DISTRIBUTOR MEETING 2017

Stenungsund October 12-13

Quality assurance activities at LabRobot

- For better products and satisfied customers

Jimmy Kjellén, Quality Manager

– A PART OF AddLife

Quality Assurance at LabRobot


QUALITY CERTIFICATE

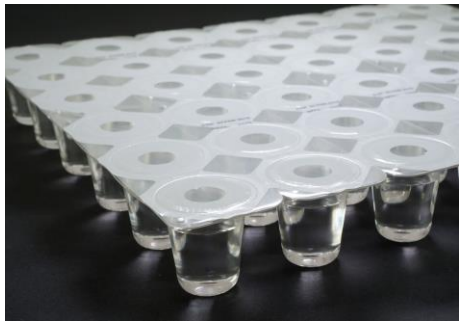
Product: DILUCUP® ELEGANCE – MRD x.x mL

Batch: xxxx

Expiry date: dd MÅN ÅÅÅÅ

Article: 40DEMRDx

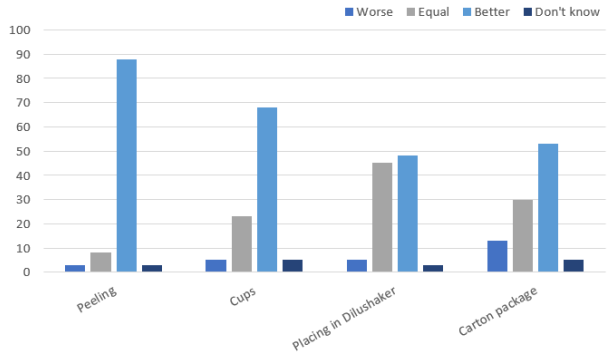
Dilucup System

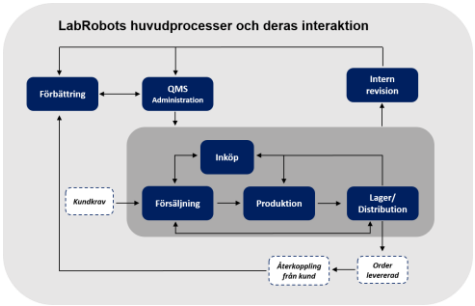




ISO 9001:2015







Lab Robot Dilucup Serial Dilution System™

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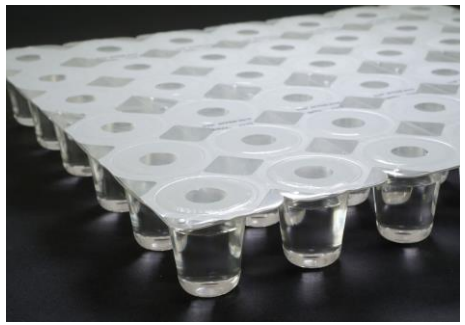
Quality Control of

Dilucup™ ELEGANCE

PHYSICAL/CHEMICAL EVALUATION OK? ☑

MICROBIOLOGICAL EVALUATION OK? ☑

Issue certificate and release batch →



LabRobot Dilucup Serial Dilution System

SP Certified ISO 9001

QUALITY CERTIFICATE

Product: DILUCUP® ELEGANCE – MRD x.x mL

Batch: xxxx

Article: 40DEMRDx Expiry date: **dd-MÅN-åååå**

The expiry date is 20 months from production date when Dilucups are kept in the sealed aluminium package at +2ºC to +25ºC.
Once the aluminium package is opened Dilucups must be kept dry at +2ºC to +8ºC and be used within 2 months.

Medium formula
Buffered solution containing
NaCl 0.85%, Peptone 0.1% and de-ionized water (according to EN ISO 6887-1:1999).

pH
Adjusted to 7.0 ± 0.2 at 25°C (according to EN ISO 6887-1:1999).

Sterilization
E-Beam dose: >25 kGy.
Sterility control shows < 1 CFU/mL after radiation.

Volume control
Target volume is x.x mL.
Density at 20°C: 1.004 which means that 9.0 mL= 9.04 g.
Accepted deviation < ± 2% (according to EN ISO 6887-1:1999).
Minimum measured deviation: x.xx %
Maximum measured deviation: x.xx %.

Productivity
Verified with *E. coli* strain WDCM 00012 and *S. aureus* strain WDCM 00034 (according to EN ISO 11133:2014).
Results for this batch: *E. coli* X %, *S. aureus* X %.

Volume, pH, sterility & productivity certified by:

Month dd, åååå

Namn
Quality manager

Warranty:
Warranties arising in connection with the use of the products where such liability results from the actor omission of LabRobot Products AB shall be limited to the free replacement of the product(s) in question.
For sterility guaranty, please refer to our ***Sterility Test Procedures in Dilucup Production PLR02-0501***

LabRobot Products AB – SWEDEN
www.labrobot.com

B06-0701a / 2017-03-15

Quality Control of Dilushaker III



Software OK?
LED panel OK?
Foot pedal OK?
Power supply OK?
Stability OK?
RPM OK?
Aesthetics OK?

Issue certificate and release

QUALITY CERTIFICATE

Product: Dilushaker III digital
Product number: 40DS42PRXT
Serial number: xxxxxx
Firmware version: Skak 42:14

TECHNICAL SPECIFICATIONS
Motor: PAPST VD-3-43.10
Speed: 400 rpm ~ 600 rpm ±5%
Mains: AC 100-240 V 50/60 Hz
Dimensions: LxWxH 345x260x118 mm
Weight: 5,4 kg

This instrument was released by Quality Control after a full check of the following criteria. All criteria satisfied the requirements as defined in LabRobot| Procedures.

