost</i>	⊖ ⊖

⊖ Marks an Optional Feature to machine at an *additional cost*