Foot pedal function.
Speed. *The instrument used to measure this criterion was calibrated and met the LabRobot standards of traceability. The measures are traceable to international standards, i.e. COFRAC or DKD.*
Measurement results:

Speed	*Value*	*Value displayed*
1	*400 rpm*	*xxx rpm*
2	*500 rpm*	*xxx rpm*
3	*600 rpm*	*xxx rpm*

Time.
Stability.
Appearance.
Power supply.

Issued on: Month dd, åååå.

Certified by:

Namn
Quality Manager

Warranty:
Warranties arising in connection with the use of the products where such liability results from the actor omission of LabRobot Products AB shall be limited to the free replacement of the product(s) in question.

LabRobot Products AB – SWEDEN
www.labrobot.com

806-0702b / 2017-01-09

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Quality Control of

Dilucup™ ELEGANCE

PHYSICAL/CHEMICAL EVALUATION

PRE PRODUCTION

- pH control of product
- Weight and volume dispensed in cups

DURING PRODUCTION

- Weight and volume dispensed in cups
- Tearing test
- Peeling test
- Vacuum control
- Aroma test (MRD only)
- Print (label) inspection

POST PRODUCTION

- pH control of product
- Weight and volume dispensed in cups
- Vacuum control
- Peeling test

Lab Robot Dilucup Serial Dilution System™

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Quality Control of Dilucup™ ELEGANCE

MICROBIOLOGICAL EVALUATION

Test	Why?	When?	QC limits
Contamination test	To determine initial and final microbiological load	Before and after sterilization	< 50 CFU/ml before sterilization < 1 CFU/ml after sterilization
***Bacillus pumilus* test**	To determine efficiency of sterilization	After sterilization	< 1 CFU/ml
Productivity test	To ensure that Dilucup solution doesn't affect growth of microorganisms (*E. coli* and *S aureus*)	After sterilization	< 30 % difference between sample t_0 min and t_{45} min

Lab Robot Dilucup Serial Dilution System™

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Interior of Quality Control Lab





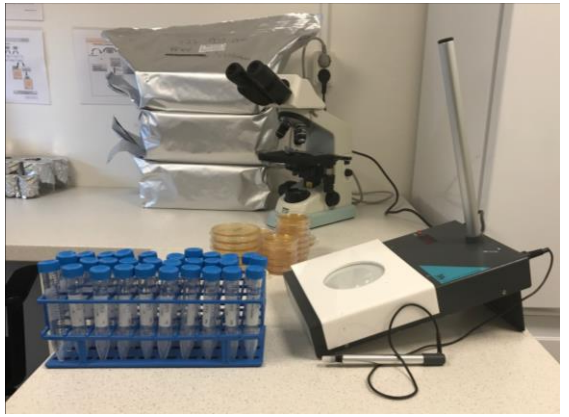












Lab Robot Dilucup Serial Dilution System™

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Interior of Clean Room









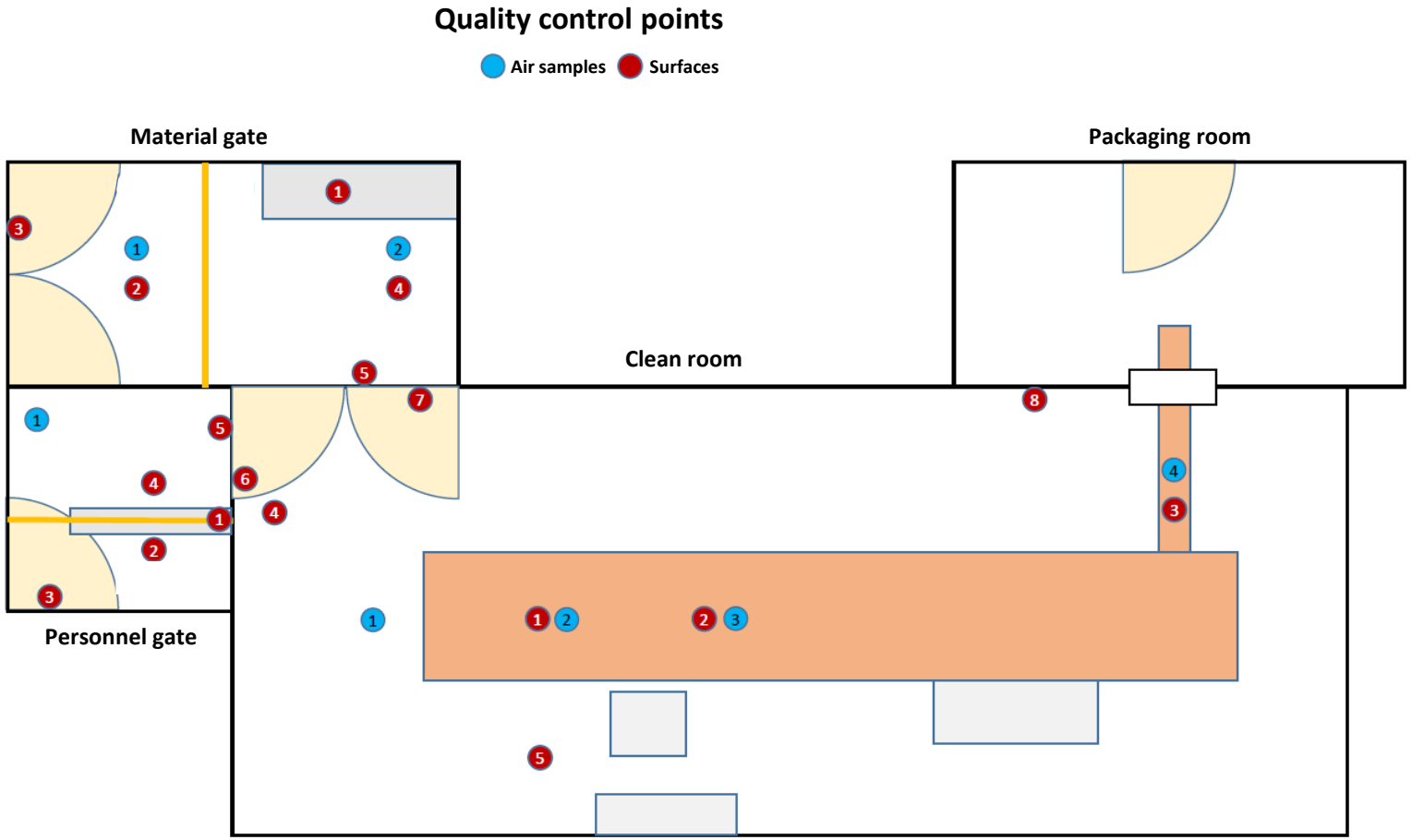




Lab Robot Dilucup Serial Dilution System™

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Quality Control Clean Room



Contact plates for surface sampling



Regular plates for air sampling



Lab Robot Dilucup Serial Dilution System™

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Feedback from distributor meeting 2015

Comments on meeting venue and content

- Location for meeting 100 %
- Presentations 83 %
- Length of meeting 93 %
- Overall experience 93 %

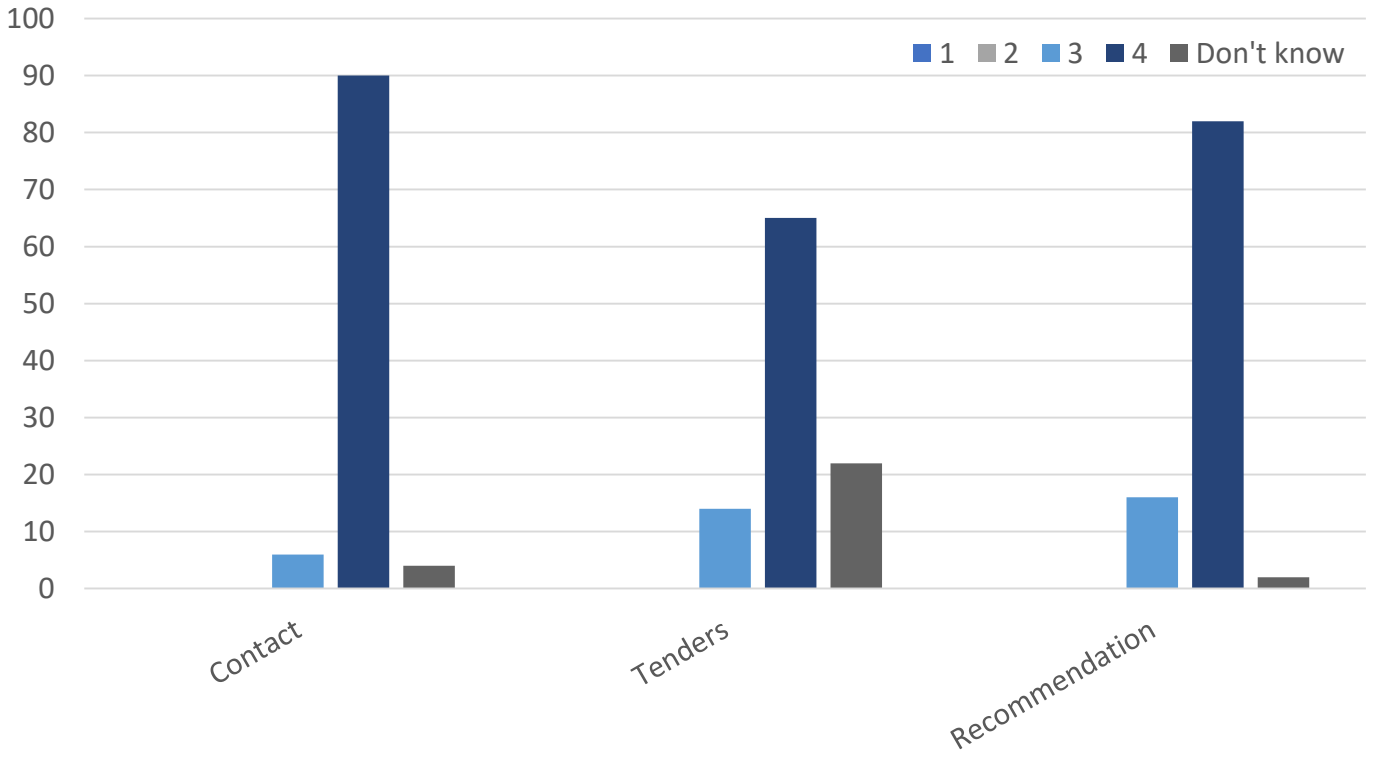
Suggested improvements for 2017 meeting

- Sharing of success and failure stories among participants (presentations)
  - Customers in new areas?
- More hands-on information concerning new products/change to products
- More dialogue regarding customer applications and ”exotic” customers

Customer Survey 2017

- Survey sent to 117 customers and distributors
- Questions on customer views on:
  - LabRobot as supplier
  - Ease of use of the Dilucup system
  - Quality of the Dilucup system
  - Delivery quality
  - Products and services
  - Customer service
  - ISO 9001/14001
  - Dilucup Elegance
- Rating from 1 (lowest) to 4 (highest)

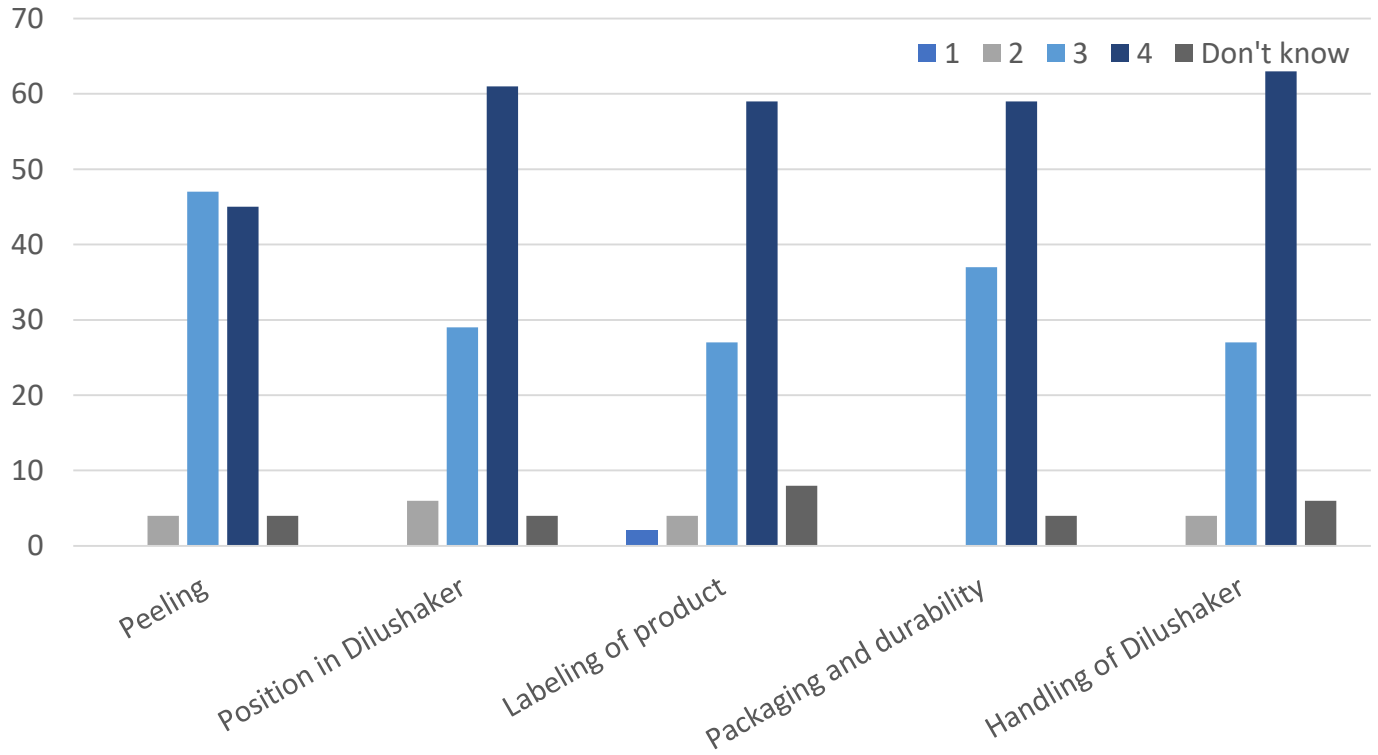
Customer Survey 2017
- LabRobot as supplier



	Average	
Question	**2017**	**2015**
Total	3.9	3.6
Contact	3.9	3.8
Tenders	3.8	3.4
Recommend LabRobot	3.8	3.7

LabRobot is generally highly regarded among customers

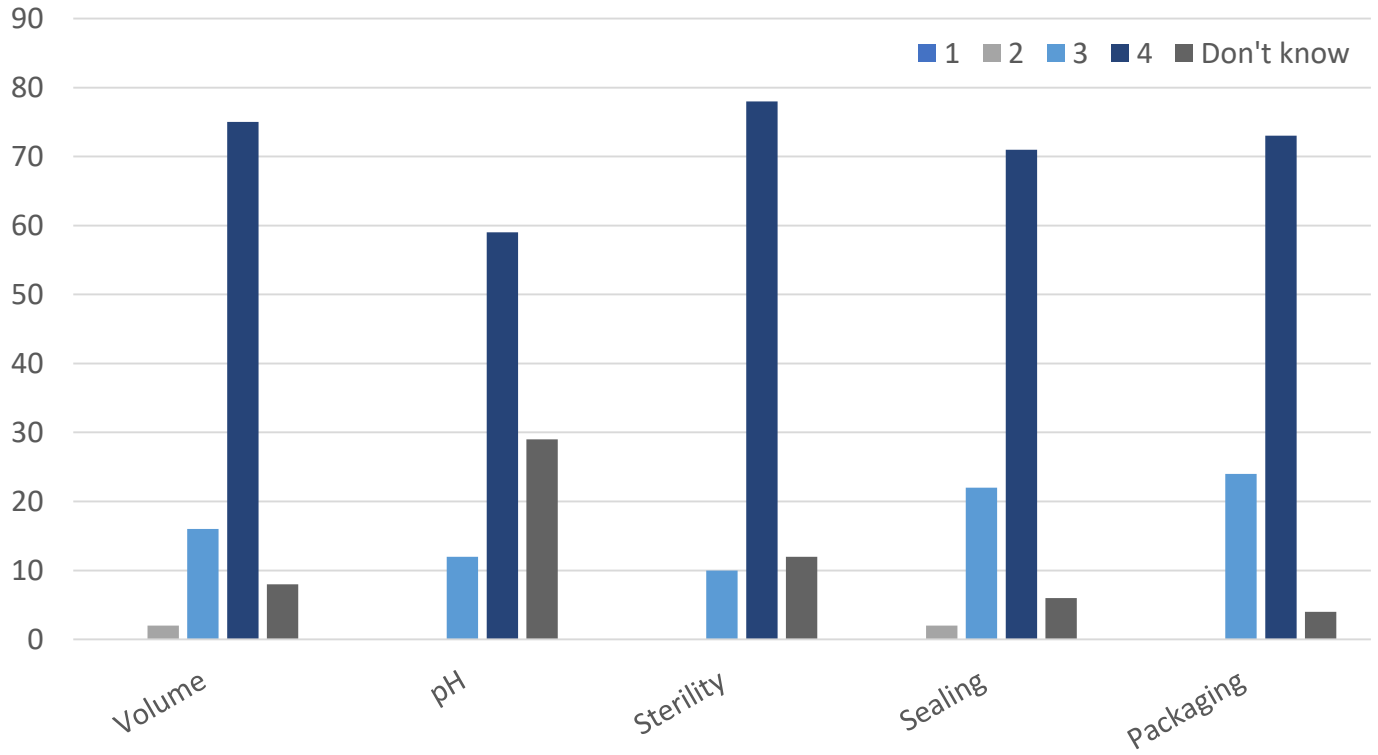
Customer Survey 2017
- Ease of use of the Dilucup system



	Average	
Question	**2017**	**2015**
Total	3.6	3.3
Peeling	3.4	2.8
Position in Dilushaker	3.6	3.2
Labeling of product	3.6	3.5
Packaging and durability	3.6	3.6
Handling of Dilushaker	3.6	3.3

- **Dilucup System generally percieved as easy to handle**
- **Experience of peeling has improved**

Customer Survey 2017
- Quality of the Dilucup system



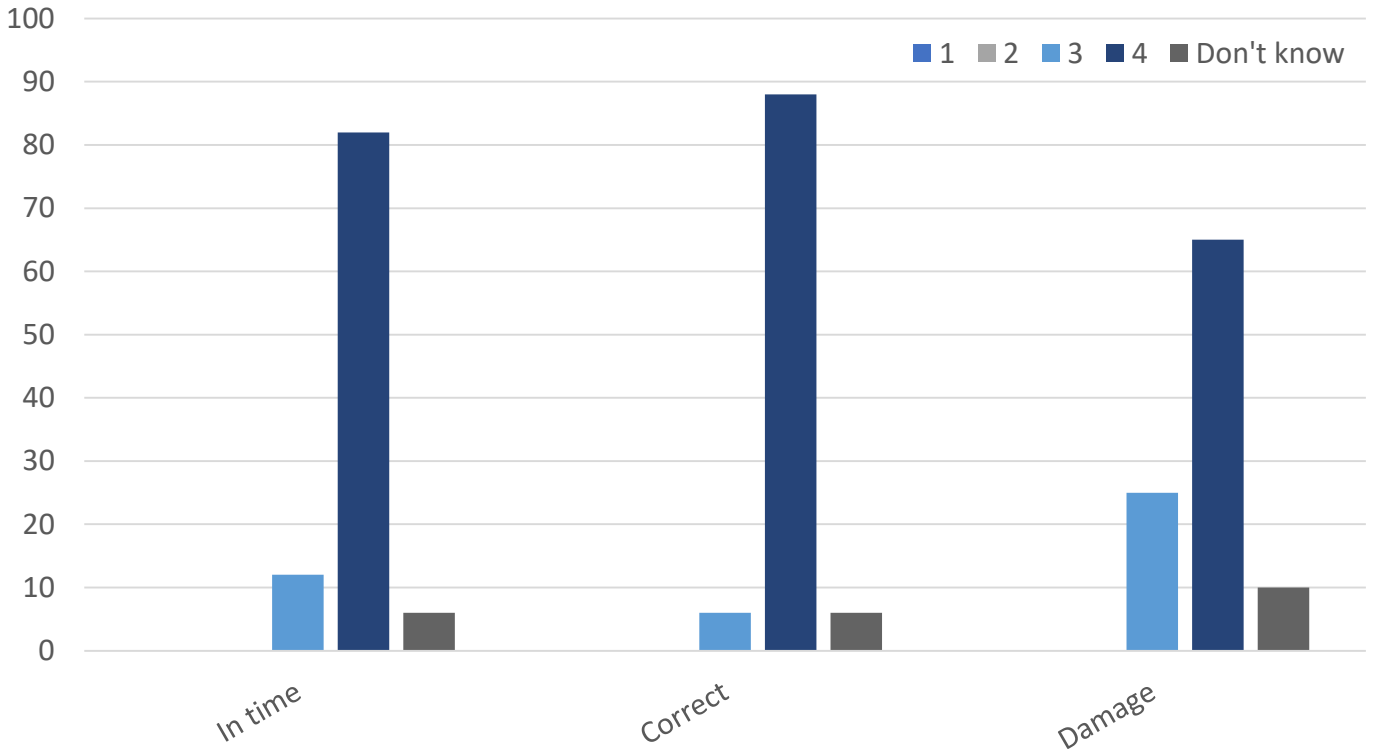
	Average	
Question	**2017**	**2015**
Total	3.8	3.8
Volume	3.8	3.8
pH	3.8	3.9
Sterility	3.9	3.8
Sealing	3.7	3.5
Packaging	3.8	3.8

- **Overall good customer impression of quality**
- **Sealing of cups has improved**
- **Many customers do not measure pH**

Lab Robot Dilucup Serial Dilution System™

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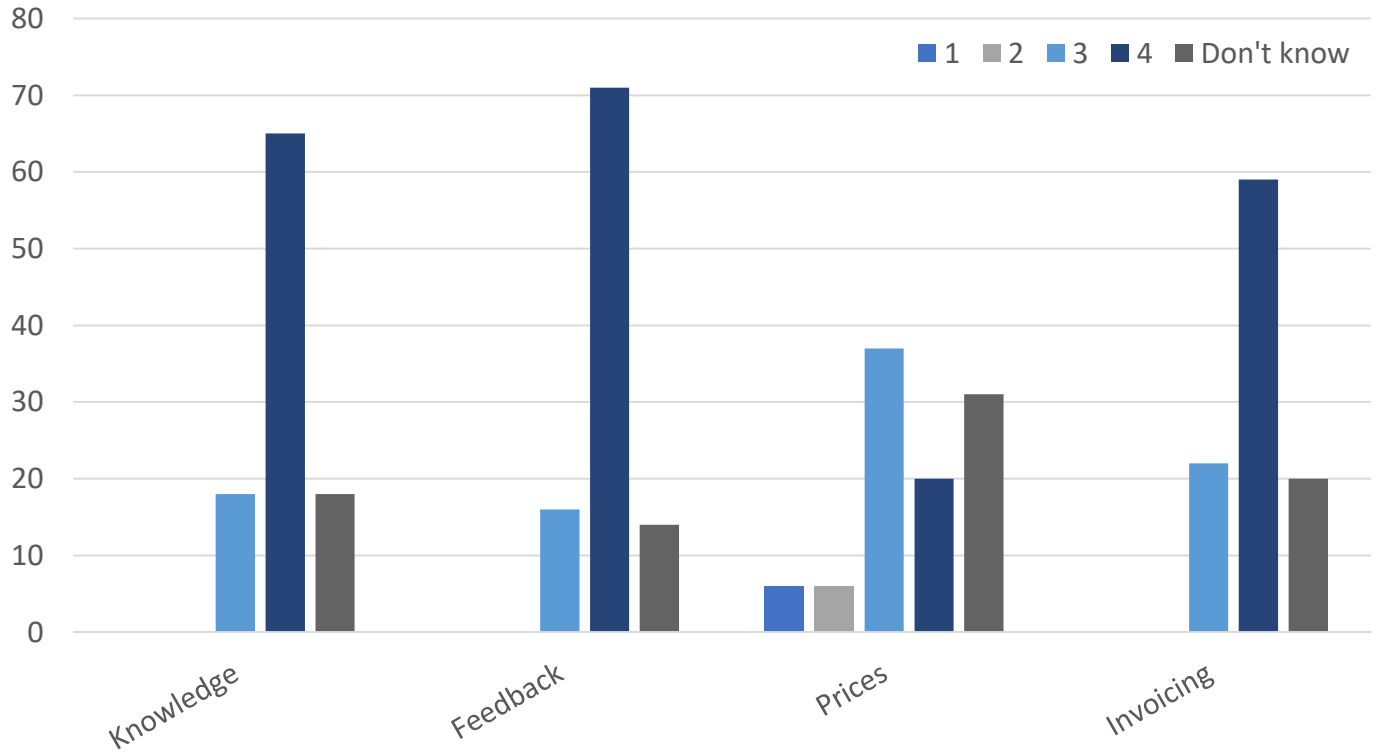
Customer Survey 2017
- Delivery quality



	Average	
Question	**2017**	**2015**
Total	3.9	3.7
In time	3.9	3.8
Correct	3.9	3.8
Damage	3.7	3.6

Good delivery time, but still some problems with damage during transportation (improved routine in place for increased traceability, integration with online system)

Customer Survey 2017
- Products and services

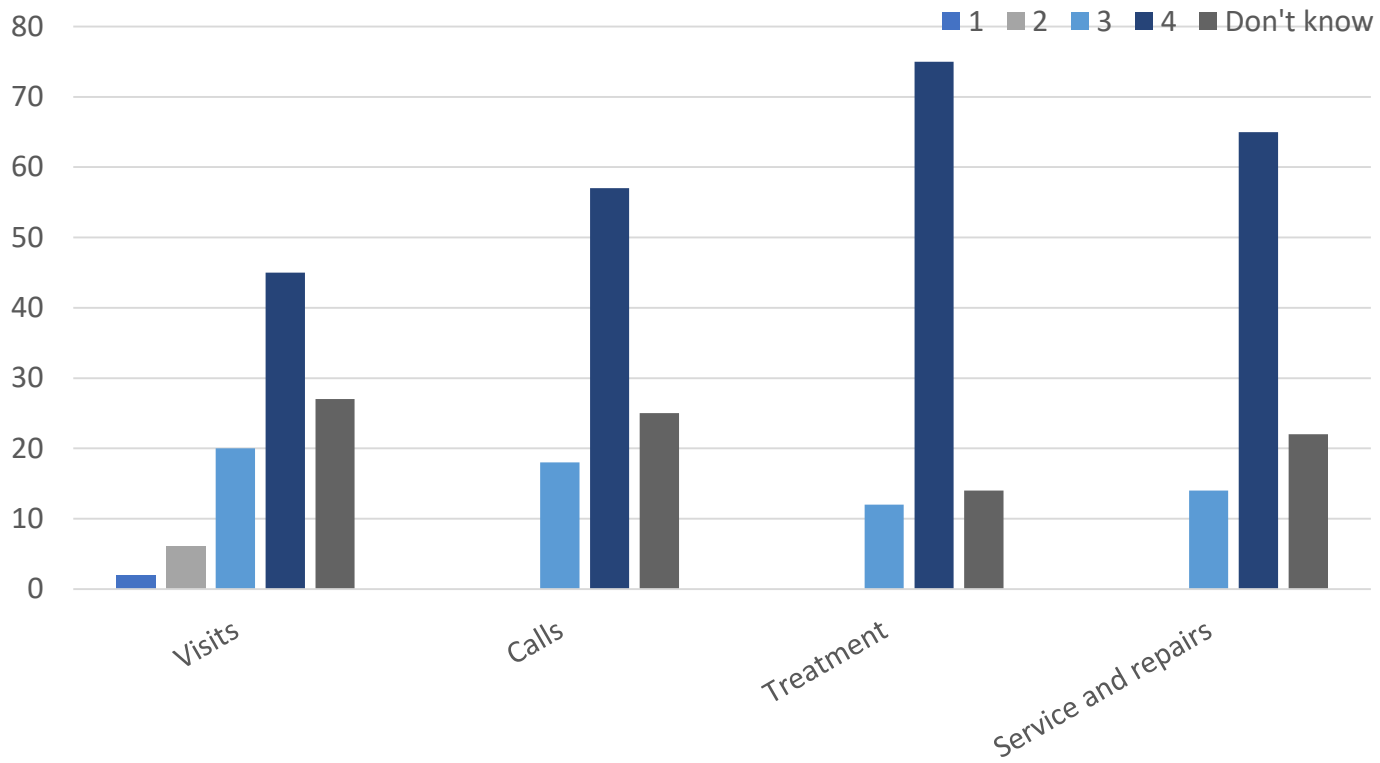


	Average	
Question	**2017**	**2015**
Total	3.6	3.5
Knowledge	3.8	3.6
Feedback	3.8	3.8
Prices	3.0	2.9
Invoicing	3.7	3.5

Increased customer satisfaction in three out of four categories, even when it comes to prices! ☺

Customer Survey 2017

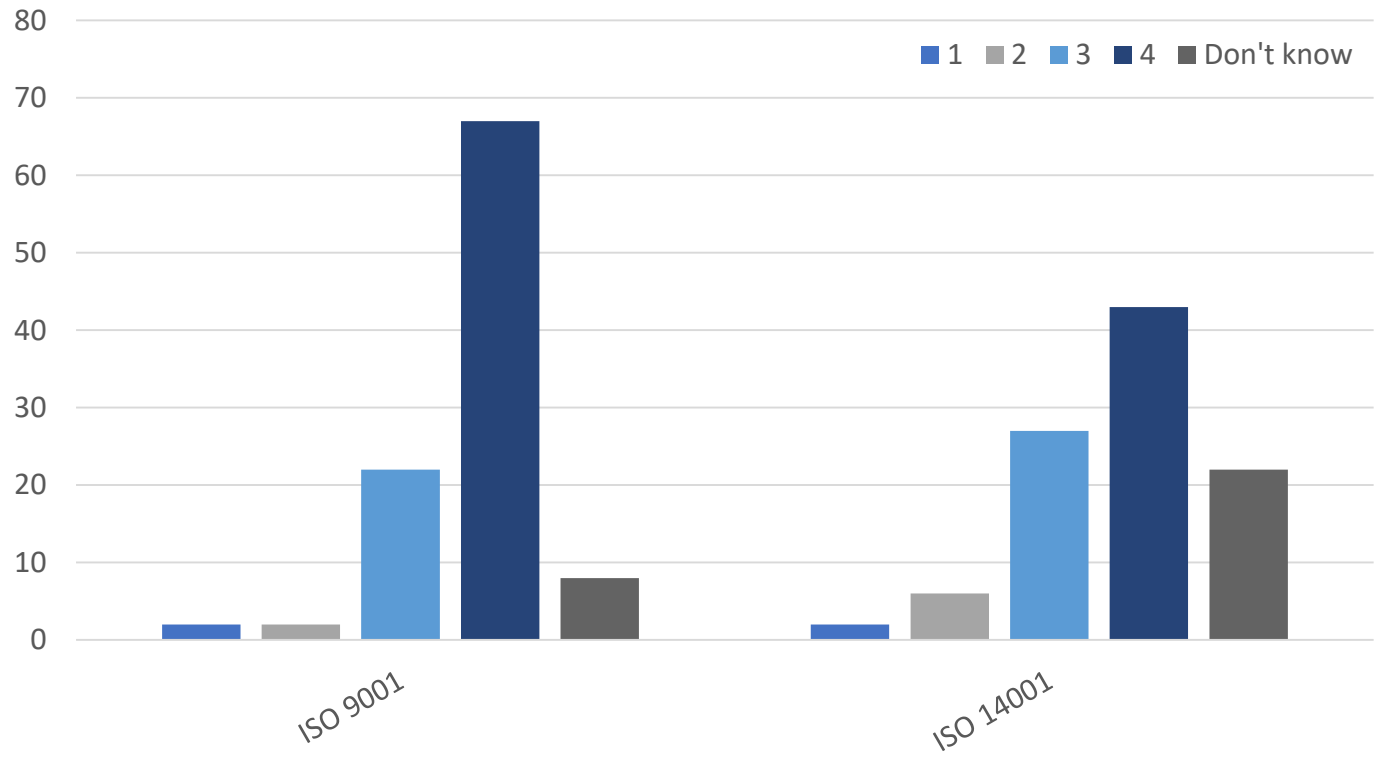
- Customer service



	Average	
Question	**2017**	**2015**
Total	3.7	3.6
Visits	3.5	3.6
Calls	3.8	3.7
Treatment	3.9	3.6
Service and repairs	3.8	3.6

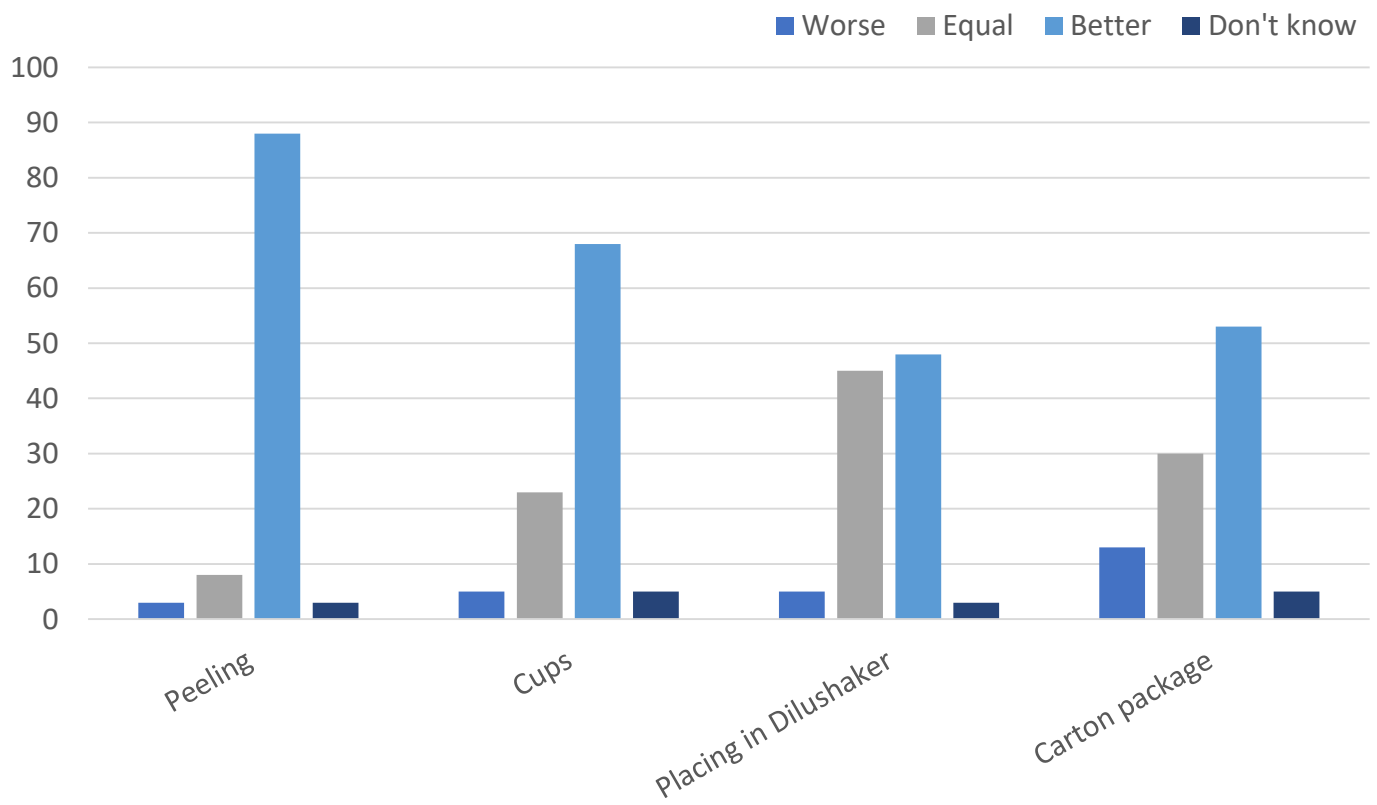
Good customer service, but a general wish for more visits (both from the customer and distributor side).

Customer Survey 2017
- Quality/Environmental assurance



- **Customers view LabRobot certification to ISO 9001 as important**
- **ISO 14001 certification slightly less important to customers**

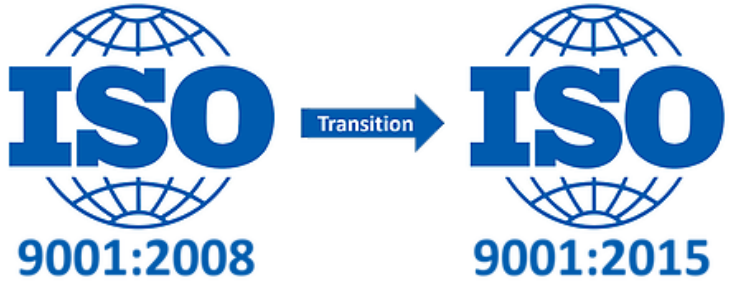
Customer Survey 2017
- Dilucup Elegance



High customer satisfaction with changes in peeling and rounding of edges of Dilucups

Up-coming Challenges 2017-18

- Transition from ISO 9001:2008 to ISO 9001:2015
  - Increased focus on controlling risks
  - General overview of QMS
  - Spot weaknesses in order to improve QMS



- Development of new products
  - Butterfield's buffer
  - Dilushaker IV

- Lower irradiation dosage
  - Higher product integrity
  - Potential to keep current price level

Thank you for your attention!